BAMF Health

109 Michigan St. NW
Suite 110
Grand Rapids, MI 49503

bamfhealth.com

April 11, 2022

Materials Licensing Branch
Attn: Tammy Tomczak
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: CN 630398 [Docket No. 030-39267, Sealed Sources and AU]

Ms. Tomczak,

Please augment our March 8, 2022, amendment request assigned Mail Control Number 630398 for License No. 21-35632-01 to include a change to the listing of sealed sources and to add an additional authorized user.

Specifically, replace Items 6.G-J, 7.G-J, 8.G-J, and 9.G-J with the following sole conditions:

6.G. Any byproduct material permitted by 10 CFR 35.65
7.G. Sealed sources
8.G. 100 millicuries total
9.G. For use in calibration and checking of the licensee's instruments

This change is requested to align our accelerator license with our recently issued commercial radiopharmacy license (No. 21-35632-03MD) which has the same conditions. While our two licenses cover different operations within the same facility, the same sealed sources are used interchangeably.

In addition, please add Bradley Knorr to Section 12 as an authorized user who will handle licensed material. Mr. Knorr has approximately 19 years of relevant experience as a cyclotron operator and engineer. He was most recently listed as an authorized user (cyclotron operator) on multiple agreement state licenses for SOFIE where he handled radioisotopes and quantities using cyclotrons similar to our facility.

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The following radioactive radioactive materials licenses are attached which list Mr. Knorr as an AU:

a. State of California, License No. 7131-43
b. State of Ohio, License No. 02500180001
c. State of Florida, License No. 3287-1
d. State of New York, License No. C5707

Thank you,

**Matthew DeLong, PharmD**
VP Radiopharmacy

# Amendment for Sealed Sources 35.65 and Knorr

Final Audit Report 2022-04-11

| | |
|---|---|
| Created: | 2022-04-11 |
| By: | Colten Conrad (colten.conrad@bamfhealth.com) |
| Status: | Signed |
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## "Amendment for Sealed Sources 35.65 and Knorr" History

Document created by Colten Conrad (colten.conrad@bamfhealth.com)
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E-signature obtained using URL retrieved through the Adobe Acrobat Sign API
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# RADIOACTIVE MATERIAL LICENSE

*Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the California Department of Public Health now or hereafter in effect and to any standard or specific condition specified in this license.*

| | | | |
|---|---|---|---|
| 1. Licensee: | Sofie Network, Inc. dba Sofie, Co.<br>fka Zevacor Pharma | 3. License Number: 7131-43 | Amendment Number: 41 |
| 2. Address: | 21000 Atlantic Blvd., Suite 730<br>Dulles, VA 20166 | 4. Expiration date: June 16, 2028 | (2) |
| Attention: | **Matthew A. Hadden**<br>Corporate Radiation Safety Officer | 5. Inspection agency: | Radiologic Health Branch<br>North |

**License Number 7131-43 is hereby amended as follows:**

| 6. Nuclide | 7. Form | 8. Possession Limit |
|---|---|---|
| A.<br>1. Any radionuclide with atomic numbers 1-83, except as listed below.<br>2. Germanium-68<br>3. Gallium-68<br>4. Copper-64 | A. Any | A.<br>1. Total possession limit not to exceed 74 GBq (2 Ci).<br>2. Not to exceed 11.1 GBq (300 mCi).<br>3. Not to exceed 7.4 GBq (200 mCi).<br>4. Not to exceed 111 GBq (3 Ci). |
| B. Any radionuclide with atomic numbers 1-83. | B. Sealed, solid or liquid sources manufactured in accordance with a specific license issued by the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State. | B. Total possession limit not to exceed 7.4 GBq (200 mCi). Each source not to exceed 740 MBq (20 mCi). |
| C.<br>1. Fluorine-18<br>2. Nitrogen-13 | C. Any | C.<br>1. Total not to exceed 1.9 TBq (50 Ci).<br>2. Total not to exceed 185 GBq (5 Ci). |
| D. Any radionuclide with atomic number 3-83, inclusive. | D. Cyclotron activation products | D. Total not to exceed 148 GBq (4 Ci). |

**RADIOACTIVE MATERIAL LICENSE**

License Number: 7131-43

Amendment Number: 41

9. Authorized Use

A. Preparation and distribution of radioactive drugs including compounding of Iodine-123 and Iodine-125, and redistribution of used and unused Molybdenum-99/Technetium-99m and Germanium-68/Gallium-68 generators to authorized recipients in accordance with CCR, Title 17, Section 30210.2. Preparation and distribution of radioactive drugs and radiochemicals including compounding of Iodine-123 and Iodine-125 and redistribution of used and unused Molybdenum-99/Technetium-99m and Germanium-68/Gallium-68 generators to authorized recipients for non-medical use. Also labeling blood components, analysis of labeled or tagged biological samples.

B. Calibration and checking of the licensee's instruments and provide quality assurance testing to persons licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 or equivalent Agreement State or Licensing State requirements to authorized recipients for medical or non-medical use. Redistribution of sealed sources that have been registered either with U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State or a Licensing State and have been distributed to persons specifically authorized by U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive, possess, and use the devices/sources.

C. Manufacturing of positron emitting radionuclides for distribution using Ion Beam Applications Cyclone 18/9 cyclotrons.

D. For storage only.

*LICENSE CONDITIONS*

10. Radioactive material shall be used only at the following approved location:

(a) 5900-B Obata Way, Gilroy, CA. (Excluding the area occupied by RML 6579-43)

11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.

12. (a) Radioactive material shall be used by, or under the supervision and in the physical presence of, the following individuals:

(1) Mark A Juarez, R.Ph.

(2) Hai M. Vu, Pharm.D., Ph.D.

(3) Chinh N. Nguyen, Pharm.D.

(4) Jonathan Kataoka, Pharm.D.

(5) Duy Dang, Pharm.D.

(6) Any other radiopharmacist registered by the California State Board of Pharmacy, and also listed on a specific license of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State for a maximum period of 60 days.

(b) The Cyclotron shall be operated by, or under the supervision and in the physical presence of, the following individuals:

(1) Martin Magerl
(2) Philippe Brisard
(3) Sky Cui
(4) Gary Kenny
(5) Eric Schreiner
(6) Frery Perez
(7) Otto Garcia, Sr.
(8) Alba Perez
(9) Ahmed Baker
(10) Ying Zhang
(11) Susan Molina, R.Ph.
(12) Bradley Knorr

13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with the statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

(a) The letter dated October 29, 2015, and the letter, with attachments, dated February 24, 2016, both signed by Todd Hockemeyer, VP- Quality & Regulatory Affairs, regarding the production of C-11 and N-13, the addition of the Ge-68/Ga-68 generator, and the updated Decommissioning Funding Plan.

