

(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 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 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 _____
☐ C. RENEWAL OF LICENSE NUMBER _____

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

Millipore Sigma
3050 Spruce Street
St. Louis MO, 63103

3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED

3050 Spruce Street St. Louis MO, 63103

2425 S. 2nd Street St. Louis MO, 63104

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Lee McVay

BUSINESS TELEPHONE NUMBER

314-286-6600 X7889

BUSINESS CELLULAR TELEPHONE NUMBER

314-267-2010

BUSINESS E-MAIL ADDRESS

Lee.mcvay@milliporesigma.com

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 AND 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 (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
CATEGORY

3.1

AMOUNT
ENCLOSED \$

9,800

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

Robert Lee Mcvay Senior EHS Specialist

SIGNATURE

DATE

2-14-19

FOR NRC USE ONLY

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

**REQUEST FOR TAXPAYER
IDENTIFICATION NUMBER**

Estimated burden per response to comply with this mandatory collection request: 15 minutes. The information is required by NRC to process payments to contractors. Send comments regarding burden estimate to the Information Services Branch (T-2F43), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0188), 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.

In accordance with the Debt Collection Improvement Act of 1996, you are required to provide your taxpayer identification number. This number may be used to make payments (refunds) or for purposes of collecting and reporting on any delinquent amounts arising out of your relationship with the Federal Government.

Please complete the applicable blocks and fax the completed form to (301) 415-4135. Thank you for your assistance and cooperation. If you have any questions, please contact us. Our telephone number is (301) 415-7554.

Indicate the status of your business:**CORPORATION****CITY/STATE GOVERNMENT****OTHER** (Specify in box below)**INDIVIDUAL****PARTNERSHIP****FEDERAL GOVERNMENT****TAXPAYER IDENTIFICATION NUMBER****NRC LICENSE OR
REGISTRATION NUMBER(S)****SOCIAL SECURITY NUMBER**

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OR**EMPLOYER IDENTIFICATION NUMBER**

9	1			-	1	3	0	7	8	7	8		
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Under penalties of perjury, I certify that the number shown on this form is my correct taxpayer identification number.

SIGNATURE - TAXPAYER REPRESENTATIVE**NRC LICENSEE OR VENDOR****BILLING ADDRESS**

12822 SE 32nd St
Bellevue, WA 98005

BILLING TELEPHONE NUMBER

4256031123

BILLING EMAIL ADDRESS

jdelangen@biocontrolsys.com

PRIVACY ACT STATEMENT
NRC FORM 531
REQUEST FOR TAXPAYER IDENTIFICATION NUMBER

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by Section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission (NRC) on NRC Form 531. This information is maintained in a system of records designated as NRC-32 and described at 81 *Federal Register* 81342 (November 17, 2016), or the most recent *Federal Register* publication of the NRC's Systems of Records Notices that is located in the NRC's Agencywide Documents Access and Management System (ADAMS).

1. **AUTHORITY:** U.S.C. 552a; 5 U.S.C. 5514; 15 U.S.C. 1681; 26 U.S.C. 6103; 31 U.S.C. chapter 37; 31 U.S.C. 6501 -6508; 42 U.S.C. 2201; 42 U.S.C. 5841; 31 CFR 900 -904; 10 CFR parts 15, 16, 170, 171; Executive Order (E.O.) 9397, as amended by E.O. 13478; and E.O. 12731.
2. **PRINCIPLE PURPOSE(S):** To obtain taxpayer identification number/social security number/individual taxpayer identification number to enable the NRC to process payments and collect/report delinquent debts.
3. **ROUTINE USES:** Information from this form may be transmitted to: debt collection contractors and/or Federal agencies for collecting delinquent debts and/or collection action on such debts; any Federal, State or local agencies to conduct authorized computer matching programs and to credit reporting agencies; Treasury on past due nontax debts for the purpose of locating the debtor and/or effecting offset under Treasury Offset Program. Information may be publicly disseminated regarding the identity of delinquent nontax debtors and the existence of nontax debts under the provisions of the Debt Collection Improvement Act of 1996. Information may be disclosed in accordance with any of the Routine Uses listed in the Prefatory Statement of General Routine Uses, including to an appropriate Federal, State, local or Foreign agency in the event the information indicates a violation or potential violation of law; in the course of an administrative or judicial proceeding; to an appropriate Federal, State, local and foreign agency to the extent relevant and necessary for an NRC decision about you or to the extent relevant and necessary for that agency's decision about you; in the course of discovery under a protective order issued by a court of competent jurisdiction, and in presenting evidence; to a Congressional office to respond to their inquiry made at your request; to NRC-paid experts, consultants, and others under contract with the NRC, on a need-to-know basis; or to appropriate persons and entities for purposes of response and remedial efforts in the event of a suspected or confirmed breach of data from this system of records.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** It is mandatory that you furnish the requested information pursuant to the Debt Collection Improvement Act of 1996 (Public Law 104-134). If you do not provide the requested information, we may no longer be able to conduct business with you, and if you are due a refund, you may give up your rights to your refund.
5. **SYSTEM MANAGER AND ADDRESS:** Controller, Division of the Controller, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-001.

Form 313 Attachment for sections 5 through 11

Section 5:

A: The isotope we would like to distribute is C-14.

B: The Isotope is a sealed source used for equipment calibration

C: Each tube has an activity of 255nCi and we would never store more than 300 tubes on site at one time. A total of 76.5 uCi of C-14 material would be the maximum amount possessed at one time.

Section 6: Purpose(s) for which licensed material will be used.

This material will be sold to customers to act as a calibration standard for equipment sold by our company. Customers will usually purchase one to two tubes per machine.

Section 7: Individual(s) responsible for radiation safety program and their training and experience

Not Applicable

Section 8: Training for individuals working in or frequenting restricted areas:

Not Applicable

Section 9: Facilities and Equipment:

Not Applicable

Section 10: Radiation Safety Program

Not Applicable

Section 11: Waste management

Not Applicable

Detailed Source and Product Information required from Chapter 9.3 Of NUREG "Information Required for Specific types of Distribution Licenses"

The sources we will be adding to our kit come from Eckert & Ziegler Isotope Products Valencia, California 91355. Eckert & Ziegler have licenses through the NRC detailing the process for the creation of these count standards. Isotopes are labeled as radioactive and come with product information about handling and storage of the device. We include this information in a kit including the 255nCi C-14 tube and a blank for calibration of devices sold by our company. We do not create these standards or modify the isotope activity in any way. We will perform a QC check on the standard to ensure that activity of each tube is within an acceptable limit as does Eckert & Ziegler prior to shipping to us.

A. I have included a copy of the amendment letter sent to Frank Tran of the NRC region 3 requesting amendment to our current license to include C-14 possession on our site. I was told to go ahead and submit this application as the amendment has already been submitted to NRC update our current license to include C-14. (See attached License amendment)

B. This byproduct material will not be contained in any food, beverage, cosmetic, drug, or any other commodity designed for ingestion or inhalation by, or application, a human being. This source will be sold for use as a calibration standard only.

C. I can confirm that the byproduct material is to be in the form of a counting standard and will not be incorporated into any manufactured or assembled commodity, or product. Its sole purpose is to be used by our customers as a counting standard for equipment we sell them.

D. Eckert & Ziegler completes the process of adding isotope to these rods at the level of 225nCi per rod prior to sending them to us. We will then complete a Quality Control check to confirm that the activity is at the correct range prior to sending them to our customers.

E. Our shipping department will check outgoing packages using a wipe test on all sides of the outgoing package testing for levels of radiation higher than DOT requirements. Shipping one tube at a time to customers at an activity of 255nCi we will never approach the regulated limits for UN2910 shipping.

F. I have included a picture of the outside labeling of the tubes as they come to us from Eckert & Ziegler (Picture 1). I have also included a picture of the final kit we would ship out to customers (Picture 2).

Millipore Sigma
3050 Spruce Street
St. Louis, MO 63103

January 21-2019

Licensing Section
U.S. Nuclear Regulatory Commission Region III
Attn: Radioactive Material Licensing, Frank Tran
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Subject: EMD Millipore License No. 24-26445-01, C-14 addition

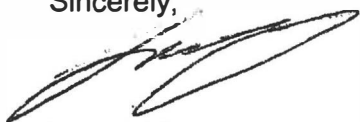
Dear Mr. Tran:

The following information is being provided in an effort to amend our current license to allow possession of C-14 Luminescent Calibrator rods at 3050 Spruce Street St. Louis, MO 63103. These are sealed sources with an activity of 225 nCi per rod. The maximum number of rods we would have on site at any one time is 300. This would set our maximum possession limit to 67.5 uCi. These rods are produced by Eckert & Ziegler Isotope Products under the part number A2500 and A2500-2. These rods will be placed into a kit box with a blank rod and stored until they are sold to customers for use as a calibration standard. I am in the process of completing the application for an Exempt Distribution License and these rods will not be sold until this license is obtained.

If kit assembly is required the C-14 rod, a blank rod, instructions for use, and a kit box will be assembled in our Hot Lab by a trained employee under the supervision of John Nichols, April Bauer, or Jacob Philips who are authorized users already on the license. Storage of these finished kits would either be at the 3050 Spruce site or our distribution warehouse located at 2425 south 2nd Street St. Louis MO, 63103 for sale to customers once an exempt distribution license is obtained. This location is still being determined by upper management and input from the NRC.

If additional assistance is needed for these actions, please contact me by e-mail – Lee.McVay@Milliporesigma.com – or by phone – (314) 267-2010. We appreciate your actions on this request.

Sincerely,



Lee McVay
Radiation Safety Officer

Picture #1

