



May 24, 2022

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 21 to License Number 19-07538-05 (Docket No. 030-31689)

Dear Sir/Madam:

The FDA requests to add Cesium-137 (Cs-137) and Cobalt-57 (Co-57) sealed sources to the Broad Scope Type A byproduct material license referenced above. The FDA also anticipates the acquisition of additional calibration, transmission, and reference sealed radioactive sources; however, the radionuclides and model numbers have not been finalized. Therefore, the FDA also requests license authorization for multiple sealed sources or plated radionuclides with atomic numbers 1 through 83. The limits for these sources will be based on 10 CFR Part 35.65.

If the authorization for multiple sealed or plated radionuclides is granted, please absorb above request for Cs-137 and Co-57 sealed sources into this item and condition. Included please find a signed NRC Form 313 and Attachment 1 which contains the details of these amendment requests.

If you have any further questions regarding this request or need additional information, please contact me or Mr. Jerette Spann at (301) 796-8561 or [jerette.spann@fda.hhs.gov](mailto:jerette.spann@fda.hhs.gov).

Sincerely,

Segaran P. Pillai -S  
Digitally signed by  
Segaran P. Pillai -S  
Date: 2022.05.24  
10:15:25 -04'00'

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

cc: Jerette Spann, FDA Radiation Safety Officer  
D. Volpe, White Oak RSC Chair  
White Oak RSC members

**Attachment 1:**

Items listed for change.

**Item 5: Radioactive Material**

Add the following Items in Table-1

**Table -1**

<b>Byproduct, Source and/or Special Nuclear Material</b>	<b>Chemical and/or Physical Form</b>	<b>Maximum Amount Which Will Be Possessed At Any One Time</b>
I. Co-57	Sealed (Eckert and Ziegler Isotope Products Model Number RV-057-5M or equivalent)	6 millicuries per source and 15 millicuries total
J. Cs-137	Sealed (Eckert and Ziegler Isotope Products Model Number RV-137-200 or equivalent)	200 microcuries per source and 1 millicurie total
K. OR Proposed Radionuclides with Atomic numbers 1-83	Sealed or plated sources	30 millicuries per source and 500 millicurie total

**Item 6: Purpose(s) for Which Licensed Material Will Be Used**

Item I: For use in research and development as defined in 10 CFR 30.4, including animal studies and invitro studies; teaching and training of students; calibration and checking of the licensee's instruments.

Item J: For use in research and development as defined in 10 CFR 30.4, including animal studies and invitro studies; teaching and training of students; calibration and checking of the licensee's instruments.

Item K: For use in research and development as defined in 10 CFR 30.4, including animal studies and invitro studies; teaching and training of students; calibration and checking of the licensee's instruments. Radionuclides used are applicable to those equipment and procedures consistent with 10 CFR 35.65 for calibration, transmission, and reference sources.

Attachment 1

## NRC FORM 313

(05-2022)  
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 FOIA, Library, and Information Collections Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to [Infocollections.Resource@nrc.gov](mailto:Infocollections.Resource@nrc.gov), and the OMB Reviewer at: OMB Office of Information and Regulatory Affairs, (3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; e-mail: [olra\\_submission@omb.eop.gov](mailto:olra_submission@omb.eop.gov). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

**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 AND TRIBAL LIAISON BRANCH  
DIVISION OF MATERIALS SAFETY, SECURITY, STATE AND TRIBAL 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 RADIOLOGICAL SAFETY AND SECURITY  
U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
475 ALLENDALE ROAD, SUITE 102  
KING OF PRUSSIA, PA 19406-1415

## 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:

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

19-07538-05

## 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

Jerette Spann

## BUSINESS TELEPHONE NUMBER

301-796-8561

## BUSINESS CELLULAR TELEPHONE NUMBER

240-595-4137

## BUSINESS E-MAIL ADDRESS

jerette.spann@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.

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

## 10. RADIATION SAFETY PROGRAM.

## 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.

## SIGNATURE

Segaran P.  
Pillai -S

Digitally signed by  
Segaran P. Pillai -S  
Date: 2022.05.24  
10:12:34 -04'00'

## DATE

5/24/2022

## FOR NRC USE ONLY

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