

MEMORANDUM

To: James S. Davis, Ph.D., CHP
Associate Vice President for Environmental Health and Safety
and Radiation Safety Officer

From: Dennis A. Stevenson Ph.D., CHP
Assistant Director EH&S/Deputy RSO

Date: December 8, 2008

Subject: Issue - Regulatory Notification to Canada regarding Export of Gammacell
1000 blood irradiator to Best Theratronics in Ontario Canada...

Following is a sequence of events regarding export of a Gammacell 1000 Blood Irradiator from Augusta GA to Best Theratronics in Ontario Canada.:

- MCG Health Inc contracted with Best Theratronics for purchase of a Gammacell 3000 Elan self –contained blood irradiator. The procurement included installation of the Gammacell 3000 by a trained technician and disposal of a Gammacell 1000 unit. “Disposal of a Gammacell 1000 S/N 0089 will be done as second stand alone visit no later than three (3) months upon installation of the new unit.” Export to Canada for disposal was scheduled for November 13, 2008.
- Following installation of a Gammacell 3000 Elan Blood Irradiator on October 30-31, 2008 by Best Theratronics and operational acceptance, a Gammacell 1000 SN0089 was shipped from MCG Health Inc to Best Theratronics in Ontario Canada on November 13-14, 2008.
- U.S. NRC Export/Import License PCB102.0 providing for “Import from Canada of Category 1 quantities of Cesium-137 contained in a Gammacell 3000 Elan Type II blood irradiator, and export to Canada of Category 2 quantities of Cesium-137 contained in sealed sources, for return of a Gammacell 1000 blood irradiator are authorized.”

- Best Theratronics, as a part of their service, agreed verbally to make all regulatory notifications for both the import of the Gammacell 3000 unit and export of the Gammacell 1000 unit.
- Meeting regulatory requirements was a consistent topic of discussion in the planning stages and readiness reviews with Best Theratronics as evidenced by the following:
 - E-mail dated OCT 21, 2008 to Leanne Usher, Best Theratronics, from Dennis A. Stevenson, MCG; Subject: Regulatory Notifications.

Leanne,

Per our conversation during the teleconference last week, I assume that regulatory notifications have been made to the U.S. NRC, CNSC, and the State of Georgia regarding the shipment of the Gammacell 3000. Please send me an e-mail verifying that the appropriate notifications have been made and that they are in accordance with mandatory regulatory notification requirements in 10 Code of Federal Regulations 110.50(b)(4) as stated in our import/export license PCB102.0 as well as any other Canadian regulatory requirements. We will maintain your response on file in our documentation.

*Dennis A. Stevenson Ph.D., CHP
Assistant Director EH&S/Deputy RSO*

Return e-mail from Leslie Garagan, Best Theratronics.

Hello Denis,

Please be advised notification has been provided in accordance with Canadian, USNRC, USDOT and all applicable State Authorities.

Regards, Leslie

Note: This was in relation to the import of the Gammacell 3000 Elan blood irradiator.

- On November 6, 2008, in anticipation of the removal and export of the Gammacell 1000 blood irradiator, I contacted Best Theratronics by phone with regard to the shipment date and regulatory notifications and received the following e-mail response from Leslie Garagan:

I have completed the pre-shipment notification to the USNRC, USDOT et al and will notify as required upon departure of the Radioactive material from your site as well as arrival at our facility.

This communication to Best Theratronics was triggered by the 7 day notification requirement and their response led me to believe that all regulatory agencies, including the Canadian CNSC had been notified in a timely manner.

- Based on a “Security Advisory for Materials Licensees (NRC and Agreement State) who Possess, Use, Ship or Receive Risk Significant Radioactive Materials” from the U.S. NRC dated November 7, 2008, I contacted the NRC

Operations Center listed on the Export/Import License PCB 102.0 for confirmation of the appropriateness of the shipment. The fact that the NRC Operations Center was aware of the shipment and had adequate information was documented in an e-mail to Jim Davis, MCG Health Inc RSO as follows:

*>>> Dennis Stevenson 11/10/2008 9:50 AM >>>
I called the NRC Operations Center regarding this topic. They indicated that they had received information on our shipment scheduled for NOV 13th and that we were still good to go. The Security Advisory applies only to the Maryland/DC Area. There are no changes to our plans necessary.*

This was a confirmation to me that Best Theratronics had made appropriate and timely notifications to the U.S. NRC. Similarly, verbal conversations with the State of Georgia Radioactive Materials Program staff indicated that the State was fully informed of the shipments, both export and import, through Best Theratronics notification.

- An e-mail from Leslie Garagan, dated NOV 11, 2008, confirmed that “Best Theratronics will take responsibility of the RAM once the freight has been loaded onto the vehicle.”
- From a security perspective:
 - A letter stating that the truck driver transporting the Gammacell 1000 to Ontario Canada had a trustworthy and reliability determination through his company was obtained. The driver’s identification (driver’s license and passport) was verified.
 - An armed MCG Public Safety Officer guarded the activities from removal of the Gammacell 1000 unit from the blood irradiator room until the truck departed MCG Health Inc.
- Prior to departure, the truck driver faxed a copy of the manifest to the U.S.-Canadian border and indicated that this had to be completed one day before arrival at the border in order to gain entry into Canada. While not a direct notification to the Canadian CNSC, it was evidence of shipment notification to the Canadian authorities.
- Dennis Stevenson received a phone call at 2:50 PM November 14, 2008, at his request, from driver Gerald Bruce of Jade Trucking that the Gammacll 1000 unit arrived at its final destination in Canada, was delivered and offloaded.
- Additionally an e-mail was received from Leslie Garagan, Best Theratronics, verifying arrival of the shipment and completion of notifications to applicable regulators.

good afternoon Dennis,

Pleased to inform you the shipment has arrived at our facility and notification to applicable authorities is now complete.

It has been a pleasure interacting with you as well and your attention

to detail has been much appreciated.

Kind regards, Leslie

- A letter dated November 17, 2008 was sent to Mr. Joseph Fievet, Georgia Radioactive Materials Program, regarding the transfer of possession of the Gammacll 1000 blood irradiator to Best Theratronics and receipt of the Gammacell 1000 unit by Best Theratronics in Canada on November 14, 2008.

From my perspective, MCG Health Inc depended on commitments made by Best Theratronics to make all required regulatory notifications for both the import of the Gammacell 3000 Elan blood irradiator and export of the Gammacell 1000 blood irradiator. Multiple inquiries of Best Theratronics and confirmations with the State of Georgia and the U.S. NRC appeared to confirm that this responsibility was being accomplished in a timely and complete manner. It is inconceivable that, for the export of the Gammacell 1000, Best Theratronics, on behalf of MCG Health Inc, notified the U.S. NRC, Georgia Radioactive Materials Program, and U.S. DOT, the US-Canadian border, but neglected to contact the Canadian Nuclear Safety Commission. MCG Health Inc depended on Best Theratronics to meet all the regulatory requirements applicable to both the import and export of the Gammacell units.

In a December 5, 2008 phone discussion in which this issue was thoroughly discussed, Best Theratronics Compliance Manager and RSO stated that it appeared that there were both internal and external communication problems on their part. Furthermore, they stated that they would meet with their service department to review this issue and identify corrective actions on their part to ensure clear communications within their organization and to the customer to prevent similar problems in the future. Best Theratronics indicated that they would send a letter to MCG Health Inc during the week of December 8-12, 2008 following their internal review.