

Commercial Nuclear Pharmacy
Inspection Checklist

Attachment 2.6-4 Vermont Department of Health Radioactive Materials Program Inspection Checklist	
Commercial Nuclear Pharmacy	
Licensee:	License No.:
Licensee Contact: Telephone Number: Email Address: Last Inspection Date: Priority:	Inspection Date:
Inspector:	
Inspection Procedure(s) used: 83822, 87127, 86730, 86740, 87137	
<u>Inspection Objectives:</u> <ul style="list-style-type: none">• To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.• To determine if licensed activities are being conducted in accordance with Vermont Department of Health regulations. <p>Note: Radiopharmacies may possess and operate an accelerator that produces Positron Emission Tomography (PET) radionuclides used to manufacture PET radioactive drugs. Inspection Procedure (IP) 87125, "Materials Processor/Manufacturer Programs," provides guidance on inspecting radionuclide production activities within these radiopharmacy facilities.</p>	
<u>Focus Elements:</u> <ol style="list-style-type: none">1. Security and Control of Licensed Materials2. Shielding of Licensed Materials3. Comprehensive Safety Measures4. Radiation Dosimetry Programs5. Radiation Instrumentation and Surveys6. Radiation Safety Training and Practices7. Management Oversight and Program Scope8. Licensed Activities Performed by Contracted Personnel	
Inspection Site Address (authorized use or storage):	
Type of Inspection: <input type="checkbox"/> Announced <input type="checkbox"/> Initial <input type="checkbox"/> Other:	<input type="checkbox"/> Unannounced <input type="checkbox"/> Routine
Date of Last Inspection:	

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Amendments and Significant Program Changes (Review from last license renewal)		
Amendment #:	Date:	Amendment Item(s):
Note:		
Program Inspection History		
Is this an initial inspection?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
List previous open items of violations:		
Have previous violation(s) been properly corrected? If no, list those items not corrected with an explanation.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
List previous items of recommendations:		
Did licensee address previous recommendation(s)? If no, explain.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
Organization [Note: Request organization chart]		
Briefly describe licensee organizational structure as it pertains to licensed activities. [L/C]		
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, 10 CFR 35.24]	<input type="checkbox"/> Yes <input type="checkbox"/> No	
RSO fulfills his/her duties as required. [L/C, 10 CFR 35.24]	<input type="checkbox"/> Yes <input type="checkbox"/> No	
To whom in the organization does the RSO report? _____		
The RSO has sufficient access to licensee's senior management?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Has there been a change in RSO?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, was the license amended?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Does the new RSO meet the Department's training requirements?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Has there been a change in the licensee contact person for the Department? Note: Confirm through discussions with management and licensee personnel whether changes have occurred in the licensee ownership, or in the RSO's authority or duties, that may impact the RSO's ability to safely conduct the licensee's radiation protection program.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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<p>Identify all individuals in attendance at entrance meeting.</p> <p>Individual 1: Individual 2: Individual 3: Individual 4:</p>	
Scope of Licensee Program	
<p>Locations where licensed materials are being used, possessed, and stored are as described on the license. [L/C, 10 CFR 30.32]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Has the mailing address changed? [10 CFR 30.32]</p> <p>Has the company ownership changed? [10 CFR 30.34]</p> <p style="padding-left: 40px;">If yes, was the Department notified? [10 CFR 30.34]</p> <p>List location(s) of licensed material and identify the location of this inspection.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Authorized Nuclear Pharmacist (ANP) is named on the license, with appropriate training documentation. [10 CFR 35.55]</p> <p>Is there a new ANP since the last inspection?</p> <p style="padding-left: 40px;">If yes, does the new ANP meet the training requirements? [L/C, 10 CFR 35.55]</p> <p style="padding-left: 40px;">Was the Department notified within 30 days with an amendment to the license?</p> <p style="padding-left: 80px;">Note: Request a list of names of the RSO, ANPs, and AUs. [10 CFR 35.14]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Are all authorized users (AUs) listed on the license? [L/C, 10 CFR 35.14]</p> <p style="padding-left: 40px;">If no, was the Department notified of changes to the AU list?</p> <p style="padding-left: 40px;">Do new AU's meet Department training requirements? [10 CFR 35.57]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Personnel interviewed at licensee address during the inspection (**indicates those individuals in attendance at exit meeting).</p> <p>Individual 1: Individual 2: Individual 3: Individual 4:</p> <p>Describe the licensed material program (types and quantities of licensed materials received, transferred, or redistributed; number of facilities/customers served; size of staff; etc.):</p>	

