



Pfizer Inc  
 Environmental Health & Safety  
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Worldwide Research & Development

**Environmental Health & Safety**

October 24, 2014

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RECORDED 10/27/14 10:02

Dennis Lawyer  
 Licensing Assistance Team  
 Nuclear Materials Safety Branch  
 U.S. Nuclear Regulatory Commission, Region I  
 2100 Renaissance Boulevard, Suite 100  
 King of Prussia, PA 19406-2713

RE: Pfizer, Inc., Request for Additional Information Concerning Application for a License Renewal, Control 584532

Dear Mr. Lawyer,

We are writing in response to your email dated October 22, 2014 requesting additional information concerning Pfizer's request to renew Nuclear Regulatory Commission License No. 06-05869-01, Docket No. 03003790. The additional information that you requested is provided below.

- 1) Pfizer no longer requires authorization to prepare and distribute radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.
- 2) Please amend Item 5 of our license renewal application to read as follows:

Element and Mass Number	Chemical and/or Physical Form	Maximum Amount that will be Possessed at Any One Time
A. Any byproduct material with atomic numbers 1 through 83	Any	300 millicuries per radionuclide and 20 curies total
B. Hydrogen-3	Any	10 Curies
C. Carbon-14	Any	10 Curies
D. Phosphorus-32	Any	500 millicuries
E. Phosphorus-33	Any	500 millicuries
F. Sulfur-35	Any	500 millicuries

584532

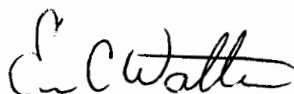
- 3) Regarding Radiation Policy Committee meetings, a quorum is established when 50 percent or more of all committee members are present.
- 4) Program changes will be documented. This documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to approval by the Radiation Policy Committee. This documentation, including approval or denial of the request, will be maintained in the Radiation Policy Committee meeting minutes.
- 5) Radiation Safety Training will be provided by a qualified instructor. A qualified instructor is deemed to mean the Radiation Safety Officer or a health physics technician who is a member of the Radiation Safety Office and is familiar with Pfizer's radiation safety program.

Learning proficiency may be evaluated by methods including, but not limited to, quizzes, hands-on demonstrations, verbal responses or observations by the instructor. Typically in-person training presentations rely on verbal responses and observations by the instructor while on-line training presentations incorporate questions that must be answered correctly in order to continue or complete the training.

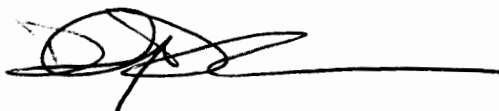
- 6) A revised Decommissioning Funding Plan is enclosed with this letter.
- 7) A revised Decommissioning Funding Plan is enclosed with this letter.
  - a) 2014 prices were used in the cost estimate.
  - b) The cost was based on an independent contractor performing the decommissioning.
  - c) A detailed cost estimate will be re-performed at least every three years as required by 10 CFR 30.35(e)(2).
  - d) The volume of onsite subsurface material containing residual radioactivity that will require remediation is addressed in the revised Decommissioning Funding Plan.

We hope that we have adequately addressed all of your questions. If you have any additional questions, please do not hesitate to contact Mr. David Durkee at (860) 441-4744 or at [david.j.durkee@pfizer.com](mailto:david.j.durkee@pfizer.com).

Sincerely,



Eric Watters  
EHS Site Lead



David J. Durkee  
Radiation Safety Officer

Enclosure:  
Revised Decommissioning Funding Plan

**Revised**

**DECOMMISSIONING FUNDING PLAN**

**PFIZER, INC  
EASTERN POINT ROAD  
GROTON, CT 06340**

**LICENSE NUMBER 06-05869-01**

October 24, 2014

## DECOMMISSIONING FUNDING PLAN

### 1.0 SCOPE

The Scope of this Decommissioning Funding Plan (DFP) is to ensure that adequate funds are provided to cover the decommissioning of the Pfizer Inc.'s Worldwide Research and Development facility located in Groton, Connecticut. This DFP is being updated in order to account for termination of radioactive materials license number 06-05869-03 as well as current labor and radioactive waste disposal costs.

### 2.0 REFERENCES

- 2.1 Pfizer, Inc. radioactive materials licenses No. 06-05869-01.
- 2.2 Code of Federal Regulations, Title 10, Part 30, Section 35
- 2.3 NUREG 1757, Volume 3, Rev 1 entitled "Consolidated NMSS Decommissioning Guidance - Financial Assurance, Recordkeeping, and Timeliness," dated February 2012.

### 3.0 DECOMMISSIONING PROCEDURE

#### 3.1 Radioactive Material Possessed

<u>Element and Mass Number</u>	<u>Chemical and/or Physical Form</u>	<u>Maximum Amount which will be Possessed at any one time</u>
(1) Any byproduct material with atomic numbers 1-83 inclusive, except as specified below	(1) Any	(1) 300 millicuries of each radionuclide with a total possession limit of 20 curies
(2) Hydrogen – 3	(2) Any	(2) 10 curies
(3) Carbon-14	(3) Any	(3) 10 curies
(4) Phosphorus – 32	(4) Any	(4) 500 millicuries
(5) Phosphorus – 33	(5) Any	(5) 500 millicuries
(6) Sulfur – 35	(6) Any	(6) 500 millicuries

### 3.2 Facility Description

Pfizer, Inc. is a large multinational health-care company engaged in a diverse spectrum of biomedical research. There are a total of 186 areas within the Groton, Connecticut facility where licensed radioactive materials are authorized to be used and/or stored.

### 3.3 Facility Decontamination

Decontamination of the facility itself will be broken into seven parts.

3.3.1 Planning and preparation of the facility for decommissioning;

3.3.2 Assessment and disposal of laboratory equipment

3.3.3 Characterization survey of the facility;

3.3.4 Development and submittal of a Decommissioning Plan (if necessary);

3.3.5 Decontamination and dismantling of radioactive facility components;

3.3.6 Packaging, shipment, and disposal of radioactive wastes;

3.3.7 Final radiation survey of the facility; and,

3.3.8 Preparing and forwarding proper documentation of decommissioning results to the Nuclear Regulatory Commission and appropriate state agencies.

## 4.0 DECOMMISSIONING COST ESTIMATE

The following are conservative cost estimates to perform the tasks described based on estimated time to complete the tasks and upon 2014 prices for services and equipment. These estimates are also made on the assumption that all operations at Pfizer, Inc. are performed in accordance with the requirements as specified in Materials License Number 06-05869-01 and other supporting documentation.

#### 4.1 Planning and Preparation of the Facility and Site for Decommissioning

##### 4.1.1 Obtain and review documentation pertinent to the decommissioning such as:

- Facility floor plans indicating laboratory and radioactive materials storage locations;
- Radioisotopes and quantities used in each area; and,
- Spills or unusual occurrences which involved the spread of contamination in and around the facility, equipment, or site.

This task is estimated to take 40 person-hours to complete. At an estimated cost of \$113 per hour for a health physicist's service, the total cost of this task is estimated to be \$4,520.

##### 4.1.2 Remove all radioactive material from the laboratories and other locations throughout the facility, transfer to the waste storage area and prepare for transfer offsite.

This task is estimated to take 100 person-hours to complete. At an estimated cost of \$76 per hour for a health physics technician's service, the total cost of this task is estimated to be \$7,600.

##### 4.1.3 Plan site characterization survey.

This task is estimated to take 30 person-hours to complete. At an estimated cost of \$113 per hour for a health physicist's service, the total cost of this task is estimated to be \$3,390.

#### 4.2 Assess Potentially Contaminated Equipment

##### 4.2.1 Assess potentially contaminated laboratory equipment and decontaminate and/or dispose of equipment as applicable.

This task is estimated to take 1,600 person-hours to complete. At an estimated cost of \$76 per hour for a health physics technician's service and \$5,000 for laboratory analysis and supplies, the total cost of this task is estimated to be \$126,600.

#### 4.3 Characterization Survey

- 4.3.1 Perform and document an extensive radiological survey of the 186 use and/or storage areas.

This task is estimated to take 1,860 person-hours to complete. At an estimated cost of \$76 per hour for a health physics technician's service and \$6,000 for laboratory analysis and supplies, the total cost of this task is estimated to be \$147,360.

#### 4.4 Develop and Submit a Decommissioning Plan

- 4.4.1 Develop a Decommissioning Plan (if necessary) along with any pertinent procedures based upon the results of the characterization survey. This plan will be forwarded to the NRC for approval. This task is estimated to take 40 person-hours to complete. At an estimated cost of \$113 per hour for a health physicist's service, the total cost of this task is estimated to be \$4,520.

#### 4.5 Decontamination and Dismantling of Radioactive Facility Components

- 4.5.1 Dismantle and/or decontaminate radioactive facility components identified in the characterization survey. These components may include fume hoods, glove boxes, sinks, drain lines, ventilation ducting, floors, walls, and work benches. It is estimated that a maximum of 1% of the areas surveyed will require corrective action and that decontamination will be used whenever feasible rather than straight disposal to help minimize radioactive waste volume.

This task is estimated to take 700 person-hours to complete. At an estimated cost of \$76 per hour for a health physics technician's service and \$2,200 for laboratory analysis and supplies, the total cost of this task is estimated to be \$55,400.

- 4.5.2 Obtain decontamination equipment such as HEPA-filtered ventilation units and vacuum cleaners, protective clothing, scabblers, saws, grinders etc. It is assumed that this equipment will be rented and not purchased.

The decontamination is estimated to take 3 weeks to complete. At a cost of \$1,500 per week, the total cost of this task is estimated to be \$4,500.

- 4.5.3 Obtain consumables and other materials used for the decontamination of the facility and also shipping containers for waste generated in the decommissioning process.

The cost of these materials is estimated to be \$6,000.

- 4.5.4 It is estimated that there will be no subsurface material containing residual radioactivity that will require remediation in order to meet the criteria for license termination.

The cost of subsurface material remediation is estimated to be \$0.

#### 4.6 Packaging, Shipment, and Disposal of Radioactive Wastes

- 4.6.1 Package all radioactive waste at the facility and store in the LLRW storage area. Waste shipment and disposal will be handled by a waste brokerage and shipping company such as Energy Solutions. Total waste volume is estimated to be:

- 300 cu. ft. of low-level radioactive waste stored at facility due to normal facility operations.
- 300 cu. ft. of waste generated during decommissioning.
- 20 liters of mixed waste

The 20 liters of mixed waste will cost more to dispose of than normal radioactive waste. The estimated cost of mixed waste disposal is \$1,500 per liter, for a total estimated disposal cost of \$30,000.

The remainder of the radioactive waste volume is estimated to be equivalent to 80 fifty-five gallon drums. At an estimated average cost of \$1,300 per drum, the cost of this task is estimated to be \$104,000.



Therefore, the total estimated cost for the disposal of all radioactive waste from the facility would be \$134,000.

#### 4.7 Final Radiation Survey of Facility

- 4.7.1 Perform and document an extensive radiological survey of the areas that were decontaminated to ensure that the facility meets the limits for release for unrestricted use.

This task is estimated to take 140 person-hours to complete. At an estimated cost of \$76 per hour for a health physics technician's service and \$1,300 for laboratory analysis and supplies the total cost of this task is estimated to be \$11,940.

#### 4.8 Prepare and Forward Proper Documentation of Decommissioning Results to the Nuclear Regulatory Commission and Appropriate State Agencies.

- 4.8.1 Obtain and review all documentation produced as a result of the decommissioning effort and develop a final report to be presented to the NRC.

This task is estimated to take 100 person-hours to complete. At an estimated cost of \$113 per hour for a health physicist's service, the total cost of this task is estimated to be \$11,300.

- 4.9 The estimated cost for the complete the decommissioning of Pfizer, Inc. is estimated to be \$517,130. Adding a 25% contingency factor to this estimate brings the total estimated cost to **\$646,413**.

### 5.0 FINANCIAL ASSURANCE MECHANISM

Pfizer, Inc. will use a Standby Trust Agreement issued by the Deutsche Bank Trust Company Americas to provide financial assurance.

### 6.0 COST ADJUSTMENTS

A detailed cost estimate will be re-performed at least every 3 years. Adjustments may be required due to changes in waste disposal costs, to account for site-specific factors (such as contamination incidents), or when the amounts and/or types of material possessed at the facility change.