

**CREIGHTON UNIVERSITY'S
RADIATION SAFETY OFFICE**

INSPECTION AND ENFORCEMENT POLICY AND PROCEDURE

Prepared and Approved by
Creighton University/Saint Joseph Hospital Radiation Safety Committee

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Section One - Purpose and Introduction

- 1.1. Purpose. The purpose of this Inspection and Enforcement Manual is to establish the procedures for the conduct of audits (inspections) by the Radiation Safety Office under §14 of the Radiation Safety Manual for Radioactive Material Users at Creighton University and Saint Joseph Hospital at Creighton University Medical Center.
- 1.2. Review and Revisions. The Inspection and Enforcement Manual will be reviewed and/or revised periodically by the Radiation Safety Officer and the Radiation Safety Committee to ensure that it operates as an effective tool to ensure compliance with requirements under Creighton University's broad scope license.
- 1.3. Distribution. The Inspection and Enforcement Manual will be distributed to each Authorized User under Creighton's broad scope license. The Radiation Safety Office will track and log distribution of the Inspection and Enforcement Manual. In addition, the Inspection and Enforcement Manual will be posted on the Radiation Safety Office web site at http://www.creighton.edu/researchcompliance/Radiation_Safety/index.htm

Section Two - Definitions

2.1 Levels of Radiation Safety Violations. The enforcement tool for this manual (i.e. corrective action program) operates using three levels of radiation safety violations as defined below:

- A. **Minor:** Violations that pose little risk to health, safety, environment, or the license but that may lead to moderate violations if not corrected.

Examples of minor violations include, but are not limited to the examples of for severity levels 4 and 5 as outlined in Appendix 17-A of the Nebraska regulations under 180 NAC 17, as amended.

- B. **Moderate:** A serious violation, multiple or recurring minor violations, or minor violations that are not corrected timely that do not present immediate risk to health, safety, the environment, or the license, but if uncorrected may lead to severe violations.

Examples of moderate violations include, but are not limited to the examples for severity levels 2 and 3 as outlined in Appendix 17-A of the Nebraska regulations under 180 NAC 17, as amended.

- C. **Severe:** This is the highest severity level of non-compliance which results from violations which may cause risk or danger to safety, health, release to the environment of reportable quantities, doses of substantial amounts to humans, or place the license in jeopardy (i.e., an incident reportable to the state).

Examples of severe violations include, but are not limited to the examples set forth for severity level 1 as outlined in Appendix 17-A of the Nebraska regulations under 180 NAC 17, as amended.

NOTE: The Radiation Safety Officer has the discretion to impose a higher level of violation despite the examples listed above based on the danger to personnel and/or the general public.

2.2 Acronyms and Terms

RSM	Radiation Safety Manual for Radioactive Material Users at Creighton University and Saint Joseph Hospital at Creighton University Medical Center.
RSO	Radiation Safety Office/Officer
RSC	Radiation Safety Committee
AU	Authorized User
Chair	Creighton University Department Chair
Dean	Creighton University Dean responsible for the AU/Department.
Supervisor/VP Support Services	Administrative Staff at Saint Joseph Hospital

Section Three - Inspections (Audits)

- 3.1 General. Throughout this Manual the term "inspection" and "audit" shall be synonymous. Authorized Users shall be inspected at least annually and subject to follow-up inspections. Inspections shall be conducted by the Radiation Safety Office or contracted personnel. Inspections shall include restricted areas under Authorized User licenses approved under the broad scope license. During the inspection, the Authorized User and his/her staff shall allow free access to all areas where the inspector reasonably believes radioactive material has been used and/or stored and shall fully cooperate during the inspection or any follow-up inspections.
- 3.2 Inspectors. The Radiation Safety Office staff or independent contractors shall conduct the inspections as set forth under §14.1.3 of the RSM or as required in this Manual.
- 3.3 Inspections
- 3.3.1 New Authorized Users. The Radiation Safety Office shall conduct the following inspections for each new Authorized User:
- An initial inspection of each restricted area approved for use by the new Authorized User within thirty (30) days from the approval date; and
 - If no radioactive material has been received prior to the initial inspection, a follow-up inspection shall be performed within thirty (30) days after the receipt of the first shipment of radioactive material by the new Authorized User.
- 3.3.2 Licensed Authorized Users. The Radiation Safety Office shall conduct an annual inspection of all restricted areas under the Authorized User's permit until such time as the Authorized User's license is terminated by the Authorized User or the RSC.

