April 8, 2025



U.S. Nuclear Regulatory Commission Nuclear Materials Licensing Section, Region III 2056 Westings Avenue, Suite 400 Naperville, IL 60563-2657

RE: U.S.NRC Radioactive Materials License No. 09-32781-02MD Jubilant DraxImage, Inc., d/b/a Jubilant Radiopharma 2252 E 14 Mile Road Warren MI 48092

Dear License Reviewer,

Please amend the above referenced material license to reflect the following modifications:

- Please add Mr. Grant Pearson, R.Ph. as an authorized Nuclear Pharmacist to this RAM license. Mr. Pearson's verification of his Michigan pharmacy license, and Texas RAM License # L07199, Amendment # 02 listing him as an authorized Nuclear Pharmacist is provided as Attachment A.
- 2. Please also change the RSO on this license to Mr. Grant Pearson, R.Ph, effective immediately. Mr. Pearson is listed as RSO on Texas RAM License # L07199, Amendment # 02 provided in Attachment A. By virtue of past training and experience, Mr. Pearson satisfies the requirements listed in the NRC regulations for Radiation Safety Officer. Jubilant Radiopharma Management agrees to provide the RSO with sufficient authority organizational freedom, time, resources, and management prerogative to perform the duties as assigned. A signed RSO Delegation of Authority is provide as Attachment B.

Please forward the amended radioactive materials license to Jubilant DraxImage, Inc., d/b/a Jubilant Radiopharma, 790 Township Line Road, Suite 325, Yardley, PA 19067. Should you have specific questions about this amendment request you may contact me at 407-257-8998 or by email at Craig.Kinne@jubl.com

Sincerely,

Craig Kinne, CHP, MHP Jubilant DraxImage, Inc., d/b/a Jubilant Radiopharma Associate Director Radiation Safety, EHS, RSO Mobile: (407) 257-8998 E-mail: <u>Craig.Kinne@jubl.com</u>

Attachments

cc: Grant Pearson, R.Ph. RSO/Pharmacy Manager Debra Rogers, MA- Paralegal Licensing and Regulatory Coordinator Jubilant Radiopharma Quality and Safety Department

--- OUR VALUES ---



Jubilant DraxImage Inc., dba Jubilant Radiopharma 790 Township Line Road, Suite 325 Yardley, PA 19067 Telephone: 215.550.2783 www.jubilantradiopharma.com

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Attachment A

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License Status: Active 03/28/2027 County: Non-Michigan County

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#### Texas Department of State Health Services

## RADIOACTIVE MATERIAL LICENSE

Pursuant to the Texas Radiation Control Act and Texas Department of State Health Services (Department) regulations on radiation, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer 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 Department now or hereafter in effect and to any conditions specified below.

LICENSEE 1. Name PHARMALOGIC AUSTIN LLC					ense Number	L07199				
ATTN GRANT PEARSON RPH 2. Address 10600 NORTH LAMAR BOULEVARD AUSTN TX 78753				4. Ex	piration Date	October 31, 2033				
					ndment Number	002				
This license is amended in accordance with correspondence dated May 10, 2024.										
5. Radioisotope		6. Form of Material	7. Maximum Activity		8. Authorized Use					
A. Any radioactive material with atomic number 1 through 83 with a half-life less than 120 days		A. Activated solids	<ul> <li>A. 5 curies per radionuclide and curies total</li> </ul>	10	A. Possession of activated materials incidental to the accelerator operation.					
B. Any radioactive material with atomic number 1 through 83 with a half-life greater then than 120 days		B. Activated solids	B. 500 millicuries		B. Possession of activated materials incidental to the accelerator operation					
C. Carbon-11		C. Any, except sealed source	C. 3.5 Curies		C. Manufacture and accordance with	d distribution in 25 TAC §289.252(u).				

RADIOACTIVE MATERIAL LICENSE

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LICENSE NUMBER

AMENDMENT NUMBER

#### 6. Form of Material 5. Radioisotope 7. Maximum Activity 8. Authorized Use D. 250 microcuries per D. Calibration and reference. Redistribution D. Cesium-137 D. Sealed source radionuclide and 500 of sealed sources initially distributed by a (International manufacturer licensed in accordance with Isotopes Model microcuries total BM06E-37) 25 TAC §289.252(o). E. Cesium-137 F. Sealed source F. F. 1 millicurie F. Calibration and reference. Redistribution (International of sealed sources initially distributed by a **Isotopes Model** manufacturer licensed in accordance with BM06-37) 25 TAC §289.252(o). F. Calibration and Reference. Redistribution F. Cobalt-57 F. Sealed source F. 5 millicuries per (International radionuclide and 10 of sealed sources initially distributed by a Isotopes Model millicuries total manufacturer licensed in accordance with BM06E-57) 25 TAC §289.252(o). G. Cobalt-57 G. Sealed source G. Calibration and reference. Redistribution G. 1 millicurie (International of sealed sources initially distributed by a Isotopes Model manufacturer licensed in accordance with BM06-57) 25 TAC §289.252(o). H. Liquid H. Copper-64 H. 500 millicuries H. Manufacture and distribution in accordance with 25 TAC §289.252(u). I. Fluorine-18 I. 20 Curies I. Manufacture and distribution in I. Any, except sealed accordance with 25 TAC §289.252(u). source J. Any, except sealed J. 400 millicuries J. Gallium-68 J. Preparation and distribution of radioactive drugs in accordance with source 25 TAC §289.252(r) and radiochemicals for non-medical use. K. Germanium-68 K. Sealed source K. 1 millicurie K. Calibration and reference. Redistribution of sealed sources initially distributed by a (International Isotopes. Model manufacturer licensed in accordance with BM06-68) 25 TAC §289.252(o).

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LICENSE NUMBER L07199

AMENDMENT NUMBER 002

### RADIOACTIVE MATERIAL LICENSE

5. Radioisotope	6. Form of Material	7. Maximum Activity	8. Authorized Use
L. Germanium-68	L. Generator	L. 400 millicuries	L. Preparation of radioactive drugs permitted by 25 TAC §289.256(q) using the ITM GeGant <sup>®</sup> generator, Eckert & Ziegler GalliaPharm <sup>™</sup> , ITG Ge-68/Ga-68 or IRE Galli-Eo <sup>®</sup> .
M. Iodine-124	M. Any, except sealed source	M. 5 Curies	M. Manufacture and distribution in accordance with 25 TAC §289.252(u).
N. Iodine-131	N. Any, except sealed source	N. 5 Curies	N. Manufacture and distribution in accordance with 25 TAC §289.252(u).
O. Lead-203	O. Liquid	O. 100 millicuries	O. Manufacture and distribution in accordance with 25 TAC §289.252(u).
P. Lead-212	P. Liquid	P. 100 millicuries	P. Manufacture and distribution in accordance with 25 TAC §289.252(u).
Q. Lutetium-177	Q. Liquid	Q. 25 Curies	Q. Manufacture and distribution in accordance with 25 TAC §289.252(u).
R. Nitrogen-13	R. Any, except sealed source	R. 2 Curies	R. Manufacture and distribution in accordance with 25 TAC §289.252(u).
S. Oxygen-15	S. Any, except sealed source	S. 1.2 Curies	S. Manufacture and distribution in accordance with 25 TAC §289.252(u).
T. Sodium-22	T. Sealed source (Eckert & Ziegler Model GF-022- 1836)	T. 1 millicurie	T. Calibration and reference. Redistribution of sealed sources initially distributed by a manufacturer licensed in accordance with 25 TAC §289.252(o).
U. Zirconium-89	U. Liquid	U. 2 Curies	U. Manufacture and distribution in accordance with 25 TAC §289.252(u).

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#### RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER AMENDMENT NUMBER

9. Radioactive material shall only be stored and used at:

Site NumberLocation000Austin - 10600 North Lamar Boulevard

- 10. This license is issued in accordance with Title 25 Texas Administrative Code sections:
  - A. §289.252(u), "Specific Licenses for Other Manufacture and Commercial Distribution of Radioactive Material."
- 11. The individual designated to perform the functions of Radiation Safety Officer (RSO) for activities covered by this license is Grant Pearson, R.Ph.
- 12. Licensed material shall be used by, or under the supervision of:
  - A. <u>Authorized Nuclear Pharmacist</u>
     Dolan, G. T. James, Pharm D.
     Garza, Lucio, R.Ph.
     Osterberg, David Michael, R.Ph.
     Pearson, Grant, R.Ph.
     Phatthanaphuti, Sana, Pharm. D.
  - B. Other individuals who have successfully completed the training described in the application dated December 8, 2022.
- 13. The licensee shall not open sealed sources containing radioactive material or remove sources from source holders.
- 14. A copy of the current operating and emergency procedures shall be kept at the accelerator control panel. The accelerator shall be secured to prevent unauthorized use when not in operation.

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	LICENSE NUMBER	AMENDMENT NUMBER	
RADIOACTIVE MATERIAL LICENSE	L07199	002	

- 15. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage and dispose of it as non-radioactive in accordance with procedures described in application dated December 8, 2022.
- 16. The licensee is authorized to distribute radioactive materials to licensed recipients for non-medical uses.
- 17. The licensee shall maintain the financial assurance letter of credit for \$1,095,242.00, current and in good standing.
- 18. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material authorized by this license in accordance with statements, representations, and procedures contained in the following:

Application received December 8, 2022,

Letter dated May 10, 2024,

Electronic mails dated January 31, 2023, February 9, 2023, February 13, 2023, March 6, 2023, and April 3, 2023, **July 9, 2024, September 3, 2024**, and

Decommissioning cost estimate dated January 1, 2023.

Title 25 TAC §289 shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.

JSK:sk

Date September 10, 2024

FOR THE DEPARTMENT OF STATE HEALTH SERVICES

J. Scott Kee

Digitally signed by J. Scott Kee Date: 2024.09.10 08:51:46 -05'00'

J. Scott Kee, Program Coordinator Medical and Academic Licensing Program

# Attachment B

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### **RSO Delegation of Authority**

April 8, 2025

To: Grant Pearson, R.Ph.

From: Craig Kinne, CHP, MHP, Radiopharmacies Radiation Safety Officer

Effective as of April 8, 2025, you, Grant Pearson have been appointed the Radiation Safety Officer ("RSO") and are responsible for ensuring the safe storage, use, handling, packaging, shipping and transportation of radioactive materials for the Jubilant Radiopharma pharmacy located at

#### Jubilant DraxImage Inc, d/b/a Jubilant Radiopharma 2252 E. 14 Mile Road Warren, MI 48092

You are responsible for managing the radiation protection program, identifying radiation protection problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, stopping unsafe activities, and ensuring compliance with Jubilant Radiopharma's radiation protection program rules. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements to do so and shutting down operations when justified by radiation safety issues. You are required to notify management if employees do not cooperate and do not properly address radiation safety issues. In addition, you are free to raise issues with the NRC at any time. It is estimated that you will spend eight (8) hours per week conducting radiation protection activities.

The RSO is responsible for establishing, implementing, managing, and auditing the radiation protection program, including employee training and ALARA program implementation, identifying and investigating radiation safety problems, initiating recommendations and ensuring implementation of corrective actions, ensuring compliance with all regulatory requirements, termination of unsafe practices and conditions, timely reporting of safety or employee incidents involving radiation exposure and timely reporting of all quality related incidents to the Jubilant Quality and Safety management team. The RSO must always report incidents to Jubilant Radiopharma incident reporting system and if required by regulation or license commitment, to the NRC.

Jubilant Management agrees to provide you, as the RSO of the above pharmacy, with sufficient authority, organizational freedom, time, resources, and management prerogative, to perform the following duties:

- a) Identification of radiation safety problems, and,
- b) Initiation of recommendations, or provide corrective actions, and,
- c) Stopping unsafe operations, and,
- d) Verification of timely implementation of corrective actions, and,
- e) Assumption of the full responsibilities for radiation protection and safety programs.

OUR VALUES



Jubilant DraxImage Inc., dba Jubilant Radiopharma 790 Township Line Road, Suite 325 Yardley, PA 19067 Telephone: 215.550.2783 www.jubilantradiopharma.com



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You agree, by your signature below as RSO, to accept responsibility for implementing the radiation protection program and shall ensure that radiation safety activities are being performed in accordance with Jubilant Radiopharma's Policies and Procedures and NRC regulations.

I accept these RSO responsibilities;

Pharmacy RSO Name (printed):

Grant Pearson, R.Ph.

**Pharmacy RSO Signature:** 

Date:

4-8-25

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**Radiopharmacies Radiation Safety Officer:** 

**Radiopharmacies Radiation Safety Officer Signature:** 

Craig Kinne, CHP, MHP

Craig Kinne Digitally signed by Craig Kinne Date: 2025.04.08 18:31:31

Date: