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.

Additional Documents You May Need to Have for Your Application Submission.

There are some additional documents and forms that may aid you in completing your application, these are as follows:

To document the training and experience of individuals applying to be Authorized Users, Authorized Medical Physicts, Authorized Nuclear Pharmacists, Radiation Safety Officers, and Associate Radiation Safety Officers under certain conditions an authorized preceptor must document that the individual obtained certain training or supervised clinical experience under their supervision and that the individual can perform the duties and supervise the responsibilities for the position that they will assume. Preceptor Forms may be found on the DWMRC website on the Forms page under the DWMRC-02A Series heading. Be certain to use the most recent version of the form because the qualifications for the positions change over time. More than one signed preceptor form may be necessary to document the required training and experience. The webpage for the DWMRC Forms is:

https://deq.utah.gov/waste-management-and-radiation-control/forms-division-of-waste-management-and-radiation-control

Choose the form from the series that is appropriate for the position being requested. Additionally, the DWMRC will accept the NRC's Form 313A Series or all of the information presented in a different format. If the information is presented in a different format, the preceptor's must provide a certification/signature, their name, and their licensee's name and number. The certifications/signatures must document and provide the same certifications and verifications that are found on the preceptor statements if the information is documented using a different format. A different format does not negate the need for the preceptor certifications or signatures.

In addition, there are constant changes to devices and/or radionuclides that are used for human medical use. The NRC cannot conduct rule-making activities quickly enough to address the apparent safety issues and needs associated with the safe use of these devices and radionuclides. Therefore, if additional safety issues must be addressed, the devices/ radionuclides are regulated under 10 CFR 35.1000. The NRC writes special guidance documents to address these devices/radionuclides. The guidance documents are found on a table found under emerging technologies on the NRC webpage:

https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html.

The guidance documents may also be found on the DWMRC's Radioactive Materials Regulatory Program webpage:

https://deq.utah.gov/waste-management-and-radiation-control/radioactive-materials-regulatory-program

by scrolling down the page until you find the bulleted list containing the license guidance documents. The emerging technology guidance documents are listed under the link to the guidance for "Human Medical Use."

The applicant must provide the information requested in the applicable Emerging Technology guidance document(s) associated with those uses for which they are requesting authorization.

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	• <u>All</u> "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 • <u>Contact information for the named individual(s) provided –</u> 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.	[ ] [ ] [ ]

Items 5 and 6: Radioactive Material and Use

"Sensitive security-related information that is included in application is marked “Sensitive Security-Related Information—Protected Under 63G-2-201(3)(b)" ❑ **Yes** ❑ **No**

Radionuclide	Form or Mfr/Mod No.	Max Qty	Purpose of Use
❒Any radioctive material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
❒Any radioactive material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
❒Any radioactive material permitted by 10 CFR 35.300 (Note: Only use this request if requesting to use all radionuclides covered by 10 CFR 35.300; otherwise, request radionuclide to limit use).	Any	_____ millicuries (mCi)	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300. ❒inpatient (applicant has provided facility diagram of patient room(s)) [Note: If patient(s) are releasable under 10 CFR 35.75 no additional information is necessary]
❒Iodine-131 permitted by 10 CFR 35.300	Any	___mCi	Oral administration of sodium iodide iodine-131. ❒inpatient [applicant attached facility diagram of patient room(s)]
	Applicant provided max dose & max total Activities		
❒Samarium-153 permitted by 10 CFR 35.300	Any	___mCi	Parenteral administration of samarium-153 ❒inpatient [applicant attached facility diagram of patient room(s)]
	Applicant provided max dose & max total Activities		
❒Radium-223 permitted by 10 CFR 35.300	Any	___mCi	Parenteral administration of radium-223 ❒inpatient [applicant attached facility diagram of patient room(s)]
	Applicant provided max dose & max total Activities		
❒Lutetium-177 permitted by 10 CFR 35.300	Any	___mCi	Parenteral administration of lutetium-177 ❒inpatient [applicant attached facility diagram of patient room(s)]
	Applicant provided max dose & max total Activities Applicant also included a request to hold Lu-177 for Decay in Storage in accordance with 10 CFR 35.92 as modified by R313-32 to allow for the presence of Lu-177m contamination if necessary (See NRC memo 1 Jun 2018)		

Items 5 and 6: Radioactive Material and Use (Continued)

Sensitive security-related information that is included in application is marked "Sensitive Security-Related Information—Protected Under 63G-2-201(3)(b) Yes No

