



NMSB 2

February 13, 2006

Licensing Assistance Team
Division of Nuclear Materials Safety
U. S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415
Attention: Bryan Lawyer

1864 Concert Drive
Virginia Beach, VA 23453
OFFICE 24 HRS.: 1-800-TISSUE-1
FAX: 757-464-5721

45-25601-01
03036058

Dear Mr. Lawyer,

This application submission is for a license amendment for Radiation Safety Officer (RSO) change and update of authorized users.

Lloyd Wolfinbarger, Jr.
Chief Science Officer

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REGION 1
2006 FEB 22 AM 11:18



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NMCS/RCN MATERIALS-002

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NRC FORM 313

U.S. NUCLEAR REGULATORY COMMISSION

(10-2005)

10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2008

Estimated burden per response to comply with this mandatory collection request: 4.4 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. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

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 BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

0303 6058

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 45-25601-01
- ☐ C. RENEWAL OF LICENSE NUMBER _____

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

LifeNet
1864 Concert Drive
Virginia Beach, Virginia 23453

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

LifeNet
1864 Concert Drive
Virginia Beach, Virginia 23453

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Katrina L. Ruth, RSO

TELEPHONE NUMBER

(757) 609-4355

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. LICENSE 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

Lloyd Wolfenbarger, Jr., Chief Science Officer

SIGNATURE



DATE

2/21/06

FOR NRC USE ONLY

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

APPROVED BY _____ DATE _____

138468

Applicant Responses for Items 5 through 11.

ITEM 5:

RADIOACTIVE MATERIAL

- A. Element and mass number.
- B. Chemical and/or physical form.
- C. Maximum amount, which will be possessed at any one time.

A. Element and mass number	B. Chemical and/or physical form	C. Maximum amount, which will be possessed at any one time.
(1) Hydrogen -3	Radiolabeled biochemicals	150 mCi (1.85 GBq)
(2) Carbon -14	Radio labeled biochemicals	50 mCi (1.85 GBq)

ITEM 6:

PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Byproduct material will be used by the licensee for biomedical research and development.

ITEM 7:

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

- A. Radiation Safety Officer:

Katrina L. Ruth

B. Authorized Users:

1. Katrina L Ruth
2. Alyce Linthurst Jones
3. Lloyd Wolfenbarger, Jr.
4. Allison O'Neal
5. Bill Brownlow
6. Xiaofei Quin
7. Sherry Triplett

All personnel have been trained commensurate with the requirements. The Authorized User List above will conduct biomedical research and development activities using radioactive material.

ITEM 8:

**TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING
RESTRICTED AREAS**

A. Training for Users of Radioactive Material:

All radiation workers will receive instruction in accordance with 10 CFR 19.12 before they may work with radioactive material unsupervised. To be approved to work independently with radioactive material:

1. The individual must receive formal training from the licensee's RSO or other qualified individual (such as a person that meets the qualifications for RSO) who is familiar with the scope of the licensee's radiation protection program. Individuals must demonstrate their competency by satisfactory completion of a test; or,
2. The individual can provide the licensee's RSO proof that he/she has previously received training from a credible source, i.e., from a course offered by an academic institution, a commercial radiation safety consulting company, or a professional organization of radiation protection experts. Individuals who seek approval in this manner must also receive site-specific training as determined by the licensee's RSO.

B. Training for Ancillary Personnel:

Ancillary personnel, with a reasonable opportunity to frequent restricted areas or whose duties require them to work in the vicinity of radioactive material, will receive instruction concerning hazard recognition and appropriate precautions to be taken to avoid those hazards which they are likely to encounter. Training for ancillary personnel will be specific to, and commensurate with the level of hazard(s) which they may encounter.

ITEM 9:

FACILITIES AND EQUIPMENT

A. General Description of Facilities and Equipment:

Laboratories where radioactive materials are used and/or stored shall have access controlled by locked doors. Such restricted areas shall be secured when unoccupied to prevent unauthorized entry.

Countertops are composed of Kemresin, a black resin laboratory top. Floors are sealed sheet vinyl "Medintech".

Disposable gloves will be used whenever manipulating radioactive material. Laboratory coats are worn routinely. Work surfaces are covered with absorbent paper backed with an impermeable material to absorb, then contain radioactive material in case of a spill. Trays with raised edges and lined with absorbent paper may also be used to contain spills.

Shielding materials will be used in work and storage areas as necessary and feasible to keep doses to occupationally exposed workers to levels as low as reasonably achievable (ALARA).

Remote handling devices such as forceps or extension handles will be used as necessary and feasible to keep doses to occupationally exposed workers to levels of ALARA.

Labels and signs will be posted as required by 10 CFR 20, Subpart J (§ 20.1901, §20.1902, §20.1903, §20.1904, and §20.1905)

Attachment 4 is a floor plan and description of the licensee's proposed lab, 1457 Miller Store Road, Suite 105, Virginia Beach, VA.

ITEM 10:

RADIATION PROTECTION PROGRAM

A. Audit Program

Audits of the content and implementation of the licensee's Radiation Protection Program will be conducted at intervals not to exceed 12 months as required by 10 CFR 20.1101. Records of such audits will be maintained for at least 3 years. Review will consist of (but are not limited to) issues concerning:

1. Compliance with US NRC and DOT regulations (as applicable);
2. Compliance with the terms and conditions of the licensee's US NRC materials license; and,
3. Occupational doses to the licensee's employees, and doses to members of the public from activities involving radioactive materials at the licensee's Virginia Beach, VA facility.

Applicable elements of US NRC NUREG-1556, Vol. 7, Appendix L, "sample Audit Program" will be considered and incorporated in any comprehensive audit of the Radiation Protection Program.

B. Radiation Detection and Monitoring Equipment:

The following is the minimum number of radiation detection and monitoring instruments available to all users of radioactive material at the licensee's facility, and the scheduled calibration frequency for each instrument:

<i>Type of Instrument</i>	<i>Number</i>	<i>Calibration Frequency</i>
G-M detectors/Portable	1	Annually

The licensee will use instruments that meet the radiation monitoring instrument specification published in Appendix M to NUREG-1556, Vol. 7 "Program-Specific Scope," (December, 1999). The licensee reserves the right to upgrade its inventory of survey instruments as necessary.

C. Radioactive Material Receipt and Accountability:

Authorized Users must procure radioactive material through the licensee's purchase order system. The RSO or Authorized User must verify in advance of the order that the form of the material is consistent with the conditions of the license and the activity ordered, when added to existing inventory, does not exceed the licensee's activity limits as approved by the Commission.

Vendors will be directed to ship all radioactive materials to LifeNet, 1864 Concert Drive, Virginia Beach, VA, 23453. The RSO or other qualified individual shall receive, open, verify the contents of, and conduct any survey of packages containing radioactive material as required by 10 CFR 20.1906. Written procedures for receiving and opening packages containing radioactive material shall be documented and maintained by the licensee.

Transfer of byproduct material to and from the licensee's facility is solely the responsibility of the RSO, an Authorized User or qualified firm contracted by the licensee. Procedures for the control of transferred radioactive material are identical to those described for purchased material.

The licensee will conduct physical inventories at intervals not to exceed 6 months to account for all radioactive material received and possessed under the license.

D. Occupational Dose

Personal monitoring devices shall be mandatory for those occupationally exposed workers who are likely to receive radiation doses in excess of 10% of those dose limits described in 10 CFR 20 (§20.1201, §20.1207, and §20.1208). Personal monitoring devices may also be issued to individuals other than described above to evaluate the effectiveness of the licensee's ALARA program.

"Public dose," as defined in 10 CFR 20, will be evaluated at least annually and included in the licensee's annual audit of its radiation protection program.

E. Safe Use of Radionuclides and Emergency Procedures

1. Safe Use of Radionuclides:

- a. A laboratory coat or other protective clothing will be worn at all times when working with licensed radioactive material;
- b. Disposable gloves will be used at all times when handling licensed materials;
- c. Eating, drinking, smoking, applying cosmetics and the storage of food and/or drink is prohibited in any area where licensed material is used and/or stored;
- d. Personal monitoring device, if required, shall be worn at all times by individuals in areas in which licensed materials are used and/or stored; and,

- e. Areas in which radioactive materials are used and/or stored shall be secured at all times when that area is unattended to prevent unauthorized entry.

Written procedures for the safe use of radioactive materials will be made available by the licensee to all employees who work with, or who have the opportunity to frequent areas in which radioactive materials are used and/or stored.

2. Emergency Procedures

(See attachment 5 for emergency procedures)

F. Surveys

The licensee will conduct routine surveys (and other surveys as necessary and prudent) for potential radiological hazards. Contamination levels will be kept ALARA, but certainly below those levels published in Appendix Q to draft NUREG-1556, Vol. 7, "Program-Specific Guidance About Academic, Research and Development and Other Licenses of Limited Scope" (December, 1999).

Surveys for fixed and removable contamination will be conducted bimonthly. Records of such surveys shall be maintained by the licensee for at least 3 years from the date the survey was made as described in 10 CFR 20.2103. Each survey record for removable and fixed contamination shall include the following information (as applicable):

1. A diagram of the area surveyed;
2. A listed or description of the equipment surveyed;
3. Specific locations identified on the diagram where the wipe test or fixed contamination survey was performed;
4. Contamination levels (where applicable) recorded in appropriate units;
5. The make and model of the instrument used to evaluate the survey sample;
6. The name of the person who conducted the survey, and the date the survey was completed; and
7. A description of any corrective actions(s) taken and the results of the/those actions.

ITEM 11:

WASTE MANAGEMENT

Radioactive waste will be stored in a secure location, in appropriate containers that shall be labeled. Reasonable and prudent measures will be undertaken by the licensee to minimize waste.

Radioactive waste generated by the licensee, shall be managed and disposed by the licensee in the following manner depending on the characteristics of the waste:

1. Solid radioactive waste with half-lives greater than 120 days shall be transferred to a licensed broker for disposal at a licensed disposal site.
2. Radioactive material with half-lives less than 120 days shall be held for decay in storage and disposed of as ordinary trash provided that:
 - a. The material is held in storage for a minimum of ten (10) half-lives before disposal;
 - b. The material is surveyed and it has been determined that the material's radiation levels are indistinguishable from background; and,
 - c. All radiation label and markings are removed, defaced or otherwise obliterated prior to disposal.
3. Liquid radioactive waste may be disposed of in the sanitary sewer-system provided that:
 - a. The material is readily soluble in water;
 - b. The activity of the licensed material released into the sanitary sewer each month does not exceed the concentration specified in 10 CFR 20, Appendix B, Table 3 based on the licensee's monthly volume of water released into the sewer;
 - c. The sum of the monthly ratios of licensed material does not exceed unity (if more than one radionuclide is released); and
 - d. The total quantity of licensed material released in a year does not exceed:
 - (1) 185 GBq (5Ci) of H-3;
 - (2) 37 GBq (1 Ci) of C-14; and,
 - (3) 37 GBq (1Ci) of all other radionuclides combined.

Records of waste transfer and disposal shall be maintained by the licensee as described in 10 CFR 20.2108.

This is to acknowledge the receipt of your letter/application dated
L72470 / NRC 313 DTG
2/13/2006 / 2/21/2006, and to inform you that the initial processing which
includes a 1 administrative review has been performed.

☒ ATTEND. 45-25601-01
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 138468.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.