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USNRC

November 29, 2004 (1:35pm)

Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC  
20555-0001  
United States

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

Attention: Rulemaking and Adjudication Staff

**RE: Export and Import of Nuclear Equipment and Radioactive Materials:**  
**Security Policies**  
**RIN 3150-AH44**  
**Federal Register Vol.69, No.179, September 16, 2004**

Dear Sir or Madam:

MDS Nordion welcomes the opportunity to comment on the United States Nuclear Regulatory Commission's (USNRC) proposed security rules for import and export of radioactive material. We recognize that the NRC is taking a leading role, as other countries have yet to propose rules to implement the International Atomic Energy Agency (IAEA) Code of Conduct or the IAEA Guidance for the Import and Export of Radioactive Sources (Guidance).

Our general comment, which is captured in the specific comments below, is that the proposed amendments to the regulations should be harmonized with the IAEA Code of Conduct and Guidance. Harmonization is needed because implementation by other countries needs to work smoothly with NRC regulations to be effective and efficient, and so all implementations should operate from a common set of definitions and operating principles. In addition, the international implementations of the Code of Conduct and Guidance should be uniform so as to maintain equitable trade opportunities.

Template = SECY-067

SECY-02

## **110.27          General license for import**

Although the proposed rule not only includes the Category 1 and 2 radioactive sources as identified in the Code of Conduct it also includes a more encompassing term “radioactive material.” Therefore, unlike the Code of Conduct the proposed rule encompasses the import and export shipments of bulk radioactive material, in addition to sealed sources.

Comment: This difference has no immediate consequences for MDS Nordion but may affect other companies. It may also lead to confusion and problems with international shipments, as foreign States or facilities may not realize that the proposed USNRC rule also applies to bulk material and inadvertently ship this material to or from the US without proper authorization.

## **110.42 (e)(1) Export licensing criteria**

The receiving country has the appropriate technical and administrative capability, resources and regulatory structure to manage the material in a secure manner.

Comment: Findings concerning the acceptability of importing states should be performed in an internationally harmonized manner in order to avoid confusion and maintain a fair balance of trade. Therefore, implementation should occur only after guidance is developed in an international setting. In the absence of such guidance, the USNRC should provide guidance regarding the principles by which it will establish its findings, and make public a list of countries to which export is permitted.

## **110.42 (e)(2) Export licensing criteria**

The foreign recipient is authorized to receive and possess the material.

Comment: For Category 2 amounts of radioactive material, the USNRC should permit the exporting facility the authority to determine whether the importing facility is authorized to receive the radioactive material. This is permitted by the Guidance and is needed due to the high volume of Category 2 shipments.

## **110.42 (e)(3) Export licensing criteria**

In exceptional circumstances, that an alternative arrangement has been made to manage the material in a safe and secure manner.

Comment: The USNRC should provide criteria consistent with the IAEA guidance regarding the meaning of “exceptional circumstances.” Interpretation of “exceptional circumstances” should be internationally harmonized in order to avoid confusion and ensure fair balance of trade.

## **110.50 (b)(4) Terms**

The NRC office responsible for receiving advance notifications for all export and import shipments will be specified on each specific export and import licence.

Comment: The USNRC has not designated one point of contact for importers wanting to obtain a licence to import to the United States, as is recommended by the Guidance.

Notifications must be made at least 24 hours in advance of each shipment, and to the extent practical, 10 days in advance of each shipment.

Comment: The USNRC request that the notification be made 10 days in advance as opposed to 7 days in the Guidance. The USNRC should change the notification period to 7 days.

## **2.390 Public inspections, exemptions, requests for withholding**

Subject to the provisions of paragraphs (b), (d), (e) and (f) of this section, final NRC records and documents, including but not limited to correspondence to and from the NRC regarding the issuance, denial, amendment, transfer, renewal, modification, suspension, revocation of a license, permit, or order, or regarding a rulemaking proceeding subject to this part shall not, in the absence of an NRC determination of a compelling reasons for nondisclosure after a balancing of the interests of the person or agency urging nondisclosure and the public interest in disclosure, be exempt from disclosure and will be made available for inspection and copying at the NRC web site and/or at the NRC Public Document Room.

Comment: Much of the information exchange between the USNRC and importers and exporters will be sensitive information from a security or business perspective. The rule should contain a discussion of this issues and explanation how the USNRC will protect this information from public disclosure.

If you have any questions or require further information please feel free to contact me by telephone at [mcharette@mds.nordion.com](mailto:mcharette@mds.nordion.com).

Yours sincerely



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