November 4, 2016

Samantha Mason
Best Theratronics, Ltd.
413 March Road
Ottawa, Ontario, Canada K2K 0E4

SUBJECT: NRC INSPECTION REPORT 71-0943/2016-201 AND NOTICE OF VIOLATION

Dear Ms. Mason:

From September 20 through 22, 2016, 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 Compliances (CoCs), Safety Analysis Reports, and Best's NRC-approved Quality Assurance Program (QAP). The team inspected Best's management, design, fabrication, and maintenance 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 marginal in meeting the QA requirements of 10 CFR Part 71 and 10 CFR Part 21. The team identified examples where records were not properly maintained, measures were not established for the selection and suitability of materials, activities affecting quality were not prescribed in documented procedures, and the effectiveness of the control of quality by contractors was not assessed at intervals consistent with the importance, complexity, and quantity of the service. As such, the NRC will maintain Best on an increased inspection frequency.

Based on the results of this inspection, the NRC has determined that four Severity Level IV violations (some with multiple examples) of NRC requirements occurred. These four violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them 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 within 30 days and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will consider extending the response time if Best can demonstrate good cause for the NRC to do so. 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 Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

/RA/

Patricia Silva, Chief
Inspections and Operations Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards

Docket No. 71-0943

Enclosures:
1. NRC Inspection Report No. 71-0943/2016-201
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 Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

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Docket No. 71-0943

Enclosures:
1. NRC Inspection Report No. 71-0943/2016-201
2. Notice of Violation (Notice)

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Office of Nuclear Material Safety and Safeguards
Division of Spent Fuel Management

Inspection Report

Docket No.	71-0943
Report No.	71-0943/2016-201
Certificate Holder:	Best Theratronics, Ltd. 413 March Road Ottawa, Ontario, Canada K2K 0E4
Inspection Location:	Best Theratronics, Ltd. 413 March Road Ottawa, Ontario, Canada K2K 0E4
Inspection Dates:	September 20 - 22, 2016
Inspection Team:	Jon Woodfield, Team Leader, Safety Inspector, DSFM, IOB Marlone Davis, Senior Safety Inspector, DSFM, IOB Jeremy Tapp, Safety Inspector, DSFM, IOB
Approved by:	Patricia Silva, Branch Chief Inspections and Operations Branch Division of Spent Fuel Management Office of Nuclear Material Safety and Safeguards

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

EXECUTIVE SUMMARY

Best Theratronics, Ltd.
NRC Inspection Report 71-0943/2016-201

From September 20 through 22, 2016, 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 Compliances (CoCs), Safety Analysis Reports (SARs), and Best's NRC-approved quality assurance program (QAP). The team inspected Best's management, design, fabrication, and maintenance 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, documentation controls, as well as various audit activities. The team determined that Best's implementation in this area was assessed to be minimally adequate due to the following findings which are described in the attached Notice of Violation (10 CFR 71.91 and 10 CFR 71.115):

(10 CFR 71.91) As the holder of CoC 9290 for packaging model F-430, Best failed to maintain sufficient written records to furnish evidence of the quality of five packaging units. Best has only maintained between 50 and 70 percent of the original F-430 fabrication records for unit serial numbers 5, 6, 7, 8 and 9.

(10 CFR 71.115)
1. Best has not been performing external audits of contractor Nordion's sealed source receipt inspection program.

2. Best has not been performing external audits of contractor Nordion's package maintenance program.

Design Controls

The team reviewed design controls in all phases of Best's design process, from the onset of design through the completion of fabrication. The team examined original designs and design modifications to ensure that adequate evaluations and reviews were performed by qualified personnel. Best is marginally adequate in implementing its NRC-approved QAP with respect to design development and modification based on the following two findings which are described in the attached Notice of Violation (10 CFR 71.107):

1. Best has not performed engineering evaluations to support the assignment of Important-to-Safety categories for the components of the three packaging models for which it is the CoC holder.

2. Best does not have a Commercial Grade Dedication (CGD) procedure for commercially purchased components or materials used in Important-to-Safety applications for its packagings.

Fabrication Controls

The team evaluated fabrication controls to ensure that fabrication was controlled and verifiable from the onset of material and component procurement through the completion of the manufacturing process. The team inspected fabrication controls in the areas of material procurement, fabrication and assembly, test and inspection, and tools and equipment. The team determined that Best's implementation in this area was minimally adequate based on the observed lack of a CGD program to support the procurement process.

Maintenance

The team reviewed maintenance documents associated with and interviewed Best personnel about maintenance controls for activities affecting quality. The team determined that Best's implementation in this area was assessed to be minimally adequate based on the following finding which is described in the attached Notice of Violation (10 CFR 71.111):

Best failed to incorporate three maintenance program activities described in the F-430 and F-431 SARs, Section 8.2.3, which formed the basis of the NRC's approval of the packagings, into the Best maintenance procedure IN/IM 2548 F000.

Overall

The team assessed that Best's overall implementation of its NRC-approved QAP was minimally 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
71.91	Records	1	Level IV Violation	2.4.2
71.107	Package design control	2	Level IV Violation	3.2.2
71.111	Instructions, procedures, and drawings	1	Level IV Violation	5.2.2
71.115	Control of purchased material, equipment, and services	2	Level IV Violation	2.5.2

REPORT DETAILS

1.0 Inspection Scope

The team inspected Best Theratronics' (Best) management, design, fabrication, and maintenance 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. The team reviewed Best's CoC's for the following packagings:

Model	Package ID#	Certificate	Revision	Expiration Date
F-430	USA/9290/B(U)-85	9290	7	2/28/2017
F-423	USA/9299/B(U)-85	9299	5	3/31/2017
F-431	USA/9310/B(U)-96	9310	6	6/30/2019

1.1 Inspection Procedures/Guidance Documents Used

IP 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings"
NUREG/CR-6314, "Quality Assurance Inspections for Shipping and Storage Containers"
NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety"

1.2 List of Acronyms Used

ASL	Approved Suppliers List
CAPA	Corrective Action and Preventive Actions
CFR	Code of Federal Regulations
CoC	Certificate of Compliance
CGD	Commercial Grade Dedication
DC	Design Change
DM	Document Management
DMDB	Document Management Database
ITS	Important-to-Safety
M&TE	Measuring and Test Equipment
NCR	Nonconformance Report
NIAC	Nuclear Industry Assessment Committee
NOV	Notice of Violation
NRC	U.S. Nuclear Regulatory Commission
NUPIC	Nuclear Procurement Issues Committee
PT	Liquid Dye Penetrant Inspection
QA	Quality Assurance
QAP	Quality Assurance Program
SAR	Safety Analysis Report
WPDS	Welding Procedure Data Sheet

1.3 Persons Contacted

The team held an entrance meeting with Best on the morning of September 20, 2016, to present the scope and objectives of the NRC inspection. On the afternoon of September 22, 2016, 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 Meeting Attendees

Name	Affiliation	Entrance	Exit
Jon Woodfield	NRC	X	X
Marlone Davis	NRC	X	X
Jeremy Tapp	NRC	X	X
Samantha Mason	Best Theratronics	X	X
Mike de van der Schueren	Best Theratronics	X	X
Victor Moga	Best Theratronics	X	
Andrei Ciresianu	Best Theratronics	X	
John Smith	Best Theratronics	X	
Gwen McCaffrey	Best Theratronics	X	
Pietro Zanetti	Best Theratronics		X

2.0 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 instructions 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 NRC inspection team reviewed Best's quality assurance policies and implementing procedures to verify how Best conducted activities in accordance with their Certificates of Compliance and the NRC-approved QAP. The team reviewed Best's NRC-approved QAP procedure 5.05-QA-03, "Part 71 QA Program," Revision A. The team verified that Best clearly defined and documented the quality program authorities and responsibilities and that the quality assurance organization functioned as an independent group. The team also verified that Best used a graded approached for identifying Important-to-Safety (ITS) components and applied this graded quality level to procurement documents. The team also reviewed a sample of personnel qualifications and indoctrination training records.

The team assessed that Best had programs and procedures in place to conduct activities in accordance with their CoCs, NRC-approved QAP, and Part 71 requirements. However, the team noted that Best did not have engineering evaluations justifying its basis for applying its graded approach to ITS identified materials, structures, systems, and components. The team evaluated the lack of engineering evaluations for Best's graded approach under the design control section 3.0.

The team assessed that Best's training records provided the appropriate information for certification and qualification of personnel.

2.2.3 Conclusion

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

2.3 Nonconformance Controls

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 evaluated how Best identified, segregated, tracked, and controlled, nonconforming items and any program deficiencies. The team inspected nonconformance reports (NCR), 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 reviewed a sample of nonconformance reports and interviewed selected personnel to verify that Best effectively implemented a nonconformance control program. The sampling was to verify that Best completed corrective actions for identified

deficiencies and nonconformances with a technical basis and in a timely manner. Specifically, the team reviewed the following Best quality procedures:

- 5.00-QA-19, “Nonconformance,” Revision D
- 5.00-QA-20, “Corrective Action and Preventive Action,” Revision G

The inspectors reviewed nonconformances and corrective action & preventive actions (CAPA) from the previous four years prior to this inspection. The team also discussed the nonconformances and CAPAs with the Best staff. Additionally, the team reviewed an associated Part 21 Procedure 5.03-AA-41, “Evaluation of Possible Defect for NRC Registered Sources/Devices, Corrective Action and Notification,” Revision C, to verify if provisions were in place for reporting defects that could cause a substantial safety hazard and complete the required notification. The inspectors requested a list of Part 21 evaluations and notifications associated with the Best transportation packaging and interviewed personnel to verify if they were familiar with the implementing procedure 5.03-AA-41. The team also verified that Best complied with the 10 CFR 21.6, “Posting requirements.”

The team also evaluated a number of nonconformance reports that were determined to not provide adequate technical justifications or initiate CAPAs for some of the use-as-is dispositions in accordance with the two procedures. This was not in compliance with Section 5.3 of 5.00-QA-20, which states, in part, that CAPAs will be initiated to analyze the quality system, processes, work operations affecting product quality, etc., to detect and eliminate potential causes of nonconforming product. For instance, the team reviewed NCRs 44724 and 44596, that identified nonconformances with a component’s material and a crack in the component, however; the dispositions did not describe the cause of the degraded material and how large of a crack was in the component. The team noted that the NCRs required Best personnel to initiate CAPAs to detect and eliminate potential causes of the nonconforming component/product. However, Best personnel did not initiate CAPAs in accordance with the written procedures. The team assessed that this was a violation of NRC requirements for following procedures but determined it was a minor violation since it did not affect the function of the ITS components. The team also assessed that provisions were in place for reporting defects that could cause a substantial safety hazard, as required by 10 CFR Part 21. The inspectors noted that there were no defects or Part 21 noncompliance reports identified for the Best Type B packagings.

2.3.3 Conclusion

Overall, the team assessed that Best’s implementation of its nonconformance, corrective action, and Part 21 programs was marginally adequate and an area for improvement based on the minor violation. The team discussed its observations in these areas with Best during the inspection and exit meeting.

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, document releases by authorized personnel, and document availability to personnel. The team reviewed the control of such documents as inspection and test work orders, 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 Best's document control and records implementing procedures and interviewed responsible personnel to verify that Best was effectively implementing its control of documents and quality records program. Specifically, the team reviewed the following Best quality procedures:

- 3.24-AA-08, "Handling Procedures for Document Masters," Revision 3
- 5.00-QA-05, "Control of Documents," Revision E
- 5.00-QA-18, "Quality Records," Revision H
- 5.09-DM-01, "Document Management Operating Procedure," Revision D

The team had extensive discussions with the Best individual responsible for the Document Management (DM) department. The individual demonstrated to the team, Best's Document Management Database (DMDB) system on their computer. The DMDB contains document identifiers, version level, title, status, and effective date of all current quality procedures. The DMDB also contains the numbers used for paper controlled copies and all information concerning the distribution of controlled copies. DM advises holders of controlled copies that the documents have been made non-current or obsolete and it is the responsibility of the holders to remove/destroy the old copies. The DM controls and files all the hard copy original signed/approved documents and calls them Master Documents. The team reviewed the process for maintaining current revisions of procedures at shop work stations and found it acceptable.

The team discussed with the Best Engineering department how engineering drawings, specifications, and design changes were controlled since it was responsible for the control of these documents. The team found the revision control processes and computer database master lists for engineering documents to be adequate.

All electronic documents and records on the Best computer server are backed up on a daily basis. The backup of the Best computer system is controlled by a third party.

For every medical device product manufactured by Best, Best maintains a Device Master Record Index which references quality records such as: Product specifications, engineering drawings, inspection and test procedures, manufacturing process sheets, and manufacturing bill of materials.

The team determined that the current document controls in place by Best were adequate.

The team asked Best if the original fabrication records for the model F-423, F-430, and F-431 packaging units used to transport the Gammacells were retrievable and available for review. Best had purchased the three models from Nordion and as the current CoC holder for each is responsible for all the fabrication and maintenance quality records for all the units of the three packaging models. Best stated that it did not know where the original fabrication records were or if they had them. By the last day of the onsite inspection Best did find some original fabrication records for the packaging units purchased from Nordion. A few days after the onsite inspection, and after further review by Best of the records it found, Best provided an assessment of the records it had in its possession to the team. Best stated that it had all the original fabrication records for the F-431 units, all the original fabrication records for the F-423 units still in service, and all the original fabrication records for four of the nine F-430 units. Best further stated that it had between 50 and 70 percent of the original fabrication records for each of the five F-430 units without complete fabrication records.

Since Best cannot find all the original quality records for the F-430 units for which it is the CoC holder, this is a violation of regulation 10 CFR 71.91, "Records." 10 CFR 71.91 states, in part, the certificate holder shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by 71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. The team evaluated the violation in accordance with Section 2.3 of the NRC Enforcement Policy and characterized the finding as a Severity Level IV violation. Because Best did not enter this issue into their corrective action program before the end of the inspection, the violation is being cited as a Notice of Violation (NOV).

The team also observed that Best was not properly maintaining its records for the fabrication of its medical equipment which becomes part of the transportation packaging during shipment. The fabrication records are in paper form and not electronically scanned. The storage of the paper records is in folders on open storage shelves. The storage area has inadequate fire protection against record loss from fire. This is a violation against properly maintaining records but identified as minor since currently none of the records have been lost or damaged. The team made Best aware of this minor violation.

2.4.3 Conclusion

Overall, the team assessed that Best was marginally adequate in implementing its document control and records program, with the team identifying this area needing improvement. One Severity Level IV NOV was identified for inadequate maintenance of original fabrication records for packagings.

The above issue will be identified as a violation of 10 CFR 71.91, "Records," in the Notice of Violation attached to this report.

2.5 Audit Program

2.5.1 Scope

The team reviewed Best's audit program to determine whether audit plans, procedures, and records were developed and maintained. The team evaluated whether Best scheduled and performed internal QA audits and vendor audits in accordance with approved procedures or checklists; whether qualified and 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

Internal Audits

The team reviewed the internal audit program as defined in quality procedure 5.00-QA-08, "Internal Quality Audits," Revision G. This was to verify that the program was comprehensive and that audits were scheduled and conducted periodically in accordance with approved procedures by trained and qualified audit personnel who documented the audit results and followed up deficient areas via the corrective action program. The team reviewed a selection of internal audits performed in 2013 and 2016 as well as the 2015 and 2016 internal audit schedule to verify that they were conducted in accordance with the program as previously defined. The team also reviewed a selection of auditor training and qualification records to assess whether those performing audits were trained and qualified as required by Best approved procedures.

