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Science Advancing Health

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USNRC

December 19, 2002 (4:02PM)

Ms. Annette L. Vietti-Cook  
Secretary of the Commission  
U.S. Nuclear Regulatory Commission  
11555 Rockville Pike  
Rockville, Maryland 20852

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

Dear Ms. Vietti-Cook:

SUBJECT: PROPOSED RULE: FINANCIAL ASSURANCE AMENDMENTS  
FOR MATERIALS LICENSEES

I am writing to you on behalf of the gamma processing industry to provide constructive input which is intended to help address security concerns amongst the industry and the public as it relates to gamma irradiation facilities.

The Gamma Industry Processing Alliance (GIPA) is being formed to ensure our specific interest area is being represented in the various legislative and regulatory initiatives that could affect our industry. While in the early stages of formation, 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 (see attached list). The gamma sterilization services we provide make an essential contribution to the reliability and viability of the US national health care system. In addition it should be noted that the U.S. healthcare industry produces 50% of all of the sterile single use medical devices used worldwide of which some 50% are gamma sterilized. Any disruption of these activities would have global consequences.

GIPA welcomes the opportunity to comment on the proposed Amendments to the regulations for financial assurance as it applies to large irradiators. Our specific comments are in the attachment to this letter. While generally supportive of the USNRC proposed amendment, we believe that any decommissioning plan must consider the commercial value of the cobalt-60 sealed sources. As discussed in the attachment, we believe that the commercial value of cobalt in irradiators affects the decommissioning cost beyond the certification amount (as revised), and irradiator decommissioning can therefore continue to be covered under this amount.

We would like to thank you for the opportunity to discuss the proposed Amendments and provide written comments prior to their being finalized. We look forward to working with the USNRC in the future on these and other licensing matters. Should you require any clarification of our comments, please address them to me and I will ensure that they are replied to.

Grant Malkoske  
Chairman,  
Gamma Industry Processing Alliance  
Attachment

Template = SECY-067

SECY-02

## *Gamma Industry Processing Alliance*

### **Comments on USNRC Proposed Rule: Financial Assurance Amendments for Materials Licensees**

The following comments address the proposed rule only from the perspective of large irradiator licensees and have been compiled through the Gamma Industry Processing Alliance (GIPA).

For large irradiator licenses, the principal change proposed is modifying the method for financial assurance evaluations from a certification amount to a site-specific decommissioning cost estimate. While the regulations do not specifically address the assumptions to be applied in the cost estimate, NUREG/CR-6280 includes cost of source disposal in most of the decommissioning scenarios that were evaluated. In the discussion accompanying the rulemaking, there is a general acknowledgement that sources may be returned to the manufacturer and not sent for disposal. However, there is a clear implication that disposal costs are a principal consideration in the rulemaking.

In comparing the necessity for a site-specific decommissioning estimate versus a certification amount, there should be an acknowledgement that the cobalt sources in the irradiators are a commodity with commercial value exceeding the cost of removal and shipping. The commercial value of sources that would be removed from a decommissioned irradiator offsets any costs that would not be easily covered by the certification amount, were that to be allowed.

Assuming no source leaks have occurred at the facility and given that there is a resale value for the sources, there is only a slight probability that any radioactive waste disposal costs would be incurred during irradiator decommissioning. Therefore, the cost for decommissioning large irradiators is relatively stable, with the variability in cost for irradiators with different licensed possession limits arising almost exclusively from the greater effort required to remove the additional sources. That is, aside from the time required to remove and transport the sources from an irradiator with a licensed possession limit of, for example, five megacuries versus one with a limit of one megacurie, the cost for decommissioning (e.g., surveys and documentation) does not vary greatly. With the additional cost of removal and transport for the sources being recovered from the resale or redistribution value of the sources, there is little difference in the cost for decommissioning an irradiator that falls below the limit for certification amounts in the proposed regulation (i.e., 1 MCi) as compared to one that requires a site-specific decommissioning cost estimate.

Therefore, large irradiator licensees should be allowed to use the certification amount for decommissioning financial assurance. Given that the current certification amount of \$75,000 is outdated, GIPA acknowledges that this amount would need to be increased. The proposed certification amount of \$113,000 should be adequate to address decommissioning an irradiator if the commercial value of the sources is used to offset the decommissioning cost.

The impetus for a three-year evaluation period on financial assurance requirements is the increasing radioactive waste disposal costs. As stated above, decommissioning of an irradiator where there have been no leaking sources does not involve disposal of materials as radioactive waste. Therefore, the time interval for reassessing the financial assurance provisions should be a five years, in order to be coincident with the license renewal period.

**Gamma Industry Processing Alliance**

**List of products commonly processed by Cobalt 60:**

<p><b><u>Surgical Products:</u></b>          Airways and Tubes          Alcohol Wipes          Bandages          Biopsy Punches, Guns, Accessories          Bone Saw          Catheters (Foley, Angiographic, Urinary)          Cement (Implants)          Colostomy Appliances, Accessories          Drainage Bags          ECG Electrodes          Electrocautery Devices          Fetal Probes          Grounding Pads          Hypodermic Needles and Syringes          Implants (hips, knees, fingers, etc.)          Instruments          Intrauterine Devices          Irrigation Kits (Surgical, Ophthalmic)          IV Administration Sets          Laparotomy Pads</p>	<p>Laparoscopy Accessories          Luer Lock IV Injection Sites          Marking Pens          Needle Counters          OR Towels          Ostomy Appliances, Accessories          Protheses (arterial, vascular, orthopedic)          Scalpel Blades          Shunts          Sponges, Gauze          Sterile Water          Stockinettes          Stopcocks          Surgeons Gloves/Powders          Surgeons Scrub Brushes (plain and impregnated)          Surgical Drapes and Gowns          Surgical Procedure Packs and Trays          Sutures          Swabs          Syringes (water, saline, etc.)</p>
<p><b><u>Medical/Pharmaceutical Products:</u></b>          Aluminum Hydroxide          Aluminum Tubes          Artificial Insemination Pipettes          Bandages, Impregnated and Plain          Bioassay Dishes and Tubes          Blood and Bleeder Bags          Blood Collection Tubes          Blood Lancets          Blood gas Syringes          Blood Serum          Body Bags          Burn Blankets, Pads and Ointments          Centrifuge Tubes          Charcoal Suspension          Clean Room Supplies          Closures (inserts, caps, plugs, rings, etc.)          Cotton Balls          Culture Flasks, Tubes and Trays          Dental Anchors, Burrs and Sponges          Drainage Bags          Drug Delivery Pumps          Drug Products          Saline Solutions and Wipes          Specimen Containers          Taurine          Test Tubes</p>	<p>Drug Mixing/Dispensing Systems          Drum Liners          Diagnostics          Empty Poly Bottles and Closures          Enteral Feeding Bags and Kits          Enzymes          Equipment Covers          Excipients          Eye Droppers and Ointments          Fetal Blood Sampling Kit          Fetal Calf Serum          Filters (syringe, IV, membrane)          Garments (disposable and reusable)          Lubrication Gels          Magnesium Aluminum Silicate          Magnesium Glycerophosphate          Mastitis Ointments and Test Kits          Petri Dishes          Pipettes          Plasma Pooling Bottles          Proteins          Pump/Trigger Spray Assembles          Thermometers/Covers          Tissue Culture Labware          Tongue Depressors          Topical Ointments</p>