

From: [Rusty Beeler](#)
To: [Hann, Patrick-John](#); [Philip Birt](#)
Subject: [External_Sender] NRMCM Renewal License#24-05245-01
Date: Monday, July 26, 2021 12:29:49 PM
Attachments: [NRMCLicenserenewal.pdf](#)

Patrick,

I am cc the director of radiology on this email he is my direct supervisor. I have enclosed the application for renewal. I wanted to verify all the policies were still in place before sending it to you. If you have any questions please let me know.

Thanks

Rusty

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Rusty Beeler, RT(R) | Lead Nuclear Medicine Technologist and Radiation Safety Officer | Northeast Regional Medical Center | 315 S. Osteopathy| Kirksville, MO 63501 |PH: 660-785-1610|Fax: 660-785-1356 <http://www.nermc.com>

Suggested Format for Providing Information Requested in Items 5 Through 11 of U.S. Nuclear Regulatory Commission Form 313

This Appendix contains the suggested format that may be used to assist in organizing an application, including the U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License," (Appendix B) and the NRC Form 313A series, "Medical Use Training and Experience and Preceptor Attestation," which can be found on the Medical Uses Licensee Toolkit Web page. Also refer to the NRC Forms Web site at: <https://www.nrc.gov/reading-rm/doc-collections/forms/> for the NRC Form 313A series. Verify that the most current version of the NRC Form 313A is being used by checking the "Expires" date in the right, top-hand corner of the form. An applicant may copy the checklist and include it in the license application.

Items 1–4 and 12–13 may be completed on NRC Form 313. Table C–1 provides a suggested format for providing information requested in Item 5 (Radioactive Material) and Item 6 (Purpose of Use), and Table C–2 provides a suggested format for providing information requested in Items 7 and 8 (Training and Experience), Item 9 (Facilities and Equipment), Item 10 (Radiation Safety Program), and Item 11 (Waste Management). Table C–3, Applicable Appendices Describing Model Procedures, may be helpful to applicants in developing procedures for inclusion in their radiation safety program. Please note that the procedures provided are not all-inclusive (e.g., full calibration and emergency procedures for therapy devices are not included and only references to American Association of Physicists in Medicine and American National Standards Institute standards are made in this NUREG document). In addition, uses conducted under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000 may require procedures specific to the emerging technology; however, the procedures described in the document may be helpful in developing these procedures. Finally, Appendices X, Y, and Z of this NUREG are not model procedures; however, they are included in Table C–3 to remind licensees of recordkeeping, reporting, and transportation requirements.

The applicant should review the guidance in Chapter 6, "Identifying and Protecting Sensitive Information," and mark security-related sensitive information appropriately.

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" ☐ Yes ☒ No

Radionuclide	Form or Mfr/Mod No.	Max Qty	Purpose of Use
<input checked="" 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 checked="" 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" ☐ Yes ☒ 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" ☐ Yes ☒ 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 checked="" type="checkbox"/> Gadolinium-153 permitted by 10 CFR 35.500	Sealed sources (Manufacturer <u>ISOTOPE PRODUCTS LAB</u> , Model No. <u>NE58497</u>) Device (Manufacturer <u>Phillip MEDICAL</u> , Model No. <u>CARDIOMD-AC</u>)	<u>300</u> curies per source and <u>1200</u> 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 checked="" 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" ☐ Yes ☒ 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 <u>Medical Uses Licensee Toolkit</u> 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 checked="" 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>AS NEEDED</i>	<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" ☐ Yes ☒ 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 <u>NRC Medical Uses Licensee Toolkit</u> 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) **RUSTY R. BEELER
RT(R)**
- ☐ 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 # 24-05245-01 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.

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

OR

☐ **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:**

☐ 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

AND

☐ 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 under 10 CFR 35.50(a)**

☐ 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).

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

OR

☐ **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)]**

☐ 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.

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

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 applying simultaneously to be the RSO and AU on a new license under 10 CFR 35.50(c)(3)**

☐ Attach the license application that includes documentation of the training and experience of the new AU

AND

☐ 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

OR

☐ **Individual is qualifying by classroom/laboratory training and supervised radiation safety experience under 10 CFR 35.50(b):**

☐ 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.

AND

☐ 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.

AND

☐ 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.

AND

☐ If applicable, attach 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, 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

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

- ☐ 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

- ☒ Identify an in-house representative who will serve as the point of contact during the RSO's absence.

