



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

June 10, 2019

Barry Scott Monfore, M.D.  
Radiation Safety Officer  
Avera St. Mary's Hospital  
801 East Sioux Avenue  
Pierre, SD 57501

SUBJECT: RESPONSE TO LETTER DATED MAY 20, 2019 AND LICENSE AMENDMENT

Dear Dr. Monfore:

On letter dated May 20, 2019, you requested the Nuclear Regulatory Commission (NRC) to amend condition 10 of NRC license number 40-07328-03 issued to Avera St. Mary's Hospital to reflect the terms described in 10 CFR 35.80 authorizing the use of mobile nuclear medicine services. Please note that NRC regulation 10 CFR 35.80, "Provision of mobile medical service," applies to licensee's providing [emphasis added] mobile medical services. Avera McKennan holder of NRC license number 40-16571-01 will be the licensee providing the mobile nuclear medical service at a temporary job site, in this case at Avera St. Mary's Hospital, as authorized in revised condition 10.I. of Avera McKennan's license (amendment number 78 issued on June 10, 2019). Therefore, the NRC cannot amend condition 10 of NRC license number 40-07328-03 as requested by you since such request is not needed. The NRC has taken this opportunity to update another section of license number 40-07328-01 as explained in the next paragraph.

Please find enclosed Amendment No. 20 to NRC License No. 40-07328-03 removing condition 13 that made reference to decommissioning financial assurance requirements since this condition is not application for the types and quantities of material authorized in license number 40-07328-03. An environmental assessment for this licensing action is not required since this action is categorically excluded under 10 CFR 51.22(c) as applicable. Note that your license and license conditions have been updated in a new format. You should review this license carefully and be sure that you understand all conditions. You can contact me at 817-200-1189 if you have any questions about this license.

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 [www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html](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 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.

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: [www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html](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: <https://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).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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 [www.nrc.gov/reading-rm/adams.html](http://www.nrc.gov/reading-rm/adams.html).

Thank you for your cooperation.

Sincerely,

**/RA/**

Roberto J. Torres, M.S., Senior Health Physicist  
Materials Licensing and Decommissioning Branch

Docket: 030-12639  
License: 40-07328-03  
Control: 612317

Enclosure: As stated