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Fax: 1 (301) 415-5144

RE: RSPS-TF

Company: USNRC

Date: February 10, 2006

Sender Carol Chateauvert

Copy:

on behalf of Grant Malkoske,

Chairman, Gamma Industry Processing Alliance

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Message:

RE: RSPS-TF
Radiation Source Protection and Security Task Force – Request for Public Comment

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GIPA

GAMMA INDUSTRY PROCESSING ALLIANCE

*Working together to prevent
disease through irradiation*

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February 10, 2006

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Chief
Rules and Directives Branch
Division of Administrative Services
Offices of Administration
Mail Stop T6-D59
U.S. Nuclear Regulatory Commission
Washington, DC
20555-0001, United States

**RE: RSPS-TF
Radiation Source Protection and Security Task Force
Request for Public Comment**

Dear Sir or Madam:

These comments concerning Radiation Source Protection and Security Task Force are submitted on behalf of Gamma Industry Processing Alliance (GIPA). The Gamma Industry Processing Alliance (GIPA) represents the suppliers and users of Cobalt- 60 sealed sources used in large commercial irradiators for various commercial processes including the sterilization of medical devices and the treatment of food products to reduce harmful bacteria. The alliance has 15 member organizations from the gamma processing industry that include all of the large irradiator owners. The mission of GIPA is to promote the safe, effective and commercially viable use of gamma technology through industry collaboration on technical, business and regulatory issues.

Current Members Include:

Abbott Laboratories	Bausch & Lomb	Baxter Healthcare
Becton Dickinson	Cardinal Health	Ethicon Endo-Surgery, Inc.
GRAY*STAR, Inc.	SteriGenics	MDS Nordion
REVISS Services, Inc.	STERIS Corporation	STERIS Isomedix
Terumo Medial Corporation	Tyco/Healthcare/Kendall	3M Health Care Group

The comments and suggestions proffered below are specific to the use of cobalt-60 in commercial irradiators under USNRC regulations (10CFR36). Commercial cobalt-60 irradiators are a small subset of the total use of isotopes under USNRC jurisdiction. However, both the regulation and the physical nature of commercial irradiators provide inherent security protections. These inherent protections, in most cases, provide greater security than other uses of isotopes in the United States.

It is vital that the task force has a full understanding of the nature of commercial irradiators. The Gamma Industry takes security issues very seriously. Security is the responsibility of both the industry as well as its regulators (USNRC). GIPA, as the representative of the Gamma Industry is ideally positioned to provide direct support for the regulators. GIPA respectfully requests that the task force include representatives from the Gamma Industry. Without direct participation, the task force might lead to even more onerous inconsistencies that would be counter to its purpose, potentially damaging a vital segment of our economy, and perhaps, ultimately leading to a less secure use of isotopes.

Below are specific comments:

Topic No. 1 – The list of radiation sources requiring security based on potential attractiveness of the source to terrorists and the extent of the threat to public health and safety.

- GIPA strongly urges the NRC and the task force to be consistent in its approach to categorization for applicability of source protection and security measures with the IAEA Code of Conduct thresholds. The USNRC should continue only with Category 1 and 2 sources.
- Cobalt 60 Sources used in Commercial Irradiators are not attractive to terrorists:

The non-dispersible nature of cobalt-60 is not conducive to a radiological terrorist device.

The inherently high radiation levels make the handling of cobalt-60 (without significant infrastructure) virtually impossible.

The design and operation of irradiators would make it extremely difficult for a terrorist to gain access to the cobalt-60.

The operations and regulations for a cobalt-60 irradiator make it very difficult for a person or persons with the intent to do harm to be undetected.

The limited number of commercial irradiator assures a close working relationship with the USNRC and Agreement State equivalents.

Topic No. 2 – The national system for recovery of lost or stolen radiation sources.

- Recovery of sources in Commercial Irradiators is well managed, safe, and secure. Commercial Irradiators use relatively few, very expensive, encapsulated sources. The sources are the heart of the irradiator. They are usually in use 24/7. The concept that a source could be lost or stolen without the immediate knowledge of the Material License holder is highly unlikely.

Topic No. 3 – Storage of radiation sources that are not used in a safe and secure manner.

- Storage requirements for Commercial Irradiators are well regulated, safe and secure.

Topic No. 4 – The national source tracking system for radiation sources.

