

Inspection Background

Sterigenics is the holder of a 10 CFR Part 71 Quality Assurance Program (QAP) Approval. During a review of shipping records at the headquarters of MDS Nordion (located in Kanata, Ontario, Canada) in late 2009, the NRC noted that Sterigenics had signed shipping papers as the offeror of licensed material for export shipments to Nordion from various Sterigenics facilities in the United States. The NRC determined, through consultation with the U.S. Department of Transportation (DOT), that Sterigenics had not registered with DOT as a user of the Type B packagings used for the exports. Further review of shipping records by DOT and NRC inspectors identified potential non-compliances by Sterigenics with NRC and DOT regulations; specifically, failure to comply with Certificate of Compliance (CoC) conditions for the packagings used for the export shipments in the 2008-2010 time frame. Based on these concerns, the NRC determined that it should inspect Sterigenics' implementation of its NRC-approved QAP. The DOT co-conducted an inspection at the same time as the NRC inspection to confirm the nature and number of potential DOT regulatory non-compliances. While the DOT non-compliances could also be cited under NRC's Part 71 regulations, specifically 10 CFR 71.5 that requires NRC licensees to adhere to DOT transport regulations, in accordance with the NRC/DOT Memorandum of Understanding (dated 07/02/79), and with DOT's agreement, the potential violations of 10 CFR 71.5 requirements were turned over to DOT for enforcement to preclude duplicative action by the agencies. It should be noted that Sterigenics is treated as an NRC licensee under 10 CFR Part 110 when exporting licensed material.

Inspection Results

The inspection team performed a systematic review of Sterigenics' Cask Quality Procedures (CQPs), submitted as the basis for their NRC Part 71 QAP Approval, to determine whether quality activities as described in the procedures were being properly implemented. The inspection team identified the following issues:

- CQP-002, "Document Control," addresses the issuance of Cask QA manuals and control of any changes. The CQP addresses only hard copy distribution and controls on the Cask QA manuals. The team was informed that Sterigenics had implemented an electronic records system and that the Cask QA manuals had been deleted as of May 2010.
- CQP-005, "Assignment of Quality Levels," assigns Quality Levels (QL) to contracts and programs for deliverable products or services. CQP-005 describes the criteria for assigning a designation of QL 1, QL 2, or QL 3. CQP-006, "Procurement Control," requires that procurement of products, services or operations be denoted as QL 1, 2 or 3, and CQP-007, "Approval of Subcontractors," utilizes the designation of QL 1, 2, or 3, as defined in CQP-005. The team determined that corporate level procedure, WI-001-PUR-NA, "Supplier Approval," effective May 28, 2010, defines QL 1, 2, and 3 in essentially the reverse order of CQP-005. The corporate level procedure defines the method for approving suppliers.
- CQP-007 states that Cask Program Management shall maintain an Approved Supplier Log (ASL). The team was informed that the ASL is maintained at the corporate level and utilizes the process controlled by WI-001-PUR-NA.
- CQP-009, "Training," requires maintenance of qualification records for various personnel, including for those performing audits. Qualification records could not be produced for the Cask Program Manager who is also a lead auditor.

- CQP-010, "Audits," states that Cask Program Management shall utilize or assure that auditors are trained and certified in accordance with ISO Standard No. 10011 or N45.2.23, or equivalent ANSI/ASME NQA-1, Section 18, requirements. The team determined that auditor qualification is controlled by corporate level procedure QSP-012, "Internal Audits," and that this procedure does not specify any of the standards listed in CQP-010 for auditor qualification.
- CQP-010 requires the planning and scheduling of planned QA audits. The team determined that while audits of packaging operations have been performed, no audit of overall Part 71 QAP activities has ever been performed.
- CQP-015, "Control of Measuring and Test Equipment (M&TE)," states that all M&TE shall be calibrated. The team determined that several recently procured torque wrenches, used at various Sterigenics locations, did not have calibration records on file.
- CQP-016, "Quality Assurance Program," states that at least annually, the Cask Quality Program shall be reviewed to ensure its continued applicability and effectiveness. The team was informed that such a review was not performed in 2010, that past reviews have not been adequate in meeting this requirement, and that the last such review was performed in March 2003.

Based on the above issues, the team determined that Sterigenics failed to properly maintain and execute its NRC-approved QAP. This constitutes a violation of 10 CFR 71.101, "Quality Assurance Requirements," subpart (b), that states, in part, each licensee shall maintain and execute a QAP satisfying each of the applicable criteria of 10 CFR 71.101 through 71.137. The above referenced CQPs all implement various criteria of 10 CFR 71.101 through 71.137.