Radioactive Materials (RAM) Program

New / Renewal Medical License Checklist

Licensee_____ Lic. #_____

☐ **Submit 1 copy only.** Number all pages sequentially that are submitted for review.

☐ Review the NUREG-1556 Volume 9 It can be used as guidance to complete this checklist.
☐ Submit all Policy and Procedures to the Nevada Radiation Control Program.
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/

☐ **Submit the Application** signed by executive management or a person authorized to sign original documents.
☐ If the licensee is an IC participant, all information is minimum Official Use Only. Treat all information regarding this licensee with the appropriate caution and sensitivity.

☐ **Financial Assurance, Decommissioning and Emergency Plans:**
☐ If financial assurance is required, submit documentation required by NAC 459.1955.
☐ If emergency Plan is required per NAC 459.1951, submit the plan required by NAC 459.195.

☐ Mark all materials below that are requested, and submit the use for each selection.

Radioactive Material	Form	Max Quantity
☐ Any radioactive material permitted by 10 CFR 35.100	Any	As needed
☐ Any radioactive material permitted by 10 CFR 35.200**; except gases, generators and PET radioisotopes**	Any	As needed
☐ PET_____ permitted by 10 CFR 35.200	Liquid (or other form)	_____ millicuries (_____GBq); _____ millicuries (_____GBq) per dose
☐ Gasses_____ permitted by 10 CFR 35.200	Gas	_____ millicuries (_____GBq); _____ millicuries (_____GBq) per dose
☐ Technetium-99m & Thallium-201 permitted by 10 CFR 35.200	Any	As needed ***Cardiac Clinics ONLY***
☐ Strontium/Rubidium-82 generators & Strontium-85 as a contaminant	Solid & liquid	_____ millicuries (_____GBq); _____ millicuries (_____GBq) ; _____ millicuries (_____GBq)
☐ Iodine-131 permitted by 10 CFR 35.300	Sodium iodide capsules (commitment to capsules for a reduced bioassay condition)	_____ millicuries (_____GBq); _____ millicuries (_____GBq) per dose
☐ Strontium-89 permitted by 10 CFR 35.300	Liquid (Metastron®)	_____millicuries (_____ GBq); _____millicuries (_____MBq) per dose
☐ Samarium-153 permitted by 10 CFR 35.300	Liquid (Quadramet®)	_____millicuries (_____GBq); _____millicuries (_____ GBq) per dose
☐ Yttrium-90 permitted by 10 CFR 35.300	Liquid Ibritumomab Tiuxetan (Zevalin®)	_____millicuries (_____ GBq); _____millicuries (_____ GBq) per dose
☐ Radium-223 permitted by 10 CFR 35.300	Liquid (Xofigo®)	_____ millicuries (_____ MBq); _____ millicuries (_____ MBq) per dose

*Medical Use - Sealed sources (Manufacturer and Model Number)

☐ Strontium-90 permitted by 10 CFR 35.400	*Sealed sources (Manufacturer and Model Number)	_____ millicuries (_____GBq)
☐ Palladium-103 permitted by 10 CFR 35.400	*Sealed sources (Manufacturer and Model Number)	_____ curie (_____ GBq); _____ millicuries (_____GBq) per seed
☐ Iodine-125 permitted by 10 CFR 35.400	*Sealed sources (Manufacturer and Model Number)	_____ curie (_____ GBq); _____ millicuries (_____ MBq) per seed
☐ Iodine-125 permitted by 10 CFR 35.400	*Sealed sources (Manufacturer and Model Number)	_____ curies (_____ GBq)
☐ Cesium-131 permitted by 10 CFR 35.400	*Sealed sources (Manufacturer and Model Number)	_____ curie (_____ GBq); _____ millicuries (_____ GBq) per seed
☐ Gadolinium-153 permitted by 10 CFR 35.500	*Sealed sources (Manufacturer and Model Number)	_____ curies (_____ GBq); _____ millicuries (_____ GBq) per source
☐ Iridium-192 permitted by 10 CFR 35.600	*Sealed sources (Manufacturer and Model Number)	**21** curies (**777** GBq)
☐ Cobalt-60 permitted by 10 CFR 35.600	*Sealed sources (Manufacturer and Model Number) ***Teletherapy or Stereotactic***	_____ curies (_____ GBq); _____ millicuries (_____ GBq) per source
☐ Phosphorous-32 permitted by 10 CFR 35.1000	*Sealed sources (Manufacturer and Model Number)	_____curies (_____GBq); _____millicuries (_____GBq) per source assembly
☐ Strontium-90/ Yttrium-90 permitted by 10 CFR 35.1000	*Sealed sources (Manufacturer and Model Number)	_____curie (_____ GBq); _____millicuries (_____ MBq) per source
☐ Yttrium-90 permitted by 10 CFR 35.1000	*Microsphere sealed sources (Manufacturer and Model Number) ***TheraSphere® or SIR-Sphere***	_____curies (_____ GBq); _____ millicuries (_____ GBq) per vial
☐ Cobalt-57	Sealed sources	_____ millicuries (____ GBq); _____ millicuries (____ GBq) per source
☐ Cesium-137	Sealed sources	_____ millicuries (____ GBq); _____ millicuries (____ GBq) per source
☐ Yttrium-90	Liquid	_____ millicuries (_____ GBq)
☐ Any radioactive material permitted by 10 CFR 35.65	Any form permitted by 10 CFR 35.65	As permitted by 10 CFR 35.65
☐ Depleted Uranium	Metal	_____ kilograms
☐ Other:	Form:	_____ Units:

☐ **Sealed sources** Policy & Procedure –
- ☐ Submit a complete current inventory with the date & RSO initials
  Include: Manufacturer, model no. & serial no., nuclide & activity and storage location
- ☐ Commit to a physical inventory every 6 months / maintain for **3 years**.
- ☐ Commit to submitting an inventory change to the RAM Program if +/- from permanent inventory.
- ☐ Commit to Leak Testing as ≤ 6 months / maintain for **5 years** and submit:
  - ☐ Include the name of the company supplying kits and analyzing the leak tests.
  - ☐ If they are self-analyzed, submit Licensee's procedures for analysis.
  - ☐ List of Users to perform leak tests other than the RSO, & submit their training.

☐**Storage and use facility** address and diagram
- ☐ Addresses of the business office & use facility
- ☐ Complete facility diagram: direction N↑, labeled immediate/surrounding rooms and hallways, storage area, secure areas, occupancy factor and scale.
- ☐ For generators, PET, or HDR: Submit shielding report and commitments to shielding
- ☐ Describe means of preventing access to unauthorized personnel, locks, key pads etc.
- ☐ Submit a copy of letter from the land lord stating that they are aware of the storage/use of RAM.
  -If property is owned by the company, have executive management write letter stating this.
- ☐ Submit a copy of State or local business license with the storage address.

☐ **RSO**: Review 10 CFR 35.50 & NUREG 1556 requirements. (*The alternate RSO is not required*)
- ☐ Submit an organizational chart and a Delegation of Authority form with wet signatures to act on the license: http://health.nv.gov/PDFs/Radiology/Forms/RSO_DelegationAuthority.pdf
- ☐ Submit current RAM license from NV, NRC or other state, must be named as RSO for same uses, or
- ☐ New RSO & ARSO submit NRC Form 313A (RSO) Recentness of training per 10 CFR 35.59

☐ **AU** or change in Authorized use request. (*Submit a complete list of all AU's and uses.)*
- ☐ Submit a current RAM license from NV, NRC or other state showing the AU for same uses.
- ☐ Submit the appropriate NRC Form 313A for the uses requested, signed by the Preceptor.
- ☐ For a new 10 CFR 35.300, submit at least 3 AU supervised cases in last 6 months.
- ☐ Submit a copy of approved Specialty Board Cert. (10 CFR 35 subpart D, E, G, or H)
- ☐ Submit a current Nevada Medical Examiners Board card for each AU.

