

Chapter X: Radiation Safety Audit Program

Policy

All laboratories using radioactive material shall be reviewed as required by the Illinois Emergency Management Agency (IEMA), Division of Nuclear Safety regulations, the University radioactive material license, and other relevant safety, health and environmental regulations. Reviews shall be conducted by representatives of the Office of Radiation Safety.

Authority and Responsibility

Office of Radiation Safety is responsible for:

- 1 Developing a Laboratory Radiation Safety Audit Program;
- 2 Conduct annual reviews of all radioactive material laboratories;
- 3 Conducting follow-up reviews of all laboratory areas identified for re-inspection;
- 4 Immediately stopping any work practices posing an imminent radiation safety hazard to faculty, staff, students and visitors;
- 5 Suspending a principal investigator radioactive material protocol if conditions or practices warrant such action;
- 6 Conducting an exit interview with the principal investigator, laboratory designee or other laboratory representative following the review;
- 7 Providing written reports to the principal investigator and laboratory designee;
- 8 Reporting audit results to the University Radiation Safety Committee; and
- 9 Ensuring corrective action is followed through for identified concerns.

Principal Investigators and Laboratory Designee are responsible for:

- 1 Complying with all aspects of the Radiation Safety Audit Program;
- 2 Providing access to all areas and rooms under their responsibility;
- 3 Acting immediately to correct any work practices identified as imminently hazardous which includes taking the appropriate corrective actions;
- 4 Addressing any concerns discovered during the laboratory radiation safety audit under their responsibility within 90 days unless otherwise established; and
- 5 Cooperating with outside regulatory agencies.

Purpose

The Office of Radiation Safety periodically conducts laboratory audits for the purpose of reviewing each research group's compliance with the University radiation safety program and the Illinois Emergency Management Agency (IEMA), Division of Nuclear Safety regulations. The audit process involves the review of recordkeeping (e.g. usage log, waste disposal manifest, and lab survey reports) and general radiation safety practices.

Frequency

Initial Review

All principal investigators with a radioactive material protocol and possessing radioactive material during the previous year shall be reviewed annually. Radiation Safety concerns identified during the radiation safety audit shall be corrected within 90

days, unless a shorter period is allowed due to the severity of concerns or a longer period of time is necessary because of operational considerations. Longer periods of time shall be agreed upon by the Office of Radiation Safety.

Follow-up Review

Follow-up reviews are based on risk which is determined by the number and severity of deficiencies. Twenty-five percent of laboratories scheduled shall be re-evaluated 90 days after the initial review. Laboratories selected for re-inspections shall be based on those laboratories with the highest number of concerns noted during the initial inspection. All laboratories with serious concerns shall be reviewed in accordance with the time frame identified on the report. All concerns shall be tracked until corrective action plans have been completed.

Procedure

To prepare each Principal Investigators laboratory for a state inspection the health physicists from the Office of Radiation Safety will conduct unannounced laboratory audits to simulate the state inspection process.

Your lab will be evaluated on four categories:

- 1 Radioactive Material Usage and Storage
- 2 Laboratory Surveys
- 3 Radioactive Waste Management
- 4 General Radiation Safety Practices

Listed below is a breakdown of the four categories and examples of deficiencies for each category.

Once the final review of the audit results is conducted, a report will be submitted to the principle investigator and the laboratory designee. If deficiencies are noted during the laboratory audit a written corrective action plan will be required from the principal investigator. The correction action plan must describe what actions/procedures have been implemented to ensure future compliance with each non-compliance item noted in the audit report. Please note that all audit results will be reviewed by the University Radiation Safety Committee.

If you should have any questions regarding the radiation safety audit program, feel free to contact the Office of Radiation Safety at 773-702-6299.

Radioactive Material Usage and Storage

- Receipt and usage logs accessible – Inaccessible logs (Lab staff do not know where the active or completed logs are located)
- All receipt and usage logs on file in lab – Missing logs (some logs have been lost or misplaced)
- Receipt and usage logs properly completed – Incomplete or improperly completed logs (missing usage, user initials or waste information)
- Radioactive material properly stored and secured against inadvertent entry and theft – Improper storage or unlocked radioactive material lab with no one present or use of radioactive material in unauthorized area(s)

- All items listed on inventory are present and accessible (Conduct a physical inventory of material currently listed on the PI inventory.) – Items listed on radioactive material inventory cannot be located
- Storage units containing radioactive material are properly labeled – Units used for storage of radioactive materials (e.g. stock vials, samples) do not have proper markings
- Radioactive material labels on required areas/items of use – Labels not posted on required areas/items (e.g. work benches, centrifuge, fume hood, incubator, pipettes, etc.) used for radioactive material experiments.

