



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION IV  
1600 E. LAMAR BLVD  
ARLINGTON TX 76011-4511

October 16, 2015

Ms. Traci Hollingshead  
Radiation Safety Officer  
Avera McKennan  
1325 South Cliff Avenue  
Sioux Falls, SD 57117-5045

**SUBJECT: LICENSE AMENDMENT**

Please find enclosed Amendment Number 61 to NRC License Number 40-16571-01 adding a new location for your PET-CT on the campus of Avera McKennan Hospital. An environmental assessment for this licensing action is not required since this action is categorically excluded under 10 CFR 51.22(c)(14)(iv). You should review this license carefully and be sure that you understand all conditions. You can contact me at 817-200-1132 if you have any questions about this license.

You must prepare and submit to NRC a Final Status Survey (FSS) report for your old PET-CT satellite location when you vacate it. This survey report should include all areas within this facility where licensed materials were used and stored. The final status survey is one of the most important aspects of decommissioning a site since it is the primary document supporting the decision to release a facility or area within a facility for unrestricted use. Your survey should be performed in accordance with 10 CFR Part 30.36.

You should identify your wipe test results in terms of disintegrations per minute rather than counts per minute. Key the results to specific points on a facility diagram. Indicate the detection equipment that was used to assay the wipes, the method used to calibrate this equipment, the date of calibration, and specific calculations of instrument sensitivity. Optionally, you can choose to send your wipes to a vendor for analysis. Should you choose this option, you should provide the name and Agreement State or NRC license number of the vendor.

Please reference Mail Control Number 588391 so that we'll know that this is a continuation of this amendment request.

Upon receipt of a satisfactory FSS report, we will issue an amendment to your license that will authorize the release of this facility for unrestricted use.

Please note that previous Condition 13 was deleted from your license because all the sealed sources authorized on your license are for medical use in accordance with 10 CFR Part 35. Please notify this office immediately if our understanding is not correct.

In addition, please note that previous Condition 15 was deleted from your license because it is a regulation in accordance with 10 CFR 35.67.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and 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.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through the NRC's Agencywide Documents Access and Management System (ADAMS). The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/>. Pursuant to NRC's RIS 2005-31, the enclosed materials license will not be made publicly available.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate by NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC in writing of any change in mailing address.
3. By 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
  - a. When you decide to terminate all activities involving materials authorized under the license whether at the entire site or any separate building or outdoor area;
  - b. If you decide not to acquire or possess and use authorized material; or
  - c. When no principal activities under the license have been conducted for a period of 24 months.
4. In accordance with 10 CFR 35.14, notify the NRC no later than 30 days after:
  - a. The date that the licensee permits an individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under 10 CFR 35.13(b)(1) through (b)(4);
  - b. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues duties under the license or has a name change;
  - c. The licensee's mailing address changes;

- d. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 10 CFR 30.34(b); or
  - e. The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either 35.100 or 35.200.
5. Request and obtain a license amendment before you:
- a. Change Radiation Safety Officers;
  - b. Order byproduct material in excess of the amount, radionuclide or form authorized on the license;
  - c. Add or change the areas or address(es) of use identified in the license application or on the license, except for areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 35.200; or
  - d. Change the name or ownership of your organization.
6. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant. Since the NRC also accepts a letter requesting amendment of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available on the following internet address: <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

An electronic version of the NRC's regulations is available on the NRC Web site at [www.nrc.gov](http://www.nrc.gov). Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

T. Hollingshead

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The NRC medical list server has been set up. The list server will send automatic e-mail notifications of medical-related generic communications, Federal Register Notices, and NMSS/FSME newsletters as they are published. Anyone may subscribe/unsubscribe to the new medical list server by sending an e-mail to [medical-gc@nrc.gov](mailto:medical-gc@nrc.gov) with "Subscribe" or "Unsubscribe" in the subject line.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter 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>.

Thank you for your cooperation.

Sincerely,

*/RA/*

Jacqueline D. Cook, Senior Health Physicist  
Nuclear Materials Safety Branch B

Docket: 030-11252  
License: 40-16571-01  
Control: 588391

Enclosure: As stated