

HOUSEY
P H A R M A

September 18, 2019

BY E-MAIL

Mr. Frank Tran
Health Physicist/License Reviewer
U.S. Nuclear Regulatory Commission, Region III
Division of Nuclear Materials Safety
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Termination of License No. 21-32481-01

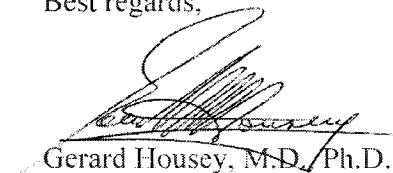
Dear Mr. Tran:

This is in regard to the additional information you requested in connection with the above-referenced NRC License. Following up on your phone conversation with Ms. Monica Balash, Housey Pharmaceutical Research Laboratories (HPRL) currently does not have any radioactive materials in storage, nor have we had any radioactive materials on-site since 2010.

The main reason we have decided to terminate the license at the present time is HPRL has renewed and maintained our possession and storage only NRC license for 2 consecutive terms, yet has not purchased or stored any radioactive materials on-site since 2010. Looking ahead to the upcoming experiments in the lab, we do not see us performing any experiments that would require the use of radioactivity within the next 12-24 months. Given the current NRC guidelines explained to us, we feel it is best at this time to terminate the license. When the lab receives some additional funding sources and principal activities are planned which may require the use of radioactivity, we will contact the NRC at such time to re-apply for a license for use of radioactive material.

Thank you for your assistance in this matter. Please feel free to contact either myself or Monica if you have any further questions regarding the termination of our license or need any additional information.

Best regards,



Gerard Housey, M.D., Ph.D.
President/Radiation Safety Officer

Housey Pharmaceutical Research Laboratories
16800 West 12 Mile Road, Suite 201 Southfield, MI 48076
Telephone: (248) 663-7000 • Facsimile: (248) 663-7007
WWW.HOUSEY.COM



CERTIFICATE OF DISPOSITION OF MATERIALS

Estimated burden per response to comply with this mandatory collection request: 30 minutes. This submittal is used by NRC as part of the basis for its determination that the facility is released for unrestricted use. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collection's Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to infocollection@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOR-10202, (3150-0028), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

LICENSEE NAME AND ADDRESS

Housey Pharmaceutical Research Laboratories, LLC.
16800 W. Twelve Mile Rd., Suite 201
Southfield, MI 48076

LICENSE NUMBER

21-32481-01

DOCKET NUMBER

030-3425

LICENSE EXPIRATION DATE

October 31, 2018

A. LICENSE STATUS (Check the appropriate box)

- ☒ This license has expired. ☐ This license has not yet expired; please terminate it.

B. DISPOSAL OF RADIOACTIVE MATERIAL

(Check the appropriate boxes and complete as necessary. If additional space is needed, provide attachments)

The licensee, or any individual executing this certificate on behalf of the licensee, certifies that:

- ☐ 1. No radioactive materials have ever been procured or possessed by the licensee under this license.
- ☒ 2. All activities authorized by this license have ceased, and all radioactive materials procured and/or possessed by the licensee under this license number cited above have been disposed of in the following manner:
- ☐ a. Transfer of radioactive materials to the licensee listed below:
- ☒ b. Disposal of radioactive materials:
- ☒ 1. Directly by the licensee:
- Decay-in-storage
- ☐ 2. By licensed disposal site:
- ☐ 3. By waste contractor:
- ☐ c. All radioactive materials have been removed such that any remaining residual radioactivity is within the limits of 10 CFR Part 20, Subpart E, and is ALARA.

C. SURVEYS PERFORMED AND REPORTED

- ☒ 1. A radiation survey was conducted by the licensee. The survey confirms:
- ☒ a. the absence of licensed radioactive materials
- ☐ b. that any remaining residual radioactivity is within the limits of 10 CFR 20, Subpart E, and is ALARA.
- ☒ 2. A copy of the radiation survey results:
- ☒ a. is attached; or ☐ b. is not attached (Provide explanation); or ☐ c. was forwarded to NRC on: _____ Date _____
- ☐ 3. A radiation survey is not required as only sealed sources were ever possessed under this license, and
- ☐ a. The results of the latest leak test are attached; and/or ☐ b. No leaking sources have ever been identified.

The person to be contacted regarding the information provided on this form:

NAME	TITLE	TELEPHONE (Include Area Code)	E-MAIL ADDRESS
Monica Balash	Sr. Research Scientist	(248) 663-7000 x223	mbalash@housey.com

Mail all future correspondence regarding this license to:

16800 W. Twelve Mile Rd., Suite 201, Southfield, MI 48076

C. CERTIFYING OFFICIAL

I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT

PRINTED NAME AND TITLE

Monica Balash, Sr. Research Scientist

SIGNATURE

Monica Balash

DATE

08/20/2019

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECT. 18 U.S.C. SECTION 1001 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.

NRC FORM 314 - CERTIFICATE OF DISPOSITION OF MATERIALS

C. SURVEYS PERFORMED AND REPORTED

Radioactive material, ^{32}P , was stored in Suite 200, the laboratory facility.

Surveys were performed on Fridays of weeks when Radioactivity was used. Surveys were also performed a week later, and at the end of the month.

