



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

April 23, 2020

EA-19-068

Mr. Eduardo Diaz Montés
Senior Manager of Operations
Lantheus Medical Imaging
150 Federico Costa, Suite 1
San Juan, PR 00918-1303

SUBJECT: LANTHEUS MEDICAL IMAGING, NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF A CIVIL PENALTY - \$7,500 - NRC OFFICE OF INVESTIGATION REPORT 1-2018-014 AND NRC INSPECTION REPORT NO. 03038114/2018002

Dear Mr. Diaz Montés:

This letter refers to an inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on February 14, 2018, March 7, 2018, and April 10, 2018, with continued in-office review through November 13, 2019, at the Lantheus Medical Imaging (LMI) facilities in Billerica, Massachusetts and San Juan, Puerto Rico and an associated NRC investigation completed on June 6, 2019. The purpose of the inspection, in part, was to review LMI's dosimetry program as it related to handling and use of licensed nuclear material from cyclotron production. The purpose of the investigation, in part, was to determine whether an employee at the LMI facility in San Juan, Puerto Rico willfully caused LMI to violate NRC requirements by failing to wear required dosimetry and by providing inaccurate information to an NRC inspector.

Based on the results of the inspection and investigation, three apparent violations (AVs) were identified. The AVs were discussed in the NRC letter sent to you on January 27, 2020, (ML20027C039).¹ The first AV (AV1) involved LMI's failure to monitor the occupational radiation exposure of an employee (the former senior technical support specialist at LMI's facility in San Juan), as required by Title 10 of the *Code of Federal Regulations* (10 CFR) Section 20.1502. Specifically, the NRC determined that the specialist did not wear required dosimetry while performing cyclotron operations for periods of time between January 2014 and December 2017. The second AV (AV2) involved the failure by LMI to provide information to the NRC that was complete and accurate in all material respects, as required by 10 CFR 30.9(a). Namely, on February 14, 2018, the LMI senior technical support specialist informed an NRC inspector that he wore the required dosimetry. However, as noted above, for periods of time between January 2014 and December 2017, the specialist did not wear required dosimetry. Based on the investigation, the NRC determined that these AVs were the result of deliberate misconduct by the former senior technical support specialist. Section 1.2 of the NRC Enforcement Policy states that licensees are responsible for the acts of their employees and the NRC may cite licensees for violations committed by their employees.

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 third AV (AV3) involved the failure by LMI to comply with Condition 12 of its NRC license, which required that licensed material shall be used by, or under the supervision of, an individual specifically named in the license. On August 15, 2018, LMI terminated the employment of the individual named in Condition 12. However, LMI continued to use licensed material and did not submit to the NRC an amendment request to replace the individual named in Condition 12 of its license until September 21, 2018. The amended license was issued on September 24, 2018.

In the NRC letter dated January 27, 2020, we provided you the opportunity to address the AVs by attending a pre-decisional enforcement conference, providing a written response, or requesting Alternative Dispute Resolution before we made our final enforcement decision. In a letter dated February 20, 2020 (ML20057D437), Mr. W. Scott Claunch, LMI's Vice President of Nuclear Operations, provided a response to the apparent violations and described the actions taken and planned by LMI in response to these issues, as further described below. In the letter, Mr. Claunch also stated that LMI did not contest any of the violations.

Based on the information developed during the inspection and investigation, and the information provided in your February 20, 2020 response, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them were described in detail in the subject inspection and investigation reports.

As described above, the first violation involved LMI's failure to monitor the occupational radiation exposure of the senior technical support specialist due to the specialist's failure to wear dosimetry for periods of time between January 2014 and December 2017. This violation has been categorized at Severity Level (SL) III in accordance with the NRC's Enforcement Policy because the specialist worked with significant quantities of radioactive material while maintaining the cyclotron and, by not monitoring the specialist's radiation dose, LMI could have failed to identify or prevent a potential over-exposure. The second violation involved providing inaccurate and incomplete information to the NRC on February 14, 2018, when the senior technical support specialist informed an NRC inspector that he wore the required dosimetry. This violation has been categorized at SL III because the senior technical support specialist was listed on LMI's NRC license as the authorized user for the cyclotron; therefore, the specialist was the licensee staff member primarily responsible for its safe operation. 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 the NRC, the specialist impacted the inspector's ability to accurately evaluate the licensee's radiation safety program.

