



License: ~~40~~-15697-01
Docket: U30-09603
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Huron Regional Medical Center
172 4th Street SE
Huron, SD 57350
(605) 353-6565
Main Fax (605) 353-6300

FACSIMILE TRANSMISSION

(CNRC)

TO: Jacqueline D. Cook FROM: Deborah Rysaert (HRMC)
FAX # 817-200-1263 FAX # 605-353-6317
DATE: 4/9/15 TIME: 0930 Total # of Pages (incl. cover sheet) 19

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MESSAGE: Please accept the updated license
application pages to reflect the current
NUREG-1556, Vol. 9, Revision 2 tables C.2 and C.3,
along with the delegation of Authority found in
Appendix I.

NON-PUBLIC
☐ Immediate Release
☒ Normal Release
☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:

Reviewer: JRC

Date: 4/9/15

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use <i>(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)</i>				
<input type="checkbox"/> Yes <input type="checkbox"/> No	This response includes security-related sensitive information (see Section 5.2) which is included in Attachment _____ and marked "Security-related information - withhold under 10 CFR 2.390"			
Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
x	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
x	Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
	F-18	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	O-15	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	C-11	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
x	Any byproduct material permitted by 10 CFR 35.300	Any	_____ millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	_____ millicuries	Administration of I-131 sodium iodide.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____ Model No. _____)	_____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____ Model No. _____)	_____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____ Model No. _____)	_____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____ Model No. _____)	_____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.

APPENDIX C

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use <i>(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)</i>				
Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Strontium-90	Sealed source or device (Manufacturer _____ Model No. _____)	_____ millicuries	Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.500 Check all that apply: <input type="checkbox"/> Gd-153; <input type="checkbox"/> I-125; <input type="checkbox"/> Other, describe _____	Sealed source or 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).
	Iridium-192	Sealed source or device (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 afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.
	Cobalt-60	Sealed source or device (Manufacturer _____ Model No. _____)	_____ curies per source and _____ curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____ Model No. _____ teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.
	Cobalt-60	Sealed source or device (Manufacturer _____ Model No. _____)	_____ curies per source and _____ curies total	For medical use permitted by 10 CFR 35.600, in a Manufacturer _____ Model No. _____ stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the sources in the stereotactic

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use <i>(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)</i>				
Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
				radiosurgery device.
	Any byproduct material under 10 CFR 31.11	Prepackaged kits	____ millicuries	In vitro studies.
	Depleted uranium	Metal	____ kilograms	Shielding in a teletherapy unit.
	Depleted uranium	Metal	____ kilograms	Shielding in a linear accelerator.
	Any radionuclide in excess of 30 millicuries for use in calibration, transmission, and reference sources. (List radionuclide: _____)	Sealed source or device (Manufacturer _____ Model No. _____)	____ millicuries	For use in a Manufacturer _____ Model No. _____ for calibration and checking of licensee's survey instruments.
	Americium-241	Sealed source or device (Manufacturer _____ Model No. _____)	____ millicuries per source and _____ millicuries total	Use as an anatomical marker.
	Plutonium (principal radionuclide Pu-238)	Sealed sources	____ millicuries per source and _____ grams total	As a component of Manufacturer _____ Model No. _____ nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explantation, recovery, disposal, and implantation.
x	Other Sr-90	Form or Manufacturer/Model No. Tracerlab/RA-2A	100 millicuries	Purpose of use Storage Only

APPENDIX C

Table C.3 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 in Table C.3 and then check the boxes indicating which documents pertaining to the RSO are being included in the license application. An applicant may copy the checklist and include it in the license application.

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APPENDIX C

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Radiation Safety Officer Name: Jim Schwaiger ML Lic. # 40-15697-01	<i>For an individual previously identified as an RSO on an NRC or Agreement State license or permit:</i> Previous license number (if issued by the NRC), or a copy of a license (if issued by an Agreement State), or a copy of a permit (if issued by an NRC master materials licensee) on which the individual was specifically named as the RSO.	<input checked="" type="checkbox"/>
	<i>For an individual qualifying under 10 CFR 35.57(a)(3):</i> Documentation that the individual was: <ul style="list-style-type: none"> the RSO for only the medical uses of accelerator-produced radioactive material or discrete sources of Ra-226 included in the definition of byproduct material as a result of the EPAct; the RSO for the medical uses of these materials before or during the effective period of NRC's waiver of August 31, 2005. 	<input type="checkbox"/>
	<i>For an individual qualifying under 10 CFR 35.50(a):</i> Copy of certification by a specialty board whose certification process has been recognized ¹⁰ by NRC or an Agreement State under 10 CFR 35.50(a). AND	<input type="checkbox"/>
	Description of the training and experience specified in 10 CFR 35.50(e) 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. AND	<input type="checkbox"/>
	Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed training in and experience required for certification, as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO. AND	<input type="checkbox"/>
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>

PUBLIC

- ☐ Immediate Release
☒ Normal Release

NON-PUBLIC

- ☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:

¹⁰The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/mia/ined/recognized.html>

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Item Number and Title	Suggested Response	Check box to indicate material included in application
	<p><i>For an individual qualifying under 10 CFR 35.50(b):</i></p> <p>Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience 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;">AND</p>	<input type="checkbox"/>
	<p>Description of the training and experience specified in 10 CFR 35.50(c) 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;">AND</p>	<input type="checkbox"/>
	<p>Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the required training and experience specified in 10 CFR 35.50(b), as well as the training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR 35.50(c)(1):</i></p> <p>Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized¹¹ by the NRC or an Agreement State under 10 CFR 35.51(a) and description of the experience specified in 10 CFR 35.50(c)(1) demonstrating that the proposed RSO is qualified by experience 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;">AND</p>	<input type="checkbox"/>
	<p>Description of the training and experience specified in 10 CFR 35.50(e) 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;">AND</p>	<input type="checkbox"/>

¹¹The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-usc-toolkit.html>.

Item Number and Title	Suggested Response	Check box to indicate material included in application
	<p>Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the required training and experience specified for certification, as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR 35.50(c)(2):</i></p>	
	<p>Copy of the licensee's license indicating that the individual is an AU, AMP, or ANP identified on the licensee's license 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.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>Description of the training and experience specified in 10 CFR 35.50(e) 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;">AND</p>	<input type="checkbox"/>
	<p>Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in 10 CFR 35.50(c)(2), as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>

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APPENDIX C

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Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Authorized Users for medical uses: Name(s), (including license number authorizing practice of medicine, podiatry, or dentistry if not provided previously or in attachment); Requested uses for each individual	<i>For an individual previously identified as an AU on an NRC or Agreement State license or permit:</i> See attached Item 7 Previous license number (if issued by the NRC), 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, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested.	<input checked="" type="checkbox"/>
	<i>For an AU requesting authorization for an additional medical use:</i> Description of the additional training and experience to demonstrate the AU is also qualified for the new medical uses requested (e.g., training and experience needed to meet the requirements in 10 CFR 35.290 (b), 35.396, 35.390(b)(1)(ii)(G), or 35.690(c)). AND	<input type="checkbox"/>
	A preceptor attestation, if required (e.g., attestation is required to meet the requirements in 10 CFR 35.396, 35.390(b)(1)(ii)(G), or 35.690(c)).	
	<i>For an individual qualifying under 10 CFR 35.57(b)(3):</i> Documentation that the physician, podiatrist, or dentist: <ul style="list-style-type: none"> used only accelerator-produced radioactive materials, or discrete sources of Ra-226, or both, for medical uses before or during the effective period of NRC's waiver of August 31, 2003; and used these materials for the same medical uses requested. 	<input type="checkbox"/>
	<i>For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is board-certified:</i> Copy of the certification(s) by a specialty board(s) whose certification process has been recognized ¹² by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested. AND	<input type="checkbox"/>

PUBLIC

- ☐ Immediate Release
☒ Normal Release

NON-PUBLIC

- ☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal

Other

¹²The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

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Reviewer: *[Signature]*

Date: *4/1/15*

Item Number and Title	Suggested Response	Check box to indicate material included in application
	<p>For an individual with a board certification recognized under 10 CFR 35.390, a description of the supervised work experience administering dosages of radioactive drugs required in 10 CFR 35.390(b)(1)(ii)(G) demonstrating that the proposed AU is qualified for the types of administrations for which authorization is sought;</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>For an individual with a board certification recognized under 10 CFR 35.390 for medical uses described in 10 CFR 35.200, a description of the supervised work experience eluting generator systems required in 10 CFR 35.290(c)(1)(ii)(G) demonstrating the proposed AU is also qualified for imaging and localization medical uses;</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>For an individual with a board certification recognized under 10 CFR 35.490 or 35.690 seeking authorization under 10 CFR 35.396(d), a description of the classroom and laboratory training and supervised work experience required to demonstrate qualifications for administering parenteral administrations of unsealed byproduct material requiring a written directive;</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>For an individual seeking authorization under 10 CFR Part 35, Subpart H, description of the training specified in 10 CFR 35.690(c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought;</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>Written attestation, signed by a preceptor physician AU, that the training and experience specified for certification, as well as the clinical casework, or training and experience required by 10 CFR 35.396(d), or training for 10 CFR 35.600 types of use, if appropriate, have been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved;</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>

APPENDIX C

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal <i>(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate material included in application
	<p><i>For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is not board-certified:</i></p> <p>A description of the training and experience identified in 10 CFR Part 35, Subparts D, E, F, G, and H, demonstrating that the proposed AU is qualified by training and experience for the use(s) requested.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>For an individual seeking authorization under 10 CFR Part 35, Subpart H, description of the training specified in 10 CFR 35.690 (c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>Written attestation, signed by a preceptor physician AU, that the above training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>
Item 7: Authorized Nuclear Pharmacists	<p><i>For an individual previously identified as an ANP on an NRC or Agreement State license or permit:</i></p>	
Name(s) and license to practice pharmacy:	<p>Previous license number (if issued by the NRC), 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, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named ANP.</p>	<input type="checkbox"/>
N/A		
	<p><i>For an individual qualifying under 10 CFR 35.57(a)(3):</i></p> <p>Documentation that the nuclear pharmacist:</p> <ul style="list-style-type: none"> used only accelerator-produced radioactive materials or discrete sources of Ra-226, or both, in the practice of nuclear pharmacy before or during the effective period of NRC's waiver of August 31, 2005; and used these materials for the same uses requested. 	<input type="checkbox"/>

Item Number and Title	Suggested Response	Check box to indicate material included in application
	<p><i>For an individual qualifying under 10 CFR 35.55(a):</i></p> <p>Copy of the certification(s) of the specialty board whose certification process has been recognized¹³ under 10 CFR 35.55(a).</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR 35.55(b):</i></p> <p>Description 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>	<input type="checkbox"/>
	<p>Written attestation, signed by a preceptor ANP, that the above training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>
<p>Item 7: Authorized Medical Physicists</p> <p>Name(s):</p> <p style="text-align: center;">N/A</p>	<p><i>For an individual previously identified as an AMP on an NRC or Agreement State license or permit:</i></p> <p>Previous license number (if issued by the NRC), 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, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AMP for the uses requested.</p>	<input type="checkbox"/>

¹³The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

APPENDIX C

Item Number and Title	Suggested Response	Check box to indicate material included in application
	<p><i>For an individual qualifying under 10 CFR 35.57(a)(3):</i></p> <p>Documentation that the medical physicist:</p> <ul style="list-style-type: none"> used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, for medical uses before or during the effective period of NRC's waiver of August 31, 2005; and used these materials for the same medical uses requested. 	<input type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR 35.51(a):</i></p> <p>Copy of the certification(s) of the specialty board(s) whose certification process has been recognized¹⁴ under 10 CFR 35.51(a).</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>Description 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 he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>Written attestation, signed by a preceptor AMP, that the required training and experience required for certification, as well as the training and experience specified in 10 CFR 35.51(c) have been satisfactorily completed, and that a level of competency sufficient to function independently as an AMP has been achieved.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR 35.51(b):</i></p> <p>Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51(b)(1) for the uses requested.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>

¹⁴The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Item Number and Title	Suggested Response	Check box to indicate material included in application
	Description 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 he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.	<input type="checkbox"/>
	AND Written attestation, signed by a preceptor AMP, that the required training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved.	<input type="checkbox"/>
	AND If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>
Item 7: Authorized User for nonmedical uses	<i>Note:</i> For purposes of this section of the table, the term "authorized user" is used to mean individuals authorized for the nonmedical uses described. See Sections 8.11 and 8.12.	
Name(s): Requested types, quantities, and nonmedical uses for each individual	<i>For an individual previously authorized for nonmedical use on an NRC or Agreement State license or permit:</i> Previous license number (if issued by the NRC), 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, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AU for the types, quantities, and uses requested.	<input type="checkbox"/>
	<i>For individuals qualifying under 10 CFR 30.33(a)(3):</i> Documentation of the individual's training and experience demonstrating that the individual is qualified to use the types and quantities of licensed materials for the requested uses.	<input type="checkbox"/>
Item 9: Facility Diagram	A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:	<input checked="" type="checkbox"/>
	<ul style="list-style-type: none"> Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly. Drawings should be to scale, indicating the scale used. 	<input type="checkbox"/> <input type="checkbox"/>

DNMS

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Reviewer:

Date: _____

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal <i>(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate material included in application
	When administering dosages of alpha-emitting unsealed byproduct material in other than unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72 or 10 CFR 30.32(j), <ul style="list-style-type: none"> A statement that: "Dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation." 	<input type="checkbox"/>
	OR <ul style="list-style-type: none"> We are providing a description of the dosage measurement equipment, the nationally recognized calibration standard (or manufacturer's calibration instructions), and dosage measurement procedures. 	<input type="checkbox"/>
Item 9: Therapy Unit - Calibration and Use	We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.	<input type="checkbox"/>
Item 9: Other Equipment and Facilities	Guidance in Section 5.2 was reviewed and security-related information provided is marked accordingly.	<input type="checkbox"/>
	Attached is a description, identified as Attachment 9.4, of additional facilities and equipment.	<input checked="" type="checkbox"/>
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	<input type="checkbox"/>
	For PET radionuclide use, PET radioactive drug production, and radiopharmaceutical therapy programs, we are providing a description of the additional facilities and equipment for these uses.	<input type="checkbox"/>
	For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following: <ul style="list-style-type: none"> 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 LDR 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; and Emergency response equipment. 	<input type="checkbox"/> <input type="checkbox"/>

APPENDIX C

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 10: Safety Procedures and Instructions	Attached are procedures required by 10 CFR 35.610.	<input type="checkbox"/>
	Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	<input type="checkbox"/>
Item 10: Occupational Dose	<p>A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Vol. 9, Rev. 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.'"</p> <p style="text-align: center;">OR</p>	<input checked="" type="checkbox"/>
	A description of an alternative method for demonstrating compliance with the referenced regulations.	<input type="checkbox"/>
Item 10: Area Surveys	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."	<input checked="" type="checkbox"/>
Item 10: Safe Use of Unsealed Licensed Material	A statement that: "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."	<input checked="" type="checkbox"/>
Item 10: Spill/Contamination Procedures	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."	<input checked="" type="checkbox"/>
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	<p>Name of the proposed employee and types of activities requested:</p> <p style="text-align: center;">AND</p> <p>Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.	<input type="checkbox"/>
Item 10: Minimization of Contamination	A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.15, 8.16, 8.21, 8.25, 8.27, and 8.29, on the topics: facilities and equipment, facility diagram, Radiation Protection Program, safety program, and waste management.	N/A

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal <i>(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 11: Waste Management	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."	<input checked="" type="checkbox"/>
	Attached is a description of the radioactive waste incinerator facility and related portions of the Radiation Safety Program (10 CFR 20.2004).	<input type="checkbox"/>
	Attached is a request to receive potentially contaminated radiation transport shields from consortium members receiving PET radioactive drugs noncommercially transferred under 10 CFR 30.32(j) authorization.	<input type="checkbox"/>

Item 7


Model Delegation of Authority

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APR - 9 2015

DNMS

Memo To: The Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, Jim Schwaiger, M.D. have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend 1.3 hours per week conducting radiation protection activities.

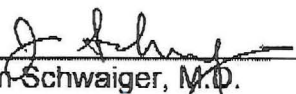


David Dick, CEO

4/9/15

Date

I accept the above responsibilities,



Jim Schwaiger, M.D.

4/9/15

Date

Cc: Affected department heads

NOTE: Jim Schwaiger, M.D. was previously identified as the Radiation Safety Officer on this license, 40-15697-01.

PUBLIC

☐ Immediate Release
☒ Normal Release

NON-PUBLIC

☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other: _____

Reviewer:  Date: 4/9/15

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