Radionuclide	Form or Mfr/Mod No.	Max Qty	Purpose of Use
❒Other radioactive material permitted by 10 CFR 35.300 _____	Any Applicant listed radonuclide(s) and provided max dose and max total Activity	___mCi	Applicant stated proposed use & ❒inpatient (facility diagram of patient room(s) attached)
❒Iodine-125 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No._____)	___mCi Max Act. per source and max Total Act.	Any manual brachytherapy procedure permitted by 10 CFR 35.400.
❒Palladium-103 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	___mCi Max Act. per source and max Total Act.	Any manual brachytherapy procedure permitted by 10 CFR 35.400.
❒Iridium-192 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	___mCi Max Act. per source and max Total Act.	Any manual brachytherapy procedure permitted by 10 CFR 35.400. If inpatient applicant attach facility diagram of patient room(s)
❒Cesium-131 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	___mCi Max Act. per source and max Total Act.	Any manual brachytherapy procedure permitted by 10 CFR 35.400.
❒Cesium-137 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	___mCi Max Act. per source and max Total Act.	Any manual brachytherapy procedure permitted by 10 CFR 35.400. If inpatient applicant attach facility diagram of patient room(s)
❒Strontium-90 permitted by 10 CFR 35.400	Sealed source (Manufacturer _____, Model No._____)	___mCi Max Act. per source and max Total Act.	Strontium-90 for ophthalmic radiotherapy permitted by 10 CFR 35.400.
❒ Other radioactive material permitted by 10 CFR 35.400 _____ (please specify)	Sealed source (Manufacturer _____, Model No. _____)	____mCi Max Act. per source and max Total Act.	_____(specify authorized use) If inpatient applicant attach facility diagram of patient room(s)

Items 5 and 6: Radioactive Material and Use (Continued)

Sensitive security-related information that is included in application is marked "Sensitive Security-Related Information—Protected Under 63G-2-201(3)(b) ❑ **Yes** ❑ **No**

Radionuclide	Form or Mfr/Mod No.	Max Qty	Purpose of Use
❒Iodine-125 permitted by 10 CFR 35.500	Sealed sources (Manufacturer _____, Model No. _____) Device (Manufacturer _____, Model No. _____)	___mCi per source and ___curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to R313-22-32(6).
❒Cesium-137 permitted by 10 CFR 35.500	Sealed sources (Manufacturer _____, Model No. _____) Device (Manufacturer _____, Model No. _____)	___curies per source and ___curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to R313-22-32(6).
❒Gadolinium-153 permitted by 10 CFR 35.500	Sealed sources (Manufacturer _____, Model No. _____) Device (Manufacturer _____, Model No. _____)	___curies per source and ___curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to R313-22-32(6). .
❒ Other radioactive material permitted by _____ (please specify) (include transmission sources bundled and exceeding single source limits in 10 CFR 35.65)	Sealed sources (Manufacturer _____, Model No. _____) Device (Manufacturer _____, Model No. _____)	___curies per source and ___curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to R313-22-32(6).

Items 5 and 6: Radioactive Material and Use (Continued)

Sensitive security-related information that is included in application is marked "Sensitive Security-Related Information—Protected Under 63G-2-201(3)(b)" ❑ **Yes** ❑ **No**

Radionuclide	Form or Mfr/Mod No.	Max Qty	Purpose of Use
❒Iridium-192 permitted by 10 CFR 35.600	Sealed sources (Manufacturer _____, Model No. _____)	___curies per source and ___curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____, Model No. _____ remote afterloader unit. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.
Note: If requesting an individual source activity of greater than 10 curies, the applicant must either verify the device is allowed to have a higher activity or commit to installing after decay.			
❒Cobalt-60 permitted by 10 CFR 35.600 (teletherapy)	Sealed sources (Manufacturer _____, Model No._____)	___curies per source and ___curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____, Model No. _____ teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.
❒Cobalt-60 permitted by 10 CFR 35.600 (gamma stereotactic radiosurgery)	Sealed sources (Manufacturer _____, Model No. _____)	___curies per source and ___curies total	For medical use permitted by 10 CFR 35.600, in a Manufacturer _____, Model No. _____ gamma stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the sources in the gamma stereotactic radiosurgery device.
❒Any radioactive material listed under R313-21-22(9) when activity exceeds the quantity listed in R313-21-22(9) .	Prepackaged kits	___mCi	*In vitro* studies.

Items 5 and 6: Radioactive Material and Use (Continued)

Sensitive security-related information that is included in application is marked "Sensitive Security-Related Information—Protected Under 63G-2-201(3)(b)" ❑ **Yes** ❑ **No**

Radionuclide	Form or Mfr/Mod No.	Max Qty	Purpose of Use
❒Depleted uranium	Metal	___kilograms	Shielding in _____.
❒Any radionuclide in excess of 30 mCi for use in calibration, transmission, and reference sources. List radionuclide: _____	Sealed source (Manufacturer _____, Model No. _____)	___mCi	For use in a Manufacturer _____, Model No. _____ for calibrations and checking of licensee's survey instruments.
❒Americium-241	Sealed source (Manufacturer _____, Model No. _____)	___mCi	For use as an anatomical marker.
❒Radioactive material permitted by 10 CFR 35.1000 _____(please specify)	_____ (please specify form or manufacturer/model no. if sealed source	____mCi	_____ (please specify purpose of use. Refer to 10 CFR 35.1000 emerging technology licensing guidance documents.
❒Other	Form or Manufacturer/ Model No. _____	___mCi	Purpose of use _____.