(b) The renewal application with attachments, dated May 10, 2013, signed by Gregory S. Hisel, CHP, Director of Health Physics, as supplemented by the revised application, with attachments, received on August 2, 2017, signed by Timothy D. Stone, Jr., President and CEO, Illinois Health and Science, the application and the letter, dated December 29, 2017, and February 12, 2018, respectively, both with attachments, signed by Frank L. Plastini, Corporate Radiation Safety Officer, and the letter dated November 15, 2017, signed by Frank L. Plastini, Corporate Radiation Safety Officer.

(c) The letter, with attachments, dated January 9, 2019, signed by Michael Levy, Director, Radiation Compliance & Environmental Health and Safety, Corporate Radiation Safety Officer, regarding the appointment of the new Radiation Safety Officer.

(d) The letters dated April 3, 2019 and May 1, 2019, both signed by Michael Levy, Director, Radiation Compliance & Environmental Health and Safety, Corporate Radiation Safety Officer, regarding the removal of temporary job sites.

(e) The letters, both with attachment, dated April 2, 2019 and May 1, 2019, both signed by Michael Levy, Director, Radiation Compliance & Environmental Health and Safety, Corporate Radiation Safety Officer, and the letters, both with attachments, dated May 28, 2019, and July 22, 2019, both signed by Patrick Phelps, President and CEO, regarding the updated Decommissioning Funding Plan.

(f) The letter, with attachments, dated July 12, 2021, signed by Michael Levy, Director, Radiation Compliance & Environmental Health and Safety, Corporate Radiation Safety Officer, regarding the remodeling of the restricted area of the 5900-B Obata Way, Gilroy, CA., use location.

(g) **The letter with attachments, dated November 22, 2021, signed by Patrick Phelps, President and CEO, et al, regarding the appointment of a new Corporate Radiation Safety Officer.**

14. (a) The Radiation Safety Officer in this program shall be Hai M. Vu, R.Ph.

(b) The Corporate Radiation Safety Officer in this program shall be **Matthew A. Hadden**.

**RADIOACTIVE MATERIAL LICENSE**

License Number: 7131-43

Amendment Number: 41

15. Sealed sources possessed under this license shall be tested for leakage and/or contamination as required by Title 17, California Code of Regulations, Section 30275 (c).

16. In lieu of the leak test intervals required by California Code of Regulations, Title 17, Section 30275 (c), sealed sources can be tested for leakage and/or contamination at longer intervals when they are specified in a certificate of registration issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. When a longer interval stipulated in a certificate of registration is used, the certificate must be maintained on file and available for inspection for as long as the associated leak test records are retained.

17. Quantitative analytical assays for the purpose of tests for leakage and/or contamination of sealed sources shall be performed only by persons specifically authorized to perform that service.

18. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Public Health:

    (a) The Radiation Safety Officer

    (b) Qualified individuals designated in writing by the Radiation Safety Officer

19. The licensee shall conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under the license. Records of the inventories shall be maintained for inspection, and may be disposed of following Department inspection.

20. Where users or their assistants are engaged in elution of generators, the exposure to the fingers or hands shall be monitored as required by Title 10, Code of Federal Regulations, Part 20, Section 20.1502 (a).

21. The licensee is authorized to hold radioactive materials with a physical half-life of less than or equal to 120 days for decay in storage before disposal in ordinary trash provided:

    (a) Radioactive waste to be disposed of in this manner shall be held for decay in storage for at least 10 half-lives.

    (b) Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    (c) Records shall be maintained of the disposal of licensed materials made by decay in storage. These records shall be sufficient to demonstrate compliance with this license condition and shall be retained for 3 years after the record is made.

    (d) Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

22. The licensee may use one constancy source for the dose calibrator constancy test provided that the dose calibrator manual indicates that only one constancy source is needed for proper Quality Control.

23. The licensee shall comply with all requirements of Title 17, California Code of Regulations, Section 30373 when transporting or delivering radioactive materials to a carrier for shipment. These requirements include; packaging, marking, labeling, loading, storage, placarding, monitoring, and accident reporting. Shipping papers shall be maintained for inspection pursuant to the U.S. Department of Transportation requirements (Title 49, Code of Federal Regulations, Part 172, Sections 172.200 through 172.204).

24. Radiopharmaceuticals may be redistributed to persons licensed pursuant to, Title 17, California Code of Regulations, Section 30195 (a) and (b), or a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State in accordance with the statements, procedures and representations in Condition 13 of this license.

**RADIOACTIVE MATERIAL LICENSE**

License Number: 7131-43

Amendment Number: 41

25. The licensee is hereby granted authorization to retrieve radioactive waste from customers' facilities in accordance with the procedures described in Condition 13 of this license. Collection of radioactive waste from customer facilities shall be limited to waste generated from materials supplied under conditions of this license.

26. Equipment for radiometric assay of pharmaceuticals, body fluids, excreta, or in vitro assay samples, shall be calibrated to ensure the reliability of data obtained. The stability of the equipment shall be checked at least once on each day of use, using appropriate standards.

27. In accordance with California Health and Safety Code Section 115000.1(h), the licensee shall annually report the radioactive waste inventory held in storage on December 31 of each year and all manifests of Low Level Radioactive Waste (LLRW) shipments to licensed LLRW disposal facilities made during the year to the Department via the online LLRW Tracking System at https://llrwts.cdph.ca.gov/.

28. In accordance with the California Code of Regulations Title 17, Section 30195.1, the licensee shall maintain an acceptable financial instrument in the amount of $514,155 that satisfies the requirements outlined in the decommissioning funding plan dated July 23, 2019.

29. At least 30 days prior to vacating any address of use listed in Condition 10 of this license, the licensee shall provide written notification of intent to vacate to the California Department of Public Health, in accordance with Title 17, California Code of Regulations, Section 30256 (b). Control of all licensed areas must be maintained until such areas are released by the Department for unrestricted use or the license is terminated, in accordance with Title 17, California Code of Regulations, Section 30256 (j).

30. A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at 5900-B Obata Way, Gilroy, CA.

Issued for the State of California Department of Public Health

Date: December 23, 2021 By: Hugh Clowers

Radiologic Health Branch
MS 7610, P.O. Box 997414
Sacramento, CA 95899-7414

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

N-Molecular, Inc.
d/b/a SOFIE
25 Walker Way, Suite 3D
Albany, New York 12205

MAR 16 2022

Attention: Brian Methe
Radiation Safety Officer

RE: NYS Dept. of Health Radioactive Materials License No. C5707
DH No. 22-122

Dear Mr. Methe:

Enclosed is Amendment No. 11 to New York State Department of Health Radioactive Materials License No. C5707, which updates Condition No. 20.A. to reflect the current decommissioning funding plan dated January 25, 2021. The next triannual update is due to our office no later than January 25, 2024.

If I may be of assistance, please contact our office at (518) 402-7590, berp@health.ny.gov, or:

New York State Department of Health
Bureau of Environmental Radiation Protection
Radioactive Materials Section
ESP – Corning Tower, Room 1245
Albany, New York 12237

Sincerely,

Ashley McDermott

Ashley M. McDermott
Associate Radiological Health Specialist

DJS/AMM:

Enclosure: Amendment No. 11

cc: Matthew Hadden
Corporate Radiation Safety Officer
(21000 Atlantic Blvd. Suite 730
Dulles, VA 20166)

# NEW YORK STATE DEPARTMENT OF HEALTH

## RADIOACTIVE MATERIALS LICENSE

Pursuant to the Public Health Law, Part 16 of the New York State Sanitary Code, Industrial Code Rule 38, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing radioactive material(s) for the purpose(s), and at the place(s) designated below. The license is subject to all applicable rules, regulations, and orders now or hereafter in effect of all appropriate regulatory agencies and to any conditions specified below.

| 1. NAME OF LICENSEE | 3. LICENSE NUMBER |
|---|---|
| FEIN 47-3590844<br>N-Molecular, Inc.<br>dba SOFIE<br>Phone (518) 464-0871 | C5707<br>4. EXPIRATION DATE<br>August 7, 2034 |
| 2. ADDRESS OF LICENSEE | 5a. REFERENCE / b. AMENDMENT NO. |
| 25 Walker Way, Suite 3D<br>Albany, New York 12205 | **DH 22-122** / 11 |

This license is subject to the following conditions:

Conditions 6 through 9 – Authorized Materials, Form, Possession Limits and Uses
Condition 10 – Authorized Users, Radiation Safety Officer, and Health Physicists
Condition 11 – Documents Incorporated by Reference
Condition 12 and beyond – License Conditions

In accordance with the letter dated January 25, 2021, signed by Michael Levy, New York State Department of Health Radioactive Materials License No. C5707 is hereby amended.

# NEW YORK STATE DEPARTMENT OF HEALTH

## RADIOACTIVE MATERIALS LICENSE

**3. License Number** C5707 **5a. Reference** DH 22-122 **b. Amendment No.** 11

AUTHORIZED MATERIALS, FORM, POSSESSION LIMITS AND USES

| 6. Radioactive Materials (element & mass no.) | 7. Chemical and/or Physical Form | 8. Maximum quantity licensee may possess at one time |
|---|---|---|
| A. Fluorine 18 | A. Any | A. 50 curies |
| B. Nitrogen 13 | B. Incidentally activated cyclotron products | B. 3 curies |
| C. Cadmium 109, Chromium 51, Cobalt 56, Cobalt 57, Cobalt 58, Cobalt 60, Iron 59, Manganese 54, Silver 110, Sodium 22, Zinc 65 | C. Solid target foils and assemblies | C. 3 curies |
| D. Any radionuclides with atomic numbers 1 to 83 | D. Incidentally activated cyclotron products | D. 3.2 curies |

9. Authorized use.

Condition 6.A.:
As produced by the activation of O-18 liquid targets during the operation of the General Electric Model 2132402 Cyclotron (NYS Dept. of Health Registration No. 01023416).

Conditions 6.B., 6.C., and 6.D.:
As produced incident to the operation of the General Electric Model 2132402 Cyclotron (NYS Dept. of Health Registration No. 01023416).

AUTHORIZED USERS, RADIATION SAFETY OFFICER, AND HEALTH PHYSICISTS

10. A. The Radiation Safety Officer (RSO) for this License is Brian Methe.

B. The General Electric PETTrace Model #2132402 cyclotron may be operated for the purpose of producing Fluorine 18 and/or Nitrogen 13 by or under the direct supervision of the following:

Gregory Eichelberger
Bradley Knorr
Christopher Paulus
Angelo Setaro
Todd Heiskell
Trevor Moomey
Timothy Pisarczyk

10. C. The RSO will be provided with regular on-site health physics support by Brian Methe. The person will be physically available and able to respond to accidents and incidents in a timely manner, and shall visit this facility for at least one working day per month to provide the routine support described in Appendix A of Radiation Guide 1.8 (Rev. 4/95). These people will also conduct or participate in the required annual audits of the licensee's radiation protection program and the performance of the RSO.

## DOCUMENTS INCORPORATED BY REFERENCE

11. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7 and 8 of this license, in accordance with statements, representations, and procedures contained in the documents (including any enclosures) listed below:

A. License Renewal Application dated October 18, 2007, signed by Anwer Rizvi, President, with attachments; letter dated April 3, 2008, signed by Duann Vanderslice, R.Ph., Corporate RSO, with attachments.

B. License Renewal Application dated March 21, 2018, signed by Frank Plastini, with attachments.

The New York State Department of Health's regulations shall govern the licensee's statements in applications or letters unless the statements are more restrictive than the regulations.

## LICENSE CONDITIONS

12. Licensed material shall be stored and used at the licensee's installation located at the address indicated in Condition 2, above.

13. A. The licensee shall instruct persons before they engage in work under the license, in accordance with 10 NYCRR 16.13(c), and shall provide annual refresher training. Such instruction shall include the licensee's operating and emergency procedures and other information contained in documents incorporated in Condition 11.

B. Records of training received pursuant to paragraph A of this Condition shall be maintained for a period of three (3) years and shall include:

i) the name of the individual who conducted the training;
ii) the name of the individual who received the training;
iii) the dates and duration of the training; and
iv) a list of topics covered.

14. A. The licensee shall submit to the Department a detailed description of any proposed changes to the facilities and equipment, described in the license application and supporting documents, before making any such changes. This shall include, but not be limited to, changes in use, floor plans, ventilation systems and usage of areas contiguous to areas where radioactive materials are used and stored.

14. B. Plans of facilities which the licensee intends to dedicate to operations involving the use of radioactive material shall be submitted to the Department for review and approval prior to such use.

15. The licensee shall submit complete decontamination procedures to the Department for approval ninety (90) days prior to the termination of authorized operations involving radioactive material in controlled areas and/or vacating installations pursuant to 10 NYCRR 16.10(b).

16. The licensee shall maintain records of information important to safe and effective decommissioning at the location specified in Condition 2 and at other locations as the licensee chooses. The records shall be maintained until this license is terminated by the Department and shall include:

A. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site;

B. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination, such as buried pipes that may be subject to contamination.

C. Records of the cost estimate performed for decommissioning funding plan or the amount certified for decommissioning, and records of the funding method used for assuring funds, if either a funding plan or certification is used.

17. The licensee shall submit full information on any proposed changes of ownership or control of licensed premises, at least 90 days prior to the proposed action.

18. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash, provided:

A. Affected radioactive waste shall be held for decay a minimum of ten (10) half-lives; and

B. Prior to disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

19. The licensee shall have available appropriate survey meters which shall be maintained operational and shall be calibrated before initial use and at subsequent intervals not exceeding twelve months by a person specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. Records of all calibrations shall be kept a minimum of three years.

20. The licensee shall implement the requirements in New York State Department of Health LICENSE ADDENDUM – Decommissioning and Financial Assurance Requirements, dated 01/02/14.

A. **The licensee shall maintain a decommissioning funding plan. The decommissioning funding plan must be resubmitted to the Department for review and approval by January 25, 2024, with any adjustments necessary to account for changes in costs and the extent of contamination.**

B. Financial Surety to cover the total amount calculated in the decommissioning funding plan and cost estimate must be maintained. The approved surety instrument must be implemented within 45 days of plan approval.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date: MAR 10 2022

By _____
Daniel J. Samson, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

DJS/AMM:

cc: Matthew Hadden,
Corporate Radiation Safety Officer
(21000 Atlantic Blvd., Suite 730
Dulles, VA 20166)

January 10, 2022

Patrick Phelps, President & CEO
SOFIE PHARMA, INC.
d/b/a Sofie
21000 Atlantic Boulevard, Suite 730
Dulles, VA 20166

Dear Mr. Phelps:

Re: State of Florida Radioactive Materials License Number 3287-1

Enclosed is amendment number 54 to the above referenced license. This amendment closes control number 20211029-1618.

**Be advised that some licensees amend their licenses, almost monthly. It would be more appropriate to develop an agreement with your clients (both medical and non-human use), to have them forward a copy of their license, each time it is amended.**

**Additionally, note that a radiopharmacy shall not deliver licensed materials to an expired license (Florida Administrative Code 64E-5.215), unless the licensee can provide an extension letter issued by the State of Florida pursuant to FAC 64E-5.212(3). Pay special attention to license expiration dates, which are located in the lower right corner on each page of the license.**

**Note that we did not add Gemy Hana to above referenced license, we did not find a nuclear pharmacist license with the State of Florida.**

Review the enclosed document carefully to be sure that you understand its terms and conditions. You must conduct your radiation safety program in accordance with the conditions of your license, representations made in your license application, and Florida regulations. Failure to conduct your program in accordance with Florida regulations, license conditions and representations in your application will result in enforcement action. Note that a license is valid only for the legal entity to which it is issued and is not subject to assignment, sale, or other transfer. Notify the department immediately if the identity of the legal entity, as listed in item 1 of the license, changes or if there is a change in the majority ownership or controlling interest of the legal entity. *Florida Statutes* require a new license application if any of these events occur.

You are responsible for verifying the accuracy of the enclosed amendment. Notify us immediately if you find anything in the enclosed amendment you consider to be in error. Please call us at 850 245-4545 if you have any questions or require further clarification. Additional bureau resources including regulatory guides, forms, regulations, and information notices may be accessed on our website at *www.FloridaHealth.gov/radiation/*.

Sincerely,

Giovanna Manning
Environmental Specialist III

Enclosure

# STATE OF FLORIDA
## DEPARTMENT OF HEALTH
## BUREAU OF RADIATION CONTROL

## RADIOACTIVE MATERIALS LICENSE

Pursuant to Chapter 404, Florida Statutes, and Chapter 64E-5, Florida Administrative Code (F.A.C.), and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to receive, acquire, possess and transfer the radioactive material(s) designated below and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the state of Florida, Department of Health now or hereafter in effect and to any conditions specified below.

| Licensee | |
|---|---|
| 1. Name: **SOFIE PHARMA, INC.** **d/b/a Sofie** | 3. License Number: **3287-1** is hereby renewed in its entirety with reference to application dated November 10, 2021 and correspondence dated October 25, 2021, November 11, 2021, November 22, 2021 December 7, 2021, December 27, 2021, and January 5, 2022. |
| 2. Address: **21000 Atlantic Boulevard, Suite 730 Dulles, VA 20166** | 4. Expiration Date: **11/30/2026** 5. Category: **3B** |

| 6. | Radioactive Material (element and mass number) | 7. | Chemical And/Or Physical Form | 8. | Maximum Quantity Licensee May Possess At Any One Time |
|---|---|---|---|---|---|
| A. | Fluorine 18 | A. | Any | A. | 60 curies |
| B. | Any byproduct material with atomic numbers 3 through 83 | B. | Incidentally activated products | B. | 400 millicuries per nuclide, 2 curies total possession, except as noted |
| C. | Nitrogen 13 | C. | Incidentally activated products | C. | 5 curies |
| D. | Cobalt 56 | D. | Incidentally activated products | D. | 800 millicuries |
| E. | Cobalt 57 | E. | Incidentally activated products | E. | 1800 millicuries |
| F. | Cobalt 58 | F. | Incidentally activated products | F. | 1200 millicuries |
| G. | Cobalt 60 | G. | Incidentally activated products | G. | 1800 millicuries |
| H. | Zinc 65 | H. | Incidentally activated products | H. | 5 curies |

# STATE OF FLORIDA
## DEPARTMENT OF HEALTH
## BUREAU OF RADIATION CONTROL

| 6. | Radioactive Material (element and mass number) | 7. | Chemical And/Or Physical Form | 8. | Maximum Quantity Licensee May Possess At Any One Time |
|---|---|---|---|---|---|
| I. | Manganese 54 | I. | Incidentally activated products | I. | 2 curies |
| J. | Iron 55 | J. | Incidentally activated products | J. | 2 curies |
| K. | Iron 59 | K. | Incidentally activated products | K. | 2 curies |
| L. | Any radioactive material authorized under section 64E-5.617, F.A.C. | L. | Any sealed source listed in section 64E-5.617, F.A.C. | L. | 200 millicuries total not to exceed 30 mCi each |
| M. | Molybdenum 99 | M. | Any molybdenum/ technetium 99m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to section 64E-5.210, F.A.C., or a specific license issued to a manufacturer by the U.S. Nuclear Regulatory Commission (NRC) or an agreement state pursuant to equivalent regulations | M. | 25 curies |
| N. | Technetium 99m | N. | Any form described in sections 64E-5.626(1) and 64E-5.627(1), F.A.C. | N. | 25 curies |
| O. | Any radioactive material except technetium 99m, described in section 64E-5.626(1), F.A.C. | O. | Any form described in section 64E-5.626(1), F.A.C. | O. | 1 curie |
| P. | Any radioactive material except technetium 99m, described in section 64E-5.627(1), F.A.C. | P. | Any form described in section 64E-5.627(1), F.A.C. | P. | 6 curies |

| 6. | Radioactive Material (element and mass number) | 7. | Chemical And/Or Physical Form | 8. | Maximum Quantity Licensee May Possess At Any One Time |
|---|---|---|---|---|---|
| Q. | Any radioactive material described in section 64E-5.630(4), F.A.C. | Q. | Any form described in section 64E-5.630(4), F.A.C. | Q. | 450 millicuries |
| R. | Any radioactive material listed in sections 64E-5 .206(7) and .206(8) F.A.C. | R. | Prepackaged in vivo and in vitro diagnostic test kits | R. | 100 millicuries total for in-vivo kits and 100 millicuries total for in-vitro kits |
| S. | Uranium 238 | S. | Depleted metal | S. | 200 kilograms |
| T. | Carbon 11 | T. | Any | T. | 16 curies |
| U. | Nitrogen 13 | U. | Liquid | U. | 5 curies |

**9. AUTHORIZED USES**

A. To be produced via (p, n) or (p, alpha) reactions using an IBA Cyclone 18/9 cyclotron to process and chemically produce radiopharmaceuticals and calibration or reference standards. The licensee shall transfer such material to persons specifically licensed by an Agreement State to possess such material. The licensee shall also use this material for the purpose of testing the production facilities and equipment at this location.

B.–K. For possession and storage of byproduct materials incidental to radionuclide production.

L. To be used for instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to section 64E-5.210, F.A.C., the licensee is authorized to redistribute sources to persons licensed pursuant to section 64E-5.601, F.A.C., or under equivalent licenses of the NRC or an agreement state.

M. Production of technetium 99m pertechnetate. Redistribution of unused generators and associated depleted uranium shielding to authorized recipients in accordance with statements, representations and procedures contained in the application.

N. For dispensing, distributing, or redistributing prepared radiopharmaceuticals to authorized recipients. For distribution as calibration or reference standard to authorized recipients.

9. AUTHORIZED USES CONTINUED:

O. For dispensing, distributing, or redistributing prepared radiopharmaceuticals to authorized recipients. For distribution as calibration or reference standard to authorized recipients. For use of technetium 99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals.

P.–Q. For dispensing, distributing, or redistributing prepared radiopharmaceuticals to authorized recipients. For distribution as calibration or reference standard to authorized recipients.

R. Redistribution to general and specific licensees in accordance with statements, representations and procedures contained in the application.

S. To be used as shielding for molybdenum 99/technetium 99m generators.

T. For dispensing or distributing prepared radiopharmaceuticals to authorized recipients for support of clinical trials approved by the FDA and for pending approvals of generic drugs.

U. For dispensing or distributing prepared radiopharmaceuticals to authorized recipients for support of clinical trials approved by the FDA and for pending approvals of generic drugs.

CONDITIONS

10. The authorized place of use is the licensee's facility located at 136 Commerce Way, Sanford, Florida 32771.

11. Failure to comply with the provisions of this license is a felony of the third degree pursuant to section 404.161, Florida Statutes. Also, violations may warrant an administrative fine of up to $1,000.00 per violation per day, pursuant to section 404.162, Florida Statutes.

12. A. Dispensing of licensed material as radiopharmaceuticals, compounding of licensed materials, and authorized use of the cyclotron shall be performed by, or under the supervision and in the physical presence of, at least one of the nuclear pharmacists listed below.

| Authorized Users | Authorized Users |
|---|---|
| Emad N. Ayad, NP<br>Kirk L. McCall, NP<br>Matthew Chellino, NP | Richard B. Toth II, NP<br>Chinh Nguyen, NP<br>Jonathon Trzupek, NP |

12. B. Compounding of licensed material and authorized use of the cyclotron shall be by, or under the supervision and in the physical presence of, at least one of the authorized cyclotron users listed below.

| Authorized Users | Authorized Users |
|---|---|
| Otto S. Garcia, Sr.<br>Frery Perez<br>Greg Weaver<br>Alba Perez<br>Sky Cui<br>Daniel Heiskell<br>Eric Schreiner | Marty Magerl<br>Philippe Brisard<br>Gary Kenny<br>Heyda Colon<br>Bradley Knorr<br>Todd Heiskell<br>John Arango |

C. The radiation safety officer is Richard B. Toth, NP.

D. The corporate radiation safety officer is Matthew Hadden.

E. Licensed material may be used by, or under the supervision and in the physical presence of a visiting nuclear pharmacist or authorized cyclotron user. When visiting they may work for up to 60 days each calendar year, provided the licensee's management approves, in writing, each visit. The licensee is required to maintain a copy of that individual's licensure from the Florida Board of Pharmacy as a nuclear pharmacist and maintains a copy of the state of Florida radioactive materials license naming the individual as a cyclotron operator; the licensee must maintain a record of each visitation. Copies of these records shall be maintained for 5 years after their last visit.

13. Radioactive material transported on public thoroughfares shall be packaged, prepared for shipment, and transported in accordance with Title 49, Code of Federal Regulations and Chapter 64E-5, F.A.C.

14. Sealed sources containing licensed material shall not be opened.

15. Pursuant to section 64E-5.210, F.A.C., the licensee is authorized to distribute the radioactive material described in Items 6, and 7 of this license to persons licensed pursuant to section 64E-5.601, F.A.C., or under equivalent licenses of the NRC or an agreement state, for the uses indicated below:

A. Unused molybdenum 99/technetium 99m or rubidium 81/krypton 81m, and associated depleted uranium shielding may be redistributed to persons licensed pursuant to section 64E-5.627, F.A.C.

15. B. Any form listed in each section, radioactive materials described in sections 64E-5.626, 64E-5.627, 64E-5.630 and 64E-5.632, F.A.C., may be redistributed to persons licensed pursuant to that section.

16. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal as ordinary trash provided that all of the following are met:

    A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

    B. Immediately prior to disposal as ordinary trash, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background using an appropriate low-level radiation detection instrument.

    C. All radiation labels will be removed or obliterated; and

    D. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal; and

    E. Records of such disposal shall be maintained.

17. The licensee shall not transfer possession or control of radioactive material, or products containing radioactive material as a contaminant except:

    A. By transfer to a specifically licensed recipient; or

    B. As provided otherwise by specific provision of this license pursuant to the requirements of Chapter 64E-5, F.A.C.

18. Radiopharmaceuticals shall be assayed in a dose calibrator to accurately measure the activity of the radiopharmaceutical before administration. Instruments utilized in the assay of pure alpha or beta-emitting radiopharmaceuticals shall be calibrated in accordance with the dose calibrator's or drug manufacturer's instructions. The licensee shall maintain copies of these procedures for inspection by the department.

19. Radiopharmaceuticals dispensed for positron emission tomography must be compounded according to the provisions of Section 121 of the Food and Drug Administration Modernization Act of 1997.

20. Repair or maintenance of the cyclotron or concrete shall only be performed by the individuals named as authorized users in Condition 12, above or by the manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission, a Licensing State, or an Agreement State to perform such services.

21. Access to the cyclotron room shall be controlled by a door at each entrance. Such doors shall normally be closed and secured against unauthorized entry. Constant surveillance by the physical presence of a user listed in Condition 12, above is adequate security against unauthorized entry.

22. The licensee shall notify the Bureau of Radiation Control at least 48 hours in advance of shipping its low-level radioactive waste to a commercial treatment, storage, or disposal facility. Notification shall consist of either calling (407) 297-2095 or writing the Bureau of Radiation Control, Department of Health, Post Office Box 680069, Orlando, Florida 32868-0069

23. The licensee shall assure that each sealed source is tested for leakage or contamination and follow the appropriate actions as required by section 64E-5.1303, F.A.C. Licensed material shall be tested at least every six months. The test sample (smear) shall be taken by the licensee using an approved leak test kit. Analysis of the test sample shall be performed by individuals who are licensed by the department, NRC, agreement state, or licensing state to provide these services. The licensee is required to retain leak test records containing the manufacturer's name, model and serial number of each sealed source tested, identity of each sealed source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, the date of the test and signature of the radiation safety officer or designee. The records shall be maintained for 3 years for inspection by the department.

24. The licensee shall conduct a physical inventory and inspection at least every 6 months to account for all sealed sources received and possessed under this license as required by section 64E-5.1304, F.A.C. Inventory records shall be maintained for 3 years from the date of the inventory for inspection by the department, and shall include the manufacturer's name, model and serial numbers of each sealed source, the identity of each sealed source radionuclide and its estimated activity, the location of each sealed source, the date of the inventory and the signature of the radiation safety officer or designee.

25 The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to, or in, the leaflet or brochure that accompanies the generator or reagent kit; otherwise reagent kits must be prepared and compounded from a prescription in accordance with the regulations of the Florida Board of Pharmacy.

26. The licensee shall perform a test to detect and quantify the activity of molybdenum 99 contamination in each elution of technetium 99m from a molybdenum 99/technetium 99m generator and in each extraction or separation of technetium 99m from molybdenum 99 not contained in a generator as required by 64E-5.628, F.A.C.

27. The licensee is authorized to collect and dispose of radioactive waste in the form of contaminated syringes, needles, vials and unused doses, except for materials described in section 64E-5.632, F.A.C., from their customers only when these materials were originally supplied by the licensee. This condition does not authorize the receipt of any other forms of radioactive waste.

28. Individuals involved in operations which utilize, at any one time or over a 3 month period, radioiodine in an unsealed form that exceeds activities specified in table 1 shall have bioassays performed at the frequency specified in 64E-5.1320(1), F.A.C. Records of the bioassays shall be maintained for inspection by the department for 3 years.

29. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:

(1) Repackaged from prepared radiopharmaceuticals that are the subject of an FDA approved New Drug Application (NDA), Abbreviated New Drug Application (ANDA) or an Investigational New Drug Application (IND), or

(2) Prepared from generators and reagent kits that are subject of an FDA approved NDA, ANDA or IND or as prescribed by an Authorized User.

B. Prepared radiopharmaceuticals for which the FDA has accepted an IND and radiopharmaceuticals prepared form generators or reagent kits for which the FDA has accepted an IND shall be dispensed and/or distributed:

(1) In accordance with the directions provided by the sponsor of the IND and

(2) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

30. The licensee shall maintain a performance bond unto the State of Florida as specified by 64E-5.217, F.A.C. and correspondence dated November 11 2021, in the amount of $574,428.13. At the time of license renewal and at intervals not to exceed 3 years, the licensee must submit a bonding determination, with adjustments as necessary to account for changes, as specified in 64E-5.217(3), F.A.C.

31. A. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, 8 and 9 of this license in accordance with statements, representations and procedures contained in the licensee's application dated November 10, 2021, signed by Patrick Phelps, President & CEO, and correspondence dated:

November 11, 2021 (complete policy, procedures, and updated bond); and
November 22, 2021 (Matthew Hadden made CO), both signed by Patrick Phelps, President & CEO.

31. B. The licensee shall comply with all applicable requirements of Chapter 64E-5, Florida Administrative Code, and these regulations shall supersede the licensee's statements in applications or correspondence, unless the statements are more restrictive than the regulations.

**For the Bureau of Radiation Control:**

**Issuance Date:** JAN 1 0 2022

**Giovanna Manning**
**Environmental Specialist III**
**4052 Bald Cypress Way – Bin C21**
**Tallahassee, FL 32399-1741**
**850-245-4545**

A party whose substantial interest is affected by this order may petition for an administrative hearing pursuant to sections 120.569 and 120.57, Florida Statutes. Such proceedings are governed by Rule 28-106, Florida Administrative Code. A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department, within twenty-one (21) days from the receipt of this order. The address of the Agency Clerk is: Agency Clerk, 4052 Bald Cypress Way, BIN # A02, Tallahassee, Florida 32399-1703. The Agency Clerk's facsimile number is 850-410-1448. A copy of the petition should also be sent to: Bureau Chief, Bureau of Radiation Control, 4052 Bald Cypress Way, BIN # C21, Tallahassee, FL 32399-1741. The Bureau Chief's facsimile number is 850-487-0435. Mediation is not available as an alternative remedy. Your failure to submit a petition for hearing within 21 days from receipt of this order will constitute a waiver of your right to an administrative hearing, and this order shall become a "final order." Should this order become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

