



DEFENSE HEALTH AGENCY
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

MAR - 5 2020

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region 1
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2713

Re: Defense Health Agency Application Request for Amendment of license number: 45-35423-01, docket number: 030-39046


Ladies and Gentlemen:

Further to our amendment request letter dated 24 Jan 2020, Defense Health Agency (DHA) requests the following additional changes to its license:

- A. Item 12(O) should be changed to:
Major Brett Mattison for 10CFR35.100, 10CFR35.200, 10CFR35.300 uses.
Note: ARSO Mattison has been promoted to Major.
- B. Item 12(T) should be changed to:
SSgt Ramiro A. Cruz for 10CFR35.100, 10CFR35.200, 10CFR35.300 uses [Enclosure 5].
Note: SSgt Cruz replaces TSgt Natalie Shimasaki-Alenepi as ARSO.
- C. Item 12(ZE) should be changed to:
Mr. William House for 10CFR35.100, 10CFR35.200 uses [Enclosure 6].
Note: Mr. House replaces Commander Kristin S. Wehrung as ARSO.

If you have any questions regarding this matter, the point of contact is Mr. Shabbir Shivji at shabbir.shivji.civ@mail.mil or (703) 681-5698.

Sincerely,


for **RONALD J. PLACE**
LTG, MC, USA
Director

Enclosures:
As stated

cc:
DHA Radiation Safety Committee

ENCLOSURE 5



**RADIATION SAFETY OFFICER TRAINING
AND EXPERIENCE AND PRECEPTOR ATTESTATION**
[10 CFR 35.50]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 06/30/2019

Name of Proposed Radiation Safety Officer

Ramiro A. Cruz

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply):*

- 35.100
 35.200
 35.300
 35.400
 35.500
 35.600 (remote afterloader)
 35.600 (teletherapy)
 35.600 (gamma stereotactic radiosurgery)
 35.1000 (_____)

PART I – TRAINING AND EXPERIENCE
(Select one of the four methods below)

*Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

1. Board Certification

- a. Provide a copy of the board certification.
- b. Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Skip to and complete Part II Preceptor Attestation.

OR

2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Uses Checked Above

- a. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO is sought.
- b. Skip to and complete Part II Preceptor Attestation.

OR

3. Structured Educational Program for Proposed Radiation Safety Officer

a. Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Medical Education and Training Campus (METC) Fort Sam Houston, TX	222	04 Jan 17 - 22 May 17
Radiation protection	Medical Education and Training Campus (METC) Fort Sam Houston, TX	141	04 Jan 17 - 22 May 17
Mathematics pertaining to the use and measurement of radioactivity	Medical Education and Training Campus (METC) Fort Sam Houston, TX	77	04 Jan 17 - 22 May 17
Radiation biology	Medical Education and Training Campus (METC) Fort Sam Houston, TX	28	04 Jan 17 - 22 May 17
Radiation dosimetry	Medical Education and Training Campus (METC) Fort Sam Houston, TX	30	04 Jan 17 - 22 May 17
Total Hours of Training:		498	

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys	88 MDG Wright-Patterson AFB, OH-04682-04/11AFP	06 Feb 18 - 15 Mar 19
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides	88 MDG Wright-Patterson AFB, OH-04682-04/11AFP	06 Feb 18 - 15 Mar 19
Securing and controlling byproduct material	88 MDG Wright-Patterson AFB, OH-04682-04/11AFP	06 Feb 18 - 15 Mar 19
Using administrative controls to avoid mistakes in administration of byproduct material	88 MDG Wright-Patterson AFB, OH-04682-04/11AFP	06 Feb 18 - 15 Mar 19
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	88 MDG Wright-Patterson AFB, OH-04682-04/11AFP	06 Feb 18 - 15 Mar 19
Using emergency procedures to control byproduct material	88 MDG Wright-Patterson AFB, OH-04682-04/11AFP	06 Feb 18 - 15 Mar 19
Disposing of byproduct material	88 MDG Wright-Patterson AFB, OH-04682-04/11AFP	06 Feb 18 - 15 Mar 19
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ <u>35.100, 35.200, 35.300</u>	88 MDG Wright-Patterson AFB, OH-04682-04/11AFP	06 Feb 18 - 15 Mar 19

* Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer
Joshua Hubbell, Maj, MRSO	OH-04682-04/11 APP
This license authorizes the following medical uses:	
<input checked="" type="checkbox"/> 35.100	<input checked="" type="checkbox"/> 35.200
<input checked="" type="checkbox"/> 35.300	<input type="checkbox"/> 35.400
<input type="checkbox"/> 35.500	<input type="checkbox"/> 35.600 (remote afterloader)
<input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)	<input type="checkbox"/> 35.600 (teletherapy)
	<input type="checkbox"/> 35.1000 ()

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses	Joshua L. Hubbell Wright-Patterson AFB Medical Center	06 Feb 18 - 15 Mar 19
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	Joshua L. Hubbell Wright-Patterson AFB Medical Center	06 Feb 18 - 15 Mar 19
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	N/A	N/A
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses	N/A	N/A
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses	N/A	N/A
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses	N/A	N/A
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):	N/A	N/A

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual *if training was provided by supervising RSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)* License/Permit Number listing supervising individual

Joshua Hubbell, Maj, MRSO OH-04682-04/11 AFP

License/Permit lists supervising individual as:

- Radiation Safety Officer Authorized User Authorized Nuclear Pharmacist
- Authorized Medical Physicist

Authorized as RSO, AU, ANP, or AMP for the following medical uses:

- 35.100 35.200 35.300 35.400
- 35.500 35.600 (remote afterloader) 35.600 (teletherapy)
- 35.600 (gamma stereotactic radiosurgery) 35.1000 ()

d. Skip to and complete Part II Preceptor Attestation.

OR

4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on the licensee's license

- a. Provide license number.
- b. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Skip to and complete Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Check one of the following:

1. Board Certification

I attest that _____ has satisfactorily completed the requirements in

Name of Proposed Radiation Safety Officer

10 CFR 35.50(a)(1)(i) and (a)(1)(ii); or 35.50 (a)(2)(i) and (a)(2)(ii); or 35.50(c)(1).

OR

2. Structured Educational Program for Proposed Radiation Safety Officers

I attest that Ramiro A. Cruz RT(R) (CNMT) has satisfactorily completed a structural educational

Name of Proposed Radiation Safety Officer

program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

OR

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

Check one of the following:

3. Additional Authorization as Radiation Safety Officer

I attest that _____ is an
Name of Proposed Radiation Safety Officer

- Authorized User Authorized Nuclear Pharmacist
- Authorized Medical Physicist

identified on the Licensee's license and has experience with the radiation safety aspects of similar type of use of byproduct material for which the individual has Radiation Safety Officer responsibilities

AND

Second Section

Complete for all (check all that apply):

I attest that Ramiro A. Cruz RT(R) (CNMT) has training in the radiation safety, regulatory issues, and
Name of Proposed Radiation Safety Officer

emergency procedures for the following types of use:

- 35.100
- 35.200
- 35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required
- 35.300 oral administration of greater than 33 millicuries of sodium iodide I-131
- 35.300 parenteral administration of any beta-emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- 35.300 parenteral administration of any other radionuclide for which a written directive is required
- 35.400
- 35.500
- 35.600 remote afterloader units
- 35.600 teletherapy units
- 35.600 gamma stereotactic radiosurgery units
- 35.1000 emerging technologies, including:

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

AND

**Third Section
Complete for ALL**

I attest that Ramiro A. Cruz RT(R) (CNMT) has achieved a level of radiation safety knowledge
Name of Proposed Radiation Safety Officer
sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

**Fourth Section
Complete the following for Preceptor Attestation and signature**

I am the Radiation Safety Officer for 88 MDG Wright-Patterson AFB, OH
Name of Facility

License/Permit Number: OH-04682-04/11 AFP

Name of Preceptor

Joshua Hubbell, Maj, MRSO

Signature



Telephone Number

(937) 257-9458

Date

04/18/2019

ENCLOSURE 6

Department of Veterans Affairs

Page 1 of 4 pages	MATERIALS PERMIT	Amendment No. 77
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In accordance with VHA Directive 1105 and reliance on statements made by the applicant, permission is hereby granted to receive, possess, transfer, and store radioactive materials listed below, and to use this material for the purpose and at the places listed below.

<p style="text-align: center;">Permittee</p> <p>1. South Texas Veterans Health Care System Audie L. Murphy Memorial Veterans Hospital Division</p> <p>2. 7400 Merton Minter Boulevard San Antonio, Texas 78229</p>	<p>3. In accordance with your request of March 1, 2019, Permit Number 42-15881-01 is amended to read as follows.</p> <p>4. Expiration date: December 31, 2027</p> <p>5. Docket or Reference Number: 030-09959</p>
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- | | | |
|---|--|--|
| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Any byproduct material with Atomic Numbers 1-83</p> <p>E. Technetium 99m</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Liquid</p> | <p>8. Maximum amount permittee may possess at any one time under this permit</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 2 curies (Ci)</p> <p>D. 250 millicuries (mCi) per radionuclide and 5 Ci total</p> <p>E. 150 mCi</p> |
|---|--|--|

9. Authorized Use.
- A. Any use permitted by 10 CFR 35.100.
 - B. Any use permitted by 10 CFR 35.200.
 - C. Any use permitted by 10 CFR 35.300.
 - D. Research and development as defined in 10 CFR 30.4, including animal studies, instrument calibration, student instruction, and *in vitro* studies.
 - E. For shielding evaluations conducted by, or under the supervision of, the Radiation Safety Officer or Assistant Radiation Safety Officer.

CONDITIONS

- 10. Permitted material may be used or stored only at the permittee's facilities located at 7400 Merton Minter Boulevard, San Antonio, Texas.
- 11. The Radiation Safety Officer for this permit is **William House**. A written continuity plan for a qualified Radiation Safety Officer shall be kept current and be approved, annually, by the Radiation Safety Committee. If the Radiation Safety Officer permanently discontinues duties under this permit, the permittee shall immediately notify the National Health Physics Program. Permit activities must cease without a qualified Radiation Safety Officer who meets Nuclear Regulatory Commission requirements.
- 12. Permitted material is only authorized for use by, or under the supervision of:

MATERIALS PERMIT
SUPPLEMENTARY SHEET

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Permit Number: 42-15881-01

Docket or Reference Number: 030-09959

Amendment No. 77

- A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for the materials and uses indicated.

<u>Authorized User</u>	<u>Materials and Use</u>
Ralph A. DeFronzo, M.D.	35.100
Devjit Tripathy, M.D.	35.100
Daniel H. Duffy, M.D.	35.100, 35.200, 35.300
Michel-Alexis Courtines, M.D.	35.100, 35.200, 35.300
Ildiko Agoston, M.D.	35.200 (cardiology studies only)
Rushit Kanakia, M.D.	35.200 (cardiology studies only)
Janet V. Hays, M.D.	35.200 (cardiology studies only)

- C. Permitted material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

13. Permitted material shall not be used in or on humans except as provided otherwise by specific condition of this permit.
14. Permitted material shall not be used in field applications where activity is released except as provided otherwise by specific condition of this permit.
15. Experimental animals, or the products from experimental animals, that have been administered permitted material, shall not be used for human consumption.
16. This permit does not authorize commercial distribution of permitted material.
17. For sealed sources not associated with 10 CFR 35 use, the following conditions apply.
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified by the certificate of registration issued by the Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
- B. Notwithstanding Paragraph A of this permit condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. Each sealed source fabricated by the permittee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- D. In the absence of a certificate from a transferor indicating a leak test has been made within the intervals specified in the certificate of registration issued by the Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- E. Sealed sources need not be tested if they contain only hydrogen 3, or they contain only a radioactive gas, or the half-life of the isotope is 30 days or less, or they contain not more than 100 microcuries of beta- and/or gamma-emitting material, or not more than 10 microcuries of alpha-emitting material.
- F. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185

MATERIALS PERMIT
SUPPLEMENTARY SHEET

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becquerels) or more of removable contamination, a report shall be filed with the National Health Physics Program in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Nuclear Regulatory Commission regulations.