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal

Item 7: Radiation Safety Officer (RSO) or Associate Radiation Safety Officer (ARSO)

❒ Name of the proposed RSO is provided (RSO is required for all licenses)

❒ Name(s) of proposed ARSO(s), if desired (A licensee may choose to identify one or more individuals as ARSOs to support the RSO) is/are provided:

- for each proposed ARSO, the types of use of radioactive material for which the individual may be assigned duties and tasks under the licensee's program in oversight of the radiation protection program are identified (examples below):

  ❒ 10 CFR 35.100 ❒ 10 CFR 35.200 ❒ 10 CFR 35.300 ❒ 10 CFR 35.400
  ❒ 10 CFR 35.500 ❒ 10 CFR 35.600 (teletherapy) ❒ 10 CFR 35.600 (HDR)
  ❒ 10 CFR 35.600 (gamma stereotactic radiosurgery)
  ❒ 10 CFR 35.1000- (_____)

❒ **If the proposed RSO/ARSO is currently or was previously identified (within past 7 years) as an RSO or ARSO on a DWMRC, an NRC, or Agreement State license or Master Material License permit for the same materials and use:** The applicant provided an Radioactive Materials License #_____ or a copy of the full radioactive materials license (if issued by the NRC or an Agreement State) or a copy of the full permit issued by an NRC master materials licensee on which the individual was named as the RSO or ARSO[1].

AND

❒ If applicable (over 7 years prior), the applicant attached documentation of recent, related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the proposed RSO/ARSO is a current RSO or ARSO seeking authorization to be recognized as a RSO or ARSO for additional medical uses,** the applicant attached documentation of completion of the supervised training and experience specified in 10 CFR 35.50(d) for any new materials or new medical uses requested.

AND

❒ If not qualified under 10 CFR 35.57(a)(1) or board certified by an NRC-recognized board,the applicant attached a written attestation as prescribed in 10 CFR 35.50(b)(2), signed by a preceptor RSO or ARSO, that the individual has successfully completed the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and is able to independently fulfill the radiation safety-related duties as an RSO or as an ARSO for a medical use licensee. Provide documentation of the board certification, if applicable. NOTE: If Board certification is used for the qualification, a copy of the Board Certificate MUST be submitted. Certain information is only available on the certificate.

[1]Some Agreement States list ARSOs on licenses prior to implementing equivalent Agreement State requirements to 10 CFR 35.50 effective January 14, 2019. Until all the Agreement States implement the rule which went into effect on January 14, 2019, the licensee will have to document that a proposed ARSO listed on an Agreement State license meets the NRC requirements under a different pathway.

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

OR

❒ **If the proposed RSO is qualified under 10 CFR 35.57(a)(4) because the individual was an RSO for only accelerator-produced materials or discrete sources of radium 226 or both**, the applicant attached documentation that the proposed RSO was the RSO for only medical uses of accelerator-produced radioactive materials, discrete sources of Ra-226, or both, 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 (Note accelerator produced radioactive materials and discrete sources of radium were regulated in Agreement States before the above dates)

AND

❒ The applicant attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the Proposed RSO/ARSO is Board certified by an NRC-recognized board under 10 CFR 35.50(a) [See NRC Specialty Board Website: https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html to verify certificate].** The applicant attached a copy of board certification issued by a specialty board whose certification process has been recognized[2] by the NRC or an Agreement State under 10 CFR 35.50(a).

AND

❒ The applicant has attached documentation of supervised training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the applicant seeks approval of the individual as the RSO or ARSO.

AND

❒ If applicable, the applicant provided documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is board certified as a medical physicist by an NRC-recognized board qualifying under 10 CFR 35.50(c)(1) [see 10 CFR 35.51(a)],** the applicant attached a copy of the board certification issued by a specialty board whose certification process has been recognized by the NRC or an Agreement State under 10 CFR 35.51(a) and documentation of the experience specified in 10 CFR 35.50(c)(1) demonstrating that the proposed RSO or ARSO is qualified by experience with the radiation safety aspects of similar types of use of radioactive material for which the applicant seeks approval of the individual as the RSO or ARSO.

[2]Specialty board certifications recognized by the NRC are posted on the Medical Uses Licensee Toolkit Web page. Board certificates should contain prescribed language and shows issuance within specified dates as described on the Web page [https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html].

Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

AND

❒ The applicant attached documentation of supervised training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the applicant seeks approval of the individual as the RSO or ARSO.

AND

❒ If applicable, the applicant has attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is Board certified by an NRC-recognized board qualifying under 10 CFR 35.57(a)(2),** the applicant has attached a copy of the board certification issued on or before October 24, 2005, by a specialty board whose certification is listed in 10 CFR 35.57(a)(2).

AND

❒ The applicant attached documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005.

AND

❒ The attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is an AU, ANP, or AMP qualifying under 10 CFR 35.50(c)(2)** the applicant attached a copy of the NRC or Agreement State license, permit issued by a NRC master material licensee, permit issued by a NRC or Agreement State licensee of broad scope, or permit issued by a NRC master material license permittee of broad scope indicating that the individual is an AU, AMP, or ANP identified on the license or permit and has experience with radiation safety aspects of similar types of use of radioactive material for which the applicant seeks approval of an individual to serve as RSO or ARSO.

