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KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 30, 2009
Docket No. 030-19199 License No. 45-19757-01
EA-09-146

Krishnan Suthanthiran
President
Best Medical International, Inc.
7643 Fullerton Road
Springfield, VA 22153

SUBJECT: RESPONSE TO DISPUTED VIOLATIONS - NOTICE OF VIOLATION AND NRC INSPECTION REPORT NO. 030-19199/2009-001

Dear Mr. Suthanthiran:

We have completed our review of the letter received on April 30, 2009, from Ruth Bergin, your Senior Vice President and Counsel, in response to our letter and Notice of Violation dated March 12, 2009. Our letter and Notice of Violation cited three Severity Level IV violations, identified during an inspection conducted on January 26-27 and February 17, 2009. In your response, you denied all or parts of all three violations.

Violation A of the Notice of Violation (NOV) involved the failure to maintain records showing the receipt, transfer and disposal of byproduct material, specifically because of inaccuracies in accounting for the amount of cobalt-60 you possess. Violation B of the NOV involved the failure to perform adequate surveys (evaluations) of occupational dose to individuals employed by other persons where licensed materials were used (B.1), and effluent air concentrations at the required sensitivity (B.2). Violation C of the NOV involved the failure to review the radiation protection program content and implementation annually, specifically, the bi-weekly audits (performed in lieu of a single annual review) over the past two years, did not include a review of all areas of the program (such as the dosimetry, the annual dose to workers, and the annual effluent releases), and did not identify that the inventory of cobalt-60 was incorrect.

In the response received on April 30, 2009, Ms. Bergin: acknowledged a portion of Violation A, but questioned the validity of the remainder of Violation A; acknowledged Violation B.1, but specifically contested the validity of Violation B.2; and specifically contested the validity of Violation C. A re-statement of the violations, your response to the violations, and our assessment of your response, is described in the Enclosure. Based on our review of the information submitted in your response received on April 30, 2009, the NRC determined that you did not provide a sufficient basis for NRC to withdraw any of the violations.

In several places in your letter, you noted that your practices had existed during an extended period of time, and prior NRC inspectors did not identify these practices as violations. Inspectors do not normally review every area of the licensed program, and those areas that are reviewed are only sampled. Therefore, you should recognize that violations not being identified during an inspection does not assure licensees are in full compliance with regulatory and license requirements.

The NRC has concluded that, for Violations B and C, the information regarding the reasons for the violations, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, have been adequately addressed.

However, additional information is needed with regard to Violation A as requested in the Enclosure. Your response should follow the original instructions specified in the Notice of Violation. Please submit to this office within thirty days of receipt of this letter a written statement containing the requested information for Violation A.

With regard to our request for additional information for Violation A, we are willing to meet with you to further discuss Violation A and our expectation for your determination of the current inventory of cobalt-60. If such a meeting is needed, please contact us within ten days of receipt of this letter, to request a meeting and to request an extension for your response. If you desire a meeting or have other questions, please contact James Dwyer, Chief, Commercial and R&D Branch at (610) 337-5309.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

Sincerely,

Original signed by Daniel S. Collins

John D. Kinneman, Director
Division of Nuclear Materials Safety

cc w/ enclosure:
Billy G. Bass, Ph.D., Radiation Safety Officer
Commonwealth of Virginia

Enclosure: Review of Violations

The NRC has concluded that, for Violations B and C, the information regarding the reasons for the violations, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, have been adequately addressed. The corrective and preventive actions for these violations will be reviewed during the next inspection. However, additional information is needed with regard to Violation A as requested in the Enclosure. Your response should follow the original instructions specified in the Notice of Violation. Please submit to this office within seven (7) days of receipt of this letter a written statement containing the requested information for Violation A.

With regard to our request for additional information for Violation A, we are willing to meet with you to further discuss Violation A and our expectation for your determination of the current inventory of cobalt-60. If such a meeting is needed, please contact us within ten days of receipt of this letter, to request a meeting and to request an extension for your response. If you desire a meeting or have other questions, please contact James Dwyer, Chief, Commercial and R&D Branch at (610) 337-5309.

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Sincerely,

/RA by Daniel S. Collins For/

John D. Kinneman, Director
Division of Nuclear Materials Safety

cc w/ enclosure:
Billy G. Bass, Ph.D., Radiation Safety Officer
Commonwealth of Virginia

Enclosure: Review of Violations

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*see previous concurrence
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Best Medical International, Inc.
Springfield, VA
EA-09-146

Docket No. 030-19199
License No. 45-17757-01

VIOLATION A

10 CFR 30.51 requires, in part, that licensees keep records showing the receipt, transfer, and disposal of all byproduct material.

Contrary to the above, during the period of January 2007 through January 2009, the licensee did not keep records showing receipt, transfer, and disposal of all byproduct material. Specifically, the licensee received and transferred cobalt-60 (Co-60) that is an activation product in the casing of the iridium-192 (Ir-192) seeds but did not know the actual total amount of Co-60 they possessed as of January 26, 2009. The licensee's weekly inventory of total licensed materials possessed during the period up to January 19, 2009, did not contain the correct total amount of Co-60 because it did not include the Co-60 in waste (a difference of approximately 6 curies, according to the licensee's waste records presented during the inspection). In addition, the licensee's determination of the amount of Co-60 is incorrect because the licensee used a ratio of 0.006 Co-60 activity/Ir-192 activity to estimate the Co-60 activity without knowing at what point in time after activation that ratio is correct. Specifically, as of January 26, 2009, the licensee applied the 0.006 ratio at the time the Ir-192 seeds were sent for storage as waste; and for the weekly inventory dated February 2, 2009 and the weekly inventory dated February 9, 2009, the 0.006 ratio was used for all seeds present in manufacturing as well as in waste, without regard to the amount of time since the seeds were activated and received at the facility. Although the February 2009 total inventory report now includes the amount of Co-60 in both waste and in manufacturing, the use of the 0.006 ratio is incorrect in that this ratio is only applicable at one specific point in time after activation. Although the licensee does not know that point in time, the licensee used that ratio for Ir-192 seeds in manufacturing and Ir-192 seeds in waste. If the 0.006 ratio is applied at a time which is greater than one half-life from the point in time at which the amount of activity Co-60 actually is equal to 0.006 of the activity of the Ir-192, the amount of Co-60 actually present could be double the amount calculated by ratio; that error increases with the length of time past the point in time at which the ratio applies.

Best Medical International response:

"10 CFR 30.51 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 10 CFR 30.51, the NRC questions the appropriateness of the 0.006 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 0.006 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 0.006 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 0.006 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."

NRC review of the Best Medical International response:

With regard to recordkeeping, we acknowledge that your records will now account for cobalt-60 activity in both the waste and manufacturing streams. Thank you for this corrective action. However, the NRC maintains the cobalt-60 inventory record is not accurate, because of the manner in which you estimate your cobalt-60 activity. During the inspection, the inspector was told that the ratio of cobalt-60 activity to iridium-192 activity is 0.006. The NRC understands that this ratio was developed for you by scientists from the National Institutes of Standards and Technology (NIST), and do not question the appropriateness of this ratio. However, the NRC disagrees with the manner in which this ratio is being used to calculate the cobalt-60 inventory. During the inspection, your staff was unable to identify at what point in time the ratio of cobalt-60 to iridium-192 is 0.006 (at the end of seed irradiation, at the time the iridium-192 seeds were shipped to medical users or, less likely, when the seeds were returned as waste). It appears that your staff used this factor to estimate the amount of cobalt-60 in the manufacturing area and the amount of cobalt-60 in the waste without correcting for the obvious difference in the age of the seeds in these two areas. This difference is very important to the accuracy of your cobalt-60 estimate.

