



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

8/7/2023

Frank DiGregorio, Chief Executive Officer
Molecular Imaging Services, Inc.
10 Whitaker Court
Bear, DE 19701

SUBJECT: MOLECULAR IMAGING SERVICES, INC., LICENSE RENEWAL, MAIL
CONTROL NO. 634108

Dear Mr. DiGregorio:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the license. Please review the license carefully and be sure that you understand and fully implement all the conditions of the license. Please note that Enforcement Guidance Memorandum-13-003 (EGM) regarding a licensee's implementation of calibration requirements for rubidium-82 (Rb-82) and the requirement to determine the Rb-82 dosage before medical use is still in effect. A copy of this document can be obtained at <https://www.nrc.gov/docs/ML1310/ML13101A318.pdf>.

Additionally, your Positron Emission Tomography (PET) licensing basis was made for Rb-82, and a future introduction of fluorine-18 (F-18) significantly alters your shielding evaluations. In accordance with 10 CFR 35.13(a), you must request a license amendment prior to implementing an F-18 PET program.

If there are any errors or questions, please contact me at 610-337-5193 or via electronic mail at Valerie.Gray@nrc.gov so that appropriate corrections or answers can be provided.

An environmental assessment for this action was not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please be advised that your license expires at the end of the day in the month and year stated in the license. Until your license has been terminated, you must conduct your program in accordance with the conditions of your license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspections and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other appropriate regulations.
2. Notify NRC in writing 30 days in advanced of any change in mailing address.
3. In accordance with 10 CFR 30.36(d), notify NRC promptly, in writing, within 60 days 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 under 10 CFR 35.13(b)(1) through 35.13(b)(4);
 - b. An authorized user or a Radiation Safety Officer permanently discontinues duties under the license or has a name change;
 - c. 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
 - d. 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 10 CFR 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, or radionuclide, or form different than authorized on the license;
 - c. Add or change the areas of use or address or addresses 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 of your license. You will receive a reminder notice approximately 60 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a Notice of Violation, or 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 at:
<http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

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'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/safety-culture.htm>. 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.

Please be aware that, as a holder of an NRC license, you may be subject to the NRC's licensing and inspection fees in accordance with 10 CFR Part 170, and annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the License Fee and Accounts Receivable Branch at (301) 415-7544.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," 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,

Valerie Stowell, Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 07-30790-01
Docket No. 030-36176
Mail Control No. 634108

Enclosure:
Amendment No. 26

cc: Sunil Selvin, Vice President of Operations and Clinical Education

MOLECULAR IMAGING SERVICES, INC., LICENSE RENEWAL, MAIL CONTROL NO. 634108
DATED 8/7/2023

DOCUMENT NAME: G:\WBL Documents\WBL License Cover Letter\L07-30790-01.634108.docx

SUNSI Review Complete: V. Stowell

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NAME	V. Stowell (VS)						
DATE	8/7/2023						

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