AND

- ☐ 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

- ☒ 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):

☒ Uses requested: 10 CFR 35.100 AND 35.200

- ☐ Provide medical, podiatry, or dental license number and issuing entity (e.g., state or territory)

☒ **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**

- 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

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

OR

Attachment 1

Please at the following users to License# 24-05245-01. Enclosed will be license#0085-1-78-M1 from the Iowa Department of Public Health.

Requested uses are 10 CFR 35.100 and 35.200

Jason A. Arthur, MD

Gregory R. Beyer, MD

Robert J. Forbes, MD

Annabel Galva, MD

Christopher M. Hasiak, MD

James F. Smith, MD

Remove from License# 24-05245-01

Paul M. Williams, DO

Larry Nussbaum, MD

Thanks

Rusty R. Beeler RT®, RSO

Northeast Regional Medical Center
315 S. Osteopathy
Kirksville, MO 65301
660-785-1000



STATE CAPITOL OF IOWA DES MOINES, IOWA

Official Use Only-Security Related Information

IOWA DEPARTMENT OF PUBLIC HEALTH

Page 1 of 3 Pages

MATERIALS LICENSE

Pursuant to Chapter 136C of the Iowa Code and 641-37 through 45 (136C) of the Iowa Administrative Code and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer radioactive materials designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the rules of the applicable chapter(s). This license is subject to all applicable rules and orders of the Iowa Department of Public Health including the Iowa Rules for Radiation Machines and Radioactive Materials [641-37 through 45] now or hereafter in effect, and to any conditions specified below.

Licensee

In accordance with the *letter* dated
September 19, 2019, License No.: 0085-1-78-M1
is *amended* to read as follows:

1. Jennie Edmundson Hospital
d.b.a. Methodist Jennie Edmundson
2. 933 East Pierce Street
Council Bluffs, Iowa 51501

3. **License Number:** 0085-1-78-M1
Amendment 01

4. **Expiration Date:** February 1, 2024

5. Byproduct, Source, Special
Nuclear and/or Natural
Occurring or Accelerator
Produced Radioactive Material

6. Chemical and/or Physical
Form

7. Maximum Amount that
Licensee May Possess At Any
One Time Under This License

A. Any radioactive material
authorized by 641-41.2(31)

A. Any form authorized by
641-41.2(31)

A. As needed

B. Any radioactive material
authorized by 641-41.2(33)

B. Any form authorized by
641-41.2(33) excluding
generators

B. As needed

C. Any radioactive material
authorized by 641-41.2(37)

C. Any form material
authorized by 641-41.2(37)

C. As needed

8. AUTHORIZED USE

- A. Medical use described in 641-41.2(31).
- B. Medical use described in 641-41.2(33).
- C. Medical use described in 641-41.2(37).



STATE CAPITOL OF IOWA DES MOINES, IOWA

MATERIALS LICENSE

Supplementary Sheet

License No. 0085-1-78-M1
Amendment 01

CONDITIONS

9. Licensed material shall be used and stored only at the licensee's facilities located at 933 East Pierce Street and One Edmundson Place, Suite #306, Council Bluffs, Iowa.
10. Licensed material shall be used by, or under the supervision of:
 - Robert W. Armbruster, MD, for materials described in 641-41.2(33), cardiovascular imaging only.
 - Jason A. Arthur, MD, for materials described in 641-41.2(31); (33); and (37), Iodine-131 only.
 - Gregory R. Beyer, MD, for materials described in 641-41.2(31); (33); and (37), Iodine-131 only.
 - Thomas Ray Brandt, MD, for materials described in 641-41.2(33), cardiovascular imaging only.
 - Anand Deshmukh, MD, for materials described in 641-41.2(33), cardiovascular imaging only.
 - Robert J. Forbes, MD for materials described in 641-41.2(31); (33); and (37), Iodine-131 only.
 - Annabel Galva, MD, for materials described in 641-41.2(31) and (33).
 - Christopher M. Hasiak, MD, for materials described in 641-41.2(31); (33); and (37), Iodine-131 only.
 - Sajan Thapar Mahajan, MD, for materials described in 641-41.2(31); (33); and (37), Iodine-131 only.
 - James F. Smith, MD for materials described in 641-41.2(31); (33); and (37), Iodine-131, Strontium-89, Samarium-153 and Yttrium-90 only.
 - Farid A. Thanawalla, MD, for materials described in 641-41.2(31) and (33).*
 - Rajkumar Yarlagadda, for materials described in 641-41.2(31); (33); and (37), Iodine-131 only.
11. The Radiation Safety Officer for licensed activities is Robert J. Forbes, MD.
12. The licensee is authorized to transport licensed material only in accordance with the provisions of 641-39.5(136C), "Transportation of Radioactive Material."



