



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

March 29, 2018

Ruth S. Bergin
Senior Vice President and Counsel
Best Theratronics, Ltd.
7643 Fullerton Road
Springfield, VA 22153

**SUBJECT: NRC INSPECTION REPORT NO. 03037620/2018001, BEST THERATRONICS,
LTD. SPRINGFIELD, VA, AND NOTICE OF VIOLATION**

Dear Ms. Bergin:

On February 15, 2018, Randolph Ragland, of our King of Prussia, Pennsylvania, office, conducted an NRC inspection of Best Theratronics, Ltd. (NRC License 45-31299-01) at Medstar Washington Hospital Center, while your representative, Mr. Bert Lalonde, prepared an MDS Nordion Gamma Cell 3000 irradiator for shipment in a F-431 Transport Package. The inspection included an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The inspection continued in-office until March 13, 2018. Additional information provided by Victor Moga, Manager, Technical Services, and Mojgan Soleimani, Radiation Safety Officer, of your organization, was also examined as part of the inspection, and was discussed in the inspection closeout telephone call on March 13, 2018.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that one violation of NRC requirements occurred. The violation is related to the failure to ensure that bolts on the internal and main covers of the F-431 transport package were torqued to specified levels as required by the transport package Certificate of Compliance (CoC) number 9310 and the corresponding F-431 transport package safety analysis report. The violation is cited in the enclosed Notice of Violation (Notice), because the violation was identified by the NRC.

During our inspection exit meeting on March 13, 2018, Mr. Victor Moga acknowledged the deficiency and indicated that Best Theratronics, Ltd. would take prompt corrective actions to address the violation and that you are committed to radiation safety and to compliance with NRC regulations and licensed conditions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's Web Site at www.nrc.gov; select Nuclear Materials; Med, Ind, & Academic Uses; then Regulations, Guidance and

Communications. The current Enforcement Policy is included on the NRC's Web Site at www.nrc.gov; select About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents; then Enforcement Policy (Under 'Related Information'). You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web Site at: <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

If you have any questions regarding this matter, please contact Randolph Ragland of my staff at 610-337-5083 or via electronic mail at Randolph.Ragland@nrc.gov.

Thank you for your cooperation.

Sincerely,

A handwritten signature in black ink, appearing to read 'Arthur Burritt', with a long horizontal flourish extending to the right.

Arthur Burritt, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

Docket No. 030-37620
License No. 45-31299-01

Enclosure: Notice of Violation

cc w/Enclosure: Mojgan Soleimani, Radiation Safety Officer
Commonwealth of Virginia

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Thank you for your cooperation.

Sincerely,

/RA/

Arthur Burritt, Chief
Commercial, Industrial, R&D
and Academic Branch
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cc w/Enclosure: Mojgan Soleimani, Radiation Safety Officer
Commonwealth of Virginia

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R1Enforcement

J. Trapp

J. Nick

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SUNSI Review Complete: R. Ragland

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OFFICE	RI:DNMS	RI:DNMS					
NAME	RRagland/rcr	A. Burritt					
DATE	3/14/18	3/29/18					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Best Theratronics, Ltd.
Springfield, Virginia

License No. 45-31299-01
Docket No. 030-37620

During an NRC inspection conducted on February 15, 2018, and continued in-office until March 13, 2018, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the Code of Federal Regulations (CFR) Part 71.17(c)(2) issues a general license to a licensee of the Commission to transport licensed material in a package for which a Certificate of Compliance (CoC) has been issued by the NRC, if the licensee complies with the terms and conditions of the CoC.

Certificate of Compliance No. 9310, for package identification number USA/9310/B(U)-96, Revision 6, dated August 6, 2015, requires the transport package to be prepared for shipment and operated in accordance with the Operating Procedures in Chapter 7 of the application.

MDS Nordion, F-431 Transport Package Safety Analysis Report, IN/TR 1913 F431 (2), dated April 14, 2004, Chapter 7 – Operating Procedures, Section 7.3, steps 4 and 5, require the inner and main covers of the transport package to each be secured with sixteen 5/8" bolts torqued to 80 ft-lb.

Contrary to the above, on February 15, 2018, while loading an F-431 Transport Package with an MDS Nordion Gamma Cell 3000 self-shielded irradiator, at Medstar Washington Hospital Center, Best Theratronics, Ltd, did not fully comply with the terms and conditions of the CoC when loading and preparing the F-431 package for shipment. Specifically, the licensee tightened the bolts to the inner and main covers of the transport cask without using a torque wrench to ensure that the bolts were torqued to 80 ft-lb.

This is a Severity Level IV violation (Section 6.8).

Pursuant to the provisions of 10 CFR 2.201, Best Theratronics, Ltd. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, 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, (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 to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 29TH day of March 2018