



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 1, 2018

PAR STERILE PRODUCTS
GL-705371-23
ATTN: ANNETTE SOMMERS
MGR EHS
870 PARKDALE ROAD
BLDG-100
ROCHESTER, MI 48307

SUBJECT: PAST DUE GENERAL LICENSE DEVICE ANNUAL REGISTRATION

Dear ANNETTE

This letter refers to the general license device annual registration packet sent to the above address on January 30, 2018 (copy enclosed). The U.S. Nuclear Regulatory Commission (NRC) requires annual registration of certain devices that are possessed under the general license issued in Section 31.5 of Title 10 U.S. Code of Federal Regulations [10 CFR 31.5(c)(13)(1)]. NRC's general license database indicates that you are in possession of a general license for a device requiring annual registration. Please complete and return the registration packet within 15 calendar days from the date of this letter. If you do not respond, NRC may take additional action which may include inspection of your facility and possible enforcement action.

Information about the general license registration program is available on the internet at <http://www.nrc.gov/materials/miau/miau-reg-initiatives/gen-license.html>.

Questions regarding your submittal or your responsibilities as a general licensee can be answered by contacting Donald Lowman at (301) 415-5452 or email at Donald.Lowman@nrc.gov.

Sincerely,

A handwritten signature in black ink that reads "Don Lowman".

Donald Lowman
Office of Nuclear Material Safety
and Safeguards
Division of Material Safety, State, Tribal
and Rulemaking Programs
Material Safety Licensing Branch

**INSTRUCTIONS FOR COMPLETING NRC FORM 664
"GENERAL LICENSEE REGISTRATION"**

Review all six sections of this registration form. If any information is incorrect or missing, make corrections in the applicable boxes. If you have more devices than space provided in the form, **copy the form before starting, as needed.** Use black ink and print in **CAPITAL LETTERS.** Start information in the first box provided. If the information contains a number with a dash (-) or a decimal point (.), include the dash or decimal point as an individual character. Use the "ø" character to represent the number 0 (zero).

Verify information about the devices by reviewing the label on the outside of the device. **For safety reasons, DO NOT TRY TO TAKE APART any device to verify this information.** If you are uncertain how to identify the device's label, contact the device's manufacturer or an authorized service agent for this information. Also, contact the manufacturer for any additional information about NRC requirements. You may also review 10 CFR 31.5 and other applicable regulations on the NRC web site at <http://www.nrc.gov/reading-rm/doc-collections/cfr/>, or review specific information about the general licensee project at <http://www.nrc.gov/materials/miau/miau-reg-initiatives/gen-license.html>

Note to specific licensees: If you believe the device(s) listed on the registration form are possessed under your specific license, then verify the device label does not state the device is subject to a general license. If the labels indicate the device is subject to a general license, then complete the registration form as instructed below. If not, complete the registration as instructed below, however, in Section 2, follow the instructions for "not in possession of device" and complete one Section 4 page per device transferred to your specific license.

Section 1 - General Licensee Information. Provide the requested information about you, the general licensee.

On Page 1, provide the street address/location where your device(s) are used. For portable devices, provide the storage location. P.O. Box addresses are not allowed.

Do not write in the box marked **For NRC Use Only.**

On Page 2, provide the name, telephone number, and title of the individual responsible for your device(s), and a mailing address where correspondence about your device(s) can be sent. The mailing address should be specific to the physical location where the devices are used and/or stored (P.O. boxes may be used if this is the only available mailing address). The individual indicated in this section as responsible for your device(s) must also verify and sign the form in Section 5.

Section 2 - Devices Subject to Registration. This section lists each device subject to registration and in your possession, according to NRC records. Devices subject to registration include those containing at least one of the radionuclides listed in Table 1, with the activity indicated, at the time of manufacture.

Table 1. Criteria for Registration

Radionuclide	Activity greater than or equal to:
Strontium-90, Radium-226	3.7 megabecquerel (0.1 millicurie)
Cobalt-60, Curium-244, Americium-241, and Californium-252	37 megabecquerel (1 millicurie)
Cesium-137	370 megabecquerel (10 millicurie)

Use the codes from Table 2 when correcting isotope information for devices in this section. If you do not possess a device on this list, blacken the "not in possession of device" circle, and provide the relevant information in Section 4. Note that each device is assigned a unique six-digit number called the NRC Device Key.

Table 2. Isotope Codes for Sections 2 and 3

Radionuclide	Code for form	Radionuclide	Code for form
Americium-241	AM241	Curium-244	CM244
Californium-252	CF252	Strontium-90	SR90
Cesium-137	CS137	Radium-226	RA226
Cobalt-60	CO60		

Section 3 - Additional Devices. If you have other generally licensed devices (not listed in Section 2) that meet the conditions for registration listed in Table 1, provide information about each additional device. **Before starting, copy this section as needed for your additional devices.** Also indicate how you acquired each device by blackening the proper circle.

When entering isotope and unit information for your device(s), use the codes listed in Table 2 of Section 2 for isotope information, and use the codes from Table 3 for unit information:

Table 3. Unit Codes for Section 3

Unit	Code for form	Unit	Code for form
picocurie	PCI	becquerel	BQ
nanocurie	NCI	kilobecquerel	KBQ
microcurie	UCI	megabecquerel	MBQ
millicurie	MCI	gigabecquerel	GBQ
curie	CI	terabecquerel	TBQ
pound	LB	microgram	UG
		milligram	MG
kilogram	KG	gram	G

Section 4 - Not in Possession of Device. Use this section to report any devices that are listed in Sections 2 or 6, but that you no longer possess. **Before starting, copy this section as needed for additional devices that are not in your possession.** Enter the NRC Device Key, as listed in Section 2 or 6. Blacken the circle (choose only one) that best describes the disposition of the device and complete the rest of the section as appropriate.

Section 5 - Certification and Signature. The responsible individual must certify, sign, and date Section 5.

Section 6 - Devices Not Subject to Registration. This list contains information about devices that NRC records indicate are in your possession, but **are not subject to registration.** If you no longer have one or more of the listed devices, you are required to make a transfer report to NRC in accordance with 10 CFR 31.5(c)(8) or (9), as applicable. You may use Section 4 for this purpose. This section does not list any static eliminators containing polonium-210 (Po-210), or luminous exit signs containing tritium (H-3). These devices are not subject to registration, and are not included in this section in an effort to reduce the length of this form.

RETURN THE COMPLETED FORM IN THE ENCLOSED ENVELOPE WITH PROPER POSTAGE.



GL-705371-23
01/26/2018

SECTION 5 - CERTIFICATION

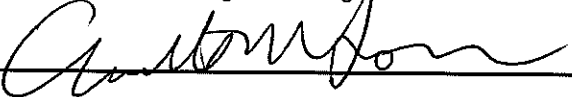
SECTION 5
PAGE 1 of 1

I hereby certify that:

- A. All information contained in this registration is true and complete to the best of my knowledge and belief.
- B. A physical inventory of the devices subject to registration has been completed, and the device information on this form has been checked against the device labeling.
- C. I am aware of the requirements of the general license, provided in 10 CFR 31.5.

(Copies of applicable regulations may be viewed at the NRC website at:

<http://www.nrc.gov/reading-rm/doc-collections/cfr>)



08 AUG 2018

SIGNATURE - RESPONSIBLE INDIVIDUAL (Listed in Section 1)

DATE

WARNING: FALSE STATEMENTS MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL ASPECTS. 18 U.S.C. SECTION 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY WRONG STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER IN ITS JURISDICTION.





GL-705371-23
01/26/2018

SECTION 6 - DEVICES NOT SUBJECT TO REGISTRATION

SECTION 6

PAGE 1 of 1

NRC Device Key:

Manufacturer License No:

Manufacturer Name:

Model Number:

Serial #:

Transfer Date: