



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

TELEFAX TRANSMITTAL

DATE October 15, 2009

NUMBER OF PAGES 2

SEND TO Wendy Boufford, Chief Nuclear Medicine Technologist

LOCATION Medical Clinic of Northville

FAX NUMBER (248) 349-3195

VERIFY BY CALLING

FROM: Bill Reichhold
(Sender)

TELEPHONE NUMBER (630) 829-9839

FAX NUMBER (630) 515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE See accompanying documents.

NOTICE

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The following additional information is needed to review your request.

Thank you for your facsimile response received October 14, 2009, to our initial request for additional information. However, I still need some additional details about your facility as described below:

1. Please provide a key or identify the objects marked with letters on the facility diagram.
2. Please put the address of the facility **on the facility diagram**. This helps us identify the location of the facility shown in the diagram.
3. Please indicate the scale of the facility diagram, such as one inch = one foot.
OR Specify the room dimensions such as 12 feet by 14 feet.
4. Please specify the room numbers where radionuclides are used or stored. If there are no room numbers, please state so.
5. Please specify what areas are above or below rooms or areas where radionuclides are used or stored. For example, above is unoccupied attic space and below is unoccupied basement.

Also, since Dr. Ross Summers signed the renewal application, please specify his title. For example, Owner, Chief Executive Officer, etc.

Please send a facsimile (630- 515-1078) of your response to the above within 5 days and refer to control 318184. Please call me at 630-829-9839 if you have any questions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this facsimile and the attached documents will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

From the desk of:


Bill Reichhold

TRANSMISSION VERIFICATION REPORT

TIME : 09/28/2009 09:43
NAME : USNRC RIII
FAX : 6308299782
TEL :
SER.# : 000A7J925774

DATE, TIME	09/28 09:36
FAX NO./NAME	82483493195
DURATION	00:07:29
PAGE(S)	25
RESULT	OK
MODE	STANDARD ECM



UNITED STATES
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LISLE, ILLINOIS 60532-4352

TELEFAX TRANSMITTAL

DATE September 28, 2009

NUMBER OF PAGES 25

SEND TO Wendy Boufford, Chief Nuclear Medicine Technologist

LOCATION Medical Clinic of Northville

FAX NUMBER (248) 349-3195

VERIFY BY CALLING

FROM: Bill Reichhold
(Sender)

TELEPHONE NUMBER (630) 829-9839

FAX NUMBER (630) 515-1078

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MESSAGE See accompanying documents.



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TELEFAX TRANSMITTAL

DATE September 28, 2009

NUMBER OF PAGES 25

SEND TO Wendy Boufford, Chief Nuclear Medicine Technologist

LOCATION Medical Clinic of Northville

FAX NUMBER (248) 349-3195

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The following additional information is needed to review your request. The Nuclear Regulatory Commission (NRC) issued Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses in NUREG-1556, Volume 9, Revision 2, in January 2008, to provide guidance for completing an application to use radionuclides for medical purposes. NUREG-1556, Volume 9, Revision 2, outlines the necessary information needed to complete your renewal application. Your renewal application referenced old documents from 1999, so please use the current guidance as requested in the NUREG - 1556, Volume 9, Revision 2.

Please resubmit your renewal application using Appendix C, " License Application Checklists". See copy of Appendix C enclosed. You may also view a copy of NUREG-1556, Volume 9, Revision 2 at the NRC website at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>

Also, please clarify the title for Ross Summers, M.D.

Please send a facsimile (630- 515-1078) of your response to the above within 7 days and refer to control 318184. Please call me at 630-829-9839 if you have any questions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this facsimile and the attached documents will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

From the desk of:


Bill Reichhold

AMENDMENTS AND RENEWALS TO A LICENSE

changes and additions to the 10 CFR 35.100 and 10 CFR 35.200 medical use area do not require a license amendment and can be made, provided NRC is notified as required by 10 CFR 35.14 within 30 days following the changes, and

- Revising procedures required by 10 CFR 35.610, 35.642, 35.643, and 35.645, when the revision reduces the level of radiation safety.

In case of a medical emergency requiring an expedited license amendment, contact the materials licensing staff at the appropriate NRC Regional Office.

For both renewal and amendment requests, applicants should do the following:

- Use the most recent guidance in preparing an amendment or renewal request,
- Submit in duplicate either an NRC Form 313 or a letter requesting an amendment or renewal, and
- Provide the license number.

