



RADIOACTIVE MATERIALS (RAM) PROGRAM

New/Renewal Medical License Checklist

Licensee:

License Number:

- ☐ **Review the NUREG-1556 Volume 9** (obtain the current revision from the website).
<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.html>
- ☐ **Submit the Application** signed by executive management, or a person authorized to make commitments for the business entity requesting / possessing the license. If signed by someone other than senior management or Radiation Safety Officer (RSO) /Alternate Radiation Safety Officer (ARSO) provide a non-RSO delegation of authority form:
[https://dpbh.nv.gov/Reg/RAM/dta/Forms/Radioactive_Material_Program_\(RAM\)-_Forms/](https://dpbh.nv.gov/Reg/RAM/dta/Forms/Radioactive_Material_Program_(RAM)-_Forms/).
- ☐ **Financial Assurance, Decommissioning and Emergency Plans:**
 - ☐ If financial assurance is required, submit documentation required by Nevada Administrative Code (NAC) 459.1995.
 - ☐ If an emergency plan is required per NAC 459.1951, submit the plan required by NAC 459.195.
- ☐ **Materials:** Mark all materials below that are requested and submit the use for each section.

Radioactive Material	Form	Maximum Quantity
☐ Any radioactive material permitted by 10 CFR 35.100.	Any	As needed
☐ Any radioactive material permitted by 10 CFR 35.200; except gasses, generators and PET radioisotopes	Any	As needed
☐ PET _____ (list isotope) permitted by 10 CFR 35.200.	Liquid or other form	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per dose
☐ Gasses _____	Gas	_____ mCi (_____ GBq);

Radioactive Material	Form	Maximum Quantity
(list isotope) permitted by 10 CFR 35.200.		_____ mCi (_____ GBq) per dose
☐ Strontium/Rubidium – 82 generators and Strontium – 85 as a contaminant permitted by 10 CFR 35.200.	Solid and Liquid	_____ mCi (_____ GBq); _____ mCi (_____ GBq); _____ mCi (_____ GBq)
☐ Iodine-131 permitted by 10 CFR 35.300	Sodium Iodide capsules (commitment to capsules for a reduced bioassay condition), Liquid	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per dose
☐ Strontium-89 permitted by 10 CFR 35.300	Liquid (Metastron®)	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per dose
☐ Samarium-153 permitted by 10 CFR 35.300	Liquid (Quadramet ®)	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per dose
☐ Yttrium-90 permitted by 10 CFR 35.300	Liquid Ibriumomab, Tiuxetan (Zevalin ®)	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per dose
☐ Radium-223 permitted by 10 CFR 35.300	Liquid (Xofigo ®)	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per dose
☐ Lutetium-177 permitted by 10 CFR 35.300	Liquid (Lutathera®)	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per dose
☐ Lutetium-177 permitted by 10 CFR 35.300	Liquid (Pluvicto®)	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per dose
☐ Strontium-90 permitted by 10 CFR 35.400	Sealed sources (provide Manufacturer and Model Number)	_____ mCi (_____ GBq);
☐ Palladium-103 permitted by 10 CFR 35.400	Sealed sources (provide Manufacturer and Model Number)	_____ Ci (_____ GBq); _____ mCi (_____ GBq) per seed

Radioactive Material	Form	Maximum Quantity
☐ Iodine-125 permitted by 10 CFR 35.400	Sealed sources (provide Manufacturer and Model Number)	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per seed
☐ Iodine-125 permitted by 10 CFR 35.400	Sealed sources (provide Manufacturer and Model Number)	_____ Ci (_____ GBq);
☐ Cesium-131 permitted by 10 CFR 35.400	Sealed sources (provide Manufacturer and Model Number)	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per seed
☐ Gadolinium-153 permitted by 10 CFR 35.500	Sealed sources (provide Manufacturer and Model Number)	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per source
☐ Iridium-192 permitted by 10 CFR 35.600	Sealed sources (provide device Manufacturer and Model Number)	21 Curies (777 GBq) maximum
☐ Cobalt-60 permitted by 10 CFR 35.600 Requires completion of the 10 CFR Part 37 checklist	Sealed sources (provide device Manufacturer and Model Number) Teletherapy or Stereotactic	_____ Ci (_____ TBq); _____ Ci (_____ GBq) per source
☐ Phosphorous-32 permitted by 10 CFR 35.1000	Sealed sources (provide Manufacturer and Model Number)	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per source assembly
☐ Strontium-90/Yttrium-90 permitted by 10 CFR 35.1000	Sealed sources (provide Manufacturer and Model Number)	_____ Ci (_____ GBq); _____ mCi (_____ MBq) per source
☐ Yttrium-90 permitted by 10 CFR 35.1000	Microsphere sealed sources (provide Manufacturer and Model) TheraSphere® or SIR-Spheres®	_____ mCi (_____ GBq); _____ mCi (_____ GBq) per Vial

Radioactive Material	Form	Maximum Quantity
☐ Cobalt-57	Sealed sources	_____ Ci (_____ GBq); _____ mCi (_____ MBq) per source
☐ Cesium-137	Sealed sources	_____ Ci (_____ GBq); _____ mCi (_____ MBq) per source
☐ Yttrium-90	Liquid	_____ Ci (_____ GBq);
☐ Any radioactive materials permitted by 10 CFR 35.65	Any form permitted by 10 CFR 35.65	As permitted by 10 CFR 35.65
☐ Depleted Uranium	Metal	_____ kg
☐ Other: List isotope	List form:	_____ List Units
☐ Other: List isotope	List form:	_____ List Units
☐ Other: List isotope	List form:	_____ List Units
☐ Other: List isotope	List form:	_____ List Units
☐ Other: List isotope	List form:	_____ List Units

☐ **Storage and use facility address and diagram**

- ☐ Provide the addresses for the business office and use facility as applicable.
- ☐ Provide a facility diagram, with the following details as applicable: indication of north; labeled immediate / surrounding rooms, hallways, storage area, secure areas; occupancy factors; alarm system components including cameras, sensors; and scale or physical dimensions of facility / building. Ensure the diagram is marked as Official Use Only – Security-Related Information as applicable.
- ☐ For licensees using generators, PET isotopes, High Dose Rate (HDR) autoloaders, and / or gamma knife submit shielding report and commitments to shielding.
- ☐ Describe the means of preventing access to unauthorized personnel. Include information and training for receiving staff if materials are received outside of normal business hours.

- ☐ Submit a copy of the Landlord Acknowledgement of Responsibilities Related to Radioactive Materials form available at:
[http://dpbh.nv.gov/uploadedFiles/dpbhnavgov/content/Reg/Radoactive-Mtl/Docs/LandlordAcknowledgementForm\(11-17-15\).pdf](http://dpbh.nv.gov/uploadedFiles/dpbhnavgov/content/Reg/Radoactive-Mtl/Docs/LandlordAcknowledgementForm(11-17-15).pdf)
- ☐ Submit a copy of a local business license with the storage address and a state business license.
- ☐ **Authorized Users AUs:**
 - ☐ Submit a complete list of all AUs and their authorized uses.
 - ☐ Submit a current Nevada State Board of Medical Examiners or Nevada Board of Osteopathic Medicine card / printout for each AU or new physician to be added to the license.
 - ☐ Provide proof of training and experience for any new physicians to be added as an AU with the following options. Do not provide diplomas, curricula vitae, resumes, publishing histories or similar documents as none of which provide acceptable proof of training and experience. Please see 10 CFR 35.190, 290, 390, 490, 590, and 690 for the applicable requirements for the specialty of the physician available at: <https://www.ecfr.gov/current/title-10/chapter-I/part-35?toc=1>.
 - ☐ Submit a current RAM license from the Nuclear Regulatory Commission (NRC), another agreement state or the State of Nevada for the same use(s) as requested for the new AU, or
 - ☐ Submit a copy of an approved specialty board certification per 10 CFR 35 subpart D, E, G, or H. The list of approved specialty board certifications recognized can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>, or
 - ☐ Submit a completed NRC form 313A appropriate for the desired use. The forms and instructions can be found from: [https://dpbh.nv.gov/Reg/RAM/dta/Forms/Radioactive_Material_Program_\(RAM\)_-_Forms/](https://dpbh.nv.gov/Reg/RAM/dta/Forms/Radioactive_Material_Program_(RAM)_-_Forms/).
- ☐ **Authorized Medical Physicists (AMP):**
 - ☐ Submit a complete list of all AMPs and their authorized specialties.
 - ☐ Provide proof of training and experience for any new physicists to be added with the following options. Do not provide curricula vitae, resumes, publishing histories or similar documents as none of which provide acceptable proof of training and experience. Please see 10 CFR 35.51 for the applicable requirements.
 - ☐ Submit a current RAM license from the NRC, another agreement state or the State of Nevada for the same use(s) as requested for the new AMP, or

