University of Maryland, Baltimore

Radiation Safety Procedure

Procedure Number: 1.2

Title: Radiation Safety Records

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Technical Review and Approval:

_____ **Date:**_____
Radiation Safety Officer

Radiation Safety Committee Approval:

_____ **Date:**_____
Chair, Radiation Safety Committee

PROCEDURE 1.2 – RADIATION SAFETY RECORDS

1.0 Purpose:

This procedure provides instructions for creating, reviewing, routing, storing, and maintaining records that are necessary for the proper documentation of UMB radiation safety activities. In particular, this procedure addresses many of the regulatory requirements found in COMAR Sections D.1101 – D.1111 and G.6.

2.0 Scope:

This procedure addresses the creation, review, routing, storage, and maintenance of records that are required by COMAR, UMB's radioactive material licenses, and other EHS radiation safety procedures.

3.0 Procedure:

3.1. General Requirements for Radiation Safety Record Content and Quality

3.1.1. All hard copies of radiation safety records shall be created in legible form. Hand written records and reports shall be created in black, blue or other reproducible color ink or other permanent marking substance. Records generated by computer or other machine processes shall meet similar standards.

3.1.2. Records that are created and maintained in electronic format (e.g., computer files) shall be maintained in a format that is approved by EHS management to ensure future retrievability throughout the required retention period [D.1111].

3.1.3. Records, including microforms, shall be created and maintained in a form that ensures their legibility throughout the required retention period [D.1111].

3.1.4. Retained records shall be an original or a reproduced copy or microform. Any reproduced copy must be authenticated by the RSO or other authorized individual [D.1111].

3.1.5. Records such as letters, drawings, and specifications that bear stamps, initials, or signatures, shall include all pertinent information [D.1111].

3.1.6. Unless otherwise specified (e.g., shipment manifests) radiation safety records may use either the traditional special units or SI units for radiation and radioactivity. The units used shall be clearly specified on the applicable records and reports [D.1101(a)].

3.2. General Requirements for Record Retention

Unless otherwise specified, EHS shall establish processes to ensure all radiation safety records are maintained until MDE terminates the applicable UMB radioactive material license or registration requiring the license [D.1102(a)].

3.3. Retention Requirements for Records of Program Audits and Reviews

Records of audits or other reviews of UMB's radiation safety program and its implementation shall be maintained for no less than three years after the record is created [D.1102(b), G.6(c)(2)(iii)].

3.4. Retention Requirements for Survey and Calibration Records

3.4.1. Records of radiological surveys that are performed for the purposes of determining individual dose equivalents, including external dose surveys, air sampling measurements, measurements and calculations used in assessing internal dose, bioassays, and measurements and calculations to evaluate effluent releases, shall be maintained until the applicable license is terminated [D.1103(b)].

3.4.2. Records of radiological surveys and measurements that are performed for purposes other than individual dose equivalent or effluent release determination and records of radiation monitoring instrument calibrations shall be maintained for no less than three years after the record is created [D.1103(a)].

3.5. Retention Requirements for Sealed Source Leak Tests

Records of sealed radioactive source leak tests shall be maintained until the sealed source is transferred from UMB control (transfer or disposal) [D.1104].

3.6. Retention Requirements for Records of Individual Prior Occupational Dose

EHS shall maintain records of individual prior occupational dose on MDE Form ND216 or equivalent until the applicable license is terminated or other time that MDE determines is appropriate [D.1105].

3.7. Retention Requirements for Records of Individual Monitoring Results

EHS shall maintain individual monitoring records until the applicable license is terminated or other time that MDE determines is appropriate [D.1107(e)].

3.8. Records of Dose to Individual Members of the Public

EHS shall maintain records sufficient to demonstrate compliance with the dose limits for individual members of the public until the applicable license is terminated or other time that MDE determines is appropriate [D.1108(a) & (b)].

3.9. Records of Waste Disposal

EHS shall maintain records of the disposal of licensed radioactive material until the applicable license is terminated or other time that MDE determines is appropriate [D.1109(a) & (b)].

3.10. Records of Testing Entry Control Devices for Very High Radiation Areas

EHS shall maintain records of tests of entry control devices for high radiation areas, including the time, date, and test results, for a period of not less than three years after the record is created [D.1110(a) & (b)].

3.11. Records of Recordable Events

3.11.1. EHS shall create and maintain records of recordable events, as defined in COMAR Section G2. In response to notification of a recordable event, EHS shall ensure that the following steps are taken within 30 days of the event:

- The relevant facts, including the event cause, are assembled [G.6(c)(3)(i)]; and
- Any corrective action necessary to prevent recurrence is identified [G.6(c)(3)(ii)].

3.11.2. Records of the information associated with recordable events shall be maintained for no less than three years [G.6(c)(3)(iii)].

3.12. Records of Written Directives

UMB shall maintain records of each written directive and each administered radiation dose or radiopharmaceutical dosage requiring a written directive [G.6(c)(4)(i & ii)]. Such records shall be maintained for no less than three years after the administration date [G.6(c)(3)(ii)].

3.13. Records of Misadministration Reports

UMB shall maintain records of reports of misadministrations for no less than five years after creation of the report [D.1209(b)]. The record shall include:

- The names of all individuals involved (including the prescribing physician, allied health personnel, the individual receiving the misadministration, and the individual's referring physician) [D.1209(b)];
- The individual's Social Security number or other identification number, if assigned [D.1209(b)];
- A brief description of the misadministration [D.1209(b)];
- The cause of the misadministration [D.1209(b)];
- The effect on the individual [D.1209()];
- Improvements needed to prevent recurrence [D.1209(b)]; and
- Actions taken to prevent recurrence [D.1209(b)].

4.0 Records and Reports:

4.1. Records

Radiation safety records shall be created and maintained consistent with the requirements of this procedure.

4.2. Reports

Radiation safety reports shall be created and filed consistent with the requirements of Procedure 1.3, *Radiation Safety Reports*.

5.0 References:

COMAR 26.12.01.01, Part D.1101 – 1111 and G.6
UMB Radiation Safety Program
Maryland License MD-07-014-01
USNRC Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs"