

Best[®] Theratronics

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Sept 30, 2009

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 Parts 21 and 71 has occurred as described in the United States Nuclear Regulatory Commission's inspection report 71-0943/2009-201 and notice of violation dated Sept 3, 2009.

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

Please contact me if you require any further information.

Sincerely,



Mike de van der Schueren
Director, Compliance
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A. 10 CFR 21.21(a), "Notification of failure to comply or existence of a defect and its evaluation," states, in part, that each corporation subject to the regulations in this part shall adopt appropriate procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable in order to identify a reportable defect or failure to comply that could create a substantial safety hazard were it to remain uncorrected. 10 CFR 21.31, "Procurement documents," states, in part, each corporation subject to the regulations in this part shall ensure that each procurement document for a facility or a basic component issued after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

Contrary to the above, Best: a) did not adopt appropriate procedures to ensure that evaluation of defects and failures to comply would be performed, and b) had no method or process for specifying, as applicable, when 10 CFR Part 21 applies to procurement activities.

(1) the reason for the violation;

CAPA 090814 - Best Theratronics (BTL) implemented a terms and conditions form that is attached to every purchase order. Within that form is a statement that 'The provisions of 10 CFR 21 may apply to suppliers in the USA'. It was BTL's belief that the terms and conditions met the requirements of regulation.

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

BTL will assume responsibility for the requirements of 10 CFR 21 on behalf of its U.S. based suppliers. The terms and conditions statement for each purchase order has been revised so that vendors report defects to BTL.

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

A new procedure will be written to address the evaluation of defects and assessment for reporting.

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

Oct 30, 2009

B. 10 CFR 71.105(d), "Quality Assurance program," states, in part, that the licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. Contrary to the above, Best's method used to qualify and certify Quality Control inspection personnel who perform visual inspections were not appropriately certified or suitably trained to ensure that adequate competency exists for the inspection tasks performed.

(1) the reason for the violation;

CAPA 090810 - Visual inspection of welding is the responsibility of the welder as required by the Canadian Welding Bureau's standard CSA W59. BTL is certified to perform welding under CSA W47.1 Certification. BMT Fleet Technology Limited is approved by the Canadian Welding Bureau to certify BTL under W47.1 and audits BTL's welding practices every 3 months.

Lack of procedure that defines the roles and responsibility of QC and welders.

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

All transport packages have been visually inspected.

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

A visual inspection standard is being developed by BTL that will be used by both welders and QC Inspectors and is in accordance with W59.

A new visual inspection procedure is being developed by BTL. Under this new procedure all welders and QC Inspectors will require visual inspection training.

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

Oct 30, 2009

C. 10 CFR 71.107, "Package design control," states, in part, that the certificate holder will establish measures to ensure that applicable regulatory requirements and the package design are correctly translated into specifications, drawings, procedures, and instructions. These measures shall provide for a verifying or checking process, where the certificate holder shall designate individuals or groups other than those who were responsible for the original design to verify the adequacy of the design. Contrary to the above, Best did not require or provide guidance for independent verification in Best procedures 3.24-AA-01(3), "Design Change Procedure," and 5.00-QA-04(1), "Design Control."

(1) the reason for the violation;

CAPA 090801 – BTL's design change procedure did not have sufficient controls in place to prevent the design change leader from also being the technical design authority for changes.

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

BTL procedures 3.24-AA-01, "Design Change Procedure," and 5.00-QA-04, "Design Control" have been modified so that design changes are verified by individuals other than those responsible for the change. All previous design changes were checked and updated, as necessary.

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

All affected personnel will be trained on the change to 3.24-AA-01.

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

Complete - the above procedures were modified and effective Sept 3, 2009.

Training will be completed by Sept 30, 2009

D. 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 instances were identified by the NRC 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. Best Procedure 5.00-QA-08(3), "Internal Quality Audits," does not include criteria for the review and approval of audits.

- (1) the reason for the violation;

- CAPA 090801 - The Director, Compliance approves all internal audit reports. The criteria are not documented in the internal audit procedure.

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

- BTL procedure 5.00-QA-08, "Internal Quality Audits" was updated to include criteria for the review and approval of audits.

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

- The Director, Compliance has completed training on the revised document.

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

- Procedure was modified and effective Sept 3, 2009. Training completed Sept 4, 2009.

2. BTL Procedure 3.24-AA-01(3), "Design Change Procedure," does not include the responsibilities for document management personnel.

