



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

November 16, 2018

TO: Users of Devices Subject to General License Registration

SUBJECT: ANNUAL REGISTRATION OF GENERALLY LICENSED DEVICES

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). Devices subject to registration include those containing the radioactive material and activity listed in Table 1 of the attached NRC Form 664. You are receiving this notice because NRC records indicate that you have one or more such devices. Information about the general license registration program is available NRC website at <http://www.nrc.gov/materials/miau/miau-reg-initiatives/gen-license.html>

Note that under 10 CFR 31.5(c)(11), the attached General Licensee Registration Package must be completed, signed, and returned to the NRC within 30 days from the date of this letter. Read all of the instructions prior to completing the package. Mail the completed package in the enclosed envelope to:

Director, Office of Nuclear Material Safety
and Safeguards
ATTN: GLTS
U.S. Nuclear Regulatory Commission
Washington DC 20555-0001

Registration Fee: Commission regulations (10 CFR 170.31, Category 3Q) require that you submit a registration fee with each registration on an annual basis. The registration fee is subject to change yearly, and you are required to submit the fee that is in effect as of the date of this letter. An invoice for the current amount due will be sent to you under separate cover. If you have any questions about the fee or the invoice, please contact the License Fee Billing Help Desk at 301-415-7554 or e-mail at fees.resource@nrc.gov.

NRC amended 10 CFR Parts 170.11 and 170.31 to provide that 10 CFR Part 170 fees be assessed to Federal agencies, where applicable, in accordance with the Energy Policy Act of 2005. Therefore, those Federal facilities required to register certain generally licensed devices in their possession will be required to pay the annual registration fee.

Attachment: NRC Form 664 -- General Licensee Registration and Instructions

Sincerely,

A handwritten signature in black ink, appearing to read "Donald Lowman", is written over a horizontal line.

Donald Lowman
U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and
Safeguards
Division of Material Safety, State, Tribal and
Rulemaking Programs
Materials 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



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PAGE 2 of 2

SECTION 1 - GENERAL LICENSEE INFORMATION (Continued)

Enter the name, telephone number and title of the person who is the responsible individual for the device(s).

Last Name: SOMMERS

[illegible]

First Name: ANNETTE

[illegible]

Middle Initial: M

7

Business Telephone Number: (248) 656-5370

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Extension:

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Title: MGR EHS

[illegible]

Enter the mailing address where correspondence regarding your device(s) should be sent.

Department: STERILE FILLING

[illegible]

Address Line 1: 870 PARKDALE ROAD

[illegible]

Address Line 2: BLDG-100

[illegible]

City: ROCHESTER

[illegible]

State: MI

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Zip Code: 48307

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SECTION 2
PAGE 1 of 1

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	Isotope (e.g. AM241)	Activity (e.g. 1005)	Unit (e.g. mCi)
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PAGE 1 of 1

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3.					
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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.

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

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

28 NOV 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. 10 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.





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SECTION 6 - DEVICE NOT SUBJECT TO REGISTRATION

SECTION 6

PAGE 1 of 1

NRC Device Key:

Manufacturer License No:

Manufacturer Name:

Model Number:

Serial #:

Transfer Date:

Isotope:

Activity:

Unit:

Isotope:

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NRC FORM 526
(08-2017)
10 CFR 171

U.S. NUCLEAR REGULATORY COMMISSION

CERTIFICATION OF SMALL ENTITY STATUS FOR THE PURPOSES OF ANNUAL FEES IMPOSED UNDER 10 CFR PART 171 (Effective August 29, 2017)

If you have QUESTIONS, e-mail them to: SmallEntity.Resource@nrc.gov

**SEE IMPORTANT INSTRUCTIONS FOR NRC FORM 526 -- PLEASE READ CAREFULLY
DO NOT COMPLETE OR RETURN THIS FORM IF YOU DO NOT QUALIFY AS A SMALL ENTITY**

A Licensee that is a subsidiary of a large entity, including foreign entities, does NOT qualify as a small entity.

NAME AND ADDRESS OF LICENSEE (as it appears on the invoice): <i>Par Sterile Products LLC 870 Parkdale Rd. Rochester, MI 48307</i>		INVOICE NUMBER <i>LFB 19-1095</i>	BUSINESS TELEPHONE NUMBER <i>248-656-5370</i>
		DOCKET NUMBER <i>705371</i>	CONTACT NAME <i>Annette Sommers</i>
EMAIL ADDRESS <i>annette.sommers@parpharm.com</i>	COMPANY WEBSITE ADDRESS <i>WWW.</i>	CONTACT TELEPHONE NUMBER <i>248-656-5370</i>	

SIZE STANDARDS (Check only 1 box below).

**MAXIMUM ANNUAL FEE
PER LICENSED CATEGORY
(See Items 2 and 3 on back)**

1. SMALL BUSINESS

A for-profit concern that is not engaged in manufacturing with average **GROSS** receipts of \$7.0 million or less over its last 3 completed fiscal years. For further information see 1a and 1b of attached instructions.

- entry error*
☒ A. \$485,000 TO \$7,000,000
☐ B. LESS THAN \$485,000

04 DEC 2018
 \$ 4,100
 \$ 850

2. MANUFACTURING INDUSTRY

A manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

- ☒ A. 35 to 500 EMPLOYEES
☐ B. LESS THAN 35 EMPLOYEES

\$ 4,100
 \$ 850

NAICS BUSINESS CODE (See 1b and 1e of attached instructions): *325412*

3. SMALL ORGANIZATION

A not-for-profit organization that is independently owned and operated and has annual **GROSS** receipts of \$7.0 million or less. For further information see 1a and 1b of attached instructions.

- ☐ A. \$485,000 TO \$7,000,000
☐ B. LESS THAN \$485,000

\$ 4,100
 \$ 850

4. SMALL GOVERNMENTAL JURISDICTION (INCLUDING PUBLICLY SUPPORTED EDUCATIONAL INSTITUTIONS)

A government of a city, county, town, township, village, school district, or special district with a population of less than 50,000. For further information see 1f of attached instructions.

- ☐ A. 20,000 TO 49,999 POPULATION OF JURISDICTION
☐ B. LESS THAN 20,000 POPULATION OF JURISDICTION

\$ 4,100
 \$ 850

5. SMALL EDUCATIONAL INSTITUTION THAT IS NOT STATE OR PUBLICLY SUPPORTED

Only applicable to such small educational institutions if they have 500 or less employees. For further information see 1b and 1f of attached instructions.

- ☐ A. 35 to 500 EMPLOYEES
☐ B. LESS THAN 35 EMPLOYEES

\$ 4,100
 \$ 850

CERTIFICATION

This certification MUST be signed by the owner of the entity named above or an official empowered to act on behalf of the entity.

I certify that the above named NRC licensee qualifies as a small entity under the size standards established by the NRC for its licensees in 10 CFR 2.810. The licensee qualifies as a small entity under the specific size standard indicated above.

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. The submission of willful false statements is punishable by fine or imprisonment, or both, and for purposes of this certification, may result in revocation or suspension of the license.

I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.	TYPED OR PRINTED NAME AND TITLE <i>Annette Sommers</i>	SIGNATURE <i>Annette Sommers</i>	DATE <i>04 DEC 2018</i>

**IMPORTANT INSTRUCTIONS FOR NRC FORM 526 -- PLEASE READ CAREFULLY
DO NOT COMPLETE OR RETURN THIS FORM IF YOU DO NOT QUALIFY AS A SMALL ENTITY**

**CERTIFICATION OF SMALL ENTITY STATUS FOR THE PURPOSES
OF ANNUAL FEES IMPOSED UNDER 10 CFR PART 171**

A licensee who qualifies as a small entity under a specific size standard established by the NRC may pay a reduced annual fee by filing the required certification on NRC Form 526, which is on the reverse side of this page. A separate NRC Form 526 is required for each invoice. Licensees who do not qualify under one of the 5 size standards shown on NRC Form 526 should disregard this form.

1. Complete all items on NRC Form 526 as follows: **(NOTE: Incomplete or improperly completed forms will be returned as unacceptable.)**
 - Enter the licensee's name and address exactly as they appear on the invoice. Annotate name and/or address changes for billing purposes on the payment copy of the invoice -- Correcting the name and/or address on NRC Form 526 or on the invoice does not constitute a request to amend the license.
 - Enter the invoice number exactly as it appears on the invoice.
 - Enter the company's business telephone number. Enter the docket number exactly as it appears on the invoice.
 - Enter the contact person's name and email address. Enter the company's website address (if applicable), and the contact person's telephone number.
 - Check the appropriate size standard under which the licensee qualifies as a small entity. Check one box only. Note the following:
 - a. A licensee that is a subsidiary of a large entity, including foreign entities, does not qualify as a small entity. The calculation of a firm's size must include the employees or receipts of the parent company and all other affiliates. Affiliation with another concern is based on the power to control whether exercised or not. Such factors as common ownership, common management and identity of interest are indications of affiliation. The affiliated business concerns need not be in the line of business listed in the license.
 - b. Gross annual receipts, as used in the size standards, include all revenue received or accrued by your company from all sources, regardless of the form of the revenue, and not solely receipts from licensed activities. Receipts of a for-profit concern not engaged in manufacturing means average gross receipts over its last three completed fiscal years. (For additional information on calculating annual receipts, see 13 C.F.R. 121.104.) By contrast, number of employees of a manufacturing concern is based on employment during each pay period for the preceding 12 calendar months. (For additional information on calculating number of employees, see 13 C.F.R. 121.106.)
 - c. NRC's size standards on small entity are generally based on the Small Business Administration's regulations (13 C.F.R. Part 121). However, where there is a direct conflict between the Small Business Administration's regulations and NRC regulations on the subject, NRC regulations are applicable to NRC licensees.
 - d. The size standards apply to the licensee, not to the individual authorized users who may be listed in the license.

**IMPORTANT INSTRUCTIONS FOR NRC FORM 526 -- PLEASE READ CAREFULLY
DO NOT COMPLETE OR RETURN THIS FORM IF YOU DO NOT QUALIFY AS A SMALL ENTITY
(Continued)**

**CERTIFICATION OF SMALL ENTITY STATUS FOR THE PURPOSES
OF ANNUAL FEES IMPOSED UNDER 10 CFR PART 171**

- e. If you are a manufacturer, enter your North American Industry Classification System business code in the narrow, elongated box provided for that purpose under MANUFACTURING INDUSTRY on Form 526. In accordance with the North American Industry Classification System (NAICS), each business is assigned a NAICS business code. If you do not know your NAICS business code it can be obtained on the internet at www.census.gov.
 - f. As used in Form 526, "educational institution" means an entity that has education as its primary function; that offers programs accredited by a nationally recognized accrediting agency or association; that is legally authorized to provide a program of organized instruction or study; that provides an educational program for which it awards academic degrees; and that makes its educational programs available to the public.
2. If the invoice states the "Amount Billed Represents 50% Proration," the amount due is not the prorated amount shown on the invoice, but rather one-half of the maximum small entity annual fee shown on NRC Form 526 for the size standard under which the licensee qualifies (either \$2,050 or \$425) for each category billed.
 3. If the invoice amount is less than the reduced small entity annual fee shown on this form, pay the amount on the invoice; there is no further reduction. In this case, do not file NRC Form 526. However, if the invoice amount is greater than the reduced small entity annual fee, file NRC Form 526 and pay the amount applicable to the size standard you checked on the form.
 4. The completed NRC Form 526 must be submitted with the required annual fee payment and the "Payment Copy" of the invoice to the address shown on the invoice.
 5. 10 CFR 171.16(c)(3) provides that a licensee must submit a new certification with its annual fee payment each year. A licensee must pay the full amount of the invoice, if the licensee fails to submit NRC Form 526 at the time the annual fee is paid.

NRC Form 526 can be accessed on the NRC's public website at:
<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc526.pdf>.

NRC's Small Entity Compliance Guide is available online in the NRC Library at:
<http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into the Agencywide Documents Access and Management System (ADAMS), which provides text and image files of the NRC's public documents.

To obtain information quickly regarding small entities and annual fees, please contact the License Fee Billing Help Desk at (301) 415-7554 or by e-mail at:
SmallEntity.Resource@nrc.gov.