



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

October 30, 2007

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

SUBJECT: EXEMPT DISTRIBUTION LICENSE APPLICATION DATED JULY 6, 2007.

Dear Mr. Miller:

This refers to your application dated July 6, 2007, requesting authorization to distribute, pursuant to 10 CFR 32.11, irradiated gemstones containing byproduct material to persons exempt from licensing under 10 CFR 30.14. As indicated in the recent E-mail to you from Bruce Carrico, processing your application was delayed while NRC considered several policy issues related to gemstones and the applications it had received.

We find we will need the following additional information in order to complete our review of your application:

1. Regarding your request that NRC consider granting International Isotopes Inc. an exemption from complying with the concentration limits imposed by 10 CFR 30.11 and 10 CFR 30.70 Schedule A--Exempt concentrations, the agency has decided it will not consider your request. Please note that 10 CFR Part 32 does not provide a specific section which indicates NRC might consider exemptions from the regulations specified in that part. Instead, exemptions from Part 32 requirements are considered under Section 30.11, paragraph (a) of 10 CFR Part 30. This paragraph provides that the Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part and parts 31 through 36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. Since granting exemptions is at the Commission's discretion, it is not considered a denial under 10 CFR 2.103 and, as such, are not eligible for a hearing under that Part 2.

We have decided on this course of action for several reasons. First, while we can consider granting applicants exemptions from the requirements in Part 32, such as needs to occur with 10 CFR 32.11(c), the regulations in 10 CFR 30.14 only exempts a person from the requirements for a license to the extent that they to the extent that such

person receives, possesses, etc. products or materials containing byproduct material in concentrations not in excess of those listed in 10 CFR 30.70. There is nothing we might do with your license that could extend the exemption to these individuals. The exemption can only be modified through rulemaking. Secondly, all other applicants, both current and those in the past, committed to meet the current concentration limits for any gemstones transferred in the United States. Lastly, as you note, the 74 Bq/gm concentration does appear to be frequently cited within the colored gemstone industry as a recognized limit. We believe that, if we could and did consider granting an applicant an allowance for higher concentration levels, all other applicants would immediately request the same relief and, therefore, this is best handled through the rulemaking process.

With regard to your application, for the most part, most of the information you provide in the application concerning your gemstone evaluation procedures is oriented toward meeting your proposed 74 Bq/gm limit. Please modify all areas of the application as appropriate to show the release of gemstones to an individual within the United States, will comply with applicable 10 CFR Parts 30.14, 30.70, and 32.11 requirements.

2. In your cover letter, dated July 9, 2007, you request that the contents of the application be considered proprietary. Please note that proprietary information should not be included in an application unless it is the only means to adequately describe a process. Also note that NRC will not accept a request to treat an entire application as proprietary, instead the request should be limited to specific procedures, etc. that could be considered privileged or confidential trade secrets and commercial or financial information.

In order to request that NRC withhold information contained in an application from public disclosure, your submission must follow the criteria specified in 10 CFR 2.390(b). In particular, you should ensure that the information you wish to be withheld is appropriately marked and the submission must include an affidavit with the required information as outlined in 10 CFR 2.390(b). Also please note that in accordance with 10 CFR 2.390(c), the Commission either may grant or deny a request for withholding. If helpful, additional guidance regarding the submission of proprietary information is available in Section 5.11 Appendix E of NUREG-1556, Volume 3 (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v3/r1/>).

- 3 -

Please respond within 30 days and refer to the mail control number listed below. If you have any questions, you may contact me at (301) 415-2598 or Bruce Carrico at (301) 415-7826.

Paul Butler

Docket No. 030-37557
Mail Control 022631

IMNS r/f JBCarrico

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DATE	10/30/2007		10/30/2007								