

May 6, 2011

EA-11-038

Kamalesh Lahiri, M.D.
Radiation Safety Officer
Cardiovascular Diagnostics
18500 West 12 Mile Road
Southfield, Michigan 48076

SUBJECT: WITHDRAWAL OF VIOLATION - CARDIOVASCULAR DIAGNOSTICS

Dear Dr. Lahiri:

The purpose of this letter is to respond to your letter dated January 7, 2011, in which Cardiovascular Diagnostics contested two of the three violations, cited in the Notice of Violation (Notice) that was enclosed with the U.S. Nuclear Regulatory Commission (NRC) Inspection Report No. 030-31987/10-01(DNMS) issued on December 16, 2010. The Notice contained three Severity Level IV violations involving Title 10 of the Code of Federal Regulations (10 CFR) 20.1801, 10 CFR 35.67(g), and 10 CFR 30.36(d).

The two violations that were contested involved the failure to: (1) secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas as required by 10 CFR 20.1801; and (2) conduct a semi-annual physical inventory to account for all sources and/or devices received and possessed under the license as required by 10 CFR 35.67(g). You also provided additional information regarding the 10 CFR 35.67(g) violation.

In accordance with the NRC policy and procedures, Region III has completed an independent assessment and review of the contested matters. The independent reviewer has reached the following conclusions.

In your January 7, 2011, response to the Notice, you provided leak tests results that were discussed and requested during telephone conferences in November 2010. Upon further review of this issue and a review of the information that you provided with your response, the independent reviewer concluded that the violation for failure to conduct a semi-annual physical inventory in accordance with 10 CFR 35.67(g) will be withdrawn.

During a telephone interview with you conducted on March 3, 2011, you provided information regarding the failure to secure licensed material from unauthorized removal or access that is stored in controlled or unrestricted areas. The specific information pertained to your building alarm system and your ability to secure from unauthorized removal or restrict access to licensed materials that are stored in controlled or unrestricted areas. Although an alarm system is a good deterrent, an alarm system that captures pictures of anyone entering the hot lab area does not meet the requirements for securing the licensed material unless the alarm system summons a responder who prevents unauthorized removal and access.

Given that, at the time of the inspection, the inspector noted that the interior door to the imaging suite was unlocked and that the area was not otherwise secured, it is our conclusion that the violation of 10 CFR 20.1801 remains valid since the cesium-137 reference source was not secured from unauthorized removal or access when the main lobby door was unsecured.

Lastly, even though you did not specifically contest the violation of 10 CFR 30.36(d), the independent reviewer evaluated the situation and circumstances surrounding the violation. During the telephone interview with you on March 3, 2011, you stated that at the time you were not aware of the regulatory requirement. You indicated that even though you had not conducted licensed activities in over 2 years, you had paid your license fees because you wanted to maintain the license in the event that the need arose to perform nuclear medicine procedures at your facility. The intent of 10 CFR 30.36(d) is to require notification to the NRC regarding suspension or termination (planned or emergent) of licensed activities under 10 CFR Part 30. Given this, we concluded that the violation of 10 CFR 30.36(g) was valid.

We have noted that since the completion of the inspection you have taken actions to terminate your license and that you hired a consultant who has removed all licensed materials from your facility.

Based on your response and actions that you have taken, we do not require any further information concerning the violations.

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 NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions regarding this matter please contact Patrick Loudon of my staff at (630) 829-9801.

Sincerely,

/RA/

Cynthia D. Pederson
Deputy Regional Administrator

Docket No. 030-31987
License No. 21-26259-01

Given that, at the time of the inspection, the inspector noted that the interior door to the imaging suite was unlocked and that the area was not otherwise secured, it is our conclusion that the violation of 10 CFR 20.1801 remains valid since the cesium-137 reference source was not secured from unauthorized removal or access when the main lobby door was unsecured.

Lastly, even though you did not specifically contest the violation of 10 CFR 30.36(d), the independent reviewer evaluated the situation and circumstances surrounding the violation. During the telephone interview with you on March 3, 2011, you stated that at the time you were not aware of the regulatory requirement. You indicated that even though you had not conducted licensed activities in over 2 years, you had paid your license fees because you wanted to maintain the license in the event that the need arose to perform nuclear medicine procedures at your facility. The intent of 10 CFR 30.36(d) is to require notification to the NRC regarding suspension or termination (planned or emergent) of licensed activities under 10 CFR Part 30. Given this, we concluded that the violation of 10 CFR 30.36(g) was valid.

We have noted that since the completion of the inspection you have taken actions to terminate your license and that you hired a consultant who has removed all licensed materials from your facility.

Based on your response and actions that you have taken, we do not require any further information concerning the violations.

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 NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions regarding this matter please contact Patrick Loudon of my staff at (630) 829-9801.

Sincerely,
 /RA/
 Cynthia D. Pederson
 Deputy Regional Administrator

Docket No. 030-31987
 License No. 21-26259-01

Distribution:

See next page

* SEE PREVIOUS CONCURRENCE

DOCUMENT NAME: G:\DNMS\Work in progress\LTR - Cardiovascular Diagnostics - Disputed Violation - revised.docx

Publicly Available Non-Publicly Available Sensitive Non-Sensitive

To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RIII-DNMS	C	RIII-DNMS	C	RIII-EICS		
NAME	TEBloomer:jc *		PLLouden		JHeller for SKOrth		
DATE	04/11/11		04/12/11		05/03/11		
OFFICE	OE		RIII-DNMS	C	RIII-ORA	C	
NAME	KDay for ACampbell ¹		ATBoland		CDPederson		
DATE	05/02/11		05/03/11		05/06/11		

OFFICIAL RECORD COPY

¹ OE concurrence received via e-mail from K. Day on May 2, 2011.

Letter to Kamalesh Lahiri from Cynthia D. Pederson dated May 6, 2011

SUBJECT: WITHDRAWAL OF VIOLATION - CARDIOVASCULAR DIAGNOSTICS

DISTRIBUTION:

Andy Campbell
Nick Hilton
Kerstun Day
Mark Satorius
Cynthia Pederson
Terence Reis
Michele Burgess
Glenda Villamar
Duane White
Daniel Holody
Carolyn Evans
Ray Kellar
Anne Boland
Patrick Loudon
Tamara Bloomer
Steven Orth
Jared Heck
Patricia Lougheed
Paul Pelke
Magdalena Gryglak
Sarah Bakhsh
Patricia Buckley
Tammy Tomczak
MIB Inspectors
OEMAIL
EA-11-038 File