AND

❒ The applicant attached documentation of supervised training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO.

AND

❒ If applicable, the applicant attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

❑ **If the individual is applying simultaneously to be the RSO and AU on a new license under 10 CFR 35.50(c)(3),** the applicant attached the license application that includes documentation of the training and experience of the new AU

AND

❒ The applicant attached documentation of supervised training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO

OR

❒ **If the individual is qualifying by classroom/laboratory training and supervised radiation safety experience under 10 CFR 35.50(b)**, the applicant has attached documentation of the training and experience specified in 10 CFR 35.50(b)(1) using Form DWMRC-02A (RSO) or equivalent documentation demonstrating that the proposed RSO or ARSO is qualified by training and experience applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO.

AND

❒ The applicant attached documentation of supervised training and experience specified in 10 CFR 35.50(d) using Form DWMRC-02A (RSO) or equivalent documentation demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO.

AND

❒ The applicant attached a written attestation, as prescribed in 10 CFR 35.50(b)(2), signed by a preceptor RSO or ARSO, that the individual has satisfactorily completed the required training and experience specified in 10 CFR 35.50(b)(1), as well as the required training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and is able to independently fulfill the radiation safety-related duties as an RSO or ARSO for a medical use license.

AND

❒ If applicable, the applicant attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

AND

❒ **For a proposed RSO who is an outside consultant or contractor, the applicant must address the following**: An outside consultant or contractor must qualify as an RSO in accordance with 10 CFR 35.50 or 10 CFR 35.57 and 10 CFR 35.59 criteria specified above.

AND

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

❒ The applicant has identified other commitments of the consultant-RSO for other DWMRC, NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of onsite time (hours per week or days per quarter, as appropriate for the program).

AND

❒ The applicant has identified an in-house representative who will serve as the point of contact during the RSO's absence.

AND

❒ The applicant described the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.

AND

❒ The applicant has specified the maximum amount of time it will take the consultant-RSO to arrive at the facility in the event of an emergency that requires his/her presence.

Item 7: Authorized Users (AUs)

Authorized User(s) Name(s):

❒ The applicant stated the uses requested for the AU:

❒ The applicant provided medical, podiatry, or dental license number and issuing entity (e.g., state or territory)

❒ **The proposed AU is currently or was previously listed as an AU on an NRC or Agreement State license or permit for the same type of use(s) requested** and the applicant provided a DWMRC/NRC/Agreement License #_____ or a copy of the full 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 permittee of broad scope on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested

AND

❒ If applicable, the applicant attached documentation of recent continuing education and experience as required by 10 CFR 35.59.

OR

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

❒ **The individual is listed as an AU on an NRC or Agreement State license or permit but is seeking an additional authorization under 10 CFR Part 35.** The applicant provided a DWMRC License #_____ 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 permittee of broad scope on which the individual was specifically named as an AU.

AND

❒ The applicant has attached additional documentation of training and experience necessary to demonstrate the AU is qualified for the new medical uses requested:

— to add 10 CFR 35.100 authorization, for an AU qualified under 10 CFR 35.200, no additional documentation is needed.

— to add 10 CFR 35.200 authorization, for an AU qualified under 10 CFR 35.390, the applicant attached documentation of the supervised work experience eluting generator systems as required in 10 CFR 35.290(c)(1)(ii)(G);

— to add an additional authorization under 10 CFR 35.300, for an AU qualified under 10 CFR 35.390, the applicant attached documentation of casework experience for uses listed under 10 CFR 35.390(b)(1)(ii)(G)(*1*), 10 CFR 35.390(b)(1)(ii)(G)(*2*), and/or 10 CFR 35.390(b)(1)(ii)(G)(*3*), as applicable;

— to add an authorization under 10 CFR 35.300 (for uses listed in 10 CFR 35.396), for an AU qualified under 10 CFR 35.490 or 10 CFR 35.690, the applicant attached documentation of the classroom and laboratory training and supervised work experience required in 10 CFR 35.396(b)(1) and (b)(2); or

— to add an additional authorization under 10 CFR 35.600 (for use of remote afterloader units, teletherapy units, and/or gamma stereotactic radiosurgery units), the applicant attached documentation of training needed to meet the requirements in 10 CFR 35.690(c)

AND

❒ The applicant attached a preceptor attestation, if required (e.g., attestation is required for all individuals to meet the requirements in 10 CFR 35.396 and for individuals seeking authorization under the alternate training and experience pathway for 10 CFR 35.390 and 10 CFR 35.690).

AND

❒ If applicable, the applicant attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

❒ **The individual is qualified under 10 CFR 35.57(b)(3) because only accelerator-produced radioactive material was used for medical use.** The applicant attached documentation that the physician, podiatrist, or dentist used only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, for medical uses performed 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 at an earlier date as noticed by the NRC. (Note: Agreement States regulated these materials prior to these dates).

AND

❒ The applicant attached documentation that the physician, podiatrist, or dentist used these materials for the same medical uses requested.

AND

❒ The applicant attached documentation of recent continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the proposed individual was certified before October 24, 2005, by a board listed in 10 CFR 35.57(b)(2)**, the applicant attached a copy of the board certification issued before October 24, 2005, by a specialty board whose certification is listed in 10 CFR 35.57(b)(2).

AND

❒ The applicant attached documentation demonstrating that the individual was using the requested materials for the uses requested on or before October 24, 2005

AND

❒ The applicant attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is qualified under 10 CFR Part 35, Subparts D, E, F, G, and/or H because of a recognized board certification,** the applicant attached a copy of the board certification(s) issued by a specialty board whose certification process has been recognized[3] by the DWMRC, the NRC or an Agreement State under 10 CFR Part 35 Subparts D, E, F, G, or H, as applicable to the use requested.

AND

[3]Specialty board certifications recognized by the NRC are posted on the NRC's Medical Uses Licensee Toolkit Webpage. Board certificates should contain prescribed language and shows issuance within specified dates as described on the Web page.

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

❒ The applicant attached additional documentation of training and experience necessary to demonstrate the AU is qualified for the medical uses requested:

— to add 10 CFR 35.200 authorization with a board certification recognized under 10 CFR 35.390, the applicant attached documentation of the supervised work experience eluting generator systems required in 10 CFR 35.290(c)(1)(ii)(G)

— to add 10 CFR 35.390 authorization with a board certification recognized under 10 CFR 35.390, the applicant attached documentation of the supervised work experience administering dosages of radioactive drugs required in 10 CFR 35.390(b)(1)(ii)(G)(1), 35.390(b)(1)(ii)(G)(2), and/or 35.390(b)(1)(ii)(G)(3) as applicable

— to add 10 CFR 35.396 authorization with a board certification recognized under 10 CFR 35.490 or 10 CFR 35.690, the applicant attached documentation of the classroom and laboratory training and supervised work experience required in 10 CFR 35.396(b)(1) and (2) and a copy of the attestation required in 10 CFR 35.396(b)(3)

— to add 10 CFR 35.600 authorization with a board certification recognized under 10 CFR 35.690, the applicant attached documentation of the training specified in 10 CFR 35.690(c)

AND

❒ If applicable, attach documentation of recent, related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is qualified under 10 CFR Part 35, Subparts D, E, F, G, and/or H by classroom and laboratory training, supervised work experience, and supervised clinical experience,** the applicant has attached documentation of the classroom and laboratory training, supervised work experience, and supervised clinical experience identified in 10 CFR Part 35, Subparts D, E, F, G, or H, demonstrating that the proposed AU is qualified by training and experience for the use(s) requested.

AND

❒ For an individual seeking authorization under 10 CFR Part 35, Subpart G or H, the applicant has attached documentation of the training specified in 10 CFR 35.590(d) or 10 CFR 35.690(c), as applicable, demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought.

AND

❒ The applicant has attached the written attestation, signed by a preceptor physician AU, or if applicable, the residency program director, that the above training and experience have been satisfactorily completed and the individual is able to independently fulfill the radiation safety-related duties as an AU for the requested medical uses.

AND

❒ If applicable, the applicant has attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

❒ **The individual is qualified for medical use of specific emerging technologies under Subpart K, 10 CFR 35.1000,** the applicant attached documentation of training and experience as described for the technology in the applicable guidance found in the applicable guidance for the specified emerging technology.

Item 7: Authorized Nuclear Pharmacist (ANP)

The applicant provided the Proposed Authorized Nuclear Pharmacist(s) Name(s):

❒ The applicant attached documentation demonstrating that the proposed ANP has an active license to practice pharmacy. Include information on the issuing entity (e.g. state or territory)

AND

❒ If the individual currently or previously identified as an ANP on a DWMRC, an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs for the same type of use(s) requested, the applicant provided a DWMRC/NRC/Agreement State License #_____ 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 an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs.

AND

❒ If applicable, the applicant attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual only used accelerator-produced radioactive materials or discrete sources of Ra-226, or both and is qualified under 10 CFR 35.57(a)(4),** the applicant attached documentation that the nuclear pharmacist used only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, in the practice of 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 at an earlier date as noticed by the NRC.

AND

❒ The applicant attached documentation that the nuclear pharmacist used these materials for the same uses requested.

AND

❒ If applicable, the applicant attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

❒ **If the individual is board certified by an NRC-recognized board under 10 CFR 35.55(a)**, the applicant attached a copy of the board certification issued by a specialty board whose certification process has been recognized[4] by the NRC or an Agreement State under 10 CFR 35.55(a).

AND

❒ If applicable, the applicant attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is qualified by classroom/laboratory training and supervised practical experience in nuclear pharmacy under 10 CFR 35.55(b),** the applicant attached a completed Form DWMRC-02A (ANP) or equivalent documentation of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience.

AND

❒ The applicant attached a written attestation, signed by a preceptor ANP, that the above training and experience have been satisfactorily completed and the individual is able to independently fulfill the radiation safety-related duties as an ANP.