The team determined that for the internal audits reviewed, they were comprehensive in nature, used checklists to perform the audit, identified a number of issues, and the audit reports were written in a timely manner. The team found that for all the internal audit schedules reviewed, the audits were planned, at a minimum, for all 18 quality criteria. For the auditor training records that were reviewed, all were trained and qualified as required by the approved procedure. The team noted that for one of the audit plans reviewed, 10 CFR Part 71 was not mentioned as a standard that activities were being audited against. Even though all 18 criteria were being audited, the team discussed with Best personnel that Part 71 was not included in the plan and needed to be to ensure Part 71 activities would be audited along with the other quality related activities Best performs. The team also noted that the CAPA program was not specifically assessed during one of the audits reviewed, but that CAPAs were reviewed as part of other audit areas. It was discussed with Best personnel that a specific review of the CAPA program would meet standard industry audit practices even though CAPAs could be reviewed during assessment of other related areas.

Overall, the team assessed that the internal audit program was adequately implemented by performing comprehensive audits with trained and qualified personnel of all aspects of the Quality Assurance Program on an annual basis.

External Audits

The team reviewed Best's procedures associated with the qualification of external suppliers of materials & services and interviewed responsible personnel to verify that Best was effectively implementing an external audit program. Specifically, the team reviewed the following Best quality procedures:

- 3.13-AA-01, "Supplier Qualification Program," Revision E
- 5.03-AA-54, "Control of Products and Services Obtained From Suppliers," Revision A

The two external audit procedures are not based on NRC regulations. Best's process for evaluating suppliers of materials & services is primarily based on international standards. In 5.03-AA-54 Best does discuss a graded approach to its suppliers with "A" suppliers being the most critical. However, Best's graded approach is not based on NUREG/CR-6407 and Best's "A" suppliers are not the same as a supplier of NUREG/CR-6407 ITS category A materials. The Best procedures have attached forms that are used to evaluate and qualify its suppliers. Best uses forms 5.03-AA-54 F1, Supplier Evaluation Questionnaire; 5.03-AA-54 F1, Supplier Re-evaluation; and 3.13-AA-01 F2, Supplier Quality Assessment; to gather information from and on its suppliers to place them on its approved supplier list (ASL). Best relies mostly on certifications to international quality standards to place suppliers on its ASL. The Supplier Quality Assessment form does have the provision for Best to perform an actual external audit of a supplier.

The team chose for review an ASL supplier associated with the Best gammacells that are transported in the overpack packagings and designated under Best's graded approach as an "A" supplier. The team reviewed the procedure forms for this supplier for compliance. The team assessed the forms to be filled out appropriately per the procedures. The team reviewed an actual Best "quality and technical review" (external audit) report performed on a sub-contractor of the primary contractor listed on the ASL. The audit report addressed the following areas: manufacturing and QC procedures, instrument calibrations, welding process, non-conformances, training records, document control, drawings, specifications, and procedures. The team found the audit to lack the structure of an external supplier audit performed to United States Nuclear Procurement Issues Committee (NUPIC) or Nuclear Industry Assessment Committee (NIAC) audit checklist standards. The team determined that, overall; Best's external audit program was being performed in accordance with it procedures but not to United States (US) standards. The Best external audit program lacks structure and uniformity with the use of checklists like those used by NUPIC and NIAC. Best has determined suppliers are qualified for its ASL, but the evaluation process for suppliers of materials and services associated with Best's NRC CoC packagings is an area for improvement to US audit standards and processes.

Best contracts with a United Kingdom company to provide the sealed sources for its gammacells. The United Kingdom Company then uses a sub-supplier in Russia to provide the source and seal it in a capsule by welding. The sealed sources are transported to a company called Nordion which performs a receipt inspection on the sealed sources for Best. Nordion ultimately installs the sealed sources into Best's gammacells. The team asked Best for any external audit reports performed on Nordion's sealed source receipt inspection program. Best stated that it had not been performing external audits of Nordion's sealed source receipt inspection program.

Best also contracts with Nordion to perform maintenance on all the individual units of the three packaging models for which Best is the CoC holder. The team again asked Best for any external audit reports performed on Nordion's package maintenance program. Best stated again that it had not been performing external audits of Nordion's package maintenance program.

Best not performing external audits of Nordion's sealed source receipt inspection program and package maintenance program are two examples of a violation of 10 CFR 71.115, "Control of purchased materials, equipment and services." 10 CFR 71.115 states, in part, the certificate holder shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or service. These measures must include provisions for source evaluation and selection, and objective evidence of quality furnished by the contractor or subcontractor. The team evaluated the violation in accordance with Section 2.3 of the NRC Enforcement Policy and characterized the finding as a Severity Level IV violation. Because Best did not enter this issue into their corrective action program before the end of the inspection, the violation is being cited as a Notice of Violation.

2.5.3 Conclusion

Overall, the team assessed that Best was marginally adequate in implementing its audit program, with the team identifying this as an area needing improvement to US standards. One Severity Level IV NOV was identified for CoC holder Best not performing external audits to assess the effectiveness of a contractor performing quality services for them.

The above issue will be identified as a violation of 10 CFR 71.115, ""Control of purchased material, equipment, and services," in the Notice of Violation attached to this report.

3.0 Design Controls

3.1 General

The team reviewed design controls in all phases of Best's design process. 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 measures for design control interfaces and coordination among participating design organizations were implemented and practiced.

3.2.2 Observations and Findings

The team reviewed Best's design control implementing procedures and interviewed responsible personnel to verify that Best was effectively implementing its design development and modification program. Specifically, the team reviewed the following Best quality procedures:

- 3.24-AA-01, "Design Change Procedure," Revision G
- 3.24-AA-11, "Design Validation," Revision 4
- 3.24-AA-20, "Configuration Management Procedure," Revision D
- 3.24-AA-26, "Procedure for Security of PDM and CADD System Data," Revision 1
- 3.24-AA-27, "Engineering Documents & Facility Drawings Issue and Revision Control Using PDM," Revision 1
- 3.24-AA-28, "Operating Procedures for Engineering Drawings and Associated Documents," Revision 1
- 5.00-QA-04, "Design Control," Revision 2
- 5.00-QA-29, "Device Design Risk Management," Revision E

The team reviewed the current Transportation Package Information Drawing revisions for the Model F-423 (Drawing F642301-001 sheets 1 & 2), F-430 (Drawing F643001-001 sheets 1 to 3), and F-431 (F643101-001 sheets 1 & 2) packagings. The team verified that the drawings were properly reviewed and approved by Best engineering staff in accordance with their procedures.

The team selected two design change numbers identified in the revision description blocks for the F643001-001 and F643101-001 drawings which were the basis and justification for the drawings to be revised. Design changes 30806 and 30825 were reviewed by the team. The team found the design changes to be in compliance with procedure 3.24-AA-01. The design changes used the proper design change forms from the procedure and the forms were properly filled out. The design changes also contained the reason for the change, listed all the documents affected by the design change, and had the proper approval signatures from the various Best departments that reviewed the changes. No concerns were identified.

The team reviewed the training and qualification records for two members of the Best engineering staff, with the titles of senior designer and technical authority. The team found the two individuals to be qualified for their duties and their training records to be extensive and well documented.

The team asked Best for its engineering evaluations justifying its graded approach for ITS packaging components. Best stated that no engineering evaluations had been performed for the components of the three packaging models to support the assignment of ITS safety categories.

The team asked Best if it had a commercial grade dedication procedure to develop the critical characteristics for the qualification of commercially supplied materials or components used in ITS packaging component applications. Best stated that it currently

did not have a CGD procedure for commercially purchased components or materials used in ITS applications.

Best not performing evaluations justifying its packaging component ITS graded approach and not having a CGD procedure to justify the use of commercial components or materials in ITS applications are two examples of a violation of 10 CFR 71.107, "Package design control." 10 CFR 71.107 states, in part, the certificate holder shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license or CoC for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety.

The team evaluated the violation in accordance with Section 2.3 of the NRC Enforcement Policy and characterized the finding as a Severity Level IV violation. Because Best did not enter this issue into their corrective action program before the end of the inspection, the violation is being cited as a Notice of Violation.

3.2.3 Conclusion

Overall, the team assessed that Best was marginally adequate in implementing its design control program, with the team identifying this area needing improvement. One Severity Level IV NOV was identified for two examples: 1) not establishing measures to assure that appropriate quality standards are specified and included in design documents; and 2) not establishing measures for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety.

The above issue will be identified as a violation of 10 CFR 71.107, "Package design control," in a Notice of Violation attached to this report.

4.0 Fabrication Controls

4.1 General

The team evaluated the fabrication controls to ensure that fabrication was controlled and verifiable from the onset of material and component procurement 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.

4.2 Material Procurement

4.2.1 Scope

The scope of the inspection of material procurement included the review of procurement documents, material traceability documentation, drawing bill of materials, procurement 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 Best's material/component procurement implementing procedures and interviewed responsible personnel to verify that Best was effectively implementing its material procurement program. Specifically, the team reviewed the following Best quality procedures:

- 3.13-AA-05, "Purchase Order Preparation," Revision H
- 5.00-QA-07, "Procurement," Revision G
- 5.00-QA-10, "Incoming Inspection," Revision D
- 5.00-QA-13, "Identification and Traceability," Revision C

The team reviewed a sample of the procurement records for materials used to construct the Best gammacells. The team reviewed the material specifications, the purchase order for the materials, and the receipt inspection records for the material. The receipt inspection record was called a "receiver" and documented the checks that were made of the material before accepting it at Best. Identification was added to the materials at receipt inspection for future traceability when the bulk material would be cut into smaller pieces for fabrication. The "receiver" document also contained the suppliers test report certifying the material to the requirements of Best's purchase order. The team determined that the materials were procured and Best accepted in accordance with the procedures associated with procurement. The team observed that if Best had a CGD procedure for the procurement of commercial grade materials and components used in ITS category A packaging applications, the quality of receipt inspections could be improved in the procurement area. While the receipt inspections reviewed were in compliance with the procedures, and receipt inspectors did review the materials and supplier provided paperwork against the requirements of the purchase order and procurement specifications, a CGD procedure and program would have formalized a process for receipt inspectors to know the critical characteristics to verify for commercial grade materials and components to be used in category A ITS applications.

4.2.3 Conclusion

Overall, due to the lack of a CGD procedure and process, the team found that material procurement controls were marginally adequate and an area for improvement.

4.3 Fabrication and Assembly

4.3.1 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.

4.3.2 Observations and Findings

The team examined license and fabrication drawings, work control and welding procedures, and shop work orders to determine that fabrication of the Gammacell 3000 (GC3000) as part of the F-431 package met the requirements of CoC 9310. Specifically, the team reviewed drawing C103203-392, "Housing Assy," Issue C; quality procedure 5.00-QA-15, "Process Control," Revision P dated 9/6/16; welding procedure P 0690 Z00, "Welding Engineering Standard," dated 5/21/15; and welding procedure P 0684 Z00, "Welding Procedure for Flux Cored – Arc Welding of Carbon Steel," Revision 7. In addition, the team observed fabrication activities including welding, and reviewed applicable personnel qualification and certification records to determine that fabrication satisfied requirements and was accomplished by qualified personnel. The team noted that in all cases fabrication drawings, shop work orders, and welding procedures were adequately identified at various work locations and the documents reflected the correct revisions, as applicable.

