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International Isotopes Inc.

Fax Cover Sheet

To: Ms. Cindy Bladley - Attn: RADB
Company: U.S. Nuclear Regulatory Commission
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From: John Miller
Subject: Comments on Proposed Revisions

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SECTION 1

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**International Isotopes Inc.**

October 4, 2011

Ms. Cindy Bladey
Chief, Rules, Announcements, and Directives Branch
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville MD 20555-0001

VIA FAX - Attn: RADB 301-492-3446

Subject: Comments on Proposed Revisions to NRC Enforcement Policy
Docket ID NRC- 2011-0209

Dear Ms. Bladey,

International Isotopes Inc. (INIS) appreciates the opportunity to provide comments on the proposed revisions to the US Nuclear Regulatory Commission (NRC) enforcement policy published in the September 6, 2011 *Federal Register* (76 FR 54986).

INIS is an NRC licensed manufacturer of nuclear medicine calibration source standards and Category 1 and 2 quantity cobalt-60 sources. We distribute these products domestically to NRC and Agreement State licensees and abroad under specific export licenses as well as the general export license, §110.23. Prior to the August 2010 changes to Part 110, INIS imported Category 1 and 2 quantity sources under a specific import license and below Category 2 quantity sources under the general import license §110.27. The August 2010 rule change significantly altered the standard industry practice of offering a "one-for-one" source exchange. The "one-for-one" source exchange practice was offered to both domestic and international customers, sources imported under this practice where imported under a specific license if the source activity exceeded Category 2 quantities and under the general license if the activity was below the Category 2 quantity. This practice provided domestic and foreign customers with a cost-effective mechanism to disposition a source that had decayed below a useful activity. The majority of these sources were disposed of by the source manufacturer; some were recycled or reutilized. The one-for-one source exchange practice was important to the safety and health of the public and environment in that sources that have decayed below their useful life were transferred to a responsible party and where not otherwise accumulated at end user facilities or disposed of improperly. The rule change necessitating and the subsequent cost of obtaining a specific import license for non-US origin sources (regardless of category) that cannot be recycled or reutilized has greatly limited the one-for-one source exchange practice. As an importer and exporter of

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JJM-2011-53

Page 2 of 2

radioactive sources, INIS is keenly interested in the revisions to Section 2.2.5, Export and Import of NRC-Regulated Radioactive Material and Equipment of the Enforcement Policy. The following specific comments to new Section 6.15 Export and Import Activities of the Enforcement Policy are provided below:

1. A Severity Level III violation example "*Failure to submit timely notification of the import of 10 CFR part 110, Appendix P, material, as required by 10 CFR 110.50*" as provided in Section 6.15 c. 1. is excessive, in that the importing licensee may not have been given a sufficient amount of time from the exporting licensee in order to make the notification in a timely manner. In some cases the importing licensee is given no forewarning of an impending import.
2. The Severity Level IV violation example "*Export of byproduct material exceeding the possession limits authorized for the ultimate consignee, not involving a Severity Level I, II, or III violation*" as provided in Section 6.15 d. 3. should be limited to exports conducted under a specific export license. Exports conducted under the general export license provided in §110.23 are often exported to a distributor who then transfers the material to the ultimate consignee; the NRC or Agreement State licensee may never know who the ultimate consignee is. Additionally, current regulations do not require that the exporting licensee verify the ultimate consignees' possession limit when transferring radioactive materials under the §110.23 general export license, refer to §30.42(b)(6).

While these comments may appear to be minor in nature I believe they, along with the August 2010 rule change, illustrate a need for improved dialogue between Industry and the NRC in regards to the complexities associated with the import and export of radioactive materials.

Please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com if you have questions regarding the comments provided with this letter.

Sincerely,



John J. Miller, CHP
Radiation Safety Officer

JJM-2011-53