For example, if the 0.006 ratio is applicable at the end of seed irradiation and if, for calculational purposes, the amount of iridium-192 in the irradiated seed lot is 1000 curies, than the amount of cobalt-60 in the seed lot at the end of irradiation is estimated to be 0.006 X 1000 curies of iridium-192 = 6 curies of cobalt-60. If the seeds are shipped to medical users one week later, we know that the amount of iridium-192 in the seed lot has decayed to 936.4 curies and the amount of cobalt-60 in the seed lot has decayed to only 5.985 curies. However, if you apply the 0.006 ratio at this point in time, you would estimate that only 0.006 X 936.4 curies of iridium-192 = 5.618 curies of cobalt-60 was present in the seed lot – a difference of 367 millicuries. If the seeds are returned to Best for disposal 30 days later (37 days from irradiation), we know that the amount of iridium-192 in the seed lot has decayed to 706.6 curies and the amount of cobalt-60 in the seed lot has decayed to only 5.921 curies. However, if you apply the 0.006 ratio at this point in time, you would estimate that only 0.006 X 706.6 curies of iridium-192 = 4.24 curies of cobalt-60 was present in the seed lot – a difference of 1681 millicuries.

Therefore, the NRC maintains that Violation A occurred as stated in the Notice, and will not be withdrawn. Please respond to this letter describing your corrective and preventive actions. Your corrective actions should include an assessment of the current quantity of iridium-192 and cobalt-60 in your manufacturing area, the waste area, and any other location in your facilities where iridium-192 and cobalt-60 are stored that demonstrates

that you have operated within your license possession limits. Your corrective actions should also include a description, including calculations and any assumptions made, of how this factor is used to account for the cobalt-60 present in iridium-192 seeds from arrival to your facility, through the manufacturing process and customer use and return, and into waste. Your corrective actions should review past records of receipt of iridium-192 seeds to determine if the activity of cobalt-60 assumed to be in storage is reasonably correct. With the exception of sources that were not returned by customers and radioactive decay of cobalt-60, all cobalt-60 initially received at your facility should be present in your current inventory.

VIOLATION B

10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Contrary to the above, as of January 27, 2009, the licensee did not make surveys to assure compliance with:

1. 10 CFR 20.1201, which requires, in part, that the licensee control the occupational dose to individual adults, and 20.1201(f), which requires the licensee to reduce the dose that an individual may receive by the amount of occupational dose received while employed by any other person. Specifically, as of January 26, 2009, the licensee did not evaluate occupational dose for individuals who were employed by other persons where licensed materials were used, to determine if reductions in the amount of occupational dose at the licensee's facility were required.

2. 10 CFR 20.1301, which requires the licensee to conduct operations to limit dose to individual members of the public and 20.1302, which specifies the criteria for demonstrating compliance with the public dose limits, in part, by ensuring that the average annual concentration of iodine-125 released in gaseous effluent does not exceed 3 E-10 microcuries per milliliter (uCi/ml). Specifically, the licensee was unable to demonstrate that the analysis of effluent air samples was sufficiently sensitive to identify iodine-125 in effluent air at the required concentrations.

Best Medical International response:

1. "10 CFR 20.1201 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 licensed materials are used, to determine if reductions in the amount of occupational dose at the Best facility is required."

2. "10 CFR 20.1301 requires the licensee to conduct operations to limit exposure to individuals to less than 3 E-10 microcuries per milliliter (uCi/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 during 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."

NRC review of the Best Medical International response:

With regard to violation B.1, thank you for describing your actions to prevent recurrence. Note that Landauer is not the only dosimetry contractor in the industry; therefore, they may not be able to report the entire occupational dose received by your employees who are employed by other users of radioactive material.

With regard to violation B.2., the inspector observed that you analyze your charcoal filters for the presence of iodine-125 weekly, using a ratemeter with a 1 x 1" sodium iodide crystal probe. The inspector noted the following:

1. Samples were collected for one week, using a charcoal filter cartridge, and charcoal filters were re-used if the counts measured were 'small,' subtracting the previous week's result without correction for decay (92% of the previous week's value). This is not conservative as it underestimates the amount of material accumulated in the second week.

