

MATERIALS LICENSE

Amendment No. 11

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.

OFFICIAL RECORD COPY

Licensee

1. Joslin Diabetes Center, Inc.

2. One Joslin Place
Boston, Massachusetts 02215

In accordance with the letters dated
June 6, 1996 and July 31, 1996,
3. License Number 20-15266-01 is amended in
its entirety to read as follows:

4. Expiration Date December 31, 2005

5. Docket or
Reference No. 030-0088336. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This License

A. Hydrogen 3
B. Carbon 14
C. Phosphorus 32
D. Phosphorus 33
E. Sulfur 35
F. Calcium 45
G. Chromium 51
H. Iron 55
I. Strontium 85
J. Rubidium 86
K. Iodine 125
L. Iodine 131

A. Any
B. Any
C. Any
D. Any
E. Any
F. Any
G. Any
H. Any
I. Any
J. Any
K. Any
L. Any

A. 1000 millicuries
B. 80 millicuries
C. 410 millicuries
D. 325 millicuries
E. 230 millicuries
F. 10 millicuries
G. 20 millicuries
H. 10 millicuries
I. 20 millicuries
J. 30 millicuries
K. 150 millicuries
L. 76 millicuries

9. Authorized use

A. through L. Research and development as defined in 10 CFR 30.4, including animal studies and in vitro laboratory studies.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at One Joslin Place, Boston, Massachusetts.

11. A. Licensed material shall be used by, or under the supervision of, Robert John Smith, M.D., Robert G. Spiro, M.D., C. Ronald Kahn, M.D., Richard A. Jackson, M.D., Andrzej Krolewski, M.D., Ph.D., Mary R. Loeken, Ph.D., Donald C. Simonson, M.D., George L. King, M.D., Gordon C. Weir, M.D., Ronald K. Amoling II, or Marc Montminy, M.D., Ph.D.

B. The Radiation Safety Officer for this license is Ronald K. Amoling II.

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

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

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

20-15266-01

Docket or Reference Number

030-008833

Amendment No. 11

14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
15. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 90 days for decay-in-storage before disposal in ordinary trash, provided:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
 - B. 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.
 - C. A record of each such disposal permitted under this License Condition shall be retained for three 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.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
17. 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 February 27, 1995
 - B. Letter dated October 5, 1995
 - C. Letter dated November 16, 1995

Date

SEP - 5 1996

For the U.S. Nuclear Regulatory Commission

ORIGINAL SIGNED BY:

By

PENNY A. LANZISERA

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

SEP - 5 1996

Raymond Capers
Vice President and
Chief Operating Officer
Joslin Diabetes Center, Inc.
One Joslin Place
Boston, MA 02215

Dear Mr. Capers:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the license.

Also, please note that License Conditions 12 through 16 have either been added or updated with this amendment, in accordance with the current licensing procedures.

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 notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:

Penny Lanzisera
Division of Nuclear Materials Safety

License No. 20-15266-01
Jockey No. 030-08833
Control No. 123326

Enclosure:

Amendment No. 11

DOCUMENT NAME: R:\WPS\MLTR\L2015266.01

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	Lanzisera PL						
DATE	09/03/96	09/	/96	09/	/96	09/	/96

OFFICIAL RECORD COPY **ML 10**



MS 6

P-6

July 31, 1996

U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415
Attention: Ms. Penny Lanzisera

Re: Mail Control No. 123326

Dear Ms. Lanzisera:

This memo serves to inform you that Joslin Diabetes Center, Inc. wishes to amend its NRC license (no. 20-15266-01) as follows:

1. Please change the Radiation Safety Officer to Ronald K. Amoling II, MS, MBA. Ron comes to us after serving as the RSO at Children's Hospital, Boston, MA, for the past nine years. I have enclosed supplemental information concerning Ron's training and experience.
2. Also, please add Dr. Marc Montminy as a new principle investigator who will be handling and supervising the use of radionuclides in our research labs. Dr. Montminy comes to Joslin from the Salk Institute, CA, where he performed research utilizing radioactive materials for over ten years. I have enclosed supplemental information concerning Dr. Montminy's training and experience.

If you need additional information concerning these changes to our NRC license, please contact Ron Amoling at (617) 732-2682.

Sincerely,

Raymond Capers

Vice President and Chief Operating Officer

OFFICIAL RECORD COPY

ML 10

123326

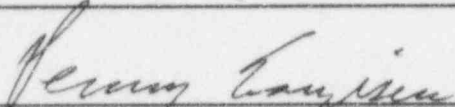
AUG 29 1996

EXHIBIT 2
SUPPLEMENT A

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION		
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER				
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Ronald K. Amoling II			2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED	
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES				
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING		
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE	
a. RADIATION PHYSICS AND INSTRUMENTATION	University of Lowell, Lowell, MA			
b. RADIATION PROTECTION	BS- Health Physics- February, 9186 MS - Health Physics - October 1986			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY				
d. RADIATION BIOLOGY				
e. RADIOPHARMACEUTICAL CHEMISTRY				
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
H-3	200	Children's Hospital, Boston, MA		RSO for Children's Hospital Broad Scope Medical License 04/87 - 04/96
C-14	100			
P-32	200			
P-33	50			
S-35	200			
Ca-45	10			
Cr-51	10			
Fe-55	10			
Sr-85	5			
Rb-86	5			
I-125	100			
I-131	100			
Ir-192	200			

EXHIBIT 2
SUPPLEMENT A

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION		
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER				
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Marc Montminy, MD, PhD		2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED		
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES				
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING		
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE	
a. RADIATION PHYSICS AND INSTRUMENTATION	1. Salk Institute: 1986 2. Tufts University Med School: 1983 3. Mass. General Hosp: 1982			
b. RADIATION PROTECTION	courses covered a-d each course was 3-4 hours lecture			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY				
d. RADIATION BIOLOGY				
e. RADIOPHARMACEUTICAL CHEMISTRY				
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
P-32	5	Salk Institute	±10 years lab use	DNA manipulations enzymatic assays protein synthesis studi
S-35	1	"		
C-14	0.200	"		

TELEPHONE CONVERSATION RECORD		Date: 7-1-96	Time: 2:30pm
Mail Control No.: 123326		License No.: 20-15266-01	Docket No.: 030-08833
Person Called: Ron Amoling, Proposed RSO		Organization: Joslin Diabetes	Telephone Number: 617 732-2400
Person Calling: Penny Lanzisera			
Subject: Amendment			
Summary: 1) Provide certification from management that they concur. 2) Provide T&E with isotopes for RSO if wishes to be named as an AU also. 3) Provide additional T&E with iodines for Dr. Montminy.			
Action Required/Taken: response			
Signature: 		Date: 7-1-96	

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ML 10



**Joslin
Diabetes
Center**

Dedicated to the
study of diabetes
and the care of
those with diabetes

One Joslin Place
Boston, Massachusetts 02215

(617) 732-2400

030 - 00838

June 6, 1996

U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Sir/Madam:

The Joslin Diabetes Center, Inc., would like to amend its license (no. 20-15266-01) in two ways:

1. Change the Radiation Safety Officer (RSO)
2. Add an additional Principle Investigator to our list of authorized users.

A check for the amendment fee of \$610.00 is enclosed.

1. The new RSO will be Ronald K. Amoling II, who comes to Joslin after serving as the RSO for Children's Hospital in Boston for the past nine years. He holds both a Bachelors and Masters degree in Health Physics from the University of Lowell, Lowell, MA. Information concerning his past training and experience is attached.

2. The new Principle Investigator is Dr. Marc Montminy, who comes to Joslin from the Salk Institute where he performed research utilizing radioactive materials for over ten years. Information concerning his past training and experience is attached.

If you have any questions concerning this amendment application, please contact me at (617) 732-2682.

Thank you for your time and consideration.

Sincerely,

Ronald K. Amoling II

EXHIBIT 2
SUPPLEMENT A

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION		
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER				
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER <i>Ronald K. Amoling II</i>		2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED		
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES				
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING		
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE	
a. RADIATION PHYSICS AND INSTRUMENTATION	Univ of Lowell Lowell MA			
b. RADIATION PROTECTION	BS - Health Physics - Feb 86 MS - Health Physics - Oct 86			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY				
d. RADIATION BIOLOGY				
e. RADIOPHARMACEUTICAL CHEMISTRY				
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
		Harvard Univ. Cambridge, MA Children's Hospital Boston, MA		RSO for Children's Broad scope medical program

4/87 - 4/96

EXHIBIT 2
SUPPLEMENT A

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION		
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER				
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER		2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED		
MARC MONTMINY				
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES				
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING		
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE	
a. RADIATION PHYSICS AND INSTRUMENTATION	① SALK INSTITUTE: 1986 (July 7-8)			
b. RADIATION PROTECTION	② TUFTS UNIVERSITY SCHOOL OF MEDICINE (1983)			
	③ MASS. GENERAL HOSPITAL (1982)			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	COURSES COVERED ITEMS a-d.			
d. RADIATION BIOLOGY	Each course was 3-4 hours lecture.			
e. RADIOPHARMACEUTICAL CHEMISTRY				
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	
TYPE OF USE				
32p	5mCi/week	Salk Institute	~10 years (lab total not personal use)	DNA manipulation
14C	200µCi/mo.	" "	"	" chloramphenicol (enzymatic assays)
35S	1mCi/mo.	" "	"	PROTEIN SYNTHESIS STUDIES

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

PROGRAM CODE: 03620
STATUS CODE: 0
FEE CATEGORY: 3M
EXP. DATE: 20051231
FEE COMMENTS: _____
DECOM FIN ASSUR REQD: Y
.....

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: JOSLIN DIABETES CENTER, INC.
RECEIVED DATE: 960611
DOCKET NO: 3008833
CONTROL NO.: 123326
LICENSE NO.: 20-15266-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED \$ 610.00
AMOUNT: 518429
CHECK NO.: _____

3. COMMENTS

SIGNED M. A. Perkins
DATE 6/22/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED ✓ 1)

1. FEE CATEGORY AND AMOUNT: 3M 8610
2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL _____
LICENSE _____

3. OTHER _____

SIGNED S. Brown
DATE 6/22/96

Log June 1 1996
Check No. 518429
Amount 8610
Fee Category 3m
Type of Fee AMD
Date Check Rec'd 6/22/96
Date Completed _____
By S. Brown