

Western Michigan University

Radiation Safety

Quality Control Program

Purpose

- A. To provide guidance in maintaining oversight of the Radiation Safety Program.

- B. To describe a means of conducting the audits and surveillances used to ensure compliance with the rules and regulations governing the use of radioactive material and radiation producing machines.

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I. Responsibilities

A. Executive Management [NUREG 1556 Vol 11]

1. Review Incident Reports and the actions taken to mitigate the incident and prevent recurrence.
2. Review audits and the actions taken to correct deficiencies.
3. Conduct or participate in audits and surveillances, both announced and unannounced.

B. Radiation Safety Officer (RSO) [NUREG 1556 Vol 11]

1. Investigate, develop, and implement actions to prevent recurrence of deficiencies described on Incident Reports
2. Conduct audits and surveillances, both announced and unannounced.
3. Review audits planned and conducted by others.
4. Develop and implement actions to prevent recurrence of deficiencies found during audits.
5. Act as the liaison between Western Michigan University (WMU) and auditors.
6. Provide storage for the records associated with this program.

C. Authorized Users (AU)

1. Initiate an Incident Report or ensure their Radiation Workers initiate Incident Reports as required.
2. Distribute the information from the audits.
3. Conduct or participate in audits as needed by the RSO
4. Provide written documentation of audits conducted.
5. Implement the actions necessary to correct deficiencies founds during audits or Incident Reports.
6. Conduct surveillances, both announced and unannounced, on the Radiation Workers under their authority.

D. Independent Auditor

1. Conduct audits as requested.
2. Follow our procedural guidelines while conducting an audit.
3. Provide written documentation of audits conducted and provide recommendations to correct deficiencies.

E. Radiation Workers (RWs) are responsible for identifying, correcting, and documenting conditions or actions that violate or can lead to a violation of our procedures, policies, rules, and regulations governing the use of radiation or radiation producing machines.

II. Definitions

Audit	A formal examination of the Radiation Safety Program or a specific area of the program.
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Findings	Points of interest that support the evaluation of a program. Findings are examples, positive or negative, of the practices, work conditions, postings, or anything else related to the control of radiation, contamination, radioactive material, and radioactive waste observed during an audit.
Incident Reports	Formal reports of events, conditions, actions, etc. that have or may have an adverse effect on the safety of the general public and WMU AUs/Radiation Workers due to radiation exposure.
Independent Auditor	An auditor that has no affiliation to WMU who is contracted for the sole purpose of performing an in-depth audit of the Radiation Safety Program. The Independent Auditor must have the experience and knowledge of a Radiation Safety Program for a Type B Broad Scope research facility.
Subprograms	The nine programs that comprise the Radiation Safety Program in order to fulfill the purpose of the Radiation Safety Policy. They are: 1) Training, 2) Radiological Controls, 3) Quality Control Program, 4) Source Inventory and Control, 5) Instrumentation and Dosimetry Program, 6) Radioactive Waste Program, 7) Transportation of Radioactive Material/Waste Program, 8) Administrative Controls, 9) Emergency Plan
Surveillance	An informal examination of radiation safety practices or the implementation of specific actions of the Radiation Safety Program.

III. Requirements

A. Incident Reports [10CFR19.12 and 13 / 10CFR20.2102]

1. Formal reports of events, conditions, actions, etc. that have or may have an adverse effect on the safety of the public, staff, students, or facility due to radiation exposure.
2. Initiated by any RW, AU, the RSO, or the Executive Manager that discovers the issue or is notified of an incident.
3. The notification and start of the Incident Report sets in motion the actions to mitigate the potential exposure, investigate the root cause of the issue(s), development actions to prevent recurrence, and implement those actions, including follow ups to ensure that the actions are effective.

B. Audits [10CFR20.2101]

1. Annual - a broad look at the entire program.
2. Sub-program – an in-depth look at a specific sub-program or portion of a sub-program deemed necessary to ensure procedures and practices are in place to minimize potential exposure of the general public and WMU AUs/Radiation Workers as determined by the RSO.
3. Announced – conducted as per a scheduled period of review.

4. Unannounced – conducted at the discretion of the Executive Manager and/or RSO as often as necessary to assure compliance with the rules and regulations governing the use of radioactive materials.

C. Surveillances [License]

1. Should be done by the AU on a frequency necessary to assure compliance by their RWs.
2. A stringent calendar schedule is not feasible due to the random use of licensed material directed the research needs.
3. Practice deficiencies should be corrected on the spot.
4. Program non-compliance shall be documented on an Incident Report for correcting, tracking, and trending.

IV. Final Conditions

- A. Incident Reports are documented, investigated, and actions are developed and implemented to prevent recurrence.
- B. Audits are completed as scheduled and conducted.
- C. Deficiencies are found, documented and corrective actions initiated to prevent recurrence.
- D. Follow-up actions are completed.
- E. All documentation is being maintained in accordance with the established retention schedule.

Appendix A Incident Reporting

NOTE: Documenting an event, action, or condition that violates or can lead to a violation of our procedures, policies, rules, and regulations governing the use of radiation will assist in correcting, preventing, and anticipating future conditions or problems.

A. The following steps to be performed by the individual discovering the reportable event:

1. Initiate an Incident Report, Enclosure 1 to Appendix A.
2. Submit the Incident Report to the RSO.

B. The following steps to be performed by the RSO:

1. Investigate the incident.
2. Initiate actions to minimize potential exposure of the general public and WMU AUs/RWs.
3. Evaluate the incident, the apparent cause, and any actions that may have been taken.
4. Develop and implement a plan of action to prevent recurrence.
5. Distribute lessons that can be learned and used to the AUs and RWs.
6. Submit a copy to the Executive Manager for review and filing.

Incident Report for Radiation Safety

Name of Investigator: _____ Investigation Date: _____
Date of Incident: _____

Type of Incident (circle): Spill Loss of Material High Exposure Transportation
Other (explain): _____

Reported by: _____ Phone: _____

A. Method of discovery and immediate actions taken:

Continuous Sheet

B. Description of incident (include who, what , where, when, and how):

Continuous Sheet

C. Investigation of Incident (verify who, what, where, and how; and explain why):

Continuous Sheet

D. Actions Taken to Prevent Recurrence:

Continuous Sheet

Investigator

Radiation Safety Officer

Appendix B Auditing

A. The following steps to be performed by the individual(s) assigned the audit:

1. Perform a historical review of previous audits, Incident Reports, and procedures governing the activities.
2. Discuss a plan to complete the audit with the RSO.
3. Send out an announcement letter, if necessary.
4. Gather the information and data necessary to evaluate the effectiveness of the program.

Information can be in the form of:

- a. Compile procedures, license(s), and regulations
 - b. Review records and pertinent documentation.
 - c. Conduct interviews and/or observations.
 - d. Use personal experiences, feelings, and thoughts.
5. Analyze the data.
 - a. Objective evidence supporting findings should be examined to the depth necessary to determine effectiveness of implementation.
 - b. If necessary gather additional information and data.
 6. Document the audit using Appendix B Enclosure (1) including all actions taken or recommended to correct noted deficiencies.
 7. Submit the audit report to the RSO for review and follow up.

B. The following steps to be performed by the RSO:

1. Develop a plan to correct any deficiencies noted in the audit.
2. Implement corrective actions to prevent recurrence.
3. Schedule follow-up actions if deemed needed sooner than the next annual audit.
4. Document on Appendix B Enclosure (1) all actions taken to correct noted deficiencies.
5. Submit the audit to the Executive Manager for review, approval, and filing.
6. Schedule follow-up actions if deemed needed sooner than the next annual audit.

Radiation Safety Program Internal Audit

1. AUDIT HISTORY:

- a. Last internal audit completed _____.
- b. Last Nuclear Regulatory Commission audit _____.
- b. List of deficiencies from previous audits (Internal and/or NRC):

Closed	Description

2. AMENDMENTS AND PROGRAM CHANGES:

- a. Amendment(s) during reporting period: _____
- b. Changes due to amendment(s):

3. TRAINING:

- ___ Initial training is being conducted.
- ___ Number of people receiving initial training during period.
- ___ Annual retraining is being conducted.
- ___ All required topics are being covered in the lesson plans.
- ___ Most current NRC Form 3 and WMU instructions are posted at labs' primary ingress/egress.

4. RADIOLOGICAL CONTROLS:

- ___ **Facilities** are used as described in license.
- ___ Access to material and facilities is controlled.

- ___ **Exposure** is being monitored and evaluated in accordance with procedures and license.
- ___ Exposures outside of normal bands is investigated and reported:

- ___ **Radiological surveys** are in accordance with procedures and license.
- ___ Radiological surveys are adequate to effectively implement ALARA.
- ___ Leak tests are performed in accordance with procedures and license.

- ___ Areas and materials are posted in accordance with procedures and regulations.
- ___ **Area postings** are adequate to communicate potential hazards and maintain exposure ALARA.

5. SOURCE INVENTORY AND CONTROL:

- Material in use is as described and authorized in license.
- Gauges in use are as described and authorized in license and Sealed Source and Device (SSD) Registration Certificate.
- Material receipt and transfer records are maintained in accordance with procedures and license.
Activity in mCi of material received in the period:
C-14 _____ P-33 _____
H-3 _____ S-35 _____
P-32 _____ I-125 _____
- All material is accounted for and gauges are inventoried every 6 months.

6. INSTRUMENTATION AND DOSIMETRY:

- Instruments in use are as described by in license.
- Instruments are calibrated in accordance with license.

7. RADIOACTIVE WASTE MANAGEMENT:

- Disposal records are in accordance with procedures and license.
Material disposed by transfer to a disposal vendor:
C-14 _____ mCi and _____ ft³
C-14 _____ mCi and _____ gal
H-3 _____ mCi and _____ ft³
H-3 _____ mCi and _____ gal
Liquid Scintillation vials _____ ft³
Decay in storage _____ mCi and _____ ft³
Decay in storage _____ mCi and _____ gal
- Disposal vendor license is on file.
- Disposal records are in accordance with procedures and license.

8. TRANSPORTATION:

- Records are maintained in accordance with procedures, DOT and NRC regulations and license.
- Shipping paperwork handling and security measures are adhered to during transportation and work at remote sites.
- Packaging meet design and regulatory requirements.

9. NOTIFICATIONS AND REPORTS:

- Reporting to NRC and/State and follow-ups were conducted in accordance with procedures and regulations.

Reports made NRC and/or State during the period:
