EA-11-131

Dr. Dennis Stephenson, Ph.D. Assistant Director EH&S/Deputy Radiation Safety Officer Medical College of Georgia 1405 Goss Lane Augusta, GA 30912

SUBJECT: NOTICE OF VIOLATION OF 10 CFR 110.50(b)(4): FAILURE TO NOTIFY

IMPORTING COUNTRY OF A SHIPMENT OF SEALED SOURCES

CONTAINING CATEGORY 2 QUANTITIES OF CS-137

Dear Dr. Stephenson:

This refers to your letter (enclosure 1) dated December 8, 2008, regarding an export of a Gammacell 1000 blood irradiator containing Category 2 quantities of Cs-137 from the Medical College of Georgia (MCG) to Best Theratronics in Canada, the import of a Gammacell 3000 from Best Theratronics to MCG, your failure to provide the U.S. Nuclear Regulatory Commission (NRC) and the Canadian Nuclear Safety Commission (CNSC) with advanced notifications for each export and import, and the actions taken to ensure that importing countries receive notification in advance of shipments to and from the United States of radioactive materials listed in Appendix P to 10 CFR Part 110. Specifically, contrary to 10 CFR 110.50(b)(4) (now 10 CFR 110.50(c)), on November 13, 2008, MCG received a Gammacell 3000 blood irradiator containing Category 2 quantities of Cs-137 from Best Theratronics Ltd., in Canada, under authority of NRC license PCB102.0, but failed to notify the NRC at least 24 hours prior to the shipment. Similarly, on October 31, 2008, MCG shipped a Gammacell 1000 blood irradiator containing Category 2 quantities of Cs-137 to Best Theratronics Ltd., in Canada, under authority of NRC license PCB105.00, but failed to notify the CNSC in advance of the shipment, and the NRC at least 24 hours prior to the shipment in violation of 10 CFR 110.50(b)(4).

Based on the information you provided in your letter, the NRC has determined that a Severity Level IV violation of the NRC requirements occurred. This violation was evaluated in accordance with the NRC Enforcement Policy included on the NRC's Web site at http://www.nrc.gov. The violation is cited in the enclosed notice of Violation (enclosure 2) because the violation was identified by the NRC.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed in correspondence provided to the NRC dated December 8, 2008 by CHW. Therefore, you are not required to respond to this letter unless the description therein 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.

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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's 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.

Sincerely,

Roy P. Zimmerman, Director Office of Enforcement

Docket No.

Enclosures:

- 1. Letter dated December 8, 2008
- 2. Notice of Violation EA-11-131

cc: (See page 3)

CC:

U.S. Department of Energy Office of Non-Proliferation Policy ATTN: Sean Oehlbert 1000 Independence Avenue, SW Washington, DC 20585

Defense Threat Reduction Agency (OP-CSNSP) ATTN: Mr. David McDarby 8725 John J. Kingman Road, MSC-6201 Fort Belvoir, VA 22060-6201

Customs & Border Protection Attn: Christopher Baugues LSS Technical Data Assessment & Teleforensics Center 12379 Sunrise Valley Drive, Suite C Reston, Virginia 20191

U.S. Department of Energy, NA-243 Office of International Regimes and Agreements ATTN: Mr. Richard S. Goorevich 1000 Independence Avenue, SW Washington, DC 20585

U.S. Department of Energy, NA-243 Office of International Regimes and Agreements ATTN: Ms. Ingrid Bruns 1000 Independence Avenue, SW Washington, DC 20585

Bureau of Industry and Security Office of Nuclear and Missile Technology ATTN: Steve Clagett 14th Street & Penn Avenue, NW, Room 2631 Washington, DC 20230

NAC International/Nuclear Materials Management Safeguards System ATTN: Peter Dessaules DOE/NMMSS 1000 Independence Ave., SW Washington, DC 20585-1290

Canadian Nuclear Safety Commission Attn: Mr. Larry Chamney P.O. Box 1046, Station B 280 Slater Street Ottawa, ON K1P 5S9 CANADA 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's document system (ADAMS) accessible

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Sincerely,

Roy P. Zimmerman, Director Office of Enforcement

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OE Case File EA-11-131

OE Day File

Accession Nos.: ML11182A016 (Package) ML11182A018 (Incoming)

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Medical College of Georgia 1405 Goss Lane Augusta, GA 30912

PCB102.0 EA-11-131

Based on your letter dated December 8, 2008, a violation of NRC requirements was acknowledged. In accordance with Enforcement policy, the particular violation is set forth below:

10 CFR Part 110.50(b)(4) (now 110.50(c)) states that a licensee authorized to export or import the radioactive material listed in Appendix P to this part is responsible for notifying NRC and, in cases of exports, the government of the importing country in advance of each shipment. A list of points of contact in importing countries is available at NRC's Office of International Programs website, accessible on the NRC Public Web Site by the following links to What We Do-International Programs. The NRC's office responsible for receiving advance notifications for all export and import shipments is the NRC Operations Center. Specific details on where to send the information will be listed in each specific export and import license. Notifications must be received by the NRC at least 7 days in advance of each shipment, to the extent practical, but in no case less than 24 hours in advance of each shipment. Notifications may be electronic or in writing on business stationary, and must contain or be accompanied by the information which follows.

- (i) For export notifications:
- (A) Part 110 export license number and expiration date;
- (B) Name of the individual and licensee making the notification, address, and telephone number;
- (C) Foreign recipient name, address, and end use location(s) (if different than recipient's address);
- (D) Radionuclides and activity level in TBq, both for single and aggregate shipments;
- (E) Make, model and serial number, for any Category 1 and 2 sealed sources, if available;
- (F) End use in the importing country, if known;
- (G) Shipment date;
- (H) A copy of the foreign recipient's authorization or confirmation of that authorization from the government of the importing country as required by § 110.32(h).

Contrary to the above, on November 13, 2008, Medical College of Georgia imported Category 2 quantities of Cs-137 from Canada, under NRC export license PXB102.0, but failed to notify the NRC at least 24 hours prior to the shipment, and on October 30-31, 2008, MCG shipped a Gammacell 1000 blood irradiator containing Category 2 quantities of Cs-137 to Best Theratronics Ltd., in Canada, under authority of NRC license PCB102.0, but failed to notify both

the CNSC and the NRC prior to the shipment. This is a Severity Level IV violation of NRC requirements.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed in correspondence provided to the NRC dated December 8, 2008 by CHW. Therefore, you are not required to respond to this letter unless the description therein 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.

Dated this day of June 2011