AND

❒ If applicable, the applicant has attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is qualified for medical use of specified emerging technologies under Subpart K, 10 CFR 35.1000,** the applicant attached documentation of training and experience as described for the technology in the applicable guidance for the specified emerging technology.

[4]Specialty board certifications recognized by the NRC are posted on the NRC's Medical Uses Licensee Toolkit Web page. Board certificates should contain prescribed language and shows issuance within specified dates as described on the Web page. https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 7: Authorized Medical Physicist (AMP)

The applicant provided the Authorized Medical Physicist(s) Name(s):

❒ **If the individual is currently or was previously listed as an AMP on an NRC or Agreement State license or permit for the same type of use(s) requested, the applicant provided** a DWMRC/NRC/Agreement State License #_____ 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 an NRC or Agreement State broad scope licensee, or a permit issued by an NRC Master Materials License permittee of broad scope on which the individual was specifically named an AMP for the uses requested.

AND

❒ If applicable, the applicant attached documentation of recent, related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is an AMP listed on a license or permit but seeking authorization for a new medical use under 10 CFR 35.51(c), the applicant provided** a DWMRC/ NRC/Agreement State License #_____ 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 an NRC or Agreement State broad scope licensee, or a permit issued by an NRC Master Materials License permittee of broad scope on which the individual was specifically named an AMP for the uses requested.

AND

❒ The applicant attached documentation of the additional training and experience specified in 10 CFR 35.51(c) demonstrating that the individual is qualified by training in the new types of use for which the applicant seeks approval of the individual as the AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.

AND

❒ If not board certified by a board recognized under 10 CFR 35.51(a) or listed in 10 CFR 35.57(a)(3), the applicant attached a written attestation, signed by a preceptor AMP, that the required training and experience in 10 CFR 35.51(c) has been satisfactorily completed and that the individual is able to independently fulfill the radiation safety-related duties as an AMP for the type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

OR

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

❒ **If the individual is qualified under 10 CFR 35.57(a)(4) because the individual was an AMP for only accelerator-produced materials or discrete sources of Ra-226 or both,** the applicant attached documentation that the AMP used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, for the medical uses 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 at an earlier date as noticed by the NRC.

AND

❒ The applicant attached documentation that the medical physicist used these materials for the same medical uses as requested.

AND

❒ If applicable, the applicant has attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is qualified by board certification under 10 CFR 35.51(a),** the applicant has attached a copy of the board certification issued by a specialty board whose certification process has been recognized[5] by the NRC or an Agreement State under 10 CFR 35.51(a).

AND

❒ The applicant attached documentation of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which the applicant seeks approval of the individual as the AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.

AND

❒ If applicable, the applicant attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is qualified by board certification under 10 CFR 35.57(a)(3),** the applicant attached a copy of the board certification issued by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, X-ray and radium physics, or radiological physics, or by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005 for the same medical uses requested.

AND

[5]Specialty board certifications recognized by the NRC are posted on the NRC's Medical Uses Licensee Toolkit Web page. Board certificates should contain prescribed language and shows issuance within specified dates as described on the Web page. https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

❒ If applicable, the applicant has attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is qualified because of degree, medical physics training, and medical physics work experience under 10 CFR 35.51(b),** the applicant has attached documentation of the training and experience specified in 10 CFR 35.51(b)(1), demonstrating that the proposed AMP is qualified by training and experience for the use(s) requested.

AND

❒ The applicant has attached documentation of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which the licensee seeks approval of an individual as the AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.

AND

❒ The applicant has attached a written attestation, signed by a preceptor AMP, that the proposed AMP has satisfactorily completed the training and experience required in 10 CFR 35.51(b)(1), as well as the training in 10 CFR 35.51(c) for the types of use specified, and that the individual is able to independently fulfill the radiation safety-related duties as an AMP for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

AND

❒ If applicable, the applicant has attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is qualified for medical use of specified emerging technologies under Subpart K, 10 CFR 35.1000,** the applicant has attached documentation of training and experience as described for the technology in the applicable emerging technology guidance document for the emerging technology being requested.

Item 7: Ophthalmic physicist

The applicant has provided the Proposed Ophthalmic Physicist(s) Name(s):

❒ **If the individual is currently or was previously listed as an authorized ophthalmic physicist on a DWMRC, an NRC or Agreement State license or permit, the applicant has provided** a DWMRC/NRC/Agreement State License #_____ 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 permittee of broad scope on which the individual was specifically named an authorized ophthalmic physicist.

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

AND

❒ If applicable, the applicant has attached documentation of recent, related continuing education and experience as required by 10 CFR 35.59.

OR

❒ **If the individual is qualified to be an ophthalmic physicist based on education and supervised work experience under 10 CFR 35.433,** the applicant has attached documentation of the training and experience specified in 10 CFR 35.433, demonstrating that the proposed ophthalmic physicist is qualified by training and experience for ophthalmic treatments using Strontium-90 sources.

AND

❒ If applicable, the applicant has attached documentation of recent related continuing education and experience as required by 10 CFR 35.59.

Item 7: Individuals Authorized for Non-Medical Use:

Name of the proposed nonmedical use AU:

❒ The applicant has attached a description of types, quantities, and proposed nonmedical uses for each individual requested.

AND

❒ The applicant has attached documentation of individual's education and radiation safety training and experience with the types of materials and uses requested. This may include the DWMRC license number or a copy of the NRC or the Agreement State license, permit issued by an NRC master materials licensee, permit issued by an NRC or Agreement State broad scope licensee, or permit issued by an NRC Master Materials License broad scope permittee on which the individual was specifically named.

AND

❒ The applicant has attach detailed radiation training and experience applicable to the use requested.

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 8: Training for Individuals Working In or Frequenting Restricted Areas

The applicant has provided the following:

❒ The applicant has provided a commitment to develop, implement, and maintain written procedures for a program for training required under 10 CFR 19.12 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."

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 9: Facility Diagram

❒ The applicant provided the following:

- Facility diagrams. The applicant's drawings are to scale, and the scale used is indicated. The direction of north is indicated on the drawing.
- Location, room numbers, and principal use of each room, including patient treatment rooms or areas where radioactive material is prepared, used, and stored are indicated on the drawing or described.
- Principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms and Positron Emission Tomography (PET) are provided or described.
- Doors are indicated, and the applicant specified which doors are access controlled (i.e., locked).
- Shielding calculations for PET facilities, in-patient rooms for 10 CFR 35.300 and 10 CFR 35.400 use, High Dose-Rate/Pulsed Dose Rate & Low Dose Rate Remote Afterloaders, Teletherapy, and Gamma stereotactic radiosurgery (GSR) are provided. The applicant Included information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations have included the workload assumptions used by the applicant.
- For PET, radiopharmaceutical, and sealed-source therapies, a description of surrounding areas, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003 were provided, For calculations of the maximum exposure in any given hour, an occupancy factor was not used.
- For teletherapy facilities, applicants have provided the directions of primary beam use and, in the case of an isocentric unit, the plane of beam rotation is identified in the shielding calculations.
- For 10 CFR 35.1000 materials (e.g., Perfexion, View-Ray), the applicant provided information described in the emerging technologies guidance for the appropriate device.

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 9: Radiation Monitoring Instruments

The applicant provided the following:

❒ The applicant committed that radiation monitoring instruments will be calibrated by a vendor who is licensed by the DWMRC, the NRC or an Agreement State to perform instrument calibrations."

AND/OR

❒ A commitment that the applicant has developed and will implement and maintain written radiation survey meter calibration procedures in accordance with the requirements in R313-15-501 and that meet the requirements of 10 CFR 35.61."

AND

❒ A description of the instrumentation (e.g., gamma counter, solid-state detector, portable or stationary count-rate meter, portable or stationary dose-rate or exposure-rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys is attached.

Item 9: Dose Calibrator and Other Dosage Measuring Equipment

For the administration of alpha, gamma, and beta emitting unsealed radioactive materials, the applicant provided the following:

❒ A commitment that equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

AND

❒ A description of the equipment used to measure the dosages.

AND

❒ For measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, the applicant has identified specialized measurement equipment and the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer's instructions to calibrate the instrument.

Item 9: Sealed Sources in Therapy Unit - Calibration and Use

❒ The applicant provided the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.

❒ The applicant for a medical use under 35.1000 should provide the procedures required by 10 CFR 35.12(b)(2) that are described in the licensing guidance for the applicable 10 CFR35.1000 emerging technology, or explain why the procedure is not provided.

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 9: Other Equipment and Facilities

The applicant has provided the following, if applicable:

- ❒ For PET radionuclide use and radiopharmaceutical therapy programs, the applicant described the additional equipment for these uses, as applicable.
- ❒ For manual brachytherapy facilities, the applicant provided a description of the emergency response equipment.
- ❒ For teletherapy, GSR, and remote afterloader facilities, the applicant provided a description of the following:
  - ❒ Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room
  - ❒ Area radiation monitoring equipment
  - ❒ Viewing and intercom systems (except for low dose-rate units)
  - ❒ Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room
  - ❒ Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons
  - ❒ Emergency response equipment
- ❒ For 10 CFR 35.1000 medical uses, the applicant provided the appropriate descriptions of other equipment and facilities as described in the appropriate emerging technology guidance document.

Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 10: Occupational Dose

The applicant has provided the following:

❒ A commitment that the applicant will maintain, for inspection by the DWMRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in R313-15-502.

OR

❒ A commitment that the applicant will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program–Occupational Dose' in NUREG–1556, Vol. 9, (Current Revision), "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees."

OR

❒ A description of an alternative method for demonstrating compliance with the referenced regulations.

Item 10: Spill/Contamination Procedures

The applicant has provided the following:

❒ A commitment that the applicant has developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with R313-15-101.

Item 10: Emergency Procedures for Therapy Devices Containing Sealed Sources

Provide the following:

❒ Attach procedures required by 10 CFR 35.610.

AND

❒ If appropriate, review 10 CFR 35.1000 medical use licensing guidance on NRC's Medical Uses Licensee Toolkit Web page, and provide safety and emergency procedures requested for the particular 10 CFR 35.1000 medical use.

Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

If requesting that the applicant's own employee(s), who are trained by the manufacturer, be authorized to perform the activities noted in section 8.10.7 of this NUREG, provide the following:

❒ Name of the proposed employee(s) and types of activities requested:

_____

_____

AND

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

❒ Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested.

AND

❒ Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.

AND

❒ Written commitment from the licensee that the trained employee will follow manufacturer procedures.

Item 10: Material Receipt and Accountability

The applicant provided the following:

❒ A commitment that the applicant will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:

- license possession limits are not exceeded
- licensed material in storage is secured from unauthorized access or removal
- 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, a commitment that the applicant will comply with the National Source Tracking System (NSTS) reporting requirement, as described in R313-15-1206.

Item 10: Leak Tests

The applicant provided the following:

For in-house leak testing of sealed sources used pursuant to 10 CFR Part 35:

❒ A commitment that the applicant has developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67.

OR

For in-house leak testing of sealed sources other than those authorized pursuant to 10 CFR Part 35 (e.g., self-shielded irradiators, calibration sources):

❒ A commitment that the applicant will conduct leak tests in-house.

AND

❒ A commitment that the applicant's attached leak test procedures will be followed for leak tests conducted in-house.

AND

❒ The applicant attached leak test procedures.

Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

OR

❒ A commitment that the applicant will implement the model leak test program of the appendix of the appropriate NUREG–1556 volume for the type of use. For instance, if an applicant possesses a self-shielded irradiator, the applicant may state, "We will implement the model leak test program published in Appendix N of NUREG–1556, Volume 5, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses."

OR

❒ If a contractor is used to perform leak testing, a commitment 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; or by using a leak test sample collection kit supplied by an organization licensed by the DWMRC, the NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit."

Item 10: Area Surveys

The applicant has provided the following:

❒ A commitment that the applicant has developed and will implement and maintain written procedures for area surveys in accordance with R313-15-101 that meet the requirements of R313-15-501 and 10 CFR 35.70."

Item 10: Safe Use of Unsealed Licensed Material

The applicant has provided the following:

❒ A commitment that the applicant has developed and will implement and maintain written procedures for safe use of unsealed radioactive material that meet the requirements of R313-15-101 and R313-15-201.

Item 10: Mobile medical service

❒ The applicant has provided the information requested in the guidance in Appendix V of NUREG-1556, Volume 9, (Current Revision) for mobile medical services.

Item 10: Minimization of Contamination

A response is not required under the following condition: The DWMRC will consider that the criteria have been met if the information provided in the applicant's responses satisfies the criteria for the following sections in this NUREG: Sections 8.9, 8.9.1, 8.10, 8.10.5, 8.10.12, and 8.11 on the following topics: facilities and equipment, facility diagram, radiation safety program, spill and contamination procedures, area surveys, and waste management.

Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 11: Waste Management

The applicant has provided the following:

❒ A commitment that the applicant has developed and will implement and maintain written waste disposal procedures for licensed material in accordance with R313-15-301, that also meet the requirements of the applicable section of R313-15-1001 through R313-15-1009, and of 10 CFR 35.92."

AND

❒ Contact the DWMRC for guidance on treatment or disposal of waste by incineration or compaction.

The following table is provided to help applicants determine which procedures must be developed, implemented, and maintained for the type of medical use requested. Several appendices in the guidance document present sample procedures that applicants may use in developing the applicable procedures.

Applicable Appendices Describing Model Procedures						
NUREG-1556, Vol 9 Appendix	**Topic**	**10 CFR 35.100 10 CFR 35.200**	**10 CFR 35.300**	**10 CFR 35.400**	**10 CFR 35.500**	**10 CFR 35.600**
G	Dose Calibrator Calibration	x	x			
H	Remote Afterloader Spot-Checks					x
I	Radiation Safety Officer Duties, Responsibilities, and Delegation	x	x	x	x	x
J	Training Program	x	x	x	x	x
K	General Radiation Monitoring Instrument Specifications and Calibration	x	x	x	x	x
L	Medical Licensee Audit	x	x	x	x	x
M	Occupational Dose Monitoring Program	x	x	x	x	x
N	General Topics for Safe Use of Radionuclides and Model Emergency Procedures	x	x	x		
O	Ordering and Receiving Packages	x	x	x	x	x
P	Safely Opening Packages Containing Radioactive Material	x	x	x	x	x
Q	Leak Tests	x	x	x	x	x
R	Area Surveys	x	x	x	x	x
S	Developing, Maintaining, and Implementing Written Directives		x	x		x
T	Safe Use of Unsealed Licensed Material	x	x			
U	Release of Patients	x	x	x		
V	Mobile Medical Service	x	x	x	x	x
W	Waste Disposal	x	x	x	x	x
X	Recordkeeping	x	x	x	x	x
Y	Reporting Requirements	x	x	x	x	x
Z	Transportation	x	x	x	x	x