



Br. 2
03004675

REC PG 10 23 18 AM 09:54

October 22, 2018

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard
Suite 100
King of Prussia, PA 19406-2713

SUBJECT: License No. 20-08361-01; Request for License Amendment for the U.S. Food and Drug Administration
Winchester Engineering and Analytical Center; Addition of Location

Dear Licensing Assistance Team:

We request the following amendment be made to our NRC License No. 20-08361-01:

1. We request to use licensed material listed in subitem No 6.AA. at the following new address:

Pacific Northwest Laboratory
22201 23rd Drive SE
Bothell, WA 98021-4421

2. We also noticed an error on item 10.A. of our license. The address should read "109 Holton Street" rather than "1090 Holton Street"

Please contact Elon Malkin if you have questions or need additional information.
He can be reached by phone at (781) 756-9814 or by email at Elon.Malkin@fda.hhs.gov.

Sincerely,

Brian L. Baker -S

Digitally signed by Brian L. Baker -S
DN: cn=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,
cn=Brian L. Baker -S, 0.9.2342.19200300.100.1.1=2000359907
Date: 2018.10.22 15:37:36 -04'00'

Brian Baker
Center Director, WEAC

U.S. Food and Drug Administration
Winchester Engineering & Analytical Center
109 Holton Street
Winchester, MD 01890
www.fda.gov

610307
UNCLASSIFIED INTERNAL USE ONLY

NRC FORM 313

U.S. NUCLEAR REGULATORY COMMISSION

(10-2017)
10 CFR 30, 32,
33, 34, 35, 36,
37, 39, and 40

APPLICATION FOR
MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 06/30/2019

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 Information Services Branch (T-2 F43), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to infocollections.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 CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
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, 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
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

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

IF YOU ARE LOCATED IN:

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
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

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 20-08361-01☐ C. RENEWAL OF LICENSE NUMBER

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

Winchester Engineering and Analytical Center (WEAC)
Department of Health and Human Services
Food and Drug Administration
109 Holton Street Winchester Massachusetts 01890-1197

3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED

FDA ORA WEAC, 109 Holton Street, Winchester,
Massachusetts; FDA ORA Northeast Lab, 158-15 Liberty
Avenue, Jamaica, New York; FDA CDER, 645 South
Newstead Avenue, Saint Louis,

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Elon Malkin, Radiation Safety Officer

BUSINESS TELEPHONE NUMBER

781-756-9814

BUSINESS CELLULAR TELEPHONE NUMBER

240-460-3141

BUSINESS E-MAIL ADDRESS

Elon.Malkin@fda.hhs.gov

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.

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*)
(See 10 CFR 170 and Section 170.31)

*Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.

FEE
CATEGORYAMOUNT
ENCLOSED \$

PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: <https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html>

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, 37, 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, Director WEAC

SIGNATURE

Brian L. Baker -S

DATE

Digitally signed by Brian L. Baker -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,
cn=Brian L. Baker -S, 0.9.2342.19200300.100.1.1=2000359907
Date: 2018.10.22 15:36:28 -0400

FOR NRC USE ONLY

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



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee U. S. Department of Health and Human Services Public Health Service, FDA ATTN: Brian L. Baker, Center Director 109 Holton Street Winchester, MA 01890-1197	Date October 24, 2018
	License Number(s) 20-08361-01
	Mail Control Number(s) 610307
	Licensing and/or Technical Reviewer or Branch Commercial, Industrial, R&D, & Academic Branch

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 10/22/2018

The initial processing, which included an administrative review, has been performed.

☒ Amendment ☐ Termination ☐ New License ☐ Renewal

☒ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239