

71-9290
 71-9299
 71-9310

Report submitted in accordance with 10 CFR 71.95	
Date of Report	November 23, 2009
USNRC Reference	Docket # 710934-2009-201 USNRC Audit of QA Program – August 10-13, 2009
Manufacturer Information	
Company Name	Best Theratronics Ltd. 413 March Road Ottawa, Ontario Canada K2K 0E4
Package Identification No.	Certificate of Compliance USA/9290/B(U)-85 for F-420 Certificate of Compliance USA/9299/B(U)-85 for F-423 Certificate of Compliance USA/9310/B(U)-96 for F-431
Report Submitted By	Mike de van der Schueren Director, Compliance
Contact Information	
Contact Name for Additional Information on Event	Mike de van der Schueren
Phone Number	613-591-2100 ext: 2488
Brief Description of Event and Significant Corrective Action Taken or Planned to Prevent Recurrence (include component or system failures that contributed to the event)	During an NRC inspection at Best Theratronics (BTL) an observation was raised with respect to possible weld discontinuities on RAM packages. All RAM packages were immediately quarantined and BTL initiated efforts to have them visually inspected to determine the extent of the condition. When confirmed, discontinuities were reworked to meet applicable workmanship standards.

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<p>Detailed Description of Event</p> <p><i>(include where possible the following specific information as appropriate)</i></p>	<p>All RAM packages were manufactured by MDS Nordion and purchased as-is by BTL as part of the acquisition of the self-contained irradiator product line on May 1, 2008. The RAM packages were not inspected by BTL and it was not known that any welding discontinuities existed.</p>
<p>(i) Status of components or systems that were inoperable at the start of the event and that contributed to the event</p>	<p>Not applicable. There were no components or systems that failed as a result of the condition.</p>
<p>(ii) Dates of event</p>	<p>August 10 to 13, 2009 (date of NRC inspection)</p>
<p>(iii) Cause of Failure</p>	<p>BTL failed to perform a visual inspection of the RAM packages when they were acquired from the seller.</p>
<p>(iv) Failure Mode, Mechanism and effect of each failed component</p>	<p>Not applicable. There were no failed components.</p>
<p>(v) List of Systems or secondary functions that were also affected for failures of components with multiple functions</p>	<p>Not applicable - no systems or secondary functions that were affected.</p>
<p>(vi) Method of discovery of failure</p>	<p>Visual inspection of welds per applicable manufacturing drawings, specifications and welding standard.</p>
<p>(vii) For each human performance-related root cause, a discussion of the cause and circumstances</p>	<p>Not applicable.</p>
<p>(viii) For events occurring during use of a packaging, the quantities and chemical and physical form of the package contents.</p>	<p>The noted conditions had no implications or impact on past shipments.</p>

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<p>Assessment of Safety Consequences and Implications of the Event</p> <p><i>(include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event)</i></p>	<p>The continuous welds on the bumper pads were primarily in question. The safety consequence is rated very low as the lower bumper pad is stitch welded in place to prevent moisture entrapment, resulting in the continuous weld having superior strength.</p> <p>No condition existed that had any safety consequences or radiological consequences.</p> <p>All weld discontinuities that were reworked will have negligible effect on the functionality of the original weld.</p>
<p>Corrective Actions Planned and Actions Taken to Reduce the Probability of Reoccurrence <i>(include the means employed to repair any defects)</i></p>	<p>All RAM packages were quarantined pending inspection of welds. Discontinuities were reworked back to specification where needed.</p> <p>BTL has implemented a new visual welding inspection standard that is endorsed by the Canadian Welding Bureau. All welders and QC inspectors have been trained on this standard and will require ongoing training at a predetermined frequency in accordance with welding procedures.</p>
<p>Previous Similar Events</p>	<p>None.</p>
<p>Extent of any Individual Exposure to Radiation or to Radioactive Materials</p>	<p>No individuals were exposed to radiation or radioactive material due to the conditions.</p>



Mike de van der Schueren
Director, Compliance

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Date