



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

May 1, 2015

Mr. Andrew Munce, Vice President
Orthopedics & Sports Medicine/Neurosciences
Sanford Medical Center
dba Sanford USD Medical Center
P.O. Box 5039
Sioux Falls, South Dakota 57117-5039

SUBJECT: PARTIAL LICENSE AMENDMENT

Please find enclosed Amendment No. 88 to NRC License No. 40-12378-01. **The Nuclear Regulatory Commission (NRC) has completed the technical review of your amendment request letter dated February 26, 2015. Below is a description of the licensing actions that were approved and those that were not approved.**

Approved

1. The request to name Steven R. Moeckly, M.S., as radiation safety officer has been approved and is reflected in condition 11 of this license.
2. The request to remove the authorization for the use of F-18 in check, calibration and reference sources for Steven A. Gasiecki, M.S., authorized medical physicist, was granted. Condition 12.E. of this license has been updated accordingly.
3. The request to list Andrew Munce, Vice President, as point of contact for this license is acknowledged and the appropriate database has been updated to reflect this change.

Not Approved

1. The request to authorize Ryan Kenneth Nowak, M.D., for 10 CFR 35.400 and 35.600 (HDR) uses was not approved because: A) the total hours of supervised work experience for 35.400 and 35.600 uses were left blank in pages 2 and 3 of NRC Form 313A(AUS), and B) Dr. Nowak has not received training in device operation, safety procedures, and clinical use with the Nucletron MicroSelectron HDR Model 106.990. You can resubmit this request once these deficiencies are corrected.
2. The request to authorize Michele M. Lohr, M.D., for 10 CFR 35.300 use was not approved because: A) copy of the board certification was not included, B) the number of clinical cases for parenteral administration of any other radionuclide (alpha emitters) for which a written directive is required was left blank and the preceptor is attesting that Dr. Lohr has completed clinical cases in this area, and C) the information provided in the preceptor attestation (Third section in page 5, Achieved a level of competency to function independently) was not completed (boxes were left unchecked). You can resubmit this request once these deficiencies are corrected.

3. **The request to expand the authorization of Steven A. Gasiecki, M.S., authorized medical physicist, to include the use of Ir-192 in an HDR unit was not processed because this authorization (use for calibrations, spot checks, and training) is already included in condition 12.E. of this license.**
4. **The request to have Fred C. Lovrien, M.D., and Richard J. Massoth, Ph.D., listed as authorized users for non-medical use for source ordering to facilitate the testing of equipment was not approved because the specific "material and use" (radionuclides and proposed use) was not indicated in the request. You can resubmit this request once this deficiency is corrected.**

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 817-200-1189 if you have any questions about this license.

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

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 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/

Roberto J. Torres, M.S., Senior Health Physicist
Nuclear Materials Safety Branch B

Docket: 030-03249
License: 40-12378-01
Control: 586351

Enclosure: As stated