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GIPA

GAMMA INDUSTRY PROCESSING ALLIANCE

*Working together to prevent
disease through irradiation*

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Via Fax No. (301) 415-1101

October 7, 2005

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

Attention: Rulemaking and Adjudication Staff

**RE: National Source Tracking of Sealed Sources
10 CFR Parts 20, 32 and 150
RIN 3150-AH48**

Dear Sir or Madam:

The Gamma Industry Processing Alliance (GIPA) welcomes the opportunity to comment on the United States Nuclear Regulatory Commission's (USNRC) proposed National Source Tracking of Sealed Sources. The GIPA members include gamma irradiation technology companies that represent or supply all of the microbial control gamma irradiation services in North America. GIPA represents almost all facilities within the United States that use cobalt-60 for the purpose of sterilization of medical supplies, and other radiation processing applications such as microbial reduction in food. Together these facilities sterilize more than 40% of the single use sterile medical supplies used daily in our hospital wards and operating rooms in the United States.

Our general comment is that the USNRC should make a commitment to international harmonization on the source tracking system, and take whatever steps are appropriate towards that prior to implementation. This will align with the recommendations in Section 11 of the International Atomic Energy Agency (IAEA) Code of Conduct. We believe that harmonization is needed because implementation by other countries needs to work smoothly with USNRC regulations if tracking systems are to be effective and efficient. If implementation by all national authorities is based on a common set of definitions and operating principles, equitable trade opportunities will be maintained.

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OFFICE OF SECRETARY
RULEMAKINGS AND
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GIPA members are the importer or exporter of almost all the high activity sealed sources entering or leaving the United States for use in gamma irradiators. The implementation of national systems should make efficient use of industry current practices to minimize cost and administrative burden. GIPA encourages the US Nuclear Regulatory Commission to harmonize their National Source Tracking System with other countries, specifically Canada and the United Kingdom to ensure a compatible web interface and data format. The use of compatible data format and transfer protocol for import/export information could be electronically transferred to the USNRC National Source Tracking System at the same time as other sealed source tracking systems situated in foreign countries.

GIPA believes that a National Source Tracking System is a good idea and encourages the USNRC to also take a consultative and practical approach to design the system. In Canada, the CNSC has engaged MDS Nordion, a member of GIPA, in discussions on design of the Canadian Sealed Source Tracking System. GIPA is willing to work with the USNRC and the CNSC to create similar data requirements for the United States National Source Tracking System.

To ensure the creation of a functionally effective National Source Tracking System, it is imperative that the USNRC include representatives of the industry, specifically manufacturers and users of Category 1 and 2 sources. We are of the opinion that representatives of the industry must be part of the National Source Tracking System design team. This will provide the opportunity to review the specification for the system to understand how the web interface will operate and what kind of 'machine readable' data format will be used.

Below are specific comments:

Section B – What Is a Nationally Tracked Source?

For consistency with the IAEA Code of Conduct, Category 3 sources should not be included in the National Source Tracking System.

Section G – What Information Would Be Collected on Source Transfer?

It is suggested that item (3) no transaction involving the use of a nationally tracked source at a temporary job site is required. The intent of the regulations is to ensure that sources are managed and handled in an appropriate and safe manner. The intent of the National Inventory is to know who has responsibility and management over the sources and not where the sources are at any given moment. When the licensee is using a source at a job site, the source has been signed out of the licensee inventory and remains under the control of the licensee.

Section J – How Would the National Source Tracking System Information Be Kept Current?

Two independent checkers for data entry is not required and is overly burdensome for electronic data transfers. Checks of the electronic data entry will be done independently through the import/export controls or transfers between licensees. For example, during the import/export of sources an electronic data file acting as the notification and containing the data fields required for the National Source Tracking System will be sent to the USNRC. The recipient, who acts as the independent checker, can verify the data and acknowledge receipt of the sources through the National Source Tracking System. This process is essentially a Quality Assurance check. As such, to ensure an efficient, effective and error free National Source Tracking System it is critical that the system be harmonized nationally and internationally.

The only occasion where two independent checkers may be required would be for a paper entry for sources transferred between two sites of the same licensee. In this case the same individual may be responsible to enter the information for the transfer.

National Source Tracking Transaction Report

The National Source Tracking Transaction Report, paper forms, provided during the National Source Tracking System Public Meeting are dysfunctional. Shipment of multiple sources would require the completion of multiple forms with the duplication of information, which could take several hours to complete. The National Source Tracking Transaction Report cannot be used in their current format and should be revised.

Once again, we appreciate the opportunity to comment on this important initiative. Please feel free to contact me should you require any clarification on our comments.

Yours truly,



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Fax Transmission

To: Secretary Fax: 1(301) 415-1101
US Nuclear Regulatory Commission

Attention: Rulemaking and Adjudication Staff

RE: National Source Tracking of Sealed Sources
10 CFR Parts 20, 32 and 150
RIN 3150-AH48

Company: **Us Nuclear Regulatory Commission**

Date: October 7, 2005

Sender Carol Chateauvert for Grant Malkoske,
Chairman, GIPA

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