NRC FORM 313 U. S. NUCLEAR REGULATORY COMMISSION

(5-1997)
10 CFR 30, 32 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

APPROVED BY: NO. 3150-0120 EXPIRES: 7/31/1999

Estimated burden per response to comply with this information collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Forward comments regarding burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0120), Office of Management and Budget, Washington, DC 20503. NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a curently valid OMB control number.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-3415

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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 JURISDICTIONS.

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

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 45-25402-01
- [ ] C. RENEWAL OF LICENSE NUMBER

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

Argonex Inc.
706 Forrest Street, Suite 1
Charlottesville, VA 22903

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

Argonex Inc.
706 Forrest Street, Suite 1
Charlottesville, VA 22903

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Kevin T. Hogan, Ph.D.

TELEPHONE NUMBER

(804)984-2040

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. maiximum 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 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 3M

AMOUNT ENCLOSED $ 620

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, 36, 39 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 OFJUNE 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.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Kevin T. Hogan, Radiation Safety Officer	K T Hogan	July 12, 1999

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		25843
APPROVED BY				DATE	

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2. NAME AND MAILING ADDRESS OF APPLICANT

Argonex Holdings, Inc. changed its name to Argonex Inc. on June 16, 1999. This change did not reflect or necessitate any changes in the ownership of the company. The address for Argonex Inc. did not change.

5. RADIOACTIVE MATERIAL:

Under our present license Argonex is allowed to possess Chromium 51, Hydrogen 3, Iodine 125, Phosphorous 32, and Sulfur 35. We are seeking to **add Carbon 14** to our license. Because of this addition, we are requesting a reduction to our possession limit for Iodine 125. These changes are highlighted in bold in the following table.

A. Element and mass number	**B. Chemical and/or physical form**	**Current maximum possession limit**	**D. Maximum amount that will be possessed at any one time**	**Proposed or current use**
Chromium 51	Any	150 mCi	150 mCi	Measurement of cell death by ^{51}Cr-release
Hydrogen 3	Any	150 mCi	150 mCi	Measurement of cell proliferation
Iodine 125	Any	100 mCi	**50 mCi**	Protein iodination
Phosphorous 32	Any	50 mCi	50 mCi	Protein and DNA labeling
Sulfur 35	Any	50 mCi	50 mCi	Protein and DNA labeling
Carbon 14	**Any**	---	**50 mCi**	**Protein labeling**
Cesium 137	Sealed source	1,155 Ci	1,155 Ci	Irradiating cells

6. PURPOSES FOR WHICH RADIOACTIVE MATERIAL WILL BE USED:

Research and development as defined by 10 CFR 30.4. Specific uses are listed in the above table, but we request continued flexibility in determining future uses .

7. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY:

We request that James M. Fredrick replace Kevin T. Hogan as the Radiation Safety Officer (RSO) at Argonex. Mr. Fredrick has served as Safety Officer at Argonex since May, 1998. During this period of time he has had the day-to-day responsibility of managing the Argonex radiation safety program. His responsibilities have included: radiation safety training; radioisotope ordering and inventory control; weekly and quarterly surveys; and record keeping for all aspects of our program. Mr. Fredrick has taken and passed both the University of Virginia "Radiation Safety Principles & Practices" and the Argonex "Radiation Safety Principles & Practices" courses, and he received certification from J.L. Shepherd and

Associates for the use of a Cesium 137 sealed source device. Mr. Fredrick has also taken and passed the 40 hour Radiation Safety Officer training class course given by CSI. A summary of Mr. Fredrick's past experience and training is attached in Appendix #1.

The individuals currently responsible for radiation safety are Kevin Hogan, Ph.D. and Mark Ross, Ph.D. We request that James Fredrick be added to this list, and that the wording in the license be changed to "Licensed material shall be used by, or under the supervision of, Kevin Hogan, Ph.D., Mark Ross, Ph.D. or James Fredrick."

8. **TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS:**

A radiation safety training program is already in place at Argonex under NRC license 45-25402-01, and will be expanded to include safety information that is specific to Carbon 14.

9. **FACILITIES AND EQUIPMENT**

The Argonex laboratories are located in leased space at 706 Forrest, Suite 1, Charlottesville, VA. Space directly adjacent to the laboratory is currently undergoing renovation for future use as both office and laboratory space (see attached floor plans). The address for this space will not change. Upon completion of the renovation, we would like to move our current radioisotope usage room and add a second storage-for-decay room. A summary of current usage and proposed usage follows:

Material receipt:

Current: Radioisotopes are currently received in the reception area (101) or at the loading dock (102), and are then brought to the radioisotope lab (114) for check-in.

Proposed: Radioisotopes will be received in what is becoming the receiving and reception room (101) or at the loading dock (102), and will then be brought to the new radioisotope lab (111) for check-in.

Storage:

Current: Radioisotopes are stored in the radioistope lab (114). Gamma emitters are stored behind lead shielding. Sufficient shielding is used to ensure that the public dose in unrestricted areas does not exceed 100 mrem in one year or 2 mrem in any one hour. Isotopes requiring storage at –80°C are stored in a locked freezer.

Radioisotopes undergoing decay-in-storage or awaiting off-site shipment are stored in the radioactive waste storage room (110A). Sufficient shielding is used to ensure that the public dose in unrestricted areas does not exceed 100 mrem in one year or 2 mrem in any one hour.

Proposed: Radioisotopes will be stored in the new radioisotope lab (111). Gamma emitters will be stored behind lead shielding. Sufficient shielding will be used to ensure that the public dose in unrestricted areas does not exceed 100 mrem in one year or 2 mrem in any one hour. Isotopes requiring storage at –80°C will be stored in locked freezers.

Radioisotopes undergoing decay-in-storage or awaiting off-site shipment will be stored in the radioactive waste storage room (110A) or the storage/emergency generator room (141). Sufficient shielding will be used to ensure that the public dose in unrestricted areas does not exceed 100 mrem in one year or 2 mrem in any one hour.

Preparation and measurement:

Current: Radioisotopes are used in the radioisotope lab (114). Gamma and scintillation counting are performed in room 115. The gamma irradiator is housed in room 105 (This room was recently created by building walls around the irradiator in room 102).

Proposed: Radioisotopes will be used and counted (gamma and scintillation) in the new radioisotope lab (111). Sufficient shielding will be used to ensure that the public dose in unrestricted areas does not exceed 100 mrem in one year or 2 mrem in any one hour. The gamma irradiator will continue to be housed in room 105.

All volatile iodine work at Argonex will continue to be performed inside a hood "insert" installed within a certified exhaust hood (as described in Argonex correspondence dated October 30, 1997). A six foot bypass fume hood is being installed in room 111 for this purpose. The ducting is a straight vertical line to roof penetration. Stack height will be between eight and ten feet above roof deck terminating with an in-line, explosion proof blower. The system will maintain negative pressure within the duct system and be capable of providing 100 linear feet per minute face velocity. The distance to the nearest air intake is approximately twenty-two feet (horizontal measurement from penetration). This intake is on the side of a 50 ton HVAC unit opposite to the exhaust stack; the HVAC unit will further serve to isolate the exhaust from the air intake. The next two nearest air intakes are approximately thirty and thirty-five feet from the exhaust stack (horizontal measurement from penetration). We will also continue to limit the amount of iodine to be handled by an individual to a maximum of 1 mCi per stock vial.

We would continue to request flexibility in designating certain rooms as radioactive materials use or storage rooms so that we can accommodate future procedural or equipment changes without the need for a license amendment.

Future requirements:

We request flexibility in the future designation of certain rooms for the receipt, use or storage of radioactive materials so that we can accommodate future procedural or equipment changes without the need for a license amendment. Laboratory space which could potentially be designated for usage in the future include rooms 110C, 113, 114, 115, 116, 117, 122, 128, 131, 132, 133, 135 and 136. Additionally, rooms 118, 119, 120, and 121 may be converted to laboratory space in the future and could potentially be a usage room as well. In keeping with our ALARA program, we will continue to minimize the number of rooms that radioactive material is used or stored in, and will ensure that regulatory exposure limits are not exceeded as indicated above.

10. RADIATION SAFETY PROGRAM

Additional information that is specific to C14 will be added to the Argonex radiation safety training that is already in place.

11. WASTE MANAGEMENT

No changes are required.

Appendix 1

James M. Fredrick

EMPLOYMENT HISTORY

Argonex Pharmaceuticals *5/98 to Present*
Charlottesville, Virginia
SAFETY OFFICER (Radiation safety duties have included: radiation safety training; radioisotope ordering and inventory control; weekly and quarterly surveys; and record keeping for all aspects of our program.)

LabCorp Analytics *9/95 to 5/98*
Richmond, Virginia
SAFETY AND ENVIRONMENTAL AFFAIRS / RADIATION SAFETY OFFICER

IMS Environmental *7/94 to 9/95*
Fredericksburg, Virginia
PROJECT MANAGER / SITE SAFETY OFFICER

RADIATION SAFETY TRAINING

Radiation Safety Officer – 40 Hour
October 19-23, 1998
CSI – Radiation Safety Training

Gamma Irradiator Operation Training
Shepherd Model 143-145
9/9/98
J.L. Shepherd & Associates

Radiation Safety Principles & Practices
7/23/98
Argonex Pharmaceuticals

Radiation Safety Principles & Practices – 8 Hour
11/19/97
University of Virginia

HAZARDOUS WASTE MANAGEMENT TRAINING

Hazardous/Toxic Waste Management – 16 Hour
1/13/98
Lion Technology

Hazardous Waste Operations & Emergency Response – 8 Hour
5/2/95
Industrial Marine Service, Inc.

Hazardous Waste Operations & Emergency Response – 40 Hour
May 2-6, 1994
Industrial Marine Service, Inc.