

University of Maryland, Baltimore

Radiation Safety Procedure

Procedure Number: 1.3

Title: Radiation Safety Reports

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Technical Review and Approval:

_____ **Date:** _____
Radiation Safety Officer

Radiation Safety Committee Approval:

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

PROCEDURE 1.3 – RADIATION SAFETY REPORTS

1.0 Purpose:

This procedure provides instructions for creating, reviewing, routing, storing, and maintaining reports that are necessary for proper documentation of UMB radiation safety activities. In particular, this procedure addresses many of the regulatory requirements found in COMAR Sections D.1201 – D.1220, J13, and G.6.

2.0 Scope:

This procedure addresses radiation safety reports that are required by COMAR and UMB's radioactive material licenses.

3.0 Procedure:

3.1. **General Requirements for Report Content and Quality**

All radiation safety reports become official records of UMB's Radiation Safety Program and therefore shall be created and maintained in accordance with the requirements of Procedure UMB-RSP-A-003, *Radiation Safety Records*.

3.2. **Reports Of Individual Radiation Doses**

- 3.2.1. EHS shall report radiation exposure data for each monitored occupationally-exposed individual no less frequently than annually and within 90 days following termination [J.13(b)].
- 3.2.2. EHS shall provide a report upon request to any individual currently or formerly monitored at UMB's licensed activities [J.13(c)]. This report shall include:
 - The dose record for each year the individual was monitored at UMB [J.13(c)]; and
 - The dates and locations of work in which the individual participated [J.13(c)].
- 3.2.3. EHS shall provide these reports within 30 days of the request, or within 30 days of determining the individual's dose, whichever is later. [J.13(c)]
- 3.2.4. EHS shall provide a written dose report to any monitored individual (or designee) who is terminating employment involving exposure to

radiation. The report shall include all radiation doses received during the current year, or fraction of the year. If the most recent individual monitoring results are not available, EHS shall provide a written estimate of the dose with a clear indication that the reported dose is an estimate [J.13(e)].

3.2.5. When EHS provides a report to MDE of any incident or event involving radiation or radioactive material and that report includes any individual exposure information, EHS shall provide a copy of that exposure information to the individual(s) involved. This report shall be transmitted to the individual(s) no later than the transmittal to MDE [J.13(d)].

3.2.6. Each report discussed above shall be in writing [J.13(a)(1)] and shall include:

- Appropriate identifying information, such as UMB's name and the exposed individual's name and identifying number (e.g., Social Security number, passport number, or other identifying number) [J.13(a)(2)];
- The individual's exposure information, including results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body [J.13(a) & (a)(3)];
- All data and results obtained as a result of individual monitoring activities undertaken by UMB [J.13(a)]; and
- A statement indicating that, "This report is furnished to you under the provisions of COMAR 26.12.01.01 Part J. You should preserve this report for further reference." [J.13(a)(4)].

3.3. *General Requirements for Radiation Safety Event And Incident Reports*

3.3.1. When EHS submits reports to MDE containing names of individuals and other identifying information, the identifying information shall be submitted in a separate, detachable portion of the report [D.1201(d), D.1202(c), D.1203(b)(ii)].

3.3.2. When EHS submits reports to MDE containing names of individuals and other identifying information, EHS shall also provide a copy of the report to the individual(s) named in the report. The report to the named individual shall be transmitted not later than the transmittal to MDE [D.1205].

3.4. Reports of Stolen, Lost, or Missing Licensed Radioactive Material or Registered Radiation Sources

- 3.4.1. EHS shall report to MDE any occurrence of a stolen, lost, or missing item of licensed radioactive material or registered source of radiation. EHS shall make such reports by telephone immediately upon discovery of the occurrence [D.1202(a)].
- 3.4.2. Within 30 days of making the telephone report required above, EHS shall file a written report with MDE providing the following information:
- A description of the radioactive material (kind, quantity, and chemical and physical form) or source of radiation (manufacturer, model, serial number, type and maximum energy of emitted radiation) involved [D.1201(b)(i)];
 - A description of the circumstances under which the loss or theft occurred [d.1201(b)(ii)];
 - A statement of disposition, or probable disposition, of the material [D.1201(b)(iii)];
 - Exposures of individuals to radiation, circumstances under which the exposures occurred, and possible total effective dose equivalents to individuals in unrestricted areas [D.1202(b)(iv)];
 - Actions that have been or will be taken to recover the material [D.1201(b)(v)]; and
 - Procedures that have been or will be adopted to prevent recurrence [D.1201(b)(vi)].
- 3.4.3. Following submittal of the 30-day report, EHS shall also report to MDE any other substantive information concerning the event within 30 days of discovering such information [D.1201(c)].

