



August 10, 2020

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

Ref.: Request for Amendment to License Number 19-07538-05 (Docket No. 030-31689)

Dear Sir/Madam:

I am writing to request an amendment to our Broad Scope Type A byproduct materials license pertaining to our license condition for annual refresher training. We are currently obligated to conduct refresher training every year. However, our program experiences very few significant changes during the course of a year. In addition, our user base consists mostly of very experienced researchers who transferred to FDA from the NIH program. We have only introduced one or two new users per year for the past several years. Further, the overall number of active investigators has steadily decreased over the past five years, as researchers who intended to use materials have since decided to discontinue their use.

In the past year our Radiation Safety Officer, CAPT Noska, has been using blanket email messages to communicate important information to all users in a timely fashion with success. While we do typically use refresher training to review important radiation safety concepts, we believe that the experience level of our users, combined with other forms of engagement (i.e., laboratory inspections, package deliveries, waste pickups, etc.) ensures that our users maintain good radiation safety practices in their laboratories. *Therefore, we are asking to amend our license such that we are only required to deliver formal refresher training on a biennial basis.*

If you have any further questions regarding this request or need additional information, please contact me or CAPT Noska at 301-796-8313 or 301-526-7956 or michael.noska@fda.hhs.gov.

Sincerely,

**Segaran P.
Pillai -S**

Digitally signed by Segaran
P. Pillai -S
Date: 2020.08.11 17:06:17
-04'00'

Segaran P. Pillai, Ph.D.
Director, Office of Laboratory Safety
Designated Agency Safety and Health Official
Food and Drug Administration



cc: M. Noska, FDA Radiation Safety Officer
A. Badal-Soler, White Oak RSC Chair
White Oak RSC members
White Oak RSC file

NRC FORM 313

(01-2020)
10 CFR 30, 32,
33, 34, 35, 36,
37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR
MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 01/31/2023

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-6 A10M), 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, NE08-10202, (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 19-07538-05
- ☐ C. RENEWAL OF LICENSE NUMBER _____

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

Department of Health and Human Services
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED

U.S. Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Michael A. Noska

BUSINESS TELEPHONE NUMBER

301-796-8313

BUSINESS CELLULAR TELEPHONE NUMBER

301-526-7956

BUSINESS E-MAIL ADDRESS

michael.noska@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.

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
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

Segaran P. Pillai, Ph.D.
Designated Agency Safety and Health Official

SIGNATURE

Segaran P.
Pillai -S

Digitally signed by Segaran P.
Pillai -S
Date: 2020.08.12 14:01:38
-0400'

DATE

FOR NRC USE ONLY

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