elan

One Research Way
Princeton, New Jersey 08540
T (609) 580 3300 F (609) 520 8250

November 5, 2003

J-5

Donna Janda
United States Nuclear Regulatory Commission

Facility Name: Elan Pharmaceuticals, formally The Liposome Company Inc.
1 Research Way
Princeton, NJ 08540

License # 29-19918-01 03019526

Dear Donna,

By copy of this letter I am informing you that Elan Pharmaceutical Operations, formally The Liposome Company Inc., will cease operations at the Princeton facility.

As a result of this action, I am requesting the materials license issued to The Liposome Company, Inc. be terminated.

Please be advised that Joel Antkowiak, of Antkowiak and Mahoney Enterprises, Inc. will be acting as our Radiation Safety Officer and executing the decommissioning of the facility. At your request I have enclosed a copy of the Decommissioning Plan.

Please advise if any additional information is needed.

Sincerely,

11/5/03.

Don Dantoni
Manager Engineering Maintenance
Elan Pharmaceutical Operations
1 Research Way
Princeton NJ, 08540
609-580-3338

133934

NMSS/RGNI MATERIALS-002

www.elan.com

nrc BIOPHARMACEUTICALS • DRUG DELIVERY

Elan Operations, Inc.
a member of the Elan Group

29-19918-01

03019526

DECOMMSSIONING PLAN
FOR

ELAN PHARMACEUTICAL
OPERATIONS, INC.

PRINCETON, NEW JERSEY

July 2003

Prepared by

Antkowiak and Mahoney
Enterprises, Inc.

Contents

1.0 Background

Elan Pharmaceutical Operations Inc. (Elan) is a pharmaceutical research company with laboratories in Princeton, New Jersey, among other locations. When Elan purchased The Liposome Company, it assumed Liposome's U.S. Nuclear Regulatory Commission license (License No. 29-19918-01) covering research activities involving the use of radioactive materials. Liposome, and then Elan, contracted with an outside health physics services company to perform monthly radiation contamination surveys as well as other services. The surveys were first performed by Teledyne Isotopes and its successors, followed by Radiation Science Inc. (RSI) beginning in 2001. Research activities at the Princeton site ceased early in 2003.

Based on the most recent monthly surveys performed by RSI personnel, there is no indication of extensive contamination. However, based on information on a past incident, there may be residual tritium contamination in the hood and associated ductwork in the room known as Organic Lab #1. In addition, there may also be contamination in one hood in Main Lab C that was used for radioactive work when the hood in Organic Lab #1 was shut down. The interior of the hoods were not usually surveyed by the health physics consultants due to other potential hazards present during periods of active research.

2.0 Objective

The purpose of this project is to survey the radioactive materials use areas of the Elan facility in Princeton, New Jersey to demonstrate levels of residual radioactivity sufficiently low to release the building for unrestricted use. There are 2 areas of concern: the building itself and the low level radioactive waste storage shed behind the building. The surveys will be performed by Antkowiak and Mahoney Enterprises, Inc. (AME) under the Elan Pharmaceutical Operations Inc. radioactive materials license. Release criteria for all material to be released under this project will be those delineated in NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual" (MARSSIM).

3.0 Organization

The responsibility for survey and radiological release activities lies with Elan Pharmaceutical Operations Inc. The decommissioning survey and decontamination (if necessary) will be conducted by AME. AME will supply sufficient qualified manpower to perform surveys and sampling that are necessary to complete this plan, as well as prepare a report presenting the results of the survey and the final status of the site.

The AME Project Manager will be Joel Antkowiak. Mr. Antkowiak has been the acting RSO for Elan since mid-2001. Mr. Antkowiak has over 13 years of experience (see Appendix I) in decommissioning facilities and other health physics work. He will report to Mr. Donald Dantoni of Elan.

4.0 Contaminants of Concern

The building was used for pharmaceutical research involving various mostly short-lived isotopes. The isotopes that were predominantly used were carbon-14 and tritium (hydrogen-3). A record search indicated that since Elan assumed control, only tritium and carbon-14 have been used. Nickel-63 has been on site in the form of sealed source in electron capture detectors. Other isotopes that have been used on site prior to Elan's purchase of the operation include iodine-125, sulfur-35, Chromium-51, phosphorus-32 and phosphorus-33. It has been a minimum of 5 years since any of these short-lived isotopes have been used at the site. While Elan's license allows other isotopes to be used, there is no indication of their use in the records that were available for review. However, all licensed isotopes will be able to be detected with the instrumentation that will be used.

5.0 Instrumentation

This project will use the following instruments or their equivalent for verification of the presence or absence of radioactive contamination:

5.1 Beta/Gamma Surveying

Ludlum Model 12 meter with 43-68 gas proportional probe or other appropriate probe calibrated to detect beta radiation. The floor will be surveyed with a Ludlum Model 12 meter with model 239-IF floor monitor equipped with a model 43-37 gas proportional probe calibrated to detect beta radiation.

