Do not use the following checklist to write your application. The following checklist is to help you verify that you have included the information necessary for your radioactive materials application before you upload the document. There are specific details in the guidance document not included in the checklist that are applicable to the application. If the checklist is used to write the application, your application's processing may be delayed.

The checklist is a high-level overview and does not necessarily include specific details for each item. It is meant to ensure only that you addressed each item necessary for the application. Details are discussed and provided for each individual item in the guidance document. The guidance document should have been used to write the application because it includes the details of what information is necessary to determine that the licensed materials will be used safely and will be properly secured. The checklist will help you to review the application to make sure that you have not forgotten to submit information regarding an item for the application.

Using the checklist, please review your application. When you have verified that you have included the information requested for an application, please proceed and follow the instructions to upload your application through the application portal and pay the application fee. Your application is not complete until the application is uploaded **AND** the fee is paid.

For future applications and payments, please make note of the following:

Renewal applications must be received by the DWMRC at least 30 days prior to the expiration date listed on the license. If not, your license may expire and you may be required to store or dispose of your radioactive materials until you can be issued a new radioactive materials license.

Annual fees are due each year on the month and day stated in the expiration date. If the license expires on March 31, 2025, an annual fee would be due on March 31, 2021, March 31, 2022, and so on. For this example, there would be no annual fee required on March 31, 2025 since a renewal is due that year.

If you have questions, please feel free to contact a member of the Radioactive Materials Section at 801-536-0200.

Checklist for Nuclear Pharmacy Radioactive Material

License Items 1 through 4: Locations & Responsible Individuals

Item No. and Title	Suggested Response	
Item 1: License Action Type	You clearly stated what type of action you are requesting and provided the license number if the request involves an existing radioactive materials license: • A NEW LICENSE application; • An AMENDMENT (change) to one or more item(s) of an existing license. [Information for only the item(s) being changed are required to be submitted;] **OR** • A LICENSE RENEWAL Application for an existing Radioactive Materials License. [**MUST BE RECEIVED by DWMRC at least 30 days prior to expiration date stated on license]**.	[ ] [ ] [ ]
Item 2: Name and Mailing Address of Applicant	• The legal name of applicant as registered with the UT Division of Corporations and Commercial Code is on the request. If operating under a "Doing Business As" company, the corporation's name and the DBA name is provided: Example: ABC, Inc. DBA Company Operating Name" • Full Mailing Address for applicant, including zip code, is provided. • If separate Billing Address is necessary, Billing Address is provided.	[ ] [ ] [ ]
Item 3: Address(es) Where Licensed Materials Will be Used or Possessed	• All "Location of Use" physical address(es) or location description(s)* (3 mi W of Power Plant on Hwy 10, City, UT) are provided. **Information showing or describing exact location of licensed materials are marked as protected [Sensitive-Security Related Information Protected Under 63G-2-201(3)(b)].** • Indication of use of devices at temporary job sites was provided. * P.O. Boxes are not accepted for locations of use. Locations of Use are locations where materials are stored, used, prepared, etc excluding temporary job sites.	[ ] [ ] [ ]
Item 4: Person(s) to be Contacted About the Application	Name of Individual(s) to contact for additional information for the application or clarification are provided • Contact information for the named individual(s) provided – Telephone numbers (cell & office), email address(es) • A completed Delegation of Authority Form for each individual who is not a member of management but who is authorized to act on behalf of the applicant/licensee was provided.	[ ] [ ] [ ]

Item 5: Materials to Be Possessed

Yes	No	Radionuclide	Form or Mfg/Model No.	Quantity	Purpose of Use	Specify Other Uses Not Listed on SSD Registration Certificate
		Radioactive Materials with Atomic No. 1-83	Any	____ mCi per nuclide, _____ total possession, except as noted:	R313-22-72 and R313-19-41	Applicant provided proposed use if outside of use approved on SSD
		Molybdenum-99	Any	____ Ci	R313-22-72 and R313-19-41	Applicant provided proposed use if outside of use approved on SSD
		Technetium-99m	Any	____Ci	R313-22-72 and R313-19-41	Applicant provided proposed use if outside of use approved on SSD
		Iodine-131	Any	____ mCi	R313-22-72 and R313-19-41	Applicant provided proposed use if outside of use approved on SSD
		Fluorine-18	Any	____ mCi	R313-22-72 and R313-19-41	Applicant provided proposed use if outside of use approved on SSD
		Iodine-123	Any	____ mCi	R313-22-72 and R313-19-41	Applicant provided proposed use if outside of use approved on SSD
		Xenon-133	Any	____Ci	R313-22-72 and R313-19-41	Applicant provided proposed use if outside of use approved on SSD
		Any radioactive Material in a Brachytherapy Source, as listed in 10 CFR 35.400	Sealed Sources	____ mCi	R313-22-74 and R313-19-41	Applicant provided proposed use if outside of use approved on SSD
		Any radioactive Material in a sealed source for diagnosis, as listed in 10 CFR 35.500	Sealed Sources	____Ci per source and Ci total	R313-22-74 and R313-19-41	Applicant provided proposed use if outside of use approved on SSD

*I*tem 5: Materials to Be Possessed *(Continued)*

Yes	No	Radionuclide	Form or Mfg/Model No.	Quantity	Purpose of Use	Specify Other Uses Not Listed on SSD Registration Certificate
		Any radioactive Material or a radiation source approved for medical use that is not specifically addressed in subparts D through H of 10 CFR Part 35, as listed in 10 CFR 35.1000		____mCi	Applicant provided proposed use	Applicant provided proposed use if outside of use approved on SSD
		Any radioactive material listed in R313-21-22(9)(a)	Prepackaged units for in vitro diagnostic tests	____mCi	R313-21-22(9)	Applicant provided proposed use if outside of use approved on SSD
		Any material authorized under 10 CFR 35.65	Sealed Sources	____mCi	Calibration and checking of the licensee's instruments and R313-22-74 and R313-19-41	Applicant provided proposed use if outside of use approved on SSD
		DU	Metal	____ kg	Shielding for molybdenum-99/technetium-99m generators	Applicant provided proposed use if outside of use approved on SSD
		Cesium-137	Sealed sources in compatible device as specified in SSD registration sheet	____Ci per source and ____ Ci total	Instrument calibration	Applicant provided proposed use if outside of use approved on SSD
		Other (specify)	Chemical/ Physical Form specify)	____ max per dose/ source/ other and _____total	Applicant provided proposed use	Applicant provided proposed use if outside of use approved on SSD

NOTE:

Item 5: Materials to Be Possessed (Continued)	
For unsealed materials:	
• The applicant identified each radionuclide (element name and mass number) that will be used, the form, and the maximum requested possession limit, or provide the requested information using the checklist above. **AND** • For potentially volatile materials (e.g., iodine-123, iodine-131), the applicant specified whether the materials will be manipulated at the commercial radiopharmacy and if so, the applicant specified where manipulation occurs (i.e., a hood or a hot cell).	[ ] [ ]
For sealed sources and discrete sources of radium (Ra)-226: (1) The applicant identified each radionuclide (element name and mass number) that will be used in each source, the activity per source, and the maximum requested (total) possession limit; (2) The applicant provided the manufacturer's or distributor's name and model number for each sealed source and device and discrete source of Ra-226 requested; (3) The applicant confirmed that each sealed source, device, source/device combination, and discrete source of Ra-226 is registered as an approved sealed source, device, or discrete source by the NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate. The applicant provided the SSD registration certificate number, if available; -- For each sealed source, device, and source and device combination that is not registered, the applicant provided the applicable information, as described in R313-22-32(6) and 10 CFR 32.210; (4) The applicant confirmed that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by the NRC or by an Agreement State; **and** (5) If the above information cannot be provided for the discrete source of Ra-226, the applicant described the discrete source;	 [ ] [ ] [ ] [ ] [ ]
For depleted uranium, the applicant specified the total amount (in kilograms)	[ ]
The applicant provided an emergency plan, if required by R313-22-32(8) and R313-22-90	[ ]
5.2 Financial Assurance and Recordkeeping for Decommissioning No response is needed from most applicants. If a decommissioning funding plan or financial assurance is required, submit the documentation required under R313-22-35 and R313-19-34, as appropriate.	[ ]

Item 6: Purpose of Use of Licensed Material

Item Number and Title	Suggested Response	Yes	Description Attached
6.1 Distribution and Redistribution of Sealed and Unsealed Materials	For all transferred, distributed, and redistributed sealed and unsealed materials, the applicant has:		
	• Provided a commitment that they have developed and will implement and maintain written procedures to meet the license verification requirements specified in accordance with R313-19-41(4).	❒	
	AND		
	• Described procedures to ensure that sealed and unsealed materials are securely and safely provided to mobile medical licensees if they are transferred, distributed, or redistributed to a mobile medical licensee's mobile van or coach, where there is no permanent structure for material storage. For example, the applicant's procedures must ensure that delivery directly to the van or coach will only occur if the van or coach is occupied by mobile medical licensee personnel at the time of delivery.		❒
	AND		
	The applicant provided the following, as applicable:		
	For radiopharmaceuticals:		
	The applicant confirmed that radiopharmaceuticals will be prepared under the supervision of an Authorized Nuclear Pharmacist (ANP) or will be obtained from a supplier authorized pursuant to R313-22-75(9), or under equivalent Agreement State requirements.	❒	
	The applicant described all licensed material to be distributed or redistributed.		❒

Item 6: Purpose of Use of Licensed Materials *(Continued)*

Item Number and Title	Suggested Response	Yes	Description Attached
	For generators:		
	The applicant confirmed that the generators will be obtained from a manufacturer licensed pursuant to R313-22-75(9), or under equivalent Agreement State requirements.	❒	
	The applicant confirmed that unused generators will be redistributed without opening or altering the manufacturer's packaging.	❒	
	For redistribution of used generators:		
	The applicant described 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.		❒
	The applicant confirmed that the manufacturer's packaging and labeling will not be altered.	❒	
	The applicant confirmed that the generator will not be distributed beyond the expiration date shown on the generator label.	❒	
	The applicant confirmed 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.	❒	
	The applicant confirmed that only generators used in accordance with the manufacturer's instructions will be redistributed.	❒	

Item 6: Purpose of Use of Licensed Materials (Continued)

Item Number and Title	Suggested Response	Yes	Description Attached
	For redistribution of sealed sources for brachytherapy or diagnosis:		
	The applicant confirmed 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 R313-22-75(10) or under equivalent NRC or Agreement State requirements.	❒	
	The applicant confirmed 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:		
	The applicant confirmed that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to R313-22-75(10), or under equivalent Agreement State requirements, to initially distribute such sources.	❒	
	The applicant confirmed 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.	❒	

Item 6: Purpose of Use of Licensed Materials (Continued)

Item Number and Title	Suggested Response	Yes	Description Attached
	For redistribution of prepackaged units for *in vitro* tests:		
	• The applicant confirmed that the prepackaged units for *in vitro* tests to be redistributed will be obtained from a manufacturer authorized to distribute the prepackaged units for *in vitro* tests in accordance with a specific license issued pursuant to R313-22-75(7) or under an equivalent license of an Agreement State.	❒	
	For redistribution of prepackaged units for in vitro tests to general licensees:		
	• The applicant confirmed that the manufacturer's packaging and labeling of the prepackaged units for *in vitro* tests will not be altered in any way.	❒	
	• The applicant confirmed that each redistributed prepackaged unit for *in vitro* tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.	❒	
	For redistribution of prepackaged units for *in vitro* tests to specific licensees:		
	• The applicant confirmed 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, the DWMRC's, or the NRC's regulations that authorize a general license (e.g., R313-22-22(9).	❒	
	• The applicant confirmed that the labeling on redistributed prepackaged units for *in vitro* tests will conform to the requirements of R313-15-901, "Caution signs" and R313-15-904, "Labeling containers."	❒	

Item 6: Purpose of Use of Licensed Materials (Continued)

Item Number and Title	Suggested Response	Yes	Description Attached
	For redistribution of discrete sources of radium-226:		
	• The applicant confirmed that the discrete sources of radium-226 will be obtained by a manufacturer authorized to distribute it.	❒	
	• The applicant confirmed 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 sources.	❒	
6.2 Preparation of Radio-pharmaceuticals	For radiopharmaceutical preparation, The applicant indicated that they expect to perform:		
	❖ compounding of iodine-131 capsules	❒	
	❖ radioiodination	❒	
	❖ chemical synthesis of Positron Emission Tomography (PET) radiopharmaceuticals	❒	
	❖ technetium (Tc)-99m kit preparation	❒	
	❖ other, please specify	❒	
6.3 Sealed Sources for Calibration and Checks and Possession of Discrete Sources of Radium-226 and Depleted Uranium	The applicant has supplied specific information concerning the use of discrete sources of radium-226, sealed sources for reference and calibration, and DU shielding.		❒
6.4 Service Activities	For all services provided and marked yes below, the applicant included the information described in NUREG–1556, Vol. 18, as applicable.		❒
	• The applicant committed to provide customers the following radiation protection services involving licensed material:		❒
	❖ sealed source leak testing	❒	
	❖ instrument calibration	❒	
	❖ other, specified by applicant	❒	❒

Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience

Item Number and Title	Suggested Response	Yes	Description Attached
7. Individual(s) Responsible for Radiation Safety Program and Their Training and Experience 7.1 RSO Name of Proposed RSO provided: _____	• The applicant submitted an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the RSO.	❒	❒
	AND		
	• The applicant provided a copy of the license (NRC or Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, ANP, or AU.	❒	❒
	OR		
	• The applicant provided a description of the training and experience demonstrating that the proposed RSO is qualified by training and experience applicable to commercial nuclear pharmacies.	❒	❒
7.2 Authorized Nuclear Pharmacist(s) Name(s) of Proposed ANP(s) provided: _____ _____ _____ _____ _____	For each proposed ANP: the applicant provided:		
	• Pharmacist's license number and issuing entity;	❒	❒
	AND		
	For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial radiopharmacy that has been authorized to identify ANPs [R313- 22-75(9)(b)(ii)(A)], the applicant provided:		
	• The previous license number (if issued by the DWMRC) or a copy of the license (if issued by the NRC or an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by a DWMRC, an NRC or Agreement State broad scope licensee, or a permit issued by an NRC Master Materials License broad scope permittee on which the individual was named as an ANP or a copy of an authorization as an ANP from a commercial radiopharmacy that has been authorized to identify ANPs. **OR**	❒	❒

Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience *(Continued)*

Item Number and Title	Suggested Response	Yes	Description Attached
	For an individual qualifying under R313-22-75(10)(d): the applicant provided:		
	• Documentation that the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material.	❒	❒
	AND		
	• Documentation that the individual practiced nuclear pharmacy at a Government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC when performing the same uses as those requested.	❒	❒
	OR		
	For an individual qualifying under 10 CFR 35.55(a), the applicant provided :		
	• A copy of the certification(s) of the specialty board whose certification process has been recognized under 10 CFR 35.55(a).	❒	❒
	AND		
	• If applicable, the applicant provided a description of recent related continuing education and experience as required by 10 CFR 35.59.	❒	❒
	OR		
	For an individual qualifying under R313-22-75(9)(b)(ii)(B), the applicant provided:		
	• A description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience.	❒	❒

Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience *(Continued)*

Item Number and Title	Suggested Response	Yes	Description Attached
	AND		
	• Written attestation, signed by a preceptor ANP, that the individual has satisfactorily completed the requirements in 10 CFR 35.55(b)(1) and is able to independently fulfill the radiation safety-related duties as an ANP.	❒	❒
	AND		
	• If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	❒	❒
7.3 Authorized User(s) Name(s) of Proposed AU(s): _____ _____ _____ _____ _____	For each proposed AU:		
	Types, quantities, and proposed uses of licensed material.	❒	❒
	AND		
	A copy of the license (NRC or Agreement State) on which the individual was specifically named as an AU for the types, quantities, and proposed uses of licensed materials.	❒	❒
	OR		
	A copy of the permit maintained by a licensee of broad scope that identifies the individual as an AU for the types, quantities, and proposed uses of licensed materials.	❒	❒
	OR		
	A description of the training and experience demonstrating that the proposed AU is qualified by training and experience to use the requested licensed materials.	❒	❒

Item 8: Training for Individuals Working in or Frequenting Restricted Areas (Instructions to Occupationally Exposed Workers and Ancillary Personnel)

Item Number and Title	Suggested Response	Yes	Description Attached
8. Training for Individuals Working In or Frequenting Restricted Areas			
8.1 Occupationally Exposed Workers and Ancillary Personnel	The applicant provided a commitment that they have developed and will implement and maintain written procedures for a training program for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training."	❒	
8.2 Training for Personnel Involved in Hazardous Materials Package Preparation and Transport	The applicant submitted a commitment that they have developed and will implement and maintain written records and written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in R313-19-100 [incorporating 49 CFR 172.700, 49 CFR 172.702, and 49 CFR 172.704 by reference], as applicable."	❒	
8.3 Training for Supervised Individuals Preparing Radio-pharmaceuticals	No response from the applicant is necessary. Supervision will be reviewed during inspection.	No response necessary for the application	

Item 9: Facilities and Equipment *(Continued)*

Item Number and Title	Suggested Response	Yes	Description Attached
9. Facilities and Equipment	• The applicant provided a copy of the registration or license from a State Board of Pharmacy as a licensed pharmacy, or provided evidence that the facility is operating as a nuclear pharmacy within a medical institution.	❒	❒
	AND		
	The applicant provided a description of the facilities and equipment at each location where radioactive material will be used, which includes the method and shielding used to physically transfer licensed material (e.g., transfer lines) to the different processes (e.g., chemical synthesis, dispensing).	❒	❒
	AND		
	The applicants diagram(s) also included:		
	• Descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive materials, and the location(s) for radioactive waste storage.	❒	❒
	• Sufficient detail in the diagram to indicate locations of shielding, the shielding thickness, and the materials used for shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety	❒	❒
	• A general description of any ventilation system that is used when handling radionuclides, including representative equipment such as glove boxes or fume hoods	❒	❒

Item 9: Facilities and Equipment (Continued)

Item Number and Title	Suggested Response	Yes	Description Attached
	The applicants diagram(s) also included: • Confirmation that such ventilation systems will be employed for the use or storage of radioactive materials that are likely to become 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 R313-15-301, and are within the constraint for air emissions established under R313-15-101(4).	❒	❒
	For PET Radiopharmacies The applicant provided a copy of the registration or license from a State Board of Pharmacy as a licensed pharmacy or evidence that the facility is operating as a nuclear pharmacy within a federal medical institution.	❒	
	AND		
	The applicant described the facilities and equipment at each location where radioactive material will be used, which included the method and shielding used to physically transfer licensed material (e.g., transfer lines) to the different processes (e.g., chemical synthesis, dispensing).	❒	❒
	AND		
	The applicant provided diagram(s) that included:		
	• Descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive materials and the location(s) for radioactive waste storage.	❒	❒