- ☐ Submit a copy of an approved specialty board certification per 10 CFR 35.51. The list of approved specialty board certifications recognized can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>, or
- ☐ Submit a completed NRC form 313A (AMP). The forms and instructions can be found from: [https://dpbh.nv.gov/Reg/RAM/dta/Forms/Radioactive_Material_Program_\(RAM\)_-_Forms/](https://dpbh.nv.gov/Reg/RAM/dta/Forms/Radioactive_Material_Program_(RAM)_-_Forms/).

☐ **RSO / ARSO:**

- ☐ Submit an organizational chart showing the RSO / ARSO relationship with management.
- ☐ Submit a completed Delegation of Authority form for the RSO / ARSO or RSO / ARSO candidates (same form is used for both the RSO and ARSO): http://dpbh.nv.gov/uploadedFiles/dpbhnavgov/content/Reg/Radoactive-Mtl/Docs/RSO_DelegationAuthority.pdf
- ☐ Provide proof of training and experience for any new RSO / ARSO to be added with the following options. Do not provide curricula vitae, resumes, publishing histories or similar documents as none of which provide acceptable proof of training and experience. Please see 10 CFR 35.50 for the applicable requirements.
 - ☐ Submit a current RAM license from the NRC, another agreement state or the State of Nevada with the new RSO / ARSO as an RSO / ARSO for the same use(s) / prospective use(s) requested.
 - ☐ Submit a copy of an approved specialty board certification per 10 CFR 35.50. The list of approved specialty board certifications recognized can be found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.
 - ☐ Submit a completed NRC form 313A (RSO). The forms and instructions can be found from: [https://dpbh.nv.gov/Reg/RAM/dta/Forms/Radioactive_Material_Program_\(RAM\)_-_Forms/](https://dpbh.nv.gov/Reg/RAM/dta/Forms/Radioactive_Material_Program_(RAM)_-_Forms/)

☐ **Sealed Source RAM Inventory Policy & Procedure**

- ☐ Submit a completed current inventory initialed by the RSO. (Renewals only)
- ☐ Commit to performing and documenting a physical inventory every six-months and maintaining records of the inventory for three years.
- ☐ Commit to leak testing as recommended by the manufacturer or Sealed Source and Device Registry, maintaining records of the leak checks for at least three years, and provide the following as applicable:
 - ☐ Provide the name of the company performing leak checks.

