



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

April 23, 2020

IA-19-033

Mr. César Blanco
HOME ADDRESS DELETED
UNDER 10 CFR 2.390

SUBJECT: NOTICE OF VIOLATION (NRC INVESTIGATION REPORT NO. 1-2018-014)

Dear Mr. Blanco:

This letter refers to the investigation completed on June 6, 2019, by the U.S. Nuclear Regulatory Commission (NRC) Office of Investigations regarding your activities at the Lantheus Medical Imaging (LMI) facility in San Juan, Puerto Rico. The investigation was conducted, in part, to determine whether you, while employed as the senior technical support specialist at the LMI facility in San Juan, willfully failed to wear required dosimetry and willfully provided inaccurate information to an NRC inspector.

In a letter dated January 27, 2020 (ML20027C380),¹ the NRC described the apparent violations to you and informed you that the NRC was considering escalated enforcement action against you. In the letter, we offered you the opportunity to address the apparent violations by either attending a pre-decisional enforcement conference (PEC), to engage the NRC in an alternative dispute resolution (ADR) mediation session, or to provide a written response before we made our final enforcement decision. In a letter dated February 20, 2020 (non-public due to the inclusion of personal privacy information), you provided a written response, in which you explained why the violations occurred and why you did not consider your actions to have been deliberate. Namely, you stated that your failure to wear dosimetry had resulted from a bad habit of not passing through the dosimetry storage area on your way to your work location. Further, you stated that you were not "transparent" with the NRC about your failure to wear dosimetry because you had a prior professional relationship with one of the NRC inspectors and were uncomfortable with that individual's presence. You also detailed training you have received since the time of the violations and expressed that you are complying with all dosimetry requirements in your current employment.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly-available using the accession number in ADAMS.

The NRC carefully considered the information you provided in your February 20, 2020 letter and determined that it did not constitute new information (i.e., material information that was not considered during the investigation). Therefore, based on the information developed during the inspection, investigation, and the information you provided in your written response dated February 20, 2020, the NRC has determined that deliberate violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) (Enclosure 1). The violations involve your deliberate failure to wear required dosimetry and your deliberate provision of inaccurate information to the NRC. Specifically, for periods of time between January 2014 and December 2017, you deliberately failed to wear required dosimetry, and on February 14, 2018, you deliberately provided false information to an NRC inspector about your dosimetry use. The failure to monitor your occupational radiation exposure is of significant concern to the NRC because you worked with significant quantities of radioactive material while maintaining the cyclotron and, by not monitoring your radiation dose, LMI could have failed to identify or prevent a potential over-exposure. Providing inaccurate information to the NRC is of concern because the NRC relies on licensee employees, especially those with substantial responsibilities concerning the use of radioactive material, to act with integrity and to communicate with candor. By providing false information to an NRC inspector, you affected the inspector's ability to accurately evaluate LMI's radiation safety program.

Your deliberate actions placed you in violation of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 30.10, "Deliberate Misconduct," and placed LMI in violation of 10 CFR 20.1502(a)(1), which requires licensees to monitor occupational exposure to radiation, and 10 CFR 30.9(a), which requires that information provided to the NRC by a licensee be complete and accurate in all material respects. A copy of the letter and Notice of Violation issued to LMI is enclosed for your information (Enclosure 2). Given the significance of the underlying issues and the deliberate nature of your actions, your violations have been categorized in accordance with the NRC Enforcement Policy at Severity Level III (SL III).

In determining the appropriate sanction to be issued in this case, the NRC considered issuing an Order prohibiting your involvement in NRC-licensed activities as a result of your actions. However, after consultation with the Director, Office of Enforcement, and after considering the circumstances of this case, including that LMI terminated your employment, I have decided to issue the enclosed Notice of Violation. Because the violations are related to each other, they are categorized collectively as a single SL III problem. You should be aware that additional deliberate violations in the future could result in significant enforcement action or may also be considered for criminal prosecution by the U.S. Department of Justice.

The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>

Because you are no longer employed by LMI, and in consideration of your February 20, 2020 letter, you are not required to respond to the Notice of Violation. If you disagree with this enforcement sanction, you may deny the violation within 30 days of the date of this letter as described in the Notice, or you may request ADR mediation with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC employs is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional

information on the NRC's ADR program can be found at: <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>.

The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. If you are interested in pursuing this issue through the ADR program, please contact: (1) the ICR at (877) 733-9415; and (2) Chris Cahill, Chief, Commercial, Industrial, R&D, and Academic Branch, at 610-337-5108 within **10** days of the date of this letter. You may also contact both ICR and Mr. Cahill for additional information.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, 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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Please note that final NRC investigation documents, such as the Office of Investigations report described above, may be made available to the public under the Freedom of Information Act (FOIA), subject to redaction of information appropriate under the FOIA. Requests under the FOIA should be made in accordance with 10 CFR 9.23, "Requests for Records." Additional information is available on the NRC website at <http://www.nrc.gov/reading-rm/foia/foia-privacy.html>. In addition, this letter will be maintained by the Office of Enforcement in an NRC Privacy Act system of records, NRC-3, "Enforcement Actions Against Individuals." This system, which is not publicly-accessible, includes all records pertaining to individuals who are being considered for, or have been considered for enforcement action, whether such action was taken or not. Detailed information about this system of records, including the NRC-3 system notice, can be accessed from the NRC Web site at <http://www.nrc.gov/reading-rm/foia/privacy-systems.html>.

Please feel free to contact Chris Cahill of my staff at 610-337-5108 if you have any questions.

Sincerely,

David C. Lew
Regional Administrator

Enclosures: 1. Notice of Violation
2. Cover Letter and Notice of
Violation to Lantheus Medical Imaging

SUBJECT: NOTICE OF VIOLATION (NRC INVESTIGATION REPORT NO. 1-2018-014)
 DATED: APRIL 23, 2020

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M Burgess, NMSS	
Enforcement Coordinators	
RII, RIII, RIV (M Kowal; J Cameron; J Groom)	
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Region I OE Files (with concurrences)

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OFFICE	RI/ORA	RI/DNMS	RI/ORA	RI/ORA	OE	NMSS
NAME	M McLaughlin/ MMM	C Cahill/ CGC via email	B Klukan/ BMK via email	R McKinley/ RRM via email	J Peralta via email	R Sun via email
DATE	3/16/2020	3/16/2020	3/17/2020	3/17/2020	4/20/2020	3/20/2020
OFFICE	OGC				RI/DNMS	RA
NAME	T Steinfeldt NLO via email				J Trapp via email	D Lew/
DATE	4/20/2020				4/20/20	4/21/20

*See previous concurrence page

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

César Blanco
[HOME ADDRESS DELETED
UNDER 10 CFR 2.390]

IA-19-033

During an NRC investigation conducted between June 22, 2018, and June 6, 2019, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 30.10(a)(1) states that any employee of a licensee may not engage in deliberate misconduct that causes a licensee to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission.

10 CFR 20.1502(a)(1) requires, in part, that each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, for periods between January 2014 and December 2017, while an employee of Lantheus Medical Imaging (Lantheus), you engaged in deliberate misconduct that caused the licensee to be in violation of a regulation. Specifically, you, as the senior technical support specialist who received exposure from Lantheus cyclotron operations, were likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a). However, you deliberately did not always wear dosimetry when performing work on the cyclotron, thereby preventing Lantheus from monitoring your occupational exposure to radiation.

- B. 10 CFR 30.10(a)(2) states that any employee of a licensee may not deliberately submit to the NRC information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

Contrary to the above, on February 14, 2018, while an employee of Lantheus Medical Imaging (Lantheus), you submitted to the NRC information that you knew to be incomplete and inaccurate. Specifically, when questioned by an NRC inspector about your dosimetry use, you responded that you wore your dosimetry as required. However, in a follow-up interview, you stated that you did not always wear required dosimetry. The information was material to the NRC because you performed work for Lantheus that caused you to be likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits of 10 CFR 20.1201(a) and, as such, Lantheus was required by NRC regulations to monitor your occupational exposure to radiation.

This is a Severity Level III problem (Enforcement Policy Sections 6.3 and 6.9).

You are not required to respond to the Notice unless you contest the violations. Should you contest the violations, a response is required within 30 days of the date of this letter, addressing the specific basis for disputing the violations. This response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, NRC Region I, 2100 Renaissance Blvd., Suite 100, King of Prussia, PA 19406, and marked Open by Addressee Only – Response to a Notice of Violation; (IA-19-033). If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's Agency-wide Document Access and Management System (ADAMS), accessible from the NRC Web site 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. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

This letter will be maintained by the Office of Enforcement in an NRC Privacy Act system of records, NRC-3, "Enforcement Actions Against Individuals." This system, which is not publicly-accessible, includes all records pertaining to individuals who are being, or have been considered, for enforcement action, whether such action was taken or not. The NRC-3 system notice, which provides detailed information about this system of records, can be accessed from the NRC Web site at <http://www.nrc.gov/reading-rm/foia/privacy-systems.html>.

Dated this 23RD day of April, 2020.