Item 9: Facilities and Equipment (Continued)

Item Number and Title	Suggested Response	Yes	Description Attached
	The applicant provided diagram(s) that included:		
	• Locations of shielding, the shielding thickness, the materials used for shielding, and the locations of hot cells for positron emitting radionuclides	❒	❒
	• The proximity of radiation sources to unrestricted areas and other items related to radiation safety such as remote handling equipment and area monitors.	❒	❒
	• A general description of any ventilation system that is used when handling radionuclides, including representative equipment, such as glove boxes or fume hoods.	❒	❒
	• Confirmation that such ventilation systems will be employed for the use or storage of radioactive material likely to become airborne	❒	❒
	• Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of R313-15-301, and are within the ALARA constraints for air emissions established under R313-15-101(4).	❒	❒

Item 10: Radiation Safety Program

Item Number and Title	Suggested Response	Yes	Description Attached
10. Radiation Safety Program			
10.1 Audit and Review of Program	No response is required. The licensee's program for auditing its Radiation Safety Program may be reviewed during inspection.	No Response is Necessary with the Application	
10.2 Radiation Monitoring Instruments	• A commitment that the applicant will use calibrated and operable equipment that is capable of detecting the type(s) of radiation being monitored (e.g., gamma, beta, alpha) and energy or energy range of the radiation being measured."		❒
	OR		
	• The applicant provided a description of the calibrated and operable instrumentation that will be used to perform radiation monitoring (e.g., portable or stationary count rate meters, LSCs, well-type scintillation counters, air monitors)		❒
	AND		
	• A commitment that the applicant reserves the right to upgrade our monitoring instrumentation as necessary, as long as the instruments are adequate to measure the type of radiation and energy range of the radiation for which they are used."		❒

Item 10: Radiation Safety Program *(Continued)*

Item Number and Title	Suggested Response	Yes	Description Attached
	AND		
	• If calibration is performed by a person or firm outside the applicant's organization, the applicant specified that the calibration will be performed by a DWMRC, an NRC or Agreement State licensee specifically authorized to perform instrument calibration as a service to other licensees and state the frequency of the calibrations.		❒
	OR		
	• If the calibration is to be performed in-house, the applicant submitted the instrument calibration procedure that will be used and state the frequency of the calibrations. In addition, identify the qualifications of the individuals who will perform the calibrations.		❒
10.3 Material Receipt and Accountability	The applicant has submitted a commitment that they will develop, implement, and maintain written procedures for safely opening packages that meet the requirements in R313-15-906.	❒	
	AND		
	The applicant provided a commitment to conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months.	❒	
	AND		
	The applicant submitted a commitment to develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:	❒	
	• License possession limits are not exceeded.	❒	
	• Licensed radioactive materials in storage are secured from unauthorized access or removal.	❒	

Item 10: Radiation Safety Program (Continued)

Item Number and Title	Suggested Response	Yes	Description Attached
	• Licensed material not in storage is maintained under constant surveillance and control.	❒	
	• Records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material are maintained."	❒	
	AND		
	• If applicable, the applicant provided a commitment that they will comply with the NSTS reporting requirement as described in R313-15-1206	❒	
10.4 Occupational Dose	The applicant provided one of the following:		
	• A commitment that the applicant will maintain, for inspection by the DWMRC, documentation that demonstrates unmonitored individuals are not likely to receive a radiation dose in excess of the limits in R313-15-502.	❒	
	OR		
	• The applicant committed to monitor individuals in accordance with the guidance in the section titled, "Radiation Safety Program–Occupational Dose" in NUREG–1556, Vol. 13, (Current Revision), "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses."	❒	
	OR, IN LIEU OF EITHER OF THE ABOVE		
	• The applicant provided a description of an alternative method for demonstrating compliance with the referenced regulations.		❒