Because these two violations are related, they have been categorized collectively as a single SL III problem. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$7,500 is considered for a SL III problem. Because the violations were willful, the NRC considered whether credit was warranted for Identification and Corrective Action in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC determined that identification credit was not warranted because the violations were identified by the NRC. The NRC determined that corrective action credit was warranted for LMI's actions taken to address the violations. These actions included performing an extent of condition review, reconstructing the radiation exposure for the senior technical support specialist and updating his dose records, implementing disciplinary action against the specialist (including termination), providing communication to staff about dosimetry requirements, and establishing new dosimetry procedures requiring investigation of all dose irregularities. Additionally, LMI re-performed annual training on compliance and data integrity and ethics for all staff that included a message from senior management about the violation.

With credit granted for corrective action, but not for identification, the civil penalty assessment process results in a proposed penalty of the base amount of \$7,500. Therefore, to emphasize the importance of compliance with regulatory requirements and of prompt identification of violations, I have been authorized, after consultation with the Director, Office of Enforcement to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$7,500.

The third violation involved LMI's failure between August 15, 2018, and September 24, 2018, to comply with Condition 12 of its NRC license which required that licensed material shall be used by, or under the supervision of, an individual specifically named in its license. This violation has been categorized at SL III because radioactive material was used without an authorized individual in place who had been evaluated by the NRC and determined to possess the necessary knowledge and training to oversee its use. As described above, a base civil penalty in the amount of \$7,500 is considered for a SL III violation. Because this violation was not willful and because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC determined that corrective action credit was warranted for the actions taken by LMI in response to this violation. Namely, LMI identified new leadership for the LMI Puerto Rico office and enhanced the corporate structure and oversight of that location. In addition, LMI conducted a third-party audit of the site radiation protection program and developed an action plan to incorporate improvements identified through the audit. LMI has scheduled a follow-up audit to be conducted this year. LMI also contracted a health physics consulting firm to provide on-going support to the Puerto Rico site.

Therefore, to encourage prompt identification and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice and to not propose a civil penalty for this violation. However, significant violations in the future could result in a civil penalty.

Issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort. The NRC also includes significant enforcement actions on its website at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

The NRC recognizes that many licensees have been impacted economically by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19). Consequently, as described in the enclosed Notice, the NRC is extending by 30 days the period of time by which the civil penalty must be paid (i.e., extending the deadline from 30 days to 60 days from the date of this Notice) and the NRC would consider a request for additional time, if appropriate. Please refer to the enclosed Notice for further instructions.

If you disagree with this enforcement sanction, you may deny the violations, as described in the Notice, or you may request alternative dispute resolution (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 has decided to employ 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 concerning 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. Your submitted signed agreement to mediate using the NRC ADR program will stay the time period for payment of the civil penalties and the required written response, as identified in the enclosed notice, until the ADR process is completed.

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in the NRC letter dated January 27, 2020, with the enclosed Inspection Report No. 03038114/2018002, and in the LMI letter dated February 20, 2020. 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.

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 document 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.

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>.

