



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 EAST LAMAR BLVD, SUITE 400
ARLINGTON, TEXAS 76011-4125

December 7, 2009

Avera Sacred Heart Hospital
Department of Radiology
ATTN: S. Guru Prasad, Ph.D.
Radiation Safety Officer
501 Summit St.
Yankton, SD 57078-3899

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

Please find enclosed Amendment Number 41 to NRC License Number 40-01683-01, **acknowledging your notifications dated April 21, 2009 and October 2, 2009, for Drs. Peterson and Canaday, respectively.** 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 with "Subscribe" or "Unsubscribe" in the subject line.

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. 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.
3. 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. 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).

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 <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,

A handwritten signature in black ink that reads "Rachel S. Browder". The signature is written in a cursive style with a large, sweeping flourish at the end.

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

Docket: 030-03235
License: 40-01683-01
Control: 472360, 472441

Enclosure: As stated

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Avera Sacred Heart Hospital Department of Radiology</p> <p>2. 501 Summit Street Yankton, South Dakota 57078-3899</p>	<p>In accordance with letters dated April 21, 2009 and October 2, 2009</p> <p>3. License number 40-01683-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date May 31, 2015</p> <p>5. Docket No. 030-03235 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Any byproduct material permitted by 10 CFR 35.400</p> <p>E. Any byproduct materials identified in 10 CFR 31.11</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Sealed sources: (IsoAid, LLC, Models IAI-125A and IAPd-103A, Theragenics Corp., Models 200 and I25.S06, Bard Brachytherapy, Inc., Model STM 125)</p> <p>F. Prepackage kits</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 300 millicuries</p> <p>D. 300 millicuries total</p> <p>E. 300 millicuries</p>
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<p>9. Authorized use:</p> <p>A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.</p> <p>B. Any imaging and localization study permitted by 10 CFR 35.200.</p> <p>C. Any use permitted by 10 CFR 35.300.</p> <p>D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.</p> <p>E. <u>In vitro</u> studies.</p>

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
40-01683-01

Docket or Reference Number
030-03235

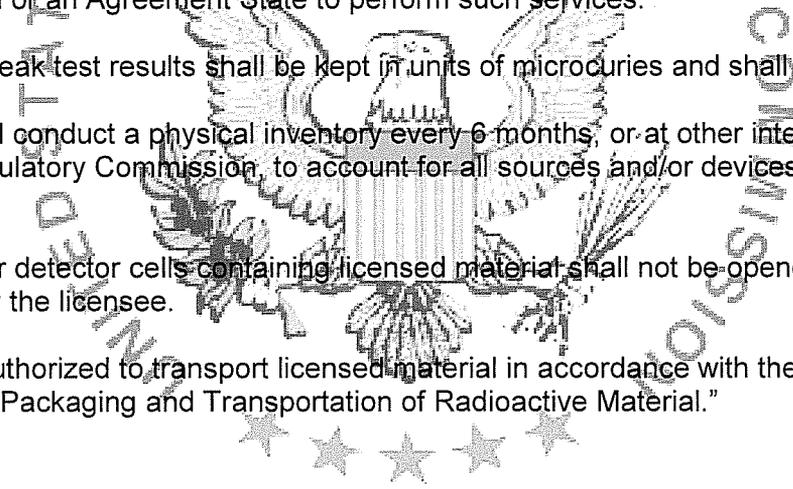
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CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 501 Summit Street, Yankton, South Dakota.
11. The Radiation Safety Officer for this license is S. Guru Prasad, Ph.D.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for the material and medical uses indicated:
- | <u>Authorized Users</u> | <u>Material and Use</u> |
|-------------------------|---------------------------------------|
| Edwin N. Cook, D.O. | 35.100; 35.200 (excluding generators) |
| Frank D. Messner, M.D. | 35.100; 35.200; 35.300; 31.11 |
| Thomas J. Posch, M.D. | 35.100; 35.200; 35.300; 31.11 |
| Michael Peterson, M.D. | 35.400 |
| David Peterson, M.D. | 35.100; 35.200 |
| Peter Canaday, M.D. | 35.100; 35.200; 31.11 |
13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
14. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

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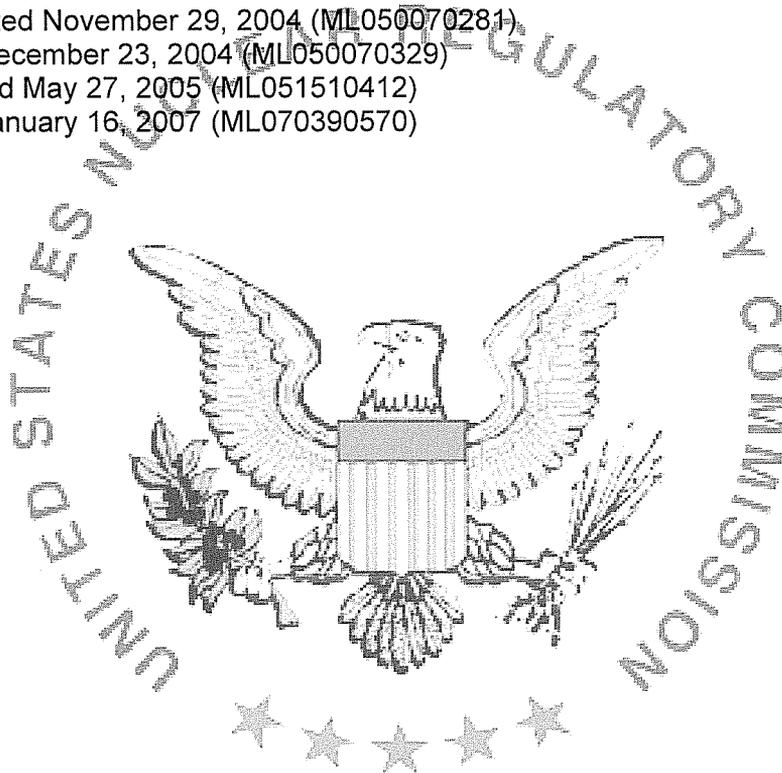
- E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 612 East Lamar Blvd., Suite 400, Arlington, Texas 76011-4125, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.
- G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.
15. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
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18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated November 29, 2004 (ML050070281)
- B. Letter dated December 23, 2004 (ML050070329)
- C. Facsimile dated May 27, 2005 (ML051510412)
- D. Letter dated January 16, 2007 (ML070390570)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: December 7, 2009By: *Rachel S. Browder*Rachel S. Browder, Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011-4125