- Cobalt 60 Sources in Commercial Irradiators are currently tracked by serial number from cradle to grave and the provision for this information under the proposed program is appropriate.
- Virtually 100% of Cobalt- 60 sealed sources used in large commercial irradiators in the United States come from two vendors who already have very robust tracking systems in place. The USNRC should take advantage of this experience when designing their source tracking system.
- The implementation of national systems should make efficient use of current practices to minimize cost and administrative burden. To ensure a practical and workable source tracking system, GIPA urges the USNRC to consult with industry while developing the system and software.

Topic No. 5 – A national system to provide for the proper disposal of radiation sources.

- The USNRC should reevaluate the financial assurance provision to more accurately and realistically account for disposal and decommissioning costs of an irradiator facility. The USNRC has ruled that the salvage value for radioactive material may not be used to directly offset the decommissioning cost. However, it is well accepted in the worldwide gamma processing industry that there is a commercial market for previously used Co-60 sources above a certain activity level. Sources above this threshold should not be subject to financial assurance and should not be used to offset the cost of disposing of lower activity sources. Source suppliers should undertake to take back sources above a certain activity level, re-encapsulate them (if required) and redistribute them to the industry. Therefore there is no burden on the taxpayer for the disposal of these sources.

- The current rule requires the licensee to provide assurance for the total licensed amount, not the current installed amount. In some cases, this difference is large. The USNRC should require financial assurance for the amount installed. If the activity is increased during the three year cycle the financial provision should be adjusted accordingly.

Topic No. 6 – Import and export controls on radiation sources to ensure that recipients of radiation sources are able and willing to adequately control radiation sources.

- The USNRC should reevaluate the need for a specific import licenses to allow the importation of a radiation source to a US licensed user. Sources imported to the United States are destined to properly licensed users who have received a license by either the USNRC or an Agreement State. Other countries that have implemented or are considering the implementation of the Import/Export requirements from the Code of Conduct do not require the need for a specific import license, and include this authorization as part of the site license. The US NRC should adopt this approach, as specific import licenses are a significant and cost administrative burden with little value. Notification of the import would still be sent, of course, and therefore the USNRC would know of the import and to whom it is destined. In essence, a specific import license is redundant.

Topic No. 7 – Procedures for improving the security and control for use and storage of radiation sources.

- GIPA believes that there is a major gap that has lead to major inconsistencies for the protection of “sensitive information”.

Topic 7 states: “Both NRC and Agreement States have inspection programs to evaluate whether licensees are meeting the requirements and can take enforcement actions against licensees to ensure compliance.” This system allows for a party to receive a license to possess and use by-product material, and then to receive and/or handle “sensitive” and SGI-M materials. They are held accountable for that material directly through their possession of a Material License.

Only the NRC Staff can determine what material is either “sensitive” or SGI-M. The NRC Staff will redact any material that it determines is “sensitive” or SGI-M from a License Application prior to public release.

A party may petition the Atomic Safety and Licensing Board (ASLB) for a hearing on an application for a Material License. Part of this process allows the Petitioner to receive a copy of the Application for a Material License. [See 10CFR36.209(f)(2)]

The question becomes, what material does the Petitioner have the right to receive? More specifically, do they have the right to receive “sensitive” and/or SGI-M

contained within the Application? And, if they do have a right to these materials, how is the material to be protected?

As stated in Topic 7, there are rules in place that allow for the enforcement of licensees to ensure compliance, but there is little if no protection for this enforcement on non-licensees. Therefore, if the ASLB gives out a License Application to a Petitioner that contains "sensitive" and/or SGI-M, there are no rules governing how these materials will be protected. Nor are there any rules on what "sensitive" or SGI-M material may be distributed by the ASLB.

Therefore, GIPA respectfully recommend that the Task Force address potential rulemaking that would:

1. Clearly define what "sensitive" materials may or may not be made available to a non-licensee (public) in an ASLB Adjudication by the Presiding Officer.
2. If it is deemed that the public has a right to these materials: Develop protection and enforcement provisions to protect the "sensitive" material.
3. Develop rules on the above that would not allow the issue of "sensitive" information to delay the hearing process beyond the time schedules put into effect in the "Changes to Adjudicatory Process; Final Rule" on February 14, 2004.

GIPA believes that there is presently no prohibition of the Presiding Officer of the ASLB to freely hand "sensitive" or SGI-M material to a member of a terrorist group that petitions for a hearing under their rights as a member of the public.

Topic No. 8 – Procedures for improving the security of transportation of radiation sources.

