

## Lu-177 Based Theranostic Checklist

**Date:** Select date

**VISN:** Enter VISN

**Station ID#/Facility Name:** Enter Station ID# & facility name

**Nuclear Medicine Chief:** Enter facility point of contact

**Facility POC:** Enter facility point of contact

The National Nuclear Medicine Program (NNMP) has developed this clinical checklist to evaluate a facility's readiness for implementing a Lutetium-177 (Lu177) based radionuclide systemic therapy program.

The checklist should be filled out by Nuclear Medicine leadership involved (facility point of contact) in the procedure and have documented concurrence from the Nuclear Medicine Chief and Radiation Safety Officer. All checklist items must be answered. For any negative responses, comments are required. NNMP will review the document and schedule a conference call to discuss your responses.

Our office looks forward to working with you and your team.

<b>Nuclear Medicine Lu177 Therapy Services that are planned</b> (check all that apply):			
<u>Imaging</u> <input type="checkbox"/> A9595 F-18-Pylarify (Prostate Cancer)			
<u>Therapeutic</u> <input type="checkbox"/> A9607 LUTETIUM 177-PLUVICTO (Prostate Cancer) <input type="checkbox"/> A9513 LUTETIUM 177-LUTATHERA (Neuroendocrine Tumor)			
<b>Section 1: Business Plan, Budget, and Contracting</b>		<b>Yes</b>	<b>No</b>
1a. Has the facility submitted Appendix A of VHA Directive 1043 Restructuring of VHA Clinical Programs (dated November 2, 2016)?		<input type="checkbox"/>	<input type="checkbox"/>

1b. Develop NM Lu177-based therapy business plan with presentation to leadership the anticipated volumes and associated costs to treat patients versus community care.  <i>[Typical return on investment is 0.7x-3.2x cost per patient (typically &gt;\$150,000 cost savings on a per patient basis); check this box upon Budget approval; note that Lu177-DOTATATE and Lu177-PSMA-617 are on FSS]</i>	<input type="checkbox"/>	<input type="checkbox"/>
1c. Develop SOW for Contracting, or purchase order, that is aligned with local clinical practice and anticipated volumes.	<input type="checkbox"/>	<input type="checkbox"/>
1d. 2237 Submission.(Contract to purchase radiopharmaceutical)	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Click or tap here to enter text.		
<b>Section 2: NM Administrative Section Preparation</b>	<b>Yes</b>	<b>No</b>
2a. Radiation Safety Committee approval complete; note that radiopharmaceuticals are typically exempt from Pharmacy Service procurement and local pharmacy and therapeutics committee approval.	<input type="checkbox"/>	<input type="checkbox"/>
2b. Develop therapy protocols for each Lu177-based treatment to be performed at the facility with associated paperwork such as AU written directive and patient release, in accordance with NHPP/NRC guidelines; this is typically completed by the Nuclear Medicine Chief and Chief Nuclear Medicine Technologist. Please be ready to demonstrate the SOP during the program office review.	<input type="checkbox"/>	<input type="checkbox"/>
2c. Update orders in electronic medical record that match workflow for initial nuclear medicine therapy consultation, treatment planning, treatment administration, post-treatment Imaging, and/or dosimetry to match local practice. Order-sets may be helpful to facilitate multi-cycle therapy and cart check prior to ordering next treatment dose.	<input type="checkbox"/>	<input type="checkbox"/>
2d. Engage in multi-disciplinary discussion to include appropriate referral source and patient management planning.	<input type="checkbox"/>	<input type="checkbox"/>
2e. Inform and work with HIM to ensure prior authorization procedures are followed so that third-party payor requirements are met when applicable; CPT coding should ensure appropriate encounter codes, therapy planning / administration/dosimetry codes, and radiopharmaceutical codes are used. <b>A9607 Lutetium 177-Pluvicto</b> – must include procedure message note; prior to initiating this therapy, patient should have had a consultation with the Nuclear Medicine Physician. If the patient has not had a consultation, please place an eConsult Nuclear Medicine Theranostics.	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Click or tap here to enter text.		

<b>Section 3: Department Preparation- Radiation Safety</b>	<b>Yes</b>	<b>No</b>
3a. After the (virtual) site visit is complete, please work with NHPP for request of RAM Permit amendment for Lu177 possession limit; for most sites 1 Ci of Lu177 will be sufficient for up to a moderate therapy volume.	<input type="checkbox"/>	<input type="checkbox"/>
3b. How many patients per year are expected to be cared for? (low volume / high risk factor)		
3c. Identify suitable administration room and nearby restroom that can be dedicated during procedure; shielding (syringes, infusion methods) and room preparation plan in place.	<input type="checkbox"/>	<input type="checkbox"/>
3d. Procedures for preparation of restroom (e.g., protective/absorbent lining and instructing patient to sit while urinating) established.	<input type="checkbox"/>	<input type="checkbox"/>
3e. Contamination, medical event, and extravasation procedures in place.	<input type="checkbox"/>	<input type="checkbox"/>
3f. Patient release criteria and documentation paperwork in place (e.g., advisable to have the patient void and survey them before they leave).	<input type="checkbox"/>	<input type="checkbox"/>
3g. Waste storage and disposal method plan in place, with consideration that half-lived radioisotopes, which may occur based on the Lu-177 production method, might in some cases prevent disposal after decay in storage as for normal medical waste.	<input type="checkbox"/>	<input type="checkbox"/>
3h. Process in place for post therapy room(s) survey with associated documentation. Surveys must be completed on day of procedure.	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Click or tap here to enter text.		
<b>Section 4: Dedicated staffing needs during therapy</b>	<b>Yes</b>	<b>No</b>
4a. Certified Nuclear Medicine Technologist.	<input type="checkbox"/>	<input type="checkbox"/>
4b. Nurse (RN)	<input type="checkbox"/>	<input type="checkbox"/>
4c. Advanced Practice Provider (APP)	<input type="checkbox"/>	<input type="checkbox"/>
4d. Nuclear Medicine Physician Authorized User (AU).	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Click or tap here to enter text.		
<b>Section 5: Equipment and Supplies</b>	<b>Yes</b>	<b>No</b>
5a. Determine and ensure availability of supplies for infusion method (examples: vent needles, luer lock connector tubing, 3-way stopcock, hypodermic needles, therapy pump appropriate syringe shield); plan for complicated IV access and confirming IV patency.	<input type="checkbox"/>	<input type="checkbox"/>
5b. Appropriately calibrated equipment (dose calibrator, survey meter & relevant scanner); additional or backup items such as tongs, dipper/well sleeve should be considered.	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Click or tap here to enter text.		
<b>Section 6: Space Requirements</b>	<b>Yes</b>	<b>No</b>

6a. Please submit floor plan of therapeutic area with package (Nuclear Medicine infusion area, patient consultation room prior to treatment).	<input type="checkbox"/>	<input type="checkbox"/>
6b. Patient treatment suite with adjacent dedicated restroom; check this box after Radiation Safety/medical physics review is complete.	<input type="checkbox"/>	<input type="checkbox"/>
6c. Nurse workstation/facilities to support safe monitoring of the patient.	<input type="checkbox"/>	<input type="checkbox"/>
6d. Hot lab plan to minimize exposure and ensure safe delivery to the treatment area.	<input type="checkbox"/>	<input type="checkbox"/>
6e. Radioactive waste storage plan.	<input type="checkbox"/>	<input type="checkbox"/>
6f. Family waiting plan.	<input type="checkbox"/>	<input type="checkbox"/>
6g. Imaging protocol(s) complete, including pre-treatment PET and post-treatment SPECT with incorporation of timing considerations to facilitate dosimetry calculations when possible.	<input type="checkbox"/>	<input type="checkbox"/>
6h. Dosimetry procedures/protocol, complete if applicable.	<input type="checkbox"/>	<input type="checkbox"/>
6i. Confirm all internal stakeholders are aware of overall workflow and procedures.		
<input type="checkbox"/> Oncology <input type="checkbox"/> Radiation Oncology <input type="checkbox"/> Urology <input type="checkbox"/> Radiation Safety <input type="checkbox"/> Primary Care <input type="checkbox"/> Community Care/PAS <input type="checkbox"/> Medical Service <input type="checkbox"/> Medical Physics <input type="checkbox"/> Surgical Service <input type="checkbox"/> Nursing Service <input type="checkbox"/> Cancer Navigators <input type="checkbox"/> Research		
Summary of stakeholder involvement: <i>(Describe anticipated patient referral process, as well as anticipated post treatment management plan) e.g., Referral through Oncology Svc.; consult Nuclear Medicine.</i>		
<b>Section 7: Communication Plan</b>	<b>Yes</b>	<b>No</b>
7a. Multidisciplinary team (example: Tumor Board) review of ordering process and clinical indications.	<input type="checkbox"/>	<input type="checkbox"/>
7b. Patient and caregiver education materials available/prepared.	<input type="checkbox"/>	<input type="checkbox"/>
7c. Between cycle patient navigator and post-therapy care plans, including radiation safety advisories.	<input type="checkbox"/>	<input type="checkbox"/>
7d. Emergency after hours plan.	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Click or tap here to enter text.		
<b>Section 8: Scheduling and Appointments</b>	<b>Yes</b>	<b>No</b>
8a. Clinic profiles established, including days of the week and timing; ensure Nuclear Medicine Technologists and MSA staff are aware of patient preparation considerations, including what patients should expect for a multi-cycle treatment, such as need for multiple return visits, labs prior to subsequent dose ordering, and facility specific factors. Check this box after related patient education/scheduling letters are complete and reproduced for distribution.	<input type="checkbox"/>	<input type="checkbox"/>

8b. A process is in place for consultation with NM MD, RSO, RN., and/or Nuclear Medicine Technologist as part of the initial pre-treatment phase prior to scheduling therapeutic administration to screen patient for procedure compliance.	<input type="checkbox"/>	<input type="checkbox"/>
8c. Ensure appropriate support staff are available to address patient barriers, including ensuring access to care issues such as travel.	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Click or tap here to enter text.		
<b>Section 9: Faculty and Staff Preparation</b>	<b>Yes</b>	<b>No</b>
9a. Lu-177 DOTATATE or PSMA-617 (Lutathera® or Pluvicto®) Clinical Evaluation Forms created for patient intake, as well as between treatment patient assessment prior to next dose ordering; helpful for use by Nuclear Medicine Physicians and/or Nuclear Medicine Service Advance Practice Providers (APPs).	<input type="checkbox"/>	<input type="checkbox"/>
9b. Complete manufacturer's customer onboarding form and training/site start plan which includes mock infusion with Medical Science Liaison when applicable	<input type="checkbox"/>	<input type="checkbox"/>
9c. Physician review of protocols and process flow (Lu177-based therapies).	<input type="checkbox"/>	<input type="checkbox"/>
9d. Written Directive and therapy related forms are in place.	<input type="checkbox"/>	<input type="checkbox"/>
9e. Patient consultation process and associated dictation templates(s) developed.	<input type="checkbox"/>	<input type="checkbox"/>
9f. Patient management plan, including pre- and post-therapy labs.	<input type="checkbox"/>	<input type="checkbox"/>
9g. Radiation safety plan for both inpatient and outpatient treatments, including release criteria.	<input type="checkbox"/>	<input type="checkbox"/>
9h. Dose administration process with consideration for local workflow.	<input type="checkbox"/>	<input type="checkbox"/>
9i. Plan for non-radiopharmaceutical medication(s); compounding pharmacy contract for Lu177-DOTATATE amino acids.	<input type="checkbox"/>	<input type="checkbox"/>
9j. Patient discharge threshold and process instructions and forms created.	<input type="checkbox"/>	<input type="checkbox"/>
9k. Reporting plan, including templates for Encounters, Imaging, Treatment administration, and Dosimetry when available.	<input type="checkbox"/>	<input type="checkbox"/>
9l. Patient selection/triaging, navigation, and follow up care plans; in some cases when Nuclear Medicine is the only cancer treatment modality performed at a facility, a survivorship care plan may be considered that is aligned with Commission on Cancer guidance.	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Click or tap here to enter text.		
<b>Section 10: Technologist Plan</b>	<b>Yes</b>	<b>No</b>
10a. Radiation safety considerations specific to Lu177-based systemic therapies	<input type="checkbox"/>	<input type="checkbox"/>
10b. Dose ordering, receipt, preparation, and waste.	<input type="checkbox"/>	<input type="checkbox"/>

10c. Coordination with multidisciplinary teams (example: Octreotide injection following Lu177-DOTATATE).	<input type="checkbox"/>	<input type="checkbox"/>
10d. Patient monitoring and care.	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Click or tap here to enter text.		
<b>Section 11: Nurse Training</b>	<b>Yes</b>	<b>No</b>
11a. Radiation safety including considerations specific to Lu177-based treatments.	<input type="checkbox"/>	<input type="checkbox"/>
11b. Non-radiopharmaceutical medication administration and support of medication management.	<input type="checkbox"/>	<input type="checkbox"/>
11c. Targeted patient care and involved in mock infusion(s).	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Click or tap here to enter text.		
<b>Section 12: Roles and Responsibilities of the Multidisciplinary Team</b>	<b>Yes</b>	<b>No</b>
12a. Radiation Safety Officer <ul style="list-style-type: none"> <li>1. Radiation safety training for all teams involved, as well as patient education.</li> <li>2. Treatment room preparation and patient release oversight.</li> <li>3. Radioactive waste management.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
12b. Physicist <ul style="list-style-type: none"> <li>1. Dosimetry measurements, if applicable, in facilities without dosimetric software analysis tools; assistance with release criteria and documentation.</li> <li>2. Review shielding design and occupancy factors to ensure appropriate use of treatment.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Click or tap here to enter text.		
12c. Nurse (RN) <ul style="list-style-type: none"> <li>1. Administration of premedication(s), such as anti-emetic, steroids, protective agents, as needed.</li> <li>2. Care coordination and possible chart checks.</li> <li>3. Monitoring patient vitals.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
12d. Advanced Practice Practitioner (APP) <ul style="list-style-type: none"> <li>1. Past medical and Oncology treatment history.</li> <li>2. Laboratory and physical exam.</li> <li>3. Imaging workup between treatment cycles.</li> <li>4. Patient and family education.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>

<p>12e. Nuclear Medicine Physician</p> <ol style="list-style-type: none"> <li>1. Authorized User with clinical privileges for Nuclear Medicine therapies and approval by Radiation Safety Committee.</li> <li>2. Tumor Board involvement to promote multidisciplinary review of cancer care and help facilitate discussion related to patient selection.</li> <li>3. Oversee initial consultation/patient selection appropriateness review.</li> <li>4. Clinical evaluation of patient including dose selection and/or modification when appropriate.</li> <li>5. Oversight of informed consent and dose administration with official reporting.</li> <li>6. Patient management of post treatment imaging, as well as clinical follow up between and after therapies; incorporation of dosimetry may better inform subsequent treatment strategy.</li> </ol>	<input type="checkbox"/>	<input type="checkbox"/>
<p>12f. Nuclear Medicine Technologist</p> <ol style="list-style-type: none"> <li>1. Dose ordering &amp; receipt.</li> <li>2. Treatment room (with Radiation Safety) and patient preparation.</li> <li>3. Dose measurement preparation.</li> <li>4. Dose administration.</li> <li>5. Post therapy room survey (with Radiation Safety).</li> <li>7. Waste disposal (with Radiation Safety).</li> </ol>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Comments:  <a href="#">Click or tap here to enter text.</a></p>		
<p><b>Section 13: Patient Education / Preparation</b></p>	<p><b>Yes</b></p>	<p><b>No</b></p>
<ol style="list-style-type: none"> <li>1. Consent form (iMedConsent).</li> <li>2. Information Sheets.</li> <li>3. Preparation for treatment day.</li> <li>4. Radiation Safety and discharge instructions.</li> <li>5. Dose administration card or letter.</li> <li>6. Instructions for family members with the patient during the treatment day.</li> <li>7. Instructions for caregivers.</li> </ol>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Comments:  <a href="#">Click or tap here to enter text.</a></p>		
<p><b>Section 14: Quality Management</b></p>	<p><b>Yes</b></p>	<p><b>No</b></p>
<p>14a. 1. Have all steps above in the checklist been reviewed by the required personnel?  2. Has the Therapeutic Radionuclide been Approved by the Radiation Safety Committee (RSC)?</p>	<input type="checkbox"/>	<input type="checkbox"/>

