October 5, 2012

Dr. Richard Wassenaar
Best Theratronics, Ltd.
413 March Road
Ottawa, Ontario
Canada K2K 0E4

SUBJECT: NRC INSPECTION REPORT 71-0943/2012-201 AND NOTICE OF VIOLATION

Dear Dr. Wassenaar:

From August 20 through 24, 2012, 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. 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 adequate in meeting the QA requirements of 10 CFR Part 71 and 10 CFR Part 21. However, the team did identify examples where corrective actions were found to be incomplete, 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 QAP description submitted to the NRC that formed the basis of the NRC's approval of the Best QAP.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations (each with multiple examples) of NRC requirements occurred. These two violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. These 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 2.390 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/reading-rm/adams.html (the Public Electronic Reading Room).

Sincerely,

/RA/

Eric Benner, 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. 71-0943/2012-201
2. Notice of Violation (Notice)

In accordance with 10 CFR 2.390 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/reading-rm/adams.html the Public Electronic Reading Room).

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Docket No. 71-0943

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Inspection Report

Docket No.	71-0943
Report No.	71-0943/2012-201
Certificate Holder:	Best Theratronics, Ltd. 413 March Road Ottawa, Ontario Canada K2K 0E4
Date:	August 20 - 24, 2012
Inspection Team:	Jim Pearson, Team Leader, Earl Love, NRC Inspector, Clyde Morell, NRC Inspector
Approved by:	Eric Benner, Chief Rules, Inspections, and Operations Branch Division of Spent Fuel Storage and Transportation Office of Nuclear Material Safety and Safeguards

EXECUTIVE SUMMARY

From August 20 through 24, 2012, 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 (SARs), 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

The team interviewed Best personnel, reviewed and verified both documented and physical aspects of the quality assurance area, nonconformance controls, documentations controls, as well as various audit activities. The team determined that Best's implementation in this area was assessed to be adequate.

Design Controls

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. Best is adequately implementing its NRC-approved QAP with respect to design development and modification.

Documentation Control

The team reviewed Best's documentation control program and determined that Best is adequately implementing its QAP in controlling quality-related documentation and records.

Nonconformance Control

The team reviewed Best's nonconformance control program to assess the effectiveness of implementation. The team also reviewed personnel training, 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." The team determined that Best is adequately implementing its NRC-approved QAP with respect to nonconformance controls.

Fabrication Controls

The team reviewed a variety of documents and interviewed Best personnel to determine the level of implementation for fabrication controls.
The team noted that overall implementation was adequate with the following exception(s) which will be noted in an attached Notice of Violation (10 CFR 71.111):

1. Sampled fabrication drawings did not identify correct construction code for stainless steel components.

2. The Best Welding Engineering Standard procedure did not identify correct construction code for stainless steel components.

3. Welding Inspection procedure for visual inspection of welds did not specify the correct construction code and appropriate quantitative or qualitative acceptance inspection criteria for stainless steel components.

Maintenance

The team reviewed maintenance documents associated with and interviewed Best personnel about, maintenance controls on activities affecting quality. The team found that the maintenance procedures provided adequate control and implementation of those procedures was determined adequate.

The team identified that Best's corrective action from the previous NRC inspection was ineffective because two unrepaired packagings were identified by the team and Best implemented training upon finding the first two packagings and the newly trained Best inspectors identified six more welding defects on two of the other packages, previously inspected.

The above issue will be identified as a violation of CFR 71.133 "Corrective Action" in a Notice of Violation attached to this report.

Overall

The team assessed that Best's overall implementation of its NRC-approved QAP was 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
71.111	Instructions, procedures, and drawings	(3)	Level IV Violation	4.2.2 4.4 5.3
71.133	Corrective action	(2)	Level IV Violation	2.6.2 5.3

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

PERSONS CONTACTED

The team held an entrance meeting with Best on the morning of August 21, 2012, to present the scope and objectives of the NRC inspection. On the afternoon of August 23, 2012, 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

Meeting Attendees

Name	Title	Entrance Meeting	Exit Meeting
J. Pearson	NRC, Senior Inspector	X	X
E. Love	NRC, Inspector	X	X
C. Morell	NRC, Inspector	X	X
R. Wassenaar	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
M. Thériault	CNSC Observer	X	X
N. Babcock	CNSC Observer	X	X

INSPECTION PROCEDURE USED

86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings"

REPORT DETAILS

1. Inspection Scope

The team inspected Best Theratronics' (Best) 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 reviewed Best's Quality Manual, 5.00-QA-00 (4) to provide a basis for control of quality activities at Best. The team evaluated the independence of the quality organization and found it to be adequate. The team noted that Best has a quality policy statement posted and included in Best documents.

2.2.3 Conclusion

Overall, responsibilities were identified in quality procedures and controls for quality activities were present. No concerns were identified.

2.3 Nonconformance Control

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 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 determined that Best has appropriate procedures in place for the identification, evaluation, segregation and reporting of defects and non-compliances that could cause a substantial safety hazard. Specifically, Best uses procedures 5.00-QA-19 (3), "Nonconformance" and 5.03-QA-41, "Evaluation of Possible Defect for NRC Registered Sources/Devices, Corrective Action and Notification," to address any product that does not conform to product requirements as identified and controlled to prevent its unintended use or delivery, as well as, Part 21 requirements.

The team noted that purchase orders, when appropriate, imposed a condition that the supplier notify Best of any changes or known defects in a provided product or service so that Best can determine whether the change or defect will have any adverse affect on the product or service.

The team reviewed various deviation reports used to process nonconforming items and noted Best's process for resolution and disposition was by virtue of a materials review board (MRB). The team noted that representatives of Procurement, Manufacturing, Engineering, Quality Assurance, and Compliance, reviewed, documented (including technical justifications) and approved final deviation dispositions, as needed.

The team also reviewed designated nonconformance storage areas located in the shop and noted a very limited quantity of material was appropriately tagged and segregated pending final disposition through the MRB process and that those materials were not important to safety. The team noted that there was no transport package or Gamma cell safety related nonconformance products.

2.3.3 Conclusion

No concerns were identified with regard to Best's compliance with control of nonconformances and 10 CFR Part 21 requirements.

2.4 Documentation Controls

2.4.1 Scope

The team reviewed Best's documentation control program to determine the effectiveness of the QAP in controlling quality-related documentation and records. The team reviewed instructions, procedures, and drawings for adequacy, approval signatures, and release by authorized personnel, and availability to personnel. The team reviewed such documents 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 determined that the implementation of Best's QAP in regard to document control was adequate. The team reviewed 5.09-DM-00(C), "Control of Quality System Documents under Best Theratronics Numbering System," and record controls based on the issuance and capture of various revised Best procedures and work documents. The team placed particular emphasis in reviewing the procedures dealing with Best's QA program implementation, corrective action program, internal and external audits, maintenance controls, and design modifications. The team also reviewed non-conformance reports, corrective action reports, internal audits, and documents related to maintenance of packagings.

In addition, the team witnessed a portion of an assembly of a Gamma cell and verified that weld, calibration, visual inspection, and nondestructive examination procedures, as well as, applicable assembly drawings, as referenced in the shop work order, were the latest approved configuration and were available at the workstation.

The team reviewed records related to the export of a Gamma cell 220 shipment, dated 10/13/2011, destined for Best, Ottawa, ON Canada, in a Type B packaging. As required

by 10 CFR Part 71 such records are to be kept for three years. The team verified that Best met the requirement.

The shipment records were also reviewed for overall compliance with 10 CFR 71.21 requirements, as well as requirements for certain notifications to be made in accordance with 10 CFR Part 110. No significant concerns were identified.

2.4.3 Conclusion

Based on the review of documents and discussions with Best personnel, the team assessed that Best had made appropriate improvements in the QAP structure and its implementation. No significant concerns were identified during the review.

2.4 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 [audits reviewed: 7774491, 7759660, 728767; procedures reviewed: 5.00-QA-08(f), Internal Quality Audits] and interviewed the Environmental, Safety, Health and Quality Manager in regard to the oversight from Best Management and annual audits on activities affecting quality. The team noted that an annual audit was satisfactorily completed, audit schedules have been developed and are used, and the audits are reviewed by Best Management. The inspection team reviewed certifications for lead auditors as well as the training for various Best personnel (Positions reviewed: Mechanical Inspector, Machinist, Assembler, Welder, and Quality Specialist).

2.5.3 Conclusion

Overall, the inspection team determined that the Best management is adequately implementing its NRC-approved QAP with respect to the audit area.

2.6 Corrective Action

2.6.1 Scope

The team inspected records and interviewed Best personnel to determine if corrective action commitments were implemented and if the corrective actions were effective in precluding repetition of the Best's QAP problems.

2.6.2 Observations and Findings

The inspection team reviewed Best's procedure; 5.00-QA-20, Version 7, "Corrective Action and Preventative Action," as well as a sample of corrective actions under CAPA-090807 which was implemented following the 2009 NRC inspection to improve performance of periodic QA Oversight.

Multiple evidential documents described a variety of training efforts by Best's staff to improve awareness and understanding of quality activities. The team also reviewed all the CAPAs initiated during the last inspection to correct the previous violations cited. In addition, the Best Environmental, Health, Safety, and Quality Specialist provided corresponding and supporting details and discussion for the corrective actions identified on each CAPA (CAPAs: 090801, 090802, 090804, 090805, 090806, 090808, 090809, 090810, 090811,and 090814). From this review the team verified that multiple Best procedures were modified to reflect the correction needed to address each violation (Best Procedures: Purchase Order PO 684-Z00 (6) "Welding Procedure for Flux Cored-Arc Welding of Carbon Steel," GCPO-42 Training for Calibrators to 100% range, I1677 (1), "Visual Inspection of Quality Welds," IN/IM 2548 F 000 "Transport Package Maintenance Overview Procedure," 03.24-AA-01 (4) "Design Control," 5.00-QA-03 (c), "Contract Review," 5.00-QA-06 (2), Measuring and Test Equipment," 5.00-QA-08 (3), Internal Quality Audits," 5.00-QA-015 (3) "Process Control," 5.00-QA-19 (3) "Nonconformance," 5.00-QA-051 (1) Control of Documents," 5.03-AA-41 (2).

On a previous NRC inspection, twenty-two packagings were identified as having repairable welding defects. Best documented these defects on DR numbers 4085 and 4092. Prior to our arrival, these packagings were repaired and presented to the team for verification that the weld repairs were complete. The team interviewed the Best inspector and the inspector indicated that AWS D1.6, "Structural Welding Code - Stainless Steel", was the construction code and the inspection acceptance criteria used by Best to inspect the twenty-two repaired packagings.

The team selected a sample of seven packagings to verify that the corrected repairs met acceptance criteria of AWS D1.6. The team identified two welds (one indication on each package), that did not meet the weld acceptance criteria.

These indications were brought to the attention of the Best management and the Best welding inspector. The Best management took the initiative to retrain their staff on evaluating welding indications to determine if they need to be repaired.
After the retraining, Best inspectors re-inspected the corrected packagings and found a total of two packagings with six repairable indications. These repairable indications were identified by Best on DR numbers 42823 and 42824.

2.6.3 Conclusion

The inspection team's review of the corrective actions associated with the twenty-two packagings weld repairs noted during the last NRC inspection were verified not to be adequate due of the following:

1. The team found two weld defects on the repaired packagings.

2. Best management retrained their staff and Best inspectors re-inspected the repaired packagings and found two additional packagings requiring six weld repairs.

The team determined that Best's corrective actions regarding the weld repairs of the twenty-two packagings were ineffective and has cited this as a violation of 10 CFR 71.133, "Corrective Action."

Overall, management involvement has increased and the QAP is marginally implemented. Best has proactively addressed all issues identified in a violation during the prior inspection as well as issues identified during this inspection.

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.

3.2.2 Observations and Findings

Best is the NRC Certificate of Compliance (CoC) holder for the F-430, USA/9290/B(U)-85 (CoC No. 9290, Revision 7); F-431, USA/9310/B(U)-96 (CoC No. 9310, Revision 4); and F-423, USA/9299/B(U)-85 (CoC No. 9299, Revision 5) transport packagings.
Based on records reviewed the team noted a design modification to include additional security features to the content of Gammacell-1000 and 3000 irradiators used in transport packages F-430 and F-431. The team noted by application dated October 21, 2011, and as supplemented February 15, and March 9, 2012, that Best requested an amendment to both CoC's. The team assessed Best's design controls specific to these changes that led to a modification of the packaging braces. The team noted that the change in bracing was considered to be of low safety significance and did not affect the package during normal conditions of transport. The team determined that Best's design change control process as prescribed by 3.24-AA-01(G), "Design Change Procedure," and that Best's system, roles and responsibilities and the process for the control, evaluation, release, and implementation of changes to drawings and documents was satisfactorily performed.
The team reviewed Design Change Form (DCR) Nos. 30680, dated 02/05/2011 and 30761, dated 10/12/2011, and associated specifications and drawings for compliance to the above noted procedure. The team noted DCR initiation and appropriate design reviews, compliance reviews, document releases, implementation and closure as

adequate. In addition, the team noted NRC approval (by letters dated 04/04/2012) to use the package for shipment of radioactive material.

The team noted that Best had performed a package design change specific to a change to the configuration of rubber gaskets used in over packs F-430 and F-431. The team reviewed DCR No. 30833, dated 03/14/2012 and consulted with NRC staff as to the acceptability of the change and determined that the change did not require revisions to the CoC's. The team noted that Best satisfactorily implemented the requirements of 3.24-AA-01(G), "Design Change Procedure."

3.2.3 Conclusion

Overall, Best is effectively implementing its NRC-approved QAP `with respect to design development and modification. The team verified that Best's activities were being conducted in accordance with the CoC and QAP and that implementing procedures were in place and that the design modifications received the same level of review as the original design, and that the modifications to include additional security features to the contents of Gammacell-1000 and 3000 were correctly reflected in the design documentation.

4. Fabrication Controls

4.1 General

The team evaluated the fabrication controls to ensure that fabrication (if it were to occur) 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 Material Procurement

4.1.2 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.

4.1.3 Observations and Findings

The team reviewed procedures controlling the purchase, receiving, and issuance of materials and found the controls were adequate.

The team reviewed bills of materials listed on licensing drawings, material purchase orders, certified material test reports, and material receiving reports and verified the packaging materials were procured in accordance with the license drawing and design.

4.1.4 Conclusion

The team found that material procurement controls were adequate.

4.2 Fabrication and Assembly

4.2.1 Scope

The team evaluated the fabrication and assembly processes to ensure that they were controlled and verifiable from the onset of fabrication through the completion of the manufacturing process.

The team reviewed fabrication and assembly procedures, specifications, and drawings to verify that all phases of the fabrication were properly controlled and implemented.

4.2.2 Observations and Findings

The team reviewed the fabrication welding procedures, welding personnel qualifications and verified they met the Canadian Bureau Welding (CWB) qualifications requirements for a qualified Canadian Standard Association (CSA) W74.1 Division 2 certified company.

The team reviewed a sample of seven fabrication drawings to determine if the fabrication drawings implemented adequate welding codes or standards for fabrication and inspection for welding fabrication of stainless steel components. The team recognized that the sampled drawings "Notes" section stated: "Welding shall be according to ASME BPV IX or CSA W59."

The team determined that the Fabrication drawings cited the use of ASME BPV IX or CSA W59 for fabrication which is for Carbon Steel fabrication and did not reference "appropriate Codes" such as AWS D 1.6, "Structural Welding Code - Stainless Steel." Therefore, the team determined that the procedure is inadequate and have cited this as a violation of 10 CFR 71.111, "Instructions, Procedures and Drawings."

The team reviewed the Best Welding Engineering Standard No.: P0690Z00 (4) to determine if there were adequate controls in place for the fabrication welding of stainless steel components. The procedure states in the general notes – paragraph 4.1.1, "All welding will be performed in conformance with CSA Standard W59 latest revision." Also paragraph 4.1.11 states, "when a fabrication is structured to the requirements of Codes other than those mentioned in paragraph 4.1.1 and 4.1.2, this standard shall not apply and reference should be made directly to the appropriate Codes." The team determined that the Best Welding Engineering Standard cited the use of CSA Standard W59 for fabrication which is for Carbon Steel fabrication and did not reference "appropriate Codes" such as AWS D 1.6, "Structural Welding Code - Stainless Steel." Therefore, the team determined that the procedure is inadequate and have cited this as a violation of 10 CFR 71.111, "Instructions, Procedures and Drawings."

