

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Avera St. Luke's **License No.:** 40-18000-01
Docket No.: 030-13778 **Mail Control No.:** 471305
Type of Action: Amend **Date of Requested Action:** 3-22-07
Reviewer Assigned: Rachel Brownder **ARM reviewer(s):** Torres

Response	Deficiencies Noted During Acceptance Review
	<ul style="list-style-type: none"> [] Open ended possession limits. Limit possession. Submit inventory. [] Submit copies of most recent leak test results. [] Add - delete IC license condition. Add IC paragraph in cover letter. [] Split license from cover letter. Add SUNSI marking to license. [] Ask the licensee if they have any type-amount of EPAct Material.

Reviewer's Initials: _____ **Date:** _____

- Yes No Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.
- Yes No Decommissioning notification should be completed within 30 days.
- Yes No Termination request < 90 days from date of expiration
- Yes No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
- Yes No TAR needed to complete action.

Branch Chief's and/or Sr. HP's Initials: RTC **Date:** 3-28-07

SUNSI Screening according to RIS 2005-31

Yes No **Non-Publicly Available, Sensitive** if any item below is checked

General guidance:

- _____ RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
- _____ Exact location of RAM (whether = or > than Category 3 or not)
- _____ Design of structure and/or equipment (site specific)
- _____ Information on nearby facilities
- _____ Detailed design drawings and/or performance information
- _____ Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

- _____ RAM quantities and inventory
- _____ Manufacturer's name and model number of sealed sources & devices
- _____ Site drawings with exact location of RAM, description of facility
- _____ RAM security program information (locks, alarms, etc.)
- _____ Emergency Plan specifics (routes to/from RAM, response to security events)
- _____ Vulnerability/security assessment/accident-safety analysis/risk assess
- _____ Mailing lists related to security response

Branch Chief's and/or Sr. HP's Initials: RTC **Date:** 3-28-07

Pre-Licensing Screening

Applicant Information:

Control No. 471305

Name: Avera St. Luke's	Type of Request: Amend Program Code(s):	
Location: SD	License No.: 40-18000-01	Docket No.: 030-13778

STEP 1—Radioactive Materials and Quantities Requested:

Instructions for Step 1: Complete Step 1 for all applications. If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay.	Yes or No
A. The request is from a new applicant.	No
B. NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit.	No
C. The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been "highlighted" by the reviewer	No

Table of Risk Significant Quantities

(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)	Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226 ²	0.4	11
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
Ir-192	0.8	22	Yb-169	3	81

¹ The primary values are TBq. The curie (Ci) values are for informational purposes only.
² The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. NOTE—If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).	Yes, No, or Not Applicable (NA)
Total Activity—multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide	—
Unity Rule—multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g., [(total activity for radionuclide A) ÷ (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) ÷ (risk significant quantity for radionuclide B)] ≥ 1.0.	—

Signature and Date for Step 1:

NTC 3-28-07
 License Reviewer and Date

RECEIVED

MAR 30 2007

DNMS

Nuclear Materials Licensing Branch
Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064
atten: Rachel S. Browder, Health Physicist

March 27, 2007

Re: License No. 40-18000-01
Control No. 471220
Subject: Additional Authorized User

Dear Ms. Browder:

Avera St. Luke's Hospital would like to reinstate our amendment request to add an additional authorized user to our Materials License.

1. Add Jack Vonk, M.D. to the list of authorized users for materials identified in 10 CFR 35.100, 35.200, 35.300 and gadolinium-153 for use in the ADAC Vantage System for patient attenuation correction.

We have enclosed additional preceptor statements along with other information on NRC Form 313A. We appreciate your help in clarifying what was required.

If you have any additional questions, please don't hesitate to call our Director of Radiology/Radiation Therapy, Lee Ann Tople, at 605-622-5068. Thank you.

Sincerely,


Ron L. Jacobson
President & CEO

Enc.

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Medical or Teletherapy

SUPPLEMENT A

Training and Experience
Authorized User or Radiation Safety Officer (RSO)

1. Name of Individual Jack Vonk, M.D. <input type="checkbox"/> Authorized User <input type="checkbox"/> Radiation Safety Officer		2. Physician who is licensed to dispense drugs in the practice of medicine in Nebraska? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
3. Certification			
3.a. Specialty Board	3.b. Category	3.c. Month and Year Certified	
4. Training Received in Basic Radioisotope Handling Techniques			
	<u>Location and Dates of Training</u>	<u>Clock Hours in Lecture or Laboratory</u>	<u>Clock Hours of Supervised Laboratory Experience</u>
4.a. Radiation Physics and Instrumentation	Radiology Residency Program - University of Nebraska Medical Center Dates: 7/1/00 - 6/30/04	50	
4.b. Radiation Protection		50	
4.c. Mathematics Pertaining to the Use and Measurement of		50	
4.d. Biological Effects of Radiation		50	
4.e. Radiopharmaceutical Chemistry		50	
5. Experience with Radiation (Actual Use of Radioisotopes or Equivalent Experience)			
<u>Isotope</u>	<u>Maximum Activity</u>	<u>Where Experience Was Gained</u>	<u>Months/Years</u> <u>Type of Use</u>
Tc-99m, Tl-201, Ga-67m, Co-57, I-123, I-131, Cr-51, In-111, Xe-133, I-125, Sr-90	200 mCi (I-131)	Nuclear Medicine Department - The Nebraska Medical Center Dates: 07/03/00 - 07/30/00, 10/21/02 - 11/17/02, 05/05/03 - 06/01/03 Veterans Administration Nebraska Western Iowa Health Care System (formerly: Omaha VA Medical Center) Dates: 4/9/01-5/5/01, 7/2/01-7/29/01, 8/27/01-9/23/01, 11/19/01-12/16/01, 4/8/02-5/5/02, 12/16/02-2/9/03, 5/2/03-7/27/03, 9/22/03-10/19/03, 5/3/04-5-30/04	3 months 480 hours 11 Months 480 hours 3/22/07 Diagnostic, therapeutic 3/22/07

NRC FORM 313A (AUD) (10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User

DR. Jack Vonk

State or Territory Where Licensed

South Dakota

Requested Authorization(s) (check all that apply)

35.100 Uptake, dilution, and excretion studies

35.200 Imaging and localization studies

35.500 Sealed sources for diagnosis (specify device _____)

PART I - TRAINING AND EXPERIENCE
(Select one of the three 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. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization

- a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
- b. Supervised Work 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 Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

35.290

35.390 + generator experience in 32.290(c)(1)(ii)(G)

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(10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use (not required for 35.590)			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience (completion of this table is not required for 35.590).
If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Avera St. Lukes Hospital Aberdeen, SD	0.5	3/22/07
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	↓	0.5	3/22/07
Calculating, measuring, and safely preparing patient or human research subject dosages	↓	0.25	3/22/07

*

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(10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience. (continued)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Avera St. Lukes Hospital Aberdeen, SD	0.25	3/22/07
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	↓	0.5	3/22/07
Administering dosages of radioactive drugs to patients or human research subjects (Already provided)	The Nebraska Medical Center Omaha, NE	3+	Multiple dates
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	Avera St. Lukes Hospital Aberdeen, SD	0.5	3/22/07

Total Hours of Experience:

Supervising Individual

Stephen R. Peters, MD

License/Permit Number listing supervising individual as an authorized user

USNRC lic. # 40-18000-01

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).

35.190

35.290

35.390

35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates
 		
 		

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

NRC FORM 313A (AUD)
(10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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. (Not required to meet training requirements in 35.590)

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User
10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

I attest that Dr. Jack Vonk has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User
experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User
10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

I attest that Dr. Jack Vonk has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.190
- 35.290
- 35.390
- 35.390 + generator experience

Name of Preceptor <u>Stephen R. Peters</u>	Signature <u>[Signature]</u>	Telephone Number <u>605-622-5540</u>	Date <u>3-22-07</u>
-----------------------------------------------	---------------------------------	-----------------------------------------	------------------------

License/Permit Number/Facility Name
US NRC Lic. # 40-18000-01 Avera St. Luke's Hospital

NRC FORM 313A (AUT)
(10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.300)
[10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User

DR. Jack Vonk

State or Territory Where Licensed

South Dakota

Requested Authorization(s) (check all that apply):

35.300 Use of unsealed byproduct material for which a written directive is required

OR

³⁹² 35.392 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

³⁹⁴ 35.394 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

³⁹⁶ 35.396 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

³⁹⁶ 35.396 Parenteral administration of any other radionuclide for which a written directive is required

PART I - TRAINING AND EXPERIENCE
(Select one of the three 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 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. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.
- c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.
- d. Skip to and complete Part II Preceptor Attestation.

