



**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 Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollect.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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

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

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 21-26030-01

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

Sterling Diagnostics, Inc.
36645 Metro Court
Sterling Heights, MI 48312

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Sterling Diagnostics, Inc.
36645 Metro Court
Sterling Heights, MI 48312

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Luz Santa Maria

BUSINESS TELEPHONE NUMBER

(586)979-2141

BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS EMAIL ADDRESS

lou@sterlingdiagnostics.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 EXPERIENCE. Noli Cruz

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)

FEE CATEGORY

3P

AMOUNT ENCLOSED \$

N/A

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, 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

Luz Santa Maria
Office Manager

SIGNATURE

DATE

03-21-14

FOR NRC USE ONLY

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



Sterling Diagnostics, Inc

36645 Metro Court

Sterling Heights, Michigan 48312 U.S.A.

Tel. Nos.: (586) 979-2141

(800) 637-2661

Fax: (586) 979-4971

Email : info@sterlingdiagnostics.com

Website : sterlingdiagnostics.com

March 21, 2014

Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Sirs:

In reference to our request for a renewal of our byproduct material license (license no. 21-26030-01), I am hereby supplying the requested information as follows:

Sterling Diagnostics Inc. will confirm, prior to receiving and redistributing in vitro radioisotope-containing kits, that the initial manufacturer and distributor of the kits possesses an NRC License under Section 32.71 of CFR Part 32 or under equivalent regulations of an Agreement State.

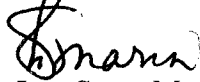
1. Sterling Diagnostics Inc. will be distributing to General Licenses under 10 CFR 31.11.
2. Radioisotopes that we distribute constitute prepackaged in vitro diagnostic test kits: Iodine-125. At no time does Sterling Diagnostics Inc. possess in excess of 1 millicurie of radioisotope based upon the total of all kits in inventory.
3. A "Radioisotope Receiving Log" is maintained and all radioisotope-containing kits are entered upon receipt (a copy was previously supplied with the initial application and has not been modified since that time). The receiving department personnel have been instructed to inspect all incoming packages for damage or leaking contents. Any damage to or leakage from a package containing a radioisotope is immediately reported to the "Radiation Safety Officer (RSO)". The RSO would scan the package for radiation and the outer shipping package, if any, to assess any radioactive contamination.
4. The holding area for radioisotope-containing kits is secure from unauthorized personnel. The storage area in the walk-in refrigerator is clearly marked: "RADIOISOTOPE STORAGE ONLY".
5. All personnel handling radioisotope-containing kits undergo instruction in the handling of radioisotopes as well as our 'in-house' Radiation Safety Program.
6. All radioisotope-containing kits are delivered by common carrier. Packages conform to conditions and limitations in 49 CFR 173.421 for accepted radioactive material.
7. Sterling Diagnostics Inc. maintains a "Radioisotope Shipping Log" (a copy was previously supplied with the initial application and has not been modified

since that time). No radioisotope is packaged for shipment to an account until entered into the "Radioisotope Shipping Log" along with the account's NRC License Number. The License Number will be entered by obtaining it from a copy of the account's NRC License on file at Sterling Diagnostics Inc. If we do not possess a copy of the license, we do not ship the radioisotope.

8. A sketch of our facilities was previously submitted to you with our initial license application and has not been modified since that time.
9. Waste Disposal - We have never had an occasion where a bottle containing an isotope was broken or leaked. If such an occasion would occur, the product would be returned to the manufacturer for disposal. The product would be returned packaged in a 4 mil plastic bag within a 4 mil plastic bag.

If you should require additional information, please contact me.

Sincerely yours,



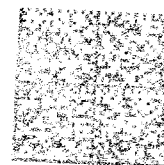
Luz Santa Maria
Office Manager



Sterling Diagnostics, Inc.

36645 Metro Court

Sterling Heights, Michigan 48312 U.S.A



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Lisle, IL 60532-4352

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