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James P. Dwyer, Chief  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
United States Nuclear Regulatory Commission  
Region I  
475 Allendale Rd  
King of Prussia, PA 19406-1415

Docket No. 030-19199  
License No. 45-19757-01

Subject: Response to NRC Inspection Report No. 030-19199/2009-001, Best Medical International, Inc. Springfield VA Site and Notice of Violation  
Springfield, Virginia

Dear Mr Dwyer,

This document is in response to the March 12, 2009 letter from the US Nuclear Regulatory Commission regarding the above subject matter. The inspection took place on January 26-27 and February 17, 2009 at the Best Medical International facility in Springfield, Virginia. The three violations listed in the letter are answered categorically in this response.

A. 10CFR30.51 requires, in part, that licensees keep records showing the receipt, transfer and disposal of all byproduct material. As acknowledged in the March 11 letter from NRC, Best Medical has corrected the total inventory count to include both waste and manufacturing, the letter states in part "...the February 2009 total inventory report now includes the amount of Co-60 in both waste and in manufacturing..." Also, an email from Best dated February 11, 2009 was provided to NRC indicating the correction was made. In a second point related to 10CFR30.51, the NRC questions the appropriateness of the .006 ratio used by Best Medical as an analytical model for computing the amount of Co-60 produced in the nuclear reactor. Best contests the validity of this violation. Best is using a model that was developed by scientists at the National Institute of Standards and Technology (NIST) in using this .006 ratio. Six inspections have been conducted by NRC representatives during the past eight years, since Best was provided in 2001 the NIST calculation of the .006 ratio and no safety violations were cited against Best Medical International. Using the shipping document received from the reactor as a reference document, and once the shipments are returned from the customers, the .006 ratio is used to calculate the Co-60 activity of the waste. As stated, Best Medical has revised the manner in which waste seeds are tallied and stored. It is believed that this change will eliminate apparent inventory discrepancies in the future.

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NMSS/RGNI MATERIALS-004



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B. 1. 10CFR20.1201 requires, in part, that the licensee control the occupational dose to adults who might receive an occupational dose and requires licensee to reduce the dose that an individual may receive by the amount of occupational dose received while employed by any other person. Best Medical provides pocket dosimeters and visitor film badges as needed for monitoring the dose received by these personnel. In addition, Best will arrange with Landauer Scientific, Best's dosimetry contractor, to provide up-to-date radiation exposure data for employees at Best Medical to evaluate occupational dose for individuals who are employed by other persons where license materials are used, to determine if reductions in the amount of occupational dose at the Best facility is required.

2. 10CFR20.1301 requires the licensee to conduct operations to limit exposure to individuals to less than  $3\text{E}-10$  micro-curies per milliliter ( $\mu\text{Ci}/\text{ml}$ ) in gaseous effluent. The NRC inspector felt that the method used by Best was not sufficient to meet the regulatory requirement for effluent measurement. Best contests this violation and asserts that it followed an approved procedure, RP:006 Rev 1 dated 9/25/2003. This procedure was evaluated and reviewed by two previous NRC inspections. However, we do note that Best immediately implemented the recommendation to replace the hand held Geiger counter to take the readings, with a single channel analyzer to count the samples. However, Best does not agree that the method it used was a violation. Rather using the single channel analyzer was an opportunity for improvement to use more sensitive instrumentation and thus Best made the modification.

C. 10CFR20.1101 requires, in part, that the licensee shall periodically (at least annually) review the radiation protection program content and implementation. Best contests this violation, in that for a number of years, Best has conducted a bi-weekly audit of its radiation safety program. This program has been reviewed at least five times over the past decade and has not been cited. At the suggestion of the most recent inspection, Best will initiate an annual audit of its radiation safety program that will incorporate all the review elements specified by the NRC inspection manual. Best has created an SOP for Radiation Protection Program Annual Management Review for implementation. In addition, we will keep in place our bi-weekly audits.

The management and staff of Best Medical appreciate the consideration and regulatory response that has been received from the Commission. Best will make every effort to follow the Commission's lead in maintaining a highly safe and productive operation. We assure you that our employees are well trained and aware of the requirements placed on them by the Commission and other regulatory bodies. In response to the subject inspection citations, Best has addressed the inspector's suggestions. In fact, most of the solutions were presented to the inspector at the exit briefing. We expect full compliance of the inspection deficiencies to be implemented within the time limit specified by the NRC.

Best has for years maintained a rigorous quality management program for its industrial management safety efforts. This program is in response to its adherence to the many regulatory bodies including NRC with which Best complies, such as IATA (International Air Transport Association) Dangerous Goods Regulations as well as OSHA and FDA Regulations.




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Please feel free to contact me at ext 128 regarding any additional questions or concerns.

I hereby affirm, on behalf of Best Medical International, Inc. that the above is true and correct to the best of my knowledge.

Very Truly Yours,



Ruth S Bergin  
Senior Vice President and Counsel

Cc;

Director, Office of Enforcement, NRC  
Krishnan Suthanthiran, President BMI  
Dr Billy Bass, RSO, BMI

