

MATERIALS LICENSE

Amendment No. 01

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		In accordance with the letter dated July 12, 1996,	
1. Massachusetts Biotechnology Research Institute		3. License Number 20-30012-01 is amended in its entirety to read as follows:	
2. One Innovation Drive Worcester, Massachusetts 01605		4. Expiration Date November 30, 2003	
		5. Docket or Reference No. 030-33047	
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. As specified in 10 CFR 33.100, Schedule A (Type C Broad License)	A. Any	A. See Condition 12.	
9. Authorized use			
A. Research and development as defined in 10 CFR 30.4.			

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at One Innovation Drive, Worcester, Massachusetts, and at 20 Hampden Street, Roxbury, Massachusetts.
11. A. Licensed material shall be used by, or under the supervision of, individuals who satisfy the requirements of 10 CFR 33.15. The licensee shall maintain records of individuals designated as users for three years after the last use of licensed material by the individual.
- B. The Radiation Safety Officer for this license is Marie I. Case.
12. A. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column II. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

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- B. Notwithstanding subitem A. of this Condition, above, and 10 CFR 33.100, Schedule A, Column II, the applicable quantities in Condition 12.A. for the following radionuclides are reduced to:

Carbon 14	100 millicuries
Krypton 85	100 millicuries
Silver 110m	1 millicurie
Iodine 129	100 microcuries

Other byproduct material
other than alpha emitting
byproduct material not
listed in 10 CFR 33.100,
Schedule A. 100 microcuries

13. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.
14. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
15. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license. Records of inventories shall be maintained for five years from the date of each inventory, and shall include the quantities and kinds of byproduct material, manufacturer name and model numbers, location of sources and/or devices, and the date of the inventory.
16. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. 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.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen-3; or

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- (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
17. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
18. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
19. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.
20. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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21. This license does not authorize commercial distribution of licensed material.
22. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days and sulfur 35 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.
23. The licensee shall not store licensed material contained in waste for more than two (2) years from the date the waste is put into storage or December 1, 1993, which ever is later. The licensee shall maintain records which indicate the date that licensed material contained in waste is put into storage. This condition does not apply to licensed material intended for disposal by decay-in-storage pursuant to 10 CFR 35.92 or other conditions of this license.
24. 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 June 30, 1993
 - B. Letter dated August 16, 1993
 - C. Letter dated September 20, 1993
 - D. Letter dated July 12, 1996
 - E. Letter dated August 15, 1996

For the U.S. Nuclear Regulatory Commission

Original Signed By:

John D. Kinneman

Date SEP 19 1996

By

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

SEP 19 1996

Marc E. Goldberg
President & Chief Executive Officer
Massachusetts Biotechnology Research Institute
One Innovation Drive
Worcester, MA 01605

Dear Mr. Goldberg:

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. The new expiration date is stated in Item 4 of the license.

Please also note that your amended license has been revised in its entirety and includes changes that were made because of revisions in the regulatory requirements and/or NRC guidance. Conditions 18 and 20 of your old license have been deleted and conditions 19, 20, 21, and 22 have been added to your amended license. 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:

John D. Kinneman, Chief
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

License No. 20-30012-01
Docket No. 030-33047
Control No. 123528

Enclosure:

Amendment No. 01

DOCUMENT NAME: R:\WPS\MLTR\L2030012.01

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	N				
NAME	SLodhi		JKinneman					
DATE	08/20/96		08/26/96		08/ /96		08/ /96	

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MBRI

MASSACHUSETTS BIOTECHNOLOGY RESEARCH INSTITUTE

One Innovation Drive
Worcester, MA 01605

MS 16
Q-2

U.S. Nuclear Regulatory Commission, Region I
Nuclear Materials Safety Section B
475 Allentown Road
King of Prussia, PA 19406
ATTN: Dr. Sattar Lodhi

August 15, 1996

Dear Dr. Lodhi,

Per our telephone conversation this morning concerning MBRI's license no. 20-30012-01 amendment request, you are assured that a GM counter will be available when radioactivity is in use. If radioactive materials are transferred between the two sites, it will be done by myself or my colleagues, Joseph Bakanauskas and Peter Chin whose credentials are on file with your office. Each of the four labs at the Roxbury site has a hood and if iodinations were done, they could be equipped with air samplers.

If you need further information, please call me at (508) 856-3209.

Thank you again for your timely review.

Sincerely,

Marie Case

Marie Case, Radiation Safety Officer

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AUG 19 1996

MNSB TELEPHONE CONVERSATION RECORD

Person Called: Marie Case, RSO Phone No.: (508) 856 3209
Person Calling: Sattar Lodhi Date: 8/14/96
Facility Name: Massachusetts Biotechnology Research Institute, Worcester, MA Time: 3:00 p.m.
License No. 20-30012-01 Docket No. 030-33047

Subject: Additional Information for amendment request

Summary: I called Ms. Case to request the following:

1. Are the radiation survey instruments available at the new site;
2. Will there be a transfer of materials between the sites, and how will the transfer take place (who will transport); and
3. If there are fume hoods available for storage and if iodinations will be performed at the new location

Mrs. Case was not available and I left a message for her to call me.

8/15 at 9:00 a.m.

Mrs. Case returned my call. She will respond in writing.

Action Required/Taken: Document/wait for response

Signature: *Sattar Lodhi* Mail Control No. 123528



030-33047

U.S. Nuclear Regulatory Commission, Region I
Nuclear Materials Safety Section B
475 Allentown Road
King of Prussia, PA 19406

July, 12, 1996

By this letter and the enclosed document, Massachusetts Biotechnology Research Institute (MBRI) seeks an amendment to NRC license no. 20-30012-01. Specifically, we wish to add 20 Hampden St., Roxbury, MA, 02119 as an approved site of use for licensed activities.

As highlighted on the enclosed drawing (Att. A.), room 130 is the radioactive waste storage room. Its floor is epoxy coated. Room 129 is the counting room and will house the liquid scintillation counter which will be purchased before use of radioactivity begins. Labs 1,2,3 and 4 will be allowed areas of use of radioactivity. All mentioned rooms are equipped with fire extinguishers, a sprinkler system, non-porous work surfaces and floors.

Radioactive shipments will only be received during normal working hours-no shipments will be accepted after 5 pm Monday through Friday nor on weekends. Licensed material will be stored under lock and key or will be within line of sight of an authorized person.

Security for this building includes a 24 hour security guard at the main door, locked, double doors into MBRI's area and combination locks into the lab area.

Per 10 CFR, 170.31,3,L, a check for \$660.00 is enclosed for this amendment.

If you need more information, please contact our Radiation Safety Officer, Marie Case at (508) 856-3209.

Thank you for your timely review.

Sincerely,

Marc E. Goldberg, President & CEO

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AUG -2 1996

OVERSIZE DOCUMENT PAGE PULLED

SEE APERTURE CARDS

NUMBER OF OVERSIZE PAGES FILMED ON APERTURE CARDS

1

9610070216-01

APERTURE CARD/HARD COPY AVAILABLE FROM

RECORDS AND REPORTS MANAGEMENT BRANCH

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620
STATUS CODE: 0
FEE CATEGORY: 3L
EXP. DATE: 20031130
FEE COMMENTS: -----
DECOM FIN ASSUR REQD: N
.....

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MASSACHUSETTS BIOTECHNOLOGY
RECEIVED DATE: 960802
DOCKET NO: 3033047
CONTROL NO.: 123528
LICENSE NO.: 20-30012-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED, ~~\$~~ 660.00
AMOUNT: -----
CHECK NO.: 5909

3. COMMENTS

SIGNED M. A. Perkins
DATE 8/14/96

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

1. FEE CATEGORY AND AMOUNT: 3L 8460

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ✓
RENEWAL -----
LICENSE -----

3. OTHER -----

SIGNED -----
DATE -----

REC'D AUG - 1 11:12

Log	<u>Aug 8</u>
Remitter	
Check No.	<u>5909</u>
Amount	<u>8660</u>
Fee Category	<u>3L</u>
Type of Fee	<u>AMD</u>
Date Check Rec'd	<u>8/18/96</u>
Date Completed	
By	<u>BB</u>