



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
612 EAST LAMAR BLVD, SUITE 400
ARLINGTON, TEXAS 76011-4125

July 11, 2008

Alaska Heart Institute, LLC
ATTN: Alan E. Skolnick, M.D.
3260 Providence Drive, Suite 537
Anchorage, AK 99508

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION
NRC LICENSE NO. 50-29111-01

Dear Dr. Skolnick:

We are in receipt of your letter dated June 4, 2008, in which you requested a license amendment to remove four authorized users from the subject license and add nine physicians as authorized users to the subject license.

In support of your request to authorize Drs. Ireland, Gray, Moronell, Mason, Amos and Scully for materials identified in 10 CFR 35.100 and §35.200, please submit an NRC Form 313A(AUD), for each individual. The NRC Form 313A(AUD) is available on the NRC website at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>, as well as enclosed. The NRC Form 313A(AUD) should document either the physician's board certification in Part I, Section 1, and the preceptor attestation in Part II; or training and experience in Part I, Section 3, and the preceptor attestation in Part II. If training and experience in Section 3 is being used as the criteria for authorization, then the supervising individual of the training and experience must be the signature authority for this Part of the form. If the physician is qualifying for 10 CFR 35.200 uses by a medical specialty board, then please verify that the respective physician's board certification has been recognized by the Commission as documented on the NRC website at: <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. In addition, please provide a copy of the board certification with your response.

Alternatively, if any of these individuals have been previously identified on a Commission or Agreement State license or permit, then please submit a copy of the license, which is sufficient documentation to authorize them on the license for Alaska Heart Institute.

The NRC received a fax copy of your Certificate of Registration, which is signed by Mr. Clyde Pearce with the State of Alaska. Currently, the State of Alaska regulates the use of accelerator produced and/or NORM radioactive materials. The authority for these radioactive materials will transition to the NRC in accordance with the Transition Plan no later than August 9, 2009. The new regulations and the Transition Plan are available on the NRC website at: <http://nrc-stp.ornl.gov/narmtoolbox.html>. As provided in the Transition Plan, users of accelerator produced and/or applicable NORM radioactive materials in non-Agreement States and U.S. Territories will be required to apply for license amendments for the new byproduct material within 6 months from the date the waiver is terminated, if they hold an NRC specific byproduct materials license, such as

ML081931014

Alaska Heart Institute. Therefore, the fax certificate does not affect the use of byproduct radioactive materials authorized under your NRC License No. 50-29111-01.

The Radiation Safety Officer authorized on your NRC License Amendment No. 14 is Dr. Mark A. Selland. NRC License Amendment No. 14 was based on Mr. Baxter Burton, CEO's request letter dated August 23, 2007. If Alaska Heart Institute has decided that you should be the Radiation Safety Officer, then please include this request as part of your response. In addition, please provide a Delegation of Authority as required by 10 CFR 35.24(b). An example of a Delegation of Authority is provided in NUREG-1556, Volume 9, Revision 2, Appendix I, enclosed. Please note, that we will not be able to act upon your amendment request until we have received authorization from management to name you as the Radiation Safety Officer, or receive a letter stating that you are authorized to make commitments on behalf of Alaska Heart Institute, LLC.

In order to continue our review of the license amendment, please provide a response within 30 days from the date of this letter. In your response, please reference the license, docket and control numbers. If you have any questions regarding this matter, please contact me at (817) 276-6552. Thank you for your cooperation.

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

Sincerely,



Rachel S. Browder, CHP
Nuclear Materials Safety Branch B

Enclosures: As Stated

License No. 50-29111-01
Docket No. 030-34474
Control No. 471843

**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 _____

State or Territory Where Licensed _____

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)

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 <i>(not required for 35.590)</i>			
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.)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

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 Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Supervising Individual		License/Permit Number listing supervising individual as an authorized user	
Supervisor meets the requirements below, or equivalent Agreement State requirements (<i>check one</i>).			
<input type="checkbox"/> 35.190 <input type="checkbox"/> 35.290 <input type="checkbox"/> 35.390 <input type="checkbox"/> 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.

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)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

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 _____ 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 _____ 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	Signature	Telephone Number	Date
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License/Permit Number/Facility Name

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Model Radiation Safety Officer Duties and Responsibilities

The duties and responsibilities of the Radiation Safety Officer (RSO) include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 35.24. As a result of implementation of the EPAct, licensed material now includes accelerator-produced radioactive materials and discrete sources of Ra-226. Licensees authorized under 10 CFR 30.32(j) to produce and noncommercially transfer PET radioactive drugs to consortium members should review the model duties and responsibilities below, expanding on them as necessary to ensure radiation safety oversight of the production and transfer only to medical use consortium members.

Typically, these duties and responsibilities include ensuring the following:

- Unsafe activities involving licensed material are stopped;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the SSDR certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;

APPENDIX I

- Medical events and precursor events are investigated and reported to NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the Radiation Protection Program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner.

Model Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected department heads