

Self-Shielded Irradiator  
Inspection Checklist

<b>Attachment 2.6-8</b> <b>Vermont Department of Health</b> <b>Radioactive Materials Program Supervisory Accompaniment</b> <b>Inspection Checklist</b> <b>Self-Shielded Irradiator</b>		
<b>Licensee:</b>	<b>License No.:</b>	
<b>Licensee Contact:</b> <b>Telephone Number:</b> <b>Email Address:</b> <b>Last Inspection Date:</b> <b>Priority:</b>		
<b>Location (Authorized Use or Storage):</b>	<b>Inspection Date:</b>	
<b>Inspector:</b>		
<b>Inspection Procedure(s) used: 87122, 83822, 87137, 86730</b>		
<b>Type of Inspection:</b> <input type="checkbox"/> Announced <input type="checkbox"/> Unannounced <input type="checkbox"/> Initial <input type="checkbox"/> Routine <input type="checkbox"/> Other:		
<p>Please note, if you record notes on the exact location of a source that exceeds 10 percent of a Category 2 quantity, the model number, possession limits, or actual inventory, the notes should be controlled in accordance with NRC Regulatory Information Summary 2005-031.</p> <p><b><u>Inspection Objectives:</u></b></p> <ul style="list-style-type: none"> <li>• To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.</li> <li>• To determine if licensed activities are being conducted in accordance with Vermont Department of Health regulations.</li> </ul> <p><b><u>Focus Elements:</u></b></p> <ol style="list-style-type: none"> <li>1. Security and Control of Licensed Materials</li> <li>2. Shielding of Licensed Materials</li> <li>3. Comprehensive Safety Measures</li> <li>4. Radiation Dosimetry Programs</li> <li>5. Radiation Instrumentation and Surveys</li> <li>6. Radiation Safety Training and Practices</li> <li>7. Management Oversight and Program Scope</li> <li>8. Licensed Activities Performed by Contracted Personnel</li> </ol>		
<b>Amendments and Program Changes (Review from last license renewal)</b>		
<b>Amendment #:</b>	<b>Date:</b>	<b>Amendment Item(s):</b>
<b>Notes:</b>		

Self-Shielded Irradiator  
Inspection Checklist

Organization	
Organizational structure meets requirements as identified on license.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Radiation Safety Officer (RSO) identified on license. [L/C]	<input type="checkbox"/> Yes <input type="checkbox"/> No
Performs duties required of RSO. [L/C]	<input type="checkbox"/> Yes <input type="checkbox"/> No
To whom does the RSO report? _____	
Has there been a change in the RSO?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, was the license amended?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has there been a change in the licensee contact person for the Department?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Identify and record all individuals in attendance at entrance meeting:</p> <p>    Individual 1:     Individual 2:     Individual 3:     Individual 4:</p> <p style="text-align: right;">Mailing address and location of use identified on license. <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Briefly describe the licensed material program (program structure, management, facilities, materials, etc.).</p>	
Management Oversight	
Management supports ALARA. [10 CFR 20.1101]	<input type="checkbox"/> Yes <input type="checkbox"/> No
Management supports RSO efforts.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are radiation protection annual audits being performed? [10 CFR 20.1101]	<input type="checkbox"/> Yes <input type="checkbox"/> No
Who conducts audits? _____	
Scope of audit (areas of the program licensee reviewed):	
Audits are conducted at intervals not exceeding 12 months.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Audits and review records of the licensee program are being maintained. [10 CFR 20.2102]	<input type="checkbox"/> Yes <input type="checkbox"/> No
Note: These records must be kept for three years after they are made.	
Were deficiencies found in the program during the last two self-audits?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Self-Shielded Irradiator  
Inspection Checklist

<p>If yes, have the deficiencies been corrected? Note: The inspector should look for repeat deficiencies.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Audit records were reviewed by Department inspector.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Performance Evaluation Factors (PEF)</p> <p>Senior management is involved with radiation safety program and RSO oversight.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>The RSO has sufficient time to perform his/her radiation safety duties.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>The licensee has sufficient staffing for their program.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Adequate audits are being implemented.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<b>Inspection History</b>	
<p>Item(s) of non-compliance cited at last inspection.</p> <p>Previous items of non-compliance(s) properly corrected. If no, list those items of non-compliance with an explanation.</p> <p>List recommendations given at last inspection:</p> <p>Did licensee address previous recommendation(s)?</p>	<p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<b>Staff Training Program</b>	
<p>AUs have received training on irradiator use in accordance with their submitted training program. [L/C]</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Annual refresher training given to personnel likely to be exposed to &gt; 100 mrem/year per <b>10 CFR 19.12</b>.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Do the AUs demonstrate adequate knowledge and understanding of the operating and emergency procedures? (Example: source not returning, interlock failure, fire, etc.)</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Identify those individuals interviewed:</p> <p>Individual 1: Individual 2: Individual 3: Individual 4:</p> <p>Training records maintained for three years per <b>10 CFR 36.81</b>.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

