Lantheus
Medical Imaging

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February 20, 2020
U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555-0001

By copy: Regional Administrator, NRC Region 1,
Renaissance Boulevard, Suite 100
King of Prussia, PA 19406

Re: Response to Apparent Violations; NRC Investigation No. 1-2018-014; EA-19-068

Dear Sir/Madam:

Lantheus Medical Imaging, Inc. (LMI) has prepared this letter in response to your January 27, 2020 request to provide information regarding:

1. The LMI corrective actions relevant to three apparent violations; and
2. Information about actions taken to address apparent programmatic breakdowns revealed by this issue.

LMI is not contesting any of the three apparent violations. Our response for each apparent violation includes:

1. reasons for the apparent violation;
2. corrective steps that have been taken and the results achieved;
3. corrective steps that will be taken; and
4. date when full compliance will be achieved.

Following our response to each of the three apparent violations is our response to the NRC's request to provide information about actions taken to address apparent programmatic breakdowns revealed by this issue, i.e.:

1. LMI's actions pertaining to oversight and implementation of the radiation safety program, including discussion of the organizational interfaces between LMI's corporate radiation safety staff and the staff at LMI's San Juan facility; and
2. The current status of actions taken and planned by LMI in response to the Radiation Safety Program audit performed for LMI by a contract radiation safety company in February/March 2019.

Apparent Violation 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 paragraph 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 20.1201(a). Specifically, the involved individual received exposure form cyclotron operations that resulted in annual dose in excess of 10 percent of the limits in 20.1201(a) and did not always wear required dosimetry when performing work on the cyclotron.

Response to Apparent Violation A

Reasons for the apparent violation:

In previous correspondence1 to the U.S. Nuclear Regulatory Commission LMI provided detailed information related to the above apparent violation.

This correspondence[1] included a summary of an internal assessment to review dosimetry records and employee dosimetry management, implementation of immediate corrective actions, the results of a dose reconstruction of the involved individual, the identification of root causes and the identification of corrective and preventive actions to ensure continued compliance with regulatory requirements.

Two causes were identified as contributing to the apparent violation:

1. Failure of the involved employee (IE) to wear dosimetry as required by site policy and procedure; and
2. Inadequate supervision related to:
    a. Supervisory or management review and analysis of Landauer dosimetry reports for doses exceeding Lantheus MI Radiopharmaceuticals, Inc. (LMI-PR) investigation levels; and
    b. Supervisory or management review of dosimetry reports that did not include analyzing employee tasks, identification of dose trends and irregularities, and established trigger levels.

Corrective steps that have been taken and results achieved for Apparent Violation A:

The corrective actions included:

1. Determination that the dosimetry irregularity was limited to the IE and not a systemic site-wide issue (Exhibit A(1));

2. An all-staff communication for PR employees reinforcing dosimetry requirements, individual dosimetry responsibilities, and available EHS and RSO resources was conducted (Exhibit A(2));
3. Disciplinary action consisting of a Human Resources warning letter to the IE, stressing the importance and requirement of wearing company issued dosimetry to be considered compliant with license requirements and conditions, site procedures, corporate procedures, and LMI Employee Handbook requirements. A copy of the disciplinary letter and our company policies was provided to the NRC in our September 28, 2018 correspondence with Special Agent McCullough[3];
4. Retraining of the IE on site policies regarding dosimetry use and management (see Exhibit A(3) for the attendance sheet);
5. Establishment of a procedure for reviewing dosimetry reports which includes analyzing employee tasks, identification of dose trends and irregularities, and established trigger levels. SOP-50, "Personnel Dosimeters Management," was provided to the NRC in the September 28, 2018 correspondence with Special Agent McCullough[3];
6. Incorporation of a standing agenda item with the LMI-PR Radiation Safety Committee and LMI-Billerica Radioisotope Safety Committee to review dosimetry trends and performance (see Exhibit A(4) for two examples of the Billerica Radioisotope Safety Committee Agendas and associated PowerPoint presentation by the LMI-PR RP staff);
7. A dose reconstruction was performed for the IE for the time period of January 2016 to July 2018, a copy of which was provided to the NRC in the June 23, 2018 letter to Inspector Craig Gordon[1]; and
8. The IE's dose records were updated appropriately for the period to accurately reflect the IE's dose (Exhibit A(5)).

The results achieved ensure that radiation doses at LMI-PR are appropriately monitored and that dose monitoring results are reviewed in a timely manner to ensure that doses received at LMI-PR continue to be below regulatory levels.

Corrective steps that will be taken for Apparent Violation A:

Subsequent investigation revealed that the IE's dose records showed similar irregularities for the time period of January 2014 to December 2016. Therefore, an additional dose reconstruction will be performed for this period and the IE's dose records will be updated appropriately to accurately reflect the IE's dose for this period.
LMI plans to implement the use of a real-time dosimeter (Instadose) in addition to the Landauer passive dosimeter to monitor dose with incorporation into the dosimetry management procedure.

Date when full compliance will be achieved:

LMI believes full compliance has been achieved with the exception that the additional dose reconstruction, updating of the corresponding dose records, and implementation of real-time dosimetry described above is expected to be completed by June 30, 2020.

Apparent Violation 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.

Response to Apparent Violation B

Reasons for the apparent violation:

The reason for the apparent violation is deliberate action taken by the IE resulting in failure to follow company procedures and failure to follow the provisions of the LMI Code of Conduct and Ethics, i.e., not wearing required dosimetry and not providing complete and accurate information to the NRC.

Corrective steps that have been taken and results achieved for Apparent Violation B:

Immediate actions taken by LMI enabled determination that the dosimetry irregularity was limited to the IE and not a systemic site-wide issue (Exhibit A(1)). LMI agrees with the NRC Office of Investigation conclusion that the IE deliberately did not wear required dosimetry and deliberately provided inaccurate information to the NRC Inspector about the IE's dosimetry use. The IE was terminated, effective August 15, 2018 because of violations of company operating procedures and the company code of conduct and ethics.

An additional step taken as a result of the apparent violation was to provide Compliance and Data Integrity Training for all LMI-PR employees and retraining to the LMI Company Code of Conduct and Ethics training which is provided annually. LMI Previously provided copies of the training to the NRC. [6] Due to the seriousness of this apparent violation the retraining was conducted by LMI Human Resources with a message from the Senior VP of Technical Operations.

Corrective steps that will be taken for Apparent Violation B:

No additional steps are planned beyond annual training to the Lantheus Medical Imaging Code of Conduct and Ethics.

Date when full compliance will be achieved for Apparent Violation B:

LMI believes that full compliance was achieved after the immediate actions were taken when LMI became aware of this issue.

Apparent Violation C

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.

Response to Apparent Violation C

Reasons for the apparent violation:

The reason for the apparent violation is an inadequate level of management and technical oversight of the LMI-PR radiation protection program as evidenced by the failure to recognize the requirement to submit a request for a license amendment to replace the named Authorized User (AU) listed on the license.

Corrective steps that have been taken and results achieved for Apparent Violation C:

LMI suspended cyclotron production operations upon becoming aware that we were operating without an AU named on the cyclotron license and that a license amendment was needed to rectify this apparent violation. An amendment request to add two AUs to the license was prepared and submitted to the NRC on September 21, 2018[2]. Upon approval of the amendment request LMI-PR restarted cyclotron operations on September 24, 2018.
Additional steps taken to address the apparent violation consisted of incremental changes to support both improvements in LMI-PR site operations and the radiation protection program, Including:

1. Restructuring LMI-PR operations, with the LMI-PR now reporting through the LMI-VP of Nuclear Operations to the Chief Operating Office;
2. Identifying the need for new site leadership in Puerto Rico and providing interim onsite leadership in Puerto Rico by the LMI-Billerica Director of Cyclotron Operations;
3. Submitting a license amendment request to the NRC to transfer the LMI-PR RSO role to the LMI-PR Associate Director of Quality (Exhibit AI(1));
4. Implementing new procedures for dosimetry management as provided to the NRC in the September 28, 2018 letter to Special Agent McCullough[3];

5. Conducting a third party audit of the radiation protection program in February of 2019 (a copy of the audit report was provided to the NRC on March 29, 2019 as part of a letter to Special Agent McCullough[5];
6. Developing an action plan for program improvements identified in the third party audit (Exhibit AI(4));
7. Contracting with a third party health physics consulting firm in October of 2019 to provide on-going radiological support services to the LMI-PR RSO (Exhibit C(1)); and
8. Initiating weekly teleconferences among the LMI-Billerica RSO and Senior EH&S Director with the LMI-PR RSO and the third party health physics consultant to review the status of LMI-PR radiation protection program improvement activities.

Corrective steps that will be taken for Apparent Violation C:

Third party health physics consulting support will continue to be retained until such time that the program improvement activities resulting from the 2019 third party audit are completed. Additionally, a follow-up audit of the LMI-PR radiation protection program is planned for 2020.

Date when full compliance will be achieved for Apparent Violation C:

Compliance with the requirement to have named AUs on the license was achieved on September 24, 2018 when the NRC approved the amendment request. Efforts continue to further develop and implement radiation protection program improvements (Exhibit AI(4)).

First NRC Request for Additional Information

LMI's actions pertaining to oversight and implementation of the radiation safety program, including discussion of the organizational interfaces between LMI's corporate radiation safety staff and the staff at LMI's San Juan facility.

Response to First NRC Request for Additional Information

In March 2019, the Radiation Safety Officer (RSO) listed on both LMI-PR licenses was changed to Rolando Garcia-Delgado, who reports to the Senior Director of Quality. In addition, a dotted line reporting structure from the LMI-PR RSO, to the LMI-Billerica Senior Director of EHS and RPO was implemented (Exhibit AI(1)).

The LMI-PR Operations Director resigned in April, 2019. The Director of Cyclotron Operations in Billerica was named Interim Operations Site Lead for LMI-PR, and was on site providing support and driving improvements. He was on site for up to 2 weeks a month from April 2019 until August 2019. Beginning in August, 2019 until January 15, 2020 the Interim Operations Site Lead was on site full time.

In September 2019, LMI filled a newly created position of Vice President of Nuclear Operations, who assumed the responsibility for the Billerica Cyclotron operations, LMI-PR Radiopharmacy Operations and the LMI distribution center in Canada.

A new Associate Director for EHS and Corporate Radiation Safety Officer at LMI-Billerica joined the organization in November 2019 and his responsibilities include providing health physics support to the LMI-PR radiation protection program.

LMI-PR radiation protection staff have a standing agenda item at the LMI-Billerica Radioisotope and Safety Committee to review dosimetry results. In addition, members of the Billerica Radiation Protection Office participate by teleconference in the LMI-PR quarterly Radiation Safety Committee meetings (Exhibit A(4)).

A weekly teleconference between the Senior Director of EHS and RPO, the Associate Director of EHS and Corporate RSO, the LMI-PR RSO and the third party health physics consultant to discuss and review issues and progress on the corrective action plan from the 2019 third party audit (Exhibit C(1)).

Additionally, as new procedures are developed at LMI-PR, the LMI-PR RSO will request collaboration and review with members of the LMI-Billerica Radiation Protection staff (Exhibit AI(2)).

Second NRC Request for Additional Information

The current status of actions taken and planned by LMI in response to the Radiation Safety Program audit performed for LMI by a contracted radiation safety company in February/March 2019.

Response to Second NRC Request for Additional Information

While developing the corrective action plan to properly address the findings described in the third party audit of LMI-PR, LMI personnel employed a method similar to the guidance provided in the NRC Information Notice No.: 96-28 Suggested Guidance Relating to Development and Implementation of Corrective Action. This Informational Notice was reviewed upon suggestion of the NRC in the Lantheus Choice Letter and Inspection Reports date January 27, 2020.

While the Information Notice referenced above is for NRC violations, LMI adopted a similar approach for the findings from the third party audit. This approach included:

- Interviews with individuals who either directly or indirectly were involved with the findings
- Reviewing and revising procedures and records that related to the findings.
- Informing Management of the findings, corrective action plan and updates on the progress of program enhancements.
- Identification of potential similar weaknesses in other program areas and including them into the corrective action plan
- LMI-PR staff have been retrained on Site and Companywide procedures and policies

We have included the corrective action plan and status (Exhibit AI(4)).

LMI has contracted the third party consultants that performed the program audit to review all associated documents and trainings listed as part of the corrective action plan (Exhibit C1).

Additionally, LMI-PR contracted with a radiopharmacist in Puerto Rico to perform an operations assessment in June 2019. The findings in this audit supported the positive organizational change which integrated the EHS and radiation safety programs under the Quality Organization (Exhibit AI(3)).

Previous correspondence from LMI to the NRC:

1. Letter dated June 13, 2018 from Eduardo Diaz, Radiation Safety Officer and Senior Operations Manager, LMI to Craig Z. Gordon, Senior Health Physicist, U.S. Nuclear Regulatory Commission.
2. Letter dated September 21, 2018 from James Hayes, Senior EH&S and RPO, LMI to Elizabeth Ullrich, Senior Health Physicist, U.S. Nuclear Regulatory Commission.
3. Letter dated September 28, 2018 from Carol Walker, Senior Vice President, Quality and EH&S to Henry McCullough, Special Agent, U.S. Nuclear Regulatory Commission.
4. Letter dated January 24, 2019 from Carol Walker, Senior Vice President, Quality and EH&S to Henry McCullough, Special Agent, U.S. Nuclear Regulatory Commission.
5. Letter dated March 29, 2019 from John Bolla, Chief Operations Officer, LMI and Carol Walker, Senior VP of Quality LMI to Henry McCullough, Special Agent, U.S. Nuclear Regulatory Commission.
6. Records provided on April, 3, 2019 from Carol Walker, Senior Vice President of Quality to Henry McCullough, Special Agent, U.S Nuclear Regulatory Commission.

Exhibits:

A(1) Internal Investigations by LMI-PR (HR-MI-2018-04) (HR-MI-2018-05)

A(2) Safety Bulletin on Dosimetry Use

A(3) Training attendance sheet from March, 2018 retraining IE on dosimetry requirements

A(4) Examples of RISC agendas and LMI-PR presentations

A(5) Letter to Landauer updating IE's dose

C(1) Proposal from RSCS for LMI–PR Health Physicist Support

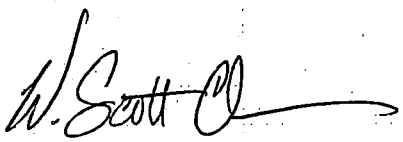
AI(1) Amendment request and acceptance of new RSO

AI(2) Example of collaboration with LMI-Billerica RP staff

AI(3) Operations Audit Conducted July, 2019

AI(4) Correct Action Plan from 3rd Party Audit 2019

Respectfully Yours,



W. Scott Claunch, Vice President, Nuclear Operations

Enclosure

Footnote 1 : Previous Correspondence from LMI to NRC – June 13, 2018 Letter to Craig Gordon from Eduardo Diaz

Lantheus Medical Imaging

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June 13, 2018

U.S. Nuclear Regulatory Commission
Attn.: Craig Z. Gordon
Senior Health Physicist
Region 1
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406

Re: Lantheus Medical Imaging, Inc. Response to NRC Observation

Dear Mr. Gordon:

As requested by the Nuclear Regulatory Commission (NRC), Lantheus MI Radiopharmaceuticals, Inc. Puerto Rico (Lantheus PR) is providing this response regarding questions identified during recent NRC Site visits regarding an employee's dosimeter readings. On 14 February 2018, the NRC performed an unannounced regulatory inspection of the Lantheus PR Facility. The NRC was following up on licensee sites impacted by Hurricanes Irma and Maria. As part of the NRC inspection, a review of 2017 dosimetry results was performed. NRC observed that for one, individual employee (IE), dosimetry results from Landauer, Inc. were reported as minimum "M" for whole body and extremity doses for months August - December 2017. The NRC requested additional information from Lantheus PR including an interview with IE and an internal assessment of the results. The NRC returned to Lantheus PR on 7 March 2018 and 10 April 2018 to follow-up on their initial observations and interview the IE.

On 10 May 2018, a call between NRC and Lantheus took place for an update on the NRC inspection, and specifically, the Lantheus PR internal assessment of the IE dosimetry. Lantheus PR subsequently agreed to provide the NRC with a written summary of the dosimetry assessment and identifications of corrective measures.

Relevant Facts:

1. IE performs target re-builds (the number per month varies based on site requirements) and performs PET isotope equipment repairs and linearity tests.
2. The catastrophic impact of Hurricanes Irma (September 6, 2017) and Maria (September 20, 2017) left millions in Puerto Rico without power for several months. They also affected business operations at Lantheus PR for multiple weeks (approximately 24 days operating on backup power).
3. As a result of the hurricanes all of Puerto Rico, including Lantheus PR, experienced significant delays in mail and postal services impacting timing and response to send dosimeters to Landauer and receive dosimetry results.
4. Lantheus PR has established annual dose limits for all employees well-below regulatory limits. All dosimetry results are tracked to ensure individual whole body and extremity dose remains below both

Lantheus PR and regulatory limits. Lantheus PR's Environmental Health and Safety (EHS) Specialist has worked to update dosimetry reports with a focus on identifying high exposures. The EHS Specialist monitors and updates dose records on a monthly basis.

5. On 12 March 2018, Lantheus PR's Management and Radiation Safety Officer (RSO) met and discussed the NRC observation with the IE. The IE indicated his use of dosimetry for the period in question (August – December 2017) was occasional when entering restricted areas.
6. On 10 April 2018, the NRC returned to Lantheus PR to interview the IE. The IE indicated he had not worn dosimeters consistently.

Lantheus Internal Assessment:
Following the February 2018, NRC inspection Lantheus PR performed an internal assessment to review dosimetry records and employee dosimetry management, implement any immediate actions to correct discrepancies, perform a dose reconstruction of the IE, identify root cause(s) associated with the observation, and identify corrective and preventative actions to ensure continued compliance with regulatory requirements.

Immediate Actions:
Lantheus PR completed the following immediate actions to address the extent of dosimetry records reporting irregularities:

1. Lantheus PR and its Radiation Safety Officer (RSO), with the support and direction from corporate Lantheus EHS located in Billerica, Massachusetts, reviewed all dosimetry data for Puerto Rico staff to evaluate dosimetry irregularities in reporting and dose trends. *Result:* According to 2017 dosimetry records, a total of 29 Lantheus PR staff wore and submitted monthly dosimeters; 14 of those staff members also wore extremity dosimeters. Based on a comprehensive review of all Landauer dosimetry reports from January through December 2017, there were no individual dosimetry reporting or management irregularities, excluding for the IE.
2. Lantheus PR Management and the RSO performed an internal inspection of all dosimetry use including an assessment of employee training records and related documentation of dosimeter readings. *Result:* Confirmation that Lantheus PR staff were wearing dosimeters in required areas.
3. Lantheus PR EHS met with the IE to review dosimetry management practices and compliance with Lantheus dosimetry management requirements. *Result:* The IE was formally retrained on Site policies regarding dosimetry use and management.
4. On 12 March 2018, Lantheus PR EHS and the RSO met to evaluate their internal Landauer report review process. The process was limited to updating dosimetry reports and identification of high exposure results that could exceed either Lantheus' internal limits or regulatory limits. *Result:* Lantheus PR RSO and PR EHS modified the Landauer dosimetry report process to include analyzing employee task, identification of dose trends and irregularities (including minimum "M" results) in addition to identification of high doses. A corrective action to document this process was identified as part of this assessment (summarized below) that includes establishing threshold reporting levels to help detection of atypical results (above or below historical levels, based on the employee position and or tasks).
5. Organizational structure changes were implemented to provide additional oversight and supervision. *Result:* A change in the Lantheus PR reporting structure resulting in the IE directly reporting to the RSO, instead of the Operations Director.

6. Since implementation of the immediate action plan in March 2018, Lantheus conducted an initial assessment review of immediate actions completed in response to the IE dosimetry observation
   Result: Lantheus PR has confirmed that the dosimetry reporting irregularity was limited to the IE and not a systemic site-wide issue.

Dose Reconstruction

Lantheus performed Dose Reconstruction for the IE to estimate the radiation dose potentially received by the IE as a result of his work activities at Lantheus PR. The results are used to estimate anticipated received dose for the period in question compared to both Lantheus and regulatory dose limits.

The IE has two main duties when it comes to his work with radioactive materials: (1) the IE performs target re-builds (the number per month varies based on site requirements) and (2) the IE performs PET isotope equipment repairs and linearity tests. ***Note: Dose Reconstruction Limitation***: A limiting factor in this reconstruction scenario is that the work performed by the IE is neither static, nor repetitive from day to day, week to week or month to month.

The information utilized in developing the Dose Reconstruction includes:

- Landauer reports for the months of Jan-July 2017 and Jan-April 2018;
- Number of target rebuilds performed by the IE for each month; and
- Approximation of dose received through PET operations support (including isotope equipment repairs and linearity tests).

In March 2018, as part of the Dose Reconstruction, Lantheus performed a target rebuild process assessment to calculate estimated whole body and extremity dose based on the IE's documented actual work practices. The IE worked with Lantheus to recreate the target rebuild scenario. Each step involved was timed and exposure rate documented. The rebuild process assessment including photographs of each step is provided as Appendix 1. Based on the assessment calculations each rebuild resulted in a whole body dose of 6.6 mrem and extremity dose of 54.8 mrem.

In April 2018, the IE was issued additional dosimetry to approximate the ratio of dose from target rebuilds to PET work. Based on the dosimetry results for the IE, the whole body ratio is 85% dose from PET, 15% dose from target rebuilds. For the IE's extremity doses, the ratio is 56% dose from PET to the right extremity and 51% of dose from PET to the left extremity. The remainder of extremity dose is based on the target rebuild.

Using the PET to target rebuild ratio and the number of target rebuilds performed each month, we were able to calculate the expected dose for August – December 2017. The following table provides both the IE actual Landauer results for January – July 2017 and the calculated results for August – December 2017.

Dose Reconstruction			
Month	**Whole Body Dose (mrem)**	**Right Extremity (mrem)**	**Left Extremity (mrem)**
January-17	47	600	620
February-17	221	1,680	1,860
March-17	108	530	540
April-17	25	120	180
May-17	32	260	270
June-17	27	260	180
July-17	327	2,640	1,940
August-17	470	2,820	3,078
September-17	94	564	616
October-17	141	846	923
November-17	282	1,692	1,847
December-17	470	2,820	3,078
Cumulative Total Dose for IE (2017)	**2,244**	**14,832**	**15,130**

Conclusion of Dose Reconstruction: the dose identified in the above table should be assigned to the IE for the months August through December 2017. Based on the cumulated dose for 2017, the IE whole body dose (2,244 mrem) and extremity dose (14,832 mrem and 15,130 mrem) are below both the regulatory limits of 5,000 mrem and 50,000 mrem, respectively.

Lantheus Root Cause Analysis and Corrective/Preventative Actions:
As part of the assessment, Lantheus PR RSO and Lantheus Management interviewed staff to help identify the source of the dosimetry record irregularity, including dosimetry management processes and the potential impact of environmental / human factors. Lantheus PR staff were questioned by the RSO based on their work function and role in supporting dosimetry management and included, specifically: the IE, EHS Specialist, Lantheus PR Management and other Lantheus PR staff required to wear dosimetry. Based on information identified during the assessment, the following causes were considered:

Dosimetry Management and Irregular Dose Reporting		
Probable Causes	**Error**	**Details**
Hypothesis 1: ☐ Accept ☐ Reject ☒ Inconclusive	External Phenomenon/ Environnemental: Non-routine condition/situation	▫ The catastrophic impact of Hurricanes Irma and Maria disrupted employee family life and work routine. Contributing factors include: weeks with no power; no communication; limited food and fresh water; and impact to business continuity. ▫ Inconclusive: insufficient information to determine this was a root cause of the dosimeter readings, though it may have played a role in the IE's actions.
Hypothesis 2: ☒ Accept	Personnel Error: Violation of	▫ IE did not wear dosimetry, as required by site policy and procedure.

Dosimetry Management and Irregular Dose Reporting		
Probable Causes	**Error**	**Details**
☐ Reject ☐ Inconclusive	requirement or procedure	▫ Accept: IE indicated that, from time to time, he left dosimetry on desk and forgot to retrieve it before entering the restricted area.
Hypothesis 3: ☐ Accept ☐ Reject ☒ Inconclusive	Personnel Error: Inattention to Detail	▫ Facility and personal stress due to severe weather conditions, loss of life, and financial hardship to family, impacted the IE's routine operations resulting in dosimetry use irregularities. ▫ Inconclusive: insufficient information to determine this was a root cause of the dosimeter readings, though it may have played a role in the IE's actions.
Hypothesis 4: ☒ Accept ☐ Reject ☐ Inconclusive	Management Error: Inadequate Supervision	▫ Review and analysis of Landauer reports regarding identification of high exposure results that could exceed either Lantheus' dose limits or regulatory limits. ▫ Accept: Dose record review process did not include additional management of analyzing employee task, identification of dose trends and irregularities (including minimum "M" results). Dose record review process did not include established threshold levels to help detection of atypical results (above or below historical levels based on the employee position and or tasks).
Hypothesis 5: ☐ Accept ☒ Reject ☐ Inconclusive	Personnel Error: Other	▫ Intentional disregard for dosimetry site policy to avoid potential consequences for increased dose exposure. ▫ Reject: No prior communication from Lantheus PR Management regarding IE dose issues or concerns; Dose reconstruction demonstrates whole body and extremity dose below Lantheus limits and regulatory limits.
Hypothesis 6: ☐ Accept ☐ Reject ☒ Inconclusive	External Phenomenon/ Environmental Conditions: Weather & Mail Interruptions	▫ As a result of the hurricanes all of Puerto Rico, including Lantheus PR, experienced significant delays in mail and postal services impacting timing and response to send dosimeters to Landauer and receive timely dosimetry results. ▫ Inconclusive: Insufficient information to assess whether mail impacted this group or the IE's dosimeter readings or reports; there was no indication that other groups or individuals experienced dosimetry issues.

Corrective and Preventative Actions (CAPAs)			
	Error	**CAPA**	**Timing**
1	External Phenomenon/ Environmental: Non-routine condition/situation	Provide a site-wide email communication reinforcing dosimetry requirements, individual dosimetry responsibilities, and available EHS and RSO resources.	**30 June 2018**
2	Personnel Error: Violation of requirement or procedure	Disciplinary action (Human Resources warning letter) was taken with IE, stressing the importance of wearing of dosimetry and being compliant with Site procedures, handbook and license requirements.	**COMPLETE**
3	Personnel Error: Inattention to Detail	∘ Retrain IE on Site policies regarding dosimetry use and management. ∘ Implement the use of a real time dosimeter (Instadose) in addition to Landauer dosimetry to monitor dose; incorporate in Dosimetry Management Procedure.	**COMPLETE** **31 July 2018**
4	Management Error: Inadequate Supervision	∘ Establish procedure for reviewing dosimetry reports to include analyzing employee task, identification of dose trends and irregularities, and established trigger levels. ∘ Hire additional nuclear pharmacist to support RSO and ensure timely review and assessment of dosimeters. ∘ Incorporate standing agenda item with Lantheus PR Radiation Safety Committee (RISC) and monthly Lantheus Billerica RISC to present dosimetry trends and performance	**15 July 2018** **15 July 2018** **15 July 2018**

Conclusion:

Lantheus and Lantheus PR have implemented corrective actions to ensure radiation exposure experienced by staff continues to be below Lantheus' and regulatory levels. Lantheus and Lantheus PR have also implemented documentary processes by which to continue to monitor these levels, in addition to making structural reporting changes. Lantheus will continue to make additional changes, as necessary, to ensure the safety of its staff and regulatory compliance.

Please contact me by telephone at 787-765-5598 (extension 2503) or email at Eduardo.Diaz@Lantheus.com if you have questions or require additional information regarding this report.

Sincerely,

Eduardo Diaz, BCNP
Radiation Safety Officer, Senior Operations Manager

Attachment 1: Cyclotron Target Rebuild Task Analysis

Cc: Noel Rodriguez, Lantheus Director Puerto Rico Operations
Angel Pagan, Lantheus EHS
James Hayes, Lantheus Senior Director EHS & RPO
Julie Hanlon, Lantheus Billerica RSO

Attachment A - Cyclotron Target Rebuild Task Analysis

$I_2 = I_1 (D_1/D_2)^2$

Task Steps	Dose rate (mR/hr)	Time (Minutes)	DDE Deep Dose Equivalent	SDE Shallow Extremity
1. Open Cyclotron shield and removing target				
a. Dose rate at front Target area (Pic. 1) 175 mR/hr				
b. Removing target and taking to shielded work station area (Pic. 2). Target high 2 ½ inches. Time - 0.53 minutes	175.00	0.53	1.55	6.18
c. Gloves survey after drop target at shielded work station area 0 mR/hr				
	Sub-TOTAL	**0.53**	**1.546**	**6.183**
	Dose rate (mR/hr)	Time (Minutes)	DDE Deep Dose Equivalent	SDE Shallow Extremity
2. Disarm Target at shielded work area				
a. Dose rate over shielded work area and above 18 inches away from bench top (Pic. 3) was 150 mR/hr				
b. Dose rate behind work area glass shield (chest exposure rate) 150 mR/hr				
c. Removing O-ring and window and bringing window to shield receptacle using a 10 inches tweezers (Pic. 4). Windows dose rate 200 mR/hr. Time – 1.52 minutes	200.00	1.52	3.80	20.27
d. Put new window, assembly tubes and target into beaker, in beaker. Time – 0.40 minutes	150.00	0.40	1.00	4.00
e. Using a 10 inches tong, take to QC Room hood. Time – 0.30 minutes	150.00	0.30	0.004	0.03
	Sub-TOTAL	**2.22**	**4.804**	**24.297**
	Dose rate (mR/hr)	Time (Minutes)	DDE Deep Dose Equivalent	SDE Shallow Extremity
3. Ultrasonic bath				
a. Adding chloroform and put it inside the ultrasonic bath cleaner (Pic. 5). Time – 0.70 minutes.	150.00	0.70	0.018	1.75
b. Wait for 20 minutes. Note: 20 minutes does not count for exposure, since there is not contact with hot items				
c. Adding Acetone and put it inside the ultrasonic bath. Time – 0.27 minutes	150.00	0.270	0.007	0.675
d. Wait for 20 minutes.				
e. Disposing Acetone Time – 0.33 minutes	150.00	0.330	0.008	0.825
f. Adding Methanol and put it inside the ultrasonic bath. Time – 0. 27 minutes	150.00	0.270	0.007	0.675
g. Wait for 20 minutes.				
h. Disposing Acetone Time – 0.47 minutes	150.00	0.470	0.012	1.175
i. Adding Distillated Water and rinse twice. Time – 1.11 minutes	150.00	1.110	0.028	2.775
j. Disposing Distillated Water Time – 0.25 minutes	150.00	0.250	0.006	0.625
k. Take beaker with target, using tong, to lab bench to rebuild target rebuild Time – 0.20 minutes	150.00	0.200	0.003	0.020
	Sub-TOTAL	**3.60**	**0.088**	**8.520**

(Pic. 1)

(Pic. 2)

(Pic. 3)

(Pic. 4)

	Dose rate (mR/hr)	Time (Minutes)	DDE Deep Dose Equivalent	SDE Shallow Extremity
4. Target Rebuild				
a. Turn on compressed air gas (no exposure) Time – 0.17 minutes				
b. Beaker with target dose rate ±4 inches from beaker 175 mR/hr				
c. Dry target, tubes and window with compressed air. Time – 1.30 minutes	175.00	1.30	0.038	3.792
d. Put new window, assembly tubes and target into beaker, in beaker and using tong, take to shielded work area. Time – 0.33 minutes	175.00	0.33	0.010	0.963
e. Installing O-ring, tubes and window to assemble the target. Time – 1.78 minutes	175.00	1.78	0.052	5.192
	Sub-TOTAL	3.41	0.099	9.946

	Dose rate (mR/hr)	Time (Minutes)	DDE Deep Dose Equivalent	SDE Shallow Extremity
5. Assemble target to Cyclotron. Time – 2.0 minutes				
a. Dose rate at front Target area 175 mR/hr	175.00	2.00	0.058	5.833
	Sub-TOTAL	2.00	0.058	5.833

		Time (hh:mm:ss)	DDE Deep Dose Equivalent (mR)	SDE Shallow Dose Extremity (mR)
Cyclotron Target Rebuild Task	TOTAL	00:11:45	6.6	54.8

Footnote 2: Previous Correspondence from LMI to NRC – September 21, 2018 Letter from James Hayes to Elizabeth Ullrich

Lantheus
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21 September 2018

Elizabeth Ulrich
Special Agent
US Nuclear Regulatory Commission
Licensing Assistance Team
475 Allendale Road
King of Prussia, PA 19406

Re: NRC License No. 52-25361-02
Request for Authorized User

Dear Ms. Ulrich:

Thanks you for speaking with me earlier today. As a result of my conversation with Mr. Gordon and the identification of concerns regarding the Operations License No. 52-25361-02 Lantheus MI Pharmaceuticals, Inc. (LMI-PR) halted production operations on Thursday (20 September 2018) immediately following our conversation.

LMI-PR has implemented the following as prompt corrective actions and requests an expedited review by the NRC in order for us to continue to safely produce, and serve patients as the only provider of, Fludeoxyglucose (F-18) in Puerto Rico. Approval: We are requesting approval to continue to produce F-18 while the amendment is finalized.

LMI-PR requests the following individuals be added to the License as Authorized Users.

1. Jose Ramos – Mr. Ramos has over 10-years of relevant experience demonstrating adequate training at an accelerator facility.
2. Bryan Fernandez Diaz – Mr. Diaz has over 3-years of relevant experience demonstrating adequate training at an accelerator facility.

In addition to their accelerator work history both individuals have received additional training specific to the radiation safety while performing accelerator activities:

- MI-PPS-3024, Operations, Cleaning and Maintence of the Cyclotron - Basic cyclotron and hot cell operations
- Operating and emergency procedures for the cyclotron and hot cells
- Activated targets and components; precautions and handling techniques
- Area monitors
- Ventilation systems, filters and effluent monitoring systems

Please remove Cesar Blanco from our license as he is no longer with the Company.

Footnote 3 : Previous Correspondence from LMI to NRC – September 28 2018 Letter from Carol Walker to Special Agent McCullough

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28 September 2018

BY OVERNIGHT COURIER

Henry McCullough
Special Agent
US Nuclear Regulatory Commission
Office of Investigations, Region 1 Field Office
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2713

Re: Request for Records/Documents

Dear Special Agent McCullough:

In response to your 15 August 2018 request to provide records/documents in support of the NRC investigation of the circumstances surrounding Mr. Cesar Blanco's failure to wear dosimetry, we have prepared this letter and attached relevant and responsive records/documents for your requests.

On 14 February 2018, the US Nuclear Regulatory Commission (NRC) performed a regulatory inspection of the Lantheus MI Radiopharmaceuticals, Inc. (LMI-PR) San Juan, Puerto Rico facility. LMI-PR is a Puerto Rico corporation and wholly-owned subsidiary of Lantheus Medical Imaging, Inc., a Delaware corporation (Lantheus). The NRC returned to LMI-PR for additional discussions in March and April 2018. In June 2018, Lantheus spoke with the NRC to address questions identified during the NRC's LMI-PR site visits regarding Cesar Blanco's dosimeter readings.

In connection with the issues that the NRC identified, Lantheus has implemented several management/organizational changes and corrective actions including:

1. LMI-PR Reporting: To align compliance management processes, Lantheus restructured reporting lines so now LMI-PR Operations reports to Billerica Manufacturing and Operations.
2. Program Management Changes: Lantheus added monthly reporting by the LMI-PR Radiation Safety Program to the Lantheus Radiation Safety Committee and implemented the use of real time dosimeter for cyclotron repairs in addition to the Landauer dosimetry.
3. Procedural Changes: LMI-PR implemented a new procedure for dosimetry review and action levels.
4. Employee Training: LMI-PR updated the Handbook of Radiation Protection, including a practical exam for both LMI-PR employee initial and refresher training.
5. Employee Termination: Mr. Cesar Blanco was terminated by LMI-PR as of August 15, 2018 (see item 1 below).

Response to NRC Request for Documents/Records:

1. Cesar BLANCO's Training Records, including refresher training, from 1/1/2016 to 5/31/2018

   Response: Attached as Item 1 are the training records for Mr. Blanco for the time period requested.

   a. Any derogatory records (counseling/reprimand, etc.) pertaining to Cesar BLANCO's performance of duties.

      Response: Attached as Item 1(a) is the warning letter issued to Mr. Blanco on 11 April 2018. On August 8, 2018, a decision was made by Lantheus and LMI-PR to terminate Mr. Blanco's employment with LMI-PR because of violations of company operating procedures and the company's code of conduct and ethics. This decision was communicated to Mr. Blanco at 10:00am on August 15, 2018 by Noel Rodriguez (LMI-PR, Director of Operations), in person, and Pia Olson (Lantheus, Director of Human Resources), by telephone. The effective date of Mr. Blanco's termination of employment was August 15, 2018. After communication of the termination by Mr. Rodriguez and Ms. Olson, Mr. Blanco was escorted off of the LMI-PR premises.

2. Cesar BLANCO's Daily Time and Attendance Records, 1/1/2017 to 5/31/2018

   Response: Mr. Blanco was a salaried employee of LMI-PR and, as such, he was not required to keep track of his actual working hours on a daily basis. To respond to your request, however, we have provided a calendar reflecting the dates on which Mr. Blanco used his security badge at the facility, based on his security badge access records from and after August 2017, which is as far back as our records go.

3. Cesar BLANCO's Dosimetry Records, 1/1/2016 to 5/31/2018

   Response: Attached as Item 3 are the LMI-PR Annual summary excel spreadsheet and the official Landauer Dosimetry reports for Mr. Blanco.

   In March 2018, LMI-PR evaluated its internal Landauer report review process. The process was limited to updating dosimetry reports and identification of high exposure results that could exceed either Lantheus' internal limits or regulatory limits. The process did not look for dosimetry results which would be low due to the employee's job role. As a corrective action, LMI-PR implemented a Personnel Dosimeters Management Procedure SOP-50 that includes analyzing employee tasks and identifying dose trends and irregularities (including minimum "M" results) in addition to identifying high doses.

   Lantheus completed an internal investigation of Mr. Blanco's dosimetry using the same dose reconstruction methodology described in the June 2018 Report (Appendix A) for the time period requested (January 2016 – May 2018). The result of the dose reconstruction demonstrates that Mr. Blanco's dose using this conservative approach was below the regulatory limits of 5,000 mrem for whole body dose and 50,000 mrem for extremity dose. The dose reconstruction spreadsheets are also provided with Item 3

4. Lantheus Puerto Rico (PR) Facility's Procedure/Policy requiring the use of dosimetry

   Response: Attached as Item 4 are the LMI-PR Personnel Dosimeters Management Procedure SOP-50 and the Handbook of Radiation Protection, which require the use of dosimetry. The Handbook was revised in 2018. The prior Handbook version also included the requirement for employees to wear dosimeters.

5. Lantheus Corporate Procedures/Policy for establishing and monitoring dosimetry

Response: Attached as Item 5 is the procedure for Calculating and Assigning External Dose (MI-PRS-3004, revised March 2016). Personnel Dosimeters Management Procedure SOP-50, provided with Item 4, also supports establishing and monitoring dosimetry

6. Lantheus Procedure for the Cyclotron Target Rebuild

Response: Attached as Item 6 is the Work Instruction (WI-9), Cyclotron Target Rebuilding – Tantalum and Niobium Work Instruction.

7. Lantheus PR Facility Procedure/Policy for frequency of the Cyclotron Target Rebuild

Response: The requested documentation is included with the Work Instruction (WI-9) Section 6, provided in Item 6.

8. Lantheus PR Facility's Records of Cyclotron Target Rebuilds and personnel involved, 1/1/17 to 5/31/18

Response: Attached as Item 8 is a summary table of target rebuilds for the time period requested. The Summary Table is based on available records including the attached Service Log Book and Target Rebuild Log.

9. Lantheus PR Facility's Production Records, 1/1/17 to 5/31/18

Response: Attached as Item 9 is the summary of LMI-PR Facility Production Records for the time period requested.

10. Lantheus PR Procedures/Policy for equipment repairs to Cyclotron Components

Response: Attached as Item 10 is the Operation and Maintenance of the Cyclotron SOP (MI-PPS-3024). This SOP describes cyclotron operation and references maintenance manuals for the cyclotron. The Siemens Maintenance Instructions referenced in the SOP have also been included in Item 10.

11. Lantheus PR Procedures/Policy for Cyclotron Preparation prior to F-18 Production Runs

Response: The requested documentation is included with the SOP (MI-PPS-3024) provided in Item 10.

12. Records related to Cyclotron equipment repairs, 6/1/17 to 5/31/18

Response: Attached as Item 12 is the Maintenance and Repair Log Book Summary based on the information provided in the attached Service Log Book.

13. Records related to Quality Control/Linearity Tests, 6/1/17 to 5/31/18

Response: Attached as Item 13 are the Production Records identifying the personnel conducting the Quality Control/Linearity Tests.

14. Identity of personnel who conducted Quality Control/Linearity Tests, to include the dates which they conducted the tests, as well as their dosimetry records, from 1/1/17 to 5/31/18

Response: In addition to the records provided in Item 13 including personnel who conducted Quality Control/Linearity tests, attached as Item 14 are Annual Dosimetry Summaries for the three individuals identified and the Landauer reports.

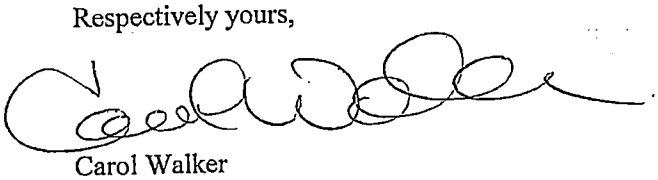
Additional Actions Planned by Lantheus

In addition to the corrective actions identified as part of the internal assessment to ensure the safety of our staff and regulatory compliance, Lantheus is also implementing the following:

- LMI-PR will submit a request to the NRC to transfer the RSO role to an approved authorized nuclear pharmacist reporting directly to the Lantheus Quality and EH&S organization.
- A comprehensive third party audit of the LMI-PR facility will focus on the Radiation Protection Program.
- LMI-PR will provide additional Compliance and Data Integrity Training for all LMI-PR employees.
- LMI-PR will notify Landauer regarding the preliminary dose reconstruction and modify the official reports to accurately reflect Mr. Blanco's dose.

Please let me know if you have any questions in connection with any of the foregoing.

Respectively yours,



Carol Walker
Senior Vice President, Quality and EH&S

Footnote 4 : Previous Correspondence from LMI to NRC – January 24, 2019 Letter from Carol Walker to Special Agent McCullough

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24 January 2019

Henry McCullough
Special Agent
US Nuclear Regulatory Commission
Office of Investigations, Region 1 Field Office
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2713

Re: Request for Additional Records and Documentation

Dear Special Agent McCullough:

In response to your recent requests to provide additional records/documents, Lantheus Medical Imaging, Inc. (Lantheus Billerica), on behalf of its wholly-owned subsidiary Lantheus MI Radiopharmaceuticals, Inc. (Lantheus Puerto Rico) (Lantheus Billerica and Lantheus Puerto are referred to, collectively, as Lantheus), has prepared this letter and attached relevant records/documents.

Response to NRC Additional Request for Documentation:

1. "Provide the records related to the cyclotron rebuilds for 2016...same as what was provided in Item 8 of your response to my original request."

   Response:

   Attached as Item 1 are the Cyclotron Target Rebuild Log Summary for the requested time period.

2. "Provide records related to Item 12 for the time period of the entire year of 2016 and up to 6/1/2017, as my original request was for 6/1/17 to 5/31/18."

   Response:

   Attached as Item 2 are the Maintenance Log Book Summary based on Service Log entries from January 1, 2016 to June 1, 2017, as well as Siemens Service Log documentation for the same time period.

3. "Annual dosimetry records, broken down by month, for BLANCO for the years 2014 & 2015"

   Response:

   Attached as Item 3 are the 2014 & 2015 Lantheus Puerto Rico Annual Dosimetry Summary and Landauer Dosimetry reports for Mr. Blanco.

4. "Provide target rebuild records, along with dosimetry records for the personnel doing those target rebuilds, for the time period of July 1, 2018 to December 31, 2018."

   Response:

   During the period of July 1, 2018 to December 31, 2018, the following employees performed the target rebuilds:

   - *Cesar Blanco (main person performing the task during July 2018 until August 15, 2018).*
   - *José Ramos (main person performing the task during August 16, 2018 to December 31, 2018).*
   - *Bryan Fernández (as assistant in the task to José Ramos in certain instances during August 16, 2018 to December 31, 2018).*

   Attached as Item 4 is the Target Rebuild Logs for rebuilt targets performed during the dates of July 1, 2018 to December 31, 2018.

   Also attached in Item 4 are the Dosimetry Summary Tables and Landauer Dosimetry Reports for Cesar Blanco, Jose Ramos and Bryan Hernandez. The records for José Ramos and Bryan Fernandez cover the complete requested period and records for Cesar Blanco covers the period until his termination (August 15, 2018).

5. NRC also requested Lantheus provide the identities and contact information for the following Lantheus employees:

   Response:

   Please note that Lantheus Billerica (which manufactures and finishes bulk radiopharmaceuticals that are sold to radiopharmacies and nuclear medicine departments worldwide) and Lantheus Puerto Rico (which operates a single radiopharmacy that prepares patient-ready unit doses of radiopharmaceuticals that are sold to hospitals and medical practices in Puerto Rico and the Caribbean) have distinct operations and separate licenses and operating procedures.

   A. "RSO for Lantheus at the corporate level during the time period of January 2016 through 2018."

      Response:

      Consistent with regulatory requirements and industry practice, Lantheus RSO responsibilities are specific to its individual site licenses. Attached in Item 5(A) are the RSO responsibilities as described in the Lantheus Billerica Broad Scope License, Issued by the Massachusetts Department of Public Health (MaDPH) Radiation Control Program.

      The Lantheus Billerica RSO from 2016 to July 2017 was the former Director of EHS, Roy Greaves. Mr. Greaves retired in July 2017. From July 2017 to present the Lantheus Billerica RSO is Julie Hanlon.

      Contact information for Ms. Hanlon: Julie.Hanlon@Lantheus.com;
      Telephone number: (978) 671-8316.

   B. "RSO for Lantheus Puerto Rico (PR) facility during the time period of January 2016 through 2018."

      Response:

      The Lantheus Puerto Rico RSO from January 2016 through 2018 was Eduardo Diaz. Lantheus Puerto Rico has submitted a request to the NRC to change the RSO to Rolando Garcia, Associate Director of Quality.

Contact information for Mr. Diaz: Eduardo.Diaz-Montes@lantheus.com
Telephone number: (787)-765-5598 ext. 2503

C. "Mr. Blanco's immediate supervisor during the time period of January 2016 through 2018."

Response:

Until March 2018, Mr. Blanco reported to the Lantheus Puerto Rico Director of Operations, Noel Rodriguez. As noted in the June 2018 response from LMI-PR to NRC Inspector, Craig Gordon, "Organizational structure changes were implemented to provide additional oversight and supervision. A change in the Lantheus Puerto Rico reporting structure resulted in Mr. Blanco directly reporting to the RSO (Eduardo Diaz) instead of the Operations Director."

Mr. Blanco reported to the Lantheus Puerto Rico RSO, Eduardo Diaz, from April 2018 until Mr. Blanco's termination in August 2018.

Contact information for Mr. Rodriguez: Noel.RodriguezQuiles@lantheus.com
Telephone number: (787) 765-5598 ext. 2507

D. "The training administrator/manager for Lantheus at the corporate level during the time period of January 2016 through 2018."

Response:

Department and individual training requirements are defined by each functional manager. The functional manager for EHS Programs at the Lantheus Billerica site was Roy Greaves until his retirement in June 2017. From June 2017 to present the training administrator/manager for EHS Programs at the Lantheus Billerica is James Hayes, Sr. Director EHS and RPO.

Contact information for Mr. Hayes: James.Hayes@lantheus.com
Telephone number: (978) 671-8969

E. "The training administrator/manager for PR facility during the time period of January 2016 through 2018."

Response:

Specific for EHS activities, the functional owner for Lantheus Puerto Rico is the EHS Sr. Specialist, Angel Pagan.

Contact information for Mr. Pagan: Angel.Pagan@lantheus.com
Telephone number 787-765-5598 ext. 2518

Lantheus would welcome telephonic or in-person interviews with any of these personnel, which can be coordinated through the Lantheus Legal Department (either Michael Duffy, General Counsel, at 978-671-8408 and michael.duffy@lantheus.com; or Dan Niedzwiecki, Deputy General Counsel, at 978-671-8648 and daniel.niedzwiecki@lantheus.com).

6. NRC has also requested the following Lantheus' Procedures and/or Policies in effect during the time period of January 2016 through 2018 for the following topics:

A. "Requirement for the use of dosimetry at the PR Facility."

Response:

Attached as Item 6(A) are the following policies and procedures for the use of dosimetry at the Lantheus Puerto Rico Facility:

- *Lantheus Puerto Rico Handbook of Radiation Protection, The Handbook; both the 2018 and 2015 version. Both versions include the requirements for employees to wear dosimeters*
- *Lantheus Puerto Rico Cyclotron and Hot Cell Entry Procedure (MI-PRS-3008), effective date: December 2017 (initial version)*
- *Lantheus Puerto Rico Personnel Dosimeters Management Procedure (SOP-50), effective date: July 2018; and Revision 2, November 2018.*

B. "Establishment and monitoring of the dosimetry program."

<u>Response:</u>

Provided in Item 6(B) is the Lantheus Puerto Rico procedure for Calculating and Assigning External Dose (MI-PPS-3004, Version 1, effective date: March 2016.

SOP-50, referenced in Item 6(A) also provides management and monitoring of the Lantheus Puerto Rico dosimetry program.

C. "Establishment, administration and duties of the Radiation Safety program at the corporate level and the PR facility."

<u>Response:</u>

As mentioned previously, Lantheus Billerica (which manufactures and finishes bulk radiopharmaceuticals that are sold to radiopharmacies and nuclear medicine departments worldwide) and Lantheus Puerto Rico (which operates a single radiopharmacy that prepares patient-ready unit doses of radiopharmaceuticals that are sold to hospitals and medical practices in Puerto Rico and the Caribbean) have distinct operations and separate licenses and operating procedures.

Provided as Item 6(C) is the Lantheus Billerica Massachusetts DPH Radiation License Renewal Application, Section 7, which provides a summary of the Radiation Safety Program and individual(s) responsible for the Radiation Safety Program. Also provided as Item 6(C) is the Lantheus Puerto Rico section of the Handbook of Radiation Protection (pages 4-6) that identifies the duties of the Lantheus Puerto Rico Radiation Safety Program.

D. "Establishment of any training program(s) and training requirements, particularly related to Mr. Blanco."

<u>Response:</u>

Provided as Item 6(D) is the list of training requirements related to Mr. Blanco for the years 2016 through 2018.

E. A description (course synopsis) and expected duration (amount of time to complete) of each training course Mr. Blanco was required to complete in 2016, 2017 and 2018.

<u>Response:</u>

Provided as Item 6(E) is the list with the description and duration of the training requirements for Mr. Blanco for the years 2016 through 2018.

F. "Provide the identity and contact information for the person who did Mr. Blanco's dosimetry reconstruction"

<u>Response:</u>

The Lantheus Puerto Rico EHS Sr. Associate, Angel Pagan, performed the dose reconstruction.

As noted in the June 2018 response by Lantheus Puerto Rico to the NRC, "In March 2018, as part of the Dose Reconstruction, Lantheus performed a target rebuild process assessment to calculate estimated whole body and extremity dose based on the individual employee's (IE's) documented actual work practices. The IE worked with Lantheus to recreate the target rebuild scenario. Each step involved was timed and exposure rate documented."

The dose reconstruction process and results were reviewed by: Lantheus Puerto Rico RSO, Eduardo Diaz; Lantheus Puerto Rico Director of Operations, Noel Rodriguez; Lantheus Billerica RSO, Julie Hanlon; and Lantheus Billerica Sr. Director EHS & RPO, James Hayes. Contact information has been provided in Response Items 5-9.

Please let me know if you have any questions in connection with any of the foregoing.

Respectively yours,

Carol Walker
Senior Vice President, Quality and EH&S

Footnote 5 : Previous Correspondence from LMI to NRC – March 29, 2019 Letter from John Bolla and Carol Walker to Special Agent McCullough

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29 March 2019

Henry McCullough
Special Agent
US Nuclear Regulatory Commission
Office of Investigations, Region 1 Field Office
2100 Renaissance Blvd., Suite 100
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Re: Lantheus Puerto Rico Radiation Program Audit

Dear Special Agent McCullough:

Lantheus Medical Imaging, Inc., (Lantheus Billerica), on behalf of its wholly-owned subsidiary Lantheus MI Radiopharmaceuticals, Inc. (Lantheus Puerto Rico) (Lantheus Billerica and Lantheus Puerto Rico are referred to, collectively, as Lantheus), has prepared this letter and attached documentation in support of the recent third party audit of the Lantheus Puerto Rico Radiation Protection Program.

In the September 2018 response to the NRC Lantheus committed to performing a comprehensive third party audit of the Puerto Rico facility Radiation Safety Program. The purpose of the audit was to evaluate the Radiation Protection organization, programs and procedures. Audit findings and recommendations will be used to develop an action plan that supports a sustainable and compliant program.

Over the past year, Lantheus has made several incremental changes at the Puerto Rico facility to support both improvements in site operations and Radiation Program. Examples of these improvements include: restructured the site operations reporting to the Lantheus Chief Operations Officer- John Bolla (previously identified as Sr. VP of Technical Operations); identified the need for new site leadership in Puerto Rico (actively pursuing candidates); submitted a request to the NRC to transfer the RSO role (NRC has accepted this change for one of the two site radiation licenses); implemented new procedures for dosimetry management; and dedicated funds to perform a 3rd party Radiation Program audit and execute a comprehensive response plan.

Lantheus contracted Radiation Safety & Control Services (RSCS) to perform the audit. The on-site audit was conducted between February 4 and February 8, 2019 including review of available Program information pre-audit and additional review of Program information post-audit. The scope of the assessment included a review of the radiation safety program for cyclotron and radiopharmacy operations. The program assessment included an evaluation of the Radiation Protection organization, programs and procedures, and implementation of processes. A copy of the Report is provided with this response.

The audit results reported by RSCS identify areas of improvement necessary to establish a sustainable and comprehensive Radiation Protection Program. Lantheus has reviewed the audit findings in detail and support the conclusion from RSCS that no items require immediate notification to the NCR. We have

committed to providing the necessary resources that can assist with implementing an audit response plan and is actively pursuing a contracted resource to assist in performing this work. This contracted resource will provide onsite support and will have the qualifications necessary to drive program improvements and provide technical oversight of the Radiation Protection Program. Expectations for the contracted resource includes the ability to: develop a detailed corrective action plan ensuring compliance improvements for all elements of the Radiation Program; drive creation of the required site procedures and processes; and develop employee training and training effectiveness to ensure the understanding of the new procedures. Lantheus anticipates significant progress in support of these improvements within the next three to six months.

Lantheus is in the process of identifying new site leadership for the Puerto Rico facility. The new site leader will be responsible for promoting the needed changes to the site culture and development of metrics to ensure continued compliance. In support of this role, Lantheus will perform periodic on-site reviews of the Radiation Program improvements to ensure audit responses and program changes are sustainable.

We appreciate the opportunity NRC has provided us to perform this comprehensive assessment of the Radiation Program and believe the execution of the steps identified above will result in a sustainable Program. Our goal is to develop a Radiation Safety Culture with the core values and behaviors resulting from commitment by Lantheus leadership and individuals to emphasize safety and compliance to ensure protection of people and the environment.

Please let me know if you have any questions in connection with any of the foregoing.

Respectively yours,

John Bolla
Chief Operations Officer

Carol Walker
Senior Vice President Quality

Footnote 6 : Previous Correspondence from LMI to NRC – April 3, 2019 Records Index from Carol Walker to Special Agent McCullough

Document Index April 5th, 2019

1. Bioassay Sample(s) for Mr. Blanco. – *Mr. Blanco was not part of any bioassay program per e-mail from Rolando Garcia-Delgado dated April 02, 2019*

2. Provide copies of the Training SOP, Doc. No. 05-001-002, revisions that would have been in effect from January 1, 2016 to October 2018, when Revision 13.1 became effective.

3. As to the Job Descriptions, how long have those been in effect? Was HAYES, DIAZ, HANLON and Pagan hired according to those description? If not, then please provide the ones they were hired under.

4. In section 10.4 of the license renewal application to the NRC for License # 52-25361-01MD in May 2012, and also in the License application for # 52-25361-02 dated 08/04/2009, Lantheus stated there is a written procedure for monitoring occupational dose. If that's included as part of another procedure, please point me in the right direction. If there's a specific procedure, then please provide a copy. This is for the PR site licenses. I understand there may be current procedures in place, effective after January 2018, but is there any prior procedures?

5. Item 6, RAD Policies: Is this for Bellerica, or both sites? *Billerica only*

6. Copy of Legal – Compliance Code, Training ID 27646, Doc # BI021711-1

7. Copy of Legal – Lantheus Company Code of Conduct and Ethics, Training ID 27628, Doc # BI102010-2

8. Copy of Radiation Safety Training, Power Point Presentation, Revisions 1 & 2

Exhibit A(1) : Internal Investigations by LMI-PR (HR-MI-2018-04) (HR-MI-2018-05)

Lantheus
Medical Imaging

Incident Investigation Report

Incident Report Number: HR-MI-2018-04

Date of Report: March 14, 2018

Brief Description: Minimum Dosimetry Results to employee performing Target Rebuild Task

Injury, Property Damage, or Other Potential: Dosimetry potentially non-monitored

Date of Incident: February 14, 2018
Time of Incident: unknown
Location: San Juan
Classification Case: Dosimetry

Pertinent Facts:

1. During February 14th Inspection, the NRC's Inspector found that employee, Cesar, in charge of Cyclotron Target Rebuild Task had minimum or "M" value dosimetry since August to December 2017
2. The NRC inspector understand that there should be at least some exposure on the reports. He also noted that for 2017 there is some exposure reflected on Cesar's dosimetry report. Based on that he leans to deduct that unless Cesar's task has changed there should be some exposure on the reports later in the year (2017).
3. During employee interview, March 12th, he said that he sometimes forgot to wear dosimeter

Additional Facts:

1. Target Rebuild Task is performed two or three times a month or when the target fail
2. Target Rebuild Task is performed on the afternoon, in order to work in a reduced dose rate field

Root Cause:

1. Employee did not use the dosimeters in the appropriate frequency
2. After a PET lab personnel dosimetry record audit, I could find that there is not employees shown minimum value for their 2017 dosimetry report, therefore, we conclude that the incident is an isolated one of a single employee.

Contributing Factors:

1.
2.

Learning Experience:

1. Dosimeter' use surveillance should be reinforced.
2.

Actions necessary to prevent recurrence:

Action description	Responsible	Timing
1. Establish a must frequent dosimeters use inspections	A. Pagán	Immediately
2. Perform the following actions: a. Task analysis (See attachment A) b. Submit recommendation to reduce dose rate c. Improve maintenance schedule	A. Pagán / E. Díaz / C. Blanco	March 23, 2018
3. Reinforce dosimeter usage section in the annual Radiation Safety Training.	A. Pagán	Last Quarter 2018

Investigated By: Angel Pagán, EHS Specialist

Written By: Angel Pagán

Date: March 14, 2018

Approved By (if not written by a supervisor or manager): _____

Lantheus
Medical Imaging

Incident Investigation Report

Incident Report Number: HR-MI-2018-05

Date of Report: July 18, 2018

Brief Description: The purpose of this investigation was to review past dosimetry reports of LMI PR employees and identify tendencies similar to the dosimetry situation NRC identifies in their February 14, 2018 inspection.

Injury, Property Damage, or Other Potential: Dosimeter non-monitored or lost

Date of Incident: Several
Time of Incident: see Dosimetry Historic Assessment table
Location: San Juan
Classification Case: Dosimetry

Pertinent Facts:

1. During February 14th Inspection, the NRC's Inspector found that individual employee (IE), in charge of high exposure tasks, had minimum or "M" value dosimetry results since August to December 2017.
2. Landauer dosimetry reports were retrospective reviewed from January 2015 through May 2018 for each employee with dosimeters assigned. We want to target inconsistencies among the Landauer reports. The following table, Dosimetry Historic Assessment, shows our findings:

Employee	Whole-body Dosimeter Issue	Ring Dosimeter Issue
CB	- Apr-2015, Missing dosimetry	- Feb-2015, Missing dosimetry
	- Mar-2016, "M" Values - Aug-2016 to Dec-2016, "M" Values	- Mar-2016, "M" Values - Aug-2016 to Dec-2016, "M" Values
	- Sep-2017 to Dec-2017, "M" Values	- Sep-2017 to Dec-2017, "M" Values
ED	- Jul-2016, Missing dosimetry	
JD	- Oct-2015, Missing dosimetry	- Feb-2015, Missing dosimetry
	- Jan-2017, Missing dosimetry	
JN		- Feb-2015, Missing dosimetry - Aug-2015, Missing dosimetry
RO	- Jan-2016, Missing dosimetry	
AP		- May-2015, Missing dosimetry - Aug-2015, Missing dosimetry
		- Jul-2016, Missing dosimetry
		- Feb-2018, Missing dosimetry
JR	- Jul-2015, Contaminated dosimeter	
OT		- Feb-2015, Missing dosimetry - Aug-2015, Missing dosimetry

Additional Facts:

1. Main finding: Employees missing dosimetry in Landauer reports.
    a. This means Landauer don't had data for the period above indicated because the dosimeter:
        i. was not returned by employee or
        ii. No physical dosimeter was received at Landauer facility (lost by mail service).
2. Missing dosimetry represents 34.0% of total errors found.
    a. could be several causes:
        i. Employee lost dosimeter and not reported it
        ii. Lost in mail.
        iii. Dosimeter sent late to Landauer
3. JR July 2015: dosimetry results from a contaminated dosimeter hadn't been notified to Landauer.
    a. JR Landauer record need to be update.
        i. Contaminated dosimeter dose reconstruction accepted by NRC, after an extensive investigation during 2015, was not notified to Landauer to correct employee dose records. (2.1% of Total errors found).
4. CB "M" values:
    a. 2016 – March, August through December (6 months).
    b. 2017 – August data was available; it could be rescue from Landauer system.
        i. 2017 "M" values period change to four (4) months instead of five (5) months.
5. Repetitive "M" values represent 63.8% of Total errors found for CB employee at high exposure area.
    a. Similar situation observed by NRC inspector during February 14th visit.
        i. Likelihood CB employee didn't used the dosimeters in the appropriate frequency.

Root Cause:

1. Monthly Landauer report assessment did not pay attention to "M" or low values. Priority was major consideration to high values.
2. Postal service reliability. Dosimeter package could get lost during return of the package to Landauer.
3. Dosimeters return schedule not documented nor establish.
4. No documentation of reconciliation process when preparing dosimeters packaging for return to Landauer.

Learning Experience:

1. Minimum "M" values in high exposure areas must be questioned and clarified when required.
2. Dosimeters return schedule must be established.
3. Documentation of dosimeter reconciliation process.

Actions necessary to prevent recurrence:

Action description	Responsible	Timing
1. Establish a must frequent dosimeters use inspections. A weekly random inspection to all personnel has been implemented.	E. Díaz / A. Pagán	February 13, 2018 to present.
2. Implement SOP-50 Personal Dosimeter Management, which include Upper and Lower Investigation Limits and Dosimeter return schedule and others dosimetry handling instructions.	E. Díaz / A. Pagán	July 31, 2018
3. Re-Train in dosimeter use to all employees with dosimetry issues.	A. Pagán	July 20, 2018
4. Interview each employee with dosimetry issues.	E. Díaz / A. Pagán	July 19 to 24
5. Submit JR Contaminated dosimeter dose reconstruction, accepted by NRC, to Landauer to correct dose records	E. Díaz / A. Pagán	July 19 to 24

Investigated By: Angel Pagán, EHS Specialist, E.Diaz, RSO

Written By: Angel Pagán/E. Diaz

Date: July 18, 2018

Approved By (if not written by a supervisor or manager): _____

Exhibit A(2) : Safety Bulletin Sent to LMI-PR Staff, May, 2018

Pagan, Angel

From: Pagan, Angel
Sent: Tuesday, May 22, 2018 3:13 PM
To: Blanco, Cesar; Castillo, Alexander; Centeno, Idarmis; Collazo, Renan; Diaz, Eduardo; Diaz, Jessica; Fernandez, Bryan; Figueroa-Diaz, Giovanna L; Flores, Charlie; Flores, Luz; Garcia-Delgado, Rolando; Maldonado, Miguel A; Morales, Reynaldo; Nieves, Jose; Ortiz, Ruben; Peña, Angel; Pineda, Awilda; Ramos, Jose O; Rodriguez, Noel; Rodriguez, Richard; Rosado, Melvin O; Santiago, Edgardo; Torres, Oscar; Vallecillo, Edgardo; Vargas, Virgen; Vazquez, Henry; Vazquez, Miguel; VegaQuinones, Juan
Subject: Boletín Informativo de Seguridad - Uso del dosímetro
Attachments: Radiation Safety Newsletter V6-Use of external dosimetry and performance of radiological surveys (Spanish) - 2018.pdf

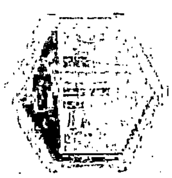
Importance: High

Lantheus MI
Radiopharmaceuticals, Inc.

Boletín Informativo de Seguridad

Tomo 6, revisión mayo de 2018

En este boletín nos concentraremos en los dos elementos más fundamentales del programa de seguridad radiológica, el uso de la dosimetría externa y el realizar monitoreos radiológicos. Es de suma importancia que todos tengamos un claro conocimiento y seamos responsables por el uso y cuidado adecuado de los dosímetros y monitorear el área de trabajo antes, durante y después de trabajar con radioactividad a fin de verificar la seguridad y el control de los materiales radiactivos.



Dosimetría Externa

Nosotros en Lantheus MI Radiopharmaceuticals, Inc. (LMI) requerimos el uso de dosímetros para cualquiera que entre a las áreas restringidas. Dosímetros de anillo se exigen si las dosis de las extremidades se espera que alcance el 10% del límite reglamentario, según el reglamento federal. Las siguientes son las reglas y orientaciones sobre el uso y cuidado adecuado de su dosímetro personal:

junto al otro para asegurarse de que están recibiendo dosis similares.

5. Al salir de la zona restringida, monitoree su dosimetría en el área de cambio de ropa para asegurar que no está contaminada.
6. Al final del día, guarde su dosímetro en un para evitar la pérdida, alteración o uso no a
7. Si su dosímetro se ha perdido o contan notificar al Oficial de Protección Radiológi inmediato y obtener reemplazos antes de v al área restringida. De no ser posible el re asignará una dosis promedio de sus últimas

Monitoreos radiológicos

Cuando se trabaja con material radiactivo, usted necesita constantemente hacerse dos preguntas: 1.) ¿Estoy controlando mi exposición?, y 2.) ¿Estoy controlando el material radiactivo? Usted puede contestarse estas preguntas al tener disponible un "*Survey Meter*", contador o metro de tasa de exposición (R/hr) y tasa de cuentas por minuto (CPM), en el área de trabajo, y utilizándolo de manera periódica

Lantheus MI
Radiopharmaceuticals, Inc.

Boletín Informativo de Seguridad

Tomo 6, revisión mayo de 2018

En este boletín nos concentraremos en los dos elementos más fundamentales del programa de seguridad radiológica, el uso de la dosimetría externa y el realizar monitoreos radiológicos. Es de suma importancia que todos tengamos un claro conocimiento y seamos responsables por el uso y cuidado adecuado de los dosímetros y monitorear el área de trabajo antes, durante y después de trabajar con radioactividad a fin de verificar la seguridad y el control de los materiales radiactivos.

Dosimetría Externa

Nosotros en Lantheus MI Radiopharmaceuticals, Inc. (LMI) requerimos el uso de dosímetros para cualquiera que entre a las áreas restringidas. Dosímetros de anillo se exigen si las dosis de las extremidades se espera que alcance el 10% del límite reglamentario, según el reglamento federal. Las siguientes son las reglas y orientaciones sobre el uso y cuidado adecuado de su dosímetro personal:

1. Ponerse el dosímetro es lo primero que debe hacer tan pronto llega al trabajo. Antes de entrar a una zona restringida, póngase sus dosímetros de cuerpo entero y de anillo, si le han asignado alguno de ellos.
2. Los dosímetros deben ser usados en el lugar donde se espera recibir la dosis máxima durante el curso del día de trabajo. Deben estar orientados hacia la fuente de radiación, (con la etiqueta orientada hacia la fuente). No se ponga el dosímetro en cordones o cuello de camisa a menos que pueda de alguna manera garantizar que el dosímetro seguirá orientado de la manera correcta.
3. Los dosímetros deben ser usados bajo la bata de laboratorio y los guantes, para evitar la contaminación. Sin embargo, si un delantal de plomo está siendo usado, el dosímetro debe usarse sobre el delantal a fin de capturar la dosis a las áreas del cuerpo expuestas.
4. Si también está utilizando los dispositivos de lectura directa de dosimetría (por ejemplo, los dosímetros de lápiz o EPD), su dosímetro regular y el de lectura directa deben ser colocados uno junto al otro para asegurarse de que están recibiendo dosis similares.


Dosímetro EPD

5. Al salir de la zona restringida, monitoree su dosimetría en el área de cambio de ropa para asegurar que no está contaminada.
6. Al final del día, guarde su dosímetro en un lugar seguro para evitar la pérdida, alteración o uso no autorizado.
7. Si su dosímetro se ha perdido o contaminado, debe notificar al Oficial de Protección Radiológica (RSO) de inmediato y obtener reemplazos antes de volver a entrar al área restringida. De no ser posible el remplazo, se le asignará una dosis promedio de sus últimas 6 lecturas.

Monitoreos radiológicos

Cuando se trabaja con material radiactivo, usted necesita constantemente hacerse dos preguntas: 1.) ¿Estoy controlando mi exposición?, y 2.) ¿Estoy controlando el material radiactivo? Usted puede contestarse estas preguntas al tener disponible un "***Survey Meter***", contador o metro de tasa de exposición (R/hr) y tasa de cuentas por minuto (CPM), en el área de trabajo, y utilizándolo de manera periódica para verificar condiciones de seguridad radiológica. Al salir del área de trabajo, los guantes deben ser monitoreados. Si están contaminados, deben ser cambiados y la fuente de contaminación encontrada. Se recomienda encarecidamente que usted no simplemente se quite y disponga de los guantes sin monitorearlos, ya que perderá información importante si están contaminados. Asimismo, el Manual de Protección Radiológica (sección IV) de LMI requiere que los empleados monitoreen y limpien las áreas de trabajo después de haber trabajado con material radiactivo. Si usted deja el área de trabajo sin monitorearla, usted está dejando una condición potencialmente peligrosa atrás donde un compañero de trabajo, sin saberlo, puede estar expuesto.

Recuerde contactar al RSO (Ext. 2503) o a la oficina de EHS (Ext. 2518) si desea adiestramiento sobre el uso del Metro y/o realizar monitoreos radiológicos.

Exhibit A (3): Training Attendance Form from March 2018 training of IE on dosimetry use

Lantheus MI
Radiopharmaceuticals, Inc.

