Official Use Only - Security-Related Information

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

JUN 8 2011

Dennis R. Szmania, M.S.
Radiation Safety Officer
Munson Medical Center
1105 Sixth Street
Traverse City, MI 49684

Dear Mr. Szmania:

Enclosed is Amendment No. 41 renewing your NRC Material License No. 21-08317-01 in accordance with your request. Please note that the major changes made to your license are printed in **bold** font.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

This amendment renews your license for a ten year period and your license will not expire until June 30, 2021.

However, there were several inconsistencies in your renewal application rendering it partially incomplete. Therefore, in order to ensure your license is complete, at this time I temporarily continued authorization for all documents in License Condition No. 20, also called the "tie-down condition."

In order to complete your renewed license, to delete "old" documents from Condition 20 and simplify compliance with and understanding of your license, please respond in writing to the following issues within 60 days of the date of this letter. If necessary, please contact me at (630) 829-9841 to arrange an alternate response date. My fax number is (630) 515-1078.

Please address your response to my attention as "additional information to control number 574084," ensure that it is signed by a senior management official and currently dated. These steps will greatly facilitate proper handling in our offices so that we may then continue our review.

The following discrepancies and issues were noted with respect to your application dated November 20, 2010, and letter dated November 10, 2010:

1. **Your application was silent with respect to continuing authorization for Dr. Linnea Priest. Therefore I continued authorization for her at this time. If you**

wish to have her deleted from the license please make the appropriate notification to us, in accordance with 10 CFR 35.13 and 35.14.

As I did not know if this was an oversight or intentional omission, please be reminded that absence of a commitment in your correspondence to us does not constitute an explicit instruction, i.e., we can only act upon specifically stated requests.

Please also be reminded that licensees are required to notify us within 30 days when an Authorized User permanently discontinues duties under the license, in accordance with 10 CFR 35.13 and 35.14.

2. Your application did not include a shielding evaluation for Positron Emission Tomography (PET) activities. Therefore I excluded authorization for PET from the license in Subitem Nos. 6.B. and 9.B.

Please be advised that, prior to performing PET imaging, you will need to amend your NRC license to include appropriate shielding information for your facility. In your amendment request you should include a copy of your facility diagrams and shielding calculations that show compliance with 10 CFR Part 20.1101, "Radiation Protection programs," 20.1301 and 20.1302, "Radiation Dose Limits for Individual Members of the Public," and 20.1501, "Surveys and Monitoring."

For a better idea about what we would need, please also see the information below and in the attached enclosure concerning shielding calculations for your HDR program.

3. During my review of your renewal application dated November 20, 2010, and letter dated November 10, 2010, I noted that your renewal request was only partially prepared in accordance with NUREG 1556, Vol. 9, Rev. 2 , although the abstract in NUREG 1556, Vol. 9, Rev.2, states, in part, "NUREG 1556, Vol. 9, Rev.2, "Consolidated Guidance about Materials Licenses: Program –Specific Guidance about Medical Use License," is the third version of the ninth program-specific guidance document developed for the new process; it is intended for use by applicants, licensees, and NRC staff and will also be available to Agreement States."

Full use of this document for all of your licensing correspondence will greatly reduce your regulatory burden, simplify your license and enhance safety by providing for more comprehensive, updated safety procedures and a complete renewal application.

Please see the enclosed guidance for additional information and advice regarding renewal of licenses.

4. Many of the details and commitments needed to continue the HDR authorization were missing from the application, including diagrams that contain the

information we need, procedures required by 10 CFR 35.610 and 35.643, detailed shielding calculations to demonstrate compliance with the radiation limits in 10 CFR Part 20, etc.

Please clarify whether there have been any changes in the design, shielding, function, or functional identity for each of the locations and areas of use authorized by this license, especially with respect to the high dose rate remote (HDR) afterloading brachytherapy rooms and all of the surrounding adjacent areas, including the spaces above and below each HDR room.

Please also see the enclosed guidance on HDR licensing for further advice and requests for information regarding the HDR program.

5. Please clarify whether "Clark D. Phelps, M.D." and "C. David Phelps, Jr., M.D." are the same person. Both are listed on the license for the use of materials in 10 CFR 35.100, 35.200 and 35.300 but "Clark D. Phelps, M.D." is also authorized for materials in 10 CFR 35.400. If one of these authorizations is a duplicate, please advise us as to which one should remain and which should be deleted. If not a duplicate, please so state.

