



FOOD AND DRUG ADMINISTRATION
109 Holton Street
Winchester, Massachusetts

REC'D 1011416 AM 09/14/8

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

Br. 2

Date: December 30, 2015

Docket No. 03004675
License No. 20-08361-01
Control No. 583771 *amy*

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

Dear Mr. Lawyer:

We are requesting an amendment to our Nuclear Regulatory Commission License (NRC)

To delete:

- (1.) Our San Francisco Facility (at Alameda, CA). The License contained the following radionuclide – Cadium-109 Solid Source. It was inadvertently left out of our Amendment after we returned our NITON Instrument (XLp 300 Series Analyzer) to the Thermo Electron Corporation. It also contained an Americium-241 source which was deleted at that time.
- (2.) We would also like to delete our Atlanta, GA Facility from our NRC License as they no longer possess any reportable Nickel-63 Detectors. The report on the decommissioning of the Facility was forwarded to your Inspector at our the last Inspection, at his request.
- (3.) In addition our Denver Facility should also be deleted. The remaining radionuclides i.e. Carbon-14, Tritium, Cesium-137 Source and Nickel-63 were recently removed. Tritium was an 'exempt solution' was used in the CHARM analysis. The Nickel-63 sources for the past 10 years of swipes showed no detectable activity.
- (4) The FDA Facility at 158-15 Liberty Avenue, Jamaica, NY – please reduce the activity from 100 millicuries to 0.5 millicuries for Tritium.

Should you have any questions regarding this amendment, please contact:
Edmond J. Baratta, Radiation Safety Officer @ 781-756-9742 and/or
edmond.baratta@fda.hhs.gov

Sincerely,

Brian Baker
Center Director, WEAC

589945

NRC/REGNI MATERIALS-002

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



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>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:</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>Same as 3</p>
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<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p> <p>Department of Health and Human Services Public Health Services/FDA Winchester Engineering and Analytical Center 109 Holton Street Winchester, MA 01890</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>Edmond J. Baratta, Radiation Safety Officer</p> <table border="1"> <tr> <td>BUSINESS TELEPHONE NUMBER</td> <td>BUSINESS CELLULAR TELEPHONE NUMBER</td> </tr> <tr> <td>(781) 756-9742</td> <td>NA</td> </tr> <tr> <td colspan="2">BUSINESS EMAIL ADDRESS</td> </tr> <tr> <td colspan="2">edmond.baratta@fda.hhs.gov</td> </tr> </table>	BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER	(781) 756-9742	NA	BUSINESS EMAIL ADDRESS		edmond.baratta@fda.hhs.gov	
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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>12. LICENSE FEES (Fees required only for new applications, with few exceptions*) (See 10 CFR 170 and Section 170.31)</p>	<p>11. WASTE MANAGEMENT.</p> <p>FEE CATEGORY <u>NA</u> AMOUNT ENCLOSED \$ _____</p>

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 Baker, Center Director</p>	<p>SIGNATURE</p> 	<p>DATE</p> <p>1/8/2014</p>
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FOR NRC USE ONLY

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

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

12/30/2015, and to inform you that the initial processing which includes an administrative review has been performed.

20-08361-01 (Amendment)
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 589945
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.