Sterigenics.

April 4, 2011

ATTN: Document Control Desk
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Reference: Inspection of Sterigenics Quality Assurance Program Approval 0524

In response to the findings of the inspection of the Sterigenics program for managing radioactive material shipments under quality assurance program approval 0524, which was conducted at the Charlotte, NC, facility on March 8 and 9, 2011, the following describes the corrective and preventive actions being taken to address the violation noted during the inspection. The Severity Level IV violation cited was a failure to properly maintain and execute a quality assurance program satisfying the applicable criteria of 10 CFR 71. Several examples were cited in the inspection report of specific areas where this failure occurred.

As discussed during the inspection, the corrective and preventive action for the cited violation is that Sterigenics will discontinue the internal program for shipping radioactive sources from our facilities. Instead, for any sources being returned to the manufacturer or any other authorized recipient, Sterigenics will contract to an authorized party to offer the package for shipment, including preparing the package and signing the applicable documentation as the shipper of the package. For the foreseeable future, the source supplier, either Nordion or Reviss, will be the contracted party for each shipment, depending on the destination of the sources.

We feel that these organizations are better equipped to remain current with the requirements and procedures than is Sterigenics, as outbound source shipments do not occur frequently within our organization. To that end, I have sent a letter requesting termination of Quality Assurance Program Approval 0524 and have confirmed the contract arrangements with Nordion for the next source shipments to occur from a Sterigenics facility.

I trust that, since we will no longer be performing these functions, that the corrective action would be considered adequate to prevent recurrence. Should you need any further information or clarification, please let me know.

Sincerely,

Mark A. Smith, Ph.D., CHP
Vice-President, Radiation Services

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