The team reviewed procedure "Visual Inspection of Welds," No.: I1677Z00 (B) to determine if appropriate welding Codes for welding inspection were identified and the procedure provided appropriate quantitative or qualitative acceptance criteria for inspecting welds of stainless steel components. The team found that the Best procedure

cites the use of CSA-W59 which is used for carbon steel fabrication, but does not contain specific acceptance or rejection criteria as in AWS D 1.6, "Structural Welding Code - Stainless Steel." Therefore, the team determined that the procedure is inadequate and have cited this as a violation of 10 CFR 71.111.

4.2.3 Conclusion

Overall, the team found the fabrication and assembly controls were adequate with the exception of those issues noted above and on the Notice of Violation attached to this report.

4.3 Test and Inspection Tools and Equipment

4.3.1 Scope - Measuring and Test Equipment Controls

The team reviewed the controls for the calibration of testing and inspection tools and verified the procedural controls for tool traceability, as well as out of calibration controls, and inspection tool range sensitivity.

4.3.2 Observations and findings

The team reviewed the Best procedure (Measuring and Test Equipment, 5.00-QA-06(E)) controls for the calibration of testing and inspection tools. The team sampled several micrometers, Vernier calipers, and dial indicators in the inspection area as well at various machining operator workstations to verify that the tools were being used and maintained per the procedural controls for tool traceability, out of calibration controls, and inspection tool range sensitivity.

4.3.3 Conclusion - Test and Inspection Tools and Equipment

The team found that the control in this area were adequate.

4.4 Conclusions of Fabrication Controls

The team found that overall fabrication control was adequate with the following exception(s):

1. Fabrication drawings did not identify a correct Construction Code for fabricating stainless steel components

2. Fabrication welding standard procedure did not identify a correct Construction Code for fabricating stainless steel components

3. Welding Inspection procedure did not specify a correct Construction Code and appropriate quantitative or qualitative acceptance and/or rejection criteria for fabricating stainless steel components

These three examples are violations against 10 CFR 71.111, "Instructions, Procedures and Drawings," which are included in the attached Notice of Violation.

5. Maintenance

5.1 Scope

The team evaluated the maintenance 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 adequately controlled and implemented.

The team inspected fabrication controls in the areas of material procurement, fabrication and assembly, test and inspection, and tools and equipment.

5.2 Observations and Findings

The team reviewed the Best maintenance procedure IN/IM 2548 F000 (D) for compliance to the NRC requirements to determine if the procedure provided adequate controls of packaging for routine, annual, and end of life inspection for the following attributes:

- radioactive contamination,
- identification (labeling of contents),
- condition of lifting attachments,
- examination of contents for damaged or missing parts,
- physical conditions (rust, paint damage, dents)
- missing items such as gaskets, bolts, and hinges.

The team also reviewed the procedure to determine if corrective actions were identified to resolve any deficiencies with these inspection attributes. The procedure stated that when a deficiency is identified a deviation report (DR) is issued. The team reviewed a sample of open and completed DRs and determined that controls were adequate to control identified deficiencies on packagings during routine and annual inspections.

The team reviewed maintenance documents and interviewed Best personnel about maintenance controls on activities affecting quality. The team found that the maintenance procedures provided adequate control and implementation was determined to be adequate with the exceptions listed below in the conclusion.

5.3 Conclusion

The team identified that Best's corrective action from the previous NRC inspection was ineffective because two unrepaired packagings were identified by the team and Best implemented training upon finding the two packagings and the newly trained Best inspectors identified six more welding defects previously overlooked.

The above issues will be identified as a violation of 10 CFR 71.133, "Corrective Action," in a Notice of Violation attached to this report.

6. Exit Meeting

The team performed an exit meeting on August 23, 2012.

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 20 through 24, 2012, 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 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.

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

   3. Best procedure [I16677Z00 (B)] “Visual Inspection of Welds” does not contain specific acceptance or rejection criteria for weld inspection for the fabrication of stainless steel components.

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

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.

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.

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 Eric Benner, 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/reading-rm/adams.html, (the Public Electronic Reading Room) 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 2.390(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 5th day of October, 2012.