The team observed welding of the GC3000 housing outer shell to the bottom component and verified it was being performed in accordance with the applicable work order, welding procedure, and required Welding Procedure Data Sheet (WPDS) and weld filler material. The team determined that Best was performing fabrication activities in accordance with the applicable work order: #222632, Revision C, and welding procedure PO 0684 Z00. In addition, the team found that WPDS FC-2 was used for the outer shell to bottom component welding activity and determined it met the requirements of the applicable drawing and work order 222632. The weld filler material used was also verified to meet the requirements of the WPDS with respect to type and size. The team noted that the work order used to perform the fabrication activities discussed above did not include enough lines or space to be able to fill out all the necessary information easily. In addition, for the information that needed to be completed on the form, it could not be clearly connected to the required work to which it was related. This observation was discussed with Best personnel.

The team reviewed the qualifications and certifications of one welder observed in the shop. The team determined through a review of records that the individual was qualified and certified by the Canadian Welding Bureau as required for the welding processes observed by the team. No issues were identified with respect to qualifications and certifications of welding personnel.

4.3.3 Conclusion

Overall, the team determined that fabrication activities along with the associated controls and processes were satisfactory and no significant concerns were identified.

4.4 Test and Inspection

4.4.1 Scope

The scope of the test and inspection review by the team was to evaluate tests and inspections to ensure that they were controlled, verifiable, and traceable, from initial fabrication through closed-out inspection reports. Documents reviewed were NDE test procedures, shop work orders, and weld inspector qualification records.

4.4.2 Observations and Findings

The team observed test and inspection activities including a Liquid Dye Penetrant inspection (PT) on the weld that joined the GC3000 outer shell to bottom component. The team verified that the inspector performed the PT in accordance with procedure I 0660 Z00, “Liquid Penetrant Examination,” dated 2/1/2010 as required, and was knowledgeable of the processes and requirements of PT.

The team noted that the inspector identified an indication during the PT. The inspector documented that the weld failed the PT and the welder subsequently reworked the area that failed. The team observed the PT performed of that area once it was considered complete by the welder and noted it passed. The team also noted that the PT inspector followed the applicable procedure adequately during both PT examinations. Once the examination report was completed for both PTs, the team reviewed it for procedural compliance and to verify it was complete. No issues of significance were identified.

The team also reviewed the qualifications and certifications for the inspector that performed the PT examination as discussed above. The team determined that the individual was qualified in accordance with procedure 5.00-QA-15, “Process Control,” and the applicable Canadian standard for qualification and certification of nondestructive testing personnel.

4.4.3 Conclusion

Overall, the team determined that for the test and inspection activities observed they were adequately performed by knowledgeable and qualified inspectors and no significant concerns were identified.

4.5 Measuring and Test Equipment

4.5.1 Scope

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

4.5.2 Observations and findings

The team reviewed Best's Measuring and Test Equipment procedure to verify that Best identified, specified, and controlled tools and equipment in accordance with applicable standards and regulatory requirements. Specifically, the team reviewed QAP implementing procedure 5.00-QA-06, "Measuring and Test Equipment," Revision F. The team verified that the implementation of the M&TE controls through direct observation of Best activities and a sampling of M&TE in actual shop service. The team reviewed the records of gauges, meters, and scales. The team verified that Best personnel used M&TE within their rated capacities and sensitivities. The team also verified that when instruments were out of calibration, procedure 5.00-QA-06 described how to justify product quality. Additionally, the team verified that the M&TE were traceable and controlled by Best personnel.

Overall, the team assessed that Best established controls of M&TE in accordance with standards and regulatory requirements. However, the team identified that one of the selected measuring test devices used to conduct visual inspections (D.L. Meter-3) was out of date for calibration since December 4, 2014. Best personnel sent the meter out for calibration after the on-site team inspection to determine if the as-found condition was within the acceptable calibration range. The results of the as-found condition showed that the meter was within the acceptable calibration range. Therefore, the team assessed this was a minor violation of NRC 10 CFR 71.125 M&TE requirements because the as-found condition was within calibration limits.

4.5.3 Conclusion

Overall, the team found that the control of measuring and test equipment was adequate, with one minor violation as described above.

5.0 Maintenance Controls

5.1 General

The team assessed the adequacy of maintenance controls in the areas of maintenance activities and tools and equipment to ensure: 1) that each packaging will meet its design task throughout its useful life; 2) suitable spare parts are used and; 3) that adequate tool and equipment controls are established. The team reviewed Best's practices and procedures, and their implementation to determine the effectiveness of maintenance controls.

5.2 Maintenance Activities

5.2.1 Scope

The team evaluated the maintenance process to ensure that it was controlled and verifiable from the onset of placing the completed packagings into service. The team verified that the maintenance procedures required the performance of packaging inspections to identify the need for maintenance and also the performance of routine

package maintenance. Documents reviewed included maintenance procedures, Safety Analysis Report (SAR) Chapter 8 requirements, maintenance checklists, and completed maintenance records.

