July 23, 2003

MEMORANDUM TO: William J. Desmond, Acting Director
Nuclear Security Policy - Project Directorate
Division of Nuclear Security, NSIR

FROM: Philip G. Brochman, Sr. Program Manager ***/RA/***
Materials, Transportation, and Waste Security Section
Division of Nuclear Security, NSIR

SUBJECT: SUMMARY OF APRIL 7, 2003, MEETING WITH GAMMA INDUSTRY ON NRC SAFEGUARDS ADVISORY SA-03-01

On April 7, 2003, U.S. Nuclear Regulatory Commission (NRC) staff held a closed meeting with members of the Gamma Industry Processing Alliance (GIPA) and a representative of the U.S. Department of Transportation, Research and Special Programs Administration. The purpose of the meeting was to discuss GIPA's potential adverse public health impacts due to shortfalls in the production of sterile single-use medical devices. A copy of GIPA's presentation and the attendance list are attached [Attachments 1 and 2].

GIPA indicated that these shortfalls of sterile single-use medical devices would occur because of industry's inability to ship replacement sources of the radionuclide ^{60}Cobalt to their irradiation facilities. In Safeguards Advisory SA-03-01, dated March 17, 2003, the NRC advised licensees to defer shipments of ^{60}Co greater than 999 terrabecquerels (TBq) [27,000 curies] during the ongoing Operation LIBERTY SHIELD.

GIPA indicated that its irradiation facilities were currently operating at 100 percent capacity and with normal decay rate for ^{60}Co [one percent per month] these facilities would shortly not be able to sterilize the volume of sterile single-use medical devices that health-care industry required to treat routine and emergency medical conditions. This situation was in response to the health care industry's practice of just-in-time delivery of medical devices, to contain rising health-care costs. GIPA also indicated that because of the nationwide nature of the shipment deferrals (i.e., all facilities were affected), GIPA members could not use other members facilities to levelize production demand. Finally, GIPA indicated that the U.S. Department of Defense had requested one member be ready to significantly ramp up production of certain sterile single-use medical devices in support of Operation IRAQI FREEDOM.

GIPA believed these circumstances met the national security or life-threatening medical condition exceptions mentioned in Safeguards Advisory SA-03-01. Accordingly, GIPA requested that the Commission consider resumption of shipments of ^{60}Co to facilities that sterilize single-use medical devices or to facilities that manufacture ^{60}Co seal sources for use in facilities that sterilize single-use medical devices.

Attachments: 1. GIPA Presentation
2. Attendance list

CONTACT: Philip Brochman, NSIR/DNS/MTWS, (301) 415-6557

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SUBJECT: SUMMARY OF APRIL 7, 2003, MEETING WITH GAMMA INDUSTRY ON NRC SAFEGUARDS ADVISORY SA-03-01

On April 7, 2003, U.S. Nuclear Regulatory Commission (NRC) staff held a closed meeting with members of the Gamma Industry Processing Alliance (GIPA) and a representative of the U.S. Department of Transportation, Research and Special Programs Administration. The purpose of the meeting was to discuss GIPA's concerns relating to adverse health impacts to the public due to shortfalls in the production of sterile single-use medical devices. A copy of GIPA's presentation is attached [Attachment 1]. A copy of the meeting attendance list is also attached [Attachment 2].

GIPA indicated that these shortfalls of sterile single-use medical devices would occur because of industry's inability to ship replacement sources of the radionuclide ^{60}Cobalt to their irradiation facilities. The NRC had advised in Safeguards Advisory SA-03-01, dated March 17, 2003, that licensees defer shipments of ^{60}Co greater than 999 terrabecquerels (TBq) [27,000 curies] during the ongoing Operation LIBERTY SHIELD.

GIPA indicated that current irradiation facilities were currently operating at 100 percent capacity and that with normal decay rate for ^{60}Co [one percent per month] these facilities would not be able to sterilize the volume of sterile single-use medical devices that health-care industry required to treat routine and emergency medical conditions. This situation was exacerbated by the health care and irradiation industries' existing practice of just-in-time delivery of medical devices as a means of containing rising health-care costs. GIPA also indicated that because of the nationwide nature of the shipment deferrals (i.e., all facilities were affected), GIPA members could not use other members facilities to levelize production demand. Finally, one of the members of GIPA indicated that U.S. Department of Defense had requested the member be ready to significantly ramp up production of certain sterile single-use medical devices to support Operation IRAQI FREEDOM.

GIPA believed these circumstances met the national security or life-threatening medical condition exceptions mentioned in Safeguards Advisory SA-03-01. Accordingly, GIPA requested that the Commission consider resumption of shipments of ^{60}Co to facilities that sterilize single-use medical devices or to facilities that manufacture ^{60}Co seal sources for use in facilities that sterilize single-use medical devices.

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