APPENDIX C

License Application Checklists

License Application Checklists

This Appendix contains checklists that may be used to assist in organizing an application. It addresses information a medical use licensee needs to provide for authorization to produce PET radioactive drugs for noncommercial transfer to consortium members. See Appendix AA for additional information.

Table C.1, Applicability Table, may be used to determine if particular information must be provided or if "N/A" (not applicable) may be the response to each item that follows. To determine those items to which applicants must respond, "highlight" the columns under the categories of materials requested in Item 5 (e.g., 10 CFR 35.300, 35.400). If any "Y" beside an item is highlighted, applicants must provide detailed information in response to that item. If the letters "N/A" are highlighted, applicants may respond "N/A" on their applications. If any "N" beside an item is highlighted, no information in response is required, but NRC regulations that apply to the given category apply to that type of license. If any "P" beside an item is highlighted, applicants should provide a commitment as described in the section referenced in the body of this document. If any "G" beside an item is highlighted, see subsequent sections for required responses. "APP" indicates that this document contains an appendix that addresses the item.

Table C.1 Applicability Table								
Section #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.5	Unsealed Byproduct Material – Uptake, Dilution, Excretion, Imaging, and Localization Studies	Y						
8.5	Unsealed Byproduct Material – Written Directive Required		Y					
8.5	Manual Brachytherapy			Y				
8.5	Sealed Sources for Diagnosis				Y			
8.5	Teletherapy Units					Y		
8.5	Remote Afterloader Units					Y		
8.5	Gamma Stereotactic Radiosurgery Units					Y		
8.5	Other Medical Uses						Y	
8.6	Sealed Sources and Devices	N	N	Y	Y	Y	Y	
8.7	Discrete Source of Ra-226 (Other than sealed sources)	Y	Y	N	N	N	Y	
8.8	Financial Assurance Determination	Y	Y	Y	Y	Y	Y	
8.9	Purpose(s) for Which Licensed Material Will Be Used	Y	Y	Y	Y	Y	Y	
8.10	Training and Experience	G	G	G	G	G	G	
8.11	Radiation Safety Officer	Y	Y	Y	Y	Y	Y	I, D
8.12	Authorized User(s) (AUs)	Y	Y	Y	Y	Y	Y	D
8.13	Authorized Nuclear Pharmacist (ANP)	Y	Y	N/A	N/A	N/A	Y	D
8.14	Authorized Medical Physicist (AMP)	N/A	N/A	Y*	N/A	Y	Y	D
8.15	Facilities and Equipment	G	G	G	G	G	G	
8.16	Facility Diagram	Y	Y	Y	Y	Y	Y	
8.17	Radiation Monitoring Instruments	Y, P	Y, P	Y, P	Y, P	Y, P	Y, P	K
8.18	Dose Calibrator and Other Equipment	P	P	N/A	N/A	N/A	P	
8.19	Therapy Unit - Calibration and Use	N/A	N/A	N	N/A	Y	N	
8.20	Other Equipment and Facilities	N	N	N	N	Y	N	
8.21	Radiation Protection Program	G	G	G	G	G	G	
8.22	Safety Procedures and Instructions	N/A	N/A	N/A	N/A	Y	N/A	
8.23	Occupational Dose	P	P	P	P	P	P	M

Table C.1 Applicability Table

Section #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.24	Area Surveys	P	P	P	P	P	P	R
8.25	Safe Use of Unsealed Licensed Material	P	P	N/A	N/A	N/A	P	T
8.26	Spill/Contamination Procedures	P	P	P	N/A	N/A	P	N
8.27	Service of Therapy Devices Containing Sealed Sources	N/A	N/A	N/A	N/A	Y	Y	
8.28	Minimization of Contamination	N	N	N	N	N	N	
8.29	Waste Management	P	P	P	P	P	P	W
8.30	Fees	Y	Y	Y	Y	Y	Y	
8.31	Certification	Y	Y	Y	Y	Y	Y	
8.32	Safety Instruction for Individuals in Restricted Areas	N	N	N	N	N	N	J
8.33	Public Dose	N	N	N	N	N	N	
8.34	Opening Packages	N	N	N	N	N	N	
8.35	Written Directive Procedures	N/A	N	N	N/A	N	N	S
8.36	Release of Patients or Human Research Subjects	N	N	N	N/A	N/A	N	U
8.37	Mobile Medical Service	N	N	N	N	N	N	V
8.38	Audit Program	N	N	N	N	N	N	L
8.39	Operating and Emergency Procedures	N	N	N	N	N	N	N
8.40	Material Receipt and Accountability	N	N	N	N	N	N	
8.41	Ordering and Receiving	N	N	N	N	N	N	O
8.42	Sealed Source Inventory	N	N	N	N	N	N	
8.43	Records of Dosages and Use of Brachytherapy Source	N	N	N	N	N	N	
8.44	Recordkeeping	N	N	N	N	N	N	X
8.45	Reporting	N	N	N	N	N	N	Y
8.46	Leak Tests	N	N	N	N	N	N	Q
8.47	Safety Procedures for Treatments when Patients are Hospitalized	N/A	N	N	N/A	N**	N	
8.48	Transportation	N	N	N	N	N	N	Z