- ☐ If self-analyzing leak test, submit procedures for analysis and equipment used for completing the leak test including proof of acceptable minimum activity detectable.
- ☐ Provide a list of staff trained to perform leak tests if other than the RSO and submit their training records.
- ☐ **Dosimetry:** Review NUREG 1556 Volume 9 – Appendix M
 - ☐ Provide the name of your current / planned dosimetry provider (must be NVLAP approved).
 - ☐ List the exchange frequency.
 - ☐ List the type of dosimetry used (whole body / extremity) (optically stimulated and thermoluminescent).
 - ☐ Commit to maintaining control badges and exposure records indefinitely.
 - ☐ Commit to having dosimetry records on site for agency technologist and students working / training at the facility.
 - ☐ Commit to all staff wearing personal dosimetry when working with RAM.
- ☐ **ALARA Program:**
 - ☐ Commit to an annual review of the Radiation Protection Plan / Policy / Procedure.
 - ☐ Provide a copy of the Radiation Protection Plan / Policy / Procedure.
 - ☐ Commit to an annual review of all written directives where applicable.
 - ☐ Provide a copy of the written directives / procedures for all uses requested under 10 CFR 35.300, 35.400, 35.600, and 35.1000 as applicable.
 - ☐ Commit to posting “Caution Radioactive Material” and “Caution Radiation Area” signs appropriately.
 - ☐ Commit to posting the current NRC1 “Notice to Employees” signage.
 - ☐ Commit to annual radiation safety training for technologists and ancillary staff as applicable.
 - ☐ Commit to having all staff that ship, pack or determine shipping of RAM will have current HAZMAT shipping training.
 - ☐ Provide a public dose estimate.
- ☐ **Training:** Review NUREG 1556 Volume 9, Appendix J
 - ☐ Commit to having all staff involved with the injection of radioactive materials complete safe injection training per Nevada Revised Statutes (NRS) 653.550.

- ☐ Commit to using only those technologists that are licensed and maintain that license with the state of Nevada in accordance with NRS 653.430.
- ☐ Commit to having training records on site for agency technologist and students working / training at this facility.
- ☐ Commit to an annual training assessment and implementation per NUREG 1556 volume 9.
- ☐ **Radiation Monitoring Equipment:** Review NUREG 1556 volume 9 – appendix K
 - ☐ Submit meter manufacturer, model and serial numbers, probes, and use (rate -v- contamination).
 - ☐ Commit to annual calibration of survey meters and to maintaining records for three years.
 - ☐ Submit the name of the company performing the calibration.
 - ☐ If performing calibrations locally, provide a copy of calibration procedures.
- ☐ **Dose Calibrator:** Review NUREG 1556 volume 9 – appendix G
 - ☐ If not using a dose calibrator per 10 CFR 35.63. commit to the following: “We will use decay correction from the unit doses from the radiopharmacy prescription.”
 - ☐ Commit to calibration in accordance with national standard or per manufacturer’s instructions.
 - ☐ Commit to maintaining records of dose calibrator calibration for three years and until replaced by a newer calibration for those completed less than annually (geometry).
- ☐ **Area Surveys:** Review NUREG 1556 Volume 9 – appendix R
 - ☐ Provide a map of daily radiation survey points and provide the associated trigger levels
 - ☐ Provide a map of weekly wipe survey points and provide the associated trigger levels
 - ☐ Commit to maintain survey records for three years.
- ☐ **Safe Use of Unsealed Materials:** Review NUREG 1556 Volume 9 – appendix T
 - ☐ Submit the policy and procedure for the safe use of unsealed material.
- ☐ **Emergency and Spill Procedures:** Review NUREG 1556 Volume 9 – appendix N
 - ☐ Submit emergency policies / procedures including those incident response procedures (fire, theft, damage) and reporting requirements. Ensure the procedures are marked as Official Use Only – Security-Related Information as needed.

- ☐ Add the State of Nevada emergency numbers and RSO contact information to postings and procedures.

Radiation Control Program (8:00 am–5:00 pm M-F)	(775) 687-7550
Radiation Control Program 24 hr Emergency Number	(877) 438-7231
Nevada Highway Patrol (24 hrs)	(775) 687-0400