Self-Shielded Irradiator  
Inspection Checklist

<b>Posting</b>	
<p>Posting required per <b>10 CFR 20.1902</b>.</p> <p>“Caution, Radioactive Material” signs are posted where required. <b>[10 CFR 20.1902]</b>            Note: “Caution, Radioactive Material” sign need not be posted if levels are less than 0.05 Sv (5 mR/hr) at 30 cm from the container surface.</p> <p>“Caution, Radiation Area” signs are posted where required. <b>[10 CFR 20.1902]</b>            Note: “Caution, Radiation Area” sign must be posted if levels are greater than 0.05 Sv (5 mR/hr) at 30 cm from the container surface.</p> <p>The following documents are posted in a conspicuous location, or a summary that states where they are located per <b>10 CFR 19.11</b>:</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Vermont Radiological Health Rule.</p> <p>The license, license conditions, or incorporated documents.</p> <p>Operating procedures.</p> <p>The following documents are posted in a conspicuous location per <b>10 CFR 19.11</b>:</p> <p>Emergency procedures.</p> <p>“Notice to Employees” form.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<b>Labeling</b>	
<p>Label on device(s) are properly attached, legible, and contain the following per <b>10 CFR 20.1904</b>:</p> <p>(1) Radiation symbol</p> <p>(2) “Caution, Radioactive Material”</p> <p>(3) Radionuclide(s) present</p> <p>(4) Estimate of quantity of radioactivity</p> <p>(5) Date of estimate</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<b>Maintenance</b>	
<p>Routine maintenance is being performed by licensee as recommended by the manufacturer. <b>[L/C]</b></p> <p>Non-routine maintenance is performed by the manufacturer or a person specifically licensed by the Department, NRC, or another Agreement State. <b>[L/C]</b></p> <p>Non-routine maintenance is performed by licensee personnel utilizing proper procedures. <b>[L/C]</b></p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>

Self-Shielded Irradiator  
Inspection Checklist

(1) List authorized individuals:	
(2) Manufacturer training records are maintained. [L/C]	<input type="checkbox"/> Yes <input type="checkbox"/> No

**Public Dose**

Has a survey or evaluation been performed to ensure that public dose is less than 2 mrem in any one hour and less than 100 mrem/year per <b>10 CFR 20.1301</b> .	<input type="checkbox"/> Yes <input type="checkbox"/> No
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**Leak Tests**

Leak test performed on each sealed source at six-month intervals unless otherwise authorized on the Sealed Source Device Register. [L/C]	<input type="checkbox"/> Yes <input type="checkbox"/> No
Leak tests are analyzed by a licensee authorized by the Department, NRC, or an Agreement State per <b>10 CFR 36.59</b> . [L/C]	<input type="checkbox"/> Yes <input type="checkbox"/> No
(1) Company Name and License Number: _____	
(2) Test kit model number: _____ Kit manufacturer: _____	
(3) The Department inspector observed a user taking a sample?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Licensee performs own leak test. [10 CFR 31.5]	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, is licensee following the approved procedures?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Leak test results are reported in becquerels or microcuries.	<input type="checkbox"/> Yes <input type="checkbox"/> No

**Facilities, Materials, and Equipment**

List the source(s)/device(s):

Receipt Date	Manufacturer	Model #	Isotope	Source #	S/N	Activity (Ci)	Activity Date	Disposal/Transfer Date

Note: Ask for most recent inventory.

Records of receipt, transfer, and disposal of licensee's radioactive material maintained for three years as per <b>10 CFR 36.81</b> .	<input type="checkbox"/> Yes <input type="checkbox"/> No
Use and storage area(s) meet the following criteria:	
(1) Same as described on license. [L/C]	<input type="checkbox"/> Yes <input type="checkbox"/> No
(2) Adequate controls in place to prevent unauthorized access to radioactive materials per <b>10 CFR 36.23</b> .	<input type="checkbox"/> Yes <input type="checkbox"/> No

