#### Attachment 2.6-4 Vermont Department of Health Radioactive Materials Program Inspection Checklist Commercial Nuclear Pharmacy

Licensee:

License No.:

**Inspection Date:** 

Licensee Contact: Telephone Number: Email Address: Last Inspection Date: Priority: Inspector:

Inspection Procedure(s) used: 83822, 87127, 86730, 86740, 87137

#### **Inspection Objectives:**

- 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.

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.

#### **Focus Elements:**

- 1. Security and Control of Licensed Materials
- 2. Shielding of Licensed Materials
- 3. Comprehensive Safety Measures
- 4. Radiation Dosimetry Programs
- 5. Radiation Instrumentation and Surveys
- 6. Radiation Safety Training and Practices
- 7. Management Oversight and Program Scope
- 8. Licensed Activities Performed by Contracted Personnel

Inspection Site Addres	s (authorized use or storage):	
Type of Inspection: Announced Initial Other:	Unannounced Routine	Date of Last Inspection:

Amendments and Significant Program	n Changes (Review from la	st license renewal)	
Amendment #:	Date:	Amendment Item(s):	
Note:			
Program Inspection History			
Is this an initial inspection?			Yes No
List previous open items of violation	ns:		
Have previous violation(s) been pro- If no, list those items not correct	Have previous violation(s) been properly corrected? If no, list those items not corrected with an explanation.		Yes No
List previous items of recommendat	ions:		
Did licensee address previous recom If no, explain.	nmendation(s)?		Yes No
Organization [Note: Request organizati	ion about		
Organizational structure meets requi	irements as identified on lice	ense.	Yes No
Radiation Safety Officer (RSO) ider	ntified on license. [L/C, 10 C	CFR 35.24]	Yes No
RSO fulfills his/her duties as rec	quired. [L/C, 10 CFR 35.24]	l	Yes No
To whom in the organization do	es the RSO report?		
The RSO has sufficient access to	o licensee's senior managem	ent?	Yes No
Has there been a change in RSO	)?		Yes No
If yes, was the license amen	ded?		Yes No
Does the new RSO meet the	e Department's training requ	irements?	Yes No
Has there been a change in the licen Note: Confirm through discussion changes have occurred in the lice that may impact the RSO's ability program.	see contact person for the Do ons with management and lic ensee ownership, or in the R ity to safely conduct the lice	epartment? censee personnel whether SO's authority or duties, nsee's radiation protection	Yes No

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

Licensee distributes:	
Photon-emitting material Generators	
Alpha- and beta-emitting material Sealed sources	
$\Box$ Indinated material (I-131 I-125 or I-123)	
The license identifies all radionuclides possessed by the licensee. [L/C]	Yes No
Radioactive materials in the licensee's possession are within quantity limits indicated	Yes No
on the license. [L/C]	
Note: Request a copy of licensee's most recent inventory of radioactive materials,	
including sealed sources.	
Management Oversight	
Management supports ALARA. [10 CFR 20.1101]	Yes No
Management supports RSO efforts.	Yes No
Are radiation protection annual audits being performed? [10 CFR 20.1101]	Yes No
Who conducts audits?	
Scope of audit (areas of the program licensee reviewed) [10 CFR 20.1101]	
Audits are conducted at intervals not exceeding 12 months [10 CFR 20 1101]	Ves No
Audits die conducted at intervals not exceeding 12 months. [10 CI K 20.1101]	
Audits and review records of the licensee program are being maintained [10 CFR	
Audits and review records of the needsee program are being maintained. [10 CFK	
20.2102]	
Note: These records must be kept for three years after they are made.	
were deficiencies found in the program following a self-audit?	🗌 Yes 🔝 No
If yes, have the deficiencies been corrected?	Ves No
Note: The inspector should look for repeat deficiencies.	
Audit records were reviewed by Department inspector.	Yes No
Performance Evaluation Factors (PEF)	
Note: PEF evaluations are best accomplished by interviewing management, RSO,	
Note: PEF evaluations are best accomplished by interviewing management, RSO, ANPs, AUs, and other licensee personnel.	
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Note: PEF evaluations are best accomplished by interviewing management, RSO, ANPs, AUs, and other licensee personnel. Senior management is involved with radiation safety program and RSO oversight	Ves No
Note: PEF evaluations are best accomplished by interviewing management, RSO, ANPs, AUs, and other licensee personnel. Senior management is involved with radiation safety program and RSO oversight.	Yes No
Note: PEF evaluations are best accomplished by interviewing management, RSO, ANPs, AUs, and other licensee personnel. Senior management is involved with radiation safety program and RSO oversight. The RSO has sufficient time to perform his/her radiation safety duties	Yes No

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

Are procedures in place to identify, evaluate, and report equipment safety component defects? [L/C, 10 CFR 32.74]	Yes No
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.	
Dose calibrators for photon-emitters. [10 CFR 35.2432]	
Constancy checked daily prior to assay of patient dosages ( $\pm$ 10% accuracy.)	Yes No
Linearity checked at installation and quarterly ( $\pm 10\%$ accuracy.)	Yes No
Geometry dependence checked at installation ( $\pm$ 10% accuracy.)	Yes No
Note: Must be checked against volumes and configurations (volumes dispensed and syringe sizes.)	
Accuracy checked at installation and yearly ( $\pm 10\%$ accuracy).	Yes No
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.	
Dose measurements for beta- and alpha-emitters. [10 CFR 35.60]	
Calibrated with each isotope used by the licensee.	Yes No
Constancy checked daily prior to assay of patient dosages ( $\pm$ 10% accuracy.)	Yes No
Geometry dependence checked at installation ( $\pm 10\%$ accuracy.)	Yes No
Accuracy checked at installation and yearly ( $\pm 10\%$ accuracy.)	Yes No
Linearity checked at installation and quarterly ( $\pm 10\%$ accuracy.)	Yes No
Dose measurement procedure available and in use. [L/C]	Yes No
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.	
Surveys and Contamination Control	
Are routine surveys performed for radiation levels and removable contamination? [L/C]	Yes No
Are area ambient surveys performed daily and records maintained? [10 CFR 20.1501 & 10 CFR 20.2103]	Yes No

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

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

At termination of employment, are workers' exposure records available upon request? [10 CFR 19.13]	Yes No
Has any licensed radioactive material been stolen, lost, or gone missing since the last inspection? [10 CFR 20.2201]	Yes No
Have any reportable events occurred since the last inspection? [10 CFR 20.2202]	Yes No
If yes, describe the root cause and corrective action taken.	
Have any occupational overexposures and/or excessive levels of radiation been reported to the Department? [10 CFR 20.2203]	Yes No
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.]	Yes No
Posting and Labeling	
Is posting required? [10 CFR 20.1902 & 20.1903]	Yes No
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 <b>10 CFR Part 20 Appendix B</b> is used or stored.	
"Caution, Radioactive Materials" signs posted where required. [10 CFR 20.1902]	Yes No
"Caution, Radiation Area" sign posted as required. [10 CFR 20.1901 & 20.1902]	Yes No
All radioactive material transport containers are labeled and legible. [10 CFR 20.1904]	Yes No
The Department's "Notice to Employees" is posted in an appropriate area. [Department Form 3]	Yes No
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.	Yes No
Are there any exemptions to posting [10 CFR 20.1903] or labeling [10 CFR 20.1905] requirements?	Yes No
Is each transport radiation shield (e.g., pig) labeled with the radiation symbol and the words "Caution, Radioactive Material?"	Yes No
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?	Yes No

Independent and Confirmatory Measurements	
Inspector performed independent surveys.	Yes No
If yes record:	
Highest radiation level in unrestricted areas: mR/hr	
Highest radiation level in restricted areas:mR/hr	
Inspector's survey instrument(s) used:	
Mfg./Make:	
Model #:	
Serial #:	
Last calibration date:	
Licensee survey instrument(s):	
Mfg /Make	
Model #:	
Nodel $\#$ .	
$\Gamma$ I ast calibration date:	
Last calibration date.	
Compare inspector instrument readings to licensee instrument readings.	
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] Reading at external surface of transportation containers:mR/hr [10 CFR 20.1906]	Yes No
Personnel Monitoring	
Is dosimetry required? [L/C, 10 CFR 20.1502]	Yes No
Dosimeters are provided to workers.	Yes No
Type:	
Film Whole Body   TLD Extremity   Luxel OSL	
Frequency of reports:	
Weekly Monthly Quarterly	
Dosimetry supplier:	
NVLAP certified? [10 CFR 20.1501]	Yes No

Monitoring reports are reviewed by the licensee: [L/C]	
Weekly Monthly Quarterly	
Note: Identify and record the reviewer.	
Personnel monitoring records are available for review.	Yes No
Monitoring results are reported in Sv or rem. [10 CFR 20.2101]	Yes No
Inspector reviewed personnel monitoring records, from to	
Maximum DDE:mSvmR	
Month Quarter Year	
Maximum SDE:mSvmR	
Month Quarter Year	
Did any worker's occupational dose exceed regulatory limits? [10 CFP 20 1101]	
Did any worker's occupational dose exceed regulatory mints: [10 CFR 20.1101]	
Are there unmonitored workers whose job has changed since the last inspection to put the worker(s) above 10% of the occupational limit?	Yes No
Are records of personnel exposure, surveys, and monitoring evaluation retained?	Yes No
If a worker declared her pregnancy, did the licensee comply with <b>10 CFR 20.1208</b> & <b>20.2106</b> ?	Yes No
lioactive Waste Management	
Waste received from customer is surveyed and checked for removeable contamination.	Yes No
Note: Any reading of 200 mR/hr or above must be reported to the Department.	
Waste storage. [L/C, 10 CFR 20.2001]	
Decay-in-storage is approved and procedures are being followed.	Yes No
All radionuclides being stored have half-lives less than 120 days.	Yes No
Radionuclides are segregated for storage according to half-life.	Yes No
Each nuclide in waste storage is stored for a minimum of 10 half-lives.	Yes No
Waste storage area is properly secured. [10 CFR 20.1801]	Yes No
Waste storage area is properly posted. [10 CFR 20.1902]	Yes No
Waste containers are properly labeled. [10 CFR 20.1904]	Yes No

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

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]	Yes No
Contamination levels at the surface of the package are checked before shipping and on return from customers.	Yes No
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]	Yes No
Emergency procedures and response telephone number(s) are available. [49 CFR 172.604]	Yes No
Shipping papers are readily accessible during transportation. [49 CFR 177.817(e)]	Yes No
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.	
Special form materials are shipped.	Yes No
Vehicle is placarded as required (Yellow-III if TI > 1.0.) [49 CFR 172.504(a)]	Yes No
Radioactive materials are secured and properly blocked and braced in transport vehicle. [49 CFR 177.834(a) & 177.842(d)]	Yes No
A QA program for packaging is in place. [L/C]	Yes No
License Conditions/Tie-downs	
All license conditions reviewed by Department inspector.	Yes No
Licensee activities are being conducted in accordance with license conditions.	Yes No
Bulletins and Information Notices	
Licensee is receiving the Department information notices and bulletins.	Yes No
Licensee has taken appropriate action in response to the notices and bulletins.	Yes No
Security Inspection	
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.	N/A
If yes,	
Licensee Contact Name:	
Contact Telephone Number:	
Contact Email Address:	

Summary of Observations Findings and Conclusions
Business Operations:
Busiliess Operations.
Facility – Visit all storage and use locations identified on the application
r dentry visit an storage and use rocations identified on the appreation
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