3.5. Immediate Notification of Incidents

- 3.5.1. EHS shall report to MDE any event involving a source of radiation that causes, or threatens to cause:
- A total effective dose equivalent of 25 rem or more [D.1202(a)(i)(1)];
 - An eye dose equivalent of 75 rem or more [D.1202(a)(i)(2)];
 - A shallow dose equivalent to the skin or extremities of 250 rad or more [D.1202(a)(i)(3)];
 - The release of radioactive material, inside or outside of a restricted area, such that an individual present for 24 hours could have

received an intake exceeding five times the Annual Limit on Intake (ALI). (Note that this requirement does not apply to a release to an area where an individual would not normally be present, such as a hot cell or process enclosure) [D.1202(a)(ii)];

- An inability to take immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or release of licensed radioactive material that could exceed regulatory limits (e.g., fires, explosions, toxic gas releases that impede protective actions) (Note: This report shall be made no later than four hours following discovery of the event) [D.1210(a)].

3.5.2. EHS shall make such reports by telephone immediately upon discovery of the occurrence [D.1202(a)].

3.6. 24 Hour Notification of Incidents

3.6.1. EHS shall report to MDE any event involving a source of radiation that causes, or threatens to cause:

- An individual to receive, in 24 hours:
- A total effective dose equivalent (TEDE) exceeding 5 rem [D.1202(b)(i)(1)];
- An eye dose equivalent exceeding 15 rem [D.1202(b)(i)(2)];
- A shallow dose equivalent to the skin or extremities exceeding 50 rem [D.1202(b)(i)(3)];
- The release of radioactive material, inside or outside of a restricted area, such that an individual been present for 24 hours could have received an intake exceeding one occupational ALI (Note that this requirement to a release to an area where an individual would not normally be present, such as a hot cell or process enclosure.) [D.1202(b)(ii)].

3.6.2. EHS shall make such reports in writing, by telegram, facsimile, or mailgram, within 24 hours of the discovery of the occurrence [D.1202(b)].

3.6.3. EHS shall also report to MDE within 24 hours after the discovery of an unplanned contamination event that:

- Results in the imposition of additional radiological controls that restrict worker or public access to the contaminated area for more than 24 hours;
- Involves a quantity of radioactive material exceeding five times the lowest ALI specified in COMAR Part D, Appendix B;

- Results in access restrictions for any reason other than to allow for the decay of radionuclides with half-lives shorter than 24 hours prior to decontamination.

3.6.4. EHS shall also report to MDE within 24 hours after the discovery of an event in which equipment is disabled or fails to function when:

- The equipment is required by regulation or license condition to function to prevent releases exceeding regulatory limits, prevent exposures to radiation and radioactive materials exceeding regulatory limits, or mitigate the consequences of an accident; and
- The equipment is required to be available and operable when it is disabled or fails to function; and
- No redundant equipment is available or operable to perform the required safety function.

3.6.5. EHS shall also report to MDE within 24 hours after the discovery of:

- An event involving the unplanned medical treatment at a medical facility of an individual having removable contamination on the clothing or skin;
- An unplanned fire or explosion that damages any licensed radioactive material or any device, container, or equipment containing licensed radioactive material when:
- The quantity of licensed radioactive material involved exceeds five times the lowest ALI specified in COMAR Part D, Appendix B;
- The damage affects the integrity of the licensed radioactive material or its container.

3.6.6. EHS shall make such reports by telephone and shall include, to the extent information is available:

- The caller's name and a call-back telephone number;
- A description of the event, including the date and time of the event;
- The exact location of the event (e.g., street address, building name or number, room number, etc.);
- A description of the licensed radioactive material involved, including the isotopes, quantities, and chemical and physical forms;
- Any individual radiation exposure data available.

3.7. 30 Day Reports

3.7.1. EHS shall submit a written report to MDE for any of the following:

- Any of the incidents described in Section 3.6, 24 Hour Notification of Incidents;
- Any doses exceeding the applicable dose limits as found in COMAR or UMB's licenses;
- Radiation levels or radioactive material concentrations in restricted or unrestricted areas exceeding the applicable limits found in COMAR Part D or UMB's licenses.

3.7.2. EHS shall submit such reports in writing within 30 days of learning of the event and shall include:

- For each individual exposed, the individual's name, Social Security Number, and date of birth. (For the embryo/fetus, the declared pregnant woman's identifying information shall be used);
- The extent of exposure of individuals to radiation and radioactive materials;
- Estimates of each individual's dose;
- The radiation levels and radioactive material concentrations involved;
- The cause of the elevated exposures, dose rates, or concentrations;
- Corrective steps taken or planned to prevent recurrence;
- The schedule for achieving compliance with the applicable limits, generally accepted environmental standards, and associated license or registration conditions.

3.7.3. EHS shall provide a follow-up written report to MDE of any of the events described in Section 3.7. EHS shall submit this report within 30 days of the initial report and shall include:

- A description of the event, including the date and time, probable cause and the manufacturer and model number of any equipment that failed or malfunctioned (if applicable);
- The exact location of the event; (e.g., street address, building name or number, room number, etc.);
- A description of the licensed radioactive material involved, including the isotopes, quantities, and chemical and physical forms;
- The extent of any individual radiation exposures involved (without identification of exposed individuals).

3.8. Reports of Leaking Sealed Radioactive Sources

If a sealed radioactive source leak test reveals that a source is leaking, EHS shall provide a written report to MDE. The report shall be submitted within five days of the discovery of the leaking source and shall describe the equipment involved, the leak test results, and any corrective action taken [D.1206].

3.9. Reports of Misadministrations

3.9.1. UMB shall report misadministrations, as defined in COMAR Section D.1208, to MDE by telephone no later than the calendar day following the discovery of the misadministration [D.1209(a)(ii)]. UMB shall also notify the referring physician and the affected individual within 24 hours of discovery of the misadministration [D.1209(a)(ii)].

Note: The referring physician should be notified first, and should ultimately decide determine if there is any reason, based on his or her medical judgment, that the affected individual or the affected individual's relative or guardian should not be informed. However, if the referring physician cannot be contacted within 24 hours, the affected individual shall be notified [D.1209(a)(iii)].

3.9.2. Within 15 days following after the discovery of the misadministration, UMB shall submit a written report to MDE [D.1209(a)(ii)]. The written report shall include:

- UMB's name [D.1209(a)(ii)];
- The prescribing physician's name [D.1209(a)(ii)];
- A brief description of the event [D.1209(a)(ii)];
- The cause of the event [D.1209(a)(ii)];
- The effect of the event on the affected individual [D.1209(a)(ii)];
- Any improvements needed to prevent recurrence [D.1209(a)(ii)];
- Whether or not the affected individual or his or her responsible relative or guardian was notified of the event and, if not, the reason for the omission [D.1209(a)(ii)]; and
- Actions taken to prevent recurrence [D.1209(a)(ii)].

3.9.3. If the affected individual or his or her responsible relative or guardian was notified of the event, UMB shall also provide a written report to that individual within 15 days of the discovery of the event [D.1209(a)(iv)]. This report shall be either a copy of the report submitted to MDE or a brief description of the event and its consequence as they may affect the individual [D.1209(a)(iv)]. If

UMB provides a brief description in lieu of the full report, UMB shall also include a statement indicating that the full report is available from UMB [D.1209(a)(iv)].

3.10. Reports of Defects and Failures to Comply

- 3.10.1. Section 1220 of COMAR Part D establishes detailed requirements for reporting the existence of defects and failures to comply that may result in substantial safety hazards. Any individual noting the existence of any such defect or failure to comply that may result in a substantial safety hazard shall immediately notify the RSO.
- 3.10.2. Upon notification of the existence of any defect or failure to comply that may result in a substantial safety hazard, the RSO shall review the applicable provisions of COMAR Section D.1220 and complete, or ensure the completion of, any required notifications and written reports.

4.0 Records and Reports:

4.1. Records

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

4.2 Reports

Radiation safety reports shall be created and filed consistent with the requirements of this procedure.

5.0 References:

COMAR 26.12.01.01, Parts D, G, and J
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"