Laboratory Surveys

- Lab survey records accessible – Survey records inaccessible (Lab staff do not know where the survey records are located)
- Lab survey records on file in lab – Missing survey records. Survey records are not available for every week with active inventory (e.g. stock material, samples or waste present in the lab)
- Lab survey records properly completed – Incomplete or improperly completed survey records (e.g. results of survey not recorded properly, survey instrument identification missing, not surveying all use and storage areas)
- Lab survey records reflective of use or active inventory – Surveys not reflective of use or items listed on inventory and therefore, not using proper probe or survey technique to identify all radioisotopes in lab (e.g. wipe test to identify H-3, crystal probe to identify I-125, etc.)
- Appropriate corrective action taken for sites of contamination, including adequate documentation – Action level exceeded with no documented corrective action of cleanup and/or shielding of the area, if needed.

Radioactive Waste Management

- Proper segregation of radioactive waste – Improper segregation of waste (e.g. mixing biohazard waste and radioactive waste without approval, mixing H-3 with P-32 without approval; placing stock vial in dry solid waste container rather than in stock vial box)
- Proper packaging of radioactive waste – Improper packaging of waste (e.g. not using Radiation Safety approved waste containers, using glass jars for liquid waste rather than Radiation Safety approved carboy)
- Storage of radioactive waste in authorized area(s) – Storage in an unauthorized area (e.g. lab is not listed on the PI protocol)
- Drain disposal records properly completed – Improperly completed records of drain disposal
- Radioactive waste manifest properly completed – Incomplete or improperly completed manifest on waste container(s).

General Radiation Safety Practices

- No evidence of food or beverage being stored or consumed in a radioactive material area of use and/or storage – Evidence of storage or consumption of

- food/beverage in radioactive material area (e.g. coffee cup in waste basket in lab, eating lunch at desk in lab, storing food or drink in refrigerator inside lab.)
- Laboratory personnel listed on application working with radioactive material – Lab personnel found working with radioactive material, but have not attended radioactive material user training and submitted the New User Amendment and Training Certification form to be listed on the PI protocol
 - Up to date Training Certification Form with all active users of radioactive material with current training dates on file with Office of Radiation Safety and posted in the lab – Training certification form not on file in Office of Radiation Safety and/or posted in the lab
 - Lab personnel using radioactive material are listed on the PI protocol, have current training (initial or annual refresher training) and have submitted the New User Amendment and Training Certification form for new users. – Radioactive material user in lab does not have up-to-date radiation safety training
 - Emergency Procedure Posting posted in at least one laboratory – Procedure not posted in lab
 - IEMA Notice to Employees posted in at least one laboratory – Notice not posted in lab
 - Proper laboratory attire worn while working with radioactive material (gloves, protective clothing, no shorts/skirts allowed, close toed shoes, and/or film badge/ring badge when applicable) – Radioactive material user found not wearing proper laboratory attire while working with radioactive material
 - No evidence of unreported spill, loss, theft, or damage to sources of radioactive material – Evidence of unreported spill, etc.
 - Laboratory survey instruments operational – Inoperative survey instrument (e.g. low battery, operational check reading outside of range limits)
 - Laboratory survey instruments operational check performed properly by lab personnel – Radioactive material user not able to perform operational check to standard

Imminent Hazards

Any work practices (e.g. handling or storage of materials, shielding) or facility deficiencies (improper fume hood operation when using volatile radioactive materials) posing an imminent hazard to faculty, staff, students and visitors identified during laboratory reviews shall be stopped and corrected immediately. The representative from the Office of Radiation Safety discovering any imminent hazard shall immediately notify the principal investigator who is responsible for appropriate follow-up corrective actions. All imminent hazards shall also be noted in the inspection report.

Progressive Resolution Process

Laboratories failing to correct concerns identified on any inspection report shall be subject to the progressive resolution process. Each identified concern shall be corrected prior to the corrective action date. For concerns not corrected, the following action shall take place:

- Stage One of Non-Compliance: A letter identifying the concerns is sent to the principal investigator and laboratory designee.

- Stage Two of Non-Compliance: If non-compliance is not addressed a letter identifying the concerns is sent to the principal investigator with a copy sent to the chairperson of the University Radiation Safety Committee.
- Stage Three of Non-Compliance: If corrective actions are not implemented the principal investigator protocol is suspended until appropriate corrective action has been implemented. The University Radiation Safety Committee is noted of suspension and may require principal investigator to attend committee meeting prior to reinstating protocol.

Outside Regulatory Agencies

The IEMA regulations in 32 Illinois Administrative Code II, Section 400 indicate that each licensee or registrant shall afford the Department at all reasonable times the opportunity to inspect such materials, machines, activities, facilities, premises and records as Department determines are necessary to establish compliance with the requirements of the license and provisions of the regulations. Reasonable times shall be any time the facility is operational.

Other outside regulatory agencies may request inspection of the University properties or review components of the radiation safety program in order to determine compliance with regulations pertaining to radioactive material and radiation safety issues.