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<p>Licensee distributes:</p> <p> <input type="checkbox"/> Photon-emitting material <input type="checkbox"/> Generators <input type="checkbox"/> Alpha- and beta-emitting material <input type="checkbox"/> Sealed sources <input type="checkbox"/> Iodinated material (I-131, I-125, or I-123) </p> <p>The license identifies all radionuclides possessed by the licensee. [L/C]</p> <p>Radioactive materials in the licensee's possession are within quantity limits indicated on the license. [L/C]</p> <p style="text-align: center;">Note: Request a copy of licensee's most recent inventory of radioactive materials, including sealed sources.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
Management Oversight	
<p>Management supports ALARA. [10 CFR 20.1101]</p> <p>Management supports RSO efforts.</p> <p>Are radiation protection annual audits being performed? [10 CFR 20.1101]</p> <p>Who conducts audits? _____</p> <p>Scope of audit (areas of the program licensee reviewed) [10 CFR 20.1101]:</p> <p>Audits are conducted at intervals not exceeding 12 months. [10 CFR 20.1101]</p> <p>Audits and review records of the licensee program are being maintained. [10 CFR 20.2102]</p> <p style="padding-left: 20px;">Note: These records must be kept for three years after they are made.</p> <p>Were deficiencies found in the program following a self-audit?</p> <p style="padding-left: 20px;">If yes, have the deficiencies been corrected?</p> <p style="padding-left: 20px;">Note: The inspector should look for repeat deficiencies.</p> <p>Audit records were reviewed by Department inspector.</p> <p>Performance Evaluation Factors (PEF)</p> <p style="padding-left: 20px;">Note: PEF evaluations are best accomplished by interviewing management, RSO, ANPs, AUs, and other licensee personnel.</p> <p>Senior management is involved with radiation safety program and RSO oversight.</p> <p>The RSO has sufficient time to perform his/her radiation safety duties.</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> <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>

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<p>The licensee has sufficient staffing to support its activities and radiation protection programs.</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>	
Pharmacy Facilities	
<p>Have the facility design and/or locations of use changed? [L/C]</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>If yes, has the license been amended? Note: The inspector should request a tour of the licensee's facilities.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>The areas for receiving, using, and storing licensed materials are secured and adequate for the licensee's activities.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>There is a clear delineation between restricted and unrestricted areas.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p style="padding-left: 40px;">Note: Check for barriers, posting, security, contamination monitoring stations, and worker's instructions.</p>	
<p>Areas assigned as receipt, use, preparation, and waste storage are identified.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>The licensee makes every reasonable effort to maintain radiation levels ALARA in areas where licensed activities are performed. [10 CFR 20.1101]</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>Are ventilation systems for iodinations adequate and all required effluent dose limits met. [L/C, 10 CFR 20.1701]</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p style="padding-left: 40px;">Note: Licensee maintains a procedure to ensure ventilation systems are working (e.g., monitoring HEPA filter weekly.)</p>	
<p>There are adequate numbers of lead shields (L-blocks) in place.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>Generators are housed in a separate room.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>If no, are generators properly shielded and isolated to keep radiation levels ALARA?</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
Survey Equipment and Instrumentation	
<p>There are sufficient numbers of portable and fixed monitoring equipment for the materials authorized by the licensee. [L/C]</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>Do survey meters meet the Department's criteria? [10 CFR 20.1501]</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>Calibration records are maintained for each fixed and portable monitor. [10 CFR 20.2103]</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>Who performs calibrations of licensee's equipment? _____</p> <p style="padding-left: 40px;"><input type="checkbox"/> In-house <input type="checkbox"/> Authorized Outside Vendor</p>	
<p>Note: Make list of monitoring equipment; check and record all pertinent information pertaining to the instrument calibrations, serial numbers, etc.</p>	

