September 3, 2009

Mr. Michael de van der Schueren
Best Theratronics, Ltd.
413 March Road
Ottawa, Ontario
Canada K2K 0E4

SUBJECT: NRC INSPECTION REPORT 71-0943/2009-201 AND NOTICE OF VIOLATION

Dear Mr. de van der Schueren:

From August 10 through 13, 2009, the U.S. Nuclear Regulatory Commission (NRC) performed an announced inspection of Best Theratronics, Ltd. (Best), at its office in Ottawa, Canada. The purpose of the inspection was to determine if activities associated with the transportation of radioactive material, being performed by Best, were in accordance with the requirements of 10 CFR Parts 21 and 71, applicable Certificates of Compliance (CoCs), related Safety Analysis Reports, and Best's NRC-approved Quality Assurance Program (QAP). The team inspected Best's management, design, maintenance, and fabrication controls. Inspection results are detailed in Enclosure 1 to this letter.

With respect to the inspection results, the NRC inspection team assessed that, overall, as presently developed and implemented, Best's QAP and procedures are marginally adequate in meeting the QA requirements of 10 CFR Part 71. The team identified multiple examples where Best personnel were not following QA procedures, where QA procedures did not contain sufficient details with regard to quality activities, and where the QA procedures did not support requirements in 10 CFR Part 71, Subpart H, 10 CFR Part 21, or in the QA Program Description submitted to the NRC that formed the basis of the NRC's approval of the Best QA program. The team also identified suspect welds on several packagings that resulted in Best quarantining their entire inventory of NRC CoC packagings pending further inspection and resolution of any weld deficiencies by Best in the post-inspection period.

At present, pending the results of Best's resolution of the weld quality issue described above, the inspection findings have no adverse safety impacts. However, many of the issues identified in the enclosed report were readily identifiable, and a more proactive and questioning attitude by Best personnel could have, and should have, identified the issues prior to the NRC inspection.

The NRC is concerned about the programmatic issues and violations identified in Best's QAP implementation. Accordingly, I have directed my staff to arrange a management meeting with you at NRC headquarters in Rockville, Maryland, at a date to be determined, to discuss the inspection findings documented in the attached inspection report and the actions you plan to take, or have already taken, to address the programmatic concerns and the specific violations.

Based on the results of this inspection, the NRC has determined that five (5) Severity Level IV violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject Inspection Report. The violations are being cited in the Notice because they were identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/NRC/ADAMS/index.html (the Public Electronic Reading Room).

Sincerely,

/RA/

David W. Pstrak, Chief
Rules, Inspections, and Operations Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-0943

Enclosures:
1. NRC Inspection Report No. 71-0943/2009-201
2. Notice of Violation (Notice)

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Sincerely,

/RA/

David W. Pstrak, Chief
Rules, Inspections, and Operations Branch
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Office of Nuclear Material Safety
and Safeguards

Docket No. 71-0943

Enclosures:
1. NRC Inspection Report No. 71-0943/2009-201
2. Notice of Violation (Notice)

Distribution:
Docket 71-0102
NRC f/c
Public
NMSS r/f
SFST r/f
EBrach, SFST
NMamish, SFST
RWharton, SFST

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OFC:	SFST	E	SFST	E	SFST	E	SFST	E				
NAME:	RTemps		JPearson		MDeBose		DPstrak					
DATE:	08/28/09		09/03/09		09/03/09		09/03/09					

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U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Spent Fuel Storage and Transportation

Inspection Report
EXECUTIVE SUMMARY

NRC Inspection Report 71-0943/2009-201

From August 10 through 13, 2009, the U.S. Nuclear Regulatory Commission (NRC) performed an announced inspection of Best Theratronics, Ltd. (Best), at its office in Ottawa, Canada. The team inspected Best's activities associated with transportation of radioactive material to determine if they were executed in accordance with the requirements of 10 CFR Parts 21 and 71, Certificates of Compliance (CoCs), Safety Analysis Reports, and Best's NRC-approved Quality Assurance Program (QAP). The team inspected Best's management, design, maintenance, and fabrication controls. The results of the inspection are as follows:

Management Controls

Best's implementation of management controls was assessed to be marginally adequate. Several violations were identified with regard to Best personnel not following QA procedures, where QA procedures did not contain sufficient details with regard to quality activities, and where the QA procedures did not support requirements in 10 CFR Part 71, Subpart H, or in the QA Program Description submitted to the NRC that formed the basis of the NRC's approval of the Best QAP. The implementation of 10 CFR Part 21 requirements was determined to be inadequate.

Design Controls

The design control process was adequate; however, a violation of NRC requirements was identified with regard to design control procedures failing to state when independent review of design activities is required.

Fabrication and Maintenance Controls

Best's implementation of fabrication and maintenance controls was assessed to be marginally adequate. The team reviewed manufacturing and maintenance activities and noted several instances of Best's failure to: a) appropriately plan, control and document maintenance and material control activities to assure that important activities have been satisfactorily accomplished and to prevent the use of incorrect weld filler material; b) establish and execute a program for inspection of activities affecting quality to assure conformance to the approved design; and c) adequately indoctrinate and train personnel performing quality inspections specific to welded joints.

Overall

The team assessed that Best's overall implementation of its NRC-approved QAP with regard to controlling activities subject to 10 CFR Part 71 was marginally adequate. A summary of inspection findings is presented in Table 1 below.

Table 1
Summary of Inspection Findings

Regulatory Requirement 10 CFR Section	Subject of Violation or Noncompliance	Number of Findings *	Type of Finding	Report Section
21.21(a) & 21.31	10 CFR Part 21	(2)	Level IV Violation	2
71.105	Indoctrination and Training	(1)	Level IV Violation	4
71.107	Design Control	(1)	Level IV Violation	3
71.111	Instructions/Procedures	(12)	Level IV Violation	2,4,5
71.133	Corrective Action	(1)	Level IV Violation	2

* Numbers in parentheses indicate the number of instances supporting the violation.

PERSONS CONTACTED

The team held an entrance meeting with Best on August 10, 2009, to present the scope and objectives of the NRC inspection. On August 13, 2009, the team held an exit meeting with Best to present the preliminary results of the inspection. Individuals present at the entrance and exit meetings are listed in Table 2.

Table 2
Entrance and Exit Meetings Attendance

Name	Title	Entrance Meeting	Exit Meeting
E. Love	NRC, Inspector	X	X
J. Pearson	NRC, Senior Inspector	X	X
R. Temps	NRC, Senior Inspector	X	X
D. Beatty	Best Theratronics	X	
J. Smith	Best Theratronics	X	X
J. McNamara	Best Theratronics	X	X
M. de van der Schueren	Best Theratronics	X	X
G. McCaffrey	Best Theratronics	X	X
B. Menna	Best Theratronics	X	X
P. Alexopoulos	Best Theratronics	X	X
M. Theriault	CNSC Observer*	X	X
J.C. Poirier	CNSC Observer *	X	X

* Individuals from the Canadian Nuclear Safety Commission who were invited to observe all or part of the inspection.

INSPECTION PROCEDURE USED

86001, “Design, Fabrication, Testing, and Maintenance of Transportation Packagings.”

REPORT DETAILS

1. Inspection Scope

The team inspected Best's management, design, maintenance, and fabrication controls to determine whether they were executed in accordance with the requirements of 10 CFR Parts 21 and 71, applicable CoCs, related SARs, and Best's NRC-approved QAP. The team reviewed documentation, interviewed personnel, and observed some activities and facility areas.

2. Management Controls

2.1 General

The team assessed the adequacy of management controls in the areas of Best's QAP implementation, nonconformance controls, documentation controls, and audit program. The team reviewed Best's practices and procedures, and their implementation, to determine the effectiveness of management controls.

2.2 Quality Assurance Program

2.2.1 Scope

The team reviewed Best's QAP to determine the effectiveness of plans and procedures that implement its program. The team inspected Best's QAP goals, objectives and practices, personnel responsibilities, QA organizational independence, management involvement, and staffing levels.

2.2.2 Observations and Findings

The team evaluated the independence of the quality organization and found it to be adequate. Overall, responsibilities were identified in quality procedures. However, the team identified that Best Procedure 3.24-AA-01(3), "Design Change Procedure," does not include the responsibilities for document management personnel. This is a violation of 10 CFR 71.111 which states, in part, that a certificate holder shall prescribe activities affecting quality by documented procedures. This violation is cited in the enclosed Notice. In response to this issue Best initiated Corrective and Preventative Action (CAPA) Report No. 090801.

Management involvement was reflected in Management Review Team Meeting minutes reviewed for June, 2008, October, 2008, February, 2009, and June, 2009. The team noted that other than an annual audit the quality assurance organization does not perform additional periodic checking or surveillance activities. In response to this issue Best initiated CAPA Report No. 090807.

2.3 Nonconformance Control and Corrective Action Program

2.3.1 Scope

The team reviewed Best's nonconformance control program to assess the effectiveness of measures established to control materials, parts, or components that did not conform

to requirements. The team determined how Best identified, segregated, tracked, and controlled, nonconforming items and any program deficiencies. The team inspected nonconformance reports, nonconforming items, and measures used to keep track of the status of nonconforming items. The team also reviewed Best's corrective action process and reviewed training and implementing procedures, internal postings, supplier notifications, reporting processes, and program controls in accordance with the provisions of 10 CFR Part 21, "Reporting of Defects and Noncompliance."

2.3.2 Observations and Findings

The team reviewed Best Procedures 5.00-QA-19(2), "Nonconformance," and 5.00-QA-20 (4), "Corrective Action and Preventive Action." The first procedure is used to control the process for documenting and resolving nonconforming product whereas the latter is used for the processing of issues within the Best corrective action and preventive action (CAPA) system. Both procedures provided adequate guidance for their respective processes and met 10 CFR Part 71 QA requirements.

The team reviewed a limited sample of nonconformance reports and noted that resolution of the issues was generally adequate and in accordance with the procedure. However, the team noted that several nonconformance reports that were dispositioned as "Use-As-Is" or "Repair" did not have documented technical justification on the deviation report or on accompanying documentation as required by Section 4.3.1 of Procedure 5.00-QA-19(2). This failure to follow procedure represents a violation of the requirements of 10 CFR 71.111 with regard to procedure adherence and is cited in the enclosed Notice. In response to this issue Best initiated CAPA Report No. 090802.

The team reviewed a sample of corrective action reports and noted that resolution of the issues appeared appropriate for the nature of the nonconformance. The team reviewed Best's corrective action for the Notice of Violation (NOV) that was issued May 29, 2009, as a result of Best conducting shipments without having the packaging CoCs transferred into their name and without an NRC approved QAP. The team noted that Best issued CAPA Report No. 090304 to capture the NOV issues and that the action plan for the CAPA simply involved obtaining NRC approval of Best's QAP and to obtain CoCs in Best Theratronics' name. 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 were not captured in the CAPA and no objective evidence was provided to the team as to how Best had arrived at these corrective actions or how they were implemented through procedure or programmatic changes. The failure of Best to document these issues, significant conditions adverse to quality, in a CAPA is a violation of 10 CFR 71.133 and is cited in the enclosed Notice. In response to this issue Best initiated CAPA Report No. 090809.

The team reviewed the manner in which Best implements the requirements of 10 CFR Part 21. The team noted that Best did not have procedural controls in place to ensure that items procured from suppliers in the United States invoked Part 21 requirements when applicable. The failure to invoke Part 21 requirements when appropriate is a violation of 10 CFR 21.31 and is cited in the enclosed Notice. In response to this issue Best initiated CAPA Report No. 090814. The team also identified that Best did not have appropriate procedures in place to evaluate deviations and failures to comply associated

with substantial safety hazards. This is a violation of the requirements of 10 CFR 21.21(a) and is cited in the enclosed Notice.

2.4 Documentation Controls

2.4.1 Scope

The team reviewed Best's documentation control program to determine the effectiveness of the QA program in controlling quality-related documentation and records. The team reviewed instructions, procedures, and drawings for adequacy, approval signatures, release by authorized personnel, and availability to personnel. The team reviewed documents such as inspection and test procedures, nonconformance reports, QA procedures, and packaging drawings. The team reviewed quality records to assure that they were properly identified, retrievable, controlled, and maintained.

2.4.2 Observations and Findings

The team reviewed procedural and record controls based on the issuance and capture of various revised Best procedures and work documents. The team noted that Best had changed some of the documents previously belonging to MDS Nordion to Best documents. Also noted, was the fact that a large number of MDS Nordion documents are still being used as Best's own documents. This particular fact was discussed with the Best Vice President and the Best Director of Compliance. The Vice President indicated at the time of the interview that no decision had been made as to the acceptance of the MDS Nordion documents as Best's own documents or if new documents would be drafted for use. While the content of many of the MDS Nordion documents still in use is presumed to be acceptable, according to Best's opinion, some modification, other than the name of the company, may eventually take place to provide official Best documents for use.

The team interviewed the QA Coordinator and the Document Management Representative in regard to how the Best document control system functioned and the distribution and receipt occurred for document users. The team tracked some sample documents from the point of origin to the user on the fabrication floor. The team also discussed the importance of version control since many documents are preprinted and available for use in a central location. The team determined that Best demonstrated adequate controls to assure that documents are approved for release by authorized personnel and distributed to applicable individuals and/or work stations. However, 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. In addition, the team reviewed Best Procedure 5.00-QA-05(1), "Control of Documents," Appendix A, and noted that the procedure prescribes the process for review and approval of Non-destructive Examination (NDE) procedures prior to release. The team noted that certain NDE procedures were missing required approvals from NDE Level III, customer and quality assurance. The failure to assure compliance to criteria defined within the procedures is a violation of 10 CFR 71.111 and is cited in the enclosed Notice. In response to this issue Best initiated CAPA Report No. 090801.

2.5 Audit Program

2.5.1 Scope

The team reviewed Best's audit program to determine whether plans, procedures, and records were available. The team determined whether Best scheduled and performed internal QA audits and vendor audits in accordance with approved procedures or checklists; whether qualified, independent, personnel performed the audits; whether Best management reviewed audit results; and whether Best took appropriate follow-up actions in those areas found to be deficient.

2.5.2 Observations and Findings

The team reviewed a variety of documents and interviewed the quality assurance coordinator in regard to the oversight from Best management and annual audits on activities affecting quality. The team reviewed an audit report that Best had completed since separating from MDS Nordion and found it adequate. The team noted from the documents reviewed that 10 CFR Part 71, Best Quality Manual 5.00-QA-00(2), "Quality Manual," Section 6.2, "Human Resources," and Best Procedures 5.00-QA-02(3) "Internal Quality Audits," and 5.00-QA-23(2) "Training," all indicate that Best personnel will be competent, trained, and aware. While an annual audit was satisfactorily completed and audit schedules exist, the team noted that Best Procedure 5.00-QA-08(3) "Internal Quality Audits," lacks guidance for the evaluation of proficiency for Best's lead auditors. In addition, the team noted that the same procedure does not provide review or acceptance criteria for the review of audits, consequently there is no evaluation being performed for either auditor proficiency or completed audits. The failure to assure compliance to criteria defined within the procedures is a violation of 10 CFR 71.111 and is cited in the enclosed Notice. In response to this issue Best initiated CAPA Report No. 090801.

2.6 Conclusions on Management Controls

Best's implementation of management controls was assessed to be marginally adequate. Several violations were identified with regard to Best personnel not following QA procedures, where QA procedures did not contain sufficient details with regard to quality activities, and where the QA procedures did not support requirements in 10 CFR Part 71, Subpart H, 10 CFR Part 21, or in the QA Program Description submitted to the NRC that formed the basis of the NRC's approval of the Best QAP. The implementation of 10 CFR Part 21 requirements was determined to be inadequate.

3. Design Controls

3.1 General

The team reviewed design controls in all phases of Best's design process, from the onset of design through the completion of testing and delivery. The team examined original designs and design modifications to ensure that adequate evaluations and reviews were performed by qualified personnel.

3.2 Design Development and Modification

3.2.1 Scope

The scope of the inspection of design development included the review of design control and design modification control, design organization interfaces, use of appropriate regulatory requirements and quality standards in design activities, and design deviation control. The team assessed Best's design development process to ensure that high standards of design control were implemented and practiced. The team also reviewed design modification controls to ensure that modifications made to the design received the same level of review as the original design, and that the modifications were correctly reflected in the design documentation.

3.2.2 Observations and Findings

The team determined through discussion with design personnel that Best does not currently, nor do they plan to, conduct new packaging designs under 10 CFR Part 71. Best does however maintain CoCs for three packaging designs subject to 10 CFR Part 71 requirements; therefore, the team focused its review on the design modification process. Best Procedures 5.00-QA-04(1), "Design Control," and 3.24-AA-01(3), "Design Change Procedure," were reviewed and determined to have adequate procedural controls for the design and design changes processes. However, the team identified that the procedures did not require or provide guidance for independent verification of initial design or design change activities. This is a violation of 10 CFR 71.107, "Package design control," which 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. The violation is cited in the enclosed Notice. In response to this issue Best initiated CAPA Report No. 090801.

The team reviewed a sampling of design change documents (drawings and procedures) and determined that the changes were made in accordance with the design change procedures and that none of the changes required submittal to the NRC for changes to licensing basis documents.

3.4 Conclusion on Design Controls

Best's design control process was assessed to be adequate; however, a violation of NRC requirements was identified with regard to design control procedures failing to state when independent review of design activities is required.

4. Fabrication Controls

4.1 Scope

The team evaluated the fabrication process to ensure that it was controlled and verifiable from the onset of design through the completion of the manufacturing process. The team reviewed fabrication controls to verify that all phases of the fabrication process were properly controlled and implemented. The team inspected fabrication controls in the

areas of material procurement, fabrication and assembly, test and inspection, and tools and equipment.

4.1.1 Observations and Findings

The team reviewed Canadian Standards Association, W47.1-03, "Certification of Companies for Fusion Welding of Steel," and determined that the standard defines minimum requirements that must be met and adhered to in order to obtain and maintain certification administered by the Canadian Welding Bureau (CWB). The team noted that certification of Best by CWB reflects that personnel, welding procedures, and equipment required are satisfactory to produce welds and weldments.

The team reviewed Best's weld engineer's records and determined them to be acceptable in that the records were compliant to certification requirements of this standard. The inspection team reviewed the qualification and proficiency records of various welders regarding stainless and carbon steel processes (FCAW/MCAW, SMAW, GTAW and GTAW) and determined that welder qualification records were compliant to certification requirements of this standard. No concerns were noted.

The team reviewed Canadian Standards Association, W59-03, "Welded Steel Construction (Metal Arc Welding)," which states that a welding inspector shall be certified or suitably trained and experienced to ensure that adequate competency exists for the inspection tasks to be performed and that all welds shall be visually inspected according to criteria defined within the standard.

In addition, the team reviewed, Canadian General Standards Board, CAN/CGSB-48.9712-2006, and International Organization for Standardization (ISO) 9712:2005, which establish systems for the qualification and certification, by a central independent body, to perform nondestructive testing (NDT). The team determined that the system described in this standard applies to visual inspection (VT) and that certain examiners specific to the Liquid Penetrant testing method were qualified by a Canadian Certifying Agency.

The team reviewed Work Orders for welding and noted the recording of filler material E491C-6M-H4. The team noted that the Weld Procedure Data Sheet (WPDS) required the use of filler material E491C-6M-H16. The team noted that H16 is the minimum requirement for hydrogen control and that H4 is the same product as far as composition and mechanical properties. According to Best, the intent of the welding procedure is to establish a minimum requirement which is H16 and anything superior such as H4 is acceptable. The failure to use material H16 as required by various weld procedures is a violation of 10 CFR 71.111 and is cited in the enclosed Notice. In response to this issue Best initiated CAPA Report No. 090811.

The team reviewed Work Orders to assure that visual inspections are accomplished to verify conformance to design and fabrication drawings. The team noted that Best failed to define operations specific to visual inspection. The team interviewed a quality control inspector and determined that visual inspections are performed to Liquid Penetrant examination criteria's; however, the results are not formally documented as part of the work order. Further, the team noted that Best's procedures lacked a requirement that invoked the need to perform and to record results of visual inspection of weld seams and joints. The failure to document performance and record results for visual inspection is a violation of 10 CFR 71.111 and is cited in the enclosed Notice. In response to this issue Best initiated CAPA Report No. 090810.

The team reviewed Best's method used to qualify and certify Quality Control (QC) inspectors and noted that inspection personnel who perform visual inspections are not appropriately certified or suitably trained to ensure that adequate competency exists for the inspection tasks performed. The failure to qualify and certify visual inspectors is a violation of 10 CFR 71.105(d) and is cited in the enclosed Notice. In response to this issue Best initiated CAPA Report No. 090813.

Further, the team identified potential weld profile deficiencies (i.e., lack of fusion, porosity, craters, insufficient leg, excessive weld build up, etc.) on several packages resulting in Best having to quarantine their entire NRC CoC inventory pending re-inspection and resolution of any weld deficiencies. The results of Best's re-inspection and associated rework will be communicated to the NRC in a report according to 10 CFR 71.95. In response to this issue Best initiated CAPA Report No. 090812.

Two (2) observations were identified with respect to: a) recording temperatures of the liquid penetrant materials and the surface of the part to be processed, as well as, the need to assure adequate illumination during the performance of liquid penetrant inspections; and b) the performance of quality assurance surveillances. The observations are noted as follows:

a. The team reviewed Best's liquid penetrant inspection process as defined by the recommended practice of the American Society for Testing and Materials (ASTM), Standard No. E 165-75, "Liquid Penetrant Inspection Method," which states that the temperature of the penetrant materials and the surface of the part to be processed should be between 60 and 125ºF (16 and 52ºC) and that adequate illumination of 32.5 footcandles (350 lx) is required to ensure no loss of sensitivity in the inspection. The team reviewed liquid penetrant inspection reports and noted that temperatures and illumination attributes were not performed.

b. The team noted that Best does not have a procedure describing the conduct of quality assurance surveillances or work monitoring, an activity affecting quality nor do they perform periodic oversight of the activities affecting quality, other than an annual audit and required QC inspections. No additional checking, work surveillance or work monitoring occurs. In response to this observation Best initiated CAPA Report No. 090807.

The team assessed Best's failure to assure compliance and procedure deficiencies as a programmatic weakness.

4.2 Material Procurement

4.2.1 Scope

The scope of the inspection of material procurement included the review of procurement documents, material traceability documentation, drawings and procedures, and the receipt inspection program. The team verified that materials were controlled, verifiable, and traceable from the time of purchase through the life of the packaging.

