



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Cardiology Associates, Inc.
1329 Lusitana Street
Suite 409
Honolulu, HI 96813

Date

12/31/2025

License Number(s)

53-29211-01

Mail Control Number(s)

654870

Licensing and/or Technical Reviewer or Branch

Materials Licensing Branch

This is to acknowledge receipt of your: ☐ Letter and/or ☒ Application Dated: 12/31/2025

The initial processing, which included an administrative review, has been performed.

☐ Amendment ☐ Termination ☐ New License ☒ Renewal

☐ There were no administrative omissions identified during our initial review.

☒ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

☒ The following administrative omissions have been identified:

Submit Appendix C of NUREG-1556, Volume 9, revision 3.

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DRSS/MLB
1600 E. Lamar Boulevard
Arlington, TX 76011-4511

APPENDIX C

**SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED IN
ITEMS 5 THROUGH 11 OF
U.S. NUCLEAR REGULATORY COMMISSION FORM 313**

Table C-1. Items 5 and 6 on NRC Form 313: Radioactive Material and Use This response includes security-related sensitive information that is included in Attachment _____ and marked "Security-Related Information—Withhold Under 10 CFR 2.390" <input type="checkbox"/> Yes <input type="checkbox"/> No			
Radionuclide	Form or Mfr/Mod No.	Max Qty	Purpose of Use
<input type="checkbox"/> Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
<input type="checkbox"/> Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
<input type="checkbox"/> Any byproduct material permitted by 10 CFR 35.300 (Note: Check this box if using all radionuclides covered by 10 CFR 35.300; otherwise, check subsequent boxes if limiting use by radionuclide).	Any	_____ millicuries (mCi)	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300. <input type="checkbox"/> inpatient (facility diagram of patient room(s) attached) <input type="checkbox"/> outpatient (Note: Check the inpatient box if keeping patients in-house who have not been released pursuant to 10 CFR 35.75. If releasable, check outpatient.)
<input type="checkbox"/> Iodine-131 permitted by 10 CFR 35.300	Any	____mCi	Oral administration of sodium iodide iodine-131. <input type="checkbox"/> inpatient (facility diagram of patient room(s) attached) <input type="checkbox"/> outpatient
<input type="checkbox"/> Samarium-153 permitted by 10 CFR 35.300	Any	____mCi	Parenteral administration of samarium-153 <input type="checkbox"/> inpatient (facility diagram of patient room(s) attached) <input type="checkbox"/> outpatient
<input type="checkbox"/> Radium-223 permitted by 10 CFR 35.300	Any	____mCi	Parenteral administration of radium-223 <input type="checkbox"/> inpatient (facility diagram of patient room(s) attached) <input type="checkbox"/> outpatient
<input type="checkbox"/> Lutetium-177 permitted by 10 CFR 35.300	Any	____mCi	Parenteral administration of lutetium-177 <input type="checkbox"/> inpatient (facility diagram of patient room(s) attached) <input type="checkbox"/> outpatient

Table C-1. Items 5 and 6 on NRC Form 313: Radioactive Material and Use (Continued) This response includes security-related sensitive information that is included in Attachment _____ and marked "Security-Related Information—Withhold Under 10 CFR 2.390" <input type="checkbox"/> Yes <input type="checkbox"/> No			
Radionuclide	Form or Mfr/Mod No.	Max Qty	Purpose of Use
<input type="checkbox"/> Other byproduct material permitted by 10 CFR 35.300 _____ (please specify)	Any	____mCi	<input type="checkbox"/> inpatient (facility diagram of patient room(s) attached) <input type="checkbox"/> outpatient
<input type="checkbox"/> Iodine-125 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	____mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400.
<input type="checkbox"/> Palladium-103 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	____mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400.
<input type="checkbox"/> Iridium-192 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	____mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400. <input type="checkbox"/> inpatient (facility diagram of patient room(s) attached)
<input type="checkbox"/> Cesium-131 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	____mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400.
<input type="checkbox"/> Cesium-137 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	____mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400. <input type="checkbox"/> inpatient (facility diagram of patient room(s) attached)
<input type="checkbox"/> Strontium-90 permitted by 10 CFR 35.400	Sealed source (Manufacturer _____, Model No. _____)	____mCi	Strontium-90 for ophthalmic radiotherapy permitted by 10 CFR 35.400.
<input type="checkbox"/> Other byproduct material permitted by 10 CFR 35.400 _____ (please specify)	Sealed source (Manufacturer _____, Model No. _____)	____mCi	_____(specify authorized use) <input type="checkbox"/> inpatient (facility diagram of patient room(s) attached) <input type="checkbox"/> outpatient

Table C-1. Items 5 and 6 on NRC Form 313: Radioactive Material and Use (Continued) This response includes security-related sensitive information that is included in Attachment _____ and marked "Security-Related Information—Withhold Under 10 CFR 2.390" <input type="checkbox"/> Yes <input type="checkbox"/> No			
Radionuclide	Form or Mfr/Mod No.	Max Qty	Purpose of Use
<input type="checkbox"/> 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 10 CFR 30.32(g).
<input type="checkbox"/> 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 10 CFR 30.32(g).
<input type="checkbox"/> 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 10 CFR 30.32(g).
<input type="checkbox"/> Other byproduct material permitted by 10 CFR 35.500 _____ (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 10 CFR 30.32(g).

Table C–1. Items 5 and 6 on NRC Form 313: Radioactive Material and Use (Continued) This response includes security-related sensitive information that is included in Attachment _____ and marked “Security-Related Information—Withhold Under 10 CFR 2.390” <input type="checkbox"/> Yes <input type="checkbox"/> No			
Radionuclide	Form or Mfr/Mod No.	Max Qty	Purpose of Use
<input type="checkbox"/> 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, see the Medical Uses Licensee Toolkit Web page for the current models approved for a higher activity.			
<input type="checkbox"/> 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.
<input type="checkbox"/> 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.
<input type="checkbox"/> Any byproduct material listed under 10 CFR 31.11 when activity exceeds the quantity listed in 10 CFR 31.11	Prepackaged kits	____ mCi	<i>In vitro</i> studies.

Table C-1. Items 5 and 6 on NRC Form 313: Radioactive Material and Use (Continued) This response includes security-related sensitive information that is included in Attachment _____ and marked "Security-Related Information—Withhold Under 10 CFR 2.390" <input type="checkbox"/> Yes <input type="checkbox"/> No			
Radionuclide	Form or Mfr/Mod No.	Max Qty	Purpose of Use
<input type="checkbox"/> Depleted uranium	Metal	____ kilograms	Shielding in _____.
<input type="checkbox"/> 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.
<input type="checkbox"/> Americium-241	Sealed source (Manufacturer _____, Model No. _____)	____ mCi	For use as an anatomical marker.
<input type="checkbox"/> Byproduct 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 licensing guidance documents on the NRC Medical Uses Licensee Toolkit Web page)
<input type="checkbox"/> Other	Form or Manufacturer/Model No. _____	____ mCi	Purpose of use _____.

[Table C-2](#) contains a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. For example, an applicant may fill in the name of the radiation safety officer (RSO) in [Table C-2](#) and then check the boxes indicating which documents pertaining to the RSO are included in the license application. An applicant may copy the checklist and include it in the license application. Personal information about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of private information are social security number, home address, home telephone number, date of birth, and radiation dose information. If private information is submitted, it should be separated from the public portion of the application and clearly marked: "Privacy Act Information—Withhold Under 10 CFR 2.390." See [Chapter 6](#), "Identifying and Protecting Sensitive Information," for more information.

Table C-2. Items 7 Through 11 on NRC Form 313: 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 (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):
- for each proposed ARSO, identify the types of use (e.g., 10 CFR 35.200, 10 CFR 35.300) of byproduct material for which the individual may be assigned duties and tasks under the licensee's program in oversight of the radiation protection program:
 - ☐ 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- (_____)

- ☐ **Individual currently or was previously identified as an RSO or ARSO on an NRC or Agreement State license or Master Material License permit for the same materials and use**

- ☐ Provide an NRC License # _____ or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee on which the individual was named as the RSO or ARSO¹.

AND

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

OR

- ☐ **Individual is a current RSO or ARSO seeking authorization to be recognized as a RSO or ARSO for the additional medical uses**

- ☐ Attach 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, attach 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.

¹Some 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.

<p>Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)</p>
<p>OR</p>
<p><input type="checkbox"/> Individual 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:</p> <p><input type="checkbox"/> Attach documentation that this individual 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</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">OR</p>
<p><input type="checkbox"/> Individual is Board certified by an NRC-recognized board under 10 CFR 35.50(a)</p> <p><input type="checkbox"/> Attach copy of board certification issued by a specialty board whose certification process has been recognized² by the NRC or an Agreement State under 10 CFR 35.50(a).</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach 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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> If applicable, documentation of recent related continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">OR</p>
<p><input type="checkbox"/> 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)]</p> <p><input type="checkbox"/> Attach copy of 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 byproduct material for which the applicant seeks approval of the individual as the RSO or ARSO.</p>

²Specialty 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.

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

AND

- ☐ Attach 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, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

- ☐ **Individual is Board certified by an NRC-recognized board qualifying under 10 CFR 35.57(a)(2)**

- ☐ Attach a copy of 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

- ☐ Attach documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005.

AND

- ☐ Attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

- ☐ **Individual is an AU, ANP, or AMP qualifying under 10 CFR 35.50(c)(2):**

- ☐ Attach 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 byproduct material for which the applicant seeks approval of an individual to serve as RSO or ARSO.

AND

- ☐ Attach 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, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.

OR

<p>Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)</p>
<p><input type="checkbox"/> Individual is applying simultaneously to be the RSO and AU on a new license under 10 CFR 35.50(c)(3)</p> <p><input type="checkbox"/> Attach the license application that includes documentation of the training and experience of the new AU</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach 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</p> <p style="text-align: center;">OR</p>
<p><input type="checkbox"/> Individual is qualifying by classroom/laboratory training and supervised radiation safety experience under 10 CFR 35.50(b):</p> <p><input type="checkbox"/> Attach documentation of the training and experience specified in 10 CFR 35.50(b)(1) in completed NRC Form 313A (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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach documentation of supervised training and experience specified in 10 CFR 35.50(d) in attached NRC Form 313A (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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach 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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> If applicable, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">AND</p>
<p><input type="checkbox"/> For a proposed RSO who is an outside consultant or contractor, address the following:</p> <p><input type="checkbox"/> 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.</p>

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)
<input type="checkbox"/> Identify other commitments of the consultant-RSO for other 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
<input type="checkbox"/> Identify an in-house representative who will serve as the point of contact during the RSO's absence.
AND
<input type="checkbox"/> Describe 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
<input type="checkbox"/> Specify 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):
<input type="checkbox"/> Uses requested:
<input type="checkbox"/> Provide medical, podiatry, or dental license number and issuing entity (e.g., state or territory)
<input type="checkbox"/> Individual 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 <ul style="list-style-type: none"> Provide an NRC License # _____ or a copy of the license (if issued by 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 physician, dentist, or podiatrist was specifically named as an AU for the uses requested
AND
<input type="checkbox"/> If applicable, attach documentation of recent continuing education and experience as required by 10 CFR 35.59.
OR

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

☐ **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**

- Provide an NRC License # _____ or a copy of the license (if issued by 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 as an AU.

AND

☐ **Attach 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, attach 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, attach 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, attach 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), attach documentation of training needed to meet the requirements in [10 CFR 35.690\(c\)](#)

AND

☐ **Attach 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, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.**

OR

<p>Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)</p>
<p><input type="checkbox"/> Individual is qualified under 10 CFR 35.57(b)(3) because only accelerator-produced byproduct material was used for medical use</p> <p><input type="checkbox"/> Attach 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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach documentation that the physician, podiatrist, or dentist used these materials for the same medical uses requested.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach documentation of recent continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">OR</p>
<p><input type="checkbox"/> Individual who was certified before October 24, 2005, by a board listed in 10 CFR 35.57(b)(2)</p> <p><input type="checkbox"/> Attach 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).</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach documentation demonstrating that the individual was using the requested materials for the uses requested on or before October 24, 2005</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">OR</p>
<p><input type="checkbox"/> Individual is qualified under 10 CFR Part 35, Subparts D, E, F, G, and/or H because of a recognized board certification.</p> <p><input type="checkbox"/> Attach a copy of the board certification(s) issued by a specialty board whose certification process has been recognized³ by the NRC or an Agreement State under 10 CFR Part 35 Subparts D, E, F, G, or H, as applicable to the use requested.</p> <p style="text-align: center;">AND</p>

³Specialty 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.

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

- ☐ Attach 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](#), attach 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](#), attach 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](#), attach 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, attach 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

☐ **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**

- ☐ Attach 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](#), attach 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

- ☐ Attach 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, attach documentation of recent related continuing education and experience as required by [10 CFR 35.59](#).

