

March 14, 2008

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

SUBJECT: RESPONSE TO LETTER RAISING ISSUES SPECIFIC TO CATEGORY 1  
EXPORTS

Dear Mr. Miller:

In your letter dated December 13, 2007, you identified five specific problems facing your company, relevant to the Nuclear Regulatory Commission's regulations for the export of Category 1 byproduct material, and provided details of the impact of these regulations on your business.

After careful review of the issues raised in your letter, the Office of International Programs has the following comments:

1. **Government to Government Consent Needed Prior to Issuing a License to Export Category 1 Material**

You noted that the timing of license issuance and obtaining government to government consent results in impractical limitations for US companies. However, OIP recently approved your export license subject to the license condition that you not export to certain destinations until the NRC informs you in writing that it has obtained the government to government consent. Issuance of the license as conditioned avoids the type of scenarios you present in your letter, while meeting NRC regulations for obtaining consent.

2. **Ultimate Consignee Listed on License**

For shipments of Category 1 byproduct material, each proposed recipient must be identified as part of the license application process on NRC Form 7. You express your concern that, once the associated list of end-users becomes publicly available, it also has the effect of identifying the licensee's customers and potentially compromises your business by publicizing the names and addresses of a portion of your client base.

The NRC's regulation contained in 10 CFR Part 2.390(a)(4)(b)(1), 'Public inspections, exemptions, requests for withholding' sets forth the process to be used to withhold certain information from the public.

3. **License expiration linked to country or foreign consignee import or possession authorization**

Your letter states: "Linking the license expiration date to a country or foreign consignee import or possession authorization places an unjustifiable restriction on the licensee." You propose

that the expiration date should be the same as the expiration date of the licensee's manufacturing and possession license. The NRC does not link the expiration date for Category 1 exports to a "country or foreign consignee import or possession authorization."

Specific licenses for export of Category 1 and Category 2 radioactive material listed in 10 CFR Part 110 have a license expiration date based on the particular destination(s) listed on the license, either for a period not to exceed 10 years, or a shorter time period. These license expiration dates are determined through a collaborative process between the NRC and the Executive Branch, and are periodically revised. For exports of category 1 material, the government of the importing country may limit the time period in which the export may occur as part of its consent. In these cases, the NRC may condition the license to prohibit exports beyond the consent imposed by the foreign government or may tie the expiration date of the license to the expiration of the consent.

#### **4. Unreasonable licensing fees**

The amount of the NRC's required fee collections is set by law. The NRC is required each year, under Omnibus Budget Reconciliation Act (OBRA-90), as amended, to recover approximately 90 percent of its budget authority through fees imposed on NRC licensees and applicants.

License and inspection fees, established in 10 CFR Part 170 under the authority of the Independent Offices Appropriation Act (IOAA) recover the NRC's costs of providing special benefits to identifiable applicants and licensees, including the review of import and export licenses.

Flat fees are calculated by multiplying the average professional staff hours needed to process the licensing actions by the professional hourly rate for the fiscal year (FY). The higher hourly rate of \$258 is the main reason for the increases in the application fees in FY 2007. Application fees for some fee categories (K.3., K.4., and K.5. under § 170.21; and 15.C., 15.D., 15.E., and 15.R., under § 170.31(3)) also increased because of the results of the biennial review of fees, which showed an increase in average time to process these types of license applications.

NRC published a proposed FY 2008 Fee rule on February 13, 2008, 73 Fed. Reg. 8503, and will evaluate public comments before publishing a final rule. The proposed FY 2008 fee rule calls for a slight reduction in our processing fees.

#### **5. Licensee's inability to determine future costs**

Your description of this problem focused on the limitations in our definition of 'minor amendment,' and the impracticality of adding "new ultimate foreign consignees which may or may not be located in a country previously included on the license." You state that there is a lack of guidance available to assist licensees in understanding what criteria are used by the NRC in determining the level of review.

We believe that our fee schedule does provide useful guidance as to what will be considered a minor amendment. 10 CFR Part 170.31, Schedule of Materials Fees, 15. E on Import and Export licenses states that minor amendments are revisions that "do not involve any substantive changes to license terms and conditions or to the type/quantity/chemical composition of the material authorized for export" and "do not require in-depth analysis, review, or consultations with other Executive Branch, U.S. host state, or foreign governments authorities." For example, adding a new ultimate foreign consignee for Category 1 exports will normally not constitute a

minor amendment, since additional review by the NRC and foreign government authority will be required before approving the export to a new consignee. Therefore, the most effective means to limit the number of non-minor changes to an export license is to provide as many potential end user addresses at one time as possible. In addition, for Category 1 exports, applicants should request an authorization to export to all potential end users contingent on the receipt of favorable consent requests. Such authorization provides export licensees with the greatest flexibility that NRC can provide with respect to license expiration dates, resulting in fewer amendment fees.

With regard to the guidance, NRC has provided guidance on export licensing regarding many countries. In addition, NRC continues to work with the international community through the International Atomic Energy Agency and the Executive Branch to make the export licensing process as transparent as possible.

Our office will review and if necessary, refer any proposed licensing scenario to the Executive Branch for analysis without cost in order to enable your company to make an informed and more cost-effective licensing decision.

Thank you for sharing your views with us and giving us an opportunity to respond to your specific concerns. I hope we have provided you with some useful solutions to your concerns. Feel free to contact us if you have any additional comments or concerns.

Sincerely,

*/RA/*

Scott W. Moore, Deputy Director  
Office of International Programs

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Sincerely,

/RA/

Scott W. Moore  
Deputy Director,  
Office of International Programs

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\*Previously concurred

\*\*Provided edits and concurred

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