☐ **AMP** addition or change in Authorized use: (35.400 & 600)
- ☐ Submit a current RAM license from NV, NRC or other state listing the AMP for same uses.
- ☐ Submit a NRC Form 313A (AMP) form for the uses requested, signed by the Preceptor.
- ☐ Submit a specialty Board Certification copy (10 CFR 35.51)

☐ **Dosimetry**: NUREG 1556 Vol. 9 Rev. 2 - Appendix M
- ☐ Provide the name of your dosimetry provider (must be NVLAP approved) and list the exchange frequency.
- ☐ Explain the type of dosimetry used (WB & finger) (film & TLD)
- ☐ Commitment to maintain Control Badges and records indefinitely
- ☐ If the licensee does not use dosimetry due to 10% rule; they need to submit proof that they are below the 10% annual exposure limit.

☐ **ALARA Program**
- ☐ Commit to an annual review of the Radiation Protection Plan, including the Written Directive Policy
- ☐ Submit a copy of the written directive, a sample for each type of therapy.
- ☐ Commit to posting "Caution Radioactive Material" and "Caution Radiation Area" signs appropriately
- ☐ Commit to posting the current NRC1 "Notice to Employees" signage
- ☐ **If required,** Commit to Radiation Safety Committee meetings and maintaining minutes for 3 years
- ☐ Commit to ALL staff that pack, ship or determine shipping of RAM will obtain HAZMAT training http://www.phmsa.dot.gov/hazmat/training-outreach

☐ **Training**: NUREG 1556 Vol. 9 Rev. 2 - Appendix J
- ☐ Commit to an annual training assessment and implementation per NUREG 1556 Vol. 9
- ☐ Commit to training & dosimetry records to be on site for Agency Techs/Students that are on site.
- ☐ Submit current HAZMAT training certificate to ship hazardous materials (49 CFR required)

☐ **Radiation Monitoring**:
- ☐ Submit meter manufacturer, model #, serial #, probes, and use (Rate -v- contamination)
- ☐ Submit the name of the company performing the calibration
- ☐ Commit to calibration annually and to maintain records for 3 years.

☐ **Dose Calibrator:**
- ☐ Commit to calibration in accordance with National Standards or per manufacturer's instructions:

TEST REQUIRED	FREQUENCY
Accuracy	at installation, then annually thereafter
Constancy	at installation, then daily thereafter
Linearity	at installation, then quarterly thereafter
Geometry	at Installation; after repair, loss of power or moving instrument

- ☐ Commit to maintain record for 3 years
- ☐ If no dose calibrator is used per 10 CFR 35.63. Commit- *"We will use decay correction for the unit dose from the radiopharmacy prescription."*

☐ **Area Surveys**: NUREG 1556 Vol. 9 Rev. 2 - Appendix R
- ☐ Area surveys for each day and area where material is used, include Trigger Level
- ☐ Weekly Wipe (Contamination) survey, include the Trigger Level
- ☐ Commit to maintain records for 3 years

☐**Safe Use of Unsealed Material**: NUREG 1556 Vol. 9 Rev. 2 - Appendix T
- ☐ Submit the Policy and Procedure

☐ **Emergency and Spill Procedures**: NUREG 1556 Vol. 9 Rev. 2 - Appendix N
- ☐ Submit the Policy and Procedure
- ☐ State of Nevada Emergency numbers and RSO contact information

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

☐ **Order & Receipt of Materials**: NUREG 1556 Vol. 9 Rev. 2 - Appendix O
- ☐ Submit the Policy and Procedure

☐ **Opening Packages containing RAM**: NUREG 1556 Vol. 9 Rev. 2 - Appendix P
- ☐ Submit the Policy and Procedure