2. **Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements (check all that apply):

35.390 35.392 35.394 35.490 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

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(10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User - *Already Provided*

a. Classroom and Laboratory Training 35.390 35.392 35.394 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience 35.390 35.392 35.394 35.396

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Already Provided

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters			
Calculating, measuring, and safely preparing patient or human research subject dosages			
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material			
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures			
Total Hours of Supervised Work Experience:			

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U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Supervising individual meets the requirements below, or equivalent Agreement State requirements (<i>check all that apply</i>)**:	
<input type="checkbox"/> 35.390	With experience administering dosages of:
<input type="checkbox"/> 35.392	<input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.394	<input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.396	<input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	<input type="checkbox"/> Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience - Already Provided
 If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required			

(List radionuclides)

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U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:	
<input type="checkbox"/> 35.390	With experience administering dosages of:
<input type="checkbox"/> 35.392	<input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.394	<input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.396	<input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	<input type="checkbox"/> Parenteral administration of any other radionuclide requiring a written directive
** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.	

d. Provide completed 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 for each requested authorization:

For 35.390:

Board Certification

I attest that _____ has satisfactorily completed the training and experience requirements in 35.390(a)(1).
Name of Proposed Authorized User

OR

Training and Experience

I attest that Dr. Jack Vonk has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

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(10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

I attest that Jack Vonk, MD has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).
Name of Proposed Authorized User

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

I attest that Jack Vonk, MD has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).
Name of Proposed Authorized User

Second Section

I attest that Jack Vonk, MD has satisfactorily completed the required clinical case experience required in 35.390(b)(1)(ii)G listed below:
Name of Proposed Authorized User

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

Third Section

I attest that Jack Vonk, MD has satisfactorily achieved a level of competency to function independently as an authorized user for:
Name of Proposed Authorized User

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) (35.392)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) (35.394)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required (35.396)
- Parenteral administration of any other radionuclide requiring a written directive (35.396)^{or}

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U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690

Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

I attest that _____ has satisfactorily completed the board certification

Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

35.390 35.392 35.394 35.396

I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor

Stephen R. Peters

Signature

[Handwritten Signature]

Telephone Number

605-622-5540

Date

3-22-07

License/Permit Number/Facility Name

US NRC Lic. # 40-18000-01 Avera St. Luke's Hospital

Use of Unsealed Radioactive Material for Therapy

Physician: Dr. Jack Vonk

Radiopharmaceutical Therapies for the following time periods at The Nebraska Medical Center (formerly known as Nebraska Health System): 07/03/00 - 07/30/00, 10/21/02 - 11/17/02, and 05/05/03 - 06/01/03.

NOTE: Does not include therapies performed at the Veteran's Administration Nebraska Western Iowa Health Care System (formerly known as the Omaha VA Hospital).

MAR 14 2007

Thyroid Carcinoma			Hyperthyroid Therapies				
Date	Activity Administered	Date	Activity Administered	Date	Activity Administered	Date	Activity Administered
07/26/2000	150 mCi	11/15/2002	176 mCi	07/05/2000	31 mCi	11/08/2002	21.1 mCi
07/28/2000	152.6 mCi			07/11/2000	45.8 mCi	11/12/2002	35.7 mCi
10/22/2002	166.0 mCi			07/14/2000	25.3 mCi	11/14/2002	26.1 mCi
10/29/2002	149.8 mCi			07/21/2000	33.9 mCi	11/15/2002	13.6 mCi
10/30/2002	148 mCi			10/25/2002	32.9 mCi	05/06/2003	28.6 mCi
10/31/2002	149.8 mCi			10/25/2002	34.4 mCi	05/08/2003	32 mCi
11/01/2002	135.9 mCi			11/05/2002	33.0 mCi	05/29/2003	26.9 mCi

