



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD
ARLINGTON TX 76011-4511

May 14, 2016

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

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment Number 29 to NRC License Number 11-27680-01MD adding authorizations in Items 6.O., 7.O., 8.O., and 9.O.; updating the reference to OP-QMS-011, Revision B in Items 9.L. and 9.M. (iii), as requested. An environmental assessment for this licensing action is not required since this action is categorically excluded under 10 CFR 51.22(c)(14)(xiii). You should review this license carefully and be sure that you understand all conditions. You can contact me at 817-200-1132 if you have any questions about this license.

In reference to your application and letter dated April 22, 2015, please note that 10 CFR 30.32(g)(1) (<http://www.nrc.gov/reading-rm/doc-collections/cfr/part030/part030-0032.html>) states in part that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number as registered with the Commission under 10 CFR 32.210 (<http://www.nrc.gov/reading-rm/doc-collections/cfr/part032/part032-0210.html>) of this chapter or contain the information identified in 10 CFR 32.210(c) of this chapter.

Additionally, please note that we are unable to approve the special form sealed source identified on the special form certificate at this time because it needs to undergo sealed source product registration in accordance with 10 CFR 32.210. (Please see NUREG-1556, Vol. 3, Rev. 2 [<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v3/r2/>] for the guidance to use to register this source).

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/regulatory/enforcement/safety-culture.html>. 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.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through the NRC's Agencywide Documents Access and Management System (ADAMS). The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/>. Pursuant to NRC's RIS 2005-31, the enclosed materials license will not be made publicly available.

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/about-nrc/regulatory/enforcement/enforce-pol.html>.

An electronic version of the NRC's regulations is available on the NRC Web site at www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated 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 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/

Jacqueline D. Cook, Senior Health Physicist
Nuclear Materials Safety Branch B

Docket: 030-35486
License: 11-27680-01MD
Control: 586650
590764

Enclosure: As stated