* Y beside item 8.13 for use under 35.400 applies to Sr-90 only.

** N/A for teletherapy and gamma stereotactic radiosurgery outpatient treatments.

APPENDIX C

Table C.2 outlines the detailed responses that may be made to Items 5 and 6 on Form 313 for the type of radioactive material requested and the purposes for which it will be used. For example, if the applicant is seeking a license for unsealed byproduct material under 10 CFR 35.100 or 35.200, then the applicant should check the "yes" column next to 10 CFR 35.100 and 35.200 in Table C.2. The table then indicates appropriate responses for that type of use. An applicant may copy the checklist and include it in the license application.

The applicant should review the guidance in Section 5.2 and mark security-related information appropriately.

Note: The NRC now has regulatory authority for accelerator-produced radioactive material and discrete sources of Ra-226, as a result of the EPAct. Uses of these materials are added to Table C.2.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

<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
	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
	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).
	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

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

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

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

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	<i>In vitro</i> 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.
	Other	Form or Manufacturer/Model No. _____	___ millicuries	Purpose of use _____

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.

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 7: Radiation Safety Officer Name:	<i>For an individual previously identified as an RSO on an NRC or Agreement State license or permit:</i>	<input type="checkbox"/>
	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.	
	<i>For an individual qualifying under 10 CFR 35.57(a)(3):</i>	<input type="checkbox"/>
	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 EPA Act; • the RSO for the medical uses of these materials before or during the effective period of NRC's waiver of August 31, 2005. 	
	<i>For an individual qualifying under 10 CFR 35.50(a):</i>	<input type="checkbox"/>
	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	
	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	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>

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/miaiu/med-use-toolkit.html>.

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
	<i>For an individual qualifying under 10 CFR 35.50(b):</i> 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. 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 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. AND	<input type="checkbox"/>
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>
	<i>For an individual qualifying under 10 CFR 35.50(c)(1):</i> Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized ¹¹ 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. 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"/>

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-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

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

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"/>

APPENDIX C

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 7: Authorized Users for medical uses:</p> <p>Name(s), (including license number authorizing practice of medicine, podiatry, or dentistry if not provided previously or in attachment); Requested uses for each individual</p>	<p><i>For an individual previously identified as an AU 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 physician, dentist, or podiatrist was specifically named as an AU for the uses requested.</p>	<input type="checkbox"/>
	<p><i>For an AU requesting authorization for an additional medical use:</i></p> <p>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)).</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>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)).</p>	
	<p><i>For an individual qualifying under 10 CFR 35.57(b)(3):</i></p> <p>Documentation that the physician, podiatrist, or dentist:</p> <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, 2005; and • used these materials for the same medical uses requested. 	<input type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is board-certified:</i></p> <p>Copy of the certification(s) by a specialty board(s) whose certification process has been recognized¹² by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>

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/mia/med-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

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

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"/>

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

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"/>
<p>Item 7: Authorized Nuclear Pharmacists</p> <p>Name(s) and license to practice pharmacy:</p>	<p><i>For an individual previously identified as an ANP 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 ANP.</p>	<input type="checkbox"/>
	<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"/>

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

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><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/miauw/med-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

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> <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> <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> <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/nuat/med-use-toolkit.html>

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

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

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 type="checkbox"/>
	<ul style="list-style-type: none"> • Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly. 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Drawings should be to scale, indicating the scale used. 	<input type="checkbox"/>