

May 22, 2003

Dr. Jill Lipoti, Assistant Director
Radiation Protection Programs
Division of Environmental Safety, Health
and Analytical Programs
Department of Environmental Protection
P.O. Box 415
Trenton, New Jersey 08625-0415

Dear Dr. Lipoti:

This is in response to an e-mail message you sent to me and other members of the U.S. Nuclear Regulatory Commission (NRC), dated April 11, 2003. In your message, you raised concerns about the NRC changing its advisory deferring shipments of ^{60}Co . Specifically, you were concerned that this action had been taken without the involvement of public stakeholders. Furthermore, you had requested an opportunity to discuss the basis for resumption of these shipments, including a clearer understanding of what constitutes "life-threatening medical conditions," but that you were not provided that opportunity before shipments resumed.

First of all, I regret that we did not have an opportunity to meet with stakeholders like you before the decision was made to allow the resumption of shipments of ^{60}Co . The NRC is interested in stakeholder involvement in the regulatory process and finds such involvement advantageous to safety. In this case, the NRC was responding to a request from the industry that ^{60}Co sources were necessary for them to continue operations and the staff decided that such action was in the public interest. Industry indicated in their presentation that an immediate medical problem existed due to the shortage of sterile single-use medical devices with the continued deferral of ^{60}Co shipments. The industry's interest in resolving this issue and resuming shipments seemed sufficiently urgent that they scheduled a meeting with the NRC on short notice. Given the time frame of the scheduling, and the fact that the concern appeared to warrant prompt action on the part of the NRC, we decided to go ahead with the meeting and address the industry's request. Due to the urgency of the issue, there was not considered to be sufficient time to follow our normal process, which would have included meetings with stakeholders and provided a forum for discussing and clarifying the meaning of terms such as "life-threatening medical conditions."

As for your concerns about the veracity of the industry's presentation, the NRC expects that information provided verbally or in writing by a licensee to be complete and accurate. On this matter, the staff found the industry's information to be reasonable. However, the NRC followed up on the matter by providing a copy of industry's presentation to the Food and Drug Administration's (FDA) Office of Device Evaluation. In a telephone conversation on April 16, 2003, FDA management indicated that they were in agreement with the industry information. FDA also noted that they do not monitor industry's business practices, i.e., capacity and

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throughput, rather they regulate the safety of the devices and the operation of an irradiation facility focusing on ensuring the safety of the medical devices. Similarly, the NRC does not regulate the design of sterile single-use medical devices or industries' business practices, i.e., just-in-time delivery. The NRC and Agreement States regulate the safety and security of sterilization facilities.

Since the resumption of shipments and the date of your e-mail, I understand from the staff that there have been additional conversations between you and the NRC and, at this time, it appears that your concerns have been addressed. However, to further improve coordination with the States in the future, the NRC has established a Materials Security Working Group to develop enhanced security requirements and engage stakeholders in our continuing efforts to resolve issues of the type you have raised.

Thank you for your comments on this matter and we appreciate the continued support and cooperation from the State of New Jersey in protecting the public.

Sincerely,

/RA/

Roy P. Zimmerman, Director
Office of Nuclear Security
and Incident Response

cc:
S. Caspersen
State of New Jersey
Office of Counter-Terrorism

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Roy P. Zimmerman, Director
Office of Nuclear Security
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cc:

S. Caspersen
State of New Jersey
Office of Counter-Terrorism

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ADAMS ACCESSION NUMBER: **ML031140031 (package)**
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* See previous concurrence page

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