- (1) the reason for the violation;

- CAPA 090801 - Although the design change process is well understood by BTL staff the responsibilities of document management personnel is not clearly defined in the documented procedure.

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

- BTL procedure 3.24-AA-01, "Design Change Procedure" has been modified to include the responsibilities of document management personnel.

- (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.

- The procedure was modified and made effective Sept 3, 2009. Training completed on Sept 30, 2009.

3. Best Procedure 3.24-AA-04(4), "Design Change and Limited Amendment Completion and Document Release Procedure," does not clearly identify how documents are marked "obsolete."

- (1) the reason for the violation;

CAPA 090801 - The procedure for the handling of obsolete documents does not clearly describe the actual process.

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

BTL procedure 3.24-AA-04, "Design Change and Limited Amendment Completion and Document Release Procedure" has been revised to make the process of obsolete documents more clear.

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

The Print Room Operator will be trained on the revised procedure.

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

The procedure was modified and made effective Sept 3, 2009. Training to be completed on Oct 2, 2009.

4. Best Procedure 5.00-QA-05(1), "Control of Documents," describes the process for review and approval of Non Destructive Examination (NDE) procedures. Best is not approving the procedures as required.

- (1) the reason for the violation;

CAPA 090801 - BTL procedure required all NDE procedures be approved by certified level II or III personnel.

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

All NDE procedures have been re-issued for approval, as appropriate.

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

5.00-QA-05, "Control of Documents" and 5.00-QA-15, "Process Control" will be modified to clarify the requirements..

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

Oct 30, 2009

5. Best Procedure 5.00-QA-19(2), "Nonconformance," Section 4.3.1, states, in part, that "Repair" or "Use As Is" dispositions require documented technical justification on the deviation report or on accompanying documentation; the NRC identified several instances where deviation reports dispositioned "Use- As-Is" or "Repair" did not have the required technical justification.

(1) the reason for the violation;

CAPA 090802 - Engineering approves all repair and use-as-is dispositions however the technical justification was not being recorded. This may be caused by lack of clarity on the deviation report form.

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

Quality Assurance approves all completed deviation reports and will ensure that effective immediately a technical justification will be recorded.

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

The deviation report will be modified to include a box that must be completed to document any adverse effects, if any, the disposition had on the product and any technical justification.

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

Oct 30, 2009

6. Best did not perform annual maintenance required by Best procedure IN/IM 2548 "Maintenance Overview Procedure."

(1) the reason for the violation;

CAPA 090804 - Annual inspections are performed and tracked by MDS Nordion (subcontract) and the record could not be found.

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

A new BTL procedure IN/IM 2548 F000 "Transport Package Maintenance Overview Procedure" was made effective Aug 7, 2009 to describe the system for annual inspection. All maintenance records since that time have been kept by BTL and maintenance files and the calibration database is used to track these records.

All transport packages were quarantined until such time that the annual inspection is completed by BTL.

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

It is anticipated that the above corrective will be sufficient to ensure that records of annual inspection will be retained by BTL.

IN/IM 2548 F000 "Transport Package Maintenance Overview Procedure" has been added to the internal audit schedule for 2010.

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

Completed Aug 17, 2009

7. Best's Weld Procedure Data Sheet (WPDS), No. FC-9, dated: March 30, 2005 and WPS P0684, Revision 5, dated 9/8/08, "Welding Procedure Specification for Flux

Cored Arc Welding of Carbon Steel" was violated by using a E491C-6MH-4 material as opposed to a E4916-6MH-16 material as defined.

(1) the reason for the violation;

CAPA 090811 - The stock filler material meets the requirements of the Welding Data Sheet, therefore its use is an acceptable practice according to the Canadian Welding Bureau. The welding procedure should have been updated to match the expanded acceptability of filler material allowed by the welding data sheet, providing consistence between both documents

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

The correct material for the application is being used.

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

Welding procedure P0684 will be updated to reference the welding data sheet. All welding procedures will be reviewed and updated, as appropriate. All welding procedures and welding data sheets require the approval of BMT Fleet Technology Ltd (welding engineer) and the Canadian Welding Bureau.

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

P0684 will be completed by Oct 30, 2009. The remainder of the welding procedures will be completed by Nov 30, 2009.

8. Best's implementing procedures and manufacturing Work Orders omit a requirement to perform and document results of visual inspection of weld seams and joints.

(1) the reason for the violation;

CAPA 090810 - Inspections are being performed by the welder but this is not documented on the work order. Under BTL's QA program the significance of manufacturing personnel signing off their operation as complete is visual evidence of conformity to requirements.

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

Visual inspections are being performed on all transport packages.

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

5.00-QA-11, "In Process Inspection" will be updated to include this requirement on the Work Order. Work orders for every weld operation will be updated on the ERP system to include a visual inspection by the welder and verification by QC inspection.

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

Oct 30, 2009

9. Gauge Calibration Procedure (GCP) -10, "Torque Wrenches," Step 5, states that each torque wrench shall be tested at 20%, 60%, and 100% of full load for accuracy. The gauge calibration report for torque wrench TQW-16, showed that it was not tested at 100% because the torque wrench testing device can only test up to 150 foot-pounds (ft-lbs) and TQW-16 is rated at 250 ft-lbs full load. Therefore, GCP-10 was not followed as written for the calibration of torque wrench TQW-16.

- (1) the reason for the violation;

CAPA 090806- Torque wrench TQW-16 was not being used in production to its full range and the QC lab incorrectly allowed this tool to be calibrated to a percentage other than 100% as per the procedure.

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

The QC inspector was retrained on the GCP procedure. All calibrations will follow the applicable GCP. In cases where the instrument cannot be calibrated in-house, it will be sent to an external calibration laboratory.

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

Same as above.

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

Completed Sept 22, 2009.

10. M&TE data base indicates which GCP is to be used for calibration purposes, however, the database frequently referred to previous revisions of the associated GCP, in some cases outdated revisions by several years.

- (1) the reason for the violation;

CAPA 090805 – The revision level of the GCP that was recorded in the calibration database was not being used. Current copies of GCPs are kept in a controlled copy binder in the QC lab.

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

The revision level of the GCPs was removed from the calibration database.

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

Best procedure 5.00-QA-06 "Measuring and Test Equipment" will be modified to include the requirement that current revisions of GCPs shall be used from the controlled copy binder.

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

Oct 9, 2009

11. Best procedure 5.00-QA-08(3) "Internal Quality Audits," does not provide guidance for determining lead auditor proficiency, consequently there is no evaluation being performed.

(1) the reason for the violation;

CAPA 090801 - Lead auditor proficiency is not specifically addressed in a procedure.

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

BTL procedure 5.00-QA-08 "Internal Quality Audits" has been updated to address how lead auditor proficiency is evaluated.

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

Same as above.

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

Completed Sept 3, 2009.

12. Best does not have quality procedures governing the use of the electronic data base system that is used to control quality related measuring and test equipment activities.

(1) the reason for the violation;

CAPA 090808 - The electronic database is used in accordance with the User Manual provided with the system. There is no reference to the system in the quality procedures.

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

5.00-QA-06 "Measuring and Test Equipment" has been issued for an update.

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

Best procedure 5.00-QA-06 "Measuring and Test Equipment" will be modified to include the procedure governing the use of the electronic database.

(5) the date when full compliance will be achieved

Oct 9, 2009

E. 10 CFR 71.133, "Corrective action," states, in part, that "the certificate holder shall establish measures to assure that conditions adverse to quality are promptly identified and corrected. In the case of a significant condition adverse to quality (SCAQ), the measures must ensure that the cause of the condition is determined and corrective actions taken to preclude repetition. The

identification of the SCAQ, the cause of the condition, and corrective action taken must be documented and reported to appropriate levels of management.”

Contrary to the above, the team reviewed Best’s corrective action for a Notice of Violation (NOV) that was issued May 29, 2009, and noted that in their response to the NOV, Best stated that they had conducted an internal investigation of how the violation occurred and had modified the process for conducting shipping reviews prior to shipping. The team determined that these actions, associated with a SCAQ, were not documented within Best’s corrective action system.

(1) the reason for the violation;

CAPA 090809 - BTL had modified the shipping review process but failed to document this change in a procedure. The response to the NOV issued on May 29, 2009 was appended to an existing CAPA that was initiated in March 2009. The scope and corrective action plan of the original CAPA was not updated to include the additional actions therefore objective evidence of the change was not recorded or verified by the CAPA originator.

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

BTL procedure 5.00-QA-03, “Contract Review” was modified to include the requirements for ‘Order Coordination’.

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

All QA staff will be re-trained on the CAPA process to prevent this from occurring again.

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

Procedure was modified and effective Sept 3, 2009. Training completed Sept 30, 2009.