



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

April 23, 2021

Eric R. Jeppesen
Radiation Safety Officer
MRI Global
425 Volker Blvd.
Kansas City, MO 64110-2299

Dear Mr. Jeppesen:

We have reviewed the licensee's application dated January 29, 2021, to renew its U.S. Nuclear Regulatory Commission (NRC) Material License No. 24-02564-02 for MRI Global.

Based on our review of the information, we have identified that additional information is needed to proceed with the renewal process. Please refer to NUREG 1556, Volume 7, Revision 1, "Consolidated Guidance About Materials Licenses," which is accessible at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/index.html> for guidance when preparing your response.

In a signed and dated letter, please provide the following information by May 21, 2021:

1. Resubmit form 313 with a senior manager's signature.
2. Please clarify the purpose of using the material. Specifically, please indicate whether the research conducted at MRI Global includes animal studies and calibration of instruments.
3. Please provide a Delegation of Authority Letter signed by senior management and the Radiation Safety Officer (RSO). Please see Appendix E in NUREG 1556, Volume 7, Revision 1 for a sample letter.
4. Please provide detailed facility diagram illustrating the four laboratories where radioactive material is used, including:
 - Indicate the address and direction of north
 - Indicate the scale/dimensions of the laboratories
 - Describe/label areas adjacent, areas above and below of laboratories where material is used
 - Illustrate details inside the laboratories (fume hoods, sinks, storage of material area, waste storage area, work area, receipt area, etc.)
 - Illustrate measures to secure material when unattended. Specifically, illustrate/describe (i.e. locked doors, locked storage cabinets, etc.)
5. Please describe access control to the laboratories where radioactive material is used and how the material is secured when in storage.

6. Please describe whether you handle Carbon-14 in a volatile form. If so, provide the schematics/diagram of the ventilation system, filtration equipment and monitoring systems.
7. Please confirm that you have Nickel-63 sealed sources that are licensed under a general license in accordance with Title 10 Code of Federal Regulations (CFR) 31.5 as you stated in your letter dated March 25, 2020.
8. In your application dated January 29, 2021, and in the description of the training program as well as other aspects of the radiation safety program, you refer to “a qualified designee” or a “designee.” Please define the terms.

9. Radiation Monitoring Instruments:

Please provide the statement, “We will use instruments that meet the radiation monitoring instrument specifications published in Appendix I in NUREG–1556, Volume 7, Revision 1, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.” We reserve the right to upgrade our survey instruments as necessary.”

AND

“Instruments will be calibrated before first use.”

10. Surveys:

Please confirm that you will conduct a radiation survey of the area/s every time after radioactive material is used in the area/s.

AND

We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M in NUREG–1556, Volume 7, Revision 1, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’”

11. Material Receipt and Accountability

Provide the commitment: “We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times.”

AND

Provide the commitment: “Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventory will be maintained for a period of 5 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer’s name and model numbers, and the date of the inventory.”

12. Please clarify your leak testing procedures by stating the following:

Please provide the statement: "Leak tests will be performed at the intervals approved by the NRC or an Agreement State and specified in the SSD registration certificate," if applicable.

AND

"We will collect leak tests, using the sealed source or plated foil manufacturer's (distributor's) and the leak test kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services."

OR

If leak tests will be analyzed by the applicant, state: "We will implement the model leak test program published in Appendix N in NUREG-1556, Volume 7, Revision 1 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope.'"

13. Safe Use of Radionuclides, Security, and Emergency Procedures:

In your application dated January 29, 2021, the licensee provided detailed emergency procedures. Further, on page 20 of your application, the licensee stated that these procedures are general in nature and may not apply to every situation.

Please note that these procedures will be tied down in your license and you will be required to implement them. If you do not wish that these procedures be tied down in your license, please state so and provide generic commitments described in Appendix B of NUREG 1556, Volume 7, Revision 1 as follows:

"We will develop, implement, and maintain procedures for safe use, security and emergencies."

OR

"We will adopt the procedures for the safe use of radionuclides, security and emergencies as published in Appendix L in NUREG-1556, Volume 7, Revision 1, 'Program- Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"

14. Waste Management:

Please provide the commitment: "We will use the "General Guidelines" in Appendix P in NUREG-1556, Volume 7, Revision 1, 'Program- Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"

E. Jeppesen

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In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390, a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Magdalena R. Grylak
Health Physicist
Materials Licensing Branch

License No. 24-02564-02
Docket No. 030-05083