- The transport security measures imposed by the USNRC have been ambiguous and have gone beyond the security measures imposed by the USDOT for other dangerous goods. Through these actions the USNRC has indicated that the transport of radioactive material possess a greater risk than other dangerous goods. The USNRC should re-evaluate the security measures imposed on the transport of radioactive material and should consider harmonizing the measures with the USDOT. Additional security measures imposed for the transport of radioactive material are causing difficulty for carriers who may no longer transport this material. The USNRC must balance these risks against the social and economic benefit gained by the use of cobalt-60 in the healthcare and other industries. Transport security measures should be compatible to those imposed on other dangerous goods with similar risk.
- Cobalt-60 sources for use in Commercial Irradiators are transported in a safe and secure manner according to guidelines. However, current treatment by State and local agencies create confusion and hand-off coordination concerns that could be eliminated with source to destination inspection reciprocity, neutral transport carrier

commercial markings, and elimination of attention attracting escorts. New generation mobile tracking devices and use of cellular communication technology should be advanced to state of the art "best available" status.

- The USNRC should take a more active role in resolving State discrepancies in the implementation of the security measures imposed by the USNRC. Inconsistent approaches and requirements amongst various States make it difficult for carriers to comply, and leads to carriers not wanting to transport this material. States should be encouraged to implement the measures as described by the USNRC and not impose additional measures.

Topic No. 9 – Background checks for individuals with access to radiation sources.

- Detailed background checks are already in place for operating personnel at Commercial Irradiators. Fingerprinting would be of questionable added value. Fingerprinting could significantly delay the ability of a licensee to certify new operators required to safely operate the irradiator. GIPA recommends that the task force perform a cost/benefit analysis on any fingerprinting requirements. If it is determined that there is an advantage to fingerprinting then GIPA suggests that the fingerprinting be required within a certain time period after a new person, requiring such, is allowed to perform their assigned function. Access to Safeguards Information, by definition, does not require this level of security (fingerprinting). A fingerprint requirement for individuals with "access to radiation sources" would be inconsistent with fingerprinting for those with access to Safeguards Information.
- The physical access to the radiation sources in a Commercial Irradiator is very restrictive even for a person defined as having "access to radiation sources". The physical nature of the irradiator and the equipment required to successfully handle the cobalt-60 sources would make it very difficult in a limited amount of time for an "individual with access to the radiation sources" to potentially use the sources for harmful intent.
- The number of personnel at an irradiator "with access to radiation sources" is very limited. It would be very difficult for an individual with harmful intent to go without suspicion.

Topic No. 10 – Alternative technologies.

- Commercial Gamma Irradiation processing has been in worldwide use for over 50 years. Approximately 45% of medical disposables worldwide are currently sterilized using gamma, and moving to a different sterilization technology would be an extremely costly and lengthy process, and would serve to increase healthcare costs. A rapid shift in technologies may even disrupt the supply of sterile medical devices.

- Many products such as medical devices are specifically designed to use gamma irradiation. Many life saving products would not be on the market today if it were not for gamma irradiation.
- For many products, gamma irradiation is the only existing technology. For example, some products cannot tolerate the elevated temperatures created in other sterilization processes, or are designed in such a way that only gamma is able to achieve full penetration and guaranteed sterility.
- Many materials such as wood plastic composites would not exist without gamma irradiation.
- When considering "alternative technologies", one must consider the cost/benefits to these technologies. In many cases, alternate technologies represent a more plausible security risk than the use of gamma irradiation. Many alternate technologies do not have the safety record of gamma irradiation.
- The US produces approximately 50% of medical devices used in the world. A shift to less competitive and effective technologies would accelerate the erosion of this market share by encouraging manufacturers to move production off shore where gamma continues to be widely accepted. Unilateral shift in technology by the US does not eliminate worldwide use of the technology. Ironically, if the US were to shift to a less attractive technology, other countries, with potentially less control on radioisotope security, may employ gamma irradiation technology.
- Ultimately the free market must determine alternate technologies. If the market determines that gamma irradiation is the preferred technology based on cost/benefit analysis, then it is the USNRC, along with the Licensees, to assure that the facilities are secure.
- Industry is always searching for new technologies that are both cost effective and efficacious. Many have been tried to replace gamma irradiation. Some have succeeded and some have failed. To determine "alternate technologies" independent from market conditions would not serve the well being of our citizens.

Yours truly



(for) Grant Malkoske
Chairman
Gamma Industry Processing Alliance (GIPA)