Item 10: Radiation Safety Program (Continued)

Item Number and Title	Suggested Response	Yes	Description Attached
10.5 Public Dose	No response is required from the applicant, but records demonstrating compliance will be examined during the inspection.	No Response Needs to Be Submitted with the Application	
10.6 Safe Use of Radio-nuclides and Emergency Procedures	The applicant has developed and will implement and maintain written procedures for the safe and secure use of radioactive materials that address:		❒
	• Facility and personnel radioactive contamination minimization, detection, and control.	❒	
	• Performing molybdenum-99 breakthrough measurements of each eluate from a molybdenum-99/technetium99m generator.	❒	
	• Reporting under the requirements in R313-19-34(8) if there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in the eluate	❒	
	• Performing breakthrough measurements on each eluate of other generators (e.g., Ge-68/Ga-68 generators)	❒	
	• Using protective clothing and equipment by personnel to support meeting the requirements in R313-15-101	❒	
	• Securing licensed material during use and storage [R313-15-801(1) and R313-15-801(2)]	❒	

Item 10: Radiation Safety Program (Continued)

Item Number and Title	Suggested Response	Yes	Description Attached
	• Conducting Mo-99/Tc-99m generator Mo-99 breakthrough tests and conducting Sr-82/Rb-82 generator breakthrough tests for Sr-82 and Sr-85 contamination in accordance with R313-19-34(8) and 10 CFR 35.204	❒	
	• Posting the operating procedures applicable to commercial radiopharmacies [R313-18-11(1)(c)]	❒	
	AND		
	The applicant has developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, that include the following:		❒
	• Lost, stolen, or missing licensed material.	❒	
	• Exposures to personnel and the public in excess of the DWMRC regulatory limits.	❒	
	• Releases of licensed materials in effluents and the sanitary sewer in excess of the DWMRC regulatory limits.	❒	
	• Excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas.	❒	
	• Radioactive spills and contamination.	❒	
	• Fires, explosions, and other disasters with the potential for the loss of containment of licensed material.	❒	
	• Routine contacts with local fire departments and LLEA to meet the requirements in R313-15-101, R313-1-1201-R313-15-1203, and R313-19-50, R313-37[incorporating 10 CFR 37.45 by reference], R313-19-50, and other requirements, as applicable.	❒	
10.7 Surveys	The applicant commits that they have developed and will implement and maintain written procedures for a survey program including the following:	❒	
	(1) performance of radiation and contamination level surveys in restricted and unrestricted areas; (2) personnel contamination monitoring; (3) action levels; (4) survey frequencies; and (5) maintenance of survey records that meet the requirements in R313-15-501, R313-15-1103, and 10 CFR 30.53, as applicable	❒ ❒ ❒ ❒ ❒	

Item 10: Radiation Safety Program (Continued)

Item Number and Title	Suggested Response	Yes	Description Attached
10.8 Dosage Measurement Systems	The applicant described 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.	❒	❒
	AND		
	For each dosage measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma-, and photon-emitting radioactive drugs, the applicant has developed, and will implement and maintain, a written procedure for the performance of dosage measurement system checks and tests that meet the requirements in R3133-22-75(9)(c).	❒	
	AND		
	The applicant included a sample calculation for determining low-energy photon-, beta-, and alpha-correction factors for dose calibrators with ionization chambers, if applicable.	❒	❒
	AND		
	The applicant provided calculations that demonstrated the applicant's ability to accurately dispense low-energy photon-, beta-, and alpha-emitting radionuclides for radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) these materials, if applicable.	❒	
	OR		
	If applicable, the applcant included a means for ensuring the accuracy of low-energy photon-, beta-, and alpha-correction factors supplied by the instrument manufacturer or other entity.	❒	❒
	AND		
	The applicant included a means for ensuring the accuracy of low-energy photon-, beta-, and alpha-correction factors supplied by the instrument manufacturer or other entity, if applicable.	❒	