- ☐ **Order and Receipt of Materials:** Review NUREG 1556 Volume 9 – Appendix O
 - ☐ Submit policies and procedures for the ordering and receipt of materials.
- ☐ **Opening Packages containing RAM:** Review NUREG 1556 Volume 9 – Appendix P
 - ☐ Submit policies and procedures for opening packages containing RAM.
- ☐ **Waste Management:** Review NUREG 1556 Volume 9 – Appendix W
 - ☐ Submit decay in storage policy and procedures for waste with a half-life of 120 days or less.
 - ☐ Commit that the transfer or disposal of sealed sources and radioactive waste will be conducted by either transferring it to a licensed radioactive waste broker, returned to the manufacturer, or by transferring it to a specific licensee authorized to possess the material.
 - ☐ Commit to the limitations for the disposal for Microsphere Brachytherapy Sources and Devices licensing guidance. The most current guidance is found at: <https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html#reg>.
 - ☐ Commit to maintain records of receipt, transfer, and disposal of all sealed sources received and possessed under the license.
 - ☐ Commit that license termination will be conducted in compliance with Nevada Administrative Code (NAC) 459.200.
- ☐ **Service Providers and Services:**
 - ☐ Identify current or planned service providers and services that involve the use of radioactive material at the use location for this license (nuclear pharmacies, nuclear medicine technologists, medical physicist, dose calibrator calibrations, nuclear medicine camera calibrations, QA / QC checks, etc.).
 - ☐ Provide the name of the service provider and services provided.
 - ☐ Identify if the service provider will be working under this license or their own license and provide the service provider's radioactive materials license number.
 - ☐ Identify who will procure and receive licensed material (sealed or unsealed sources).

- ☐ Describe the transfer of licensed material to and from the service provider.
- ☐ Describe how spills and/or emergencies will be handled and reported.
- ☐ Describe how licensed material will be returned to storage or disposed of as waste.
- ☐ For service providers working under this RML:
 - ☐ Commit to maintaining a list of all service provider personnel who've worked under this license.
 - ☐ Commit to maintaining records of licensee specific training on the following:
 - ☐ Safe Use of Unsealed Licensed Material, Emergency and Spill Procedures with contact information for RSO.
 - ☐ How the service provider coordinates receipt and return of licensed material.
 - ☐ Other applicable licensee procedures.
 - ☐ Commit to maintaining records of personnel monitoring, including written annual reports when appropriate.
- ☐ **Gases (Xe-133):**
 - ☐ Commit to manufacturer recommendations for QC / QA.
 - ☐ Commit to monthly checks of machinery (hoods, traps, etc.).
 - ☐ Commit to annual checks of ventilation calibration (negative pressure) and posting.
 - ☐ Commit to annual calibration of velometer / anemometer.
 - ☐ Submit the name of the company testing the ventilation systems for radioactive gases.
- ☐ **Radium-223 Xofigo:**
 - ☐ Submit AU verification as authorized for 10 CFR 35.300, or training per 35.396.
 - ☐ Submit the policy and procedure for the ordering, handling, use, and disposal of Ra-223.
 - ☐ Commit to following the full prescribing Information for Xofigo provided by Bayer revised on 3/2016 or most current revision and submit a copy of the full prescribing information.
 - ☐ Commit to performing annual calibrations of dose calibrators dial settings using a National Institute of Standards and Technology (NIST) traceable Radium-223 standard and submit the calibration procedure.

☐ **Manual Brachytherapy Facility: (10 CFR 35.400)**

- ☐ Submit the policies and procedure for security and accountability of devices and seeds / sources.
- ☐ Submit the policy and procedures for leak testing sources, if applicable.
- ☐ Submit the policy and procedures for emergency equipment; include a list of what equipment is available.
- ☐ Submit a copy of the policies and procedures for evaluating implant results if not included with the written directive submitted above.

☐ **Rubidium (Rb-82) generator: Bracco Diagnostics**

- ☐ Submit the manufacturer, model number, nuclide activity for each of the check sources. (Renewal only)
- ☐ Commit to the current Quality Control Procedures developed by the manufacturer and approved by the U.S. Food and Drug Administration (FDA) as revised March 2012 or later.
- ☐ Commit to and submit a copy of the current Bracco Diagnostics "Infusion System User Guide".
- ☐ Commit to and submit a copy of the current Prescribing Information (PI) for the CardioGen-82 generator.
- ☐ Submit the manufacturer and model number for the dose calibrator.
- ☐ Submit the quality control procedures for the dose calibrator for performing the standard testing.
- ☐ Submit the daily step by step PET (Sr-82, Sr-85, and Rb-82) quality control procedures for the dose calibrator.
- ☐ Submit the procedures for the storage and disposal of Sr-85 waste. Include procedures for daily surveys of the Sr-85 generator waste and the disposal of the Sr-85 generator waste shall be documented.
- ☐ Submit proof of the manufacturer's initial training for all AU's, RSO's and technologists.
- ☐ Commit to anyone who uses or supervises the use of the generator will receive device specific training by the manufacturer prior to initial use.

