

APPLICATION FOR MATERIAL LICENSE

44 28322
030-30923

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

YOU ARE LOCATED IN:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY, NMSS
WASHINGTON, DC 20555

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR
WISCONSIN, SEND APPLICATIONS TO:

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS. IF YOU ARE LOCATED IN:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA,
NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH,
OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
811 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA,
PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR
WEST VIRGINIA, SEND APPLICATIONS TO:

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON,
AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS
TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCLEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2800
ATLANTA, GA 30323

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER _____
- C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Boston Fertility Laboratories, Inc.
One Brookline Place
Brookline, Massachusetts 02146

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Boston Fertility Laboratories, Inc.
One Brookline Place
Brookline, Massachusetts 02146

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Anne Marie Farrer, MT(ASCP)

TELEPHONE NUMBER

(617) 735-9025

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3P AMOUNT ENCLOSED \$ 230.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

DATE

Anne Marie Farrer MT(ASCP)

Anne Marie Farrer, MT(ASCP)

Supervisor

12/9/88

FOR NRC USE ONLY

TYPE OF FEE APP	FEE LOG Dec. 13 th	FEE CATEGORY 3P
AMOUNT RECEIVED \$ 230	CHECK NUMBER 1207	

COMMENTS
9001250137 890315
REG1 LIC30
20-28322-01 PDR

APPROVED BY

J. Kimberley

DATE

12/20/88

109993

NRC LICENSE APPLICATION

(5) RADIOACTIVE MATERIAL

Isotope=I-125

Form=Liquid

Maximum Activity at One Time=1 milliCurie

(6) PURPOSE

The laboratory utilizing the radiation will be part of a physician's office practice involved in diagnosis and treatment of infertility. The I-125 labelled tracer is employed in an immunological reaction with the patient's serum in a test tube. After incubation, excess tracer is washed away and the remaining activity in the tubes is counted using a gamma counter. This process is used to determine the quantity of specific hormones present in the patient's serum. This determination aids the physician in prescribing appropriate treatment desirably leading to pregnancy.

(7) RADIATION SAFETY OFFICER

Anne Marie Farrer

TRAINING:

Yale University (September 1985-February 1987)

*Employed in research laboratory utilizing P-32 labelled probes for DNA analysis in the investigation of human genetic diseases

*Attended formal radiation safety seminars held by the university as a pre-requisite for handling radiation

*Average quantity handled per week=0.5 millicurie

Integrated Genetics (July 1987-January 1988)

*Employed in reference laboratory utilizing P-32 labelled probes for DNA analysis in the clinical investigation of human genetic diseases

*Attended formal radiation safety seminars held by the company as a pre-requisite for handling radiation

*Average quantity handled per week=0.5 millicurie

Central Diagnostic Laboratory (January 1988-October 1988)

*Employed in radioimmunoassay laboratory utilizing I-125 labelled tracers for the purpose of diagnosing and treating infertility

*Average quantity handled per week=0.5 millicurie

(8) TRAINING FOR INDIVIDUALS

At this time, no other persons are employed to work with radiation in the laboratory. However, additional persons will be employed in the future. Each prospective employee will be requested to submit, in writing, details of their experience with radiation previous to acceptance for employment.

(9) FACILITIES/EQUIPMENT

Gamma Counter

Manufacturer=Berthold

Model No.=2104

Quantity=1

Type of radiation=gamma

Sensitivity range=efficiency is 70%

Type of use=Assaying

Calibration procedure=method per Berthold using multiple
calibrators

Frequency of calibration=monthly

GEIGER COUNTER

Manufacturer=Ludlum Measurements, Inc.

Model No.=2

Type of radiation=gamma

Sensitivity range=40 millivolts

Type of use=Monitoring

Calibration procedure=method per Ludlum

Frequency of calibration=yearly

(10) RADIATION SAFETY PROGRAM

* Each employee will be required to wear a film badge while in the laboratory. These badges will be monitored by Tech/Ops Landauer, Inc., 2 Science Road, Glenwood, IL 60425-1586, and will be exchanged on a monthly basis.

* Each employee will be required to wear a lab coat and gloves while in the laboratory. In addition, it will be recommended, but not mandatory, that goggles and masks be worn to avoid splashing radioactive materials into the eyes or mouth.

* Each employee will be instructed as to the operation of the radiation alert monitor.

* Each employee will be notified concerning the allowable radiation exposure per calendar quarter. Results of the film badge monitoring will be available to all employees.

Radiation Safety Officer's Duties:

* Issue film badges to all employees working directly with radiation or in the area of radiation usage, and be responsible for the monthly exchange of the badges.

* Inform employees of allowable radiation dosage per calendar quarter and notify employees of results of radiation monitoring.

* Monitor all work areas on a daily basis using the radiation alert monitor.

* Enforce use of lab coats and gloves for all personnel handling radioactive materials to avoid unnecessary exposure.

(11) WASTE MANAGEMENT

Disposal of radioactive materials shall be in liquid form into a sanitary sewer in conformance with the laws of radioactive disposal in the Commonwealth of Massachusetts

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

PROGRAM CODE: _____
STATUS CODE: 3
FEE CATEGORY: _____
EXP. DATE: 0
FEE COMMENTS: _____

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: BOSTON FERTILITY LABORATORIES, INC.
RECEIVED DATE: 881212
DOCKET NO.: 3030923
CONTROL NO.: 109993
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED

AMOUNT: \$230.00
CHECK NO.: 1207

3. COMMENTS

SIGNED EMW
DATE DEC 14, 1988

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

1. FEE CATEGORY AND AMOUNT: 3P \$230

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

3. OTHER _____

SIGNED S. Kimberley
DATE 12/20/88

RECEIVED
DEC 25 1988
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