6. I adjusted the wording for Dr. Stilwill's authorization to use xenon-133 only. However, please note that NRC is no longer authorizing physician users for partial use only in 10 CFR 35.200 via exclusions or limitations, whether or not the restriction is due to lack of qualification with 10 CFR 35.290.

7. I retained the possession limit in Subitem No. 8.C. for iodine-131, as it appeared on Amendment No. 40. The application dated November 20, 2010, did not contain a possession limit for 35.300, including iodine-131.

8. I noted that your Authorized Medical Physicists (AMPs) are authorized for use of a strontium-90 ophthalmic applicator sealed source. However, no manufacturer's name and model number or possession limit for this source was submitted for this license and it was not included in Subitem No. 7.D. on the license prior to this renewal either.

In accordance with 10 CFR 35.49 and 35.400, we must list all sealed sources for medical users on the license by manufacturers' names and model numbers, which we verify in the NRC's Sealed Source and Device Registry (SSDR), and possession limits.

Please provide the manufacturer's name, model number and possession limit for a strontium-90 ophthalmic applicator sealed source, if one is possessed under this license. If it is not, please request that we delete this authorization for your AMP's.

9. It is my understanding that the vendor providing intravascular brachytherapy sources and devices under Subitem Nos. 6 through 9 E., inclusive, has either gone out of business or changed from the vendor listed in your application.

Please respond by clarifying and, if appropriate, requesting correction of this information. If the vendor has changed, please advise us of the SSDR certification number held by the vendor, the name of the vendor and the model number of the source, which corroborates the vendor's identity and authorization.

10. At this time I deleted Condition No. 14, as it appeared on Amendment No. 40, and replaced it with a new line item authorization in Subitem Nos. 6 through 9 G, inclusive, which is the more correct format for depleted uranium shielding. I also added Condition No. 19, which is a standard condition for this type of license that appeared to be missing prior to this renewal.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system.

Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf and the link for frequently asked questions regarding protection of security related sensitive information may be located at: http://www.nrc.gov/reading-rm/sensitive-info/faq.html.

A copy of this letter 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).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 21-08317-01
Docket No. 030-02074

Enclosures:

1. Amendment No. 41
2. Additional Guidance for Renewing an NRC License
3. Tables C.2 and C.3 from NUREG 1556, Vol. 9, Rev. 2, "marked-up"
4. Additional Guidance for Licensing HDR

Additional Guidance for Renewing an NRC License

Please note that using the NUREG 1556 series documents will help ensure that your licensing correspondence is prepared more completely and in a less burdensome manner.

In preparing future licensing correspondence please focus on providing the information requested in Appendix C to NUREG 1556, Volume 6. Follow the "Suggested Format.." provided in this Appendix and use the suggested responses and model procedure/appendix references whenever possible, appending descriptive information as appropriate. It is strongly advisable to read the corresponding text in the front of each NUREG to ensure a complete understanding of the commitments that you make.

Please do not submit resumes, curricula vitae, college transcripts, any personal, proprietary information, blueprint diagrams, or copies of blueprint diagram and any extraneous, prescriptive information and procedures, unless we specifically request it, which is unlikely.

If you must deviate from a model procedure or suggested response, it may be possible to simply indicate what the deviation is and still use the model procedure/ suggested response as a "basic" commitment. Descriptive information may be "recycled" from previous documents only so long as it is current, complete information equivalent to the model procedure (as appropriate) and does not contain extraneous material. This advice is particularly relevant to your high dose rate (HDR) remote afterloading brachytherapy program and the significant quantity of procedures, diagrams, commitments, etc. that we need to continue this authorization.

It is in your best interests to only provide those commitments, statements, representations and procedures, in a clear and explicit manner, that we require to issue your license. These documents will form the basis for the license in the last condition of the license, called the "tie-down" condition.

You will realize the benefit of a reduced regulatory burden while enhancing safety and maintaining compliance and efficiency if you establish your license in this manner.

In fact, the easiest way to prepare a renewal, for example, is to take a copy of NUREG 1556, Vol. 9, Rev. 2, Appendix C, especially Tables C.2 and C.3 to your copy machine and copy it out directly. Read the text in the front of the NUREG that corresponds to each section and simply fill in the checkmarks and blanks on the copied checklist, thereby making your license commitments.

Please do not re-type the checklist as errors and omissions may be introduced.. As you need to append certain information or provide an alternative procedure, please be sure to incorporate the information in the NUREG, at a minimum, to ensure completeness.

