

Western Michigan University  
Radiation Safety

**Quality Control Program**

**I. 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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## II. Definitions

Audit	A formal examination of the Radiation Safety Program or a specific area of the program.
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 or surveillance.
Incident Reports	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.
Independent Auditor	An auditor, that has no affiliation to the University, 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 seven subprograms of the Radiation Safety Program are as follows: A) Training, B) Radiological Controls, C) Quality Control Program, D)Source Inventory and Control, E) Instrumentation and Dosimetry Program, F) Radioactive Waste Program, G) Transportation of Radioactive material/Waste Program, H) Administrative Controls, I) Emergency Plan
Surveillance	An informal examination of the radiation safety program or an area of the program.

## III. Responsibilities

- A. Executive Management
  1. Approve the Annual Program Review.
  2. Conduct or participate in audits and surveillances, both announced and unannounced.
  3. Review the actions taken to correct deficiencies found during audits and/or surveillances.
  
- B. Radiation Safety Officer (RSO)
  1. Conduct the Annual Program Review.
  2. Develop an audit schedule.
  3. Conduct audits and surveillances, both announced and unannounced.
  4. Review audits and surveillances planned and conducted by others.
  5. Develop and implement actions to prevent recurrence of deficiencies found during audits and surveillances.
  6. Investigate, develop, and implement actions to prevent recurrence of deficiencies described on Incident Reports.
  7. Act as the liaison between Western Michigan University (WMU) and auditors.
  8. Provide storage for the records associated with this program.

9. Give a surveillance form to the AU with the third receipt of material.
- C. Authorized Users (AU)
1. Distribute the information from the Annual Program Review and subprogram audits.
  2. Conduct or participate in audits as needed or scheduled by the RSO.
  3. Implement the actions necessary to correct deficiencies found during audits and/or surveillances.
  4. Conduct routine surveillances, both announced and unannounced, on the Permit Holders under their authority and as requested by others.
  5. Provide written documentation of audits and surveillances conducted.
- D. Independent Auditor
1. Conduct audits and surveillances as requested.
  2. Follow our procedural guidelines while conducting their audit.
  3. Provide written documentation of audits and surveillances conducted.
- E. All personnel are responsible for identifying and correcting 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.

#### IV. Implementation

- A. Requirements
1. Audits
    - a. ***The Annual Program Review is a broad view of the entire program provided by the tabulation of subprogram audits for a broad look of entire program.***
    - b. ***An audit of each of the following subprograms will performed annually.***
      - i. Training
      - ii. Radiological Controls
      - iii. Quality Control
      - iv. Source Inventory and Control
      - v. Instrumentation and Dosimetry
      - vi. Radioactive Waste
      - vii. Transportation of Radioactive Material/Waste
      - viii. Emergency Plan
      - ix. Administrative Controls is audited in conjunction with the audits of the subprogram audits, IV A.1.b. i. - viii., above.

<b>NOTE:</b>	Surveillances should be done on a frequency necessary to assure compliance. A stringent calendar schedule is not feasible due to the random use of licensed material directed the research needs.
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2. Surveillances of active labs and rooms/areas
  - a. **Level C Lab**  
**Authorized User – as directed by the RSO**  
**RSO or Radiation Safety Staff - as necessary**
  - b. **Level B Lab**  
**Authorized User – as directed by the RSO**  
**RSO or Radiation Safety Staff - as necessary**
  - c. **Level A Lab**  
**Authorized User – weekly**  
**RSO or Radiation Safety Staff - semi-monthly**
  - d. **Radiation Producing Machine Rooms or areas**  
**Principle Investigator as requested by the RSO**  
**RSO or Radiation Safety Staff - as necessary**
  - e. The members of the Radiation Safety Committee and Executive Manager should perform unannounced surveillances as often as necessary to assure compliance with the rules and regulations governing the use of radioactive materials and radiation producing machines.
3. Initiate an incident report for events, actions, or conditions that violate or can lead to a violation of our procedures, policies, rules, and regulations governing the use of radiation or radiation producing machines.