- 3.4 Follow-up Inspections under Section 5. Follow-up inspections shall be conducted by inspectors as required under Section 5 of this Manual.
- 3.5 Scheduling and Notice of Inspections. The Radiation Office shall schedule inspections of Authorized Users to ensure that inspections outlined in §3.3 above are conducted within the stated time frames. The Radiation Safety Office shall notify the Authorized User or his/her Lab Manager prior to conducting an inspection. Follow-up inspections under Section 5 below shall be scheduled by the Radiation Safety Office to ensure they are conducted within the time frames stated in Section 5. The Radiation Office may, but is not required to provide advance notification to Authorized Users of follow-up inspections
- 3.6 Inspection Forms. The following inspection forms shall be used to conduct inspections.
- 3.6.1 Nuclear Medicine Inspection Form. The Nuclear Medicine Inspection Form, Attachment "A", shall be used when conducting inspections of the nuclear medicine area at Saint Joseph Hospital.
- 3.6.2 Radioactive Material Inspection Form. The Radioactive Material Inspection Form, Attachment "B", shall be used when conducting inspections of all other restricted areas, excluding nuclear medicine.
- 3.7 Preparation for Inspection. In preparing for inspections, the inspector shall:
- Notify and coordinate with the Authorized User and/or Lab Manager the scope and purpose of the inspection;
 - Review the internal permit file of the Authorized User;
 - Review the most recent internal inspection report for the Authorized User to determine if any findings should be incorporated into the inspection;
 - Review the most recent state inspection report to determine if any findings should be incorporated into the inspection; and
 - Review necessary records and forms associated with and/or to be used for the inspection.
 - Select the appropriate Inspection Form (Appendix "A" or "B"). If using the Radioactive Material Form, a separate page "2" must be used for each restricted area under the Authorized User's permit.

3.8 Conducting the Inspection. The inspection shall include the items listed in §14.1.2 of the RSM. In addition, the inspector shall:

- Complete the preliminary information on page 1 of the inspection form (i.e., Authorized User, room inspected, date).
- Inspect each restricted area under the Authorized User's permit. (Use a separate page "2" for each restricted area when using the Radioactive Material Inspection Form) For follow-up inspections the inspection may, at the discretion of the inspector, be limited to the areas of non-compliance.
- Conduct the inspection with the Authorized User or Lab Manager present.
- Verify that the Authorized User's permit accurately reflects the approved restricted areas and radioactive materials.
- Perform each applicable item on the appropriate inspection form. (In some cases such as follow-up inspections, not all inspection items are applicable); and
- Where applicable, conduct wipes of areas where radioactive material has been used. Exposure surveys may be done for restricted areas containing more than 1mCi of beta-gamma material, excluding H-3 and C-14.
- Verify radioactive material inventory.

3.9 Preparing the Final Inspection Report. The completed inspection form utilized for the inspection shall serve as the final inspection report. After the inspection has been performed, the inspector shall:

- Review each finding, if any, and assign a safety level violation (i.e., minor, moderate or severe);
- Explain each finding in the "Items of Non-Compliance" section;
- Where noted, provide a citation to the appropriate section in the Nebraska regulations and/or RSM supporting the basis of each finding/violation;
- As appropriate, give general comments/recommendations in the comments section;
- Attach copies of any surveys performed;
- Mark whether any follow-up inspection is required under §5, giving the appropriate time period;
- Indicate corrective action, if any, required as set forth in §5 below;

- Mark the individuals who will be given a copy of the final report; and
- Sign and date the final inspection form/report.

3.10 Tracking Items of Violations and Corrective Action. All violations will be documented by the RSO on the User Audit Tracking Sheet, Attachment "C" to track corrective action.

Section Four - Records of Inspections

- 4.1 Distribution of the Inspection Report. The inspection report will be distributed as set forth in §14.1.4 of the RSM. If violations are noted, the inspection report will be distributed to those individuals identified under §5 as it pertains to the level of violation.
- 4.2 Review of Inspection Reports. The inspection reports will be reviewed by the RSC at its quarterly meetings.
- 4.2 Maintenance and Retention of Final Inspection Reports. The Radiation Safety Office shall maintain a copy of each final report. See §14.1.4 of the RSM. The Radiation Safety Office shall make such reports available for review by the State upon request.

Section Five - Corrective Action Process

- 5.1 General. Identified radiation safety violations will be ranked according to severity as minor, moderate or severe and will be subject to corrective action as set forth below. If there are multiple levels of violations, then corrective action will be taken based on the most severe level. For example, if two minor violations and one moderate violation are identified during an audit, then corrective action will be taken at the moderate level. In some cases, corrective action may only allow for development of procedures to prevent future non-compliance (i.e. record keeping), while other cases will require correction of the violation (i.e. posting of signs).
- 5.2 Authority of RSO, Chairperson(s) and RSC. The RSO and Chairperson(s) of the RSC have authority to shorten time periods under §5.3 and §5.4 and/or take immediate corrective action on "Moderate" or "Severe" violations until such time as the RSC can meet. In all cases, the RSO and Chairperson(s) of the RSC and/or RSC have authority to impose additional corrective action measures in addition to those outlined below, including corrective action available under the Creighton University's or Saint Joseph Hospital's employee disciplinary processes.
- 5.3 Corrective Action - Tier One. This applies to first time violations occurring within a 12-month period. However, multiple findings of the same violations will result in Tier Two Corrective action.

Severity Level	Corrective Action	Responsible Party
Minor	<p>a. Written notice (via lab survey) to the Authorized User and Department Chair (Chair), or Supervisor identifying violation(s) and recommended courses of corrective action.</p> <p>b. Correct the identified violations within 30 days and provide written notice of correction to the RSO.</p>	<p>a. Radiation Safety Office (RSO)</p> <p>b. Authorized User (AU) or Supervisor</p>
<p>Moderate; OR</p> <p>3+ minor violations with the potential for health or safety impact; OR</p> <p>4+ minor violations (same audit)</p>	<p>a. Written notice to the AU, Chair and Dean, or Supervisor and V.P. Support Services identifying violation(s) and recommended courses of corrective action.</p> <p>b. Written report to Radiation Safety Office outlining an analysis of the cause, corrective actions taken, and actions taken to prevent recurrence.</p> <p>c. Correct the identified violation(s) within 10 days and written notice to RSO of correction.</p>	<p>a. RSO</p> <p>b. AU or Supervisor</p> <p>c. AU or Supervisor and VP - Support Service</p>

Tier One, continued

Severity Level	Corrective Action	Responsible Party
Moderate, cont.	<p>d. AU to attend mandatory re-training as required by RSO.</p> <p>e. Follow-up audit of area(s) of violation(s) within 60 days of notice of corrective action taken.</p>	<p>d. AU or Supervisor and RSO</p> <p>e. RSO</p>
Severe	<p>a. Written notice to the AU, Chair, Dean and V.P. - Health Sciences, or Supervisor and V.P. - Support Services identifying violation(s), recommending courses of corrective action and time period to correct.</p> <p>b. Notify RSC & RSC Chair(s).</p> <p>c. Suspend (i) approval to use radioactive materials and (ii) shipment of radioactive materials, and if necessary, remove or transfer to another AU radioactive materials until RSC reviews. In the case of clinical use of radioactive material violations, only the individual procedure using that radioactive material will be suspended until such time as it is corrected.</p> <p>d. Written report within 15 days of notice to RSO outlining an analysis of the cause, corrective actions, and actions taken to prevent recurrence.</p> <p>e. Correct violation(s) within the time period identified in the Notice and written notice to RSO when corrective action is completed.</p> <p>f. AU to complete mandatory re-training as required by RSO and/or RSC before seeking re-instatement</p> <p>g. Appear before Radiation Safety Committee to have radiation materials use approval re-instated subject to any restrictions imposed. RSC may deny re-instatement based on safety concerns.</p> <p>h. Audit prior to receipt of radioactive materials and follow-up audit within 30 days of AU's receipt of radioactive materials.</p>	<p>a. RSO</p> <p>b. RSO</p> <p>c. RSO</p> <p>d. AU, Chair or Supervisor</p> <p>e. AU, Chair or Supervisor</p> <p>f. AU and RSO</p> <p>g. AU or Supervisor and RSC</p> <p>h. RSO</p>

5.4 Corrective Action - Tier Two. This applies to multiple moderate or severe violations during a single audit, reoccurring violations (same problem) during a 12-month period, or failure to comply with Tier One corrective actions.