Self-Shielded Irradiator  
Inspection Checklist

<p>(3) Device is used in accordance with their SSD certification.</p> <p>Licensee possesses or has access to survey instruments. [L/C]</p> <p>Survey meter is properly calibrated per <b>10 CFR 20.1501</b>.</p> <p>Records are kept for three years from date they are made. [<b>10 CFR 36.81</b>]</p> <p>Physical inventories are conducted at six-month intervals. [L/C]</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<b>Independent Survey Measurements by the Department Inspector</b>	
<p>Inspector performed independent confirmatory measurements.</p> <p>If yes, record:</p> <p>Highest radiation level in an unrestricted area: _____ mR/hr</p> <p>Highest radiation level at 30 cm from device: _____ mR/hr</p> <p>Highest radiation level at 1 meter from device: _____ mR/hr</p> <p>Reading at external surface of device: _____ mR/hr</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Inspector's survey instrument(s) used:</p> <p>Mfg./Make: Model #: Serial #: Last calibration date:</p> <p>Licensee survey instrument (if available):</p> <p>Mfg./Make: Model #: Serial #: Last calibration date:</p> <p>Describe inspector instrument readings as compared to licensee instrument readings.</p> <p>Radiation levels in all unrestricted areas do not exceed 2 mrem in any one hour or 100 mrem/year.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<b>Personnel Monitoring</b>	
<p>Personnel monitoring is being used per <b>10 CFR 20.1502</b>.</p> <p>If no, was an evaluation performed to demonstrate monitoring is not required?</p> <p>Dosimeter processor is NVLAP certified per <b>10 CFR 20.1501</b>.</p> <p>Dosimetry supplier: _____</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>

Self-Shielded Irradiator  
Inspection Checklist

<p>Monitoring results reviewed by licensee:</p> <p style="padding-left: 40px;"><input type="checkbox"/> Monthly   <input type="checkbox"/> Quarterly   <input type="checkbox"/> Annually</p> <p>Licensee provides all workers a written report of their annual radiation exposure per <b>10 CFR 19.13</b>.</p> <p>Worker exposure records provided within 30 days upon request per <b>10 CFR 19.13</b>.</p> <p>Inspector reviewed personnel monitoring records, from _____ to _____.</p> <p style="padding-left: 40px;">Maximum DDE: _____ mSv   _____ mR</p> <p style="padding-left: 80px;"><input type="checkbox"/> Month   <input type="checkbox"/> Quarter   <input type="checkbox"/> Annual</p> <p style="padding-left: 40px;">Maximum SDE: _____ mSv   _____ mR</p> <p style="padding-left: 80px;"><input type="checkbox"/> Month   <input type="checkbox"/> Quarter   <input type="checkbox"/> Annual</p> <p>Personnel monitoring records are being maintained per <b>10 CFR 20.2106</b>.</p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>
<b>Notifications and Reports</b>	
<p>Have there been any occupational overexposures or excessive levels of radiation?</p> <p style="padding-left: 40px;">Were they reported to the Department per <b>10 CFR 19.13</b>?</p> <p>Have any reports of leaking source(s) been made to the Department per <b>10 CFR 36.59</b>?</p> <p>Has any theft, loss of licensed material, or radiological incident occurred and was the Department notified per <b>10 CFR 20.2201</b>?</p> <p style="padding-left: 40px;">If yes, describe the root cause and corrective actions taken for each incident.</p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>
<b>Transportation of Radioactive Materials</b>	
<p>Licensee ships their own materials.</p> <p style="padding-left: 40px;">If yes, licensee adheres to provisions of <b>10 CFR 20.2001</b>.</p> <p>Licensee uses the manufacturer/distributor or a service licensee (authorized by the Department, NRC, or another Agreement State) to ship their radioactive material.</p> <p>Shipment paperwork is maintained for three years per <b>10 CFR 71.91</b>.</p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>
<b>Decommissioning</b>	
<p>Decommissioning records for storage locations and records of other occurrences are kept in an identified location per <b>10 CFR 30.35</b>.</p> <p>(e.g. blueprints, as-built drawings, appropriate records)</p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>

Self-Shielded Irradiator  
Inspection Checklist

<b>Security Inspection</b>	
<p><b>On-site Security Review:</b> If this licensee is authorized for possession of material equal to or exceeding the Category 2 threshold, complete an on-site security review per <b>10 CFR 37.43</b>.</p> <p>If yes,</p> <p>Licensee Contact Name:</p> <p>Contact Telephone Number:</p> <p>Contact Email Address:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<b>Summary of Observations, Findings, and Conclusions</b>	
<p>Business Operations:</p> <p>Facility – Visit all storage and use locations identified on the application:</p> <p>Radiation Safety Operations.</p> <p>Personnel.</p> <p><b>Overall Assessment</b>            Note: If there is not sufficient information to conclude that licensed material will be used as specified on the license, immediately notify Department supervision.</p>	
<b>License Conditions/Tie-downs</b>	
<p>Were all license conditions reviewed by Department inspector?</p> <p>Are the licensee’s activities conducted in accordance with license conditions?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Bulletins and Information Notices</b>	
<p>Is the licensee reviewing the Department bulletins and information notices?</p> <p>Has the licensee taken appropriate action in response to the bulletins and notices?            Note: Inspector will provide copies if the licensee has not received them.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Exit Meeting at Conclusion of Inspection</b>	
<p>Identify and list the individuals in attendance.</p>	<p>Date Meeting Conducted:</p>
<p>List those issues discussed at the exit meeting:</p>	



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Inspection Checklist

**Summary of Violations and Recommendations**