5.2.2 Observations and Findings

Best is the CoC holder for three different CoCs, one each for the F-423, F-430, and F-431 model packagings. For each of the CoCs and models, the team reviewed the maintenance requirements of Chapter 8 of each associated SAR against the Best maintenance procedure, IN/IM 2548 F000, "Transport Package Maintenance Overview Procedure," dated 1/15/13. The team noted that detailed checklists were developed by Best for package maintenance activities. The team also noted that the maintenance procedures incorporated and in some cases expanded upon the SAR Chapter 8 requirements. However, the team did note some instances in which the maintenance checklists for the F-430 and F-431 CoCs did not contain certain inspection criteria stated in Chapter 8 of the applicable SAR.

Specifically, for the F-430, the SAR, Section 8.2.3 states, in part, "[t]he inner brace and plywood base inside the transport cavity are subjected to regular visual inspections." The team determined the Best maintenance procedure did not contain inspection criteria for the inner brace and plywood base of the F-430 packaging nor did any other procedure used for shipping activities performed on a routine basis. For the F-431, the SAR Section 8.2.3 states, in part, "[t]he inner braces inside the transport cavity are subjected to regular visual inspections." The Best annual maintenance procedure also does not contain inspection criteria for the inner braces of the F-431 packaging nor does any other procedure used for shipping activities performed on a routine basis. In addition, the F-431 SAR Section 8.2.3 states, in part, "[o]n an annual basis, the screws…on the tie-down collar shall be re-tightened to the specified torque." The Best maintenance procedure does not contain the requirement to re-tighten the screws on the tie-down collar for the F-431.

Contrary to the above, Best failed to incorporate the three maintenance program criteria from the F-430 and F-431 SARs, Section 8.2.3, which formed the basis of the NRC's approval of the packagings, into the Best maintenance procedure IN/IM 2548 F000. This is a violation of 10 CFR 71.111, Instructions, procedures, and drawings, based on an inadequate procedure. 10 CFR 71.111 requires, in part, the certificate holder shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances. The team determined that the violation was more than minor because the failure to have an adequate procedure to perform maintenance could have led to a more significant safety issue during transport of the packaging. The team evaluated the violation in accordance with Section 2.3 of the NRC Enforcement Policy and characterized the finding as a Severity Level IV violation. Because Best did not enter this issue into their corrective action program before the end of the inspection, the violation is being cited as a Notice of Violation.

At the time of the inspection, no maintenance or repair activities were ongoing for the three CoCs that Best holds. Therefore, the team reviewed a sampling of maintenance and repair records associated with the three packagings since 2013. The team determined that for the records reviewed, the packaging maintenance and inspection

activities were performed as required. The team noted that a torque wrench was used to perform re-tightening of hoist ring screws to a specified torque for all three packagings during annual maintenance activities. However, there was no requirement to document the torque wrench maintenance and test equipment identification number on the checklist. If an issue was identified later with a torque wrench, it would be difficult to determine what torque wrench was used to re-tighten the hoist ring screws and which maintenance activities could be affected. This observation was discussed with Best management personnel. The team also toured the Nordion facility that was in close proximity to Best because Nordion is contracted to perform maintenance activities for Best. The team found that Nordion was using the latest revision of the Best maintenance procedure and it was adequately controlled in their document management system. The team also reviewed Best's list of approved suppliers and found Nordion on the list as required.

Lastly, the team reviewed the training of one individual from Best that performed maintenance activities for the three packagings since the last inspection. The team determined that the individual was trained on the maintenance procedure as required and was qualified and certified to perform visual inspection of welds that included the requirement for a routine eye exam. No concerns were identified with respect to training of Best maintenance personnel.

5.2.3 Conclusion

Overall, the team assessed that Best adequately implemented its maintenance program, however; the team identified this as an area for improvement. One Severity Level IV NOV was identified for an inadequate procedure to perform all maintenance activities described in the SAR for the F-430 and F-431 packagings.

The above issue will be identified as a violation of 10 CFR 71.111, "Instructions, procedures, and drawings," in the Notice of Violation attached to this report.

5.3 Measuring and Test Equipment

5.3.1 Scope

See previous Section 4.5 for the team's review of maintenance M&TE. In Section 4.5 the team sampled M&TE used for fabrication and maintenance activities. The section discusses the team's review of Best's one implementing procedure used for both fabrication and maintenance M&TE controls.

6.0 Other Issues Reviewed By The Inspection Team

6.1 Corrective Action Follow-up to 2012 Best Inspection Two Notice of Violations

6.1.1 First Notice of Violation

The team reviewed Best's corrective actions associated with the first violation identified during the 2012 inspection (Report 71-0943/2012-201) to verify the corrective actions had been completed as described in their response to the violation on October 29, 2012.

Specifically, the first violation cited three examples where Best failed to follow procedures. CAPA 121002, dated October 10, 2012, documented Best's corrective actions for the first violation. For the first example where fabrication drawings did not identify the correct construction code for fabricating stainless steel components, the team determined that Best revised procedure P 0690 Z00, "Welding Engineering Standard" to specifically state the instances when AWS D1.6 is to be used when welding, as described in their response. In addition, the team found that Best initiated Design Change (DC) No. 30938 to make corresponding fabrication drawing changes when and if new overpacks were to be fabricated. This DC was still open at the time of the inspection since Best had no plans to fabricate any new overpacks.

