



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
1600 EAST LAMAR BOULEVARD  
ARLINGTON, TEXAS 76011-4511

July 9, 2012

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

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

The Nuclear Regulatory Commission (NRC) has initiated the technical review of International Isotopes' application for an amendment of NRC License 11-27680-01 dated May 22, 2012, and additional information is needed to complete the review process. Please provide the following information within 30 days of receipt of this letter. Make reference to mail control number 577573 when providing your response.

1. From the sealed source and device registration certificate GA-0269-S-103-S, indicate the maximum activity per source and total possession limit that needs to be authorized in the license for the service to be provided to the Leksell Gamma Knife Systems Models 23004, 24001, and Perfexion.
2. Please note that Lesksell Gamma Knife System Model 23016 is not authorized under GA-0269-S-103-S but instead is authorized under GA-269-D-101-S. Indicate the maximum activity per source and total possession limit that needs to be authorized in the license for the service to be provided to the Leksell Gamma Knife System Model 23016.
3. International Isotopes will have to recalculate its decommissioning financial assurance using the maximum possession limits described in Amendment No. 22 of the license and the maximum possession limit information being requested in Items 1 and 2 above. Recalculate your financial assurance and submit the following information to the NRC.
  - A. Evidence that the current financial assurance amount remains adequate for the proposed new total possession limits, or
  - B. Updated decommissioning funding plan, standby trust agreement, and surety bond for the new financial assurance amount.
4. The application states that International Isotopes may sub-contract foreign national individuals to support Co-60 field services operations. These foreign nationals, if performing activities under NRC license 11-27680-01, become de facto employees of International Isotopes for regulatory purposes and will have to receive the same radiation safety and regulatory training as International Isotopes radiation workers.
  - A. Commit to the following language: "International Isotopes will provide sub-contracted individuals that support Co-60 field service operations with radiation safety training as described in Appendix H of NUREG-1556, Volume 18. Training documentation will be maintained for NRC review during inspections."

5. Provide copies of INIS Forms F-33A and F-33B.

Please note that, as of the date of this letter, the State of California has not issued a sealed source and device registration certificate for the device MASEP Infini™ Rotating Gamma System. Therefore, at this moment the NRC cannot authorize International Isotopes' request to provide service to this specific device. International Isotopes can re-submit an amendment request to provide service to the MASEP Infini™ Rotating Gamma System once the sealed source and device registration certificate is issued by the State of California. Include the following information with such request.

1. Provide copy of the sealed source and device registration certificate that demonstrates that the combination of the sealed source Model INIS-SF-X.X-YY-AD and the device MASEP Infini™ Rotating Gamma System is compatible. Indicate the maximum activity per source and total possession limit that needs to be authorized in the license for the service to be provided to the MASEP Infini™ Rotating Gamma System.
2. Provide copy of the following procedures for the MASEP Infini™ Rotating Gamma System for NRC review.
  - A) Source installation, source exchange, source removal,
  - B) Device maintenance and repair, and
  - C) Radiation surveys, and wipe tests.

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/

Roberto J. Torres, Senior Health Physicist  
Nuclear Materials Safety Branch B

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License: 11-27680-01  
Control: 577573