

PROTOMETRIX[®] INC.

Unleashing The Power of The Proteome

688 East Main Street • Branford, Connecticut 06405

Tel: 203.848.1100 • Fax: 203.848.1155

RECEIVED
SECTION 1

APR 14 2005

April 6, 2005

Mr. John Nicholson
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region I
Nuclear Material Section B
Commercial and R&D Branch
475 Allendale Road
King of Prussia, PA 19406

Docket No. 030-35868
NRC License No. 06-30693-01

Dear Mr. Nicholson,

With its recent expansion of the Research and Discovery efforts, Protometrix Inc. is requesting the addition of a small radioactive materials room to its NRC License #06-30693-01. This room will be labeled as Hot Lab #2 and is adjacent to the existing radioactive materials Hot Lab #1 and the radioactive waste storage room. The proposed radioactive materials protocols, radioisotopes, activities, radiation safety facilities, equipment and procedures will be similar to those in the current NRC license conditions described in the letter dated September 22, 2002. Although Protometrix is currently only using small quantities of phosphorus-33, it would like to continue to maintain the ability to order and use the additional radioisotopes listed in its license if needed in the future. Radioactive waste handling and storage procedures will also be consistent with those described in the NRC R&D specific License # 06-30693-01. Protometrix Inc. proposes that a generic laboratory diagram for Hot Lab 2 be included on this license in accordance with 10 CFR 2.390 and NUREG 1556 volume 7, December 1999, appendix Q-7. A generic laboratory diagram for Hot Lab 2 is attached for your review and reference.

As part of this License amendment request, Protometrix Inc. would propose naming Mr. Gregory Waterbury, Facilities Manager and Safety Officer, as the new Radiation Safety Officer replacing Mr. Gregory Michaud, Ph.D., Group Leader, on the current NRC License No. 06-30693-01. Mr. Waterbury has extensive experience with radioisotopes and NRC licensing requirements in both academic settings and research and development biotechnology facilities. In this capacity, he will be able to direct the Radiation Safety Program by providing radiation safety supervision and program oversight functions to

ensure compliance with the NRC license conditions and regulations. Mr. Waterbury's radiation safety training and experience are attached for your review and approval. Protometrix Inc. would also propose appointing Mr. Charles Piazza, Ph.D., Vice President and General Manager, as the Management Representative for this NRC license in place of Ms. Hollis Kleinert, Ph.D., former President and CEO. In his current position, Mr. Piazza will oversee and direct all general business operations at the 688 East Main Street, Branford, CT 06405 facility.

If you require additional information or have questions, please contact Mr. Gregory Waterbury at (203) 848-1138. Since there is an urgency associated with this license amendment, any consideration you can give us in expediting the above requests will be greatly appreciated.

Thank you,

A handwritten signature in black ink, appearing to read "G. Waterbury", written over the printed name.

Mr. Gregory Waterbury
Facilities Manager and Safety Officer
Protometrix, Inc.
688 East Main Street
Branford, CT 06405

cc: Mr. Charles Piazza, Ph.D. General Manager

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

APPLICATION FOR MATERIAL LICENSE

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 currently 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 23TB5
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 76011-6064

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
☒ B. AMENDMENT TO LICENSE NUMBER 06-30693-01
☐ C. RENEWAL OF LICENSE NUMBER _____

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

Protometrix, Inc.

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

688 E. Main St.
Branford, CT 06405

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mr. G. Waterbury

TELEPHONE NUMBER

203-848-1104

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 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

AMOUNT
ENCLOSED \$

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 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.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

SIGNATURE

DATE

Greg Waterbury Manager, Facilities

G. Waterbury

4/8/05

FOR NRC USE ONLY

| TYPE OF FEE | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED | CHECK NUMBER | COMMENTS |
|-------------|---------|--------------|-----------------|--------------|----------|
| | | | \$ | | |

APPROVED BY

DATE

Attachment #1

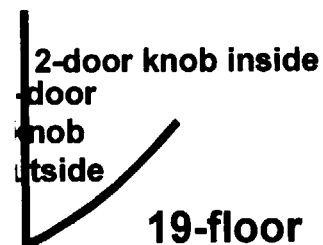
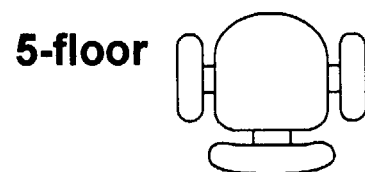
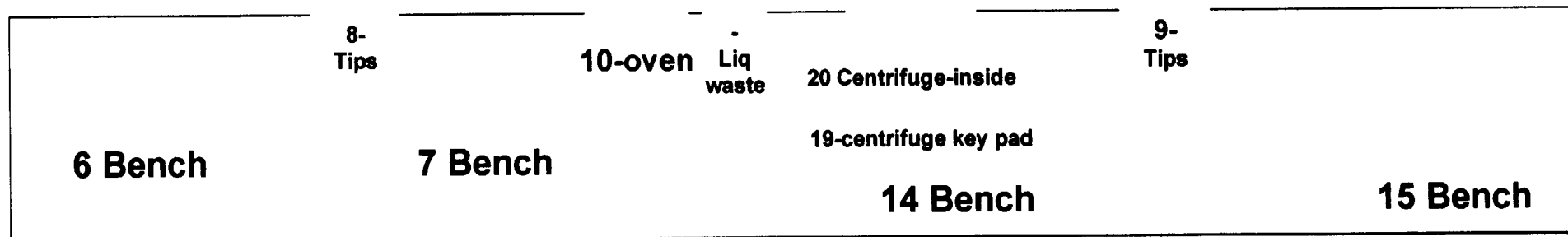
April 6, 2005

Mr. Gregory Waterbury's - Radiation Safety Training and Experience

| Institution | Formal course | Type | Date | Duration | On the job (duration) |
|-------------------------|---|-----------------|------------|------------|-----------------------------------|
| Yale University | Radiation safety for research personnel | Orientation | 2/19/1992 | 1 – 1.5 hr | 6 years; greater than 40 hrs/week |
| Yale University | Radiation safety for research personnel | Special seminar | 1/07/1993 | 1 – 1.5 hr | |
| Yale University | Radiation safety for research personnel | Refresher | 11/19/1996 | 1 – 1.5 hr | |
| Yale University | Radiation safety for research personnel | Orientation | 7/24/1998 | 1 – 1.5 hr | |
| Molecular Staging, Inc. | Radiation safety for research personnel | Orientation | 1998 | 1 – 1.5 hr | 5 years; greater than 40 hrs/week |
| Molecular Staging, Inc. | Radiation safety for research personnel | Refresher | 1999 | 1 – 1.5 hr | |
| Molecular Staging, Inc. | Radiation safety for research personnel | Refresher | 2000 | 1 – 1.5 hr | |
| Molecular Staging, Inc. | Radiation safety for research personnel | Refresher | 2001 | 1 – 1.5 hr | |
| Molecular Staging, Inc. | Radiation safety for research personnel | Refresher | 2002 | 1 – 1.5 hr | |
| Molecular | Radiation | Refresher | 2003 | 1 – 1.5 hr | |

| | | | | | |
|-------------------------|---|-------------|------------|------------|--------------------------|
| Staging, Inc. | safety for research personnel | | | | |
| Molecular Staging, Inc. | Radiation safety for research personnel | Refresher | 2004 | 1 – 1.5 hr | |
| Protometrix, Inc. | Radiation safety for research personnel | Orientation | 12/21/2004 | 1.5 hrs | greater than 40 hrs/week |

As a laboratory manager and authorized user of licensed radioactive materials for over 13 years, Mr. Waterbury 1) worked with low levels (i.e. approximately 5 mCi or less) of licensed radioisotopes typically used in research laboratories, such as, phosphorus-32, phosphorus-33, sulfur-35, tritium, radioactivity with similar energies and activities, 2) provided initial laboratory specific orientation overview and NRC regulatory requirements to employees prior to attending the formal orientation radiation safety training course 3) conducted, approved and supervised routine radiation safety lab surveys, 4) maintained scintillation, gamma and GM counters 5) supervised laboratory employees using radioactivity resulting in a history of no significant laboratory incidents or spills, 6) maintained radiation safety records of surveys, receipt and disposal of radioactive materials in accordance with NRC license conditions, 7) ensured that all employees received orientation and refresher training 8) ensured proper radioactive waste handling and storage procedures were implemented, and 9) contracted and oversaw licensed material disposal procedures.



Hot Lab II

20-floor

21-floor

17-floor

18-floor

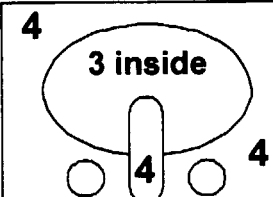
22
waste
cart

23
refrigerator



25
cyclone

26 Bench



This is to acknowledge the receipt of your letter/application dated

4/6/2005, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 06-30693-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 136821.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

BETWEEN: : (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
License Fee Management Branch, ARM : Program Code: 03620
and : Status Code: 0
Regional Licensing Sections : Fee Category: 3M
: Exp. Date: 20111130
: Fee Comments: _____
: Decom Fin Assur Req'd: N
: ::::::::::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
Applicant/Licensee: PROTOMETRIX, INC.
Received Date: 20050414
Docket No: 3035868
Control No.: 136821
License No.: 06-30693-01
Action Type: Amendment

2. FEE ATTACHED
Amount: /
Check No.: /

3. COMMENTS

Signed Michael J. Ford
Date 4/15/2008

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
Amendment _____
Renewal _____
License _____

3. OTHER _____

Signed _____
Date _____