Exposure rate measurements will be taken using a Ludlum Model 19 microR meter or equivalent.

5.2 Sample Analysis

Smear samples for removable contamination, as well as water samples, will be analyzed by liquid scintillation counting using a Beckman Model LS5801 Liquid Scintillation Analyzer, serial number 214555, or other appropriate counter. The unit specified is currently on site. The disposition of this unit will be determined at the end of the project.

The results of the liquid scintillation analyses are presented by channel number. Channel 1 is set for optimum tritium efficiency (0-19 kev); channel 2 is set for optimum carbon-14 efficiency (19-156 kev) and channel 3 is set for all other higher energy beta emitters (156-1000 kev). Any samples that exhibit activity will be recounted for 5 minutes to verify the activity and obtain an accurate measurement.

6.0 Survey and Sampling Methods

6.1 Removable Radioactive Contamination

Removable activity samples will be obtained by smearing an area of approximately 100 cm^2 with an absorbent filter paper. Data recorded with each swipe will include sample location and date.

6.2 Survey Methods

Scanning will be performed on all MARSIMM class I, II and III survey units. Scanning coverage of 100% will be performed on class I and II survey units, whereas 50% coverage will be the standard for class III survey units.

Direct scalar measurements will be taken at the following rates:

a) one every square meter for class I survey units,
b) one every 4 square meters for class II survey units, and
c) one every 10 square meters for class III survey units.

Direct measurements will be performed for beta and gamma emitters.

Dose rate measurements will be taken by walking through the site while holding a meter in hand and noting the dose rate of the area. Passes will be made at intervals of 2 meters or where the project manager deems it prudent to measure.

7.0 Survey Units

There are 24 areas that were being surveyed on a routine basis prior to the cessation of activities at the site. They are:

Table 1: Affected Areas

Animal Prep	Animal Support	Instrument Hall
Stock Room	Cold Room	Organic Lab #1
Room #218	Room #316	Organic Lab #2
Room #226	Main Lab – B	Laboratory Hall
Room #228	Main Lab – B Annex	Main Lab-C (No Window)
Room #232	Main Lab-B Annex #2	Main Lab-C (w/Window)
Room #233	Lab Prep Room	Cell Culture Room
Room #237		
Room #242		Waste Storage

These are classified as follows.

7.1 Vivarium Rooms

The vivarium consisted of all rooms in the first column of Table 1 above. Only occasional doing of laboratory animals was performed in these rooms. They are classified as MARSIMM Class II. These are survey units 1 through 9.

7.2 Support Rooms

This category consists of rooms that provided support for the research being conducted in the laboratories and the vivarium. These include Animal Support, Cold Room, Room #316, Lab Prep Room, Instrument Hall, Laboratory Hall, and the Cell Culture Room. They are classified as MARSIMM Class II. These are survey units 10 through 16.

7.3 Main Research Laboratories

The remaining rooms in the main building are the areas where the majority of the research was completed. The bulk of radioactive materials use was done in these areas. They include Main Lab – B, Main Lab – B Annex, Main Lab – B Annex #2, Main Lab – C (two parts), Organic Lab #1, and Organic Lab #2. They are classified as MARSIMM Class I and constitute survey units 17 through 23.

7.4 Waste Storage

Sealed containers of low-level radioactive waste were placed inside a shed just off the paved area of the parking lot. All low level radioactive waste was stored in this building. Waste was transported to the building in sealed plastic bags (dry waste) or in containers utilizing secondary containment (liquid wastes and scintillation vials). Although there were never any incidents involving spills of waste materials at the site, this will be considered a MARSIMM Class I survey area. The storage shed is survey unit 24.

7.5 Unaffected Areas

The corridors outside the laboratory areas, as well as the hallway inside the vivarium, will be surveyed as unaffected areas. They will be considered a MARSIMM Class III survey area. These hallways are survey unit 25.

7.6 Other Survey Units

Some of the survey units may have to be broken into smaller units, such as the Main Lab C. If this is necessary, They will be designated with their original survey unit number, with a letter (i.e., survey unit 1a, 1b, etc.).

8.0 Data Analysis and Reporting

8.1 Removable Activity

Samples taken for removable activity will be analyzed for beta and gamma emissions using the aforementioned liquid scintillation counter. Results of these analyses will be reported in activity per 100 cm^2. The locations where the samples were taken will be noted on a diagram or picture of the areas surveyed with the results of the analyses on the same page as the diagram.

8.2 Direct Activity

The results of the scanning survey will be presented on the diagrams of the areas surveyed. If no elevated readings are found, a general statement will be made within the text of the report describing the conditions that were found. Only readings that are above the minimum detectable activity level for the survey equipment used will be noted. All areas of elevated readings that are more than 1.5x background will also have a direct scalar reading taken at that point.

The locations of direct scalar measurements will be noted on each diagram. Any elevated readings will be marked and the corresponding activity noted.

An attempt will be made to clean any contamination that is found. Only the final status of each area will be reported.

9.0 Release Criteria

The NRC has published DandD Version 2 software to determine radionuclide-specific screening levels for structural surfaces and open land areas. The values for some radionuclides were derived by the NRC using default inputs and were published in FR notices (FRN) dated November 18, 1998 and December 7, 1999. These dose-based screening values can be used to show compliance with the dose criterion of 25 mrem TEDE without submitting site-specific values for NRC approval. More recently, the NRC provided additional guidance for the calculation and use of screening values in FRN dated June 13, 2000. In this FRN, the NRC states that DandD may be used to derive screening values for radionuclides not published in previous FRNs using the guidance provided in NUREG/CR-5512, Residual Radioactive Contamination From Decommissioning, Parameter Analysis, Draft Report for Comment, NRC 1999. These screening values are used as a guideline for the $DCGL_W$ values for this survey. For radionuclides that do not have a published value, DandD was used to derive a value based on default inputs. The $DCGL_W$ values for structural surface total contamination were derived. The $DCGL_W$ values for removable contamination are 10 percent of the total contamination values, consistent with NUREG/CR-5512. The use of the screening values as $DCGL_W$ values is conservative. The values used are listed in Table 1

Table 2 – $DCGL_W$ Values

Radionuclide	Total Contamination ($dpm/100cm^2$)	Removable Contamination[1] ($dpm/100cm^2$)
H-3	124,000,000#	12,400,000
C-14	3,670,000#	367,000
S-35	12,700,000#	1,270,000
I-125	690,000##	69,000

Notes:

[1]Removable criteria = Total/10

From Table 5.19, NUREG/CR-5512 Vol. 3, P_{crit} = 0.10

From DandD v2.1 iteration

* From Table 6.91, NUREG/CR-5512 Vol. 3, P_{crit} = 0.90

** From DandD v2.1 iteration

Because of the high $DCGL_W$ values that were determined and the objective of the survey, the actual release limits adopted by Elan will be much lower than the $DCGL_W$ values reported.

APPENDIX I

Resume: Joel Antkowiak

Joel Antkowiak
[redacted]
Phone:
E-mail:

EMPLOYMENT EXPERIENCE

Antkowiak and Mahoney Enterprises, Inc., Chester, New York

President / Health Physicist: Management of special projects including large contamination survey projects and decommissioning projects. Perform radiation surveys of analytical, industrial, and diagnostic x-ray equipment; present radiation protection training programs; perform survey meter calibrations, air and water effluent monitoring; prepare license applications and amendment requests for submittal to governing bodies; and perform audits of radiation safety programs. Prepare decommissioning plans. Responsible for all accounting. Off-site Radiation Safety Officer for Elan Pharmaceutical Operations in Princeton, NJ. Radiation Safety Officer for New York State license.

Emerson RSI, Inc. / Radiation Science Inc. (RSI), Cranbury, New Jersey
November 1999 – April 2003

Health Physicist / Manager of Health Physics Services: Management of special projects including large contamination survey projects and decommissioning projects. Perform radiation surveys of analytical, industrial, and diagnostic x-ray equipment; present radiation protection training programs; perform survey meter calibrations, air and water effluent monitoring; prepare license applications and amendment requests for submittal to governing bodies; and perform audits of radiation safety programs. Prepare decommissioning funding plans, as well as survey plans, quality assurance plans, and health and safety plans. Off-site Radiation Safety Officer for Alfacell Corp. in Bloomfield, NJ, and Elan Pharmaceutical Operations in Princeton, NJ. Radiation Safety Officer for RSI's NRC and State of New Jersey radioactive waste brokerage licenses. Manage a staff of up to 10 people.

Teledyne Brown Engineering - Environmental Services, Westwood, New Jersey
July 1990 - November 1999

Health Physics Supervisor and Radiation Safety Officer: Responsible for in-house radiation safety program as well as management of all Commercial Health Physics Services, including radiological contamination surveys, decommissioning projects, survey meter calibrations, and analytical equipment quality assurance. Off-site Radiation Safety Officer for Unilever Research US in Edgewater, NJ and Alfacell Corp. in Bloomfield, NJ. From February 1999 through November 1999, radiation safety officer on 5 NRC licenses, including a broad scope license, special nuclear materials license and a radioactive waste brokerage license, as well as a State of New Jersey license.

Duties include performing radiation safety surveys of over 200 pharmaceutical research laboratories monthly. Perform radiation surveys of analytical, industrial, and diagnostic x-ray equipment; present radiation protection training programs; sample analyses by solid and liquid scintillation counting, and gamma spectroscopy; air and water effluent monitoring; personnel exposure monitoring via bioassays by urinalysis, in-vivo thyroid bioassays, and TLD dosimeters; management of low level radioactive waste; prepare license applications and amendment requests for submittal to governing bodies; and perform audits of radiation safety programs.

EDUCATION & TRAINING

New York University
Sterling Forest, New York
M. S. - Environmental Health Science, May 1996.

University of Pittsburgh
Pittsburgh, Pennsylvania
B. S. - Physics, April 1985

Certified by the National Association of Mold Professionals as Mold Inspector and Remediator, August 2003.
Completed training for the revised OSHA Respiratory Protection Program requirements in June 1998.Completed OSHA Hazardous Waste Operations site 8 hour Supervisor training in November 1995.
Completed short course entitled "Procedures and Practices for Asbestos Control" in February 1994.

PROFESSIONAL AFFILIATIONS

Member of the New Jersey Chapter of the Health Physics Society since 1993.

APPENDIX II

Elan Pharmaceutical Operations Inc.

US NRC License

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 08

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, 39, 40, and 70, 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 September 14, 2000,
1. The Liposome Company, Inc.	3. License number 29-19918-01 is amended in its entirety to read as follows:
2. 1 Research Way Princeton, New Jersey 08540	4. Expiration date November 30, 2003
	5. Docket No. 030-19526 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
A. Hydrogen 3	A. Any	A. 125 millicuries
B. Carbon 14	B. Any	B. 25 millicuries
C. Phosphorus 32	C. Any	C. 50 millicuries
D. Phosphorus 33	D. Any	D. 50 millicuries
E. Sulfur 35	E. Any	E. 25 millicuries
F. Calcium 45	F. Any	F. 25 millicuries
G. Scandium 46	G. Any	G. 10 millicuries
H. Chromium 51	H. Any	H. 25 millicuries
I. Iron 59	I. Any	I. 20 millicuries
J. Zinc 65	J. Any	J. 20 millicuries
K. Strontium 85	K. Any	K. 10 millicuries
L. Niobium 95	L. Any	L. 10 millicuries
M. Technetium 99m	M. Any	M. 100 millicuries
N. Cadmium 109	N. Any	N. 20 millicuries

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
29-19918-01

Docket or Reference Number
030-19526

Amendment No. 08

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
O. Iodine 125	O. Any	O. 25 millicuries
P. Iodine 131	P. Any	P. 5 millicuriesP

9. Authorized use:

A. through P. Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 1 Research Way, Princeton, New Jersey.

11. A. Licensed material shall be used by, or under the supervision of, Lee Buccheri, or Andrew S. Janoff, Ph.D. Licensed material specified in Items 6.A., 6.B., 6.H., and 6.O., may also be used by or under the supervision of Walter R. Perkins, Ph.D. Licensed material specified in Items 6.A., 6.B., and 6.O. may also be used by or under the supervision of Christine S. Swenson, Ph.D.

B. The Radiation Safety Officer for this license is Lee Buccheri.

12. Licensed material shall not be used in or on human beings.

13. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
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030-19526

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16. 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. The 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 March 27, 1992
B. Letter dated August 25, 1993
C. Letter dated October 20, 1993
D. Letter dated September 14, 2000
E. Letter dated September 28, 2000

For the U.S. Nuclear Regulatory Commission

Date November 13, 2000

Original signed by Sattar Lodhi, Ph.D.

By _____

Sattar Lodhi, Ph.D.
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

43661456

This is to acknowledge the receipt of your letter/application dated

11/5/2003, and to inform you that the initial processing which includes an administrative review has been performed.

☑ TERM. 29-19918-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

_____.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 133934.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader

	:	(FOR LFMS USE)
	:	INFORMATION FROM LTS
BETWEEN:	:	----------
	:	
License Fee Management Branch, ARM	:	Program Code: 03620
and	:	Status Code: 0
Regional Licensing Sections	:	Fee Category: 3M
	:	Exp. Date: 20031130
	:	Fee Comments: _____
	:	Decom Fin Assur Reqd: Y
	::	

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
   Applicant/Licensee: ELAN OPERATIONS, INC.
   Received Date: 20031105
   Docket No: 3019526
   Control No.: 133934
   License No.: 29-19918-01
   Action Type: Termination

2. FEE ATTACHED
   Amount: /
   Check No.: /

3. COMMENTS

Signed M. A. Perkins
Date 11/5/2003

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License _____

3. OTHER _____
   _____

Signed _____
Date _____