Attachment 2.6-6
Vermont Department of Health
Radioactive Materials Program Supervisory Accompaniment
Inspection Checklist

Brachytherapy

Licensee:

License No.:

Licensee Contact: **Inspection Date:**
Telephone Number:
Email:
Last Inspection Date:
Priority:

Inspection Objectives:

- To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public, and patients.
- To determine if licensed activities are being conducted in accordance with Vermont Department of Health regulations.

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
9. Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

Inspection Site Address (authorized use or storage):

Type of Inspection:		**Date of Last Inspection:**
☐ Announced	☐ Unannounced	
☐ Initial	☐ Routine	
☐ Other**:**		

Amendments and Significant Program Changes (Review from last license renewal)

Amendment #:	Date:	Amendment Item(s):

Note:

Program Inspection History

Is this an initial inspection?	☐ Yes ☐ No

List previous open items of violations:	
Have previous violation(s) been properly corrected? If no, list those items not corrected with an explanation.	☐ Yes ☐ No ☐ N/A
List previous items of recommendations:	
Did licensee address previous recommendation(s)? If no, explain.	☐ Yes ☐ No ☐ 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.	☐ Yes ☐ No
Radiation Safety Officer (RSO) identified on license. **[L/C, 10 CFR 35.24]**	☐ Yes ☐ No
RSO fulfills his/her duties as required. **[L/C, 10 CFR 35.24]**	☐ Yes ☐ No
To whom in the organization does the RSO report? _____	
The RSO has sufficient access to licensee's senior management?	☐ Yes ☐ No
Has there been a change in RSO?	☐ Yes ☐ No
If yes, was the license amended?	☐ Yes ☐ No
Does the new RSO meet the Department's training requirements?	☐ Yes ☐ No
Has there been a change in the licensee contact person for the Department?	☐ Yes ☐ No
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.	
Identify all individuals in attendance at entrance meeting. Individual 1: Individual 2: Individual 3: Individual 4:	

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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.	☐ Yes ☐ No
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 AUs 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.):	

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]**:	☐ Yes ☐ No

Audits are conducted at intervals not exceeding 12 months. **[10 CFR 20.1101]**	☐ Yes ☐ No
Audits and review records of the licensee program are being maintained. **[10 CFR 20.2102]** Note: These records must be kept for three years after they are made.	☐ Yes ☐ No
Were deficiencies found in the program following a self-audit?	☐ Yes ☐ No
If yes, have the deficiencies been corrected? Note: The inspector should look for repeat deficiencies.	☐ Yes ☐ No
Audit records were reviewed by Department inspector.	☐ Yes ☐ No
Performance Evaluation Factors (PEF) 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
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 programs.	☐ Yes ☐ No
Adequate audits are being implemented.	☐ Yes ☐ No

Liquid Brachytherapy, GliaSite Therapy

Inspection Procedures Used: 87132, 87134, 83822

Inspection Site Address:

Location authorized on license?	☐ Yes ☐ No
Use authorized on license?	☐ Yes ☐ No
Manufacturer: _____	
Are authorized users approved on the license or by the RSC? **[L/C]** List the authorized users.	☐ Yes ☐ No
The AU has specific vendor training in the use of the Proxima Therapeutics' GliaSite RTS. **[L/C]**	☐ Yes ☐ No

Written Directive:	
Prior to implantation the written directive includes the treatment site, the radionuclide (including the chemical and physical form), and dose. **[10 CFR 35.40]**	☐ Yes ☐ No
After implantation but prior to completion of the procedure, the written directive includes the radionuclide (including the chemical and physical form), the treatment site, and the total dose. **[10 CFR 35.40]**	☐ Yes ☐ No
Procedures are in place to confirm that the balloon does not leak prior to injection of the radionuclide and implantation in the patient or human research subject. **[L/C]**	☐ Yes ☐ No
(1) Has the licensee had a leaking source?	☐ Yes ☐ No
(2) If yes, was the Department notified within five working days?	☐ Yes ☐ No
The licensee labels syringes containing I-125 Iotrex™ and syringe radiation shields with the radionuclide and therapeutic procedure (i.e. I-125 Iotrex™ for brain brachytherapy.)	☐ Yes ☐ No
Have any medical events occurred associated with the liquid brachytherapy program (e.g., mislabeled syringes, color code syringe/vial errors, picking up the wrong syringe, etc.)?	☐ Yes ☐ No
The licensee acquired an SSD certificate prior to medical use of the liquid source.	☐ Yes ☐ No
Is the licensee following the SSD limitations/physical conditions of use?	☐ Yes ☐ No
If no, was a safety evaluation performed by the broad scope medical use licensee that addressed the conditions of use? [Note: A safety evaluation must be performed by a broad scope medical use licensee if the physical conditions of use, as stated in the SSD certificate, are exceeded.] **[L/C]**	☐ Yes ☐ No
Did the licensee perform a survey after implanting the source? **[10 CFR 35.404]**	☐ Yes ☐ No
Did the licensee perform a survey after removing the source? **[10 CFR 35.404]**	☐ Yes ☐ No
Microsphere Brachytherapy Sources and Devices	
Inspection Site Address:	
Location authorized on license?	☐ Yes ☐ No

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Use authorized on license? Manufacturer: _____	☐ Yes ☐ No
Are authorized users approved on the license or by the RSC? **[L/C]** List the authorized users.	☐ Yes ☐ No
The AU has specific vendor training in the use of microspheres and the microsphere delivery system **[L/C]**	☐ Yes ☐ No
All requirements for brachytherapy sources and manual brachytherapy use are being met. [Note: Leak tests are not required because the activity per microsphere (the sealed source) meets the criteria in **10 CFR 35.67**.] **[10 CFR 35, Subpart F]**	☐ Yes ☐ No
Written Directive: (1) Prior to implantation the written directive includes the treatment site, the radionuclide including the chemical and physical form (i.e., Y-90 microspheres), and dose. [Note: For Y-90 microspheres, "prescribed dose" in the written directive means the total dose.] **[10 CFR 35.40]**	☐ Yes ☐ No
(2) After implantation but prior to completion of the procedure, the written directive includes the radionuclide (including the chemical and physical form), the treatment site, and the total dose. **[10 CFR 35.40]**	☐ Yes ☐ No
(3) Is the licensee following the written directive procedures that describe how to quantify the total dose to the treatment site as well as the total dose to other sites upon completion of the administration? **[10 CFR 35.41, L/C]**	☐ Yes ☐ No
Are quarterly inventories of sealed sources and brachytherapy sources performed?	☐ Yes ☐ No
Do the inventories include the individual aggregates of the microspheres identifying the radioisotope, the container of the aggregate, the total activity of the aggregate, and the container location? **[10 CFR 35.2406, L/C]** .	☐ Yes ☐ No
Are procedures in place to ensure that the bremsstrahlung emissions from each patient permit release? [Note: TEDE < 5 mSv (500 mrem) to others and TEDE < 1 mSv (100 mrem) to breast-feeding infant or child.] **[10 CFR 35.75]**	☐ Yes ☐ No
Y-90 microspheres placed in vials, syringes, or radiation shields are labeled by the manufacturer or by the licensee	☐ Yes ☐ No

The administration syringes and syringe radiation shields are labeled with the radioisotope, form, and therapeutic procedure (i.e., Y-90 microspheres, brachytherapy)	☐ Yes ☐ No
The required SSD certificate for the Y-90 microsphere delivery system is available for review.	☐ Yes ☐ No
(1) Is the licensee following the SSD limitations/physical conditions of use?	☐ Yes ☐ No
(2) If no, was a safety evaluation performed by the broad scope medical use licensee that addressed the conditions of use? [Note: A safety evaluation must be performed by a broad scope medical use licensee if the physical conditions of use, as stated in the SSD certificate, are exceeded.] **[L/C]**	☐ Yes ☐ No
Note: The U.S. Food and Drug Administration currently approves the MDS NORDION Y-90 TheraSphere® microspheres under the provisions of a "Humanitarian Device Exemption" (HDE No H9800006). An Institutional Review Board review and approval is required before a humanitarian use device is used at a facility as well as continuing review of its use.	
Intervascular Brachytherapy (IVB)	☐ Yes ☐ No ☐ N/A
Inspection Site Address:	
Location authorized on license?	☐ Yes ☐ No
Use authorized on license?	☐ Yes ☐ No
Manufacturer: _____	
Are authorized users and authorized medical physicist approved on the license or by the RSC? **[L/C]**	☐ Yes ☐ No
List the authorized users and authorized medical physicist.	
Have the Authorized User, Interventional Cardiologist/Physician, and Authorized Medical Physicist received the vendor training for use of the device?	☐ Yes ☐ No
Does the Authorized User consult with the Interventional Cardiologist/Physician and Authorized Medical Physicist (AMP) prior to initiating treatment?	☐ Yes ☐ No
Are all procedures conducted in the physical presence of the Authorized User or the AMP? **[L/C]**	☐ Yes ☐ No

