

APPLICATION FOR MATERIAL LICENSE

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:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20566

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCLEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

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

ARKANSAS, CALIFORNIA, 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 IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

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 V
NUCLEAR MATERIALS SAFETY SECTION
1480 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

MAR 13 1989

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)

Biogenetic Services, Inc.
2308 6th St. East
Brookings, SD 57006

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

Same as above (see item #2).

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dr. Theresa Lemme, Lab. Mgr.; or Dr. Alex Kahler, President

TELEPHONE NUMBER

605/697-8506 or 8500

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 170.3)

FEE CATEGORY 3, P. 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

Dr. Theresa Lemme

Dr. Theresa Lemme

Lab. Manager

3/2/89

9001240104 89051B
REG 4 LIC 30
40-26983-01 PDR

462458

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
App	Proc-3-TV	3M	Note: Reviewed as R+D - clarified as non R+D in def. ltr of 4/6/89/response, 462458	Th. Theresa
AMOUNT RECEIVED	CHECK NUMBER			DATE
1230/4470	614/616			4/6/89

5. Radioactive Material:

- a. 32 phosphorus
- b. 32 phosphorus labelled nucleotides
- c. 30 mCi

6. PURPOSE:

The 32-phosphorus labelled nucleotides will be used as an in vitro probe using standard analytical methods in laboratory assays of DNA and in the development of a library of genetic probes.

7. Individuals responsible for radiation safety program and their training and experience.

Theresa H. Lemme (Radiation Safety Officer)

B.S. 1975, Microbiology major, chemistry minor, South Dakota State University

M.S. 1984, Microbiology major, South Dakota State University

Ph.D. 1988, Agronomy major, South Dakota State University

1977 - 1979 technician, Live Sciences Department, University of Nebraska - Lincoln, Lincoln, Nebraska, used tritiated thymidine incorporation to determine chicken embryo tissue cell growth by scintillation count, trained in handling radioisotopes and supervised by trained personnel.

1979 - 1981 technician, Microbiology and Public Health Department, Michigan State University, East Lansing, Michigan, used tritiated thymidine and carbon-14 thymidine incorporation to quantify DNA recovery from microbial samples by scintillation count, trained in handling radioisotopes and supervised by trained personnel.

1982 participated in Chemistry 660, graduate class in radioisotopic techniques taught by Dr. Eugene Whiteside, Chemistry Department, SDSU, Brookings, SD. Three lectures and one 3 hour laboratory per week were attended for 14 weeks. Lecture topics covered included:

The Code of Federal Regulations (Parts 19,20,30,31,&71)

An Introduction to the Radioisotope

Nuclear Equations and Nuclear Energetics

Nuclear Stability

Characteristics of Ionizing Radiations

Radiation Detection Methods

Preparation of Counting Samples

Errors in Measurements

Design and Execution of Radiotracer Experiments

Analysis by Isotope Dilutions

Neutron Activation and Activation Analysis

Safe Handling of Radioisotopes

Laboratory topic covered:

Determining the operating potential and Resolving time of a Geiger-Muller counter

Decontamination and Determining the Half-life of phosphorus-32

Backscatter

Quantitative analysis using a radioisotope

Uptake of labelled phosphorus in the rat, incorporation of radioactive glycine into a protein

Blood volume, Biosynthesis of Cholesterol from acetate

Anion uptake by resting yeast cells, orthophosphate uptake by seedling plants.

7. Individuals responsible for radiation safety program and their training and experience. (continued)

Joanne Matthees (Radiation Safety Officer)

B.S. 1975, Chemistry major, William Paterson College, N.J.
M.S. 1979, Biochemistry major, University of Maryland

1975 - 1979 University of Maryland, graduate student.
Performed experiments using tritium and carbon-14 labelled compounds. Trained in radioisotopic handling by major advisor.

1984 - 1986 Lab technician, USDA Northern Grain Insects Laboratory, Brookings, SD. Obtained license to use ^{32}P in research projects to determine restriction fragment length polymorphisms in plants. ID# 40-ARS-040-022-4. Radiation Safety Officer for the location, performed wipe tests and safety monitoring.