2. The concentration of iodine-125 on the sampling media was evaluated using a rate meter (Ludlum 3 with Model 44-3 probe), which is not usually a suitable way to measure small quantities of radioactive material. In addition, the licensee did not do any evaluation of the minimum detectable activity (MDA) for the measurement system used; and the calculation did not include filter collection efficiency. This is important because licensee reports stack airborne concentrations in the range of 1 E-11 and 1 E-10 microcuries (uCi) per milliliter (ml) and the regulatory limit for unrestricted areas is 3 E-10 uCi/ml. In addition, the constraint on air emissions of radioactive material requires that the licensee determine if effluent released exceeds 20% of the 3 E-10 uCi/ml limit (6 E-11 uCi/ml). Most instrumentation references do not provide a calculation for MDA from a ratemeter but generally recommend that it be determined empirically. One text (Gollnick) provides a calculation using the instrument time

constant but this has not been accepted universally. Most instrumentation references require that analytical measurement be performed in scaler mode, where the statistical fluctuations of the ratemeter mode become unimportant and an MDA calculation can be performed with known certainty.

3. During the inspection, the licensee was asked to demonstrate that this system of analysis was sufficiently sensitive to detect the airborne concentrations at the applicable limits. The licensee was unable to so demonstrate and elected instead to purchase a scaler system for analyzing future air samples. The licensee also stated, during the inspection, that they would account for decay if charcoal samplers were re-used, but stated that they intended to use new charcoal air samplers each week

The NRC concludes that there exists a valid basis for Violation B.2; therefore, it will not be withdrawn.

VIOLATION C

10 CFR 20.1101 requires, in part, that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, as of January 26, 2009, the licensee did not review the radiation protection program content and implementation at least annually. Specifically, although the licensee conducted a weekly audit, the weekly audit did not include all areas of the radiation protection program (for example, it did not include a review of dosimetry, annual dose to workers, or annual effluent releases) and the weekly audits did not identify that the inventory of Co-60 was incorrect for a period of at least two years.

Best Medical International response:

"10 CFR 20.1101 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 had 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."

NRC review of Best Medical International response:

While we acknowledge the fact that you performed bi-weekly audits, your audits did not review the entire radiation safety program. Specifically, your audits did not review worker dosimetry results, annual worker internal and external exposures, or annual effluent releases. As a result, several violations related to your dosimetry program were identified during the inspection. These violations were not cited because actual worker exposures did not exceed the conditions in 10 CFR 20.1502 requiring personnel

monitoring and the violations were therefore considered to be minor. These minor violations included: failure to determine the total dose to at least one worker who wore temporary dosimetry for a period of time when the personal dosimetry was not available; failure to determine the internal doses to workers because thyroid bioassay calculations were not completed and the weekly results were not summed for the year; and failure to demonstrate that the analysis of room air samples was sufficiently sensitive to demonstrate compliance with airborne concentrations for workers. In addition, the failure to include effluent releases in the bi-weekly audits resulted in your missing internally established action levels and no assessment of compliance with the constraint on air emissions was achieved. Again, no violation was cited because, based on the air monitoring results, no effluent limit or constraint was in danger of being exceeded based on your results. Also, the bi-weekly audits did not identify that the inventory of cobalt-60 was inaccurate for a period of at least two years.

The inspector's review of the information on which the bi-weekly audit reports are based indicates that there is a lack of consistent and comprehensive oversight of the radiation safety program. The bi-weekly audit appeared to be the result of receiving information from other workers and assembling the report, without a good understanding of the basis for that information. For example, the auditor was not aware that the iridium-192 and cobalt-60 data he received was only from the manufacturing facility and did not include cobalt-60 in waste material; the auditor believed that the iridium-192 activity provided for waste disposal was the activity as of the original date that the material was received at Best and not the iridium-192 activity as of the date sent to the waste storage area; and neither the Radiation Safety Officer nor the Alternate Radiation Safety Officer were familiar with the way that the Health Physics Technician analyzed air samples or calculated thyroid intake.

The NRC concludes that there exists a valid basis for this violation; therefore, it will not be withdrawn.