STATE CAPITOL OF IOWA DES MOINES, IOWA

Iowa Department of Public Health

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MATERIALS LICENSE

Supplementary Sheet

License No. 0085-1-78-M1
Amendment 01

13. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Iowa Department of Public Health rules shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the rules.

A. Application dated December 10, 2018 (with attachments).

B. Letter dated September 19, 2019 (with attachments).

For the Iowa Department of Public Health

Date 10-7-2019

By R. S. Dahlin
Randal S. Dahlin
Radioactive Materials Program

Date 10-7-2019

Concurrence Stuart R. Jordan
Stuart R. Jordan
Radioactive Materials Program

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

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 qualified under 10 CFR 35.57(b)(3) because only accelerator-produced byproduct material was used for medical use**

☐ 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.

AND

☐ Attach documentation that the physician, podiatrist, or dentist used these materials for the same medical uses requested.

AND

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

OR

☐ **Individual who was certified before October 24, 2005, by a board listed in 10 CFR 35.57(b)(2)**

☐ 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).

AND

☐ Attach documentation demonstrating that the individual was using the requested materials for the uses requested 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 qualified under 10 CFR Part 35, Subparts D, E, F, G, and/or H because of a recognized board certification.**

☐ 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.

AND

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.

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 qualified for medical use of specific emerging technologies under Subpart K, 10 CFR 35.1000**

☐ Attach documentation of training and experience as described for the technology in the applicable guidance found on the Medical Uses Licensee Toolkit Web page.

Item 7: Authorized Nuclear Pharmacist (ANP)

Authorized Nuclear Pharmacist(s) Name(s):

☐ 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)

AND

☐ 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

- 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.

AND

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

OR

☐ **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)**

☐ 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.

AND

☐ Attach documentation that the nuclear pharmacist used these materials for the same uses requested.

AND

☐ If applicable, attach documentation of recent related 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 board certified by an NRC-recognized board under 10 CFR 35.55(a)**

- ☐ 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).

AND

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

OR

☐ **Individual is qualified by classroom/laboratory training and supervised practical experience in nuclear pharmacy under 10 CFR 35.55(b)**

- ☐ 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.

AND

- ☐ 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.

AND

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

OR

☐ **Individual is qualified for medical use of specified emerging technologies under Subpart K, 10 CFR 35.1000**

- ☐ Attach documentation of training and experience as described for the technology in the applicable guidance found on the Medical Uses Licensee Toolkit Web page.

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

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 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:**

☐ 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.

AND

☐ Attach documentation that the medical physicist used these materials for the same medical uses as requested.

AND

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

OR

☐ **Individual is qualified by board certification under 10 CFR 35.51(a)**

☐ 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).

AND

☐ 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.

AND

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

OR

☐ **Individual is qualified by board certification under 10 CFR 35.57(a)(3)**

☐ 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.

AND

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.

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

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

OR

- ☐ **Individual is qualified because of degree, medical physics training, and medical physics work experience under 10 CFR 35.51(b)**

- ☐ 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.

AND

- ☐ 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.

AND

- ☐ 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.

AND

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

OR

- ☐ **Individual is qualified for medical use of specified emerging technologies under Subpart K, 10 CFR 35.1000**

- ☐ Attach documentation of training and experience as described for the technology in the applicable guidance found on the Medical Uses Licensee Toolkit Web page.

Item 7: Ophthalmic physicist

Ophthalmic Physicist(s) Name(s):

- ☐ **Individual is currently or was previously listed as an authorized ophthalmic physicist on an NRC or Agreement State license or permit**

- ☐ 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.

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

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

AND

OR

- ☐ **Individual is qualified to be an ophthalmic physicist based on education and supervised work experience under 10 CFR 35.433**

- ☐ 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.

AND

- ☐ If applicable, attach 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:

- ☐ Attach a description of types, quantities, and proposed nonmedical uses for each individual requested.

AND

- ☐ 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.

AND

- ☐ Attach detailed radiation training and experience applicable to the use requested.

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:

- | |
|--|
| <p><input checked="" type="checkbox"/> 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."</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 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.

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

OR

- ☐ 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."

OR

- ☒ 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."

Item 10: Area Surveys

Provide the following:

- ☒ 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."

Item 10: Safe Use of Unsealed Licensed Material

Provide the following:

- ☒ 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."

Item 10: Mobile medical service

- ☐ Review the guidance in Appendix V of this NUREG to determine the response required.

Item 10: Minimization of Contamination

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.

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:

☒ 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

☒ Contact the appropriate NRC Regional Office for guidance on treatment or disposal of waste by incineration or compaction.