4.2.2 Observations and Findings

The team reviewed the Best Quality Manual, Revision 4, Section 7, "Purchasing" and Best Procedure 5.00-QA-06 (2), "Procurement." The team also interviewed the Best Director of Operations in regard to the purchase and control of materials. In addition, the team toured the Best fabrication facility and verified a sample of material control and the purchase numbers on each of the items located in the Best material warehouse and the process for physical inspection of the attributes for each procurement by Best inspectors. The team also verified the purchase order identification and control of a procured material at the point of use. Both process and procedure were found to be adequate for the sample purchase orders reviewed.

4.3 Measuring and Test Equipment (M&TE) Controls

The team reviewed Best's controls on M&TE. Procedure 5.00-QA-06(2), "Measuring and Test Equipment," describes the procedural controls describing the methods and responsibilities for selecting, calibrating, and controlling M&TE. The team reviewed the procedure and assessed that it provided adequate controls on use and calibration of M&TE. However, the team identified several instances where M&TE procedures were not being followed or were inadequate.

Procedure 5.00-QA-06(2), Section 5.9, states that Gauge Calibration Procedures (GCPs) will be maintained to describe the methods of calibrating each piece of M&TE and that each GCP will include equipment type, identification number, location, frequency of checks, calibration method, and acceptance criteria. However, based on review of the GCPs, the majority of the information described in Section 5.9 is actually maintained in an electronic M&TE data base that is used to control the scheduling of M&TE and also maintains the calibration history and testing records. GCPs generally just describe the method used to inspect and test a particular type of M&TE. The team concluded that Procedure 5.00-QA-06(2) is inaccurate with regard to the content of GCPs and that Best does not have quality procedures governing the use of the electronic data system that is used to control quality related M&TE activities. The failure to control quality activities in prescribed procedures is a violation of 10 CFR 71.111 and is cited in the enclosed Notice. In response to this issue Best initiated CAPA Report No. 090808.

The team reviewed the calibration history of a sampling of M&TE. All records reviewed showed the sampled M&TE was within calibration frequency and that calibration records were retrievable. The team noted that for each instrument type, the M&TE database indicated which GCP was to be used for calibration purposes. The team noted that the M&TE database frequently referred to previous revisions of the associated GCP, in some cases outdated by several years. This indicated a lack of questioning attitude and attention to detail by Best personnel. In response to this issue Best initiated CAPA Report No. 090805.

The team reviewed the calibration history record for torque wrench TQW-16. The torque wrench was rated to 250 foot-pounds (ft-lbs) and was calibrated in accordance with GCP 10, "Torque Wrenches." GCP-10, Step 5, states that each wrench shall be tested at 20%, 60%, and 100% of full load for accuracy. The gauge calibration report for the wrench showed that it was tested at 50 and 150 ft-lbs, 20% and 60% of full load (range), but no value for 100% was recorded. A note in the "Other Info." block of the calibration record stated, in part, that "Can be used up to 150 ft lbs. Normally they use up to 100 ft lbs only. Limited use as our tester goes up to 150 ft lbs." The team determined that the torque wrench testing device can only test up to 150 ft-lbs and that GCP-10 cannot be

performed as written for any torque wrench rated above 150 ft-lbs. No limitation was imposed on torque wrench TQW-16, other than the statement in the calibration history record that would have prevented its use above 150 ft-lbs. The inability to perform the procedure as written was never identified as a problem in Best's corrective action system and represents a lack of questioning attitude by Best personnel with regard to procedure adequacy and adherence. The failure to follow GCP-10 as written for the calibration of torque wrench TQW-16 represents a violation of 10 CFR 71.111 with regard to procedure adherence and is cited in the enclosed Notice. In response to this issue Best initiated CAPA Report No. 090806.

4.4 Conclusions of Fabrication Controls

Best's implementation of fabrication controls was assessed to be marginally adequate. The team reviewed manufacturing activities and noted several instances of Best's failure to: a) appropriately plan, control and document material control (i.e., weld filler) activities to assure that important activities are satisfactorily accomplished and to prevent the incorrect use; b) establish and execute a program for inspection of activities affecting quality to assure conformance to the approved design; and c) adequately indoctrinate and train personnel performing quality inspections specific to welded joints. Details of the inspection findings are cited in the enclosed Notice.

