



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 21, 2021

Mr. John J. Miller, CHP
Radiation Safety Officer
International Isotopes, Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

SUBJECT: INTERNATIONAL ISOTOPES, INC., AMENDMENT OF EXEMPT
DISTRIBUTION LICENSE 11-27680-02E

Dear Mr. Miller:

Enclosed is Amendment No. 4 to your U.S. Nuclear Regulatory Commission (NRC) Exempt Distribution License No. 11-27680-02E in accordance with your application dated May 6, 2021. The license has been amended to expand the material authorization in section 9.B., as requested. Please note: the same labelling is required, as stated in Title 10 of the *Code of Federal Regulations* (10 CFR) 32.19 and as described in your letter with enclosures dated June 12, 2018.

During our review of your amendment request we updated License Condition No. 12 and 13 of your license in accordance with current, standard license conditions. The changes to your license described in this paragraph do not result in effective changes to the requirements of your license.

Please be advised that you must distribute the products in accordance with the statements and representations contained in your application, with enclosures thereto, and the information set out in your license and registration certificate if applicable. As a general rule, you must request and obtain an amendment to the license before you make changes or modifications to the information submitted to obtain them. You are also obligated to notify us promptly in writing should you decide to no longer distribute the product

Please be advised that you must conduct your program involving radioactive materials in accordance with the conditions specified in your NRC license, representations made in your license application, and other rules, regulations, and orders of the NRC, now or hereafter in effect, to include the following:

1. Comply with applicable NRC regulations in 10 CFR Part 30, "Rules of General Applicability to domestic Licensing of Byproduct Material"; 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; and other applicable regulations.

NOTE: Licensees authorized to distribute or initially transfer products containing byproduct material must also possess a valid possession license issued either by NRC or an Agreement State(s) which authorizes possession and use of byproduct material.

2. Distribute only those products containing radioactive material which are specifically authorized in your license.
3. Notify NRC in writing within 30 days of any change in mailing address.
4. In accordance with 10 CFR Sections 30.33, 30.34 and 30.38, please file appropriate documentation with the NRC prior to any changes to your organization, change locations of distribution of products containing radioactive material, facilities, equipment, procedures, change in the contact person or the person responsible for the quality assurance program for licensed activities, or any other changes in your program which are contrary to the license conditions or representations made in your license application and any supplemental correspondence with the NRC.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You should receive a reminder notice approximately 60 days before the expiration date. Continued distribution of products containing radioactive material after your license expires is a violation of NRC regulations.
6. In accordance with 10 CFR 30.36, request termination of your license if you plan to permanently discontinue activities involving distribution of products containing radioactive material.

You will be periodically inspected by NRC. Failure to conduct your program in compliance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action(s) against you. This could include issuance of a notice of violation; proposed imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of Policy and Procedures for NRC Enforcement Actions," (NUREG-1600).

Please be aware that, as a holder of an NRC license, you may be subject to the NRC's annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the Accounts Receivable Branch at (301) 415-7554.

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 Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions regarding your Exempt Distribution License, you may contact me at (301) 415-3257, or by electronic mail at Michelle.Hammond@nrc.gov.

Sincerely,

Michelle M. Hammond, M.Sc., Health Physicist
Materials Safety and Tribal Liaison Branch
Division of Material Safety, Security, States,
and Tribal Program
Office of Nuclear Material Safety
and Safeguards

Docket No.: 030-37557
License No.: 11-27680-02E
Control No.: 625713

Enclosure:
License No. 11-27680-02E

SUBJECT: INTERNATIONAL ISOTOPES, INC., AMENDMENT OF EXEMPT
DISTRIBUTION LICENSE 11-27680-02E

DATED: July 21, 2021

ADAMS Accession Number: ML21131A246

OFFICE	MSST/MSTB	MSST/MSTB	MSST/MSTB	MSST/MSTB
NAME	MMH	MPringle	SXu	MMH
DATE	07/13/2021	07/21/2021	07/20/2021	07/21/2021

OFFICIAL RECORD COPY