



FOOD AND DRUG ADMINISTRATION
109 Holton Street
Winchester, MA 01890-1197
Tel. 1-781-729-5700
Fax 1-781-729-3593

October 13, 2009

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
License: *20-08361-01 RLS* 20-8361-01
Expiration date: June 30, 2016
Docket No. 03004675
Control No. 138288

RECEIVED
REGION 1
2009 OCT 14 AM 10:51

Dear Gentlemen/Madams:

We wish to amend our current broad scope license as identified above. The license application form is attached – Amendment No. 34. It is our intent to add four isotopes to our license: Radium -228 (²²⁸Ra), Thorium -228 (²²⁸Th), Thorium-230 (²³⁰Th) and Thorium-232 (²³²Th). We would like these isotopes to be in any chemical or physical form. The maximum activity to be on hand would be 500 microcuries (18.5 MBq) for ²²⁸Ra and 500 microcuries (18.5MBq) for each of the thorium isotopes. These isotopes would be used in the research and development of analytical methods to rapidly qualitatively and quantitatively determine the existence of radioactive material in food.

Attached is our application for this amendment. All supporting documentation may be found in our license application. Should have any questions regarding this matter please contact James J. Cherniack, Radiation Safety Officer at (781) 729-5700, extension 713.

Sincerely Yours,

Brian L. Baker, Director
Winchester Engineering and Analytical Center

Attachment

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

APPLICATION FOR MATERIALS LICENSE

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.

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
- B. AMENDMENT TO LICENSE NUMBER 20-08361-0
- C. RENEWAL OF LICENSE NUMBER _____

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

Dept of Health & Human Services
Public Health Service
U.S. Food & Drug Administration, W.E.A.C.
109 Holton Street Winchester, MA 01890-1197

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Same As #2

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

James J. Cherniack

TELEPHONE NUMBER

(781) 729-5700

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 N/A 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

Brian L. Baker, Center Director, WEAC

SIGNATURE

DATE

FOR NRC USE ONLY

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

APPROVED BY

DATE

10/13/09

ITEM # 5

We wish to amend our current license to include the following radionuclides

<u>Element & Mass No.</u>	<u>Chemical and/or Physical Form</u>	<u>Possession Limit</u>
Thorium 232	Any	500 μ Ci (18.5 MBq)
Thorium 230	Any	500 μ Ci (18.5 MBq)
Thorium 228	Any	500 μ Ci (18.5 MBq)
Radium 228	Any	500 μ Ci (18.5 MBq)

ITEM #6

These radionuclides will be used in the development of analytical techniques to analyze food matrices for radionuclides.

ITEM # 7

As stated in license number 20-08361-0.

ITEM # 8

As stated in license number 20-08361-0.

Item # 9

As stated in license number 20-08361-0.

Item #10

As stated in license number 20-08361-0.

Item # 11

As stated in license number 20-08361-0.

This is to acknowledge the receipt of your letter application dated

10/13/09, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (20-08361-01)
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 144233.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.