5.0 Maintenance Controls

5.1 Scope

The team interviewed selected personnel and reviewed selected maintenance records to determine if adequate maintenance controls were implemented. The team reviewed selected drawings, procedures, and records, and observed selected activities to determine if maintenance activities met design specifications identified in the SAR and CoC.

5.1.1 Observations and Findings

The team reviewed Best's controls for inspecting and maintaining Radioactive Material (RAM) transport packages. Procedure IN/IM 2548 F000(1), "Transport Package Maintenance Overview," describes the procedural controls that are subjected to routine inspections after every return and annually. The team noted that Transport Package inspection and maintenance is performed under contract by MDS Nordion according to Best specifications.

The team reviewed the procedure and assessed that it provided adequate controls. However, the team identified several instances where the procedure was not being followed. Specifically, Procedure IN/IM 2548 F000(1), states that all RAM transport packages must receive a detailed inspection annually and that inspection results are to be recorded and filed with Quality Control maintenance records. However, based on a review of routine inspection records of F-430 (s/n: 5) and F-431 (s/n's: 5, 6, and 12) packages, the team determined that annual maintenance results were not recorded and filed as required. The failure to document inspection and maintenance results according to the prescribed procedure is a violation of 10 CFR 71.111 and is cited in the enclosed Notice. In response to this issue Best initiated CAPA Report No. 090804.

Two (2) observations were identified with respect to: a) weighing overpacks during annual maintenance and b) a bolt torque requirement of the inner and main covers. The observations are noted as follows:

a. The team noted that Procedure Nos. IN/DS 1891 F430(4) and 1892 F431(1), "Design, Manufacturing and Operating Specifications" require overpack components to be weighed and that the weight of each component may not change from its original weight by more than -1% or +3%. The inspection team reviewed various annual maintenance records and noted that, although the weights were recorded, no accept or reject criteria was evident to assure compliance to the above-stated requirement. In response to this observation Best initiated CAPA Report No. 090803.

b. The team noted a requirement to torque inner and main covers bolts to 60 ft-lbs, however, Procedure No. IN/IM 2548 F000(1), "Transport Package Maintenance Overview," requires a bolt torque value of 80 ft-lb. The team noted that actual bolt torque values were performed to 80 ft-lb which was determined to comply with Best's design drawings and operating procedures according to Best's Safety Analysis Report.

The team determined Best's failure to assure compliance and identify procedure deficiencies as a programmatic weakness.

5.2 Conclusions of Maintenance Controls

Best's implementation of maintenance controls was assessed to be adequate with the exception of isolated instances of failure to document inspection and maintenance results which occurred during the transfer of ownership of the F-423, F-430, and F-431 RAM packages. In addition the team identified two observations with regard to validation of acceptance criteria concerning weighing of packages and documented procedural discrepancies for torqueing transport packages.

6.0 Exit Meeting

The team performed an exit meeting on August 13, 2009.

NOTICE OF VIOLATION

Best Theratronics, Ltd. Docket 71-0943
Ottawa, Ontario, Canada

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted from August 10 through 13, 2009, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

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.

   This is a Severity Level IV violation (Supplement VI).

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.

   This is a Severity Level IV violation (Supplement VI).

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.”

This is a Severity Level IV violation (Supplement VI).

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.

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

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.”

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

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.

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

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.

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.

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.

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.

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.

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.

This is a Severity Level IV violation (Supplement VI).

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.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Best is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to David W. Pstrak, Chief, Rules, Inspections, and Operations Branch, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous

docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), http://www.nrc.gov/NRC/ADAMS/index.html, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, (the Public Electronic Reading Room). If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 3rd day of September, 2009.