

Enclosure

Additional Information for
the registration of Teletherapy
and Gamma Irradiation Sources

International Isotopes Inc. (I³) application dated October 15, 2004, contained insufficient information on the issues below. Guidance on addressing the issues may be found in "Consolidated Guidance About Materials Licenses: Application for Sealed Source and Device Evaluation and Registration," NUREG-1556, Vol. 3, Rev. 1. The document is available at the NRC web-site: www.nrc.gov.

1. Licensing:

- 1.1 Your current NRC License, 11-2768-01, Authorizes I³ to possess 8,000 Curies of unsealed cobalt-60. Please note that you must amend your license with NRC's Region IV office to reflect the amounts of cobalt-60 that will be at your facility.
- 1.2 Please note that the licensed material listed in the State of Texas, sealed source and device registration certificate TX-1153-S-102-S will have to be registered with the NRC now that International Isotopes Inc. is located in the State of Idaho, a non-agreement state. Please note that the NRC will issue a new certificate for the byproduct material listed in that certificate.
- 1.3 A user leak test will be required for the teletherapy sources.

2. Description/Construction:

- 2.1 Please specify the materials used for the end caps.
- 2.2 Attachment 1 of your application contains two drawings, one for a double welded cap design and the other for a single welded cap design. Please explain any differences between the two and the intended use for each design. Please also describe how the single welded design will be fabricated; specifically address the issue of how you will fabricate the capsule and assure that the specified wall thickness of 0.045 inches is maintained
- 2.3 The application specified that the principal use of the "L" series sources will be for Category III gamma irradiation (page 2 of 6). Category III irradiators are self-contained wet source storage irradiators (ref. ANSI N43.10-2001). But the application in the section "Conditions of Normal Use" stated that the sources are to be "used in a protected environment such as a laboratory or medical clinic" (page 3 of 6). Please clarify the discrepancy.

3. Prototype Testing:

- 3.1 The application requested registration of sources with dimensions that range from a diameter of 0.225 to 1.25 inches and lengths of 1.335 to 8.00 inches. However, the prototypes that were subjected to the ANSI 43.6 classification tests were in the range of diameters from 1.01 to 1.25 inches, with the length not specified. Please provide information that demonstrates that the prototype tests represent the full range of possible source configurations, regarding dimensions as well as the single welded and double welded designs.
- 3.2 On page 4 of your application under Manufacturer's Safety Analysis of Sealed Source Review you stated that the INIS-SF-X-YY series design meets the performance classification ANSI 97E53424 per ANSI/HPS N43.6-1997, that is the highest classification for irradiator sources but a Medical Teletherapy source requires a level 5 impact test. Please provide prototype tests for a level 5 impact test or justify why the current test is acceptable for teletherapy sources.
- 3.3 On page 4 of your application stated that a "static force equal to 2000 N (102 kg) was applied to the Force Cylinder utilizing a press that locked in position for the duration of the test", for the bend test. Please clarify what amount of force was used: 1000 N (102 kg) or 2000 N (204 kg)?
- 3.4 Please specify the design used for prototype testing; i.e. the double welded or single welded cap.

4. Quality Assurance and Control:

- 4.1 Please review the provisions of the applicable guidance in NUREG 1556, Vol 3. Rev. 1, Section 10.7 that outline the quality assurance and quality control requirements. Under "Test Control & Control on Test and Measuring Equipment" on page 3 of Attachment 3 of your application, you state that all finished products and appropriate components and materials are routinely inspected to verify compliance. Please describe the inspections and tests you perform, such as leak tests, sampling methods, and design conformity checks, on the sources prior to distribution.
- 4.2 On page 2 of your application, you state that the open ends of the steel housings will be seal welded. Please state the weld testing acceptance criteria that I³ will use.

5. Accompanying Documentation:

Please describe the information that is provided to the user of the sources to safely operate and maintain them. This includes instructions for operation, maintenance, calibration, damage and failure, specific warnings, leak tests, and radiation surveys.

6. Servicing:

Please provide a list of services, if any, that International Isotopes Inc., will provide to specific licensees.

January 19, 2005

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

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON TELETHERAPY AND
GAMMA IRRADIATION SOURCES

Dear Mr. Miller,

This letter is in response to your application dated October 15, 2004, to register teletherapy and gamma irradiation sources. In reviewing your application, we find that it is lacking required information. In the Enclosure of this letter, we have summarized the issues not addressed in your application.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

If you have any questions, please contact me at (301) 415-7138 or Mr. Nima Ashkeboussi at (301) 415-7637.

Sincerely,

/RA/

Tomas Herrera
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

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