Roldan, Lizette

From: Roldan, Lizette
Sent: Friday, July 01, 2011 10:27 AM
To: 'jhb12345@gmail.com'
Subject: REQUEST FOR ADDITIONAL INFORMATION REGARDING CONTROL 575037
Attachments: sr1556v9r2-final.pdf; nrc313a(aud).pdf

License No.: 25-29088-01
Docket No.: 030-33800
Control No.: 574992

Dear Dr. Brewer:

This is in reference to your application dated April 28, 2011 requesting to renew Nuclear Regulatory Commission License No. 25-29088-01. In order to continue our review, we need the following additional information:

1. Please resubmit your renewal application using Chapter 8 and Appendix C of the attached NUREG-1556 Volume 9, Rev. 2. The NUREG-1556 series supersedes the Regulatory Guide 10.8 Revision 2 you refer to in your renewal application.

2. You have requested to be authorized for 35.11 – In vitro studies. The authorization you are requesting is under 10 CFR 31.11 not 10 CFR part 35. In addition, you did not propose an authorized user for this request. Please propose an individual or individuals that will conduct the in vitro studies under 31.11.

3. You have proposed multiple authorized users (AU), with the exception of Dr. Alan Wray, please provide either an NRC license number or copy of an Agreement State license where the proposed individuals are listed as an AU for the same types of use you are requesting. If a proposed individual is not listed on an NRC or Agreement State license, please fill out the attached NRC Form 313A(AUD) to show the individual is qualified by training and experience, and has a preceptor statement.

We will continue our review upon receipt of this information. Please reply to my attention and refer to Mail Control No. 574992. If you reply via email, please attach a signed letter in PDF format or you may fax your response to (817) 860-8263. If we do not receive a reply from you by August 31, 2011, we will assume that you do not wish to pursue your application.

If you have any technical questions regarding this deficiency letter, please call me at (817) 276-6596.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material;** then **Regulations, Guidance, and Communications.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Sincerely,

Lizette Roldán-Otero, Ph.D.
Health Physicist
Nuclear Regulatory Commission
612 E. Lamar Blvd., Suite 400
Arlington, TX 76011
Office: 817-276-6596
Fax: 817-860-8263

Medical Physics Services, LLC

James H. Brewer, Ph.D. | 15 Isaiah Tr. | Belgrade, MT 59714 | (406) 581-9867 | (866) 215-5014 FAX

Lizette Roldan-Otero, Ph.D.
Health Physicist
Nuclear Regulatory Commission
612 E. Lamar Blvd. Suite 400
Arlington, TX 76011

Dear Ms. Roldan-Otero

I respectfully submit a revised application for renewal of USNRC license # 25-29088-01. This revised application was prepared following the instructions in NUREG-1556 Volume 9, Rev. 2.

Please note that the request for authorization for 35.11 – In vitro studies has been removed.

The individuals named as authorized users are on the existing license # 25-29088-01 or are listed on USNRC license # 11-27404-01.

The form 313a, signed by the administrator and ATT 9.1.1 (department layout) were previously sent as part of the original renewal application.

I hope that the information that accompanies this letter is sufficient to allow the renewal application to go forward.

Best regards

James H. Brewer

James H. Brewer, Ph.D., DABR
Medical Physicist

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

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

❑ Yes ☒ 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).
	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.

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: James H. Brewer	*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.Previous License # USNRC No. 25-29088-01	☒
	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 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 speciality board whose certification process has been recognized[10] by the NRC or an Agreement State under 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.	☐

[10]The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page 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 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**	❐

[11]The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page 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 authorized user, authorized medical physicist, or authorized nuclear pharmacist 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.	❒

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 Name(s), (including license number authorizing practice of medicine, podiatry or dentistry if not provided previously or in attachment) and requested Uses for Each Individual	*For an individual previously identified as an AU 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 physician, dentist, or podiatrist was specifically named as an AU for the uses requested. See ATT. 7.1.0	
	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. (For example, 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. (For example, 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 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**	

[12]The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page 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 administrations of 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, has 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.	❒

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 has 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 NA Name(s) and license to practice pharmacy:	*For an individual previously identified as an ANP 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 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 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 has 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 has 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 NA Name(s):	*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.	☐
	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 during the effective period of	☐

[13]The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page 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
	• 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) has 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**	☐
	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 has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved. **AND**	☐

[14]The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page 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
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
Item 7: Authorized User for non-medical uses NA Name(s): Requested types, quantities, and non-medical uses for each individual	***Note:*** For purposes of this section of the table, the term authorized user is used to mean individuals authorized for 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:	
	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: Previously submitted	☒
	• 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.	☒
	• 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 identify 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).	☐

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 applic provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	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. See ATT 9.1.0 **AND**	☒
	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 NA	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	☐
	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 NA	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.	☐

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 9: Other Equipment and Facilities NA	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.	☐
	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) are 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.	☐
Item 10. Safety Procedures and Instructions	Attached are procedures required by 10 CFR 35.610.	☐
	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 Licensees."	☒
	OR	
	A description of an alternative method for demonstrating compliance with the referenced regulations.	☐

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: 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."	☒
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."	☒
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."	☒
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources NA	Name of the proposed employee and types of activities requested: _____ **AND**	☐
	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
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 to 10 CFR Part 20, Subpart K, and 10 CFR 35.92."	☒
	Attached is a description of the radioactive waste incinerator facility and 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.	☐

ATT 7.1.0 Authorized Users

Authorized Users on USNRC License # 25-29088-01	Material and Use
William R. Austin, M.D.	10 CFR 35.100, 35.200
Tyler H. Gill M.D.	10 CFR 35.100, 35.200.

The individuals identified on USNRC License #11-27404-01 Amendment No. 05 corrected copy (copy follows) may provide services to the licensee from time to time. We request that they be authorized users on License #25-29088-01 for the same Materials and Use as identified on #11-27404-01.

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Amendment No. 05

MATERIALS LICENSE

CORRECTED COPY

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with letter dated November 20, 2007
1. Danny L. Davis, CNMT dba Teton Nuclear Medicine Service, L.L.C. 2. 2001 South Woodruff Avenue, Suite 20 Idaho Falls, Idaho 83404	3. License number 11-27404-01 is amended in its entirety to read as follows: 4. Expiration date January 31, 2012 5. Docket No. 030-32428 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed

9. Authorized use

A. Medical use described in 10 CFR 35.100.
B. Medical use described in 10 CFR 35.200.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at Teton Nuclear Medicine Service, 2001 South Woodruff, Suite 20, Idaho Falls, Idaho.

11. The Radiation Safety Officer for this license is Danny L. Davis, CNMT.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
11-27404-01

Docket or Reference Number
030-32428

Amendment No. 05
CORRECTED COPY

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
John D. Chambers, Jr., M.D.	35.200
James Neeley, M.D.	35.100 and 35.200
Marc Cardinal, M.D.	35.100 and 35.200
Alan Wray, M.D.	35.100 and 35.200
James P. Edlin, M.D.	35.100 and 35.200
John J. Strobel, M.D.	35.100 and 35.200
James B. Harris, M.D.	35.100 and 35.200
James F. Schmutz, M.D.	35.100 and 35.200
Michael C. Biddulph, M.D.	35.100 and 35.200
David R. Warden III, M.D.	35.100 and 35.200
Steven D. Smith, M.D.	35.100 and 35.200
R. Douglas Greally, M.D.	35.100 and 35.200
Thomas J. Maley, M.D.	35.200

13. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 11-27404-01
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	Amendment No. 05 CORRECTED COPY

14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated October 18, 2001
    B. Letter dated November 20, 2007

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: January 3, 2008

By: Rachel S. Browder

Rachel S. Browder, Health Physicist
Nuclear Materials Licensing Branch
Region IV
Arlington, Texas 76011