- H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the permittee or by other persons specifically licensed by the Nuclear Regulatory Commission or an Agreement State to perform such services.
18. Sealed sources containing permitted material shall not be opened or sources removed from source holders by the permittee.
19. A. The permittee shall conduct physical inventories to account for all sealed sources and/or devices received and possessed under this permit.
- (1) Quarterly, for sealed sources with either current activity greater than 1 millicurie or current activity greater than 1000 times the quantities in 10 CFR 20, Appendix C.
- (2) Semiannually, for all other sealed sources, except sources specifically exempted by 10 CFR 30.
- B. The permittee shall maintain records for 3 years from the date of each inventory and include the radionuclides, quantities, manufacturer's name and model numbers, location of the sources and/or devices, and the date of the inventory.
- C. The permittee shall classify sealed sources, not in active use for their intended clinical or research purpose for a period of 24 months, as disused sources and evaluate the disused sources for disposal as expeditiously as possible.
- D. The permittee shall provide oversight for security of radioactive materials by:
- (1) Compliance with regulations per 10 CFR 20.1801 and 10 CFR 20.1802.
- (2) Prevention of adversary or unauthorized removal of, or access to, radioactive materials.
- (3) Use of two delay methods for sealed sources not in use.
- (4) Focus to security commensurate with possible risks of radioactive materials unauthorized use.
20. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism that prevents the foil temperature from exceeding that specified by the manufacturer and approved by the Nuclear Regulatory Commission.
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
21. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Nuclear Regulatory Commission or an Agreement State to perform such services.
22. For radioactive material held for decay in storage other than that held in accordance with 10 CFR 35.92, the permittee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay in storage before disposal in ordinary trash, provided:

MATERIALS PERMIT
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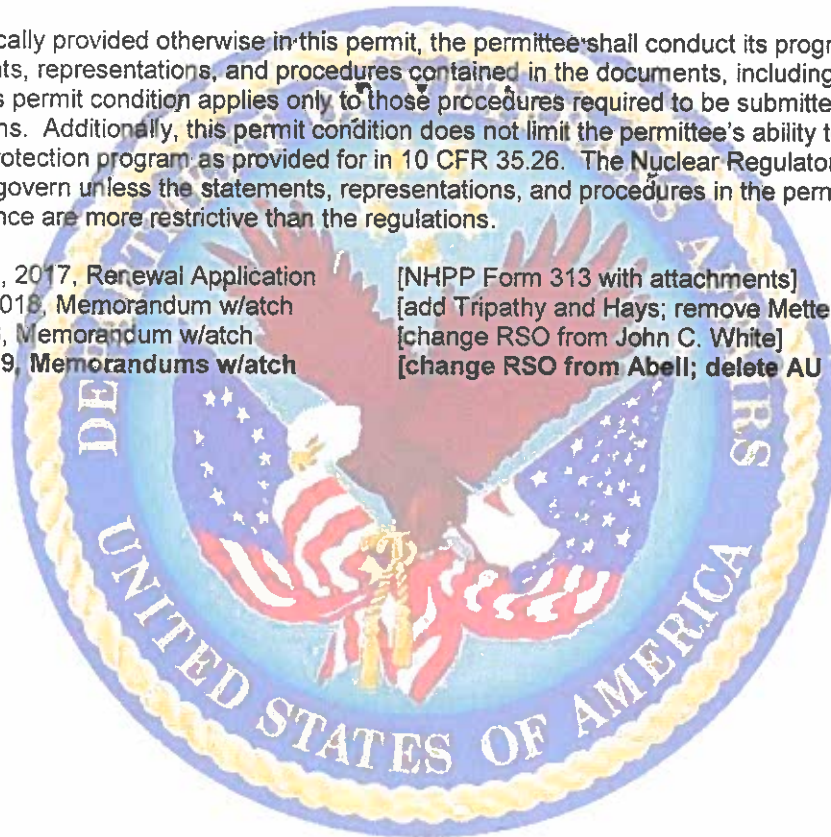
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Permit Number: 42-15881-01

Docket or Reference Number: 030-09959

Amendment No. 77

- A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
- B. A record of each such disposal permitted under this permit condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
23. The permittee is authorized to transport permitted material only in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."
24. Except as specifically provided otherwise in this permit, the permittee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This permit condition applies only to those procedures required to be submitted in accordance with the regulations. Additionally, this permit condition does not limit the permittee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the permittee's application and correspondence are more restrictive than the regulations.
- A. November 27, 2017, Renewal Application [NHPP Form 313 with attachments]
B. February 8, 2018, Memorandum w/atch [add Tripathy and Hays; remove Metter as AUs]
C. May 15, 2018, Memorandum w/atch [change RSO from John C. White]
D. March 1, 2019, Memorandums w/atch [change RSO from Abell; delete AU Phillips]



FOR THE DEPARTMENT OF VETERANS AFFAIRS

Date April 13, 2019

By Edwin M. Leidholdt 398105
Digitally signed by Edwin M. Leidholdt 398105
Date: 2019.04.13 16:38:27 -07'00'
Edwin M. Leidholdt, Jr., Ph.D., FACR
Director, National Health Physics Program
North Little Rock, Arkansas