# OHIO DEPARTMENT OF HEALTH
# LICENSE FOR RADIOACTIVE MATERIAL

**Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the applications of Chapter 3748 of the Ohio Revised Code and all rules promulgated thereunder. This license shall be deemed subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.**

| LICENSEE | LICENSE NUMBER |
|---|---|
| 1. **N-Molecular, Inc. dba SOFIE** | 3. **02500180001** |
| | EXPIRATION DATE |
| 2. **21000 Atlantic Blvd.<br>Suite 730<br>Dulles, VA 20166** | 4. ***December 1, 2026*** |
| | FILE / ID NUMBER |
| | 5. **501082 / *16748*** |

| 6. RADIOACTIVE MATERIAL | 7. CHEMICAL AND/OR PHYSICAL FORM | 8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE |
|---|---|---|
| A. **Any radioactive material permitted by OAC 3701:1-46-11** | A. **Prepackaged units for in vitro diagnostic tests** | A. **740 MBq (20 mCi)** |
| B. **Any radioactive material with atomic numbers 1 to 83 inclusive, except other nuclides listed herein** | B. **Any** | B. **222 GBq (6 Ci)** |
| C. **Fluorine-18** | C. **Elemental and / or radiopharmaceutical form** | C. **1850 GBq (50 Ci)** |
| D. **Carbon-11** | D. **Elemental and / or radiopharmaceutical form** | D. **592 GBq (16 Ci)** |
| E. **Oxygen-15** | E. **Elemental and / or radiopharmaceutical form** | E. **370 GBq (10 Ci)** |
| F. **Nitrogen-13** | F. **Elemental and / or radiopharmaceutical form** | F. **370 GBq (10 Ci)** |
| G. **Iodine-124** | G. **Elemental and / or radiopharmaceutical form** | G. **16.6 GBq (450 mCi)** |
| H. **Copper-64** | H. **Any** | H. **111 GBq (3.0 Ci)** |
| I. **Any sealed source permitted by OAC 3701:1-58-26** | I. **Sealed sources** | I. **7.4 GBq (200 mCi) total, no single source to exceed 740 MBq (20 mCi)** |
| J. **Technetium-99m** | J. **Sodium Pertechnetate and products labeled in accordance with manufacturer's instructions** | J. **740 GBq (20.0 Ci)** |
| K. **Molybdenum-99** | K. **Molybdenum-99 / Technetium-99m generators** | K. **740 GBq (20.0 Ci)** |
| L. **Strontium-82 / Rubidium-82** | L. **Any form. Generators and radioisotopes derived to prepare radioactive drugs for medical use** | L. **33.3 GBq (900 mCi)** |
| M. **Germanium-68 / Gallium-68** | M. **Any form.** | M. **3.7 GBq (100 mCi) of Germanium<br>3.7 BGq (100 mCi) of Gallium** |
| N. **Strontium-85** | N. **Any** | N. **77.7 GBq (2.1 Ci)** |
| O. **Activation Products** | O. **Any radioactive materials produced by activation of cyclotron facilities and machine parts by the operation of the particle accelerator** | O. **111 GBq (3.0 Ci)** |

| | | |
|---|---|---|
| P. **Uranium (depleted in isotopes Uranium-235)** | P. **Metal for generator and product shielding** | P. **200 kilograms** |

9. **Authorized Use**

A. **Redistribution of prepackaged in vitro kits to general and specific licenses as permitted by OAC 3701:1-46-42 provided the packaging and labeling remain unchanged.**

B.- H. **Preparation and distribution/redistribution of radioactive drugs to authorized recipients.**

I. **Authorization for calibration, transmission, and reference sources for in house use and distribution/retrieval to/from licensed recipients that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to OAC 3701:1-46-44, or equivalent NRC or Agreement State regulations.**

J. - L. **For use in producing Technetium-99m Pertechnetate and redistribution of generators to authorized recipients. Generators will be obtained from a manufacturer licensed pursuant to OAC 3701:1-46-43, or equivalent NRC or agreement state regulations. Unused generators will be redistributed without opening or altering the manufacturer's packaging. Used generators will be redistributed without altering the manufacturer's packaging and labeling. A generator will not be distributed beyond the expiration date shown on the generator label. Redistributed generators will be accompanied by the manufacturer supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.**

M. **For use of the Eckert and Ziegler GalliaPharm™ generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies. For preparation and distribution of radioactive drugs in accordance with OAC 3701:1:46-43 and radiochemicals for non-medical use to authorized recipients.**

N. **By-product (impurity) of Sr-82/Rb-82 generators.**

O. **Activation products as a result of cyclotron operation.**

P. **Shielding**

## CONDITIONS

10. **Licensed material may only be used at the licensee's facilities located at:** **7650 First Place**
**Building B, Suite A**
**Oakwood Village, Ohio 44146**

11. **The Corporate Radiation Safety Officer for this license is:** ***Matthew A. Hadden***

**The Radiation Safety Officer for this license is:** ***Patel, Kunal M., Pharm.D***

12. **Materials may only be used by, or under the supervision of, the below listed individual(s) designated in writing:**

Authorized Nuclear Pharmacist(s)

A. **Chwojdak, Lynn, Pharm.D.**
B. **Patel, Kunal M., Pharm.D**
C. **Pratschler, Shannon, R.Ph.**
D. **Williams, Bryan H., Pharm D.**

**The following individuals are authorized for cyclotron use:**

**Authorized Individual / Authorization Use**

A. **Armbruster, John - Operator and Maintenance**
B. **Brisard, Philippa - Operator and Maintenance**
C. **Chwojdak, Lynn, Pharm.D. - Operator and Maintenance**
D. **Crandall-Carney, Laura - Operator**
E. **Ecklund, Andrew - Operator**
F. **Heiskell, Todd - Operator and Maintenance**
G. **Knorr, Bradley - Operator and Maintenance**
H. **Magerl, Marty - Operator and Maintenance**
I. **Patel, Kunal M., Pharm.D - Operator and Maintenance**
J. **Patel, Priyanka- Operator**
K. **Pratschler, Shannon, R.Ph. - Operator and Maintenance**
L. ***Rhein, Cameron - Operator and Maintenance***
M. **Voelker, Ken - Operator and Maintenance**
N. **Weaver, Greg - Operator and Maintenance**
O. **Williams, Bryan H., Pharm D. - Operator and Maintenance**

13. **Nuclear Pharmacists performing licensed activities shall be licensed by and in good standing with the State of Ohio.**