ATTENDANT SHEET

Course or Meeting Title: Dosimetry USe	Date: MAR-12-2018
SOP Code:	Place/ Room: PET LAB
Revision:	Time: 1:00 PM

Training ☐ / Meeting ☐:
- ☐ SOP ☐ New ☐ Revised
- ☑ Operations, EHS, QA/QC
- ☐ Sales / Customer Service
- ☐ Staff Meeting, HR, Administrative
- ☐ Other_____

Resource:
- ☑ Employee
- ☐ External / Consultant
- ☐ Self Study – I Certify that I have study the procedure /program
- ☐ Corporate Training

Duration:_____ (HH:MM)

Instructor Name	Signature	Title/Company
Angel Pagan		EHS Specialist
☐ Training	☑ Re-training	☐ Refresher

	Name	Signature	Department/ Business/Area	Supervisor
1	Cesar Blanco		pet	N. Rodriguez
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

Exhibit A(4) : Examples of RISC agenda's and LMI-PR presentations

Date: August 16, 2018

To: Billerica Radioisotope and Safety Committee

From: Julie Hanlon

Subject: **AGENDA FOR RISC MEETING –August 23, 2018**

Our next Radioisotope and Safety Committee meeting is scheduled for August 23, 2018 at 9:00 AM in Building 300-2, Conference Room 1. An agenda follows:

Guests' Agenda

Investigation Reports and CAPAs

- **RPO Action Level Responses for Review/Approval:**
  - RPO-18-11 M. Schmidt Long lived radioactive material found in Hold-For-Decay
  - RPO-18-12 C. Kincaid Removable Contamination Exceeding Action Level
  - RPO-18-13 M. Schmidt Broken Tl-201 Vial in Vial line Unload
  - RPO-18-14 C. Kincaid WB exposure Exceeding Monthly Action Level

Pending Completion:

- RPO-18-16 S. Whitney Missing/Lost Xe-133 Vial
- RPO018-17 M. Wojtas Generators sent off Site with Incorrect Labels

- **August 2018 Corrective Actions Pending Closure/Review of Closed Items – Guests and RISC Member**
- **Presentations and Special Issue Updates:**
  - Quarterly Manager Report (with Waste Minimization Update)
    - Cyclotron Ops G. Barbin
    - Cyclotron Support J. Singelais
    - Product Shipment F. Yeschanin (or designee)
    - Mo-99 and Xe-133 F. Yeschanin (or designee)
    - Vial Team F. Yeschanin (or designee)
    - Process Support V. Molina
  - LMI Puerto Rico July Dose Review – E. Diaz
  - EHS 2nd Quarter Report – R. Naylor

Members' Agenda

Routine Items – RISC Members

1. **Acceptance of July 26, 2018 RISC Meeting Minutes**
2. **Previous Next Steps: Review and Update July 26, 2018 RISC Next Steps**
3. **Authorized Users and Managers of Radiological Operations – J. Hanlon**
4. **DOT Inspection Update – J. Hanlon/J. Hayes**
5. **Regulatory Update- J. Hanlon, D. Brown**

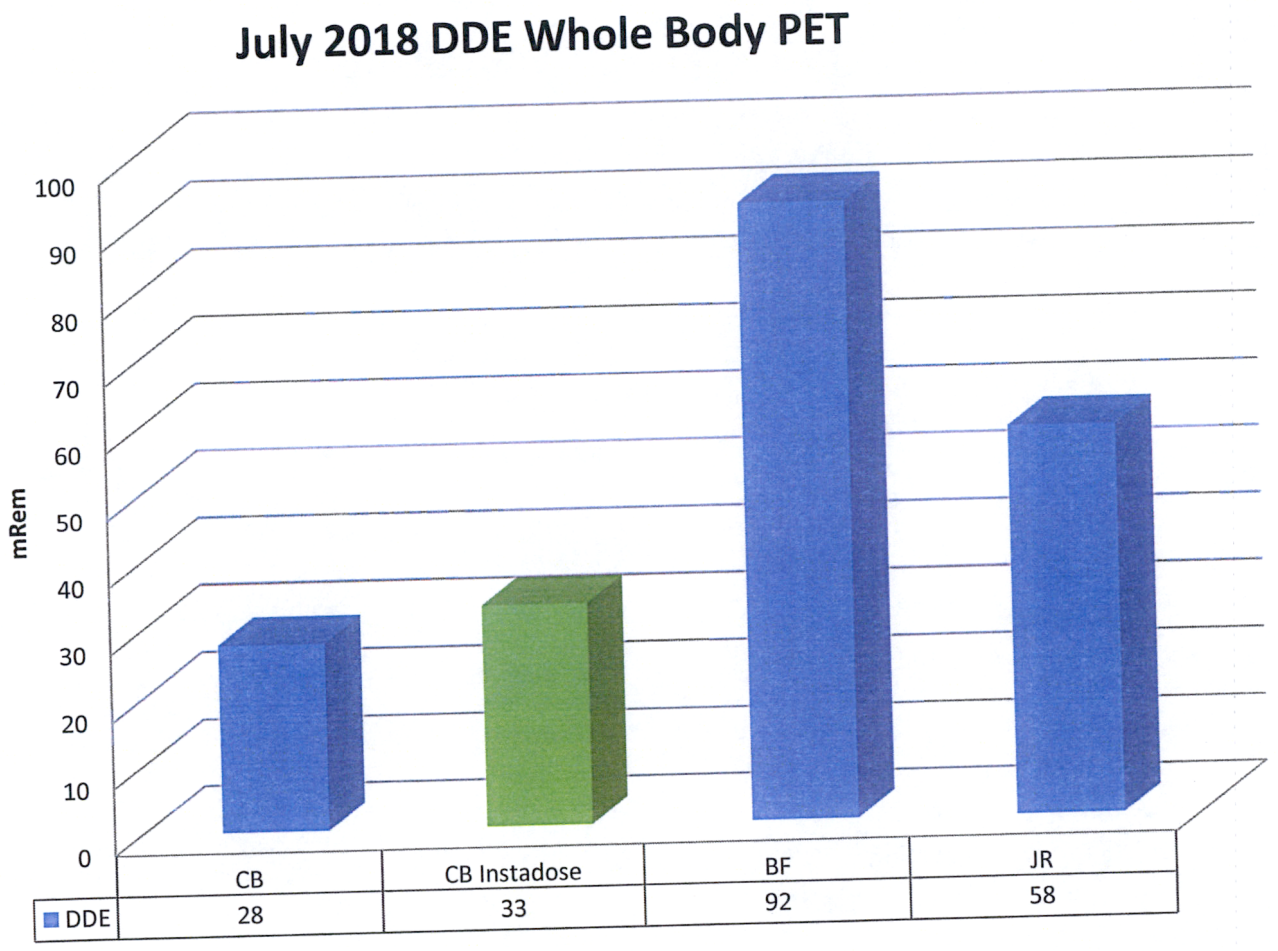
- New NRC regulation about Mo Breakthrough

6. **Pulse Check on RISC Objectives – All**

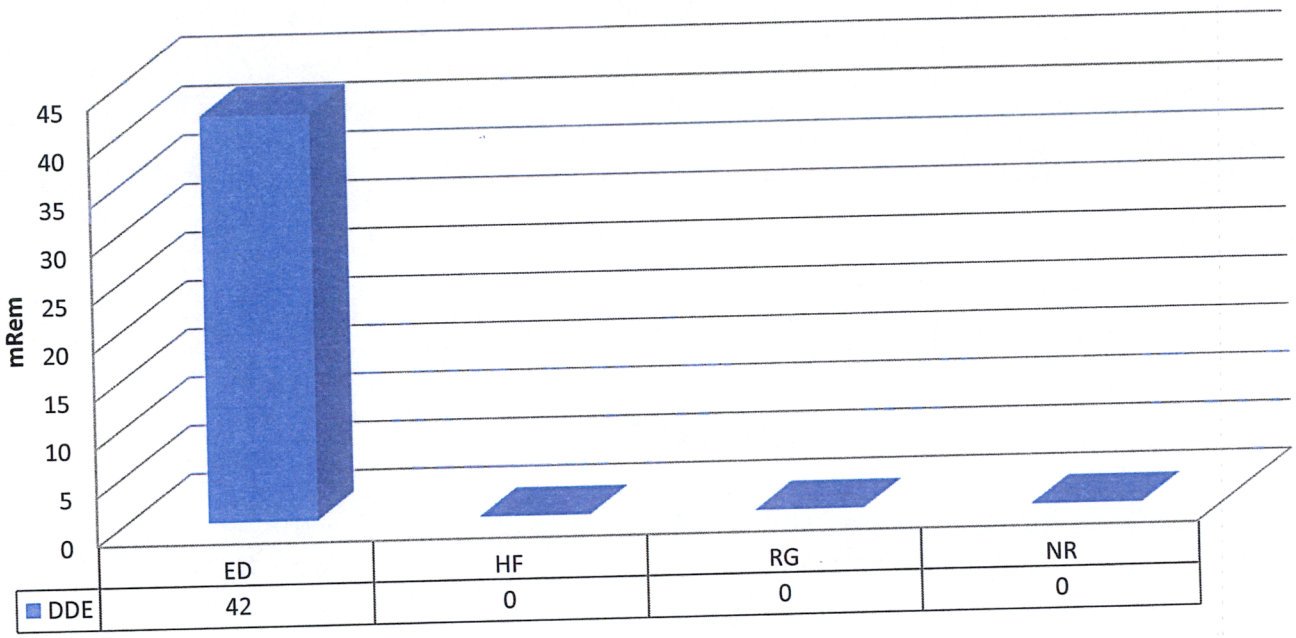
7. **Performance Against RISC Target Tracking for July Review and Discuss- All**

Closing Items

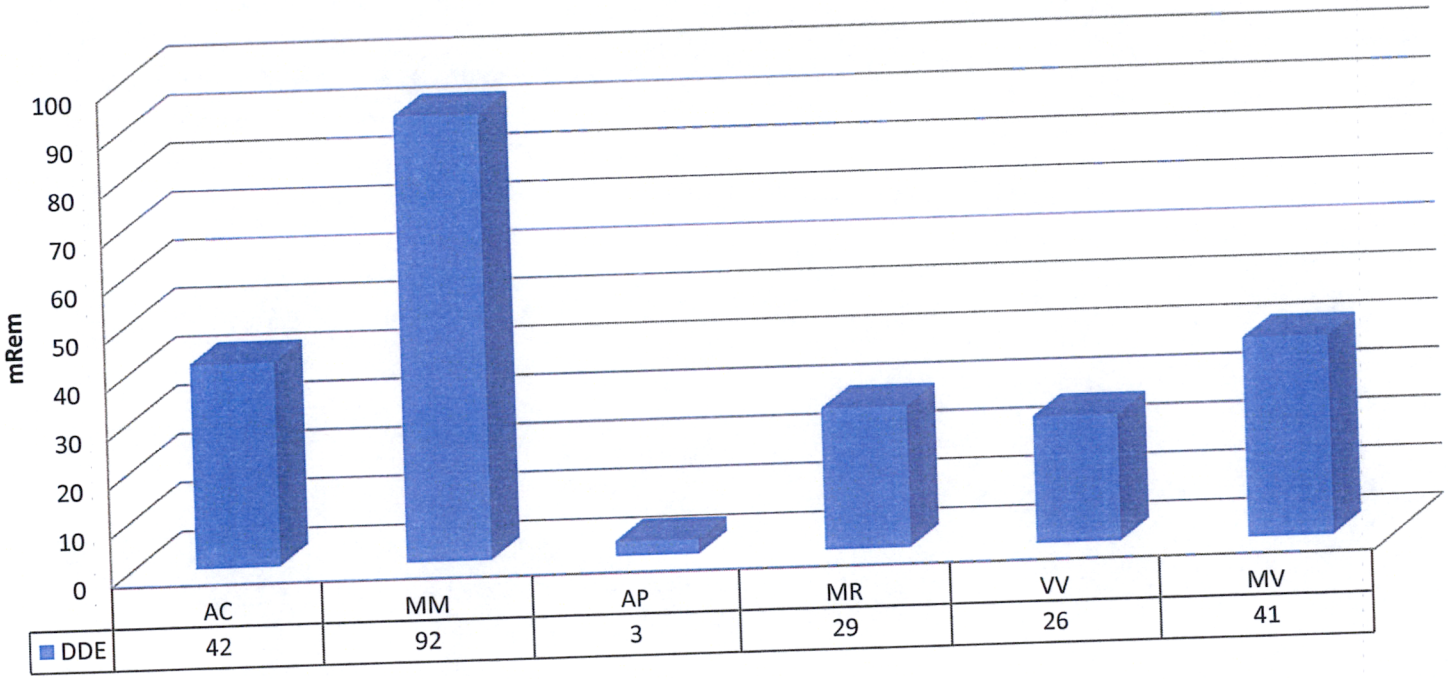
1. **Other Business – RISC Members**
2. **Review New Next Steps from this Meeting – F. Yeschanin**
3. **Important Messages from this Meeting – RISC Members**


July 2018 DDE Whole Body PET
mRem
100
90
80
70
60
50
40
30
20
10
0
CB
CB Instadose
BF
JR
DDE
28
33
92
58

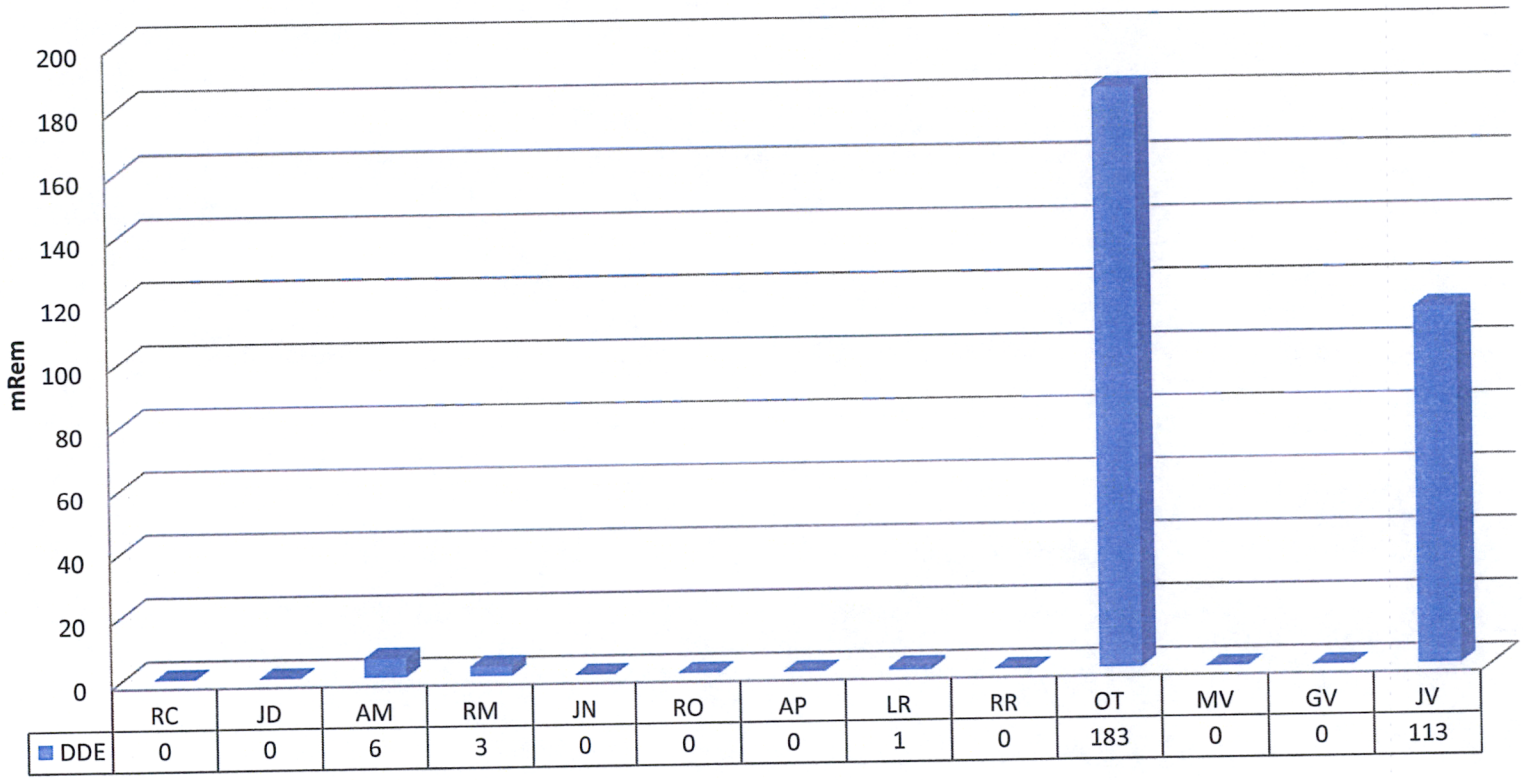
July 2018 DDE Whole Body - Radiopharmacist



July 2018 DDE Whole Body
SPER



July 2018 DDE Whole Body - CSD



	RC	JD	AM	RM	JN	RO	AP	LR	RR	OT	MV	GV	JV
DDE	0	0	6	3	0	0	0	1	0	183	0	0	113

Date: January 16, 2020

To: Billerica Radioisotope and Safety Committee

From: Julie Hanlon

Subject: **AGENDA FOR RISC MEETING- January 23, 2020**

Our next Radioisotope and Safety Committee meeting is scheduled for January 23, 2020 at 9:00 AM in Building 300-2, Conference Room 1. An agenda follows:

Guests' Agenda

Investigation Reports and CAPAs

- **Investigations that Required Revisions (none):**
- **Investigations for Review and Approval:**
  - RP-19-25 F Yeschanin Removable Contamination above Action Level

Pending Completion (February 2020 RISC Meeting):

- RP-19-27 S. Chandler/V. Molina Dropped sterilizer tray and associated personal contamination
- RP-20-01 C. Kincaid Personal contamination
- RP-20-02 S. Chandler Xe release above action level

- **January 2020 Corrective Actions Pending Closure/Review of Closed Items – Guests and RISC Member**
- **Presentations and Special Issue Updates:**
  - LMI Puerto Rico Dose Review – PR (informational purposes only)
  - Molyworld update – J. Haepers
  - PSC update – J. Singelais
  - EHS 4th Quarter Report- B. Naylor
  - 3rd Quarter Manager Report
    Product Shipment Sean Whitney (or designee)

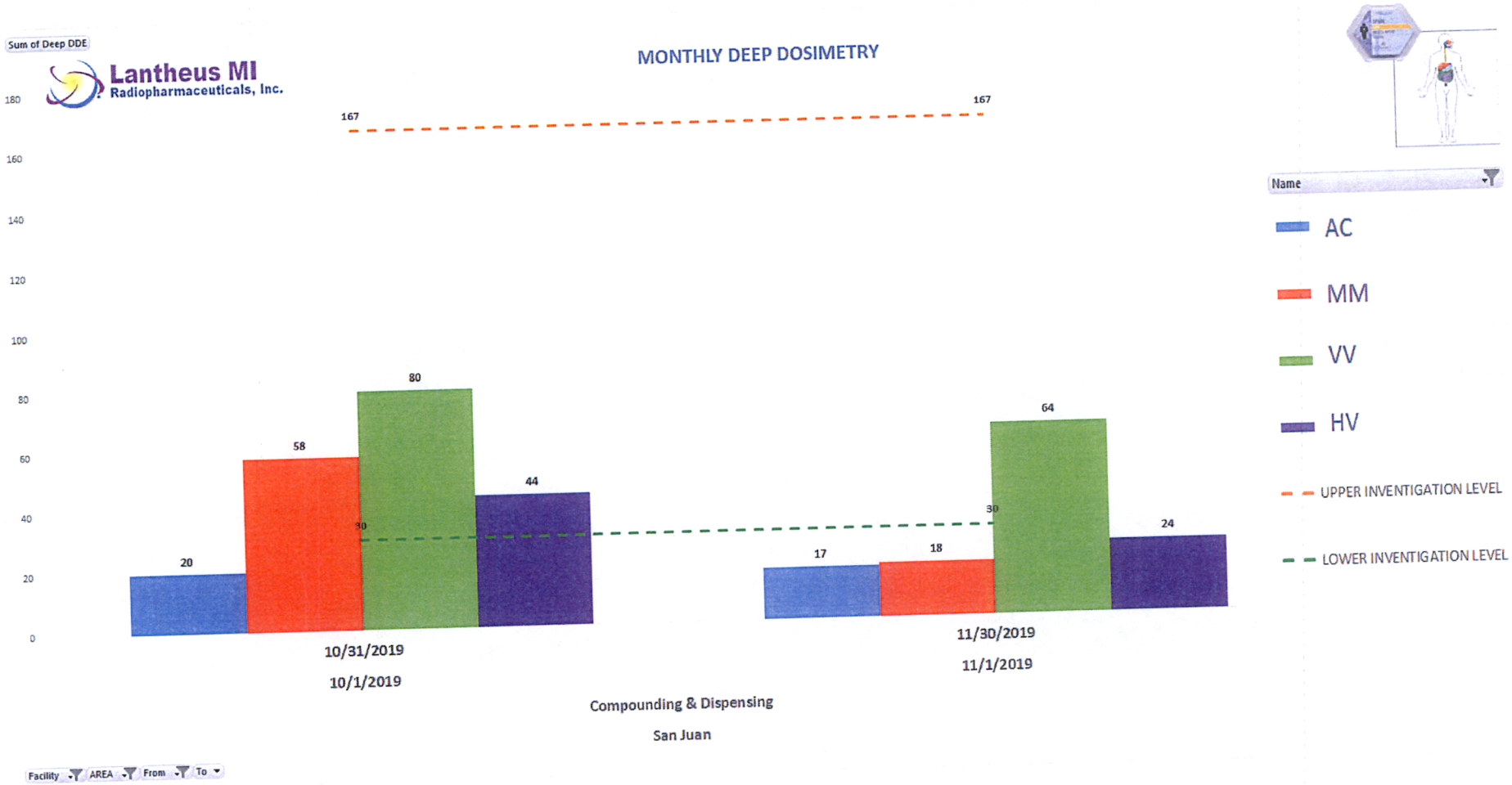
Routine Items – RISC Members

1. **Acceptance of December 5, 2019 RISC Meeting Minutes- All**
2. **Previous Next Steps: Review and Update December 5, 2019 RISC Next Steps- All**
3. **Review of SP-01 Subcommittee Update – C. Grant**
4. **RISC Objective/ALARA discussion – M. Kralian/J. Hanlon**
5. **New RSO Status- J. Hanlon**
6. **Authorized Users and Managers of Radiological Operations – J. Hanlon**

Closing Items

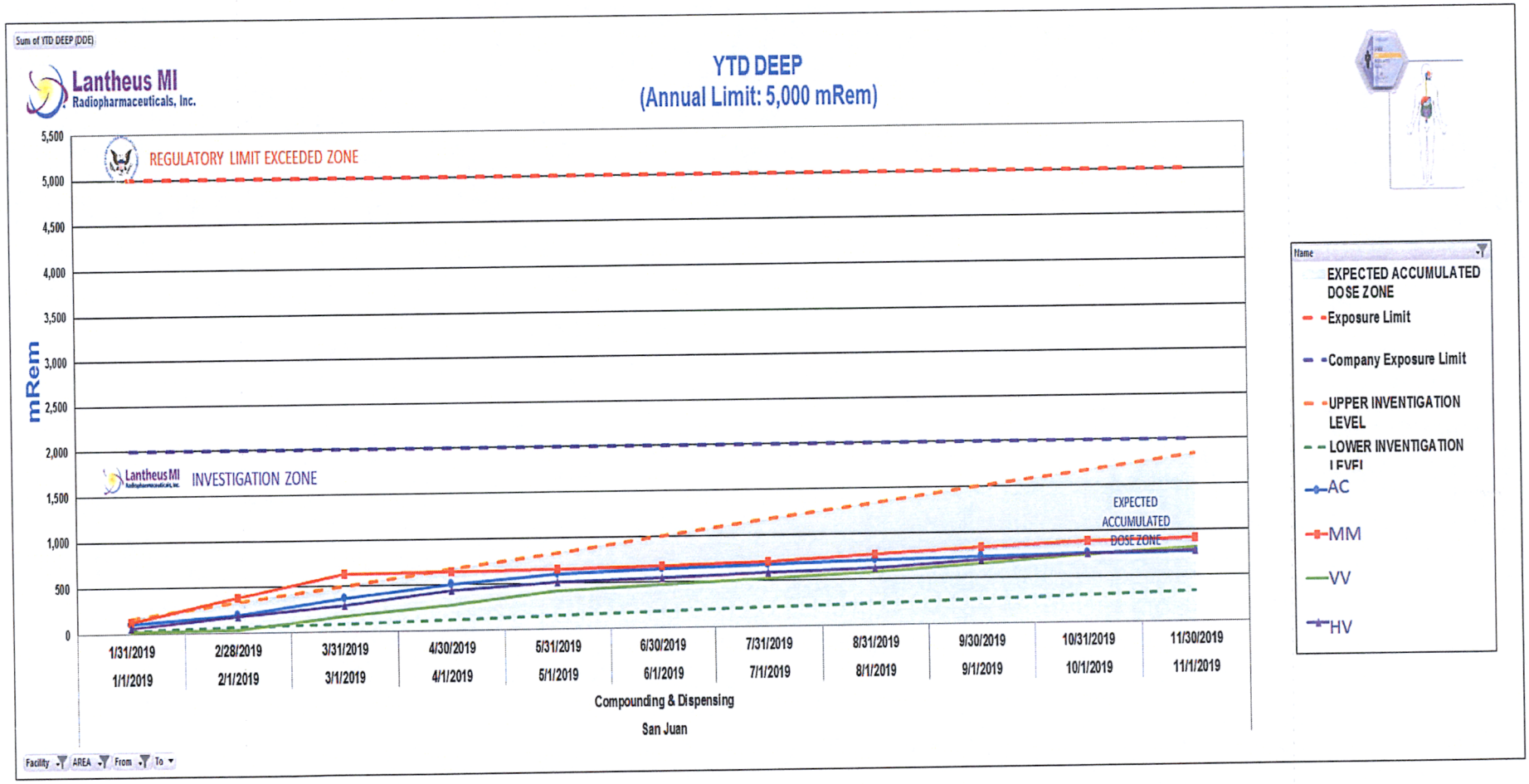
1. **Other Business – RISC Members**
   Review New Next Steps from this Meeting –J. Hanlon
2. **Important Messages from this Meeting – RISC Members**

SPER Lab , Compounding Task, Deep Dose by Month
Oct 2019 to Nov 2019

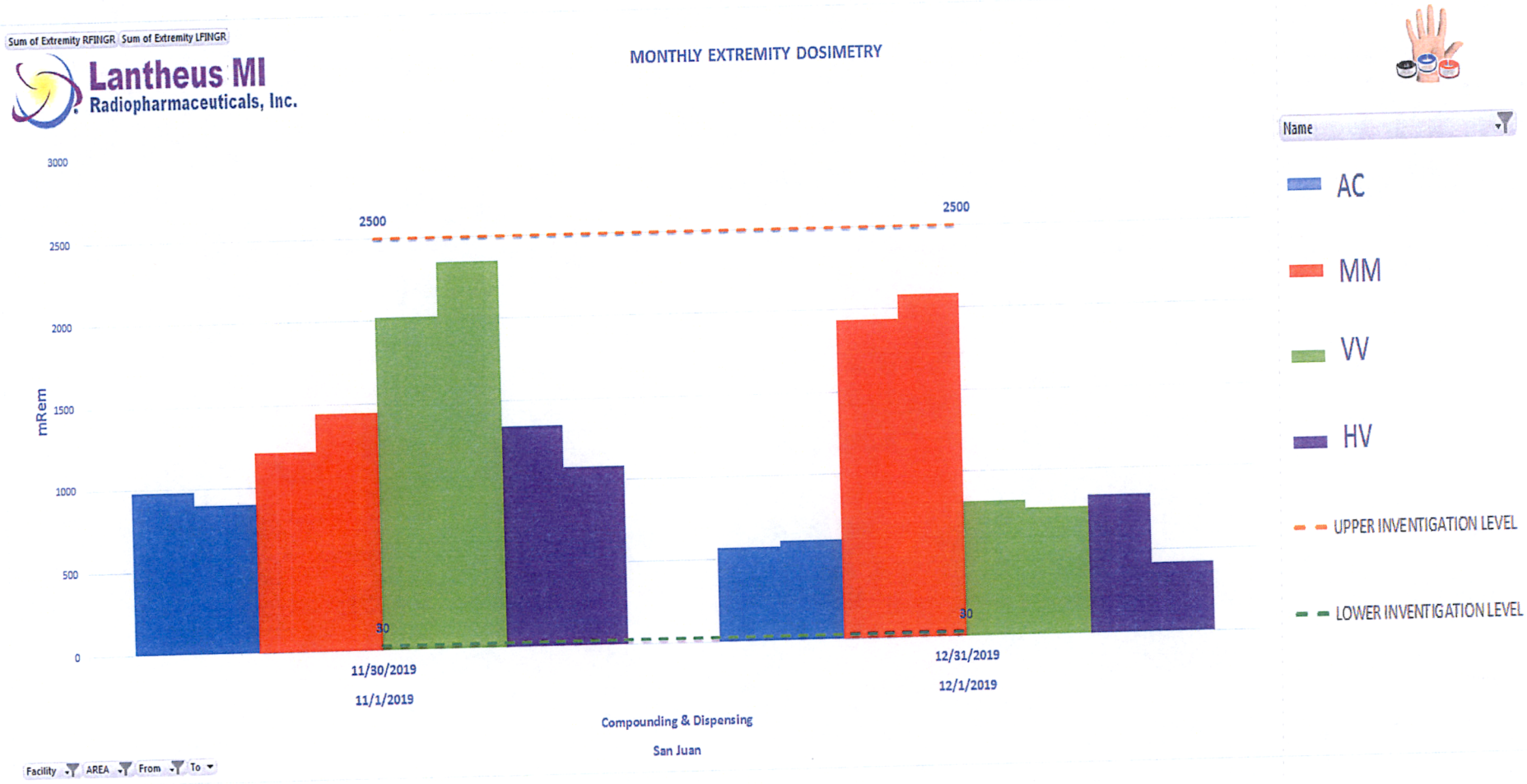


SPER Lab , Compounding Task, Deep Dose:

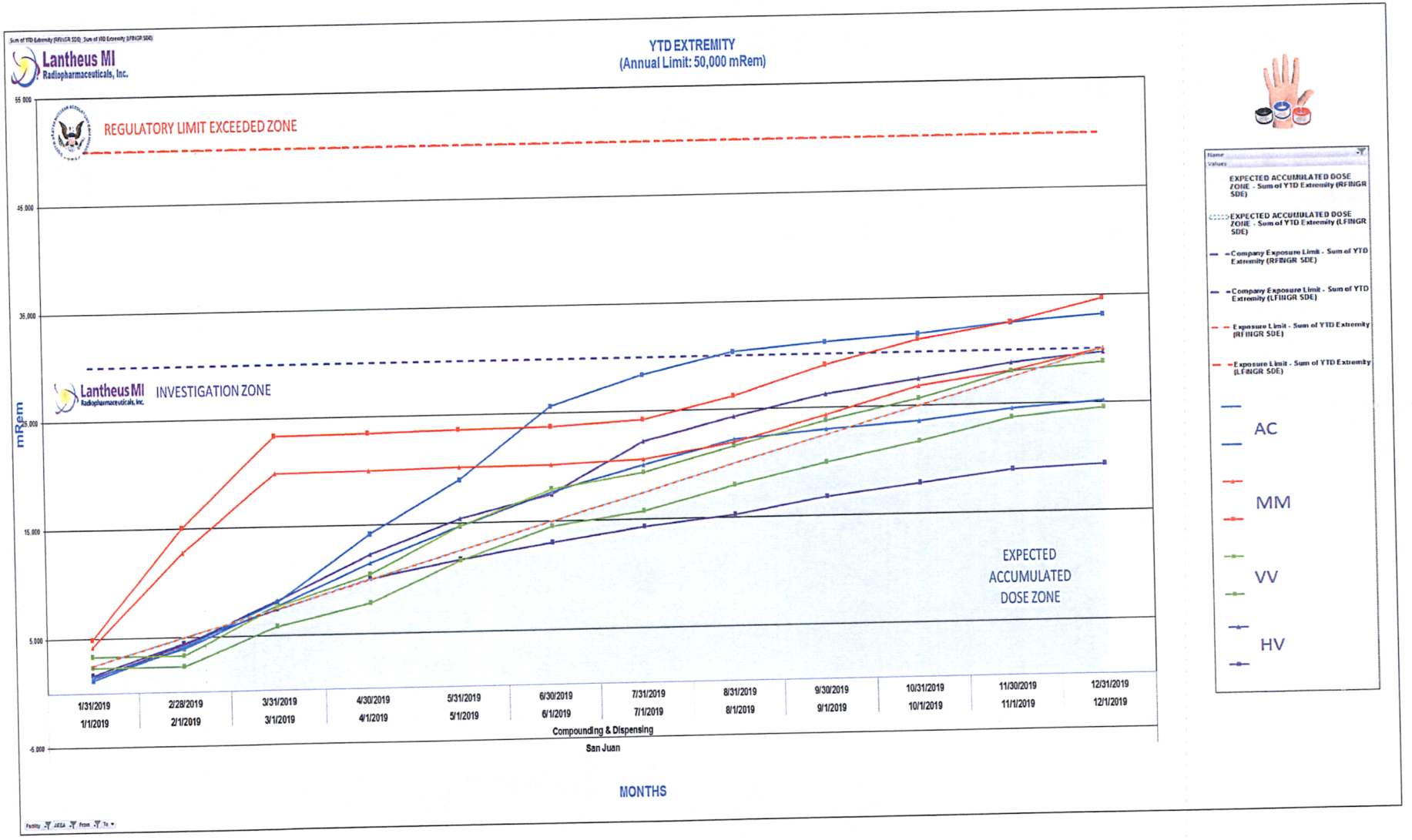
SPER Lab , Compounding Task
Accumulated Deep Dose YTD
Jan 2019 to Nov 2019



SPER Lab , Extremity Dose by Month
Nov to Dec 2019



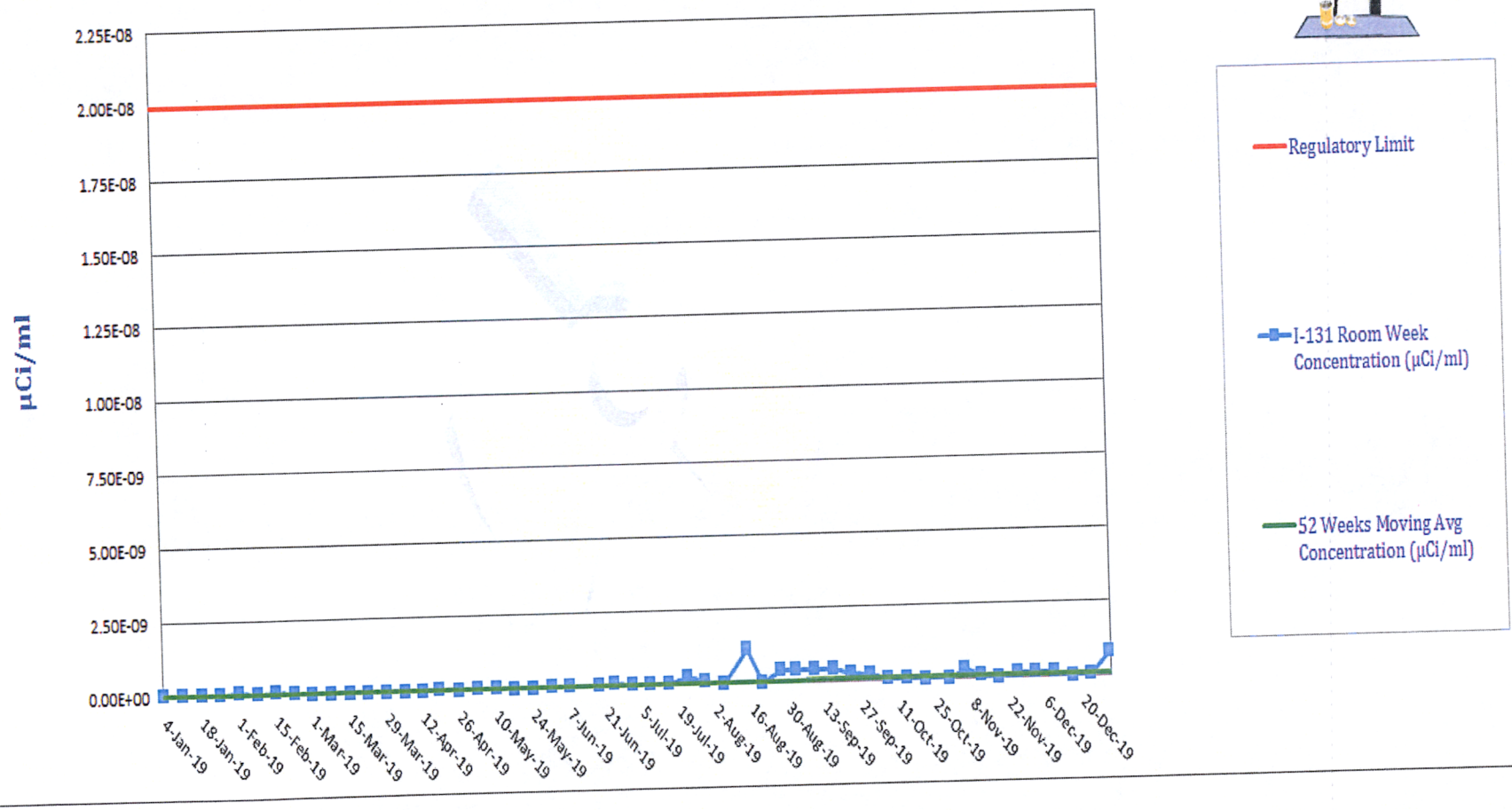
SPER Lab , Compounding Task
Accumulated Extremity Dose YTD
Jan 2019 to Dec 2019



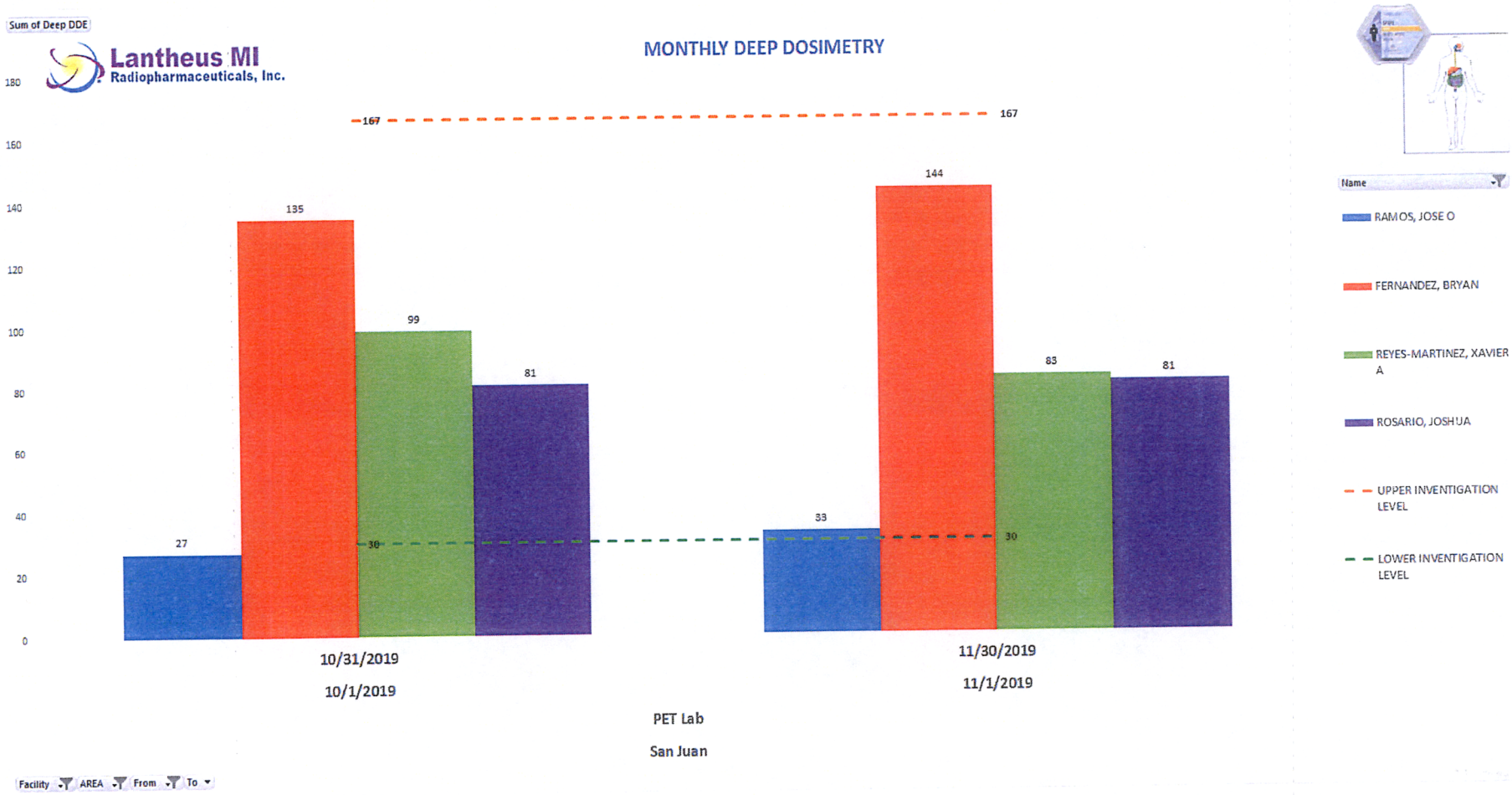
Lantheus MI
Radiopharmaceuticals, Inc.

2019

I-131 Room Inhalation Concentration

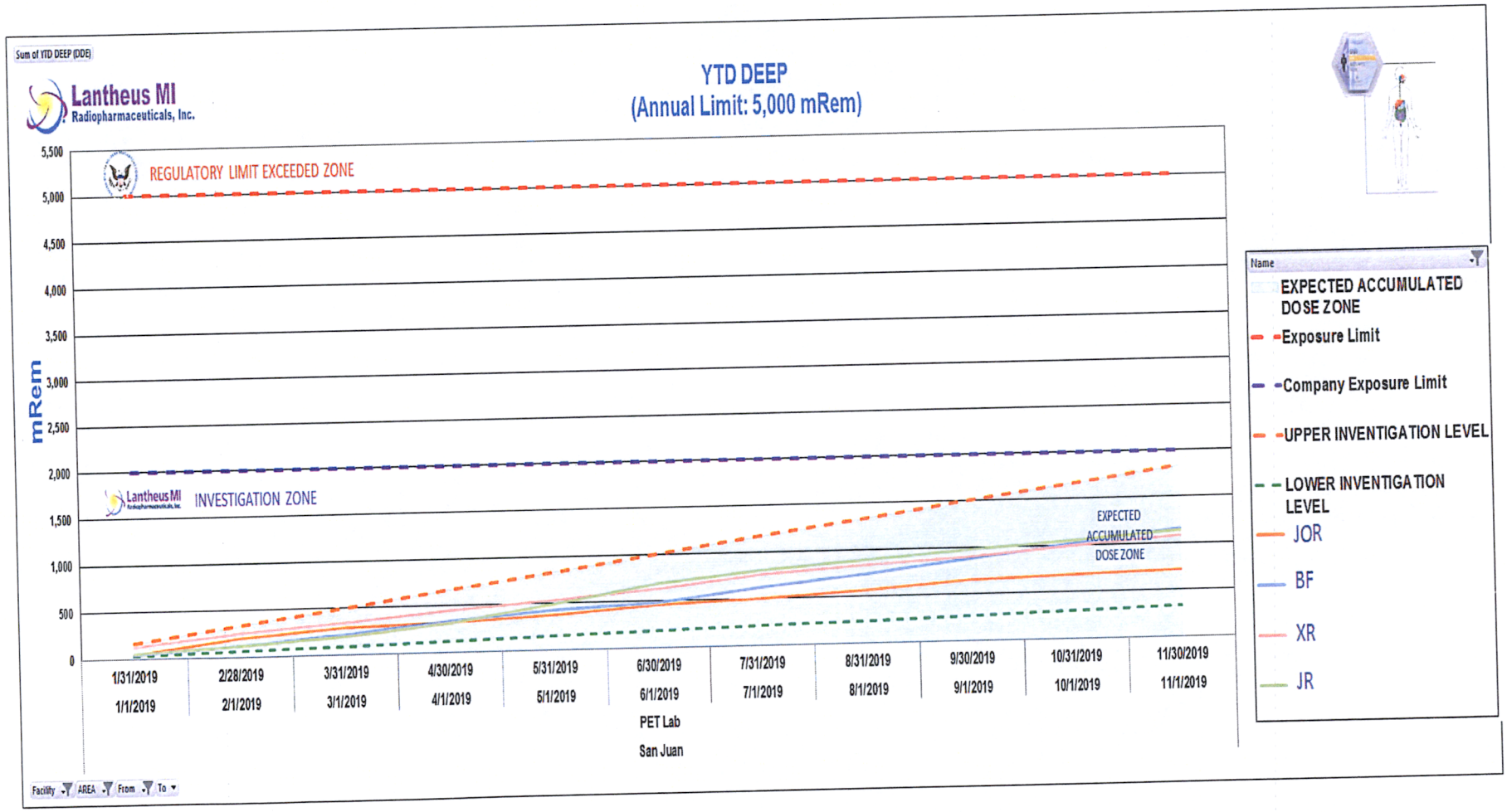


PET Lab , Deep Dose by Month
Oct - Nov 2019

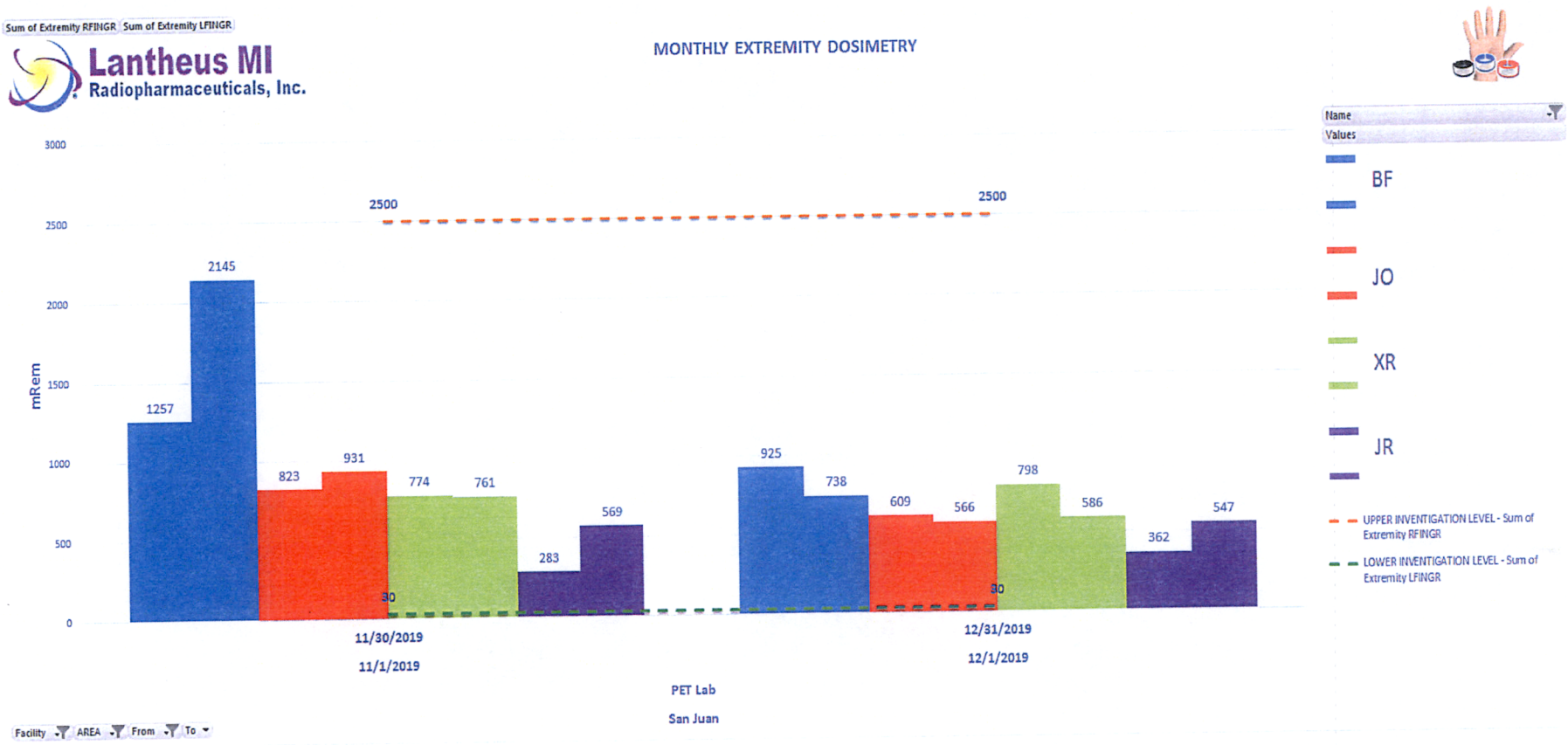


PET Lab, Deep Dose:

