



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

September 22, 2008

Avera McKennan Hospital
ATTN: David A. Swanson, M.D.
Radiation Safety Officer
800 East 21st Street
Sioux Falls, South Dakota 57117

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment No. 34 to License No. 40-16571-01 **authorizing the possession and use of depleted uranium as requested.** An environmental assessment for this action is not required, since this action is categorically excluded under Title 10 of the Code of Federal Regulations, Section 51.22(c)(14)(iv). You should review this license carefully and be sure that you understand all conditions. If you have any questions, please contact me at 817-860-8189.

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.

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/>.

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,

/RA/

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

Docket: 030-11252
License: 40-16571-01
Control: 471923

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.

Licensee 1. Avera McKennan Hospital 2. 800 East 21st Street Sioux Falls, South Dakota 57117	In accordance with application dated August 19, 2008 3. License number 40-16571-01 is amended in its entirety to read as follows: 4. Expiration date November 30, 2013 5. Docket No. 030-11252 Reference No.
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6. Byproduct, source, and/or special nuclear material A. Any byproduct material permitted by 10 CFR 35.100 B. Any byproduct material permitted by 10 CFR 35.200 C. Any byproduct material permitted by 10 CFR 35.300 D. Any byproduct material permitted by 10 CFR 35.400 E. Any byproduct material permitted by 10 CFR 31.11 F. Depleted Uranium	7. Chemical and/or physical form A. Any B. Any C. Any D. Brachytherapy sealed source (3M Model 6500 series, or AEA Technology Model 6500 Series) E. Prepackaged Kits F. Metal	8. Maximum amount that licensee may possess at any one time under this license A. As needed B. As needed C. 500 millicuries total D. 550 millicuries total E. 500 millicuries total F. 200 kilograms
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9. Authorized use:

- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100
- B. Any imaging and localization study permitted by 10 CFR 35.200
- C. Any use permitted by 10 CFR 35.300
- D. Any manual brachytherapy procedure permitted by 10 CFR 35.400
- E. In vitro studies.
- F. For use as shielding contained inside generators used to elute material permitted under 10 CFR 35.200.

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CONDITIONS

10. Licensed material may be used or stored only at the following licensee's facilities.
- A. Byproduct material identified in Items 6.A. through 6.F. may be used/stored at Avera McKennan Hospital, 800 East 21st Street, Sioux Falls, South Dakota.
 - B. Byproduct material identified in Item 6.B. may be used/stored at Heart Hospital of South Dakota, 4500 West 69th Street, Sioux Falls, South Dakota.
 - C. Byproduct material identified in Item 6.B. may be used/stored at North Central Heart Institute, 4520 West 69th Street, Sioux Falls, South Dakota.
 - D. Byproduct material identified in Item 6.B. may be used at Gutnik Associates, 911 East 20th Street, Physicians Office Building, Sioux Falls, South Dakota.
 - E. Byproduct material identified in Item 6.A through 6.E. may be used/stored at Avera St. Benedict Hospital 401 West Glynn Drive, Parkston, South Dakota.
 - F. Byproduct material identified in Item 6.B. may be used/stored at Mitchell Clinic, Ltd., 818 W. Havens Street, Mitchell, South Dakota.
 - G. Byproduct material identified in Items 6.A. and 6.B. may be used/stored at Mitchell Diagnostic, Ltd., 2200 North Kimball, Mitchell, South Dakota.
 - H. Byproduct material identified in Item 6.A and Item 6.B (except generators) may also be used at any hospital located in the states of South Dakota, provided:
 - (1) The hospital does not have a byproduct material license under Section 35.18 of 10 CFR Part 35, and
 - (2) The licensee addresses all use and record keeping requirements outlined in Section 35.80 of 10 CFR Part 35, and
 - (3) The licensee has the prior written permission from the hospital's Administrator, and
 - (4) The licensee maintains a list of all hospitals serviced.
- The licensee shall maintain for inspection by the Commission, copies of written permission specified in Subitem 3 and the list specified in Subitem 4.
11. The Radiation Safety Officer for this license is David A. Swanson, M.D.

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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 medical use:

<u>Authorized Users</u>	<u>Material and Use</u>
Henry P. Travers, M.D.	35.100, 35.200, 31.11
David Allan Swanson, M.D.	35.100, 35.200, 35.300, 31.11
Arif Azam, M.D.	35.100, 35.200, 35.300, 31.11
Steven P. Olson, M.D.	35.100, 35.200, 35.300, 31.11
T. A. Shultz, M.D.	35.100, 35.200, 35.300, 31.11
Andrew I. Soyle, M.D.	35.300, 31.11
Kirsten R. Erickson, M.D.	35.400
John F. Griffin, M.D.	35.400
Steven C. McGraw, M.D.	35.400
Larry R. Past, M.D.	35.400
Kathleen L. Schneekloth, M.D.	35.400

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. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. The licensee shall conduct a physical inventory every six 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.

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17. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
18. 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 leak 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.
- 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 Boulevard, 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 persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

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19. 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 January 7, 2003
- B. Facsimile dated July 16, 2003
- C. Letter dated August 14, 2003
- D. Letter received September 10, 2003
- E. Facsimile dated October 23, 2003
- F. Letter dated October 27, 2003
- G. Letter dated November 4, 2003
- H. Letter dated March 8, 2004
- I. Letter dated October 27, 2004
- J. Application dated February 6, 2006
- K. Letter dated February 16, 2006



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: September 22, 2008By /RA/
Roberto J. Torres, Senior Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011