



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD., Suite 100
KING OF PRUSSIA, PA 19406-2713

September 25, 2017

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

SUBJECT: BEST THERATRONICS LTD. – NRC INSPECTION NO. 03037620/2017001
AND NOTICE OF VIOLATION

Dear Ms. Bergin:

This letter refers to the inspection conducted on August 9, 2017, at your Springfield, Virginia location, with further in office review of records through August 28, 2017. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>). The violation is cited in the enclosed Notice of Violation (Notice) because the violation was identified by the NRC.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket and include: amending your NRC license to include Gamma Beam 500 irradiators and entering an item into your Corrective and Preventative Action Program (CAPA #170713). Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, 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 website 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 website 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-

R. Bergin

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866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

If you have any questions regarding this matter, please contact Orysia Masnyk Bailey of my staff at 864-427-1032 or via electronic email at Orysia.masnykbailey@nrc.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Raymond J. Powell". The signature is fluid and cursive, with a large, stylized "P" and "R".

Raymond J. Powell, Chief
Decommissioning and Technical Support
Division of Nuclear Materials Safety

Docket No.: 03037620
License No.: 45-31299-01

Enclosure: Notice of Violation

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

R. Bergin

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Sincerely,

/RA/

Raymond J. Powell, Chief
Decommissioning and Technical Support
Division of Nuclear Materials Safety

Docket No: 03037620
License No: 45-31299-01

Enclosure: Notice of Violation

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

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NAME	OMasnykBailey/sth for		RPowell <i>RP</i>			
DATE	9/1/17		<i>9-25-17</i>			

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If you have any questions regarding this matter, please contact Orysia Masnyk Bailey of my staff at 864-427-1032 or via electronic mail at orysia.masnykbailey@nrc.gov.

Sincerely,

Raymond J. Powell, Chief
Decommissioning and Technical Support
Division of Nuclear Materials Safety

Docket No: 03037620
License No: 45-31299-01

Enclosure: Notice of Violation

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

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OFFICE	DNMS/RI	N	DNMS/RI	DNMS/RI			
NAME	OMasnykBailey <i>STH</i>		RPowell				
DATE	<i>9/1/17</i>						

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NOTICE OF VIOLATION

Best Theratronics, Ltd.
Springfield, VA

Docket No. 03037620
License No. 45-31299-01

During an NRC inspection conducted on August 9, 2017, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

- A. Condition 9.A. and B. of NRC License No. 45-31299-01 permits distribution of Best Theratronics, Ltd. devices listed in Condition 10.A. and also allows installation of radioactive sources into those same devices.

Contrary to the above, Best Theratronics, Ltd. distributed two Gamma Beam 500 irradiators and installed sources into the irradiators without the devices being listed on Condition 10.A. of NRC License No. 45-31299-01. Specifically, between April 21, 2016, and February 11, 2017, Best Theratronics, Ltd. shipped a Gamma Beam 500 irradiator to Brigham Hospital in Massachusetts and installed a radioactive source into the irradiator. Also, between October 6, 2016, and November 1, 2016, Best Theratronics, Ltd. shipped a Gamma Beam 500 irradiator to Karmanos Cancer Center in Michigan and installed a radioactive source into the irradiator.

This is a Severity Level IV violation (Enforcement Policy Section 6.3.d).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it 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).

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 D.C., 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 publicly 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 25 day of September 2017.