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

Sincerely,

David C. Lew
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254, "Payment Methods"

Docket No.: 03038114

License No.: 52-25361-02

Cc w/ encl:

John Bulla, Chief Operations Officer, LMI
Commonwealth of Puerto Rico
Commonwealth of Massachusetts

SUBJECT: LANTHEUS MEDICAL THRASHER ENGINEERING, INC. - IMAGING, NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF A CIVIL PENALTY DATED: APRIL 23, 2020

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Region I OE Files (with concurrences)	

ML20073L433

DOCUMENT NAME: S:\Enf-allg\Enforcement\Proposed-Actions\Region1\Lantheus NOV-III-CP EA-19-068 ML20073L433 .docx

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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

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Lantheus Medical Imaging.
San Juan, Puerto Rico

Docket No. 03038114
License No. 52-25361-02
EA-19-068

During an NRC inspection conducted on February 14, 2018, March 7, 2018, and April 10, 2018, with continued in-office review through November 13, 2019, and investigation completed on June 6, 2019, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

- A. 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, the licensee did not monitor occupational exposure to radiation from licensed radiation sources under the control of the licensee and did not require the use of individual monitoring devices by an adult 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). Specifically, the involved individual received exposure from cyclotron operations that could have resulted in annual dose in excess of 10 percent of the limits in 10 CFR 20.1201(a) because the individual did not always wear required dosimetry when performing work on the cyclotron.

- B. 10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee shall be complete and accurate in all material respects.

Contrary to the above, on February 14, 2018, the licensee provided information to the NRC that was not complete and accurate in all material respects. Specifically, when questioned by an NRC inspector about dosimetry use, an individual employee of the licensee responded that the individual always wore dosimetry as required. Later, in April 2018, the same individual told the inspector that the individual did not always wear the required dosimetry when maintaining the cyclotron. During a subsequent NRC investigation, the individual admitted that the individual did not wear the required dosimetry for extended periods of time between 2014 and 2017.

This is a Severity Level III problem. (Enforcement Policy Sections 6.3 and 6.9)
Civil Penalty - \$7,500 (EA-19-068)

II. Violation Not Assessed a Civil Penalty

- A. Condition 12 of NRC License No. 52-25361-02, Amendment 0, requires that licensed material shall be used by, or under the supervision of, a named individual.

Contrary to the above, from August 15, 2018, through September 24, 2018, the licensee used licensed material without the specified supervision. Specifically, the supervising individual listed at Condition 12 of the license left the licensee's employment on August 15, 2018, but the licensee did not request an amendment to the license to name a new authorized user until September 21, 2018. NRC did not issue the amendment with the new authorized user until September 24, 2018.

This is a Severity Level III violation. (Enforcement Policy Section 6.3)

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in the NRC letter dated January 27, 2020, with the enclosed Inspection Report No. 03038114/2018002, and in the letter from the licensee, dated February 20, 2020. However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation (EA-19-068)," and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 2100 Renaissance Blvd. King of Prussia, PA 19406, and a copy to the Document Control Desk, Washington, DC 20555-0001.

The Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Within 30 days of the date of this Notice, the Licensee must either confirm to the NRC in writing that it will pay the civil penalty or provide its written answer protesting the civil penalty. However, in the event the Licensee elects to pay the civil penalty, in recognition of the economic impact to licensees by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19), the NRC is extending the period of time by which the civil penalty must be paid from 30 days to 60 days from the date of this Notice. Should the Licensee fail to pay the civil penalty within 60 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation (EA-19-068)" and may: (1) deny the violations listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the civil penalty. Separately, the Licensee may request an additional extension of time to pay the civil penalty as a result of impacts to the

licensee from COVID-19. Such an extension request must be in writing and should explain the basis for the request and should specify the amount of additional time being requested. This extension request must be submitted to the NRC no later than 50 days from the date of this Notice (i.e., at least 10 days before the initial 60-day deadline to pay the civil penalty).

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205, should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty. Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Extension of time to pay the civil penalty, Statement as to payment of civil penalty, and Answer to a Notice of Violation, should be addressed to: George Wilson, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 2100 Renaissance Blvd. Suite 100, King of Prussia, PA 19406, and a copy to the Document Control Center, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in 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 that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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.

In accordance with 10 CFR 19.11, you are required to post this Notice within two working days of receipt.

Dated this 23rd day of April, 2020.