



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

August 2, 2013

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

SUBJECT: DISCONTINUATION OF EVALUATION OF APPLICATION FOR SEALED
SOURCE AND DEVICE REGISTRATION

Dear Mr. Miller:

This letter is in response to your application dated May 3, 2013, requesting amendment of your Registration Certificate NR-1235-S-101-S to designate International Isotopes' Model INIS-SF-XX-YY-Z series of sources as replacements for six sources manufactured by other licensees. In the application, you referenced the NRC Regulatory Issue Summary (RIS) 2013-01, "Use of Aftermarket Sealed Sources Registered Under 10 CFR 32.210," as the basis for registration of the replacements.

Please note that RIS 2013-01 delineates two sets of requirements for replacement sealed sources to be in compliance with the requirements of 10 CFR 32.210: (1) equivalency of the physical, chemical, and radiological properties, and (2) compliance with the registration requirements. Regarding compliance with the registration requirements, RIS 2013-01 provides five pathways which the NRC determined as acceptable methods to register replacement sources. Your request is not in agreement with any of these five pathways. Specifically, the pathways state how device manufacturers or user licensees could add replacement sources to registration certificates or to user licenses. Furthermore, RIS 2013-01 states that the device manufacturers or user licensees should request from their "respective regulatory authority (the NRC or Agreement State)" an amendment for the use of replacement sources. International Isotopes Inc., is a source manufacturer, and you requested the NRC to designate other source manufacturers' registration certificates regarding equivalency and registration. Please note that the NRC and the Agreement States issue registration certificates in response to a request from the certificate holder only, not from a request from another party. We consider International Isotopes Inc., to be another party regarding the registration certificates which you listed in your application. Consequently, we cannot amend your Registration Certificate NR-1235-S-101-S as you requested.

Additionally, we noted several discrepancies in your application. For example, source models C-146 and C-151 are currently distributed by Best Theratronics, Ltd, Springfield, VA, not by Nordion (Canada) Inc., as indicated in your listing. There are also differences between these sources and your Model INIS-SF-XX-YY-Z series regarding activity levels, ANSI N43.6 classifications, and physical dimensions. The Model C-188, distributed by Nordion (Canada) Inc., is also different from the Model INIS-SF-XX-YY-Z series regarding activity levels, ANSI

N43.6 classifications, and physical dimensions. The Model NPTT series and the Model JLS-7810 sources are registered by the Agreement States of Maryland and California respectively; the NRC does not maintain documentation for these registrations and, consequently, the NRC could not determine equivalency. In addition, the registration certificate for the Model JLS-7810 source lists already International Isotopes Inc., as an authorized manufacturer.

If you have any questions, please contact Dr. John P. Jankovich of my staff at (301) 415-7904, or e-mail john.jankovich@nrc.gov.

Sincerely,

/RA/

Margie Kotzalas, Chief

Licensing Branch

Division of Materials Safety and

State Agreements

Office of Federal and State Materials and

Environmental Management Programs

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Sincerely,
/RA/
Margie Kotzalas, Chief
Licensing Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials and
Environmental Management Programs

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DATE	7/29/2013	7/30/2013	7/30/2013	8/2/2013

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