Are written directives signed and dated prior to all treatments, specifying treatment site, the radionuclide, and dose? **[10 CFR 35.40]**	☐ Yes ☐ No
The AMP performs independent measurement of the source output prior to the first patient treatment using a dosimetry system that meets the requirements of **10 CFR 35.630**.	☐ Yes ☐ No
Has the licensee developed, implemented, and maintained written emergency procedures for both stuck and detached sources, including the provisions for appropriate emergency response equipment and appropriate surgical procedures? **[L/C]**	☐ Yes ☐ No
Does the licensee survey the patient and the IVB treatment catheter immediately following source retraction or removal confirming complete retraction of the source(s)? **[10 CFR 35.404]**	☐ Yes ☐ No
Are source trains removed from use after the "use by" date? **[L/C]**	☐ Yes ☐ No
Does the licensee perform "source stepping?" **[L/C]**	☐ Yes ☐ No
Is the licensee properly using portable shields? **[L/C]**	☐ N/A ☐ Yes ☐ No
In a three-ribbon set containing 6, 10, or 14 seeds per ribbon, no single seed exceeds 35 millicuries, or a total or 1.1 curies per set.	☐ Yes ☐ No
Novoste Beta-Cath™ IVB System	☐ Yes ☐ No
Manufacturer: _____	
Is the licensee authorized for Strontium-90 sealed sources, 5 mCi per source and a total of 800 mCi? [Note: The exposure rate from this system is greater than 1,200 rads/hr.] **[L/C]**	☐ Yes ☐ No
Are Authorized Users and Authorized Medical Physicist approved on the license or by the RSC? **[L/C]** List the authorized users and authorized medical physicist.	☐ Yes ☐ No
Have the Authorized User, Interventional Cardiologist/Physician, and Authorized Medical Physicist received the vendor training for use of the device?	☐ Yes ☐ No
Does the Authorized User consult with the Interventional Cardiologist/Physician and Authorized Medical Physicist (AMP) prior to initiating treatment?	☐ Yes ☐ No
Are all procedures conducted in the physical presence of the Authorized User or the AMP? **[L/C]**	☐ Yes ☐ No

Are written directives signed and dated prior to all treatments, specifying treatment site, the radionuclide, and dose? **[10 CFR 35.40]**	☐ Yes ☐ No
Does the licensee perform "source stepping?" **[L/C]**	☐ Yes ☐ No ☐ N/A
If yes, does the licensee have written procedures for "source stepping?" **[L/C]**	☐ Yes ☐ No
Does the licensee survey the patient and the IVB treatment catheter immediately following source retraction or removal confirming complete retraction of the source(s)? **[10 CFR 35.404]**	☐ Yes ☐ No
Is an introducer sheath used, unless contraindicated? **[L/C]**	☐ Yes ☐ No
Is a dual syringe system used? **[L/C]**	☐ Yes ☐ No
Has the licensee developed, implemented, and maintained written emergency procedures for both stuck and detached sources, including the provisions for appropriate emergency response equipment and appropriate surgical procedures? **[L/C]**	☐ Yes ☐ No
Is the source storage container locked in a secured location? [Note: Because Sr-90 is a pure beta-emitter, shielding calculations are not necessary for areas outside of the treatment room and device storage areas.]	☐ Yes ☐ No
Has the AMP performed an independent measurement of source output prior to first treatment? **[L/C]**	☐ Yes ☐ No
Were the independent measurements performed with a dosimetry system that meets the requirements of **10 CFR 35.630**? **[L/C]**	☐ Yes ☐ No
Is the IVB system inspected and serviced at intervals recommended by the manufacturer? **[L/C]**	☐ Yes ☐ No
Is maintenance and repair performed only by the manufacturer or persons specifically licensed by the Department, NRC, or an Agreement State? **[L/C]**	☐ Yes ☐ No
Guidant Galileo™ IVB System [Note: Guidant Corporation VI Model Galileo™ intravascular brachytherapy high dose rate afterloader devices.]	
Are authorized users and authorized medical physicist approved on the license or by the RSC? **[L/C]**	☐ Yes ☐ No
List the authorized users and authorized medical physicist.	

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Have the Authorized User, Interventional Cardiologist/Physician, and Authorized Medical Physicist received the vendor training for use of the device?	☐ Yes ☐ No
Does the Authorized User consult with the Interventional Cardiologist/Physician and Authorized Medical Physicist (AMP) prior to initiating treatment?	☐ Yes ☐ No
Are all procedures conducted in the physical presence of the Authorized User or the AMP? **[L/C]**	☐ Yes ☐ No
Are written directives signed and dated prior to all treatments, specifying treatment site, the radionuclide, and dose? **[10 CFR 35.40]**	☐ Yes ☐ No
Does the licensee perform "source stepping" or "pullback" procedures? **[L/C]**	☐ Yes ☐ No
If yes, does the licensee have written procedures? **[L/C]**	☐ Yes ☐ No
Does the licensee survey the patient and the IVB treatment catheter immediately following source retraction or removal confirming complete retraction of the source(s)? **[10 CFR 35.404]**	☐ Yes ☐ No
Has the licensee developed, implemented, and maintained written emergency procedures for both stuck and detached sources, including the provisions for appropriate emergency response equipment and appropriate surgical procedures? **[L/C]**	☐ Yes ☐ No
Are the delivery device and source assembly secured in locked storage when not in use? [Note: Because P-32 is a pure beta-emitter, shielding calculations are not necessary for areas outside of the treatment room and device storage areas.] **[L/C]**	☐ Yes ☐ No
Does the licensee have a method for key control for the console? **[L/C]**	☐ Yes ☐ No
Has the AMP performed an independent measurement of source output prior to first treatment? **[L/C]**	☐ Yes ☐ No
Were the independent measurements performed with a dosimetry system that meets the requirements of **10 CFR 35.630**? **[L/C]**	☐ Yes ☐ No
Is the IVB system inspected and serviced at intervals recommended by the manufacturer? **[L/C]**	☐ Yes ☐ No
The source assembly/cartridge are not used for more than 60 days or 650 cycles, whichever comes first, in accordance with the manufacturer's guidance. **[L/C]**	☐ Yes ☐ No

Is maintenance and repair performed only by the manufacturer or persons specifically licensed by the Department, NRC, or an Agreement State? **[L/C]**	☐ Yes ☐ No
The following daily checks are performed prior to each patient treatment: ☐ Indicator lamps ☐ Source status indicators ☐ Visual inspection of the integrity of the source centering catheter and connectors ☐ Accuracy of source positioning	☐ Yes ☐ No
The following tests are performed at each source exchange prior to patient treatment: ☐ Source uniformity via autoradiograph ☐ Source positioning accuracy within +/- 1 mm ☐ Battery backup for emergency source retraction upon power failure ☐ Source transit time to meet manufacturer's specifications ☐ Timer accuracy and linearity to meet manufacturer's specifications	
High Dose Rate Afterloader (HDR)	
Unauthorized individuals are prevented from entering the use area.	☐ Yes ☐ No
Remote afterloaders placed in treatment rooms containing radiation-producing machines have interlocks preventing simultaneous activation.	☐ Yes ☐ No
Areas of use are as indicated on the license.	☐ Yes ☐ No
Treatment rooms are equipped with redundant audio and visual monitors and checked daily prior to patient treatments.	☐ Yes ☐ No
Patients can be monitored to ensure that sources and catheter guide tubes are not disturbed during treatment/use.	☐ Yes ☐ No
Have alterations to the treatment console been performed by unauthorized individuals?	☐ Yes ☐ No
HDR units are calibrated in accordance with **10 CFR 35.633**.	☐ Yes ☐ No
Only authorized HDR units that are on the license are in use.	☐ Yes ☐ No
Emergency equipment is available near each treatment room, including shielded containers, remote handling tools, and surgical supplies in the unlikely event that a source needs to be surgically removed.	☐ Yes ☐ No

HDR units and storage devices are properly labeled.	☐ Yes ☐ No
HDR treatment units, the console, and the console key are secured from unauthorized entry and removal when not in use.	☐ Yes ☐ No
HDR unit keys are controlled.	☐ Yes ☐ No
Operating and emergency procedures are maintained at the treatment console. **[10 CFR 35.610]**	☐ Yes ☐ No
Licensee implements actions to verify that:	
Prior to treatment, the treatment plan is in accordance with the written directive.	☐ Yes ☐ No
Prior to treatment, the treatment parameters (source positioning, HDR unit settings, applicator type and size, etc.) are in accordance with the written directive.	☐ 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**. If yes, Licensee Contact Name: Contact Telephone Number: Contact Email Address:	☐ Yes ☐ No ☐ N/A

Summary of Observations, Findings, and Conclusions

Business Operations:

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

Radiation Safety Operations.

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:

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Date Meeting Conducted:
List those issues discussed at the exit meeting:
Summary of Violations and Recommendations