

June 18, 2009

MEMORANDUM TO: Nader Mamish, Deputy Director
Licensing and Inspection Directorate
Division of Spent Fuel Storage and Transportation, NMSS

FROM: Jessica Glenny, Project Manager **/RA/**
Rules, Inspections, and Operations Branch
Division of Spent Fuel Storage and Transportation, NMSS

SUBJECT: SUMMARY OF MAY 21, 2009, MEETING WITH BEST
THERATRONICS

Background

A public meeting was held on May 21, 2009, in Rockville, Maryland, between U.S. Nuclear Regulatory Commission (NRC) staff and Best Theratronics (Best), to follow up on a March 23, 2009, conference call. The purpose of the meeting was to discuss details surrounding recent shipments of radioactive material completed by Best. NRC recognized that Best had not transferred the Certificates of Compliance (CoCs) for the transportation packages they recently acquired from MDS Nordion, to their name, prior to shipping radioactive material in the packages. As a result, Best made shipments of licensed material in Model No. F-423, CoC No. 9299, without a license, in violation of 10 CFR 71.3. In addition, Best had not submitted their quality assurance (QA) program for approval and had not registered with the NRC to use the transportation package, both requirements of 10 CFR Part 71.17(b) and (c)(3), respectively. While the NRC is not aware of any actual safety consequences associated with the shipments, the staff expressed concern that Best did not recognize their responsibilities prior to shipping radioactive material under 10 CFR Part 71.

Discussion

The purpose of the meeting was for Best to present to NRC staff information in several areas, including the events leading up to a potential non-compliance which included Best's history as it related to the transition of business assets from MDS Nordion; the use of CoC Nos. 9290, 9299 and 9310 for the Model Nos. F-430/GC-40, F-423, and F-431 Transport Packages, respectively; recent shipping experience; current status of Best's QA program; and Best's planned corrective actions to NRC's concerns. Three points were highlighted by NRC staff at the beginning of the discussion: 1) the fundamental role of the Division of Spent Fuel Storage and Transportation, 2) the expectation and requirement to be in full compliance with the certificate, and 3) the expectation that use of any package is in full compliance with the certificate.

During the meeting, Best discussed that both Best and MDS Nordion have been the same company for over 50 years and carried personnel over from MDS Nordion into Best as an added benefit to the transition. Best also responded that MDS Nordion uses the same CoCs for the transportation packages but maintains ownership of the packages. Best indicated that, based on discussions with MDS Nordion, upon expiration of the certificates Best will take over ownership of the packages and request a name change to be reflected in the certificates. NRC

staff clarified that any entity making a shipment in the United States must be registered with the NRC. To further emphasize this point, NRC staff stated that shippers must be registered users of a package prior to first use and must have a QA program in place. To avoid further confusion, NRC staff made a clear differentiation between certificate holders versus a transfer of a certificate.

NRC staff inquired about any corrective actions that Best may have implemented when the noncompliances were identified. It was not clear if Best took any corrective actions. Best stated that they performed an investigation against their transportation plan, which references 10 CFR Part 71. Best's finding was that they were in compliance and met the "spirit" of the regulations. NRC staff clarified that since Best did not register as a user of the package and did not have a NRC-approved QA program, they did not have a general license in accordance with 10 CFR 71.17.

In March 2009, Best had stopped shipping radioactive materials in Type B packages in consideration of NRC concerns. Furthermore, Best has completed an investigation and modified their process for review of shipments. Best has also submitted requests to have NRC a) approve its QA program, b) transfer ownership of the CoC's, and c) register them as package users. NRC inquired about shipping commitments to clients. The NRC made no regulatory commitments but made Best aware of three potential outcomes based on the information discussed at the meeting: 1) no violation, 2) issuance of a Notice of Violation (NOV) with a required response, or 3) issuance of an NOV with no response required.

Docket Nos. 71-9290, 71-9299, 71-9310
TAC No. LA0119

Enclosures:

1. Meeting Agenda
2. List of Meeting Attendees
3. Best Theratronics Presentation

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Agenda
Thursday, May 21, 2009, 1:00 p.m. – 3:00 p.m.
Best Theratronics

Purpose: To discuss Best Theratronics' business, the material to be transported, recent shipping experience, the implementation of their Quality Assurance Program, and compliance with the certificates for their packages.

1:00 p.m. General Meeting Information and Introductions

1:05 p.m. Best Theratronics' Presentation and Discussion

2:20 p.m. Public Comments

2:30 p.m. NRC staff caucus

3:00 p.m. Meeting Adjourned

Meeting Between Best Theratronics and the Nuclear Regulatory Commission
May 21, 2009
Meeting Attendees

Bill Brach	NRC/SFST
Nader Mamish	NRC/SFST
Dave Pstrak	NRC/SFST
Jessica Glenn	NRC/SFST
Earl Love	NRC/SFST
Jim Pearson	NRC/SFST
Eric Benner	NRC/SFST
Christopher Staab	NRC/SFST
Ruth Bergin	Best Theratronics
Michael DeVanDerSchueren	Best Theratronics
Abe Ghosh	Best Theratronics
Blair Menna	Best Theratronics
Paul Moses	Best Theratronics
Krishnan Suthanthiran	Best Theratronics
Jag Uppal	Best Theratronics
Mark Vist	Best Theratronics