DEPARTMENT OF THE ARMY
U.S. ARMY RESEARCH INSTITUTE OF ENVIRONMENTAL MEDICINE
KANSAS STREET, BUILDING 42
NATICK MA 01760-5007

REPLY TO
ATTENTION OF

Office of the Commander

September 17, 2010

Br.2

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

Dear Sir/Ms:

03036434

We would like to request that three amendments be made to Nuclear Regulatory Commission Materials License 20-30847-01. We request that Iodine 125 be removed from our Materials License and be put under a "General License" (please see enclosed NRC Form 483). This action was recommended by NRC Inspector Steven Courtemanche during his site visit earlier this year. Request #2 is to remove the requirement for dosimetry monitoring since our program makes it highly unlikely that any individual at USARIEM would receive a dose in excess of 10 percent of the annual limit. This was also a recommendation of Inspector Courtemanche and of a Radiation Protection Survey performed by the U.S. Army Center for Health Promotion and Preventive Medicine (2009). Request #3 is to remove Dr. Durkot's name from our Materials License as an authorized user since he has retired.

Attached to these amendments you will find our revised NRC Form 313 which documents these requests as well as Mr. Blaha's educational record and radiological work experience. Mr. Blaha has since attended the 40-hour Radiation Safety Officer Course offered by Radiation Safety Academy (September 2009).

The purpose of these actions is to make our license more accurately reflect the nature of the radionuclide work performed here at USARIEM, and to remove Dr. Durkot's name as an authorized user (due to his retirement). I can be reached at 508 233-4811 for additional information.

Sincerely,

Gaston P. Bathalon
Colonel, Army Medical Specialist Corps
Commanding

Enclosure

NRC FORM 483 (8-2009) U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0038 EXPIRES: 1/31/2012

Estimated burden per response to comply with this mandatory collection request: 8 minutes. The validated registration serves as evidence to suppliers of byproduct material that the registrant is entitled to receive the byproduct material. 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.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0038), 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.

REGISTRATION CERTIFICATE -- *in vitro* TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE

Section 31.11 of 10 CFR 31 establishes a general license authorizing physicians, clinical laboratories, hospitals, and veterinarians in the practice of veterinary medicine to possess certain small quantities of byproduct material for *in vitro* clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under 10 CFR 31.11 is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed NRC Form 483 and received from the Commission a validated copy of NRC Form 483 with a registration number.

1. NAME AND ADDRESS OF APPLICANT *(See Instruction 3.B. below)*

Colonel Gaston P. Bathalon, Commander
Department of the Army
U.S. Army Research Institute of Environmental Medicine
(USARIEM), Bldg 42
Kansas Street, Natick, MA 01760

TELEPHONE NUMBER (Include Area Code):
(508) 233-4811

2. APPLICATION *(Check one box only)*

I hereby apply for a registration number pursuant to 10 CFR 31, Section 31.11, for use of byproduct materials for:

- ☐ Myself, a duly licensed physician authorized to disperse drugs in the practice of medicine.
- ☑ The above-named clinical laboratory.
- ☐ The above named hospital.
- ☐ Veterinarian in the practice of veterinary medicine.

INSTRUCTIONS

A. Submit this form to:

Division of Materials Safety & State Agreements (T-8 E24)
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

(At NRC, a registration number will be assigned and a validated copy of NRC Form 483 will be returned.)

B. In the box above, print or type the name, address (including ZIP Code), and telephone number of the registrant physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine for whom or for which this registration form is filed.

4. REGISTRATION

REGISTRATION NUMBER:

(If this an initial registration, leave this space blank -- number to be assigned by NRC. If this is a change of information from a previously registered general license, include your registration number.)

5. If place of use is different from address listed above, give complete address.

6. CERTIFICATION

I hereby certify that:

A. All information in this registration certificate is true and complete.

B. The registrant has appropriate radiation measuring instruments to carry out the tests for which byproduct material will be used under the general license of 10 CFR 31.11. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials.

C. I understand that Commission regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Director, Office of Federal and State Materials and Environmental Management Programs within 30 days from the effective date of such change.

D. I have read and understand the provisions of Section 31.11 of NRC regulations 10 CFR 31 (reprinted on the reverse side of this form); and I understand that the registrant is required to comply with those provisions as to all byproduct material which he receives, acquires, possesses, uses, or transfers under the general license for which this Registration Certificate is filed with the U.S. Nuclear Regulatory Commission.

PRINTED OR TYPED NAME AND TITLE OF APPLICANT	SIGNATURE	DATE
Colonel Gaston P. Bathalon, Commander (USARIEM)	Gaston P. Bathalon	19 SEP 10

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. 18 U.S.C. 1001 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.

NRC FORM 483 (8-2009)

Original NRC Form 483 was mailed to Headquarters
on 09/24/2010 - RLJ

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 10 CFR 31.11

§31.11 General license for use of byproduct materials for certain in vitro clinical or laboratory testing.

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(1) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen 3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(5) Iron 59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(6) Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americum-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(8) Cobalt 57, in units not exceeding 0.37 megabecquerel (10 microcuries) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) A person shall not receive, acquire, possess, use or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:

(1) Has filed NRC Form 483, "Registration Certificate - in vitro Testing with Byproduct Material Under General License," with the Director, Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in §30.6(a), and has received from the Commission a validated copy of NRC Form 483 with registration number assigned; or

(2) Has a license that authorizes the medical use of byproduct material that was issued under Part 35 of this chapter.

(c) A person who receives, acquires, possesses or uses byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) The general licensee shall not possess at any one time, under the general license in paragraph (a) of this section, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 7.4 megabecquerels (200 microcuries).

(2) The general licensee shall store the byproduct material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee shall not transfer the byproduct material except by transfer to a person authorized to receive it by a license pursuant to this chapter or from an Agreement State, nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(5) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in paragraph (a)(7) of this section as required by § 20.2001.

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of § 32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State, or before November 30, 2007, and the provisions of a specific license issued by a State with comparable provisions to § 32.71 that authorize manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State or the State with comparable provisions to § 32.71.

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____

(NAME OF MANUFACTURER)

e) The registrant possessing or using byproduct materials under the general license of paragraph (a) of this section shall report in writing to the Director, Office of Federal and State Materials and Environmental Management Programs, any changes in the information furnished by him in the "Registration Certificate—In Vitro Testing With Byproduct Material Under General License." Form NRC–483. The report shall be furnished within 30 days after the effective date of such change.

(f) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of parts 19, 20, and 21, of this chapter with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in paragraph (a)(7) of this section shall comply with the provisions of §§ 20.2001, 20.2201, and 20.2202.

NOTES

[1] A State to which certain regulatory authority over radioactive material has been transferred by formal agreement, pursuant to section 274 of the Atomic Energy Act of 1954, as amended.

[2] Labels authorized by the regulations in effect on September 26, 1979 may be used until one year from September 27, 1979.

[3] A new triplicate set of this Registration Certificate, NRC Form 483, may be used to report any change of information furnished by a registrant as required by §31.11(e).

If larger quantities or other forms of byproduct material than those specified in the general license of 10 CFR 31.11 are required, file NRC Form 313, "Application for Byproduct Material License," to obtain a specific byproduct material license. Copies of application and registration forms may be obtained from the Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

NRC FORM 313 (3-2009) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 3/31/2012**

Estimated burden per response to comply with this mandatory collection request: 4.3 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.resource@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.

APPLICATION FOR MATERIALS 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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
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, 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, MISSISSIPPI, 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
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

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 **20-30847-01**
- [ ] C. RENEWAL OF LICENSE NUMBER

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

COL Gaston P. Bathalon, Commander USARIEM
Kansas Street, Bldg. 42
Natick, MA 01760

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

USARIEM
Kansas Street, Bldg. 42
Natick, MA 01760

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

COL Gaston P. Bathalon

TELEPHONE NUMBER

(508) 233-4811

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. 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 CONTANED 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
COL Gaston P. Bathalon, Commander USARIEM	Gaston P. Bathalon	19 SEP 10

FOR NRC USE ONLY

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

Items 5 – 12 for NRC Form 313

5. Radioactive Material: Same as listed on Original License # 20-30847-01, but with removal of Iodine 125 (put under a General License).

6. Purpose for which licensed material will be used: Same as listed on Original License # 20-30847-01.

7. Individual responsible for Radiation Safety Program and their training experience: Mr. Michael Blaha. Mr. Blaha's experience is detailed in the Original License as well as the amendment memorandum.

8. Training for individuals working in or frequenting restricted areas: Bi-annual training will be performed by our RSO for individuals likely to receive an annual radiation dose in excess of 100mREM.

9. Facilities and Equipment: Gamma counter (Perkin Elmer 10 channel Wizard).

10. Radiation Safety Program: Same as listed on Original License #20-30847-01, but with change of RSO name.

11. Waste Management: Same as listed on Original License #20-30847-01.

12, License Fees Category: Same as listed on Original License #20-30847-01.

Reference NRC Form 313 Item #5

RADIOACTIVE MATERIAL

Element and Mass Number	Chemical and/or Physical Form	Maximum Activity
Hydrogen – 3	Any	100 mCi
Carbon – 14	Any	100 mCi
Phosphorus – 32	Any	10 mCi
Phosphorus – 33	Any	10 mCi
Sulphur – 35	Any	10 mCi

Reference NRC Form 313 Item #6

PURPOSE(S) for WHICH LICENSED MATERIAL WILL BE USED

Research and development in laboratory analysis, exploration or experimentation; or the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, materials, and processes to include substrate analysis. This may include the internal or external administration of byproduct material, or the radiation therefrom into cell cultures and/or animal models. This **will not include** the administration of radioactive material to human beings.

Reference NRC Form 313 Item #7

INDIVIDUALS RESPONSIBLE for RADIATION SAFETY and THEIR TRAINING EXPERIENCE

Mr. Michael D. Blaha, U.S. Army Research Institute of Environmental Medicine, Radiation Safety Officer

Vocational Experience with Radiation:

Radiation Safety Officer — September 2009 - Present
U.S. Army Research Institute of Environmental Medicine
FAX: 508 233-5298 **email: michael.blaha@us.army.mil**

Education:

1972	B.S. (Biology), C.W. Post College, L.I.U.
1989	M.S. Food/Nutrition, Framingham State College
1983 – Present	Research Biologist, United States Army Research Institute of Environmental Medicine, Natick, Massachusetts

Radiation Training, Formal Courses:

Radiation Safety Officer Course – Radiation Safety Academy, Gaithersberg, MD (40Hrs, Sept 2009)

Also, college coursework related to radionuclides: Physics (1 yr), Biochemistry (1 ½ yr), Nutritional Biochemistry (Food Irradiation).

Radiation-Related Experience:

On-the-job training and experience since 1975 with the following radionuclides:
P^{32} exchange determinations
C^{14}
H^{3}
S^{35}
I^{125}

[All of the above were μCi activities as part of laboratory assays or kits]

As Lab Manager for 20 years I have trained numerous military and civilian employees in how to safely handle and conduct assays involving radionuclides.

Attended approximately 12 annual Radiation Safety Training sessions run by Paul Angelis, the Radiation Safety Officer.

Had been a participating member of the Natick Soldier System's Center's Radiation Safety Committee from 1994-2004, a group tasked with upholding the NRC license requirements for all Principal Users and Radiation Workers at the Natick Facility.

Have an outstanding safety record and reputation for fastidious work.

Reference NRC Form 313 Item #8

TRAINING for INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Individuals who receive, transfer, store or use radioactive materials and are likely to receive in a year an occupational dose in excess of 100 mREM (1mSv), shall **bi-annually** be trained of the precautions or procedures to minimize exposure, health protection problems associated with exposure to radioactive materials and the purposes and functions of protective devices employed. **Bi-annual training** will be IAW NRC Regulatory Guide 8.29 (Instruction Concerning Risks from Occupational Radiation Exposure) for their protection from exposure to ionizing radiation. Training will be before duties with or in the vicinity of radioactive materials and will be re-instructed whenever there is a significant change in duties, regulations or terms of NRC License. **Bi-annual training will be conducted by Mr. Michael Blaha, Radiation Safety Officer, who has 25 years experience using radioisotopes. Training may be assessed by course content exams.**

This training will also include:

Waste Management, see Reference NRC Form 313 Item #10, section 13.

Installation's ALARA Policy, see Reference NRC Form 313 Item #10, section 6, and their appropriate response to an unusual occurrence or emergency that may involve radioactive material contamination with or without injuries, see Reference NRC Form 313 Item #10, Appendix B.

Reference NRC Form 313 Item #9

FACILITIES and EQUIPMENT

Facilities:

Locations within the U.S. Army Research Institute of Environmental Medicine (USARIEM) where radioactive materials are stored or used are conventional chemical, biological, and physical science laboratories. Laboratories are equipped with laboratory hoods where necessary, lockable refrigerators or freezers for storage of radioactive materials, sinks connected to the municipal sanitary sewerage system, impervious laboratory bench top working areas, etc. There are no changes in the locations and characteristics of the laboratories where radioactive materials will be stored or used, or in the receiving area for the Institute.

Low Level Radioactive Waste (LLRW) is held in a LLRW secure enclosure, located on the Penthouse fourth floor of USARIEM.

Radiation Detection Instrumentation:

Portable Survey Instruments

Manufacturer	Model #	Qty	Radiation Measured
Eberline Instrument Corp	E-530	2	Gamma Monitor

We reserve the right to upgrade our survey instruments as necessary.

Radiation Laboratory (counting room) Instrumentation

Manufacturer	Model #	Detector	Radiation Measured
Packard	1900 TR	Tri CarbLiquid Scintillation Analyzer	Beta
Perkin Elmer	Wizard	End-well Type (10) Thailium activated sodium Iodide crystal	Gamma

We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG-1556, Volume 7.

Calibration Frequency:

Portable Survey Instruments will be calibrated at least annually commercially, after a repair or as determined necessary by the RSO. Radiation Laboratory instruments will be calibrated as required for usage. See Reference NRC Form 313 Item #10, Appendix C.

Reference NRC Form 313 Item #10

Monitoring and Radioactive Contamination.

We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year a radiation dose in excess of 10% of the allowable limits in 10CFR 20 or we will monitor individuals in accordance with the criteria in the section entitled "Radiation Safety Program-Occupational Dose" in NUREG-1556, Volume 7".

We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG-1556, Volume 7. Leak tests will be performed at the intervals approved by the NRC and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by NRC to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instruction. As an alternative, we will implement the model leak test program published in Appendix R to NUREG-1556, Volume 7.

We will develop and maintain procedures for ensuring material accountability.

Emergency Procedures.

The procedures for safe use, including security of material, and emergencies have been developed. These procedures may be revised only if 1) changes are reviewed and approved by the licensee management and the RSO in writing; 2) the staff is provided training in the revised procedures prior to the implementation; 3) the changes are in compliance with the NRC regulations and the license; and 4) the changes do not degrade the effectiveness of the program.

Mr. Michael D. Blaha
USARIEM Radiation Safety Officer

Reference NRC Form 313 Item #11.

WASTE MANAGEMENT

We will use the model Decay-in-Storage and Disposal of Liquids into Sanitary Sewer model waste procedures that are published in Appendix T to NUREG-1556, Volume 7.

AUTHORIZED USERS

1) **Michael D. Blaha**

Radiation Training, Formal Courses:

Radiation Safety Officer Course – Radiation Safety Academy, Gaithersberg, MD (40Hrs, Sept 2009)

Also, college coursework related to radionuclides: Physics (1 yr), Biochemistry (1 ½ yr), Nutritional Biochemistry (Food Irradiation).

Radiation-Related Experience:

On-the-job training and experience since 1975 with the following radionuclides:

P^{32} exchange determinations

C^{14}

H^{3}

S^{35}

I^{125}

[All of the above were μCi activities as part of laboratory assays or kits]

As Lab Manager for 20 years I have trained numerous military and civilian employees in how to safely handle and conduct assays involving radionuclides.

Attended approximately 12 annual Radiation Safety Training sessions run by Paul Angelis, the Radiation Safety Officer.

Had been a participating member of the Natick Soldier System's Center's Radiation Safety Committee from 1994-2004, a group tasked with upholding the NRC license requirements for all Principal Users and Radiation Workers at the Natick Facility.

Have an outstanding safety record and reputation for fastidious work.

2) **Bradley C. Nindl, Ph.D.**

Training in Radiation, Formal Courses:

1) Principles and Practices of Radiation Use and Protection – The Pennsylvania State University Graduate Course 1995
2) Soldier System Command Annual Radiation Safety Course
3) Iodine – 125 (used in Radioimmunoassays, uCi amounts)

copy of current license 9/14/10 mdb

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 02

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the letter dated September 16, 2009,
1. Department of the Army U. S. Army Soldier Research Institute of Environmental Medicine (USARIEM)	3. License number 20-30847-01 is amended in its entirety to read as follows:
2. Building 42 Kansas Street Natick, Massachusetts 01760	4. Expiration date January 31, 2014
	5. Docket No. 030-36434 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Hydrogen 3	A. Any	A. 100 millicuries
B. Carbon 14	B. Any	B. 100 millicuries
C. Phosphorus 32	C. Any	C. 10 millicuries
D. Phosphorus 33	D. Any	D. 10 millicuries
E. Sulfur 35	E. Any	E. 10 millicuries
F. Iodine 125	F. Any	F. 20 millicuries

9. Authorized use:

A. through F. Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Building 42, Kansas Street, Natick, Massachusetts.

11. Licensed material shall be used by, or under the supervision of, Michael John Durkot, Ph. D. or Michael D. Blaha. Licensed material listed in Item F. shall be used by, or under the supervision of, Bradley C. Nindl, Ph.D.

12. The Radiation Safety Officer for this license is Michael Blaha.

13. The licensee shall not use licensed material in or on human beings.

MATERIALS LICENSE SUPPLEMENTARY SHEET

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14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.

15. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

16. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

    A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

    B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

    C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Letter dated January 9, 2004 [ML040360196]
B. Letter received January 28, 2004 [ML040430143]
C. Letter dated June 29, 2009 [ML091900407]

For the U.S. Nuclear Regulatory Commission

Date October 2, 2009

By ***Original signed by Thomas K. Thompson***

Thomas K. Thompson
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Friday, October 2, 2009 15:11:54

This is to acknowledge the receipt of your letter/application dated 9/19/2010, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (20-30847-01)

[X] 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** 573579.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader