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Medical Imaging

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May 02, 2016

F6

U.S. Nuclear Regulatory Commission

Attn.: Dennis Lawyer
Health Physicist
Division of Nuclear Material Safety
Region 1
Licensing Assistance Team

2100 Renaissance Boulevard
Suite 100
King of Prussia, PA 19406-2713

Reference: **License No. 52-25361-02**
Docket Number 03038114
Mail Control Number 588543
Updated Facility Decontamination and Decommissioning Cost Estimate

Dear Mr. Lawyer:

Attached is an updated decontamination and decommissioning cost estimate dated May 02, 2016 for the Lantheus Medical Imaging PET Cyclotron Facility located at 150 Frederica Costa Street (Suite 1) San Juan, Puerto Rico.

As the Radiation Safety Officer and Director of Environment, Health and Safety at Lantheus Medical Imaging's home office, my staff and I collaborated with Philotechnics, Ltd. to develop an updated facility decontamination and decommissioning cost estimate (DDCE) to supersede the DDCE provided to your office dated March 23, 2016.

The attached, updated DDCE compiled by Philotechnics addresses the questions/comments identified within your email dated April 05, 2016.

As discussed, Lantheus Medical Imaging will retain the current financial assurance surety value at $553,472, pending approval of the attached DDCE dated May 02, 2016.

Please contact me by telephone or email if you have any questions or require additional documentation concerning this matter.

Roy Greaves

Roy Greaves, Radiation Safety Officer
Director, Environment Health and Safety

588543

NMSS/RGN1 MATERIALS-002

3.4 FACILITY DECOMMISSIONING SUMMARY

Radioactive Material license numbers and types (i.e., Byproduct, Source):
U.S. Nuclear Regulatory License 52-25361-02
Types and quantities of materials authorized under the licenses listed above:
A. F-18 is produced in quantities of 30 Curies maximum. B. Any byproduct material atomic numbers 1-83 as incidentally activated products; 30 mCi each, 1 Ci total. C. Mn-54 as incidentally activated products, 200 mCi maximum. D. Co-60 as incidentally activated product, 100 mCi total. E. Zn-65 as incidentally activated products, 100 mCi maximum. G. Any byproduct material permitted within 10 CFR 35.65(a) as sealed sources, 50 mCi maximum. The facility is in operation. Therefore, activation products are present in the internal cyclotron target components, and within cyclotron shielding materials.
Description of how licensed materials are used:
Fluorine-18 is produced on the cyclotron and processed, dispensed, and packaged for off site shipment and use. Radioactive waste is held for decay and does not accumulate more than a few drums.
Description of facility, including buildings, rooms, grounds, and description of where particular types of materials are used:
The cyclotron room contains the RDS Eclipse cyclotron including spent target material, laboratory benches, and accumulated waste. Negative ventilation removes air from the cyclotron room and discharges on the roof through a high efficiency particulate air (HEPA) filter. Total area of these rooms is approximately 3500 square feet.
Quantities of materials or waste accumulated before shipping or disposal
A few drums of short lived waste to allow for decay. Waste storage space is minimal.

Use this table to summarize relevant features of the facility. Copy and complete the table as necessary for each room, laboratory, or area. Rooms laboratories, or areas with similar levels of contamination may be consolidated into one table.				
Name of room, laboratory, or area:	Cyclotron and shielding			
Level of Contamination:	Low; some activated equipment and structures			
Component	Number of Components	Dimensions of Component (specify units)	Total Dimensions (specify units)	
Cyclotron Vessel	1		23000	ft3
Fume Hoods				ft3
Lab Benches				ft3
Sinks				ft3
Drains				ft3
Floors				ft2
Walls				ft2
Ceilings				ft2
Ventilation/Ductwork				ft3
Hot Cells				ft3
Equipment/Materials				lb
Soil Plots				ft2
Storage Areas				ft3
Radwaste Areas				ft3
Cyclotron Composite Shielding	1 set of shielding		59190	lb
Lead Shielding	19,380 lbs to be surveyed for release		0	lb
Equipment Decon Areas				ft3
Accumulated Radwaste	Approx. 2 drums DAW		150	lb
Concrete floor				ft3
		Feature/Equipment Mass	82340	lb
		Waste Fraction	1.00	
		Waste Mass	82340	lb

3.6 PLANNING AND PREPARATION

(Work Days)

Estimate the number of workdays, by specific labor category, that will be required to complete planning and preparation activities. Include all labor categories, including Supervisor, Foreman, Craftsman, Technician, Health Physicist, Laborer, Clerical, and others as needed.

Activity	Project Mgr/Health Physicist		Shipper	HP Technician	Radiation Workers	Clerical
Preparation of Documentation for Regulatory Agencies	2		2			1
Submittal of Decommissioning Plan to NRC when required by 10 CFR 30.36(g)(1), 40.42(g)(1), or 70.38(g)(1)	2					0.5
Development of Work Plans	5			2		5
Procurement of Special Equipment	2					1
Staff Training	2		1	2	6	2
Characterization of Radiological Condition (including sampling, soil and tailings analysis, or groundwater analysis, if applicable)	2			4		
Other (specify) Mobilization	1		1	2		
TOTALS	16		4	10	6	9.5

3.7 DECONTAMINATION OR DISMANTLING OF RADIOACTIVE FACILITY COMPONENTS (Work Days)

Estimate the number of workdays, by specific labor category, that will be required to complete decontamination and/or dismantling activities for each facility component. Copy and complete this table as necessary for each room, laboratory, or area. Rooms, laboratories, or areas with similar levels of contamination may be consolidated in one table.

Name of room, laboratory, or area:							
Level of Contamination:		Low					
Component	Decon Method	Project Mgr/Health Physicist		Shipper	HP Technician	Radiation Workers	Clerical
Glove Boxes	Remove/Disp						
Fume Hoods	Remove/Disp						
Lab Benches	Remove/Disp				2	2	0.1
Sinks	Remove/Disp						
Drains	Remove/Disp						
Floors	Scabble						
Walls	Remove/Disp						
Ceilings	Vac/Wipe						
Ventilation/Ductwork	Remove/Disp	2			2	4	0.5
Hot Cells	Remove/Disp						
Equipment/Materials	Sur/Rem/Disp						
Soil Plots	Sample						
Storage Tanks	N/A						
Storage Areas	Remove/Disp						
Radwaste Areas	Remove/Disp	0.25		0.5	0.5	1	0.25
Scrap Recovery Areas	N/A						
Maintenance Shop	Remove/Disp						
Equipment Decontamination	Remove/Disp						
Shield blocks	Remove/Disp	2		2	4	8	2
Cyclotron	Remove/Disp	2		2	4	8	2
TOTALS		6.25		4.5	12.5	23	4.85

3.8 RESTORATION OF CONTAMINATED AREAS ON FACILITY GROUNDS
(Work Days)

Estimate the number of work days, by specific labor category, that will be required to restore contaminated areas on the facility grounds.

Activity	Project Mgr/Health Physicist		Shipper	HP Technician	Radiation Workers	Clerical
Restore Floors						
Restore Walls						
Restore Roof						
Restore Utilites						
TOTALS	0		0	0	0	0

3.9 FINAL RADIATION SURVEY

(Work Days)

Estimate the number of work days, by specific labor category, that will be required to conduct a final radiation survey.						
Activity	Project Mgr/Health Physicist		Shipper	HP Technician	Radiation Workers	Clerical
FSS Setup	2					1
Survey Packages	1					1
Class 1	5			10		1
Class 2	1			2		0.5
Class 3	1			2		0.5
TOTALS	10		0	14	0	4

3.10 SITE STABILIZATION AND LONG-TERM SURVEILLANCE
(Work Days)

Estimate the number of work days, by specific labor category, that will be required to complete site stabilization and long-term surveillance activities.

Activity	Project Mgr/Health Physicist		Shipper	HP Technician	Radiation Workers	Clerical
TOTALS	0		0	0	0	0

3.11 TOTAL WORK DAYS BY LABOR CATEGORY

Enter the total work days for each specific labor category from the applicable table above (i.e., from the bottom rows of Tables 3.6 through 3.10).						
Task	Project Mgr/Health Physicist		Shipper	HP Technician	Radiation Workers	Clerical
Planning and Preparation (TOTALS from Table 3.6)	16		4	10	6	9.5
Decontamination and/or Dismantling of Radioactive Facility Components (Sum of TOTALS from all copies of Table 3.7)	6.25		4.5	12.5	23	4.85
Restoration of Contaminated Areas on Facility Grounds (TOTALS from Table 3.8)	0		0	0	0	0
Final Radiation Survey (TOTALS from Table 3.9)	10		0	14	0	4
Site Stabilization and Long-Term Surveillance (TOTALS from Table 3.10)	0		0	0	0	0

3.12 WORKER UNIT COST SCHEDULE

Estimate labor costs (including salary, fringe benefits, and corporate overhead). Include all appropriate labor categories, including Supervisor, Foreman, Craftsman, Technician, Health Physicist, Laborer, Clerical, and others as needed.

Labor Cost Component	Project Mgr/Health Physicist		Shipper	HP Technician	Radiation Workers	Clerical
Salary ($/year)	$94,950		$57,530	$75,960	$42,730	$34,500
Overhead Rate (%)	100%		100%	100%	100%	100%
Total Cost Per Year	$189,900		$115,060	$151,920	$85,460	$69,000
Living Expenses (PD*7/5)[1]	$396		$396	$396	$396	0
Total Cost Per Work Day[2]	$1,127		$839	$981	$725	$265

[1] Per Diem Rate: $283 per day.

[2] Based on 260 work days per year (e.g., 260).

3.13 TOTAL LABOR COSTS BY MAJOR DECOMMISSIONING TASK

Multiply the estimated work days for each specific labor category (from Table 3.11) by the total cost per work day for the corresponding labor category (from Table 3.12), and enter the results in the table below. Then, add across all labor categories to determine the total labor costs for each major decommissioning task.

Labor Cost Component	Project Mgr/Health Physicist	0	Shipper	HP Technician	Radiation Workers	Clerical	Total Labor Cost
Planning and Preparation	$18,025	$0	$3,355	$9,805	$4,349	$2,521	$38,056
Decontamination and/or Dismantling of Radioactive Facility Components	$7,041	$0	$3,774	$12,256	$16,673	$1,287	$41,031
Restoration of Contaminated Areas on Facility Grounds	$0	$0	$0	$0	$0	$0	$0
Final Radiation Survey	$11,266	$0	$0	$13,727	$0	$1,062	$26,054
Site Stabilization and Long-Term Surveillance	$0	$0	$0	$0	$0	$0	$0

3.14 PACKAGING, SHIPPING, AND DISPOSAL OF RADIOACTIVE WASTES (Excluding Labor Costs)

(a) Packing Material Costs

Estimate the types and volumes of waste expected to be generated, along with the number and types of containers required for packaging the waste. Multiply the number of containers required by the unit cost per container.

Waste Type	Volume (ft3)	Number of Containers	Type of Containers	Unit Cost of Container	Total Packaging Costs
DAW	15	0.1	20' Sealand	$2,200	$220
Concrete	0	0	0	$0	$0
Activated Cyclotron Shield, composite material	987	1.5	20' Sealand	$2,200	$3,300
Metal	230	0.4	20' Sealand	$2,200	$880
TOTAL					$4,400

(b) Shipping Costs

Estimate the types and volumes of waste expected to be generated, along with the number and types of containers required for packaging the waste. Multiply the number of containers required by the unit cost per container.

Waste Type	Number of Truckloads	Unit Cost ($/mile/truckload)	Ocean Transport*	Overweight Charges ($/mile)	Distance Shipped (miles)	Total Shipping Costs
DAW	0.1	$2.00	1	$ -	875	$263
Activated Cyclotron Shield, composite material	1.5	$2.00	1	$ -	875	$3,939
Metal	0.4	$2.00	1	$ -	875	$1,050
Ocean Transport estimate						$50,000
TOTAL	2					$55,252

* Add $25,000 per Sealand Container to account for ocean transport

(c) Waste Disposal Costs

Estimate the volume of waste to be disposed. Multiply the volume of waste disposed by the unit disposal cost (including any volume based surcharges). Add any surcharges that are based on the number of containers of waste along with the number and types of containers required for packaging the waste. Multiply the number of containers required by the unit cost per container.

Waste Type	Disposal Volume (ft3)	Density (lb/ft3)	Disposal Mass (lbs)	Unit Cost	Surcharges ($/ft3 or $/container)	Total Disposal Costs
DAW	15	10	150	6.25	1	$938
Activated Cyclotron Shield, composite material	987	60	59190	0.60	1	$35,514
Metal	230	100	23000	6.25	1	$143,750
TOTAL	1232					$180,202

3.15 EQUIPMENT/SUPPLY COSTS (Excluding Containers)

Estimate the quantity of equipment and supplies required for decommissioning and multiply that quantity by the appropriate unit costs.			
Equipment/Supplies	Quantity	Unit Cost	Total Equipment/Supply Cost
Protective Clothing	200	$2	$400
Respirators	10	$20	$200
Instrumentation	5	$100	$500
Air Fare (round trip)	5	$700	$3,500
Crane and Crew (days)	2	$3,000	$6,000
TOTAL			$10,600

3.16 LABORATORY COSTS

If applicable, estimate the costs for analyses to be performed by an independent third party laboratory.			
Activity	Quantity	Unit Cost	Total Item Cost
Sampling & Analysis	20	$250	$5,000
Transport of Samples	20	$10	$200
Testing and Analysis			$0
Other (specify)			
TOTAL			$5,200

3.17 MISCELLANEOUS COSTS

Estimate any other applicable costs.	
Activity	Total Cost
License Fees (Reciprocity)	$1,900
Insurance	$2,872
Taxes	$16,479
Other (specify): Security	$1,303
TOTAL	$22,554

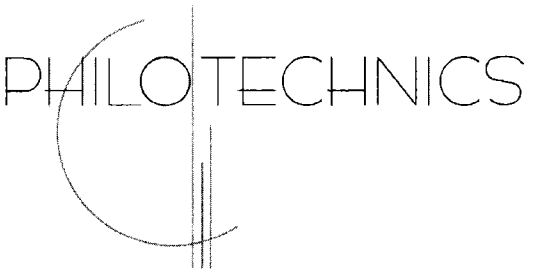
3.18 TOTAL DECOMMISSIONING COSTS

Enter the total costs reported in Tables 3.13, 3.14(a)-(c), 3.15, 3.16, and 3.17 into the appropriate cells below, and add then to obtain a subtotal. Add to the subtotal a contingency allowance in the amount of 25 percent of the total decommissioning cost estimate. Also, calculate for each task/component the percentage it represents of the total.		
Task/Component	Cost	Percentage
Planning and Preparation (from Table 3.13)	$38,056	9.9%
Decontamination and/or Dismantling of Radioactive Facility (From Table 3.13)	$41,031	10.7%
Restoration of Contaminated Areas on Facility Grounds (From Table 3.13)	$0	0.0%
Final Radiation Survey (From Table 3.13)	$26,054	6.8%
Packing Material Costs (TOTAL from Table 3.14(a))	$4,400	1.1%
Shipping Costs (TOTAL from Table 3.14(b))	$55,252	14.4%
Waste Disposal Costs (TOTAL from Table 3.14(c))	$180,202	47.0%
Equipment/Supply Costs (TOTAL from Table 3.15)	$10,600	2.8%
Laboratory Costs (TOTAL from Table 3.16)	$5,200	1.4%
Miscellaneous Costs (TOTAL from Table 3.17)	$22,554	5.9%
SUBTOTAL	$383,350	100.0%
25% Contingency	$95,837	25.0%
TOTAL DECOMMISSIONING COST ESTIMATE	$479,187	125.0%

Decontamination and Decommissioning Cost Estimate For PET Cyclotron Facility

Lantheus Medical Imaging
150 Frederica Costa Street, Suite #1
San Juan, Puerto Rico

Prepared by:



Philotechnics, Ltd.
201 Renovare Boulevard
Oak Ridge, TN 37830

May 02, 2016

I. Executive Summary

Lantheus Medical Imaging (Lantheus) operates a cyclotron facility in San Juan, Puerto Rico under the authority of U.S. Nuclear Regulatory License 52-25361-02. The purpose of this facility is to produce radionuclides for medical imaging using positron emission tomography (PET). To estimate future decommissioning costs, Lantheus contracted Philotechnics, Ltd. to develop facility decommissioning cost estimates in accordance with the guidance provided in NUREG 1757, Consolidated NMSS Decommissioning Guidance. The facility consists of a Siemens RDS Eclipse 11 MeV self-shielded cyclotron producing F-18 under NRC License 52-25361-02. F-18 is short-lived. No long-lived radioactive contamination is expected to be detected within the facility during decommissioning activities, with the exception of some internal cyclotron components and the external cyclotron shielding component. Based upon information obtained from multiple industry sources, no activation of the facility concrete flooring requiring remediation is expected. This information is specific to the current generation of self-shielded PET cyclotron as in use at this facility.

Per Lantheus' request, Philotechnics developed detailed "bottom-up" cost estimates based on review of facility design features, current and historical radionuclide use, present radiological conditions and physical waste inventory. Philotechnics also evaluated Decontamination and Decommissioning (D&D) work approaches and task sequences in order to estimate labor, materials and supplies.

This report describes the overall process applied to developing the cost estimate, the general assumptions regarding facility D&D, general assumptions regarding radioactive waste processing and disposal, and specific assumptions and calculations with respect to this facility.

Cost estimates were developed using conservative, realistic assumptions regarding likely extent and duration of remediation activities. Remediation was assumed to proceed to unrestricted levels. Cost estimates were prepared in accordance with and in the format of NUREG 1757 Consolidated NMSS Decommissioning Guidance[1] Volume 3. Per NUREG 1757 a contingency of 25% is required to be added to decommissioning estimates to address unidentified and unanticipated conditions. The overall estimate for the San Juan facility is:

Estimate	25% Contingency	Total
$383,350	**$95,837**	**$479,187**

[1] "Consolidated NMSS Decommissioning Guidance", NUREG-1757, US Nuclear Regulatory Commission, September 2006, Washington, DC.

This decommissioning plan should be evaluated in 3 years and revised to account for any changes in the costs required for decommissioning activities.

II. Objectives

The principal objectives of this analysis are to: 1) develop reliable estimated total facility decommissioning costs for Lantheus' San Juan operations, and 2) provide a documented inventory of facility features and characteristics. These cost estimates were performed to support Lantheus' management in addressing the requirements for periodically updating the facility decommissioning funding plan.

Cost estimates for decommissioning activities were based on the methodology contained in the US Nuclear Regulatory Commission's (NRC) NUREG 1757. This methodology was modified and supplemented as necessary to account for realities associated with project field implementation in San Juan.

III. Process

To achieve the project objectives concerning facility D&D, a "bottom-up" approach was used consistent with the guidance provided in NUREG 1757. Specifically, facility floor plans and system drawings were obtained, and the principle features and equipment were inventoried and categorized. The work scope and activity sequence to support unrestricted release of the facility was developed. Cost estimates for projects were based on anticipated Time and Materials rates for goods, labor and services necessary to complete each project phase.

Estimates for facility decommissioning followed the form and content of Appendix A of the NUREG 1757, Volume 3. This document is the federal standard for reviewing the completeness and adequacy of decommissioning plans submitted by holders of radioactive materials licenses issued by the US NRC.

A schedule of equipment, features and characteristics was developed to capture the size of each space and key features relevant to developing decommissioning cost estimates.

Radioactive waste estimates were based upon the volume of material in the storage areas and supporting systems. Material that is not likely to be contaminated above release limits is not considered as radioactive waste.

Some shielding material may be activated; however it is suitable for Tennessee's Bulk Survey for Release (BSFR) program.

Labor estimates were derived from the work scope, and a project plan outline was developed for the facility detailing the sequence of tasks required to decommission the facility and terminate its radioactive material license. An overall project schedule was estimated that considered work to be performed, material flow paths, and optimal crew size and constraints in the D&D process. Crew sizes and task durations were estimated based on the numbers and locations of tasks to be performed.

Marketplace rates were obtained for each element of the project including project labor, materials, supplies, sampling and waste packaging, processing and disposal. NUREG 1757 requires the cost estimate to assume an out-of-state contractor performs the work; therefore nationwide mean salaries for the appropriate labor categories were used based on the latest available data from the U.S. Department of Labor, Bureau of labor Statistics. The unit rates were applied through the estimated quantities to determine total cost for each line item. Costs were summed by each element of the project to determine sub-total by element. Element sub-totals were summed to total project cost.

IV. Current Radiological Conditions

The facility is currently in operation. Therefore, activation products are present in cyclotron components – especially in the vicinity of the targets, and on cyclotron surfaces.

V. Assumptions

Philotechnics provides waste brokerage and decontamination and decommissioning (D&D) services throughout the nation. The estimated costs for packaging, transportation and disposal, as well as labor needs, are realistic estimates based on experience and contractual arrangements with waste processors and disposal facilities

Assumptions were made concerning likely extent and duration of necessary remedial activities. Remediation to unrestricted levels (i.e., the facility could be released for any future use without restrictions) was assumed, meaning there are no long term costs associated with site surveillance and monitoring following decommissioning.

The radioactive materials of concern at this site are primarily short-lived products in the form of F-18 which is used for PET scanning. The cyclotron itself, targets, and target assemblies are expected to be activated and require disposal as radioactive waste. Portions of the self-shielding enclosure are expected to be activated to low levels; this material will go through Tennessee's bulk survey for release (BSFR) program. Additionally, a few drums of waste are expected from decommissioning activities. It is assumed decommissioning activities will begin within a few months after cyclotron operation ceases; short-lived activation products will have decayed to negligible levels.

Radioactive Waste Materials

The cyclotron assembly weighs 23,000 pounds and the entire unit is expected to be handled as radioactive waste. Unlike older models, the RDS Eclipse is designed and installed such that activation of concrete flooring underneath the unit is not expected. Experience – and detailed sampling by the manufacturer, Siemens PETNET Solutions – has shown that only a small fraction of the shielding material surrounding the cyclotron is activated to low levels. All shielding materials will be acceptable for the BSFR program. Supporting equipment such as control panels, cooling systems, and electrical cabinets is not radioactive and will be surveyed for unconditional release.

Shielding that surrounds the cyclotron consists of approximately 59,190 pounds of composite material shielding which includes 19,380 pounds of lead. Experience has shown only the composite shielding material becomes activated and will be acceptable for the BSFR program. Lead will be surveyed for unrestricted release.

The walls of the Cyclotron Room are expected to be neither activated nor contaminated.

The balance of the facility consists of ventilation system, target preparation area and storage of accumulated waste. With the exception of radioactive waste storage, none of the equipment is expected to be contaminated at the time of decommissioning because F-18 will have decayed to background levels. All other material is expected to be surveyed for unrestricted release.

Waste mass is multiplied by marketplace rates for waste processing and disposal. Packaging and transportation costs were estimated by volume and were added to the total waste disposal figure. Actual volume of waste expected to be removed from the site was considered

This decommissioning plan will be evaluated at least every 3 years or more frequently if the amounts or types of material at the facility change, facility conditions or operations change, changes occur in expected decommissioning procedures, or to account for inflation.