8. Training for individuals working in or frequenting restricted areas.

No untrained individuals will work in the radiation work space. Training of individuals will be carried out by a radiation safety officer to conform with 10CFR19. Concepts such as keeping radiation "as low as reasonably achievable" (ALARA), safety methods, and monitoring will be included in the training to conform with regulations.

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9. Facilities and equipment

An inventory of ^{32}P will be maintained. All radioisotopic material in the laboratory will be held under locked storage conditions until use.

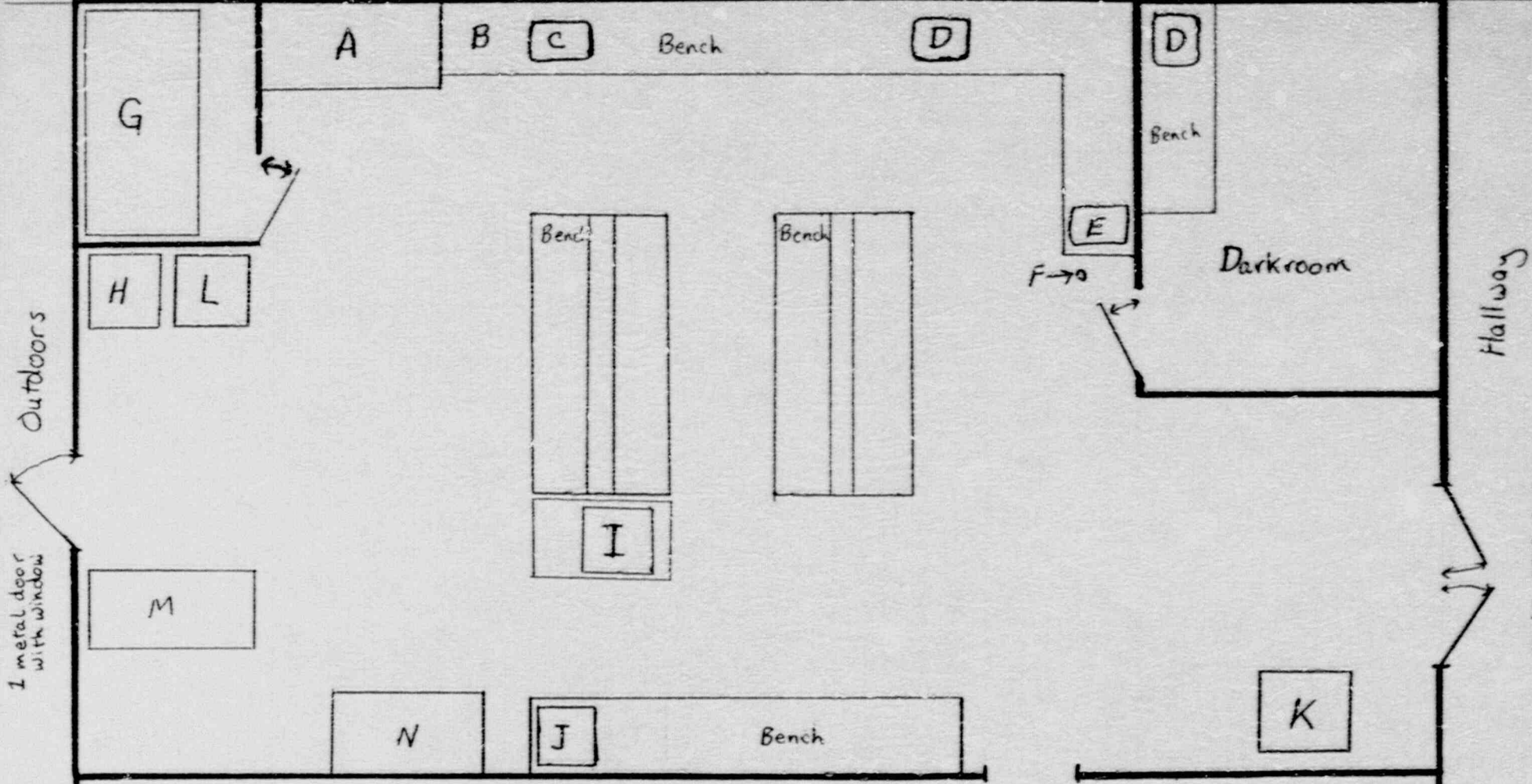
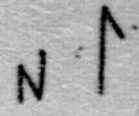
All ^{32}P will be handled in one laboratory within the facility (see Figure). Within this room, a stainless steel fume hood and a stainless steel sink are available, a beta shield (leucite) and leucite storage boxes will be utilized. Autoradiography development will be performed in the enclosed darkroom.

A portable hand held contamination monitor (Cole Parmer J8990-10) will be used for monitoring ^{32}P contamination. This monitor has a large-area, thin window Geiger-Muller detector with ranges of 0 - 500, 0 - 5,000, and 0 - 50,000 cpm.

Liquid and solid waste materials will be held in containers until radiation levels have decreased (through half-life decays) to levels acceptable for disposal by sanitary sewage system or incineration. A waste storage room within the laboratory will hold radioactive waste within a plexiglass container to conform with regulations.

Personnel will be required to wear disposable gloves and lab coats when working with radioactive materials. Bench tops and the fume hood will be covered with protective absorbant sheets to contain possible accidental spillage.

Another Business ↑



Outdoors

1 metal door with window

Hallway

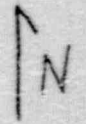
2 metal 3ft. doors

- A = Stainless Steel Fume Hood
- B = Radiation work area
- C = Stainless Steel Sink
- D = Sink
- E = Autoclave
- F = Safety Shower /eyewash
- G = Radioactive waste storage container
- H = Freezer
- I = Oven
- J = Centrifuge
- K = -80°C freezer
- L = Freeze Drier (Lyophilizer)
- M = Desk
- N = Refrigerated Electrophoresis Chamber

↑
 open doorway to
 isozyme lab

Scale
 5 feet

(No radioactive substances used)



10. Radiation Safety Program

All orders and receipt of radioactive materials will be conducted by a Radiation Safety Officer. Packages will be received and tested in accord with 10CFR20.205. An inventory of radioactive materials will be maintained by the radiation safety officer.

Personnel will use a contamination monitor to survey the work area, equipment used, and themselves after performing any experiment utilizing radioisotopes. Radiation badges will be worn at all times by personnel within the laboratory. These badges will be provided and exposures evaluated by a licensed organization such as SIEMENS, Des Plaines, Illinois.

Radiation surveys will be conducted monthly by the radiation safety officer in the radioactive work area and where radioactive materials are stored. These surveys by contamination monitor will detect external exposure to personnel, surface contamination, and concentrations of airborne radioactive materials in the facility.

Formal instrument surveys shall be conducted in the laboratory at least once per calendar quarter. Work surfaces, sinks, fume hood, floors, storage and waste disposal areas and equipment will be checked. These data and survey results will be kept on file by the radiation safety officer.

Should a survey result in observed contamination of 150% of background, cleanup procedures will be initiated, including washes and decontamination, as deemed necessary to reduce said contamination to levels within the acceptable range.

The survey monitor will be sent to a licensed organization such as Health Physics Associates, Northbrook, Illinois, which will perform the necessary calibration checks twice yearly. When the monitor is not available, due to calibration, a loaned monitor will be requested from the licensed organization so that a monitor will continue to be present at all times.

11. Waste management

Liquid radioactive waste (32P) will be stored in plastic containers through six half lives (14.3 days/half life) or until disposal through release into the Brookings sanitary sewage system will result in levels of radioactivity in accordance with 10CFR20 appendix B.

Solid waste will be stored through six half lives and then disposed. This waste will include plastic tubes, pipette tips, absorbant paper, empty vials, contaminated disposable lab coats, etc. as used in the laboratory.

12. Licensee fees

Fee Catagory: 3. P. Amount Enclosed: \$230.00

462458

(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 1

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: BIOGENETIC SERVICES, INC.
RECEIVED DATE: 890313
DOCKET NO: 3031054
CONTROL NO.: 462458
LICENSE NO.: _____
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
AMOUNT: _____
CHECK NO.: _____

3. COMMENTS

*no check in package
as indicated.*

SIGNED
DATE

Billie Yrasquenzi
3/13/89

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

1. FEE CATEGORY AND AMOUNT: 3M

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

3. OTHER _____

SIGNED
DATE

M. Messer
4/6/89