- ☐ Commit to the Certified / Registered Nuclear Medicine Technologists who use the generator and the RSO must annually receive the manufacturer's refresher or recertification training for this device.
- ☐ Commit to completing the Sr-82/Sr-85 Testing worksheet, Calibration worksheet, Volume Tracking worksheet and the Monthly Receipt/Return Worksheet to include the generator lot number, serial number and calibration date.
- ☐ Commit to each generator the licensee shall maintain an on-going record of all eluate volumes (washing, testing and dosing volumes) including a summary of the cumulative volume of eluate.
- ☐ Commit to measuring and calculating the Strontium 82 (Sr-82)/ Rubidium 82 (Rb-82) and Strontium 85 (Sr-85)/Rb-82 concentrations using an approved dose calibrator set on its most sensitive microcurie (μCi) scale and record all values with at least one significant figure and at least two places to the right of the decimal place according to the following schedule below.
 - ☐ Daily on days of use prior to administration; and
 - ☐ Additional daily test at the midpoint of the day should the initial test concentrations of Sr-82 reach 0.002 μCi per millicurie (mCi) of Rb-82; or
 - ☐ The initial test concentrations of Sr-85 reach 0.02 μCi per mCi of Rb-82; or
 - ☐ When 14 liters of total eluate has passed through the generator at the time points determined by the day's elution volumes where tests are performed at every 750 milliliters eluate use for that day. (i.e., one additional test when 750 milliliters of eluate is used during the day, a second additional test when 1,500 milliliter of eluate is used during the day and an additional test for each 750 milliliters of eluate used during the day.
- ☐ Commit to stop using the generator on patients at the expiration limits listed below:
 - ☐ 17 liters for the generator's cumulative eluate volume; or
 - ☐ 42 days post generator calibration date; or
 - ☐ An eluate concentration of Sr-82 of equal to or greater than 0.01 μCi per mCi of Rb-82; or
 - ☐ An eluate concentration of Sr-85 of equal to or greater than 0.10 μCi per mCi of Rb-82.
- ☐ Commit to following the manufacturer's annual preventative maintenance schedule for the Infusion Cart System and complete all of the recommended corrective actions.
- ☐ Commit to participating in the manufacturer's generator and infusion cart system online monitoring programs to determine use or stability of these products.

- ☐ Commit to reporting to the RAM Program any generator leaks, generator or cart failures, and each occurrence when the eluate concentration of Sr-82 equals or exceeds 0.02 μCi per mCi of Rb-82 or the eluate concentration of Sr-85 equals or exceeds 0.20 μCi per mCi of Rb-82.
- ☐ Commit that all records of these tests and reports will be maintained for three years and made available for inspection by the RAM Program.
- ☐ Commit to not sharing this generator with any other licensees, AU's, or PET trailers.
- ☐ Submit the policies and procedures for inventory and leak testing sources, if applicable.
- ☐ **Rubidium Rb-82 generators:** Ruby Fill (Drax Image):
 - ☐ Commit to following the current Quality Control Procedures developed by the manufacturer and approved by the U.S. Food and Drug Administration (FDA) for the RUBY Rubidium Elution System™ User Manual as revised April 2019 or later.
 - ☐ Commit to following the RUBY Rubidium Elution System™ user manual and maintaining records necessary to demonstrate compliance.
 - ☐ Submit a copy of the Full Prescribing Information (FPI) for the RUBY-FILL (Rubidium Rb-82) generator.
 - ☐ Commit to following the Full Prescribing Information (FPI) for the RUBY-FILL (Rubidium Rb-82) generator and maintain records to demonstrate compliance.
 - ☐ Commit to using the RUBY Rubidium Elution System™ including the dose calibrator included in the system.
 - ☐ Commit to following the manufacturer's annual preventative maintenance schedule for the RUBY Rubidium Elution System™ and to complete all the recommended maintenance items.
 - ☐ Identify the Nuclear Pharmacy with a medical distribution radioactive materials license (RML) which will be providing the generators and submit a copy of their RML. If you cannot obtain a copy of the RML then please submit: the RML number, the name of the agency who issued the license, and the name and phone number of the Radiation Safety Officer (RSO).
 - ☐ Submit procedures for receipt, storage, and return or disposal of the RUBY-FILL Rb-82 generators.
 - ☐ Submit the procedures for the storage and disposal of generator radioactive waste including Sr-85 waste.