Please see the attached marked-up copy of Tables C.2 and C.3, NUREG 1556, Vol. 9, Rev. 2, Appendix C. A hard copy of this document should have been sent to you already. It is also available on our website at:

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/

I indicated, via manual markings on the copy, where there are items that appear to be missing or incomplete.

If you wish, you may contact me at the telephone number above to discuss further on how best to go about generating the resubmittal of your renewal application. We would be happy to assist you as we are able.

Additional Guidance for Licensing HDR

I understand your HDR program is pre-existing but in order to continue it into the renewed license and delete the "old" documents in your "tie-down" condition, all elements of the HDR program must be resubmitted in the renewal. Most of this information was missing in your renewal application.

As your HDR diagrams consisted of copies of blueprints, which we strongly discourage submitting (blueprints show a lot of information we do not need and very little of what we do need), I was unable to gain a full understanding of your HDR facilities.

Please provide revised diagrams (simple, hand-drawn diagrams are good) that clearly show the HDR treatment room and the location and functional identity of all contiguous rooms, areas and/or spaces surrounding it, especially the areas above and below the room. Some of this information was included in your application's attachments but some of it was not, or was difficult to decipher.

Your diagrams should be either drawn to scale or actual dimensions given; room numbers provided; show the direction of north; the functional identity of each room, space or area; the elevation/grade clearly described; indicate where you anticipate the patient to be located; the composition and thickness of each barrier in each direction; whether each area is restricted or unrestricted; and the distances from the source to the barriers/walls in all directions.

Please indicate clearly whether persons may gain access to an area above or below the proposed HDR treatment room. If this area may be occupied during treatment, please either submit exposure rate calculations to demonstrate that the doses received will not exceed the limits in 10 CFR 20.1301 or describe the administrative controls (training, posting, surveillance, lock-out, etc.) that will be put in place to prevent occupation during HDR treatment.

Please provide revised, simple and complete shielding calculations, showing your work, detailed assumptions, defined terms, equations, constants, substitutions, parameters, and diagrams to demonstrate that radiation levels in all adjacent areas, including above and below the room, will not exceed levels in 10 CFR 20.1301.

Please include your calculations for the barrier transmission factors and indicate whether poured concrete is the only barrier employed.

It appeared to me that the calculations already submitted were based upon assumptions involving a linear accelerator. Please confirm that your shielding calculations, as revised, will be based only upon the HDR device.

Please indicate the thicknesses and composition of the thinnest wall/barrier(s) for the HDR room.

Please indicate the elevation of your proposed facility.

Include the following details in your submission:

a. **expected radiation levels for each adjacent area, under the most adverse and typical source orientations and maximum source activity;**

b. **all parameters used to perform the calculations, including: distance to each area of concern, the type and thickness of material(s) used as shields, and the transmission factor of the shields;**

c. **the maximum "beam-on time" per hour and per week; the number of patients/treatments (i.e., workload) per week; and occupancy factors used for all adjacent areas; and**

d. **demonstrate by calculation the dose received by the individual member of the public likely to receive the highest dose from HDR procedures when present in unrestricted area (in mrem/hr and mrem/yr). These calculations must demonstrate that the limits specified in 10 CFR 20.1301(a) will not be exceeded.**

e. **Please include in your shielding calculations sufficient information, in a simple, readily understandable format using traditional units (preferred) to permit us to independently evaluate the adequacy of shielding in your proposed room.**

It may be helpful for you to refer to 10 CFR 35.600-35.657 (Subpart H) and corresponding sections in NUREG 1556, Vol. 9, Rev. 2 for assistance.

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
Item 7: Radiation Safety Officer Name:	*For an individual previously identified as an RSO on an NRC or Agreement State license or permit:* 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.	☐
incumbent D. Szumski M.S.	*For an individual qualifying under 10 CFR 35.57(a)(3):* Documentation that the individual was: • 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.	☐
	For an individual qualifying under 10 CFR 35.50(a): 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**	☐
	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.	☐

ok

[10]The 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
	For an individual qualifying under 10 CFR 35.50(b):	
	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	
	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	
	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	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
	For an individual qualifying under 10 CFR 35.50(c)(1):	
	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	
	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	

ok

[11]The 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
	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.	☐
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
	For an individual qualifying under 10 CFR 35.50(c)(2):	
	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.	☐
	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	
	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.	☐
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐

OK

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
Item 7: Authorized Users for medical uses:	*For an individual previously identified as an AU on an NRC or Agreement State license or permit:*	
Name(s), (including license number authorizing practice of medicine, podiatry, or dentistry if not provided previously or in attachment); Requested uses for each individual	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.	☐
	For an AU requesting authorization for an additional medical use:	
	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	
	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)).	
	For an individual qualifying under 10 CFR 35.57(b)(3):	
	Documentation that the physician, podiatrist, or dentist: • 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.	☐
	For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is board-certified:	
	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	

Dr. Priest? Dr. Phelps? Dr. Stilwell? see cover letter

[12]The 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
	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; **AND**	☐
	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; **AND**	☐
	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; **AND**	☐
	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; **AND**	☐
	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; **AND**	☐
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐

OK

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
	For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is not board-certified:	
	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.	☐
	AND	
	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.	☐
	AND	
	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.	☐
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
Item 7: Authorized Nuclear Pharmacists	*For an individual previously identified as an ANP on an NRC or Agreement State license or permit:*	
Name(s) and license to practice pharmacy:	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.	☐
	For an individual qualifying under 10 CFR 35.57(a)(3):	
	Documentation that the nuclear pharmacist: • 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.	☐

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
	For an individual qualifying under 10 CFR 35.55(a):	
	Copy of the certification(s) of the specialty board whose certification process has been recognized[13] under 10 CFR 35.55(a).	☐
	AND	
	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.	☐
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
	For an individual qualifying under 10 CFR 35.55(b):	
	Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience.	☐
	AND	
	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.	☐
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
Item 7: Authorized Medical Physicists Name(s): incumbents	*For an individual previously identified as an AMP on an NRC or Agreement State license or permit:*	
	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.	☐

[13]The 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
	For an individual qualifying under 10 CFR 35.57(a)(3):	
	Documentation that the medical physicist: • 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.	☐
	For an individual qualifying under 10 CFR 35.51(a):	
	Copy of the certification(s) of the specialty board(s) whose certification process has been recognized[14] under 10 CFR 35.51(a). **AND**	☐
	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. **AND**	☐
	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. **AND**	☐
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
	For an individual qualifying under 10 CFR 35.51(b):	
	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. **AND**	☐

ok

[14]The 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
	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.	☐
	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.	☐
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
Item 7: Authorized User for nonmedical uses	*Note:* 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.	
	For an individual previously authorized for nonmedical use on an NRC or Agreement State license or permit:	
Name(s): Requested types, quantities, and nonmedical uses for each individual	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.	☐
	For individuals qualifying under 10 CFR 30.33(a)(3):	
	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.	☐
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:	☐
	• 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.	☐

Deficient

Resubmit in entirety for all authorizations Nuclear Medicine Radiation Therapy 35.400 & HDR

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
	• Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, location of direct transfer delivery tubes from a PET radionuclide/radioactive drug production facility or production area of PET radioactive drugs under 10 CFR 30.32(j), and areas where higher energy gamma- emitting radionuclides (e.g., PET radionuclides) are used;	☐
	• Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms, indicating whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and	☐
	• Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including 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).	☐
	In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.	☐
Item 9: Radiation Monitoring Instruments	A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."	☑
	AND/OR	
	A statement that: "We have developed and will implement and maintain written 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.	☑
	AND	
missing	A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."	☐
Item 9: Dose Calibrator and Other Dosage Measuring Equipment	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	☑

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
	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), • 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." **OR**	☐
	• We are providing a description of the dosage measurement equipment, the nationally recognized calibration standard (or manufacturer's calibration instructions), and dosage measurement procedures.	☐
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. Please submit	☐
Item 9: Other Equipment and Facilities	Guidance in Section 5.2 was reviewed and security-related information provided is marked accordingly.	☐
	Attached is a description, identified as Attachment 9.4, of additional facilities and equipment.	☐
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	☐
excluded	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.	☐
	For ~~teletherapy, GSR, and~~ remote afterloader facilities, we are providing 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 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.	☐

deficient

deficient

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
Item 10: Safety Procedures and Instructions	Attached are procedures required by 10 CFR 35.610. missing	☐
deficient	Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	☐
Item 10: Occupational Dose	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.' " **OR**	☐ ok
	A description of an alternative method for demonstrating compliance with the referenced regulations.	☐ /
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."	☐ ok
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."	☐ ok
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."	☐ ok
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	Name of the proposed employee and types of activities requested: _____ **AND**	☐ ok
	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.	☐
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

(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
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."	☐ ok.
	Attached is a description of the radioactive waste incinerator facility and related portions of the Radiation Safety Program (10 CFR 20.2004).	☐
	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.	☐