UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 E. LAMAR BLVD., SUITE 400
ARLINGTON, TEXAS 76011-4005

May 13, 2008

Midwest Regional Imaging Services, LLC
ATTN: Richard J. Massoth, Ph.D.
Radiation Safety Officer
6001 S. Sharon Avenue, Suite #2
Sioux Falls, South Dakota 57108

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment No. 01 to NRC License No. 40-27764-01, **authorizing a change in mailing address, updating the facility drawing and updating the Authorized Users, as requested by letter dated, February 11, 2008. Please note a change to NRC Region IV's mailing address as documented in our letterhead, above.** An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)((iv). Please 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.

NRC's statutory authority for regulating NARM does not take effect until the waiver terminates for a particular State or jurisdiction. The Phase 2 waiver terminations will occur on September 30, 2008, for the following entities: Vermont, West Virginia, Missouri, Idaho, South Dakota, Guam, and all other Territories and possessions of the U.S. that were not identified in Phase 1. Once the waiver is terminated, then an existing licensee has 6 months to submit a license amendment and a new applicant has 1 year to submit a license application. Currently, the NRC does not have any jurisdiction for the regulation of accelerator-produced radioactive materials in the State of South Dakota.

When the waiver is terminated and the NRC has regulatory authority over accelerator-produced radioactive materials, then any additions or changes to your facility which have not been approved by the NRC, to include areas, facilities, or locations where NARM is used or possessed, or modifications to procedures or equipment, should be provided as a license amendment. This license amendment approves the changes requested by your letter dated February 11, 2008, because the facility plan is also being used for the currently authorized radioactive materials, even though the facility plan incorporates shielding designs for PET radionuclides. The facility plan is authorized on your license as License Condition 18.C. It is not necessary to submit further shielding design documents in a separate license amendment request once the waiver is terminated on September 30, 2008. If any additional changes are necessary in the future, then shielding design documents should be included with the respective license amendment request at that time.

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. 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. 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/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,

Rachel S. Browder

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

Docket: 030-36393
License: 40-27764-01
Control: 471675

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.

Licensee	In accordance with letter dated February 11, 2008
1. Midwest Regional Imaging Services, LLC	3. License number 40-27764-01 is amended in its entirety to read as follows:
2. 6001 South Sharon Avenue, Suite # 2 Sioux Falls, South Dakota 57108	4. Expiration date November 30, 2013
	5. Docket No. 030-36393 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material identified in 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any	C. 900 millicuries

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 diagnostic study or therapy procedure permitted by 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Midwest Regional PET/CT Center, 6001 South Sharon Avenue, Suite #2, Sioux Falls, South Dakota.

11. The Radiation Safety Officer for this license is Richard J. Massoth, Ph.D.

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12. License 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:

	Material and Use
Thomas M. Cink, M.D.	35.100; 35.200; and 35.300
Andrew I. Soye, M.D.	35.100; 35.200; and 35.300
Gary L. Famestad, M.D.	35.100; 35.200; and Iodine-131 sodium iodide for imaging and localization studies that require a written directive in accordance with 10 CFR 35.40 and 35.300
Thomas E. Masterson, M.D.	35.100 and 35.200
Michael J. Kihne, M.D.	35.100; 35.200; and 35.300
Cameron L. Stokka, M.D.	35.100; 35.200; and 35.300
Randal L. Welter, M.D.	35.100; 35.200; and Iodine-131 sodium iodide for imaging and localization studies that require a written directive in accordance with 10 CFR 35.40 and 35.300
Thomas W. Free, D.O.	35.100; 35.200; and 35.300
Patrick A. Nelson, M.D.	35.100 and 35.200
Brad Alan Paulson, M.D.	35.100 and 35.200
Joseph Jeffery Baka, M.D.	35.100 and 35.200
Edward J. Czarnecki, M.D.	35.100; 35.200; and Iodine-131 sodium iodide for imaging and localization studies that require a written directive in accordance with 10 CFR 35.40 and 35.300
Susan F. Duffek, M.D.	35.100 and 35.200
Phillip G. Benzmiller, M.D.	35.100 and 35.200
Daryl C. Rife, M.D.	35.100; 35.200; and 35.300
Sabina Choudhry, M.D.	35.100; 35.200; and 35.300
Charles F. Flohr, M.D.	35.100; 35.200; and 35.300
Josie R. Alpers, M.D.	35.100; 35.200; and 35.300
Christopher Gregory, M.D.	35.100; 35.200; and 35.300

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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 financial assurance for decommissioning.

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 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. 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.

    G. 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, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.

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.

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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."

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 July 29, 2003 (ML033160587)
    B. Letter dated October 23, 2003 (ML033160587)
    C. Letter dated Febraury 11, 2008 (ML080630188)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: May 13, 2008

By: Rachel S. Browder

Rachel S. Browder, Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011