Item 10: Radiation Safety Program (Continued)

Item Number and Title	Suggested Response	Yes	Description Attached
10.9 Transportation	No response is required. The licensee's program for transportation of radioactive materials will be reviewed during inspection.	No Response Needs to Be Submitted with the Application	
10.10 Minimization of Contamination	The applicant does not need to provide a response to this item under the following condition: The DWMRC will consider that the criteria have been met if the applicant's responses meet the criteria for the following sections of NUREG-1556, Volume 13, (Current Revision) "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses" :	**No Response Needs to Be Submitted with the Application if following criteria have been met:**	
	• Facilities and Equipment	❒	
	• Radiation Safety Program-Safe Use of Radionuclides and Emergency Procedures	❒	
	• Radiation Safety Program-Surveys	❒	
	• Radiation Safety Program-Leak Tests	❒	
	• Waste Management	❒	
10.11 Radioactive Drug Labeling for Distribution	The applicant described all labels, including the colors used on the labels accompanying the products and described where each label is placed (e.g., on the "transport radiation shield" or the container used to hold the radioactive drug).	❒	❒
	AND		
	The applicant provided a commitment to affix required labels to all "transport radiation shields" and each container used to hold the radioactive drugs.	❒	

Item 10: Radiation Safety Program (Continued)

Item Number and Title	Suggested Response	Yes	Description Attached
10.12 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), the applicant has provided the following:	❒	
	• 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.	❒	
	• An indication of 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.	❒	
10.13 Leak Tests	The applicant has provided one of the following commitments:	❒	
	• The applicant has committed that leak test sample collection and analysis will be performed by an organization authorized by the DWMRC, the NRC or an Agreement State to provide leak testing services to other licensees. The commitment allows leak tests to be collected by the applicant using a leak test kit and the supplier's instructions. The commitment stated that each leak test kit be supplied by an organization authorized by the DWMRC, the NRC or an Agreement State to provide leak testing services.	❒	
	OR		
	• The applicant has provided a commitment that leak test sample collection and analysis will be done by the applicant. The applicant has also provided the information requested in Appendix H of the guidance document to support the request to perform leak test sample collection and sample analysis and either made a commitment to follow the model procedures in Appendix H or has submitted alternate procedures as stated in the guidance.	❒	

Item 10 & 11: Radiation Safety Program (Continued) & Waste Management

Item Number and Title	Suggested Response	Yes	Description Attached
10.14 Security Program for Category 1 and Category 2 Materials	No response is required from an applicant or licensee. Compliance with access authorization and security program requirements may be reviewed during NRC inspections.	No Response is necessary for the application	
11. Waste Management (Commercial Radio-pharmacy-Generated Radioactive Wastes)	The applicant has developed, and will implement and maintain, written procedures for waste management that meets the requirements in R313-12-51, R313-15-904(2), R313-15-1001, R313-15-1003, R313-15-1004, R313-15-1005, R313-15-1006, R313-15-1007, R313-15-1008, and R313-15-1108, as applicable.	❒	❒
	AND		
	If needed, the applicant requested authorization for extended interim storage of waste (For example Lu-177m). The applicant used the references listed at the end of Section 8.11 of the Guidance Document for guidance and submited the required information with the application.	❒	❒
11.1 Returned Wastes from Customers	The applicant has developed, and will implement and maintain, written procedures for customer return of commercial radiopharmacy-supplied syringes and vials and their contents, to specify that:	❒	
	• Only commercial radiopharmacy-supplied syringes and vials and their contents may be returned to the commercial radiopharmacy.	❒	
	• Instructions will be provided to commercial radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the commercial radiopharmacy.	❒	
	• Instructions will be provided to commercial radiopharmacy staff for the pick-up, receipt, and disposal of the returned radioactive waste to ensure compliance with R313-15-1001(1), R313-22-33, and R313-19-100(5), as applicable.	❒	