14b. 1. Name(s) of Authorized User (AU): \_\_\_\_\_

2. Nuclear Medicine Chief: \_\_\_\_\_

3. Physicist and/or Radiation Safety Officer(s): \_\_\_\_\_

**Additional Comments/Supporting Documentation**

(Description of local considerations not included above, such as experience with related phase III trials or similar systemic radionuclide treatments, as well as any factors listed or described in detail above)

Comments:

Click or tap here to enter text.

<b>This section ONLY to be used by Program Office:</b>	
<b>Full Facility name/location City/State:</b>	Parent facility if approval is for CBOC, HCC, OPC
	<input type="checkbox"/> On-Site <input type="checkbox"/> Virtual
IEWS Number	
Isotope:	<input type="checkbox"/> Lutathera <input type="checkbox"/> Pluvicto
Directive 1043 (signed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Network Director Memo (signed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Organization Chart (signed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Attachment B Readiness Checklist completed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Meets Authorized User experience / credential requirements	<input type="checkbox"/> Yes <input type="checkbox"/> No
Lutetium (Lu-177) SOP	<input type="checkbox"/> Yes <input type="checkbox"/> No
Emergency Plan	<input type="checkbox"/> Yes <input type="checkbox"/> No
Floor Plan	<input type="checkbox"/> Yes <input type="checkbox"/> No
Access to equipment	<input type="checkbox"/> SPECT/CT <input type="checkbox"/> PET/CT
Inpatient capability	<input type="checkbox"/> Yes <input type="checkbox"/> No
Current Possession Limit.	Ci
RAM permit amendment increase.	<input type="checkbox"/> Yes <input type="checkbox"/> No
NHPP assessment of possession limit supports approval of Lu - 177 use.	<input type="checkbox"/> Yes <input type="checkbox"/> No
NHPP assessment of radiation safety program status supports approval of Lu-177 use.	<input type="checkbox"/> Yes <input type="checkbox"/> No
NHPP assessment of consultant RSO availability and/or onsite representative to assist with procedures supports approval of Lu-177 use.	<input type="checkbox"/> Yes <input type="checkbox"/> No



NHPP assessment of consultant RSO and/or facility ability to respond to an emergency supports approval of Lu-177 use.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Virtual/Onsite Meeting Attendance:	(The MD/AU, NMT, & RSO must be present for the site visit)
VHA Clinical Diagnostics	
Executive Director National Nuclear Medicine	
HSS National Nuclear Medicine/Radiology	
Executive Director National Health Physics Program	
NHPP Program Managers	
VA Facility	
Network Director	
Medical Facility Director	
Deputy Chief of Staff	
Chief of Staff	
Chief of Radiology	
Chief of Nuclear Medicine	
Authorized User (AU)	
Radiation Safety Officer (RSO)	
Radiology Administrator	
Nurse Practitioner	
Nurse Navigator	
Supervisor Nuclear Medicine Technologist	
Lead Nuclear Medicine Technologist	
Therapeutic Nuclear Medicine Technologist	
Other	

<b>This section to be completed six (6) months post approval:</b>	
Demonstration of approval stipulations:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Lu-177 SOP (demonstrate facility specific changes).	<input type="checkbox"/> Yes <input type="checkbox"/> No
VHA Directive 1105 & 1105.02 compliance.	<input type="checkbox"/> Yes <input type="checkbox"/> No
NHPP permit w increased limits (demonstrate).	<input type="checkbox"/> Yes <input type="checkbox"/> No
Quality Improvement Plan (QIP) w/ performance metrics (demonstrate).	<input type="checkbox"/> Yes <input type="checkbox"/> No
Competencies with current/new team members completed.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Summary and final recommendation:	