PET Lab
Accumulated Deep Dose YTD
Jan 2019 to Nov 2019

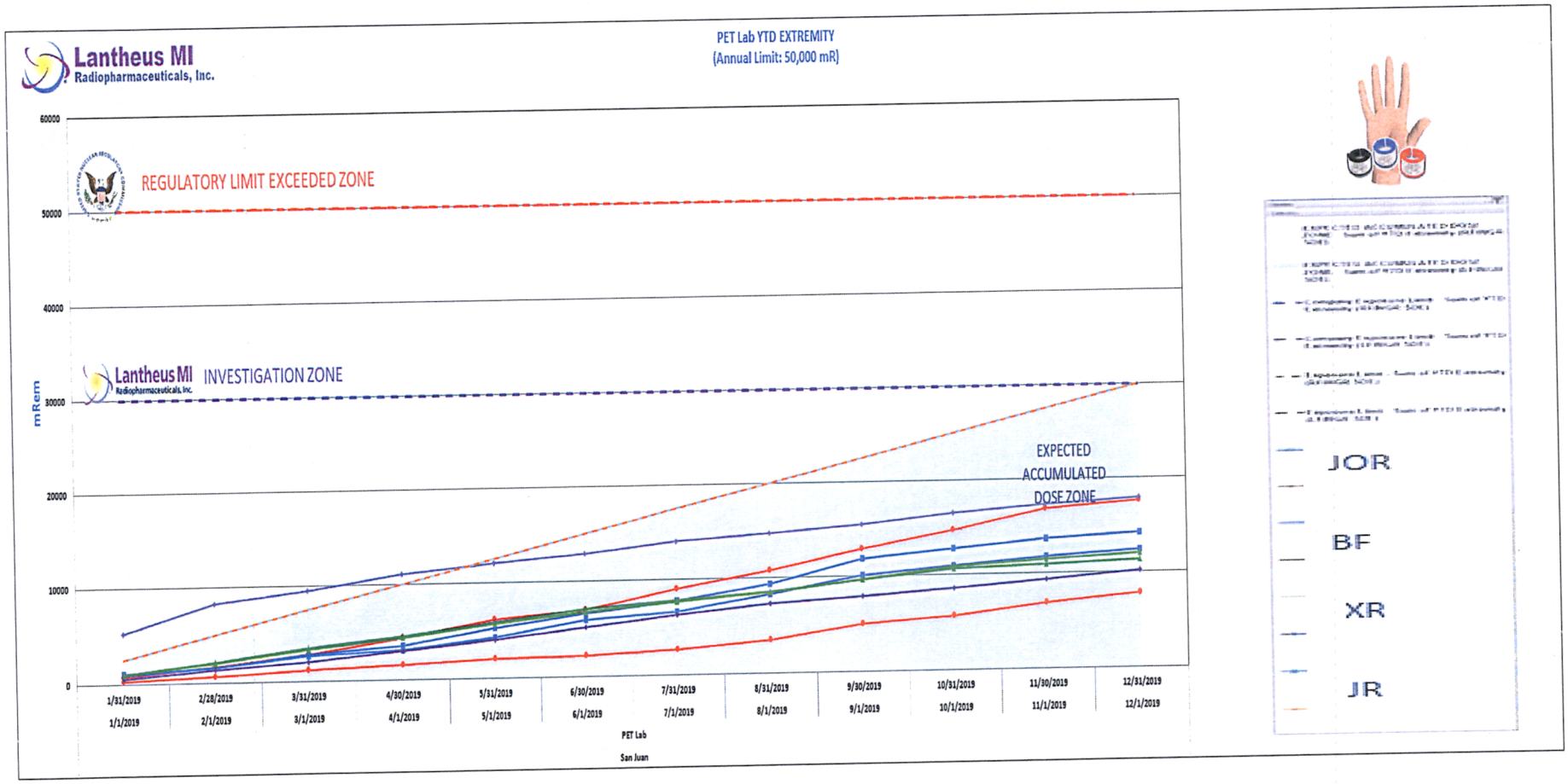


PET Lab , Extremity Dose by Month
Nov - Dec 2019

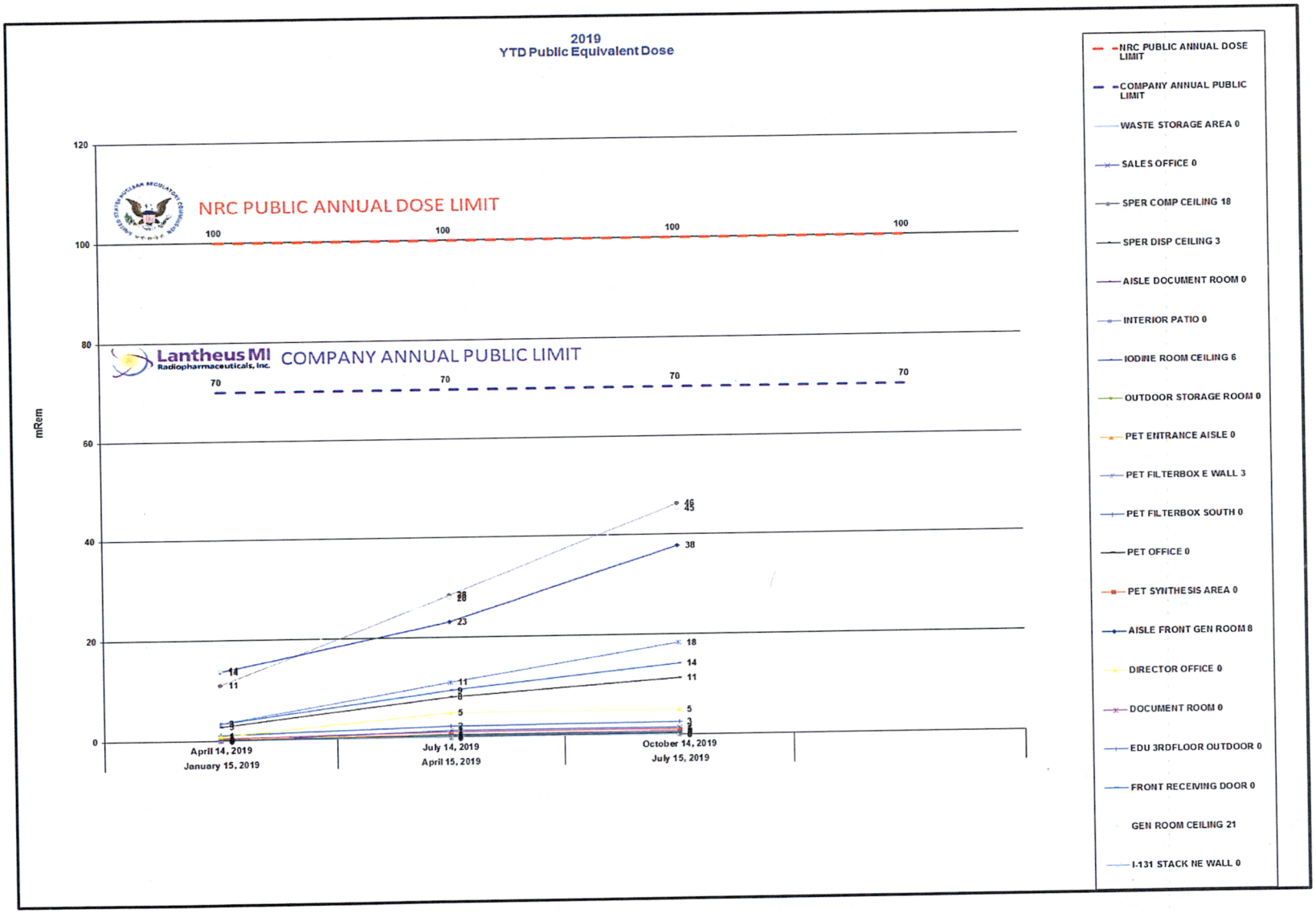


PET Lab, Extremity Dose:
BF was also covering JO during Nov 2019

PET Lab
Accumulated Extremity Dose YTD
Jan 2019 to Dec 2019



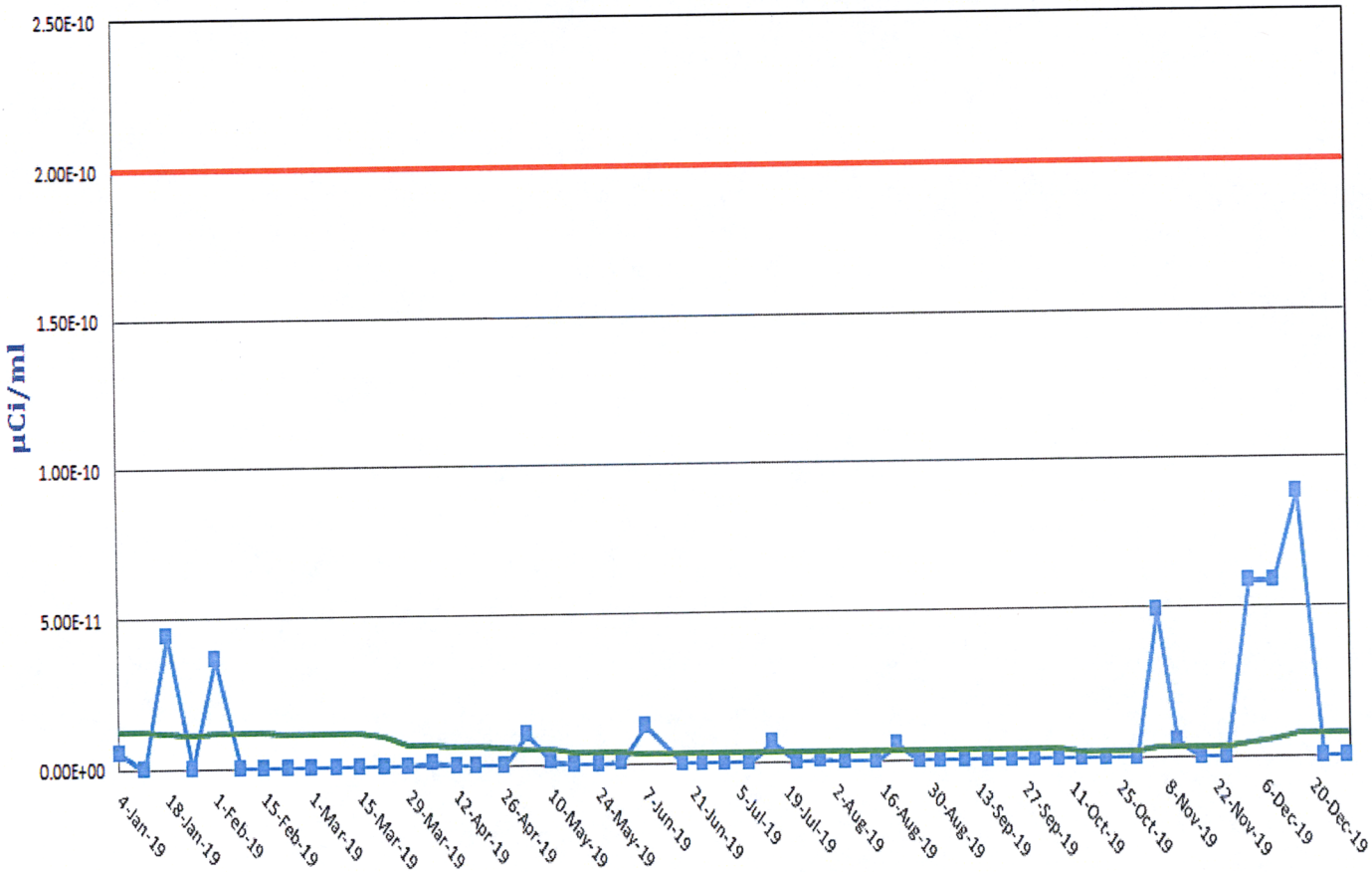
PUBLIC Dose by Quarter
Jan to Oct 2019



Lantheus MI
Radiopharmaceuticals, Inc.

2019

I-131 Concentration at stack release



NRC's DAC Limit for I-131 (µCi/ml)

I-131 Stack Week Concentration (µCi/ml)

52 Weeks Moving Avg Concentration (µCi/ml)

Exhibit A(5) : Letter to Landauer updating IE dose

February 5, 2020

2.0.10/29/99

Landauer Inc.
2 Science Road
Glenwood, IL. 60425-1586

Re: Landauer Accounts: 153052

Dear Landauer Representative,

Please add the following dose to the employee: Cesar Blanco; ID: 153052-00084, for the given exposure period. This dose is **in-lieu** of any dose received during this exposure period.

Call me at (787) 765-5598 if you have questions.
Sincerely,

Rolando Garcia
Radiation Safety Officer

Internal EXPOSURE ASSIGMENTS

Period	DEEP	LENS	SKIN	Right hand Extremity Dose (mrem)	Left hand Extremity Dose (mrem)
Jan-2016	188	191	192	1,245	1,429
Feb-2016	282	287	288	1,868	2,144
Mar-2016	188	191	192	1,245	1,429
Apr-2016	188	191	192	1,245	1,429
May-2016	188	191	192	1,245	1,429
Jun-2016	282	287	288	1,868	2,144
Jul-2016	188	191	192	1,245	1,429
Aug-2016	188	191	192	1,245	1,429
Sep-2016	235	239	240	1,557	1,787
Oct-2016	329	335	336	2,179	2,501
Nov-2016	235	239	240	1,557	1,787
Dec-2016	329	335	336	2,179	2,501
2016 Total	2,820	2,868	2,880	18,680	21,440
Jan-2017	141	143	144	934	1,072
Feb-2017	235	239	240	1,680	1,860
Mar-2017	329	335	336	2,179	2,501
Apr-2017	235	239	240	1,557	1,787
May-2017	141	143	144	934	1,072
Jun-2017	188	191	192	1,245	1,429
Jul-2017	327	331	331	2,640	1,940
Aug-2017	470	478	480	3,113	3,573
Sep-2017	94	96	96	623	715
Oct-2017	141	143	144	934	1,072
Nov-2017	282	287	288	1,868	2,144
Dec-2017	470	478	480	3,113	3,573
2017 Total	3,053	3,103	3,115	20,821	22,739
Jan-2018	235	239	240	1,557	1,787
Feb-2018	399	401	401	2,820	2,859
Mar-2018	179	180	180	1,610	1,290
Apr-2018	371	372	372	2,510	6,378
May-2018	143	146	146	1,094	1,503
Jun-2018	131	133	133	1,140	1,409
Jul-2018	28	29	29	163	122
Aug-2018	35	36	36	283	397
Sep-2018					
Oct-2018					
Nov-2018					
Dec-2018					
2018 Total	1,486	1,500	1,501	11,162	15,725

Exhibit C (1) : Contract with 3rd Party for Radiation Safety Support

RSCS
Radiation Safety & Control Services

PROPOSAL

For

Radiological Support Services

To

Lantheus Medical Imaging, Inc.

Submitted By:

Radiation Safety & Control Services, Inc.
93 Ledge Road
Seabrook, NH 03874

Submitted On:

October 8, 2019

Proposal No. LANTHEUS-008, Revision 04

Table of Contents

1 Introduction

Radiation Safety & Control Services, Inc. (RSCS) is pleased to submit this proposal to Lantheus Medical Imaging, Inc. (LMI) for radiological support services for the LMI Puerto Rico (LMI PR) facility. A description of the scope of work is provided in Section 4.

Revision 02 to this proposal was issued to change the pricing structure from time and materials (T&M) to Firm Fixed Price (FFP) and to incorporate the results of our meeting at LMI on 6/17/19 which changed the requested scope of work to reflect work already in progress by LMI personnel. Revision 03 to this proposal was issued to respond to LMI comments and provide clarification in Task 3 and Task 7. Revision 04 is issued to assign estimated timeframes for completion of tasks in Section 4.

2 RSCS Company Overview

RSCS, Inc. was established in 1989 and is owned and operated by three principals. The company is fully insured and is an equal opportunity small business employer. Each of the principals has earned Health Physics degrees from the University of Massachusetts Lowell in Radiological Sciences and Protection and has earned Comprehensive Certification from the American Board of Health Physics.

The company is actively involved in: radiation protection consulting, instrumentation consulting, instrument repair and calibrations, radon testing and remediation, training in radiation protection and radiochemistry, instrumentation sales and service, and professional staffing services. The RSCS corporate headquarters in Seabrook, New Hampshire is home to our support offices, our analytical laboratory, and our instrument calibration and repair facility. The RSCS home office staff includes radiation protection professionals including administrators, project managers, health physicists, radiochemists, and laboratory and instrumentation specialists. The RSCS field support staff includes individuals experienced in radiation protection, engineering, industrial safety, and project management.

Radiation Safety and Control Services (RSCS) provides full spectrum service assisting our clients with innovative and cost effective solutions for use of radioactive materials and radiation generating equipment: Our range of services include:

- Health Physics Consulting
- Management and Technical Support
- Shielding Evaluations in support of Dental and Medical facilities
- Incident Response, On-Site and Off-Site Exposure Evaluations
- Radiation Safety Program Audits
- License Applications and Amendments
- Procedure and Program Writing
- Environmental, Area/Facility and Personnel Monitoring and Reporting
- Groundwater Contamination Support
- Decommissioning Support (MARSSIM)
- Waste Minimization, Characterization, Shipping
- Sample Analysis Data Management and Reporting

- Instrumentation calibration and repair services

RSCS specializes in assisting licensees such as hospitals, laboratories, universities and industrial organizations. Services include staff support, license application and program development, facility audits, facility and personnel monitoring, staff training, and environmental sampling and monitoring. On-going support such as Radiation Safety Officer (RSO) oversight and annual audits to satisfy 10 CFR 20 requirements represent RSCS core competencies.

3 Our Staff

We recognize that the utilization of people with the appropriate education and experience is critical for project success; and RSCS provides project support personnel with the skill set needed to successfully complete the required project tasks in the most cost-effective manner possible.

We have experience dealing with the public and many of our senior staff have years of experience acting as site representatives on advisory committees and speaker's bureaus set up to address public issues related to nuclear operations and decommissioning.

The RSCS consulting / technical support staff has included the following professionals:

- Certified and Senior Health Physicists
- Radiation Protection Managers
- Health Physics Managers and Supervisors
- Radioactive Material Shipping Specialists
- Decontamination Supervisors and Specialists
- Health Physics Specialists
- Radiological Engineers
- Radiological Waste Characterization and Shipping Specialists
- Hydrologists and Groundwater Specialists
- Cost-Estimation Engineers
- Regulatory Control and Licensing Engineers
- Outage and Decommissioning Project Managers

4 Scope of Services

We propose to provide our services to support the implementation by LMI PR of a resource loaded corrective action plan to improve the content, structure and implementation of the LMI PR Radiation Protection Program and to also provide input to the overall Radiation Safety Program for Lantheus Medical Imaging, Inc. The scope of services we envision providing is provided in the following tasks. It is understood that some of the tasks are for consideration and may be implemented at a future date. Estimated timeframes for completion of the tasks assume effective communications with timely responses and the provision of needed documents, as detailed in the specific tasks below. It is recommended that prior to initiation of the initial task upon contract award, a conference call or meeting be conducted to discuss the current activities and initiatives underway at LMI PR.

4.1 Task 1

- Review and comment on LMI PR Radiation Protection Program procedures. The review will encompass determining functional adequacy, addressing of previously identified issues and determining missing program scope.
- Based on the waste inventory provided by LMI, review and comment on the LMI PR waste management strategy and disposal options for long lived radionuclides.
- The deliverable will be an RSCS Technical Support Document (TSD) describing the results of our review, comments, observations, conclusions and recommendations.
- Approximate time to complete task – 1 month (can be done in parallel with Tasks 2 and 3)

4.2 Task 2

- Review the implementation status of the LMI PR Corrective Action Plan.
- The deliverable will be a report (RSCS TSD) describing the results of our review, comments, observations, conclusions, and recommendations.
- Approximate time to complete task – 1 month (can be done in parallel with Tasks 1 and 3)

4.3 Task 3

- Review the new Radiation Safety Training materials developed by LMI PR.
- The deliverable will be a report (RSCS TSD) describing the results of our review, comments, observations, conclusions, and recommendations. The cost for Task 3, provided in Section 5.3, assumes one round of comments and comment resolution.
- Approximate time to complete task – 1 month (can be done in parallel with Tasks 1 and 2)

4.4 Task 4

- Review LMI Billerica KPI's and provide guidance on how best to revise them to be specific to LMI PR.
- The deliverable will be a report (RSCS TSD) describing the results of our review, comments, proposed revisions to the KPI's and new more detailed KPI's if applicable.
- Approximate time to complete task – 2 weeks (can be done in parallel with Task 7)

4.5 Task 5

- Review and comment on the Cyclotron License Renewal application documentation. The review will include and require previous license applications and amendments to ensure all commitments are met.
- The deliverable will be a report (RSCS TSD) describing the results of our review, comments, conclusions and recommendations
- Approximate time to complete task - 2 weeks

4.6 Task 6

- Perform an effluent release assessment for the LMI PR facility to provide a basis for the determination of the level of effluent monitoring required.
- The deliverable will be a report (RSCS TSD) describing the results of our assessment, conclusions, and recommendations. The report will form a comprehensive basis for effluent monitoring at LMI PR.
- Approximate time to complete task – 4 weeks

4.7 Task 7

- Develop high level LMI Radiation Protection policy documents/statements. The documents produced would address 2 levels, the first would be a high level corporate vision and the second would be focused more on how the vision is implemented. We envision working closely with LMI to focus our approach and developing 4 to 5 concise documents to encompass this task.
- The deliverable will be provision of the documents. The documents will be provided in MS Word format to facilitate edits, comments and additions.
- Approximate time to complete task – 2 weeks (can be done in parallel with Task 4)

We propose to provide the services of Bill Cash as our Project lead. Bill has over 40 years of experience as a professional Health Physicist providing radiation protection and consulting services to a wide spectrum of users of radioactive material. Bill was the Radiation Protection Manager at Seabrook Station from 1993 to 2006 and has significant experience in program management, technical oversight, and RP program development. He also has key experience in supervising and mentoring personnel, ALARA work planning, radiological services, respiratory protection, environmental monitoring, and technical sections of Radiation Protection Programs. Bill was a key member of the team that provided support to Lantheus in the evaluation of potential Sr-90 internal exposure issues. He has a BS in Radiological Health Physics from Lowell Technological Institute and an MS in Environmental Engineering from the University of Florida. Bill will be supported by other RSCS personnel on as needed basis for input and review.

5 Project Cost

The radiological support services described in Section 4 will be provided on a firm fixed price (FFP) basis. The FFP for each of the tasks is presented below.

5.1 Task 1

- The FFP for Task 1 is $7,100
- Cost assumptions
  - The procedures provided for review will be in English. Of the 12 procedures provided to date, one was in Spanish.

5.2 Task 2

- The FFP for Task 2 is $2,600

5.3 Task 3

- The FFP for Task 3 is $2,900
- Cost assumptions
  - The cost assumes one round of comments and comment resolution.
  - The Radiation Safety Training materials to be reviewed are provided in English. The materials provided to date were in Spanish.
  - The scope of our review is assumed to not include the adequacy or content for the training and qualifications of the LMI PR Radiation Safety Officer (RSO).

5.4 Task 4

- The FFP for Task 4 is $2,100

5.5 Task 5

- The FFP for Task 5 is $3,500

5.6 Task 6

- The FFP for Task 6 is $6,900
- Cost assumptions
  - LMI PR facility drawings and ventilation system details (e.g., flow rates) will be available and provided upon request.
  - Site or regional meteorological data will be available.
  - Assumed radionuclide release rates and durations will be available to allow determination of annual release concentrations and quantities.

5.7 Task 7

- The FFP for Task 7 is $4,300
- Cost assumptions
  - As stated in Section 4.7, our cost assumes the development of 4 to 5 concise documents.

6 Invoicing and Terms

- The Firm Fixed Price services provided in Section 4 will be invoiced on a task completion basis with costs as detailed in Section 5.
- Payment is due net fifty (50) days from receipt of an undisputed invoice.
- All pricing is exclusive of any applicable sales, use or similar tax.
- RSCS reserves the right to request an increase in rates based on federally mandated programs. An example of this would be federally mandated adjustments to Employee Health Insurance.

7 Offeror

The services described herein shall be authorized by the award of contract or purchase order by Lantheus Medical Imaging, Inc. Technical questions should be directed to Greg Babineau, Director of Radiological Services (*gmbabineau@radsafety.com*, 603-474-6747). Commercial questions and contractual correspondence should be directed to Linn Giard, Business Services Manager (*ljgiard@radsafety.com*, 603-474-6726).

Authorized by: _____

Greg Babineau, Director of Radiological Services
Radiation Safety & Control Services, Inc.
93 Ledge Road
Seabrook, NH 03874
Office Phone: (603) 474 6747
Email: gmbabineau@radsafety.com

Approved by: _____

Lantheus Medical Imaging, Inc.
331 Treble Cove Road
North Billerica, MA 01862

Exhibit AI (1) : RSO Change on PR Licenses

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

February 25, 2019

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

SUBJECT: LANTHEUS MEDICAL IMAGING, LICENSE AMENDMENT, MAIL CONTROL NO. 611242

Dear Mr. Diaz:

This refers to your license amendment request dated January 23, 2019. Please find enclosed Amendment No. 2 listing Rolando Garcia, R.Ph. as the Radiation Safety Officer and Authorized User.

An environmental assessment for this action was not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please contact me at 610-337-5366 or via electronic mail at dennis.lawyer@nrc.gov so that appropriate corrections or answers can be provided.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action(s) against you. This could include issuance of a Notice of Violation, or Imposition of a Civil Penalty, or an Order Suspending, Modifying or Revoking Your License as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available at:
http://www.nrc.gov/reading-rm/doc-collections/enforcement/.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: http://www.nrc.gov/materials/miau/mat-toolkits.html. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web Site at: http://www.nrc.gov/about-nrc/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: http://www.nrc.gov/reading-rm/adams.html.

Thank you for your cooperation.

Sincerely,

Dennis R. Lawyer, Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

Docket No. 03038114
License No. 52-25361-02
Mail Control No. 611242

Enclosure:
Amendment No. 2

cc: Rolando Garcia, R. Ph., Radiation Safety Officer

Lantheus
Medical Imaging

150 Calle Federico Costa, Suite 1
San Juan, Puerto Rico 00918-1303

Tel. (787) 765-5698
Fax (787) 763-4042
www.lantheus.com

January 23, 2019

Craig V. Gordon
U.S. Nuclear Regulatory Commission
Region 1
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406

RE: Amendment Request for Radioactive Material License Numbers 52-25361-01MD and 52-25361-02, Lantheus Medical Imaging

Dear Mr. Gordon,

This is a written to request an amendment to the above referenced Radioactive Material Licenses.

I request that Rolando Garcia, R.Ph be designated as the Radiation Safety Officer (RSO). Mr. Garcia has been a Board Certified Nuclear Pharmacist since 2004 and previously held the position of RSO at the Lantheus Radiopharmacy in San Juan, Puerto Rico.

Included is a copy of Mr. Garcia's Certification Verification, resume and NRC form 313A. As you can see, Mr. Garcia's background and experience meets the training requirements for an RSO as described in 10CFR35.50.

This change will become official upon approval by the NRC of this amendment request.

If you have any questions regarding this request, please call me at (787) 765-5598 x 2503 or via email at Eduardo.Diaz@lantheus.com.

Cordially,

Eduardo Diaz, RPh, BCNP

NRC FORM 313A (RSO)
(06-2016)

U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 06/30/2019

Name of Proposed Radiation Safety Officer

Rolando Garcia

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply)*:

☐ 35.100 ☐ 35.200 ☐ 35.300 ☐ 35.400 ☑ 35.500 ☐ 35.600 (remote afterloader)

☐ 35.600 (teletherapy) ☐ 35.600 (gamma stereotactic radiosurgery) ☐ 35.1000 (_____)

PART I -- TRAINING AND EXPERIENCE
(Select one of the four methods below)

*Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ 1. **Board Certification**

a. Provide a copy of the board certification.

b. Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

c. Skip to and complete Part II Preceptor Attestation.

OR

☐ 2. **Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Uses Checked Above**

a. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO is sought.

b. Skip to and complete Part II Preceptor Attestation.

OR

☐ 3. **Structured Educational Program for Proposed Radiation Safety Officer**

a. Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			
Radiation dosimetry			
	Total Hours of Training:		

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 35.100, 35.200, etc.)+		

+ Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer

This license authorizes the following medical uses:

☐ 35.100 ☐ 35.200 ☐ 35.300 ☐ 35.400
☐ 35.500 ☐ 35.600 (remote afterloader) ☐ 35.600 (teletherapy)
☐ 35.600 (gamma stereotactic radiosurgery) ☐ 35.1000 (_____)

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses	Purdue University (August 2000) BCNP Certification -12/31/2004 BCNP recertification-12/31/2012	12/31/2004 12/31/2012
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):		

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Structured Educational Program for Proposed Radiation Safety Officer (continued)**

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual *If training was provided by supervising RSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)*	License/Permit Number listing supervising individual

License/Permit lists supervising individual as:

☐ Radiation Safety Officer ☐ Authorized User ☐ Authorized Nuclear Pharmacist

☐ Authorized Medical Physicist

Authorized as RSO, AU, ANP, or AMP for the following medical uses:

☐ 35.100 ☐ 35.200 ☐ 35.300 ☐ 35.400

☐ 35.500 ☐ 35.600 (remote afterloader) ☐ 35.600 (teletherapy)

☐ 35.600 (gamma stereotactic radiosurgery) ☐ 35.1000 (_____)

d. Skip to and complete Part II Preceptor Attestation.

OR

☑ 4. **Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on the licensee's license**

a. Provide license number.

b. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

c. Skip to and complete Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section
Check one of the following:

☑ 1. **Board Certification**

☑ I attest that Rolando Garcia has satisfactorily completed the requirements in
Name of Proposed Radiation Safety Officer

10 CFR 35.50(a)(1)(i) and (a)(1)(ii); or 35.50 (a)(2)(i) and (a)(2)(ii); or 35.50(c)(1).

OR

☐ 2. **Structured Educational Program for Proposed Radiation Safety Officers**

☐ I attest that _____ has satisfactorily completed a structural educational
Name of Proposed Radiation Safety Officer

program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

OR

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)
Check one of the following:

☐ 3. **Additional Authorization as Radiation Safety Officer**

☐ I attest that _____ is an
Name of Proposed Radiation Safety Officer

☐ Authorized User ☐ Authorized Nuclear Pharmacist

☐ Authorized Medical Physicist

identified on the Licensees license and has experience with the radiation safety aspects of similar type of use of byproduct material for which the individual has Radiation Safety Officer responsibilities

AND

Second Section
Complete for all *(check all that apply)*:

☑ I attest that Rolando Garcia has training in the radiation safety, regulatory issues, and
Name of Proposed Radiation Safety Officer

emergency procedures for the following types of use:

☐ 35.100

☐ 35.200

☐ 35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required

☐ 35.300 oral administration of greater than 33 millicuries of sodium iodide I-131

☐ 35.300 parenteral administration of any beta-emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ 35.300 parenteral administration of any other radionuclide for which a written directive is required

☐ 35.400

☑ 35.500

☐ 35.600 remote afterloader units

☐ 35.600 teletherapy units

☐ 35.600 gamma stereotactic radiosurgery units

☐ 35.1000 emerging technologies, including:

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

AND

Third Section
Complete for ALL

☑ I attest that Rolando Garcia (Name of Proposed Radiation Safety Officer) has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

Fourth Section
Complete the following for Preceptor Attestation and signature

I am the Radiation Safety Officer for Lantheus Medical Imaging Radiopharmacy Puerto Rico (Name of Facility)

License/Permit Number: 52-25361-01MD and 52-25361-02

Name of Preceptor	Signature	Telephone Number	Date
Eduardo Diaz		7877655598	01/23/19

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 2

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70 and 71, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the letter dated January 23, 2019,	4. Expiration Date: November 30, 2019
1. Lantheus Medical Imaging		5. Docket No.: 030-38114 Reference No.:
2. 150 Federico Costa Suite 1 San Juan, PR 00918-1303	3. License number: 52-25361-02 is amended in its entirety to read as follows:	

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
A. Fluorine-18	A. Any	A. 30 curies total	A. For manufacture of radiochemicals and sealed sources; packaging and distribution of manufactured radiochemicals and sealed sources to persons authorized to receive the licensed material in accordance with the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or any Agreement State.
B. Any byproduct material with Atomic Numbers 1 through 83	B. Incidentally Activated Products	B. 30 millicuries per radionuclide and 1 curie total	B. For possession and storage of byproduct materials incidental to radionuclide production.
C. Manganese-54	C. Incidentally Activated Products	C. 200 millicuries total	C. For possession and storage of byproduct materials incidental to radionuclide production.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 52-25361-02	Docket or Reference Number 030-38114
	Amendment No. 2	

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
D. Cobalt-56	D. Incidentally Activated Products	D. 200 millicuries total	D. For possession and storage of byproduct materials incidental to radionuclide production.
E. Cobalt-60	E. Incidentally Activated Products	E. 100 millicuries total	E. For possession and storage of byproduct materials incidental to radionuclide production.
F. Zinc-65	F. Incidentally Activated Products	F. 100 millicuries total	F. For possession and storage of byproduct materials incidental to radionuclide production.
G. Any byproduct material authorized under 10 CFR 35.65	G. Sealed Sources	G. 50 millicuries total	G. For use as calibration and/or reference standards, in calibration and checking of the licensee's instruments.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at: licensee's facilities, 150 Federico Costa, Suite 1, San Juan, Puerto Rico, 00918-1303

11. The Radiation Safety Officer (RSO) for this license is Rolando Garcia, R. Ph.

12. Licensed material shall only be used by, or under the supervision of, Rolando Garcia, R.Ph., Bryan Fernandez, or Jose Ramos.

13. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 52-25361-02	Docket or Reference Number 030-38114
	Amendment No. 2	

B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

C. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

D. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

E. The leak test shall be capable of detecting the presence of 185 becquerels (0.005 microcuries) of radioactive material on the test sample. If the test reveals the presence of 185 becquerels (0.005 microcuries) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

F. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

G. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.

14. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 3 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 52-25361-02	Docket or Reference Number 030-38114
	Amendment No. 2	

18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated August 4, 2009 (ML092360240)
    B. Letter dated October 20, 2009 (ML093090395)
    C. Letter dated September 24, 2018 (ML18270A096)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: February 25, 2019

By: _____

Dennis Lawyer
Region 1

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 29

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70 and 71, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with letter dated January 23, 2019.	4. Expiration Date: November 30, 2022
1. Lantheus MI Radiopharmaceuticals, Inc. 2. 150 Federico Costa St., Suite 1 San Juan, PR 00918-1303	3. License number: 52-25361-01MD is amended in its entirety to read as follows:	5. Docket No.: 030-34187 Reference No.:

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
A. Any byproduct material with Atomic Numbers 1 through 83 with half-life less than or equal to 120 days	A. Any Except Sealed Sources	A. 300 millicuries per radionuclide and 1 curie total	A. For preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
B. Carbon-11	B. Any Except Sealed Sources	B. 30 curies total	B. For preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
C. Nitrogen-13	C. Any Except Sealed Sources	C. 30 curies total	C. For preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.

NRC FORM 374A | U.S. NUCLEAR REGULATORY COMMISSION |

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number: 52-25361-01MD
Amendment No. 29
Docket or Reference Number: 030-34187

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
D. Oxygen-15	D. Any Except Sealed Sources	D. 20 curies total	D. For preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
E. Fluorine-18	E. Any Except Sealed Sources	E. 30 curies total	E. For preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
F. Gallium-67	F. Any Except Sealed Sources	F. 20 curies total	F. For preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
G. Rubidium-82	G. Any Except Sealed Sources	G. 15 curies total	G. For redistribution of used and unused Strontium-82/Rubidium-82 generators to authorized recipients in accordance with 10 CFR 32.72.
H. Strontium-82	H. Any Except Sealed Sources	H. 15 curies total	H. For redistribution of used and unused Strontium-82/Rubidium-82 generators to authorized recipients in accordance with 10 CFR 32.72.
I. Strontium-85	I. Any Except Sealed Sources	I. 15 curies total	I. For redistribution of used and unused Strontium-82/Rubidium-82 generators to authorized recipients in accordance with 10 CFR 32.72.
J. Molybdenum-99	J. Any Except Sealed Sources	J. 200 curies total	J. For redistribution of used and unused Molybdenum-99/Technetium-99m generators to authorized recipients in accordance with 10 CFR 32.72.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number: 52-25361-01MD

Amendment No. 29

Docket or Reference Number: 030-34187

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
K. Technetium-99m	K. Any Except Sealed Sources	K. 200 curies total	K. For redistribution of used and unused Molybdenum-99/Technetium-99m generators to authorized recipients in accordance with 10 CFR 32.72.
L. Iodine-131	L. Any Except Sealed Sources	L. 9.9 curies total	L. For preparation and distribution of radioactive drugs, including compounding of iodine-131 and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
M. Xenon-133	M. Any Except Sealed Sources	M. 1 curie total	M. For preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
N. Samarium-153	N. Any Except Sealed Sources	N. 1 curie total	N. For preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
O. Thallium-201	O. Any Except Sealed Sources	O. 20 curies total	O. For preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 52-25361-01MD	Docket or Reference Number 030-34187
	Amendment No. 29	

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
P. Any byproduct material permitted in 10 CFR 35.400	P. Sealed Sources	P. 500 millicuries total	P. For redistribution of sealed sources initially distributed by a manufacturer licensed in accordance to 10 CFR 32.74 to authorized recipients for medical use. For redistribution of sealed sources that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess and use the authorized device.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number: 52-25361-01MD

Amendment No. 29

Docket or Reference Number: 030-34187

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
Q. Any byproduct material permitted by 10 CFR 35.500	Q. Sealed Sources	Q. 5.5 curies total	Q. For redistribution of sealed sources initially distributed by a manufacturer licensed in accordance to 10 CFR 32.74 to authorized recipients for medical use. For redistribution of sealed sources that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess and use the authorized device.
R. Any byproduct material permitted by 10 CFR 31.11	R. Prepackaged Kits	R. 50 millicuries total	R. For redistribution to specific licensees or to general licensees in accordance with 10 CFR 31.11, provided the packaging and labeling remain unchanged.

NRC FORM 374A

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number: 52-25361-01MD

Amendment No. 29

Docket or Reference Number: 030-34187

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
S. Any byproduct material authorized under 10 CFR 35.65	S. Sealed Sources	S. 200 millicuries total	S. For use in calibration and checking of the licensee's instruments. For redistribution of sealed sources initially distributed by a manufacturer licensed in accordance to 10 CFR 32.74 to authorized recipients for medical use. For redistribution of sealed sources that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess and use the authorized device.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 150 Federico Costa Street, Suite #1, San Juan, Puerto Rico.

11. Licensed material shall only be used by, or under the supervision of:

A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) or (4).

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 52-25361-01MD	Docket or Reference Number 030-34187
	Amendment No. 29	

B. Authorized Nuclear Pharmacist(s):
Rolando Garcia, R.Ph., BCNP Eduardo Diaz Montes, R.Ph., BCNP Noel Rodriguez, R.Ph., BCNP

12. The Radiation Safety Officer (RSO) for this license is Rolando Garcia, R.Ph., BCNP.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. The licensee is authorized to retrieve, receive and dispose of radioactive waste from its customers limited to radiopharmacy supplied syringes and vials and their contents.

15. Notwithstanding the requirements of 10 CFR 32.72(c), the licensee may redistribute alpha-, beta-, or photon-emitting radioactive drugs, which have been initially distributed by another radiopharmaceutical supplier's licenses pursuant to 10 CFR 32.72, without verifying the radioactivity of the dosage. The licensee must not manipulate the dosage, including the packaging and label.

16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

17. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 3 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

18. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.

NRC FORM 374A	License Number	Docket or Reference Number
MATERIALS LICENSE SUPPLEMENTARY SHEET	52-25361-01MD	030-34187
	Amendment No. 29	

B. Not withstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

D. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

E. Sealed sources need not be tested if they contain only hydrogen 3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

F. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

G. The leak test shall be capable of detecting the presence of 185 becquerels (0.005 microcuries) of radioactive material on the test sample. If the test reveals the presence of 185 becquerels (0.005 microcuries) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 52-25361-01MD	Docket or Reference Number 030-34187
	Amendment No. 29	

l. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.

19. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash provided:

A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

B. A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

NRC FORM 374A	License Number	Docket or Reference Number
MATERIALS LICENSE SUPPLEMENTARY SHEET	52-25361-01MD	030-34187
	Amendment No. 29	

20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
    A. Application dated May 24, 2012 [ML12160A426]
    B. Letter dated October 10, 2012 [ML12296A415]
    C. Letter dated October 5, 2016 [ML16286A572]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

By: Farrah Gaskins
Region 1

Date: April 15, 2019

Exhibit AI (2) : Example of Collaboration Billerica RP staff and PR RP staff

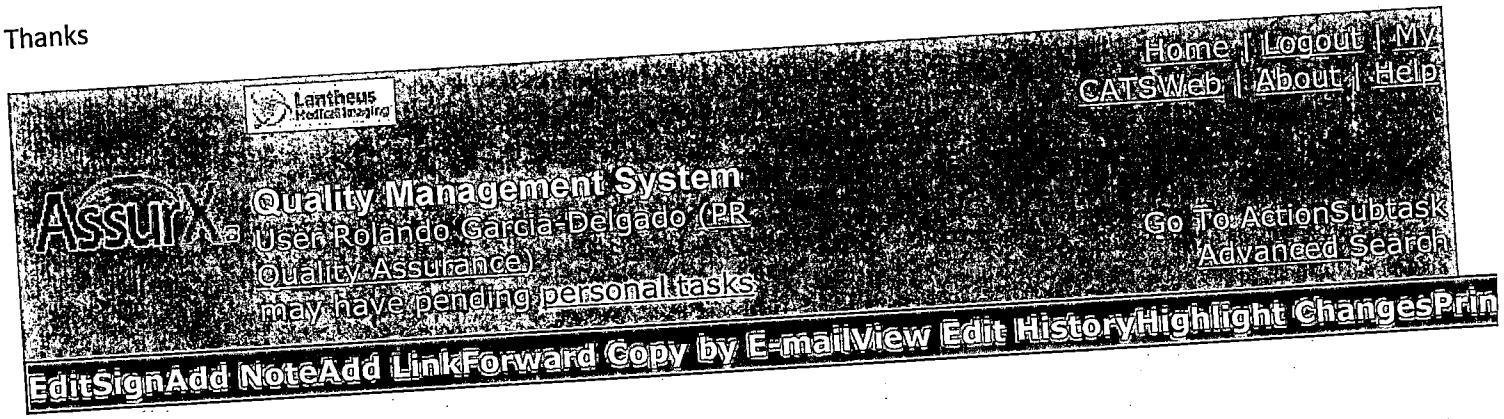
Hanlon, Julie

From: Garcia-Delgado, Rolando
Sent: Monday, August 5, 2019 11:37 AM
To: Hanlon, Julie
Subject: Workbench

Hi Julie,

Waiting your approval on this workbench

Thanks



Document Workbench #33950

REVISION WORKBENCH DETAILS

Document Title	Radiation Safety Program: Bioassay	**Workbench Stage**	Collaboration	SETUP TEAM | COLLABORATE | REVIEW | CLOSED	
Document Number	SOP-159	**Revision Number**	1.0	**Status**	Open
Document ID	33920	**Document Revision ID**	182907	**Due Date**	8/8/2019
Revision Owner	Rolando Garcia-Delgado	**Document Type**	SOP		
Checked Out	No			**DCR Number**	33917
Checked Out By		**Date Checked Out**		**Checkout Task ID**	0
Department Revision	PR Quality Assurance Rolando Garcia-Delgado				

Team Coordinator	
Reviewers	Lynne Allen,Rolando Garcia-Delgado,Christina Roberts,

Directions:
1. Ensure all Team Members are listed. Click *"Add Team Member"* to add additional people to the team.
2. Click *"Assign Tasks"*.

Additional Team Members can be added and Workbench Tasks assigned at any point until the Document
Workbench status is "Closed".

REVISION TEAM AND TASKS

Add Team Member | Additional Task

Revision Workbench Team Members

Edit Member	Team Member	Dept	Workbench Assignee	Workbench Reviewer	Remove Member
	Lynne Allen	Doc Management	Yes	Yes	
	Rolando Garcia-Delgado	PR Quality Assurance	Yes	Yes	
Edit	Eduardo Diaz	PR Fixed Mfg Plant	No	No	Delete
Edit	Julie Hanlon	Environmental H&S	No	No	Delete
Edit	Angel G Pagan-Marti	PR Fixed Mfg Plant	No	No	Delete
Edit	Christina Roberts	Training	No	Yes	Delete

Workbench Assignment Tasks

Task ID	Assignee	Task Status	Comments	Date Closed	Working Document
183343	Rolando Garcia-Delgado	Closed		28 Jun 2019	Download
186004	Rolando Garcia-Delgado	Closed		19 Jul 2019	Download
187872	Rolando Garcia-Delgado	Closed		02 Aug 2019	Download
183342	Gina Holt	Pending			
183353	Julie Hanlon	Pending			

APPROVALS & RECORD HISTORY

File Attachments

File Name	Description	Notes	Last Edit Date	Last Edit User	
SOP-159.docx	RG edits	added decision limit to sample net count. added background and sample counting times	8/2/2019 4:23:13 PM	garciadr	

Tags: There are no tags. Public

Rolando Garcia
Associate Director QA, Puerto Rico
Lantheus MI Radiopharmaceuticals Inc.
787-765-5598

https://lantheus.webex.com/join/rolando.garcia | 732 574 478

Audio Conferencing for Rolando Garcia-Delgado
Dial-in: 888-548-0001
International: 978-436-7000
Room: 9013 PIN: 1234

Exhibit AI (3) : Operational Assessment by 3rd Party

Lantheus MI Radiopharmaceuticals, Inc.

Operations Assessment

By: Joel Cordero, RPh.

6/11/19

Scope of Work

This assessment was commissioned by Lantheus Medical Imaging (LMI) to provide an overview assessment on Lantheus MI Radiopharmaceuticals Inc. (LMIR) daily operations. The assessment's scope of work included the following LMIR functional areas:

Facilities

PET Operations

SPECT Operations

Quality, EHS and Radiation Safety Programs

Staffing

The assessment was performed during night and day shift for a total of 20 hours. Based on the detailed and complexity of LMRI operations and the limitation of time, this assessment does not represent a full audit on any specific program like QA, EHS or Radiation Safety, rather is intended to provide an operations overview to LMI management that could help identify areas of opportunities to develop and strength LMIR operations.

The assessment did not evaluate others business functional areas outside of the direct radiopharmaceuticals' production. Departments that were not evaluated included Customer Service, Finance, Logistics and Sales and Marketing nor the interactions and/or integration to the LMRI business with parent company.

Background

LMRI operates a facility dedicated to compound traditional radiopharmaceuticals short lived Tc-99m products, dispensing long lived isotopes like Tl-201 and Ga-67, provide service for White Blood Cell labeling with Tc-99m and In-111 based products and to compound customized I-131 therapy capsules for specific patients per physician request (SPECT). The operation runs continuously from night shift to dayshift and shifts must be supervised by a specialized radio-pharmacist due to local and federal regulations.

The SPECT operations is not considered drug manufacturing by the state or federal regulators but requires additional controls to be in place that are above the traditional retail pharmacy operations. Following are the minimum licenses requirements to operate:

Nuclear Regulatory Commission Facility License including all Authorized Nuclear Pharmacist

SARAF - Facility must be registered with the state as a:

- Pharmacy
- Specialized Pharmacy for the dispensing of Radiopharmaceuticals

Pharmacists must possess the following licenses:

- Board of Pharmacy State Registration – NABP and PR State Law Licensing
- PR Pharmacist Association Registry
- Nuclear Pharmacy Completed Training

Sanitary License

Fire Department License

Biohazard Waste Registry

Department of Transportation Registration for Hazardous Materials

Department of State - Corporate Good Standing

Treasury Department – Merchant Certificate

Municipal Patent

State Workers Comp Registration

State Power Company Surety Bond

The PET operations have three main functional areas. The first is the cyclotron F-18 isotope production, the 18F-FDG synthesis and the dispensing area. Isotope production is not under full FDA scope and it does not have sterility requirements although the isotope production has controls and has criteria to be met by FDA guidelines. The vial assembly and drug filtering processes are under FDA regulations and requires special attention. Important to address that production of PET radiopharmaceuticals are FDA regulated under its own section, and is critical for any PET business to fully comply with the PET regulation but also equally critical is to avoid the temptation to over regulate the process implementing procedures adopted from traditional drug manufacturing processes. PET has its own set of regulations and those are the one to be follow. After drug sterility is proven, the dispensing of the PET radiopharmaceuticals will follow the pharmacy practice.

FDA requires PET processes to have operators fully trained and qualified, and the radio-pharmacist is required to batch release (defined by internal procedure) and to oversee the dispensing process as in SPECT. PET operations are under the same licensing requirement as stated above for SPECT with the addition of FDA requirements.

The LMIR building was designed to support both the SPECT and PET business simultaneously where the main supporting utilities like the HVAC and stacks/effluents releases are located in the mechanical penthouse. Facility HVAC, room differential-pressure, temperature and humidity controls are monitored using an integrated Building Management System.

Assessment

Facilities

The overall impression on the facilities current physical condition and maintenance was good although there were certain areas identified that required improvement. Since the Billerica LMI team has been supporting the LMIR operations, many of the identified areas of improvement are currently on track to be repaired/maintained, independently of that the assessment will include those observations for business reference.

The mechanical penthouse is in good shape overall. Random radiological surveys were performed on critical areas including charcoal filters for I-131 and F-18 stack release with satisfactory results. It is recommended that all HVAC units should be pressure washed to remove sediments to avoid further cost of repairs. One HVAC unit was found to be offline which has a direct impact on the facility HVAC balance and rooms differential pressure maintenance. There were also exhaust fans that were offline. Some Magnehelics pressure gauges were not functional, probably related to the unbalanced facility. Chillers and pumps were observed to be in good operating condition, although the chiller's steel subfloor is rusty and will need to be serviced to repair some damage to the structural steel.

In the electrical room, the facility battery backup system could not be properly identified if it is currently online and/or when was the last time it was service/maintained. This unit was designed to provide uninterrupted temporary emergency power to critical areas within the facility before the emergency power generator is online. It would be desired to understand if this system still in operation, what areas would cover and if critical equipment like the PET Explora units are linked to the backup system. The main concern should be if city power failed during the synthesis process, LMRI risk to have a batch production failure impacting customers/patients and risk to have a FDA intervention.

The heat transfer unit was found to be completely offline. This equipment is critical for facility humidity and temperature control. The facility was found to be out of specification for both parameters.

The most critical areas that requires attention would be to:

Repair and commission the heat transfer unit ASAP.

Repair and commission the offline HVAC units and exhaust fans and proceed to balance the facility ASAP.

To establish and supervise maintenance programs.

Office spaces, common areas, SPECT lab, PET lab and material storage areas has been properly maintained.

PET Operation

The PET Operation assessment was performed live following the nightshift production schedule. Areas evaluated were:

Overview of staff competencies and procedures compliance

QC Lab setup

Cyclotron Operation

Explora boxes set up and transfer line installation

Vial assembly and sterile techniques/manipulations within ISO environment

Activity management and production planning

The overall impression on PET staff performance, headcount vs. workload distribution and procedures adherence is robust. The developed QA programs has been improving over time and the Quality Organization has the experience to establish robust and comprehensive procedures. The staff demonstrated the competencies required for the daily operations. The high-level impression on the QA program is that it is well organized, maintained and well suited for the operation. Staff has been cross trained to perform all task.

Cyclotron maintenance was found to be satisfactory; the equipment was recently serviced by Siemens and the local operator completed the maintenance basic training. Critical spare parts are currently inhouse and additional radiation safety protection was recently established for hold to decay materials which seems adequate for the waste regeneration process.

Regarding the factory training for equipment repairs and maintenance and the business risk it represents, It would be strongly recommended to allocate resources as soon as possible in order to enroll the operator in the advance cyclotron maintenance program, but also equally important to enroll the operator in the Explora maintenance program since there is any formal factory training to service the synthesis units in place.

SPECT Operations

The SPECT operation was evaluated during the nightshift's second shift. Due to a shortage in Tc-99m experienced on the day of the evaluation the dispensing activities were lower than typical, nevertheless there was enough workload to assess the operations. Pharmacy techs were observed during the routine dispensing QC and QA tasks. The implemented QA process is well aligned with the production steps and certainly is a cornerstone for the quality achieved in dose dispensing.

The overall impression on pharmacy tech performance is satisfactory. They understand the workload and radiation issues and were pro-actively looking to reduce exposure. The provided radiation safety equipment was adequate for current business volume. Since there is one pharmacy tech out of the dose dispensing activities due to reaching exposures milestones is it clear that the increased workload could impact the rest of team for the rest of the year. EHS team is closely monitoring pharmacy tech exposure on a weekly basis, nevertheless business must flawlessly monitor results to minimize risk of non-compliance with NRC levels at least for the rest of the year.

It is recommended that LMI allocate resources to re-establish the support to LMRI for internal periodic radiation safety compliance audits. The audits could be performed every 4-5-months to allow data to be collected and be meaningful, but with enough time in advance to spot potential future deviations. Atypical deviations should be address immediately. Radiation Safety audits should be specifically based for the radio pharmacy setting and scope of work. Workload on SPECT is a manual process that happen on a short period of time, safety team should avoid the pitfall of creating procedures that operators would fail to follow, in order to have successful business model aligned with a safe operation, the feedback from all parties involved should be taken in consideration.

Quality, EHS and Radiation Safety Programs

The overall impression for QA, EHS and Radiation safety programs was satisfactory as the critical areas that must be taken care-of are/or will be soon address. There will always be areas of opportunities to improve and the team seems to be open to collaborate to continuously improve LMRI operation.

The integration of EHS And Radiation Safety Programs under the QA Organization leadership is working fantastic as the experience acquired for PET QA program developing is rolling forward to comprehensive develop robust procedures for the EHS and Radiation Safety needs. It should be recommended to continue this path forward with the input of all related parties.

Human Resources

LMIR is currently transitioning to a new business leadership model. The process was found to be in the most critical phase and is recommended to business leaders to provide full support to completely develop the leadership structure as soon as possible.

Recommendations:

QA/EHS/Radiation Safety:

Continue to develop the QA Organizations by providing the necessary support

Continue to develop EHS and Radiation Safety Programs under the QA Organization leadership

Business Operations:

Reduce Site manager numbers of direct reports immediately to reduce workload and fatigue.

Identify and develop internal talents to lead the Distribution Department route assignment.

Continue developing the new pharmacist and start distributing responsibilities ASAP accordingly to completed competencies to reduce Site Manager workload.

Better differentiate entry level pharmacist compensation vs. experience pharmacist leader

Allocate resources for a full time Administrative Assistance that could manage facility licensing requirements and assist as a liaison with subcontractors, Finance, Tax audits, IT, HR, Procurement and Logistics interactions. This position will significantly reduce Managers background workload and will provide the time to concentrate on leading the business.

PET Operations:

Consider regrouping 3 PET employees under one leader that will report to Site Manager.

Exhibit AI (4) : Corrective Action Plan from 2019 3rd Party Audit

Exhibit AI (4): Corrective Action Plan Radiation Safety Program Audit Report for the Lantheus PR Facility

<table>
<tr><th>Finding</th><th>Corrections</th></tr>
<tr><td>An ALARA policy and principles are not sufficiently established, communicated or integrated into daily work at all levels of the organization.</td><td>Approximately 14 new documents have been created to encompass the ALARA principles, from packaging and receiving to supervisory levels. These have been included in the QMS and assigned to training requirements for which employees are assigned. These procedures have been set with an annual re-training schedule.
The procedures provide requirements, such as dosimetry and protective clothing needed, and describe work precautions and ways to effectively use ALARA engineering controls (e.g., time, distance, shielding, containments, ventilation, and source reductions. To reduce personnel doses for work performed in high dose rate and high contamination areas, procedure MI-PPS-3008 was made effective for tasks with the potential of high dose and provide informed exposure rates and supervisory involvement. Internal dose is controlled over two levels: DAC monitoring and routine bioassay.
Document No. Title
FRM-1048 Radiation Safety Program: Bioassay I-131
SOP-136 Radiation Safety Program: Audit and Review of Program
SOP-143 Radiation Safety Program: Public Dose
SOP-148 Radiation Safety Program: Safe Use of Radionuclides and Emergency Procedure
SOP-149 Radiation Safety Program: Material Receipt and Accountability
SOP-159 Radiation Safety Program: Bioassay
SOP-160 Radiation Safety Program: Radiation Surveys
SOP-162 Radiation Safety Program: Dose Monitoring and Calculation Requirements
SOP-163 Radiation Safety Program: Training Requirements
SOP-167 Radiation Safety Program: Survey Meter Calibration
SOP-170 Radiation Safety Program: Occupational Air Monitoring
TRN-58 Annual Radiation Safety Training
TRN-69 Course ID 32045: Radiation Safety Training (Puerto Rico)
SOP-142 Sealed Source Leak Test
Status:
Complete</td></tr>
<tr><td>ALARA Action Levels are documented but ALARA processes are not established to dictate how ALARA principles will be met (such as the use of Radiation Work Permits, pre-job briefings, and other recommended tools).</td><td>Approximately 10 additional forms and procedure were either created and/or modified to encompass the ALARA principles and govern the radiation work performed within Lantheus Puerto Rico. These documents provide actionable levels to guide routine work for which exposure is known, monitored and controlled.
Document No. Title
FRM-459 Survey Form for SPER Lab
FRM-460 Survey Form for PET Lab
FRM-461 Survey Form for Distribution Area
FRM-462 Survey Form for Unrestricted Area
Document No. Title
FRM-695 Puerto Rico Weekly Dosimeter Reconciliation
FRM-708 Puerto Rico Monthly Dosimeter Reconciliation
FRM-710 Radiation Area Visitation Log
FRM-849 Cell Entry Log
MI-PRS-3008 Cyclotron and Hot Cell Entry/Access Procedure
SOP-50 Personnel Dosimeters Management</td></tr>
</table>

Exhibit AI (4): Corrective Action Plan Radiation Safety Program Audit Report for the Lantheus PR Facility

<table>
<tr><td>Job-specific ALARA goals are not established based on risk and work performed</td><td>Procedure SOP-50 with version history:
<table><tr><th>Rev#</th><th>Released</th><th>Effective</th><th>Status</th></tr><tr><td>3.0</td><td>18 Feb 2019</td><td>11 Mar 2019</td><td>Effective</td></tr><tr><td>2.0</td><td>05 Nov 2018</td><td>29 Nov 2018</td><td>Superseded</td></tr><tr><td>1.0</td><td>10 Jul 2018</td><td>31 Jul 2018</td><td>Superseded</td></tr></table>Provides the occupational doses permitted per functional groups. The dose limits were established as low as reasonably achievable for each functional group based on the tasks performed per the functional area.</td></tr>
<tr><td>The written Radiation Protection Program currently in effect does not reflect some of the license commitments,</td><td>A matrix for each license's commitment items was created. The matrices were used as a GAP analysis to reconcile licenses commitments with the radiation safety program.
. Items completed:
• Medi-Smart monitoring system has been installed by OEM
• NRC License renewal documentation has been submitted to reflect proposed reconciliation

Status:
Complete</td></tr>
<tr><td>No briefings were performed prior to entering a room posted as High Radiation Area.</td><td>Radiation areas were reviewed and evaluated for posting requirements per 10 CFR 20.1902. Currently there are no areas classified as high radiation areas. In addition, FRM-710, Radiation Area Visitation Log version 2.0 was made effective on April 18, 2019. This latest version contains the statement to be provided to visitors before being allowed to enter radiation areas.

Status:
Complete</td></tr>
<tr><td>Discussions with workers related to their knowledge of radiation dose rates in their work area demonstrate that workers are not briefed adequately on radiation information and do not possess adequate knowledge of site radiation risks.</td><td>Training Course #32045 Radiation Safety Training with exam was created along with training material TRN-69. The course and material were created within QMS and assigned to a training requirement for initial and annual training. The written exam was designed to test radiation workers' knowledge before permitting the worker to execute radiation tasks.

Annual training and testing has been completed for 2019. Knowledge deficiencies of radiation workers were identified through testing and corrected through re-training and verified through re-testing.

Status : complete</td></tr>
<tr><td>The program does not provide clear requirements for training new workers commensurate with their job duties and does not provide for annual refresher training.</td><td>Training Course #32045 Radiation Safety Training with exam was created along with training material TRN-69. The course and material were created within QMS and assigned to a training requirement for initial and annual training.

SOP-163 Radiation Safety Program: Training Requirements was created specifically to address the training requirements for new and current employees. This procedure has been made effective.

Status:
Complete</td></tr>
<tr><td>The Radiation Protection Handbook states the RSO provides training to personnel. Currently an EHS staff member performs initial radiation safety training and refresher training only when the handbook is revised.</td><td>Renewal license addressed this concern by stating that authorized nuclear pharmacist (ANP) and EHS personnel can provide radiation safety training.

Status: Complete</td></tr>
<tr><td></td><td></td></tr>
</table>

Exhibit AI (4): Corrective Action Plan Radiation Safety Program Audit Report for the Lantheus PR Facility

Visitors to the facility who will enter the restricted area do not sign a form that has a briefing informing them of the potential exposure to radiation and the relative risks.	FRM-710, Radiation Area Visitation Log version 2.0 was made effective on April 18, 2019. This latest version contains the statement to be provided to visitors before being allowed to enter radiation areas. Status : Complete
Survey documentation lacking for specific locations where significant amounts of radioactive material is used and stored such as fume hoods, bench tops, as well as disposal locations such as trash receptacles.	In addition procedure SOP-160 has been created and supported by form FRM-459, 460, 461 and 462 to enhance radiation surveys and monitoring. Status : Complete
Survey documentation lack the appropriate supervision review signatures.	Currently being reviewed and signed. Status : complete
Surveys lack notations and data as compared to surveys performed by trained and experienced radiation protection workers such as time of day, area postings, etc.	Training OJT Master 32621 has been created and assigned to employees with the responsibility of contamination surveys. The purpose of the OJT is to adequately train and assess workers' proficiency in performing and documenting the task. Phase 1, 2 and 3 have been completed. Phase 4 is pending completion to complete OJT.
Individuals were observed performing removable contamination surveys on containers after they are heat-shrink wrapped instead of pre-heat-shrinked. Shrink wrap prevents the detection of loose contamination via a wipe test.	SOP-146, Specification 7A, Type A Packages Closing Instructions, was made effective on April 18, 2019 and personnel training has been documented. The procedure was modeled after procedure 07-001-006, Radioactive Package Surveys (Billerica) and 49 CFR 173.443 Contamination control. The level of non-fixed contamination must be kept as low as reasonably achievable on the external surfaces of each package and does not include the surface of the lead containers. Status : Complete
Contrary to Radiation Protection handbook requirements to inspect, survey and clean work areas where ever RAM has been handled, no surveys were available for these tasks.	Current survey area forms addressed the survey of areas where RAM has been handled including biological safety cabinets. Status: Complete

Exhibit AI (4): Corrective Action Plan Radiation Safety Program Audit Report for the Lantheus PR Facility

Workers were observed exiting a restricted area without performing personnel whole body monitoring.	SOP-160 has been created to include and explicitly instruct personnel to perform monitoring before leaving area and during work form FRM-937 was created to document surveys Status : Complete
Site procedures and practices are such that individuals are using Electronic Dosimeters to perform dose rate surveys. Electronic dosimeters are calibrated to read accurately for dose but are not calibrated to be within accuracy limits for dose rate. Radiation survey meters should be used for dose rate surveys.	MI-PRS-3008 version 2.0 was made effective on 4/17/2019. The procedure was modified to remove the use of electronic dosimeters as survey meters. Status : Complete
Survey results data is pre-filled on shipping documentation prior to performing the wipe test with the presumption that the survey results will not indicate contamination on the outside of the package.	SOP-146, Specification 7A, Type A Packages Closing Instructions was made effective on April 18, 2019 for the closing of specification 7A packaging containing radioactive material. The procedure states the correct sequence of performing the tests for shipping radioactive material according to DOT and NRC regulations. The procedure enforces good documentation practices and data integrity when documenting results in shipping papers. Employees are documented as having been trained per procedure. CAPA Plan/Response #175625 was initiated to document corrective action and CAPA effectiveness. CAPA effectiveness shows CAPA was effective. Status: Complete
Contrary to these requirements two doors posted as High Radiation Areas as well as Explora units were not locked.	Explora have been provided with a locking system for daily use to secure opening of doors. Evaluation of rooms posted as High Radiation Areas indicate these rooms do not meet the definition of high radiation areas. At no point or any time a 100 mRem/hour at 30 cm is attained or exceeded. Status: Complete
No processes exist to track the license limits exists for the PR facility.	SOP-149, 1.0, Radiation Safety Program: Material Receipt and Accountability has been released for training with effective date of 5/9/2019. The procedure states the current license limits and the process to assure the limits are not exceeded at any time. Status: Complete
Radioactive source inventory and leak test data revealed several discrepancies in the documentation on how they verified sources were accounted for (i.e. no documented locations and signatures) and that leak tests were performed adequately.	SOP-142, Sealed Source Leak Test was made effective on 4/18/2019. The procedure details the process of performing leak test of sealed sources including MDA requirements and limits. The procedure is supplemented with form FRM-886 also effective. Leak source inventory are currently printed and their location stated in report. The report is signed by RSO. Status: Complete

Exhibit AI (4): Corrective Action Plan Radiation Safety Program Audit Report for the Lantheus PR Facility

A formal audit program was not available that described the process for performing the 10 CFR 20 annual audit. Audit checklists were observed but no analysis of data and discussion was included for the annual audit and no corrective active actions were tracked for closure. Audit checklists do not cover the extent of material expected to be audited. Audit checklist items were left blank on some checklists. Audit checklist items were documented as complete when they were not performed.	SOP-136, Radiation Safety Program: Audit and Review of Program Review was made effective on 4/19/2019. The document provides guidance to perform annual audit of the radiation safety program. The document contains am appendix modeled after current NUREG 1556 volume 13 and volume 21. The audit items provided in appendix intend to cover all the radiation safety program and are redacted in form of questions that should be discussed for audit closing. The procedure also includes an appendix for the implementation of corrective actions. Status: Complete
Review of incident investigation reports show a lack of detailed root cause analyses and detailed corrective actions.	SOP-136 Radiation Safety Program: Audit and Review of Program and SOP-148 Radiation Safety Program: Safe Use of Radionuclides and Emergency Procedure Were created and made effective to assure findings and incidents are investigated. Status : Complete
The site Radiation Protection Handbook states that in conjunction with management, the RSO may order a halt to any operation. The RSO should not have to consult with management, they should be delegated full halt work authority in writing from the highest level of corporate management.	Status: To be completed
The installed Medismarts system is currently not calibrated or being used and is not labelled as out of service per procedure.	System service on week of 15Jul2019. Updated software installed. Probes have been calibrated and installed. IQ provided training on use of system. Status : Complete

Exhibit AI (4): Corrective Action Plan Radiation Safety Program Audit Report for the Lantheus PR Facility

<table>
<tr>
<td>The current sampling techniques are not adequate to accurately measure stack emissions.</td>
<td>The following documents were created.
<table>
<tr><td>WI-28</td><td>Air Effluent Monitoring- Iodine-131</td></tr>
<tr><td>WI-29</td><td>Air Effluent Monitoring-Fluorine-18</td></tr>
<tr><td>FRM-909</td><td>Air Effluent Monitoring Form-Fluorine-18</td></tr>
<tr><td>FRM-910</td><td>Air Effluent Monitoring Form-Iodine-131</td></tr>
<tr><td></td><td></td></tr>
</table>
Effective 08Jul19</td>
</tr>
<tr>
<td>Dose evaluations to comply with member of the public dose requirements are not being adequately documented. External dose is monitored by area dosimetry and internal dose by air sample both I -131 and F-18. A report should be written to present the combination of the data to demonstrate compliance with the dose to member of the public. This can be incorporated into the annual program audit.</td>
<td>SOP-143, Radiation Safety Program: Public Dose has been made effective. The procedure is compliant with 10 CFR 20.1301 Dose limits for individual members of the public and 20.1302 Compliance with dose limits for individual members of the public taking into consideration to contribution of both F-18 and I-131 effluents.

Status: Complete</td>
</tr>
</table>

Exhibit AI (4): Corrective Action Plan Radiation Safety Program Audit Report for the Lantheus PR Facility

Skin contamination events: Handbook states "more serious or repeated contamination events must be promptly reported to the RSO" but there are no specific levels specified. Skin contamination events should be documented and recorded on a skin contamination survey map with the appropriate areas, levels of contamination when found and after decontamination is performed. When required skin doses shall be calculated and recorded in individual dose records. The Radiation Protection Handbook states all skin contamination events must be reported to the supervisor, but it does not state the supervisor's responsibilities..	SOP-148, Radiation Safety Program: Safe Use of Radionuclides and Emergency has been made effective (see above). Radioactive Spill Form, FRM-937 was created to be used with emergency procedure and includes fields for the documentation of contamination involving the skin of employees. The form requires dose to be assigned based on the contamination. Status: Complete	
Additional actions	• Independent review of cyclotron license by third party, RSCS, for renewal.	• Performed on November 2019
	• Independent review of license effluent releases by third party, RSCS,	• Completed January 2020
	• Independent review of license radiation safety program by third party, RSCS	• In-progress
	• 3rd Party Task 1- Review LMI PR Radiation Protection procedures	• To be completed
	• 3rd Party Task 2- Review of the implementation status of LMI PR Corrective Action Plan	• To be completed
	• 3rd Party Task 3 – Review the new training materials developed by LMI PR	• To be completed
	• 3rd Party Task 4 Review LMI Billerica's Key performance indicators and provide guidance on how best to revise them to best fit LMI PR	• To be completed
	• 3rd Party Task 5 Review and comment on cyclotron license renewal application	• Completed November 2019
	• 3rd Party Task 6 Perform an effluent release assessment for the LMI PR facility to provide basis for determination of level of effluent monitoring required	• Completed January 2020
	• 3rd Party Task 7 Develop high level LMI Radiation Protection policy documents/statements	• In- progress