



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

February 12, 2013

Docket No. 03017817
Control No. 579497

License No. 44-19518-01

Claudio D. Fort
President/CEO
North Country Hospital
189 Prouty Drive
Newport, VT 05855

SUBJECT: NORTH COUNTRY HOSPITAL, VOIDANCE OF APPLICATION FOR LICENSE AMENDMENT, CONTROL NO. 579497

Dear Mr. Fort:

This letter is in reference to your letter dated November 13, 2012, requesting an amendment to NRC License No. 44-19518-01, to add an additional location of use. Specifically, you have requested that a mobile unit provided by Alliance Health Care Services, Inc. (Alliance) be added to your license as an additional location of use of PET radiopharmaceuticals, and will be located on North Country Hospital property. Because this is a complex action involving multiple licensees, and to allow additional time to gather the additional information specified below, we have voided this application. If you wish to resubmit your request to add the mobile PET trailer as a location of use, you may resubmit your application in whole or reference Control No. 579497 and provide the following additional information:

1. Please describe the equipment that you will have for use on the Alliance trailer (e.g. dose calibrator and survey meters, well counter). If your well counter will be located in proximity to PET radiopharmaceuticals, please describe additional shielding that will be used.
2. If the Alliance trailer will be transported back to Alliance periodically, please describe closeout surveys that will be performed by North Country Hospital prior to release and return of the trailer to control of Alliance.
3. Please confirm that secured off-street parking owned or under control of North Country Hospital will be provided for the Alliance trailer. Please note that public rights-of-way are not considered part of the address of North Country Hospital.
4. Please describe how secured access will be maintained to the mobile PET trailer and confirm that there will be secured storage facilities available for storage of byproduct material and radioactive waste.
5. Please confirm that byproduct material will be delivered directly to the Alliance trailer only if the trailer is occupied by North Country Hospital personnel at the time of delivery.

6. Please confirm that you will require the supervised North Country Hospital personnel associated with PET radiopharmaceutical use to follow the instructions of the supervising authorized user and the Radiation Safety Officer for medical uses of byproduct material, written radiation protection procedures established by the North Country Hospital, regulations in 10 CFR Parts 19, 20, 30, 35, and 71, and license conditions of your license.
7. Please confirm that technologists will be trained in emergency procedures that you have developed and implemented in accordance with the Radiation Protection Program required by 10 CFR 20.1101, for activities associated with the Alliance trailer.
8. Describe who (Alliance or North Country Hospital) will be responsible for radioactive waste generated as a result of possession and use of PET radiopharmaceuticals on the Alliance trailer. For instance, will radioactive waste stay on the Alliance trailer and transferred to Alliance, or will radioactive waste be controlled under the North Country Hospital radioactive waste program? If radioactive waste will be transferred to Alliance, please note that Alliance must be licensed by NRC as a waste broker. Therefore, an amendment to their NRC license would be required.
9. Describe the method of storage and final disposal of radioactive waste. If radioactive waste will be stored in the Alliance trailer, the trailer must be properly secured and posted as a byproduct material storage location.
10. Please confirm that transportation requirements specified in 49 CFR as they relate to radioactive waste generated while the Alliance trailer is onsite at North Country Hospital, the return of unused PET radiopharmaceuticals and the transport back to Alliance of any sealed sources used for equipment QA, will be followed.
11. Confirm whether the “quiet room”, bathroom, etc. are located on the Alliance trailer or whether these facilities are located in North Country Hospital? If patients who receive PET pharmaceuticals are not releasable pursuant to 10 CFR 35.75, and are being transported to these areas in the hospital, then the “quiet room”, and bathroom, etc. are additional locations of use of PET radiopharmaceuticals in the North Country Hospital facility. If this is the case, please provide a description of following:
 - a. Patient “quiet rooms” for patients waiting to be scanned. Please describe shielding, (e.g., $\frac{1}{4}$ to $\frac{1}{2}$ inch lead shielding in walls, floor, and ceiling).
 - b. Dedicated patient bathrooms. Please describe shielding, (e.g., $\frac{1}{4}$ to $\frac{1}{2}$ inch lead shielding in walls, floor, and ceiling).
12. On a detailed version of your facility diagram, please indicate the position of the PET areas described below and describe the type, dimensions, and thickness of installed shielding (shielding specifications were not clear from the trailer diagram).
 - a. Storage of PET radiopharmaceuticals (e.g., stored in transport shielding from radiopharmacy),

- b. Preparation and dispensing of PET radiopharmaceuticals (e.g., 2 inch lead glass L-block, 511 keV syringe shields, flush counter mount for dose calibrator, shielded well counter, etc.).
- c. Scan rooms (e.g., ¼ to ½ lead shielding in walls, floor and ceiling).
- d. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. If this area is not located within your main department, describe how you will secure the material.
- e. Storage of sealed sources.

In addition, identify areas adjacent to the trailer and, for locations within the hospital, identify areas across the walls from use and storage/use locations, and show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301.

13. Identify any additional authorized users involved in the administration of PET radiopharmaceuticals, and provide their training and experience as describe in 10 CFR 35.290. NRC Form 313A (AUD) may be used to document this information.
14. Please provide a description of the sealed sources that are maintained on board the mobile PET trailer. In addition, describe the process of: 1) transferring the sources from Alliance to North Country Hospital; 2) performing sealed source inventories and leak tests required by 10 CFR 35.67; and 3) transferring sources back to Alliance.
15. From the copy of the contract between Alliance and North Country Hospital that you forwarded to us, we are unable to make a clear determination of control of the Alliance trailer while in use on North Country Hospital property. Please provide a copy of the signed contract that includes a description of the control of the trailer while in use on North Country Hospital property. In addition, the contract should address many of the items described above.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. 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 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement is not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

C. Fort

4

Thank you for your cooperation. If you have any questions regarding this letter, please call me at (610) 337-5358.

Sincerely,

Original signed by Lester Tripp

Lester Tripp
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Steven Perlin, M.D., Radiation Safety Officer
Brian Bidwell, Director of Diagnostic Imaging Services

DOCUMENT NAME: G:\WordDocs\Current\Lic Def Letter\L44-19518-01 579497.docx

SUNSI Review Complete: LTripp

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI		
NAME	LTripp/LT		JDwyer/JD				
DATE	02/12/2013		2/12/13				

OFFICIAL RECORD COPY