14. **Deliveries of radioactive material to a mobile unit may be made only when the licensed recipient has an authorized individual physically present to receive the radioactive material delivery.**

15. **The Radiation Safety Officer shall conduct an annual formal program audit. Audit review records shall be maintained for a period of three (3) years from the date of the record, and contain the date of the audit, the name of the individual performing the audit, areas audited, audit findings, corrective actions, and follow-up actions.**

16. **The licensee is authorized to retrieve, receive, and dispose of radioactive waste from its customers limited to radiopharmacy supplied syringes and vials and their contents.**

17. **The licensee is authorized to transport licensed material in accordance with the provisions of OAC 3701:1-50.**

18. **The licensee shall conduct a physical inventory every six (6) months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for at least three (3) years from the date of each inventory and shall include: the quantities and kinds of licensed material, manufacturer's name and model numbers, location of the sources and/or devices, and the date of the inventory.**

19. **The licensee shall maintain records to demonstrate compliance with dose limits for individual members of the public as delineated in OAC 3701:1-38-13(E). The licensee shall maintain records for review by the Director for a period of three years.**

20. **The following conditions must be met for revision to the radiation safety program for the use of the Eckert and Ziegler GalliaPharm™ generator:**

    1) **The revision does not require a license amendment under OAC 3701:1-58-08.**

    2) **The revision is based on the NRC's current guidance for the use of the Eckert and Ziegler GalliaPharm™ generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under OAC 3701:1-58-72 posted on the NRC Medical Uses Licensee Toolkit;**

    3) **The revision has been reviewed and approved by the licensee's Radiation Safety Officer and management;**

    4) **The affected individuals are instructed on the revised program before the change is implemented;**

    5) **The licensee shall retain a record of each change for five (5) years; and**

    6) **The record will include a copy of the current guidance for the use of the Eckert and Ziegler GalliaPharm™ generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under OAC 3701:1-58-72 , the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management representative who reviewed and approved the change.**

21. **Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Ohio Department of Health's statutes, rules, and orders shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.**

    A. ***Renewal application dated November 12, 2021. Letter dated November 23, 2021. Electronic correspondences dated November 22, 2021, December 20, 2021, and January 5, 2022; Amendment 39 renews license number 02500180001 in its entirety.***

**For the Ohio Department of Health**

**DATE:** February 3, 2022 **BY:** _____

**W. Gene Phillips, MBA, REHS**
**Chief, Bureau of Environmental Health and Radiation Protection**
**on behalf of the Director of Health**

## Pavon, Martha

**From:** Tomczak, Tammy
**Sent:** Tuesday, April 12, 2022 8:25 AM
**To:** Pavon, Sandy; Pavon, Martha
**Subject:** FW: FW: Sealed Sources
**Attachments:** BAMF Health Amendment for Sealed Sources 35.65 and Knorr - signed.pdf; 20211223 CA RAM License 7131-43 (CRSO Change) Amend 41.pdf; Acc Lic #C5707 Amend #11 (Add A. Setaro CO).pdf

Good morning, Sandy and Martha,

Please add the attached to ADAMS. Also, I will be sending a second email. Can all the documents in both emails be combined into one ADAMS document?

Please let me know.

Thanks,
Tammy

---

**From:** Mark Sitek <mark.sitek@bamfhealth.com>
**Sent:** Monday, April 11, 2022 4:16 PM
**To:** Tomczak, Tammy <Tammy.Tomczak@nrc.gov>
**Subject:** [External_Sender] FW: Sealed Sources

Tammy,

Please add the attached to the previous amendment request (CN 630398) for BAMF Health License No. 21-35632-01.

Because some files are large, a second email will follow with more attachments.

Thank you,

Mark

---

**From:** Mark Sitek
**Sent:** Wednesday, March 23, 2022 4:19 PM
**To:** Tomczak, Tammy <tammy.tomczak@nrc.gov>
**Subject:** FW: Sealed Sources

Tammy,

We plan to actually add two more amendment items so if it this has been assigned to someone please have them wait for me to send in the additional request. It should be no later than the end of next week.

Thanks,

Mark

**From:** Parker, Bryan <Bryan.Parker@nrc.gov>
**Sent:** Wednesday, March 23, 2022 6:02 AM
**To:** Mark Sitek <mark.sitek@bamfhealth.com>
**Subject:** RE: Sealed Sources

Hey Mark,

Yes, that'll be fine. Send it to Tammy Tomczak as an additional request for **CN630398**. It has been controlled in, but it hasn't been assigned to anyone yet.

Bryan

**From:** Mark Sitek <mark.sitek@bamfhealth.com>
**Sent:** Wednesday, March 23, 2022 12:19 AM
**To:** Parker, Bryan <Bryan.Parker@nrc.gov>
**Subject:** [External_Sender] Sealed Sources

Bryan,

If you haven't processed the accelerator license amendment I sent in, can I also send a request to change the sealed source condition from specific sources to the 35.65 version to match the radiopharmacy license?

Thanks,

Mark

## Pavon, Martha

**From:** Tomczak, Tammy
**Sent:** Tuesday, April 12, 2022 8:26 AM
**To:** Pavon, Sandy; Pavon, Martha
**Subject:** FW: RE: Sealed Sources
**Attachments:** 20220211 SOFIE Amend 39.pdf; State of Florida RAM License #32871 Amend 54 (2021 Renewal).pdf

Hi Sandy and Martha,

This is the second email, that should be incorporated into the previous email I just sent 😊

Thank you!!
Tammy

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**From:** Mark Sitek <mark.sitek@bamfhealth.com>
**Sent:** Monday, April 11, 2022 4:18 PM
**To:** Tomczak, Tammy <Tammy.Tomczak@nrc.gov>
**Subject:** [External_Sender] RE: Sealed Sources

Two more attachments.

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**From:** Mark Sitek
**Sent:** Monday, April 11, 2022 2:15 PM
**To:** Tomczak, Tammy <tammy.tomczak@nrc.gov>
**Subject:** FW: Sealed Sources

Tammy,

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Mark

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**Subject:** FW: Sealed Sources

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**Subject:** RE: Sealed Sources

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Bryan

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**Sent:** Wednesday, March 23, 2022 12:19 AM
**To:** Parker, Bryan <Bryan.Parker@nrc.gov>
**Subject:** [External_Sender] Sealed Sources

Bryan,

If you haven't processed the accelerator license amendment I sent in, can I also send a request to change the sealed source condition from specific sources to the 35.65 version to match the radiopharmacy license?

Thanks,

Mark