For the second example where P 0690 Z00 did not identify a construction code for the fabrication welding of stainless steel components, the team determined that Best revised procedure P 0690 Z00, "Welding Engineering Standard" to specifically state the instances when AWS D1.6 is to be used when welding, as described in their response. In addition, the team found that training on the revised procedure was provided to the applicable Best personnel.

For the third example where procedure I 1677 Z00, "Visual Inspection of Welds" did not contain specific acceptance or rejection criteria for weld inspection for the fabrication of stainless steel components, the team determined that Best revised I 1677 Z00 to include a reference to AWS D1.6 for stainless steel, which contains acceptance and rejection criteria, as described in their response. Specifically, Appendix B of the procedure now contains the AWS D1.6 acceptance and rejection criteria. In addition, the team found that training on the revised procedure was provided to the applicable Best personnel.

6.1.2 Conclusion

The team determined the corrective actions in response to the first violation were adequate and the violation is considered closed.

6.1.3 Second Notice of Violation

The team also reviewed Best's corrective actions associated with the second violation identified during the 2012 inspection to verify the corrective actions had been completed as described in their response to the violation on October 29, 2012. Specifically, the second violation cited two examples where Best failed to implement adequate corrective actions. CAPA 121003, dated October 10, 2012 documented Best's corrective actions for the second violation. For the first example to the NOV where the NRC identified two weld defects on packagings that had been inspected and found acceptable by Best, the team determined that Best: 1) repaired the defects; 2) developed a new detailed welding inspection checklist; and 3) re-inspected all packagings using a certified visual weld inspector to ensure all overpacks were in compliance with the new weld inspection procedure. These actions were performed as described in Best's response to the violation.

The team sampled the documentation of the visual re-inspection from three packagings and had no issues. The team also verified the qualifications of the visual inspector that performed the inspections were in accordance with Best's visual inspection procedure.

The team noted that in the response to the violation, Best stated that full compliance would be achieved by November 30, 2012. The team found through a review of records that full compliance was not completed until January 2016. However, the team determined that the corrective actions were completed in a reasonable timeframe commensurate with the usage of the packagings and the amount of time they were available for re-inspection. Best personnel were made aware of this observation and were encouraged to notify the NRC when Best's implementation or compliance dates for corrective actions to NOVs are delayed.

For the second example where Best inspection personnel found six additional weld defects on two additional packagings, the team determined that Best performed the same corrective actions as discussed above in the response to the violation. The team found the same corrective actions to be applicable to both the first and second examples and adequate to correct the issues.

6.1.4 Conclusion

The team concluded the corrective actions in response to the second violation were adequate and the violation is considered closed.

7.0 Exit Meeting

On September 22, 2016, the NRC inspection team presented the preliminary inspection results and observations during an on-site exit meeting. Table 2 of this report shows the attendance for the entrance and exit meetings.

NOTICE OF VIOLATION

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

Docket No.: 71-0943
Report Number 2016-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted from September 20 through 22, 2016, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, dated August 1, 2016, the violations are listed below:

A. 10 CFR 71.91, "Records," states in part, the certificate holder shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by 71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities.

   Contrary to the requirements of 10 CFR 71.91, the following instance was identified by the NRC where there was inadequate maintenance of original fabrication records to furnish evidence of the quality of packaging:

   As the holder of CoC 9290 for packaging model F-430, Best has failed to maintain sufficient written records to furnish evidence of the quality of five packaging units. Best has only maintained between 50 and 70 percent of the original F-430 fabrication records for unit serial numbers 5, 6, 7, 8 and 9.

   This is a Severity Level IV violation (Section 6.0).

B. 10 CFR 71.107, "Package design control," states in part, the certificate holder shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license or CoC for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety.

   Contrary to the above, the following instances were identified by the NRC where measures were: 1) not established to assure that appropriate quality standards were specified and included in design documents; and 2) not established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety.

1. Best has not performed engineering evaluations to support the assignment of important to safety categories for the components of the three packaging models for which it is the CoC holder.

2. Best does not have a Commercial Grade Dedication procedure for commercially purchased components or materials used in important to safety applications for its packagings.

This is a Severity Level IV violation (Section 6.0).

C. 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 requirements of 10 CFR 71.111, the following instance was identified by the NRC where a procedure that was not appropriate to the circumstances, or inadequate, prescribed maintenance activities affecting quality:

Best failed to incorporate three maintenance program activities described in the F-430 and F-431 Safety Analysis Reports, Section 8.2.3, which formed the basis of the NRC's approval of the packagings, into the Best maintenance procedure IN/IM 2548 F000. Specifically, Best failed to incorporate routine inspections of the inner bracing for both packagings, and the annual requirement to re-tighten the screws on the tie-down collar to the specified torque for the F-431 packaging.

This is a Severity Level IV violation (Section 6.0).

D. 10 CFR 71.115, "Control of purchased material, equipment, and services," states in part, the certificate holder shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or service. These measures must include provisions for source evaluation and selection, and objective evidence of quality furnished by the contractor or subcontractor.

Contrary to the above, the following instances were identified by the NRC where the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or service was not assessed.

1. Best has not been performing external audits of contractor Nordion's sealed source receipt inspection program.

2. Best has not been performing external audits of contractor Nordion's package maintenance program.

This is a Severity Level IV violation (Section 6.0).

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 Patricia Silva, Chief, Inspections and Operations Branch, Division of Spent Fuel Management, 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. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. 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), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.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. 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. If Classified Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR Part 95.

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

Dated this 4th day of November 2016.