- ☐ Commit to provide appropriate shielding of the radioactive waste from the generator, which contains Sr-82 and Sr-85.
- ☐ Commit to daily surveys of the radioactive waste, that the disposal of all radioactive waste shall be documented, and that daily surveys and disposal records shall be maintained for three years and be available for inspection by the RCP.
- ☐ Submit documentation of the manufacturer's certification training for all of AU's, RSO's, and the users (nuclear medicine technologists).
- ☐ Commit that everyone who uses or supervises the use of the generator will complete the manufacturer's certification training, from the manufacturer for this device, prior to initial use.
- ☐ Commit that the Certified/Registered Nuclear Medicine Technologists and anyone who uses the generator and the RSO will complete the manufacturer's recertification training for this device at least every two years.
- ☐ Commit to use only additive-free 0.9% Sodium Chloride Injection USP to elute the generator.
- ☐ Commit to immediately stop patient infusion and permanently discontinue the use of the affected RUBY-FILL generator whenever an incorrect eluent is used.
- ☐ Commit to providing patients instructions described in the FDA FPI.
- ☐ Commit for each generator the licensee shall maintain an on-going record of all eluate volumes (washing, testing and dosing volumes) including a summary of the cumulative volume of eluate.
- ☐ Commit to measuring and calculating the Strontium-82 (Sr-82) / Rubidium-82 (Rb-82) and Strontium-85 (Sr-85)/Rb-82 concentrations using an approved dose calibrator set on its most sensitive microcurie (μCi) scale and record all values with at least one significant figure and at least two places to the right of the decimal place according to the following schedule below.
 - ☐ Daily on days of use prior to administration; and
 - ☐ Repeat every 4 patients after an Alert Limit has been detected;
 - ☐ Alert Limits:
 - ☐ 20 L total elution volume has passed through the generator column;
 - ☐ Sr-82 level reaches 0.004 $\mu\text{Ci}/\text{mCi}$ Rb-82;
 - ☐ Sr-85 level reaches 0.04 $\mu\text{Ci}/\text{mCi}$ Rb-82;
 - ☐ Immediately after detection of the volume alert limit (20 L).

- ☐ Commit to stop using the generator on patients at the expiration limits listed below:
 - ☐ Total elution volume of 30 L has passed through the generator column.
 - ☐ Expiration date of the generator (60 days post- manufacturing);
 - ☐ An eluate Sr-82 level of 0.01 $\mu\text{Ci}/\text{mCi}$ Rb-82;
 - ☐ An eluate Sr-85 level of 0.1 $\mu\text{Ci}/\text{mCi}$ Rb-82.
- ☐ Provide the prescribed patient dosage or prescribed dosage range for the facility.
- ☐ Commit to having the RSO perform quarterly reviews of the quality assurance testing and patient dose records.
- ☐ Commit to reporting to the RCP any generator leaks, generator or cart failures, any elution of a generator with an incorrect eluent, and each occurrence when the eluate concentration of Sr-82 equals or exceeds 0.02 μCi per mCi of Rb-82 or the eluate concentration of Sr-85 equals or exceeds 0.20 μCi per mCi of Rb-82.
- ☐ Commit that all records of these tests and reports shall be maintained for three years and be available for inspection by the RAM Program.
- ☐ Commit to not sharing this generator with any other licensees, AU's or PET trailers.
- ☐ **Gamma Stereotactic Radiosurgery & Remote Afterloader Units:** (10 CFR 35.600)
 - ☐ Submit the policies and procedures for calibrations; include who will do calibrations and their training. Ensure the procedures are marked as Official Use Only – Security-Related Information as needed.
 - ☐ Commit to performing manufacture's recommended QC prior to any patient cases.
 - ☐ Commit to follow the manufacturer's recommendations for routine and extended maintenance on the unit; a copy of the manual shall be available to each person using, or having responsibility for the use of, the device.
 - ☐ Submit the description of the warning systems / controls (locks, signs, alarms, warning lights and interlocks). Ensure the procedures are marked as Official Use Only – Security-Related Information as needed.
 - ☐ Submit the description of the video and intercom communication / surveillance.
 - ☐ Submit the description of the steps to prevent two machine operations in a single treatment room if applicable by facility construction.
 - ☐ Submit the policies and procedures for security of devices and a description of the security measures used. Ensure the procedures are marked as Official Use Only – Security-Related Information as needed.