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<p>Are procedures in place to identify, evaluate, and report equipment safety component defects? [L/C, 10 CFR 32.74]</p> <p>Note: Inquire about basic components of licensee's equipment where a failure or defect has been found (voluntary report to the Department.) If left unattended, the defects could become substantial safety hazards.</p> <p>Dose calibrators for photon-emitters. [10 CFR 35.2432]</p> <p>Constancy checked daily prior to assay of patient dosages ($\pm 10\%$ accuracy.)</p> <p>Linearity checked at installation and quarterly ($\pm 10\%$ accuracy.)</p> <p>Geometry dependence checked at installation ($\pm 10\%$ accuracy.)</p> <p>Note: Must be checked against volumes and configurations (volumes dispensed and syringe sizes.)</p> <p>Accuracy checked at installation and yearly ($\pm 10\%$ accuracy).</p> <p>Note: If the dose calibrator has been repaired, relocated, or adjusted, all appropriate tests listed above must be repeated, and be within $\pm 10\%$ accuracy before putting the calibrator back in use.</p> <p>Dose measurements for beta- and alpha-emitters. [10 CFR 35.60]</p> <p>Calibrated with each isotope used by the licensee.</p> <p>Constancy checked daily prior to assay of patient dosages ($\pm 10\%$ accuracy.)</p> <p>Geometry dependence checked at installation ($\pm 10\%$ accuracy.)</p> <p>Accuracy checked at installation and yearly ($\pm 10\%$ accuracy.)</p> <p>Linearity checked at installation and quarterly ($\pm 10\%$ accuracy.)</p> <p>Dose measurement procedure available and in use. [L/C]</p> <p>Note: If the calibrator is repaired, adjusted, or relocated, all tests listed above must be repeated. If any test exceeds $\pm 10\%$ the calibrator must be repaired or replaced.</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> <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> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Surveys and Contamination Control</p>	
<p>Are routine surveys performed for radiation levels and removable contamination? [L/C]</p> <p>Are area ambient surveys performed daily and records maintained? [10 CFR 20.1501 & 10 CFR 20.2103]</p> <p>Are contamination surveys performed and records maintained? [10 CFR 20.1501 & 10 CFR 20.2103]</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>

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<p>Are radiopharmaceutical preparation areas surveyed after each run? [L/C]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Are storage and unrestricted areas surveyed weekly? [L/C]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Is proper equipment being used to detect contamination and measure radiation levels? [L/C]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Identify licensee's meter(s) used for ambient radiation level surveys. Note: Check meter type, model, serial number, calibration records, and batteries.</p>	
<p>Identify licensee's instrument(s) used for detecting removable contamination. Note: Check instrument type, model, serial number, and calibration records.</p>	
<p>Corrective actions are implemented and documented when excess radiation or contamination levels are detected.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>An action level for radiation levels is established and used. [L/C]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>An action level for removable surface contamination is established and used. [L/C]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Sealed Sources and Leak Test	
<p>A leak test is performed on each sealed source at six-month intervals or as specified in the SSD certificate. [L/C]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Leak tests performed as described in the license. [L/C]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Leak test records are maintained for three years.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Was any source found leaking since the last inspection? [10 CFR 35.67]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p style="padding-left: 40px;">If yes, was the Department notified?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Radioactive Materials Use and Controls	
<p>Radioactive materials stored in an unrestricted area are secured from unauthorized access to or removal from the area? [10 CFR 20.1801]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Radioactive materials in a controlled area, but not in storage, are under surveillance at all times? [10 CFR 20.1802]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Are procedures available for receiving and opening packages? [10 CFR 20.1906]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Are restricted and unrestricted areas delineated?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Licensed radioactive materials are transferred only to authorized recipients? [10 CFR 30.41]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Records of receipt and transfer of radioactive materials are maintained?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Note: Review licensee's most recent inventory. [10 CFR 35.2067]</p>	

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<p>Do employees use safe handling practices when working with radiopharmaceuticals (e.g., lab coats, disposable gloves, etc.)?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
Instructions to Workers	
<p>All individuals/workers who are likely to receive an occupational dose [>1 mSv (100 mR) per year] are informed of their exposures. [10 CFR 19.13]</p> <p>Annual training is provided to employees who are projected to exceed 100 mR/year. [10 CFR 19.12]</p> <p>Required records are maintained for three years. [10 CFR 35.2067]</p> <p>Other workers are given training as needed (e.g., radiopharmacy technician, courier/drivers of licensee's delivery vehicle, and ancillary personnel.) [L/C, 10 CFR 30.33]</p> <p>Training records are maintained and available for Department review.</p> <p>Workers are knowledgeable of applicable parts of NUREG-1556 Volume 13 and 10 CFR 30.33, license conditions, and licensee's operating, emergency, and safety procedures.</p> <p>Hazmat training is provided for transportation personnel (e.g., courier/drivers of licensee's delivery vehicle.) [49 CFR 172.700]</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> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
Staff Training Program	
<p>Is adequate ANP supervision provided to employees who handle radiopharmaceuticals? [L/C]</p> <p>List personnel trained to do specialized services, such as instrument calibration and leak testing. [L/C]</p> <p>Training course approved per Appendix G of NUREG-1556 Volume 15.</p> <p>RSO retains documentation of training.</p> <p>Inspector observed AU performing licensed activities.</p> <p>Are any AUs authorized to perform non-routine maintenance on dose calibrators?</p> <p>Is the AU knowledgeable and familiar with licensee's operating and emergency procedures?</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> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
Notification and Reports	
<p>Did the licensee provide monitored individuals with an annual written report of their occupational exposure? [10 CFR 19.13]</p> <p>Occupational radiation exposure reports for monitored personnel are being maintained?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>

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<p>At termination of employment, are workers' exposure records available upon request? [10 CFR 19.13]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Has any licensed radioactive material been stolen, lost, or gone missing since the last inspection? [10 CFR 20.2201]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Have any reportable events occurred since the last inspection? [10 CFR 20.2202]</p> <p style="padding-left: 20px;">If yes, describe the root cause and corrective action taken.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Have any occupational overexposures and/or excessive levels of radiation been reported to the Department? [10 CFR 20.2203]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>The RSO and all authorized users are aware of and have access to the department's emergency telephone number. [Note: Department 24-hour telephone number is 802-863-7280.]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Posting and Labeling	
<p>Is posting required? [10 CFR 20.1902 & 20.1903]</p> <p style="padding-left: 20px;">Note: "Caution, Radiation Area" sign does not need to be posted if the radiation levels are less than 0.05 mSv/hour (5 mR/hour) at 30 cm from the source. "Caution, Radioactive Materials" sign must be posted in each area or room in which licensed material exceeding 10 times the quantity listed in 10 CFR Part 20 Appendix B is used or stored.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p style="padding-left: 20px;">"Caution, Radioactive Materials" signs posted where required. [10 CFR 20.1902]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p style="padding-left: 20px;">"Caution, Radiation Area" sign posted as required. [10 CFR 20.1901 & 20.1902]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p style="padding-left: 20px;">All radioactive material transport containers are labeled and legible. [10 CFR 20.1904]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>The Department's "Notice to Employees" is posted in an appropriate area. [Department Form 3]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>The Department's rules, license, notice of items of non-compliance, and applicable sections of Vermont Radioactive Materials Rule posted, or a notice of availability is posted for employee review.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Are there any exemptions to posting [10 CFR 20.1903] or labeling [10 CFR 20.1905] requirements?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Is each transport radiation shield (e.g., pig) labeled with the radiation symbol and the words "Caution, Radioactive Material?"</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Is each syringe, vial, or other container (e.g., generator or ampule) used to hold radioactive drugs labeled with the radiation symbol and the words "Caution, Radioactive Material," and an identifier which correlates to the transport radiation shield?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

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Independent and Confirmatory Measurements	
<p>Inspector performed independent surveys.</p> <p>If yes, record: Highest radiation level in unrestricted areas: _____ mR/hr</p> <p>Highest radiation level in restricted areas: _____ mR/hr</p> <p>Inspector's survey instrument(s) used:</p> <p>Mfg./Make: Model #: Serial #: Last calibration date:</p> <p>Licensee survey instrument(s):</p> <p>Mfg./Make: Model #: Serial #: Last calibration date:</p> <p>Compare inspector instrument readings to licensee instrument readings.</p> <p>Radiation levels in all unrestricted areas do not exceed 2 mR in any one hour or 100 mR in a year. [10 CFR 20.1301]</p> <p>Reading at external surface of transportation containers: _____ mR/hr [10 CFR 20.1906]</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>
Personnel Monitoring	
<p>Is dosimetry required? [L/C, 10 CFR 20.1502]</p> <p>Dosimeters are provided to workers.</p> <p>Type:</p> <p><input type="checkbox"/> Film <input type="checkbox"/> Whole Body <input type="checkbox"/> TLD <input type="checkbox"/> Extremity <input type="checkbox"/> Luxel <input type="checkbox"/> OSL</p> <p>Frequency of reports:</p> <p><input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly</p> <p>Dosimetry supplier: _____</p> <p>NVLAP certified? [10 CFR 20.1501]</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>

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<p>Before waste is disposed, surveys are performed at the surface of each container with the survey meter set to its most sensitive scale.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Records of disposal are maintained.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Effluents from licensed material are maintained ALARA.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p style="padding-left: 40px;">The fume hood is being checked for adequate air flow.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Filters are being maintained and replaced according to the manufacturer's instructions and licensee's written procedures. [L/C]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Transportation of Radioactive Materials	
<p>Licensee makes shipments of radioactive material. [10 CFR 30.41]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p style="padding-left: 40px;">Security and all applicable regulations followed. [10 CFR 30.41]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Shipments are made through common carriers. [10 CFR 71.5]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Shipments are transported in the licensee's private vehicle(s). [10 CFR 71.5]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p style="padding-left: 40px;">Driver trained in HAZMAT communications, including loading and unloading radioactive materials. [49 CFR 177.816 & 177.842]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Licensee packages and ships radioactive materials according to regulatory procedures. [10 CFR 30.41]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Type A package used for shipping and marked "Type A." [10 CFR 71]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Shipping container normally used to transport radioactive materials:</p> <p style="padding-left: 40px;"> <input type="checkbox"/> Steel "Ammo" Box <input type="checkbox"/> Aluminum Suitcase <input type="checkbox"/> Other </p>	
<p>Package/container meets design requirements. [49 CFR 173.410 & 173.415]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>DOT 7A or other authorized packages used for shipping. [49 CFR 173.415(a)]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Package properly marked with two labels that include proper shipping name and Identification Number ("Radioactive material, N.O.S., UN 2928.")</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Those packages containing more than 10 mCi of iodinated byproduct include the letters RQ (reportable quantity.)</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Activity per package does not exceed the A-1 or A-2 limit. [49 CFR 173.424]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Only shipping labels "Radioactive White-I" or "Radioactive Yellow-II" are used.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p style="padding-left: 40px;">Note: Yellow-II labels must include the Transport Index (TI). [49 CFR 173.403]</p>	
<p style="padding-left: 40px;">Radiation levels at the external surface of the package for White-I labels are less than or equal to 0.5 mR/hr. [49 CFR 172.403]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

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<p style="text-align: center;">Radiation levels at the external surface of the package for Yellow-II labels are greater than 0.5 mR/hr but do not exceed 50 mR/hr. [49 CFR 172.403]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Contamination levels at the surface of the package are checked before shipping and on return from customers.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>All proper shipping requirements are met (shipper's name, RQ, description of shipment, hazards class, UN number, nuclide, activity category, label, TI, etc.) [49 CFR 172.200 through 172.204]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Emergency procedures and response telephone number(s) are available. [49 CFR 172.604]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Shipping papers are readily accessible during transportation. [49 CFR 177.817(e)]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Note: Papers must be placed in pocket in the door of the driver's side or placed on the passenger seat. If there is no pocket, the driver must place the papers on the driver's seat when he/she is out of the vehicle.</p>	
<p>Special form materials are shipped.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Vehicle is placarded as required (Yellow-III if TI > 1.0.) [49 CFR 172.504(a)]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Radioactive materials are secured and properly blocked and braced in transport vehicle. [49 CFR 177.834(a) & 177.842(d)]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>A QA program for packaging is in place. [L/C]</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
License Conditions/Tie-downs	
<p>All license conditions reviewed by Department inspector.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Licensee activities are being conducted in accordance with license conditions.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Bulletins and Information Notices	
<p>Licensee is receiving the Department information notices and bulletins.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Licensee has taken appropriate action in response to the notices and bulletins.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Security Inspection	
<p>On-site Security Review: If this licensee is authorized for possession of material equal to or exceeding the Category 2 threshold, complete an on-site security review per 10 CFR 37.43.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<p>If yes,</p>	
<p>Licensee Contact Name:</p>	
<p>Contact Telephone Number:</p>	
<p>Contact Email Address:</p>	

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Summary of Observations, Findings, and Conclusions

Business Operations:

Facility – Visit all storage and use locations identified on the application

Personnel:

Overall Assessment

Note: If there is not sufficient information to conclude that licensed material will be used as specified on the license, immediately notify Department supervision.

Exit Meeting at Conclusion of Inspection

Identify and list the individuals in attendance:

Date meeting conducted:

List those issues discussed at the exit meeting:

Summary of Violations and Recommendations