

OFFICE OF THE SECRETARY
CORRESPONDENCE CONTROL TICKET

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To: Zimmerman, NSIR

AUTHOR: Grant Malkoske (GIPA)
AFFILIATION:
ADDRESSEE: Chairman
SUBJECT: Concerns Gamma Industry Processing Alliance

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ACTION: Appropriate
DISTRIBUTION: Chairman, Comrs.

LETTER DATE: 03/27/2003

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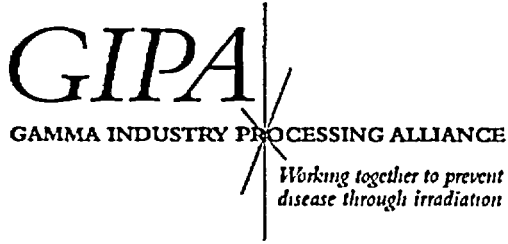
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Grant Malkoske
 Chairman

VIA COURIER AND TELEFAX
 March 27th, 2003

The Honorable Richard A. Meserve
 Chairman
 United States Nuclear Regulatory Commission
 11555 Rockville Pike
 Rockville, Md. 20852

Dear Chairman Meserve:

SUBJECT: Gamma Industry Processing Alliance

I am writing to introduce you to the Gamma Industry Processing Alliance, which has been established by the industry members in North America. The Gamma Industry Processing Alliance has been formed to ensure our specific interests are being represented and addressed in the various legislative and regulatory initiatives that could affect our industry. Of particular current interest are the security concerns amongst the industry and the public as it relates to gamma irradiation facilities. To introduce you to us, I have enclosed for you a copy of the mission statement for the Gamma Industry Processing Alliance as well as a list of our member companies and their primary representatives.

While in the early stages of formation, the Gamma Industry Processing Alliance represents almost all facilities within North America 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, as shown on the enclosed list. The gamma sterilization services we provide make an essential contribution to the reliability and viability of the U.S. national health care system. In addition, it is noteworthy 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.


Through our network of contacts in the industry, we have recently participated in the review of the USNRC Interim Compensatory Measures and Safeguards Advisory that are

directly related to our business. We would like to assure you that we agree without reservation of the need to address additional security measures following the terrorist events of September 2001, and we support the USNRC's initiative to identify and define them clearly. In fact, we have already implemented the elements identified in the USNRC Safeguards Advisory issued on December 13, 2001 as well as the recent Safeguards Advisory. We believe that it is necessary to carefully choose supplementary measures so as to maximize real security benefits while controlling administrative difficulties and costs as much as possible. This balance is important to the ongoing viability of our gamma industry that performs such an important service to the global healthcare community. In fact the medical device manufacturers, after spending many years designing sterile medical devices and more secure impermeable device packaging materials that take advantage of the unique penetrating properties of gamma radiation, have no other realistic alternative for sterilizing many of their products.

In recent months, speculation over radiological disposable devices and other potential terrorist activity involving radioactive material has been prominent in the press. Cobalt-60 technology has occasionally been mentioned in this context, and we consider this attention to be unbalanced, inappropriate, and in most if not all cases technically incorrect. For the most part, however, we have no recourse to this publicity, as entering into a debate will not serve a useful purpose. The legislation currently being proposed in response to media attention is also a major issue of concern, and we understand that the USNRC must work in this context. It is important that all of us, while acknowledging the need for increased security, help bring balance to the introduction of any new security measures by choosing them prudently to attain the necessary improvements while minimizing the negative impact on the industry. We believe we must be insistent to resist imposing measures that have the appearance of introducing high levels of security but are complex, costly, and not truly as effective as they appear.

In summary, we would like to emphasize again our agreement with the need for continued vigilance to ensure the security of cobalt-60 in gamma processing applications, especially in these perilous times. We look forward to continued consultation with the USNRC as security measures are being defined and implemented, as it relates to transport, gamma irradiators, or other matters that may affect the gamma processing industry.

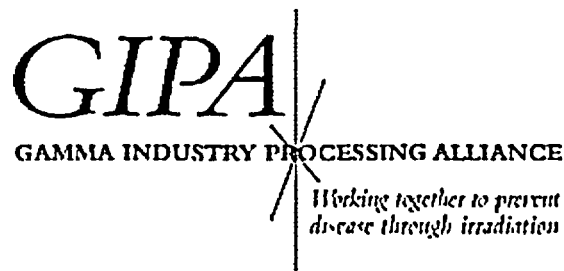
Yours truly,



Grant Malkoske,
Chairman,
Gamma Industry Processing Alliance.

Attachments

1. GIPA Mission Statement
2. GIPA Contact List
3. Gamma Processing of Medical Products



Mission

- To ensure that gamma irradiation is positioned as a safe, secure, viable technology for the sterilization of medical supplies, food irradiation and other radiation processing applications.

Objectives

- Build and enhance public, user, and media confidence in gamma irradiation as a safe and secure application of technology for the gamma processing industry.
- Build and enhance public and media confidence in transport of cobalt-60 as a safe and secure means to deliver radioisotopes for the gamma processing industry.
- Participate in the development of legislative and regulatory initiatives that impact the industry, including security concerns, and minimize any negative public relations, technical and financial impact on the commercial use of gamma irradiation technology.
- Participate in the establishment, acceptance, implementation and application of appropriate Safety Standards and Codes of Practice for gamma irradiation technology.
- Assist in the education of legislators, government agencies, professional associations and, where feasible, the public and media with respect to beneficial use of gamma irradiation technology.
- Represent the interests of the Members with national and international industry associations, legislative authorities and regulatory agencies.

Programs

To date, the ***Gamma Industry Processing Alliance (GIPA)*** has taken the following actions:

- Established a core organizing committee and extended participation to all users in North America.
- Reviewed the landscape of legislative and regulation related to security initiatives that could impact the economic viability of gamma technology.
- Initiated a working relationship with other trade organizations with similar, though more peripheral, interests on safe and beneficial uses of gamma technology.
- Commented to the USNRC on draft Interim Compensatory Measures (ICM's) for transport of large quantities of radioactive materials and panoramic irradiators.
- Organized a working group and commented on the USNRC proposed rule for Financial Assurance Amendments for Materials Licensees.

Organization

The ***Gamma Industry Processing Alliance*** members include gamma irradiation technology companies that represent or supply all of the microbial control gamma irradiation services in North America. ***GIPA*** will act as a resource or repository for information to achieve our objectives. We will respond as necessary to current and emerging issues that are relevant to our mission and objectives.

Grant Malkoske (gmalkoske@mds.nordion.com) is Chairman of ***GIPA***. Please forward to him any industry issues that warrant attention by the membership.

Background

The ***Gamma Industry Processing Alliance (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. The gamma sterilization services we provide make an essential contribution to the reliability and viability of the U.S. 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.

Members of ***GIPA*** agree without reservation of the need to address additional security measures following the terrorist events of September 2001. We support the legislative and regulatory initiatives being taken to identify and define them clearly. In fact, we have already implemented the elements identified in the NRC Safeguards Advisory issued on December 13, 2001. At the same time we request that any additional measures contemplated be chosen to maximize real security benefits while controlling administrative difficulties and costs as much as possible. This balance is important to the ongoing viability of our gamma industry that performs such an important service to the global healthcare community and other industries utilizing irradiation technology. In fact the medical device manufacturers (after spending many years designing sterile medical devices that take advantage of the unique penetrating properties of gamma radiation) have no other realistic alternative for sterilizing many of their products.

In recent months, speculation over radiological dispersion devices (dirty bombs) and other potential terrorist activity related to radioactive material has been prominent in the press. Cobalt-60 technology has occasionally been mentioned in this context, and we consider this attention to be unbalanced, inappropriate, and in most if not all cases, technically incorrect. For the most part, however, we have no recourse to this publicity, as entering into a debate will not serve a useful purpose. The legislation currently being proposed in response to media attention is also a major issue of concern, and we understand that the NRC must work in this context. It is important that all of us, while acknowledging the need for increased security, help bring balance to the introduction of any new security measures by choosing them prudently to get incremental improvements while minimizing the negative impact. We urge the NRC to resist imposing measures that have the appearance of introducing high levels of security but are complex, costly, and not truly as effective as they appear. Specifically, we recommend that the use of armed guards not be a mandatory requirement, but left as an option for jurisdictional authorities to include when deemed appropriate.

February 28, 2003

Attachment 2

Pages 1 and 2 of Attachment 2 have been redacted in their entirety.

Gamma Processing of Medical Products

List of products commonly processed by Cobalt 60:

<p><u>Surgical Products:</u> 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><u>Medical/Pharmaceutical Products:</u> 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>Laparoscopy Accessories Luer Lock IV Injection Sites Marking Pens Needle Counters OR Towels Ostomy Appliances, Accessories Prostheses (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>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 Assemblies Thermometers/Covers Tissue Culture Labware Tongue Depressors Topical Ointments</p>
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Gamma Processing of Medical Products

List of products that can not be sterilized by other means/modalities:

Certain products due to their design & manufacturing process are compatible only with gamma sterilization. Following is a list of products that can only be treated by gamma radiation technology (electron beam aside) for sterility or bio-reduction purposes.

- Labware Products – made of styrene and other plastics are temperature sensitive (eliminates heat or steam technologies) also are sensitive to chemical residuals. If contaminated by EtO or other by-products from a technology that leaves chemical residuals, cell growth in tissue culture studies, microbiological studies and other serum and biological high tech cell growth applications will be affected and is unacceptable. Gamma radiation is the only technology that is clean of chemical residuals for these types of products.
- Human/animal tissue implants to include bone allografts.
- Specific soft tissues used for implants
- Sterile Saline/Water/bicarbonate and other solutions and liquids that cannot be filter sterilized due to final packaging or viscosity.
- Products with Pyronema (although steam has been validated for this as well, gamma is clearly the method of choice)
- Filled media plates (microbiological/medical).
- Certain products, both medical and non-medical with high moisture content (ingredients, biogluce, etc.) that are temperature sensitive may form unwanted chemical residuals if processed with EtO (Chorhydrin if chloride is present, ethylene glycol and ethylene oxide).
- Wet Dressings that are temperature sensitive and/or hermetically packaged
- Prep Pads such as alcohol or PVP
- Serums (bovine & others).
- Stop – cocks and other devices or device components that are temperature sensitive and are designed occluded areas
- Filled syringes.
- Certain Biological products.
- Bee Hives.

Factors preventing the use of other sterilization technologies:

- Closed Packaged Products – Many products are designed with high strength, non-breathable materials that cannot be processed with technologies that require permeation of steam or gas & changes in atmospheric pressure. These products range from medical devices to raw materials and consumer products such as Peat Moss, Poly-lined drums, teething rings and hermetically seals products.
- Dense Materials – many raw materials are packed in boxes and drums and are very dense limiting permeation of steam or gases into the container. Further, steam and gas may cause clumping, change piratical size and have other physical effects that render the product useless. Spice, talc, raw materials, water soluble materials, powders and the like are processing only with gamma radiation for this reason.

Unwanted Chemical Residuals – Certain products have a propensity to absorb/adsorb chemical sterilants Gamma radiation is considered a “clean” process – no chemicals are involved, only pure energy.