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

July 26, 2006

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

SUBJECT: DISCONTINUATION OF SAFETY EVALUATION FOR SOURCE MODEL NOS.  
INIS-SF-CS-1J AND INIS-SF-CS-2J

Dear Mr. Miller:

This letter is in response to your letter, dated April 17, 2006, requesting the registration of source Model Nos. INIS-SF-CS-1J and INIS-SF-CS-2J containing Cs-137. A registration certificate cannot be issued for this device at this time due to significant issues that need to be addressed regarding the information enclosed with your letter dated April 17, 2006, and email dated July 7, 2006.

The provisions under 10 CFR 32.210 requires the request for review of a sealed source or a device to include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. In order for us to continue the safety evaluation of these sources to determine such reasonable assurance, you will need to address the issues outlined below. Therefore, we have discontinued the review of your application, without prejudice to its re-submission upon addressing these issues:

1. You indicated that you intend to triple encapsulate existing double encapsulated irradiator sources that have been previously registered but have exceeded their useful life. Please indicate the specific model numbers, and matching SS&D registration certificate numbers, of the sources you intend to triple encapsulate, as well as provide detailed descriptions on how each of these double encapsulated sources would be mounted inside the third encapsulation.
2. You provided a test report for the source capsules (third encapsulation). However, it is not evident that the testing was conducted on fully assembled source capsules containing doubly encapsulated sources with Cs-137, that have reached the end of their useful life. Please provide procedures for, and results of, prototype testing for such fully assembled source capsules. Please also indicate how the tested source capsules were evaluated to determine containment of the radioactive material, such as leak testing.
3. Describe in detail the effects the wear and tear of a double encapsulated source that has reached the end of its useful life, would have on the integrity of the complete triple encapsulated source.

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- 4. Describe the specifics of the fabrication technology and procedure you intend to use for re-encapsulation. In addition, describe the quality assurance tests that you intend to perform upon completion of the re-encapsulation process. Provide information that demonstrates these quality assurance tests are sufficient to indicate that the prototype test results apply to the re-encapsulation process, used in routine fabrication.
- 5. You provided a copy of International Isotopes Inc. Quality System Description. Please also provide a copy of the entire Quality Assurance Manual.

If you have any questions, or would like to meet to further discuss required information, please contact Jonathan Rivera at (301) 415-5810, or Dr. John P. Jankovich at (301) 415-7904, of my staff. You may view and attain a copy of the regulations through the Electronic Reading Room of our main website: [www.nrc.gov](http://www.nrc.gov).

Sincerely,

*IRAI*

Timothy E. Harris, Section Chief  
 Materials Safety and Inspection Branch  
 Division of Industrial and  
 Medical Nuclear Safety  
 Office of Nuclear Material Safety  
 and Safeguards

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