<p>Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)</p>
<p><input type="checkbox"/> Individual is qualified for medical use of specific emerging technologies under Subpart K, 10 CFR 35.1000</p> <p><input type="checkbox"/> Attach documentation of training and experience as described for the technology in the applicable guidance found on the Medical Uses Licensee Toolkit Web page.</p>
<p>Item 7: Authorized Nuclear Pharmacist (ANP)</p> <p>Authorized Nuclear Pharmacist(s) Name(s):</p> <p><input type="checkbox"/> Attach documentation demonstrating that the proposed ANP has an active license to practice pharmacy. Include information on the issuing entity (e.g. state or territory)</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> For an individual currently or previously identified as an ANP on 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</p> <ul style="list-style-type: none"> • Provide an NRC License # _____ or a copy of the license (if issued by 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 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. <p style="text-align: center;">AND</p> <p><input type="checkbox"/> If applicable, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">OR</p>
<p><input type="checkbox"/> 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)</p> <p><input type="checkbox"/> Attach 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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach documentation that the nuclear pharmacist used these materials for the same uses requested.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> If applicable, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">OR</p>

<p>Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)</p>
<p><input type="checkbox"/> Individual is board certified by an NRC-recognized board <u>under 10 CFR 35.55(a)</u></p> <p><input type="checkbox"/> Attach a copy of the board certification issued by a specialty board whose certification process has been recognized⁴ by the NRC or an Agreement State under 10 CFR 35.55(a).</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> If applicable, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">OR</p>
<p><input type="checkbox"/> Individual is qualified by classroom/laboratory training and supervised practical experience in nuclear pharmacy under <u>10 CFR 35.55(b)</u></p> <p><input type="checkbox"/> Attach completed NRC Form 313A (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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach 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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> If applicable, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">OR</p>
<p><input type="checkbox"/> Individual is qualified for medical use of specified emerging technologies under Subpart K, 10 CFR 35.1000</p> <p><input type="checkbox"/> Attach documentation of training and experience as described for the technology in the applicable guidance found on the <u>Medical Uses Licensee Toolkit</u> Web page.</p>

⁴Specialty 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.

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

Item 7: Authorized Medical Physicist (AMP)

Authorized Medical Physicist(s) Name(s):

☐ **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**

- Provide an NRC License # _____ or a copy of the license (if issued by 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, attach documentation of recent, related continuing education and experience as required by 10 CFR 35.59.

OR

☐ **Individual is an AMP listed on a license or permit but seeking authorization for a new medical use under 10 CFR 35.51(c)**

- Provide an NRC License # _____ or a copy of the license (if issued by 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

- ☐ Attach 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), attach 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

<p>Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)</p>
<p><input type="checkbox"/> 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:</p> <p><input type="checkbox"/> Attach 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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach documentation that the medical physicist used these materials for the same medical uses as requested.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> If applicable, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">OR</p>
<p><input type="checkbox"/> Individual is qualified by board certification under 10 CFR 35.51(a)</p> <p><input type="checkbox"/> Attach a copy of the board certification issued by a specialty board whose certification process has been recognized⁵ by the NRC or an Agreement State under 10 CFR 35.51(a).</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach 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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> If applicable, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">OR</p>
<p><input type="checkbox"/> Individual is qualified by board certification under 10 CFR 35.57(a)(3)</p> <p><input type="checkbox"/> Attach 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.</p> <p style="text-align: center;">AND</p>

⁵Specialty 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.

<p>Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)</p>
<p><input type="checkbox"/> If applicable, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">OR</p>
<p><input type="checkbox"/> Individual is qualified because of degree, medical physics training, and medical physics work experience under 10 CFR 35.51(b)</p> <p><input type="checkbox"/> Attach 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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach 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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach 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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> If applicable, attach documentation of recent related continuing education and experience as required by <u>10 CFR 35.59</u>.</p> <p style="text-align: center;">OR</p>
<p><input type="checkbox"/> Individual is qualified for medical use of specified emerging technologies under Subpart K, 10 CFR 35.1000</p> <p><input type="checkbox"/> Attach documentation of training and experience as described for the technology in the applicable guidance found on the Medical Uses Licensee Toolkit Web page.</p>
<p>Item 7: Ophthalmic physicist</p> <p>Ophthalmic Physicist(s) Name(s):</p> <p><input type="checkbox"/> Individual is currently or was previously listed as an authorized ophthalmic physicist on an NRC or Agreement State license or permit</p> <p><input type="checkbox"/> Provide an NRC License # _____ or a copy of the license (if issued by 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 authorized ophthalmic physicist.</p>

<p>Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)</p>
<p style="text-align: center;">AND</p> <p><input type="checkbox"/> If applicable, attach documentation of recent, related continuing education and experience as required by 10 CFR 35.59.</p>
<p style="text-align: center;">OR</p> <p><input type="checkbox"/> Individual is qualified to be an ophthalmic physicist based on education and supervised work experience under 10 CFR 35.433</p> <p><input type="checkbox"/> Attach 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.</p>
<p style="text-align: center;">AND</p> <p><input type="checkbox"/> If applicable, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59.</p>
<p>Item 7: Individuals Authorized for Non-Medical Use:</p> <p>Name of the proposed nonmedical use AU:</p> <p><input type="checkbox"/> Attach a description of types, quantities, and proposed nonmedical uses for each individual requested.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach documentation of individual's education and radiation safety training and experience with the types of materials and uses requested. This may include the NRC license number or a copy of 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.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Attach detailed radiation training and experience applicable to the use requested.</p>

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

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

- ☐ A statement that, "We have developed and will 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."

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

Item 9: Facility Diagram

☐ Provide the following:

- Facility diagrams. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated.
- Location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored.
- 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).
- Doors should be indicated, and specify 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). Include 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 should include the workload assumptions used.
- For PET, radiopharmaceutical, and sealed-source therapies, provide 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](#). For calculations of the maximum exposure in any given hour, an occupancy factor will not be used.
- For teletherapy facilities, applicants should provide 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](#) (e.g., Perfexion, View-Ray), applicants should provide information described in the guidance on the [Medical Uses Licensee Toolkit](#) Web page.

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

Item 9: Radiation Monitoring Instruments

Provide the following:

- ☐ A statement that: “Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations.”

AND/OR

- ☐ A statement that: “We have developed and will implement and maintain written radiation survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 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 byproduct materials, we are providing the following:

- ☐ A statement 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, identify 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

- ☐ Provide 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 posted for that 10 CFR 35.1000 medical use on NRC’s [Medical Uses Licensee Toolkit](#) Web page, or explain why the procedure is not provided.

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

Item 9: Other Equipment and Facilities

Provide the following, if applicable:

- ☐ For PET radionuclide use and radiopharmaceutical therapy programs, describe the additional equipment for these uses, as applicable.
- ☐ For manual brachytherapy facilities, provide a description of the emergency response equipment.
- ☐ For teletherapy, GSR, and remote afterloader facilities, provide 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, review the licensing guidance posted for that 10 CFR 35.1000 medical use on NRC's [Medical Uses Licensee Toolkit](#) Web page and provide the appropriate descriptions of other equipment and facilities.

Table C-2. 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

Provide the following:

- ☐ A statement that: "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502."

OR

- ☐ A statement that: "We will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program—Occupational Dose' in NUREG-1556, Vol. 9, Rev. 3, '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

Provide the following:

- ☐ A statement that: "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

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

Provide the following:

- ☐ A statement that: “We 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 statement that “We will comply with the National Source Tracking System (NSTS) reporting requirement, as described in 10 CFR 20.2207.”

Item 10: Leak Tests

Provide the following:

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

- ☐ A statement that: “We have 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 statement that: “We will conduct leak tests in-house.”

AND

- ☐ A statement that: “The attached leak test procedures will be followed for leak tests conducted in-house.”

AND

- ☐ Attach leak test procedures.

<p>Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)</p>
<p style="text-align: center;">OR</p> <p><input type="checkbox"/> A statement 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."</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> If a contractor is used to perform leak testing, a statement that: "Leak test sample collection and analysis will be performed by an organization authorized by 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 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."</p>
<p>Item 10: Area Surveys</p> <p>Provide the following:</p> <p><input type="checkbox"/> A statement that: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."</p>
<p>Item 10: Safe Use of Unsealed Licensed Material</p> <p>Provide the following:</p> <p><input type="checkbox"/> A statement that: "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201."</p>
<p>Item 10: Mobile medical service</p> <p><input type="checkbox"/> Review the guidance in Appendix V of this NUREG to determine the response required.</p>
<p>Item 10: Minimization of Contamination</p> <p>A response is not required under the following condition: The NRC 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.</p>

Table C-2. 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

Provide the following:

- | |
|--|
| <input type="checkbox"/> A statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92." |
|--|

AND

- | |
|--|
| <input type="checkbox"/> Contact the appropriate NRC Regional Office for guidance on treatment or disposal of waste by incineration or compaction. |
|--|