

NRC FORM 313
(03-2014)
10 CFR 30, 32, 33, 34
35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 05/31/2015



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 FOIA, Privacy, and Information Collections 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. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

<p>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</p> <p>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</p> <p>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</p> <p>IF YOU ARE LOCATED IN:</p> <p>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,</p> <p>SEND APPLICATIONS TO:</p> <p>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</p>	<p>IF YOU ARE LOCATED IN:</p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:</p> <p>MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352</p> <p><i>Br. 2</i></p> <p>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,</p> <p>SEND APPLICATIONS TO: <i>03004675</i></p> <p>NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511</p>
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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.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input checked="" type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <u>20-08361-01</u></p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)</p> <p>Department of Health and Human Services Public Health Service, FDA 109 Holton Street Winchester Massachusetts 01890-1197</p>
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<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p> <p>US Food and Drug Administration 645 South Newstead Avenue, Saint Louis, Missouri 63110</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>Elon Malkin, Assistant Radiation Safety Officer</p> <table border="1"> <tr> <td>BUSINESS TELEPHONE NUMBER</td> <td>BUSINESS CELLULAR TELEPHONE NUMBER</td> </tr> <tr> <td>(781) 756-9814</td> <td>(727) 687-8248</td> </tr> </table> <p>BUSINESS EMAIL ADDRESS</p> <p>Elon.Malkin@fda.hhs.gov</p>	BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER	(781) 756-9814	(727) 687-8248
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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.

<p>5. RADIOACTIVE MATERIAL</p> <p>a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>
<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>	<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.</p>
<p>10. RADIATION SAFETY PROGRAM.</p>	<p>9. FACILITIES AND EQUIPMENT.</p> <p>11. WASTE MANAGEMENT.</p>

<p>12. LICENSE FEES (Fees required only for new applications, with few exceptions*) (See 10 CFR 170 and Section 170.31)</p>	<p>FEE CATEGORY <input type="text"/></p> <p>AMOUNT ENCLOSED \$ <input type="text"/></p>
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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.

<p>CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE</p> <p>Brian L. Baker, Director, WEAC/FDA</p>	<p>SIGNATURE</p> <p><i>Brian L Baker</i></p>	<p>DATE</p> <p>4 JUN 15</p>
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FOR NRC USE ONLY					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

NRC FORM 313 (03-2014)
REC'D IN LAT 6-5-15

NMSS/RGN1 MATERIALS-002

588142



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food & Drug Administration
Winchester Engineering and Analytical Center (WEAC)
109 Holton Street, Winchester, Massachusetts 01890

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

June 4, 2015

Docket No. 03004675
License No. 20-08361-01

Subject: DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUEST FOR LICENSE AMENDMENT

We are requesting an amendment to our Nuclear Regulatory Commission License. Currently, our license lists an incorrect address for our Saint Louis, MO location. We request to correct the address of this location, and we also request to specify the Material Authorized for use at this location.

Currently, the address of our Saint Louis facility is listed as:
US Food and Drug Administration
6445 South Newstead Avenue
Saint Louis, Missouri

We request that this be changed to the correct address:
US Food and Drug Administration
645 South Newstead Avenue
Saint Louis, Missouri 63101

According to our current license conditions, line 10 states the Material Authorized for use at our Saint Louis location is "Nickel 63 (foils)". We request to update our license to specify the instrument that contains the sealed source of Nickel-63.

Please change the Material Authorized for use at the Saint Louis location to the following:

"Nickel-63 15 mCi (Sealed Ionization Source Option for Excellims RA4100 Electrospray Ionization High Resolution Ion Mobility Spectrometer, Model Number: RA1400, Serial Number 1000160)"

If any further information is needed, please contact our Assistant Radiation Safety Officer, Elon Malkin, by email Elon.Malkin@fda.hhs.gov, office phone 781-756-9814, or cell phone 727-687-8248.

Sincerely,

Brian L. Baker -S

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: 2015.06.04 13:54:29 -0400

Brian L. Baker, P.E.
Director, Winchester Engineering and Analytical Center, USFDA

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

6-4-15

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

Amend: 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** 588142.
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 (R1)
(6-96)

Sincerely,
Licensing Assistance Team Leader