



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

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

November 17, 2008

Sanford Medical Center  
dba Sanford USD Medical Center  
ATTN: Karen Tobin, Vice President  
Heart & Vascular Center of Excellence  
P.O. Box 5039  
Sioux Falls, SD 57117-5039

SUBJECT: LICENSE AMENDMENT AND NOTIFICATION PER 10 CFR 35.14(a)

Please find enclosed Amendment No. 70 to NRC License No. 40-12378-01. **This amendment acknowledges your notification to add Dr. Barbara Schlager to the license for 10 CFR 35.600 uses involving HDR. In addition, License Condition 16 was added to recognize the commitment made as part of your September 23, 2005 clarification letter, to allow future changes to the IVBT portion of your radiation safety program.** An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(iv). You should review the enclosed document carefully and be sure that you understand all conditions. If there are any questions, please contact me at 817-276-6552.

**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.**

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 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/>. Additionally, the link for frequently asked questions may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/materials.html>. 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. 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.
  
4. 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.

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/reading-rm/doc-collections/enforcement/>.

NRC no longer publishes the NRC Rules and Regulations loose leaf supplements. However, 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,

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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 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,

A handwritten signature in cursive script that reads "Rachel S. Browder". The signature is written in black ink and is positioned above the typed name.

Rachel S. Browder, Health Physicist  
Nuclear Materials Safety Branch B

Docket: 030-03249  
License: 40-12378-01  
Control: 471926

Enclosure: As stated