B. Conducting the Annual Program Review

**The following steps to be performed by the RSO:**

1. Perform a historical review of previous audits, surveillances, and procedures governing the program.
2. Gather the information and data necessary to evaluate the effectiveness of the program.
3. 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.
4. Write the Review, the report should include:
  - a. A statement as to the effectiveness of the program.
  - b. The specific audit findings used in drawing the audit conclusions.
    - i. Described the findings using two distinct sections:
      - a. Regulatory
      - b. Auditor opinion
5. Develop a plan to correct any deficiencies noted in the review.
6. Implement corrective actions to prevent recurrence.
7. Document in the Review all actions taken to correct noted deficiencies.

8. Schedule follow-up actions, if necessary.
9. File the Review.

C. Conducting a Subprogram Audit.

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

1. Perform a historical review of previous audits, surveillances, 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. Interviews and/or observations.
  - b. Reviews of record or other documentation.
  - c. 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. Write the audit report, the report should include:
  - a. A statement as to the effectiveness of the program,
  - b. The specific audit findings used in drawing the audit conclusions
    - i. Described the findings using two distinct sections:
      - a. Regulatory
      - b. Auditor opinion
    - ii. Include references for further review and interpretation.
  - c. The audit activities, such as:
    - i. List of documents reviewed,
    - ii. People interviewed,
    - iii. Dates, times, and locations where observations were conducted.
7. Submit the audit report to the RSO for review and approval.

**The following steps to be performed by the RSO:**

8. Develop a plan to correct any deficiencies noted in the audit.
9. Implement corrective actions to prevent recurrence.
10. Document on the audit all actions taken to correct noted deficiencies.
11. Schedule follow-up actions, if necessary.
12. File the completed audit.

D. Conducting a Surveillance.

**The following steps to be performed by the individual conducting the surveillance:**

1. Gather needed material.
2. Review procedures and policies governing the work you expect to be observing.

3. Proceed to the area where you will be conducting the surveillance.
4. Inform the worker you are performing a surveillance.
  - a. Inform them you will be doing a lot of writing and that is not a reflection of performance.

<b>NOTE:</b>	<b>Initiate <u>IMMEDIATE</u> Corrective Action for those deficiencies observed that might result in the reduction of safety, a violation of Federal or State regulations, or inadvertent exposure to the staff, students, or public.</b>
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5. Observe the work practices, postings, cleanliness of the work areas, and anything else related to the control of radiation, contamination, radioactive material, and radioactive waste observed during an audit or surveillance.
6. Record your observations.
  - a. Record all actions observed in a step by step fashion to verify compliance later.
  - b. Note during the data gathering phase try to remain objective and NOT judgmental.
7. Analyze the data you have collected.
  - a. Determine areas of strengths and weaknesses.
  - b. Verify those findings felt to be in violation of rules and regulation governing the use of radioactive material and radiation producing machines.
8. Determine corrective actions if necessary.
9. Document the surveillance. The document should include:
  - a. The name of the individual(s) observed,
  - b. The activity observed,
  - c. The findings that pertain to rules and regulations, e.g. not wearing their dosimetry,
  - d. The findings that pertain to good practices only, e.g. frequency of monitoring their hands while working,
  - e. Corrective actions, if necessary.
10. Discuss your surveillance with the individual(s) observed.
11. Submit the surveillance to the RSO for review and filing.

**The following steps to be performed by the RSO:**

12. Schedule, if necessary, follow-up activities.
13. File the completed surveillance.

<b>NOTE:</b>	<b>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 or radiation producing machines will assist in correcting, preventing, and anticipating future conditions or problems.</b>
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E. Incident Reporting

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

1. Initiate an Incident Report.
2. Submit the Incident Report to the RSO.

**The following steps to be performed by the RSO:**

3. Investigate the incident.
4. Initiate actions to prevent recurrence, if necessary.
5. Evaluate the incident, the apparent cause, and any actions that may have been taken.
6. Distribute lessons that can be learned and used to the AUs and Permit Holders.
7. File the completed document.

**V. Final Conditions**

- A. The Annual Radiation Safety Program Review has been completed and the information distributed.
- B. Audits are completed as scheduled and filed.
- C. Surveillances are completed per the requirements and filed.
- D. Deficiencies are found, documented, and corrective actions initiated to prevent recurrence.
- E. Follow-up action is completed.
- F. All documentation is being maintained in accordance with the Administrative Controls Program.