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December 28, 2009

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

Krishnan Suthanthiran
President
Best Theratronics Ltd.
7643 Fullerton Road
Springfield, VA 22153

SUBJECT: REQUEST FOR INFORMATION REGARDING POSSIBLE CONTAMINATION FOUND IN A GAMMACELL 40 SELF-SHIELDED IRRADIATOR

Dear Mr. Suthanthiran:

On November 6, 2009, the New York State Department of Health (NYSDOH) reported to the Nuclear Regulatory Commission (NRC) that a leaking sealed source had been identified in a Gammacell 40 self-shielded irradiator located in the State of New York (NRC Event Report No. 45480). The leaking source, AECL Model C-161, had been identified on November 3 by a Best Theratronics Ltd. (Best) Service technician who was onsite to perform a special procedure on the irradiator. Following identification of the radioactive contamination, the procedure was terminated and the irradiator was placed out of service. According to the NYSDOH, Best personnel stated they believed the radioactive contamination was the result of manufacturing problems that are known to have existed at the Oak Ridge National Laboratory (ORNL) when the Model C-161 source was encapsulated at ORNL 35 years ago. This same information was communicated to an NRC inspector during an inspection conducted in Ottawa, Canada, on December 15, 2009.

At this time, NRC is not aware of any manufacturing problems at ORNL that may have resulted in defective Model C-161 source encapsulations. NRC requests that Best provide us with any information you have regarding Model C-161 sealed source deficiencies (or deficiencies associated with any other sealed source or device listed in Conditions 10.A and 10.B of your license). NRC requests that you provide this information within 30 days of the date of this letter. Your response should include your plan for evaluating the condition of Model C-161 sealed sources that are still in use or your rationale for concluding that no evaluation is necessary. In the interim, NRC requests that you provide us, within 7 days of the date of this letter, with the names and locations of facilities within the United States where the Model C-161 source is still being used so that the responsible regulatory authorities can ensure that the licensees are aware of the increased potential for sealed source leakage. Furthermore, NRC requests that you provide the names and locations of facilities outside of the United States where the Model C-161 source is still being used to the appropriate regulatory authorities in those countries.

On December 2, 2009, Best issued a Safety Bulletin to “Users of Gammacell 40 Research Irradiators.” The Safety Bulletin described the November 3 event and stated that the contamination was found in areas “not normally accessible to the operator and there is no hazard under normal operating conditions.” The Bulletin also stated that “Users can continue to

safely use their unit in accordance with standard operating procedures and radiation safety precautions" and that "No additional action is required except in the case where dismantling work is being planned." Should this be interpreted to mean that an irradiator with a leaking source, such as the Gammacell 40 irradiator in New York State, can continue to be used if the contamination is not accessible to the operator under normal conditions? The NRC would appreciate a clarification. NRC also notes that the Bulletin was addressed to "Users of Gammacell 40 Research Irradiators." Is the Model C-161 source used in any other device?

Thank you for your cooperation. If you have any questions, please contact me at (610)337-5309.

Sincerely,

Original signed by Elizabeth Ullrich For

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
C. Douglas Beatty, Radiation Safety Officer
Robert Dansereau, New York State Department of Health
Peter Fundarek, Canadian Nuclear Safety Commission

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