Severity Level	Corrective Action	Responsible Party
Minor †	<ul style="list-style-type: none"> a. Written notice to AU, Chair, and Dean, or Supervisor identifying violation(s) and recommended courses of corrective action. b. Meet with someone from RSO c. Correct identified violations within 15 days of notice and provide written report of corrections to RSO within 30 days. d. Follow-up audit of the area(s) of violations within 60 days of notice of corrective action. 	<ul style="list-style-type: none"> a. RSO b. AU or Supervisor c. AU or Supervisor d. RSO
Moderate †	<ul style="list-style-type: none"> a. Written notice to AU, Chair, Dean and V.P. Health Sciences, or Supervisor and V.P. Support Services identifying violation(s) and recommended courses of corrective action with copy to RSC & RSC Chair(s). b. Suspend (i) approval to use radioactive materials, and (ii) shipment of radioactive materials, and if necessary, remove or transfer to another AU radioactive materials until corrective action completed. c. Meet with RSO and Radiation Safety Committee Chair(s) within 30 days. d. Written report to RSO outlining an analysis of the cause, corrective actions taken, and actions taken to prevent recurrence. e. Correct the identified violation(s) as soon as possible, but not more than 10 days from the date of notice and provide written confirmation of corrective action to RSO within 15 days of notice. f. AU to complete mandatory re-training as required by RSO. 	<ul style="list-style-type: none"> a. RSO b. RSO c. AU and Chair or Supervisor d. AU and Chair or Supervisor e. AU and Chair or Supervisor f. AU and RSO

Tier Two, continued

Severity Level	Corrective Action	Responsible Party
Moderate †, continued	<p>g. Review written report of cause and corrective action and impose any further corrective action as necessary, including restrictions on personnel/radioactive material.</p> <p>h. Follow-up audit area(s) of violation(s) within 60 days of notice of corrective action from AU.</p>	<p>g. Radiation Safety Committee.</p> <p>h. RSO</p>
Severe	<p>a. Written notice to AU, Chair, Dean and V.P. - Health Sciences or Supervisor and V.P. - Support Services identifying violation(s) and recommended courses of corrective action.</p> <p>b. Notify RSC and RSC Chair(s).</p> <p>c. Terminate approval to use radioactive materials and shipments of radioactive materials and remove or transfer to another AU, radioactive materials. In the case of clinical use radioactive material, suspension will be limited to the use where the violation occurred until such time as it is corrected.</p> <p>d. Take immediate corrective action.</p> <p>e. Appear before Radiation Safety Committee to explain violation(s).</p> <p>f. AU to complete mandatory re-training as required by RSO and/or RSC</p> <p>g. Additional Corrective Action, including imposition of possible fines against the AU and/or Department, termination, etc.</p> <p>h. AU must re-apply to the RSC for a new license to use radioactive material. Any future application for approval for radioactive materials may be denied or approved subject to restrictions or conditions, including more frequent monitoring which may be charged to the AU or Department.</p>	<p>a. RSO</p> <p>b. RSO</p> <p>c. RSO and RSC Chair(s);</p> <p>d. AU, Chair, Supervisor or RSO</p> <p>e. AU or Supervisor</p> <p>f. AU, RSO and RSC</p> <p>g. RSC</p> <p>h. RSC</p>

†Failure to comply with the corrective action for minor or moderate violations under Tier Two will result in immediate suspension of Authorized User's approval, suspension of shipments of radioactive materials and confiscation of radioactive materials. Once such violations are corrected, the Authorized User must reapply to the Radiation Safety Committee for approval to use radioactive materials, at which point the Radiation Safety Committee may deny such application or impose conditions and/or restrictions on any approval.