Radioactive Materials (RAM) Program

New / Renewal Radiopharmacy License Checklist

Licensee_____ Lic. #_____

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

☐ Review the NUREG-1556 Volume 13 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 make license commitments.
☐ 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.

☐ **For unsealed materials:** Identify each radionuclide (element name and mass number) that will be used, the form, and the maximum requested possession limit. For potentially volatile materials (e.g., iodine-131), specify whether the material will be manipulated at the radiopharmacy.

Radioactive Material	Form	Max Quantity

☐ **For sealed materials:** Identify each radionuclide (element name and mass number) that will be used in each source; provide the manufacturer's (distributor's) name and model number for each sealed source and device.
☐ Confirm that each sealed source, device, source/device combination is registered as an approved sealed source, device by NRC or by an Agreement State.
☐ We confirm that the activity per source and/or device and its maximum activity will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State.

Radioactive Material	Form	Max Quantity

☐ 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 Leak Testing as ≤ 6 months / maintain records per 459.307 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.

☐ **PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED:**
☐ **For radiopharmaceuticals:** We confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to NAC 459; and describe all licensed material to be distributed or redistributed. (Including non-radiopharmaceuticals)
☐ **For generators:** We confirm that the generators will be obtained from a manufacturer licensed pursuant to NAC 459; and confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.
☐ **For redistribution of used generators:** Submit the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.
☐ Confirm that the manufacturer's packaging and labeling will not be altered.
☐ Confirm that the generator will not be distributed beyond the expiration date shown on the generator label.
☐ Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.
☐ Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

☐ **For Redistribution of Sealed Sources -- for Brachytherapy or Diagnosis:**
- ☐ Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements.
- ☐ Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

☐ **For Redistribution of Calibration and Reference Sealed Sources:**
- ☐ Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to 10 CFR 32.74 to initially distribute such sources.
- ☐ Confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

☐ **For Redistribution of Prepackaged Units for *In Vitro* Tests:**
- ☐ Confirm that the prepackaged units for *in vitro* tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for *in vitro* tests in accordance with a specific license issued pursuant to 10 CFR 32.71 or under an equivalent license of an Agreement State.
  - ☐ For Redistribution to Specific Licensees: Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for *in vitro* tests will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11).

☐ **Radioactive Drug Labeling for Distribution:**
- ☐ Describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g., on the "transport radiation shield" or on the container used to hold the radioactive drug); and agree to affix the required labels to all "transport radiation shields" and to each container used to hold the radioactive drugs.

☐ **Radioactive Drug Shielding for Distribution:**
- ☐ For each radioactive drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package), provide:
  - ☐ The radionuclide and the maximum activity for each type of container (e.g., vial, syringe);
  - ☐ A description of the type and thickness of the “transport radiation shield” provided for each type of container, and
  - ☐ The maximum radiation level to be expected at the surface of each “transport radiation shield” when the radioactive drug container is filled with the maximum activity.

☐ **We will provide customer the following radiation protection services involving licensed material:**
Submit procedures for each select item below. NUREG 1556 vol. 11, Rev. 1, 8.6.4 Service Activities
- ☐ Leak testing;
- ☐ Instrument calibration; and
- ☐ Area surveys and contamination surveys.
- ☐ Bioassays

☐**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.
- ☐ Descriptions of the ventilation systems, including gloveboxes or fume hoods, with pertinent airflow rates, area differential pressures, filtration equipment, and monitoring systems for the use or storage of radioactive materials with the probability of becoming airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions. Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within constraints for air emissions established under 10 CFR 20.1101(d). **Include the calibration frequency.**
- ☐ For generators & PET: 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. http://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Reg/Radoactive-Mtl/Docs/LandlordAcknowledgementForm(11-17-15).pdf
- ☐ Submit a copy of State or local business license with the storage address.
- ☐ Submit the Registered certificate from the Board of Pharmacy

☐ **RSO**: Review NUREG 1556 requirements. (*The alternate RSO is not required*)
- ☐ Submit RSO & ARSO Delegation of Authority with wet signatures, include an organization chart. http://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Reg/Radoactive-Mtl/Docs/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

☐ **ANP** or change in Authorized use request. (*Submit a complete list of all ANPs 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.
- ☐ Submit a current Nevada Pharmacy Board card for each ANP.

☐ **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 training for each AU.

☐ **ALARA Program**
- ☐ Commit to an annual review of the Radiation Protection Plan.
- ☐ Commit to posting "Caution Radioactive Material" and "Caution Radiation Area" signs appropriately
- ☐ Commit to posting the current NRC1 "Notice to Employees" signage
- ☐ Commit to ALL staff that pack, ship or determine shipping of RAM will obtain HAZMAT training

☐**Audit Program**
- ☐ Commit to an annual review of the content and implementation of its Radiation Protection Program

☐ **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.

☐ **Dosimetry**:
- ☐ 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.
- ☐ Procedure for control of doses received by individual members of the public

☐**Safe Use of Unsealed Material**:
- ☐ Submit the Policy and Procedure

☐ **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

- ☐ Describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs;
- ☐ Commit to maintain record for 3 years

☐ **Emergency and Spill Procedures**:
- ☐ 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**:
- ☐ Submit the Policy and Procedure

☐ **Opening Packages containing RAM**:
- ☐ Submit the Policy and Procedure

☐ **Area Surveys**:
- ☐ 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

☐ **Waste management:**
- ☐ 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.
- ☐ **Returned waste from Customer:** Submit written procedures for customer return of pharmacy-supplied syringes and vials and their contents.
  - ☐ Only pharmacy-supplied syringes and vials and their contents may be returned to the pharmacy;
  - ☐ Instructions will be provided to radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the radiopharmacy,
  - ☐ Instructions will be provided to pharmacy staff for the pick-up, receipt and disposal of the returned radioactive waste.

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