- ☐ Submit the policies and procedures for emergency equipment.
- ☐ Submit the policies and procedures for inventory and leak testing sources, as applicable
- ☐ Commit to radiation surveys and tests that shall be performed before initiation of a high dose rate (HDR) remote afterloader / Gamma Stereotactic treatment program, and after each installation of a sealed source(s).
- ☐ Commit that the HDR remote afterloader / Gamma Stereotactic unit will not be relocated to a new facility without prior approval of the plans and details by the RAM Program.
- ☐ Commit that any changes made in the treatment room shielding, location of the unit within the treatment room, or use of the high dose rate remote afterloader / Gamma Stereotactic unit that could result in increased radiation levels in areas outside the treatment room shall be evaluated by a radiation survey and reported to the RCP within 30 days.
- ☐ Commit to submitting an inventory change to the RAM Program if +/- from permanent inventory.
- ☐ **Investigational New Drugs & Uses:** (10 CFR 35.1000)
 - ☐ Y-90 Microsphere must request the brand of therapy (TheraSphere / SIR-Spheres); and
 - ☐ AU must be interventional radiologist or authorized for 35.300 or 35.400 uses; and
 - ☐ AU must have manufactures training with 3 simulated case studies (In vitro); and
 - ☐ AU must have 3 clinical cases (In Vivo) under the supervision of an AU or Manufactures trainer.
 - ☐ RCP will approve each user after all criteria have been met. (See link below)
<http://pbadupws.nrc.gov/docs/ML1217/ML12179A353.pdf>
 - ☐ For all investigational new drugs commit to abiding by FDA protocols / regulations.
- ☐ **Mobile Imaging:** Review NUREG 1556 Volume 9 - Appendix V
 - ☐ Explain the method of transportation:
 - ☐ A coach (self-contained, materials stay with vehicle); include the VIN for the coach
 - ☐ A van (materials and camera will enter use locations) Include the address for each use location.

- ☐ Submit a Memorandum of Understanding (MOU) for each location of use.
 - ☐ Submit a facility diagram for each coach/trailer and the dispatch/hub location.
 - ☐ Commit to transporting all radioactive materials in accordance with U.S. DOT regulations.
 - ☐ Submit the Type A shipping container documentations for all shipping containers used to ship type A quantities of radioactive materials. Mark drawing and documentation as noted in NUREG 1556 Volume 9 page 6-1 as appropriate.
- ☐ **Materials Control & Security Required for all Gamma Stereotactic Radiosurgery / gamma knife locations.**
- ☐ Complete the Materials Control & Security Checklist form:
[http://dpbh.nv.gov/Reg/RAM/dta/Forms/Radioactive_Material_Program_\(RAM\)_-_Forms/](http://dpbh.nv.gov/Reg/RAM/dta/Forms/Radioactive_Material_Program_(RAM)_-_Forms/)

CERTIFICATION

The Applicant understands that all commitments that are marked above are binding and considered part of the license application; if not applicable, DO NOT mark. All applicable items that require submission must accompany the application, license fee and this checklist.

Printed Name Certifying Officer

Title

Signature

Date