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October 29, 2012

United States Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

SUBJECT: REPLY TO A NOTICE OF VIOLATION

Best Theratronics respectfully submits that a violation of 10 CFR Part 71 has occurred as described in the United States Nuclear Regulatory Commission's inspection report 71-0943/2012-201 and notice of violation dated October 5, 2012.

A detailed response including corrective actions and completion dates has been provided below.

Please contact me if you require any further information.

Sincerely,

Richard Wassenaar
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cc. Eric Benner
Chief, Rules, Inspections and Operations Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards

IE07
NMSS

A. 10 CFR 71.111, "Instructions, Procedures, and Drawings," states in part, "the certificate holder shall prescribe activities affecting quality by documented instructions, procedures or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed."

Contrary to the above, the following three examples were identified where activities affecting quality were not prescribed in documented instructions, procedures or drawings or where instructions, procedures or drawings for activities affecting quality were not followed:

1. Fabrication drawings did not identify the correct construction code for fabricating stainless steel components.

   (1) the reason for the violation;

   CSA standard W59-03 Welded Steel Construction (Metal Arc Welding) does not cover welding of stainless steel, however it has the following note in section 1.2: "When welding stainless steel, other standards such as AWS D1.6 could be referenced". BTL procedure P 0690 Z00 'Welding Engineering Standard' references AWS D1.6 but does not specifically call it off for stainless steel welds. All Welding Process Data Sheets (WPDS) involving stainless steel correctly call off AWS D1.6 as a reference standard.

   (2) the corrective steps that have been taken and the results achieved;

   BTL procedure P 0690 Z00 'Welding Engineering Standard' will be updated to specifically state the instances when AWS D1.6 is to be used when welding.

   (3) the corrective steps that will be taken to avoid further violations;

   All affected personnel will be trained on the revised procedure.

   (4) the date when full compliance will be achieved.

   November 30, 2012.

2. Best Welding Engineering Standard No.: P0690Z00 (4) did not identify a construction code for the fabrication welding of stainless steel components.

   (1) the reason for the violation;

   BTL procedure P 0690 Z00 'Welding Engineering Standard' references AWS D1.6 but does not specifically call it off for stainless steel welds. All Welding Process Data Sheets (WPDS) involving stainless steel correctly call off AWS D1.6 as a reference standard.

   (2) the corrective steps that have been taken and the results achieved;

   BTL procedure P 0690 Z00 'Welding Engineering Standard' will be updated to specifically state the instances when AWS D1.6 is to be used when welding.

(3) the corrective steps that will be taken to avoid further violations;

All affected personnel will be trained on the revised procedure.

(4) the date when full compliance will be achieved.

November 30, 2012.

3. Best procedure [I1677Z00 (B)] "Visual Inspection of Welds" does not contain specific acceptance or rejection criteria for weld inspection for the fabrication of stainless steel components

(1) the reason for the violation;

BTL procedure I 1677 Z00 'Visual Inspection of Welds' references CSA W59-03 and CSA W47.1 however these do not cover the requirements for welding of stainless steel. All Welding Process Data Sheets (WPDS) involving stainless steel correctly call off AWS D1.6 as a reference standard.

(2) the corrective steps that have been taken and the results achieved;

BTL procedure I 1677 Z00 'Visual Inspection of Welds' will be updated to include reference to AWS D1.6 for stainless steel, which contains acceptance or rejection criteria.

(3) the corrective steps that will be taken to avoid further violations;

All affected personnel will be trained on the revised procedure.

(4) the date when full compliance will be achieved.

November 30, 2012.

B. 10 CFR 71.133, "Corrective action," states in part, "The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition."

Contrary to the above, the following instances were identified by the NRC where activities affecting quality were previously identified as unacceptable and have now been determined to continue to exist even after corrective actions have been applied:.

1. The team found two weld defects on packagings that had previously been inspected for any needed repairs and found acceptable by Best.

(1) the reason for the violation;

The packagings had been inspected and corrected prior to the establishment and release of the new BTL procedure I 1677 Z00 'Visual Inspection of Welds' on December 4, 2009. BTL did not re-inspect the packagings after the release of the new procedure.

(2) the corrective steps that have been taken and the results achieved;

The two defects have been corrected so that they comply with BTL procedures for weld inspection.

(3) the corrective steps that will be taken to avoid further violations;

A new detailed welding visual inspection form/checklist will be created. This will identify and require sign-off for every weld on the packaging and will be performed by a certified weld visual inspector.

All packagings will be re-inspected to ensure that they are in compliance with the current weld inspection procedure.

(4) the date when full compliance will be achieved.

November 30, 2012.

2. Best management retrained their inspection staff and had them re-inspect the repaired packagings and found two additional packagings with six repairable defects after the retraining had been completed

(1) the reason for the violation;

The packagings had been inspected and corrected prior to the establishment and release of the new BTL procedure I 1677 Z00 'Visual Inspection of Welds' on December 4, 2009. BTL did not re-inspect the packagings after the release of the new procedure

(2) the corrective steps that have been taken and the results achieved;

The two identified packagings were corrected.

(3) the corrective steps that will be taken to avoid further violations;

A new detailed welding visual inspection form/checklist will be created. This will identify and require sign-off for every weld on the packaging and will be performed by a certified weld visual inspector.

All packagings will be re-inspected to ensure that they are in compliance with the current weld inspection procedure.

(4) the date when full compliance will be achieved.

November 30, 2012.