☐ **Waste management:** NUREG 1556 Vol. 9 Rev. 2 - Appendix W
- ☐ Commitment-"Radioactive Waste and sealed sources will be transferred to a low level waste facility, returned to the manufacturer or transferred to a specific licensee authorized to possess the material."
- ☐ Submit Decay in Storage Policy and Procedure (t1/2 <120 day is allowed)
- ☐ Commitment to maintain records of receipt, transfer, and disposal of all sealed sources received and possessed under the license
- ☐ Commitment that license termination will be conducted in compliance with Nevada Administrative Code (NAC) 459.200.
- ☐ Commit to abiding by the conditions and limitations as stated in "Licensing Guidance: Microsphere Brachytherapy Sources and Devices" REVISED JUNE 2012, which apply to use of the yttrium-90 Sirtex Medical Limited SIR-Spheres® and TheraSphere® microspheres used for permanent implantation therapy.

☐ **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 (- pressure) and posting
- ☐ Submit the name of the company testing the ventilation systems for RAM gases
- ☐ Commit to annual calibration of velometer/anemometer

☐ **Radium-223 Xofigo:**
- ☐ Submit AU verification as authorized for 35.300, or training per 35.396.
- ☐ Submit the policy and procedure for the ordering, handling & use, and disposal of Ra-223.
- ☐ Submit the written directive for Ra-223.

☐ **Manual Brachytherapy Facility** (10 CFR 35.400)
- ☐ Submit the Policy and Procedure (P & P) for security of devices
- ☐ Submit the P & P for Emergency equipment; include a list of what is available
- ☐ Submit the P & P for inventory and leak testing sources, if applicable

☐ **Rubidium (Rb-82) generator**:
- ☐ Request the minimum required licensing nuclides and amounts: Strontium (Sr)-82 = 200 mCi, Rubidium (Rb)-82 = 200mCi and Sr-85= 1Ci (as a contaminant).This allows for generator exchange.
- ☐ Submit the Manufacture, model number, nuclide activity for each of the check sources.
- ☐ 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 manufacture 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 of the AU's, RSO's and the users (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 (uCi) scale and record all values with at least one significant figure and at least two places to the right of the decimal place according the following schedule below.
  - A. Daily on days of use prior to administration; and
  - B.1. Additional daily test at the midpoint of the day should the initial test concentrations of Sr-82 reach 0.002 uCi per millicurie (mCi) of Rb-82; or
  - 2. The initial test concentrations of Sr-85 reach 0.02 uCi per mCi of Rb-82; or
  - 3. 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:
  - A. 17 liters for the generator's cumulative eluate volume; or
  - B. 42 days post generator calibration date; or
  - C. An eluate concentration of Sr-82 of equal to or greater than 0.01 uCi per mCi of Rb-82; or
  - D. An eluate concentration of Sr-85 of equal to or greater than 0.10 uCi 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 uCi per mCi of Rb-82 or the eluate concentration of Sr-85 equals or exceeds 0.20 uCi per mCi of Rb-82.
- ☐ Commit to 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 P & P for calibrations; include who will do calibrations and their training.
- ☐ 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)
- ☐ 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.
- ☐ Submit the P & P for security of devices and a description of the security measures used
- ☐ Submit the P & P for Emergency equipment
- ☐ Submit the P & P for inventory and leak testing sources, if 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 subsequent to each installation of a sealed source.
- ☐ Commit to 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 to 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.

☐ **Investigational New Drugs & Uses: (10 CFR 35.1000)**
- ☐ Y-90 Microsphere must request the brand of therapy (TheraSphere / SIR-Sphere); 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 (IND) commit to abiding by FDA protocols/regulations.
- ☐ Commit to following the IND Plans

☐ **Mobile Imaging:** NUREG 1556 Vol. 9 Rev. 2 - Appendix V
- ☐ Explain the use and transportation:
  - ☐ A coach (self-contained, materials stay with vehicle); or Include the VIN for the coach
  - ☐ A van (materials & 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 site, including the BASE.
- ☐ Commitment: "Radioactive Materials will be transported in accordance with U.S. DOT regulations."
- ☐ Commit to all of the Rb-82 Generator section above.

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.

CERTIFYING OFFICER —**PRINTED NAME**	**TITLE**	SIGNATURE	DATE