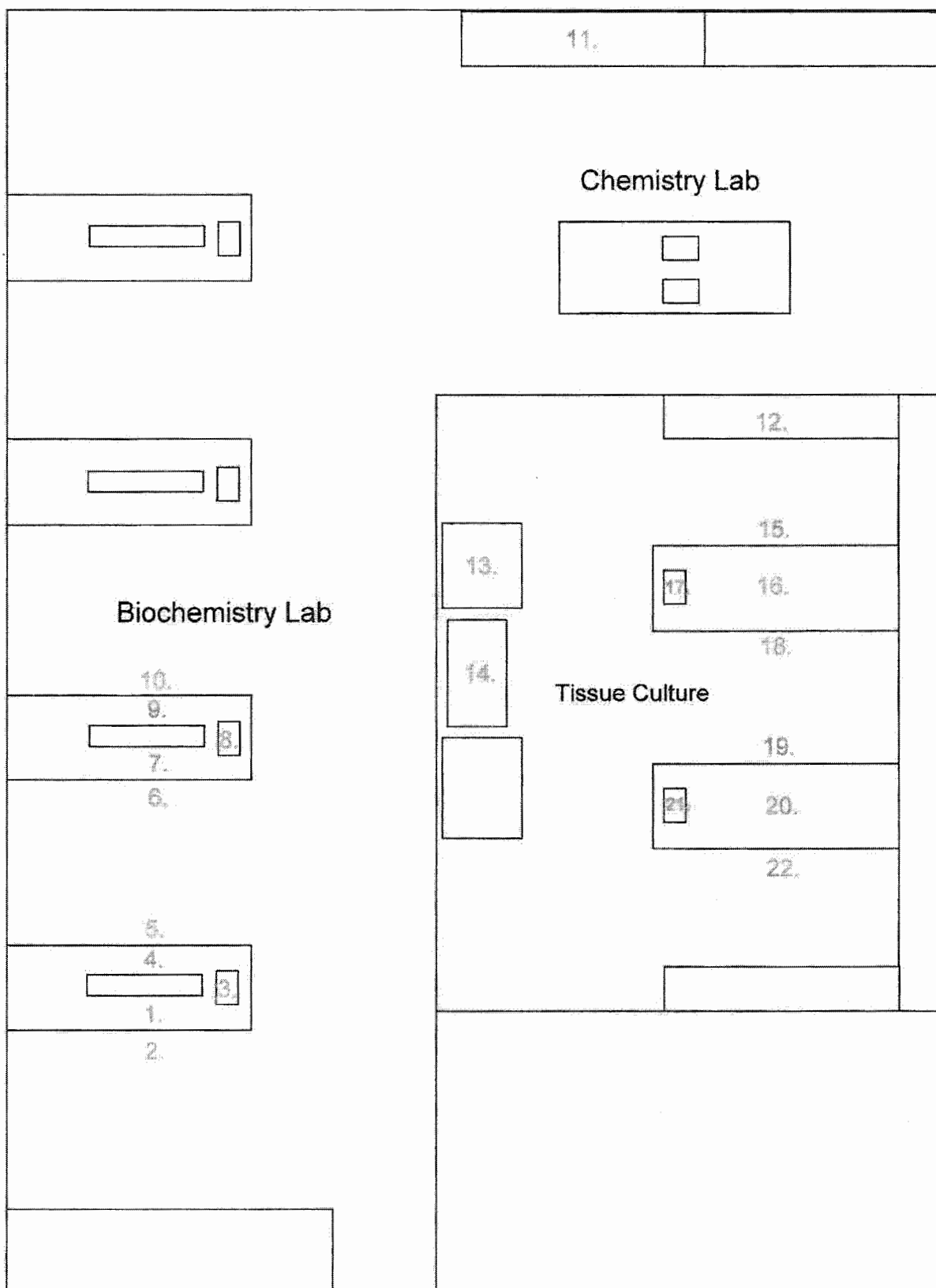
Using a Geiger-Mueller (Johnson Handheld Radioisotope Monitor; GM HP-265) for beta emission detection, designated radioactivity areas (per attached diagram) where use occurred was surveyed in a systematic order.

Maximum cpm reading obtained was recorded.

HPRL RADIATION SAFETY SURVEY RECORD:

Radiounclide:	Date Material Used:	Survey Instrument Used:	Results:	Date of Survey:	Initials:
^{32}P	6/1/10	GM HP-265 (Serial# 7537)	1. LBL* 2. LBL* 3. LBL* 4. LBL* 5. LBL*	6/4/10	MB
^{32}P	6/1/10	GM HP-265 (Serial# 7537)	1. LBL* 2. LBL* 3. LBL* 4. LBL* 5. LBL*	6/11/10	MB
^{32}P	6/1/10	GM HP-265 (Serial# 7537)	1. LBL* 2. LBL* 3. LBL* 4. LBL* 5. LBL*	6/25/10	MB/GH

* LBL is defined as Laboratory Background Level - 40cpm



- 1. Lab Bench
- 2. Floor
- 3. Sink
- 4. Lab Bench
- 5. Floor
- 6. Floor
- 7. Lab Bench

- 8. Lab Bench
- 9. Floor
- 10. Floor
- 11. Biochemical Safety Hood & Floor
- 12. Tissue Culture Hood & Floor
- 13. -20°C Freezer
- 14. -80°C Freezer
- 15. Floor

- 16. Lab Bench
- 17. Sink
- 18. Floor
- 19. Floor
- 20. Lab Bench
- 21. Sink
- 22. Floor

Song, Taehoon

From: Tran, Frank
Sent: Tuesday, October 01, 2019 10:37 AM
To: Pavon, Sandy; Song, Taehoon; Tomczak, Tammy
Cc: Pelke, Patricia
Subject: FW: RE: NRC License No. 21-32481-01
Attachments: NRC Letter and Form 314.pdf

Dear IM Center:

Please process the incoming as a termination request. Please let me know if you have any question.

Thank you,
-Frank

From: Monica Balash <mbalash@housey.com>
Sent: Tuesday, October 01, 2019 10:29 AM
To: Tran, Frank <Frank.Tran@nrc.gov>
Subject: [External_Sender] RE: NRC License No. 21-32481-01

Dear Mr. Tran,

Per your request, attached please find a letter and a completed Form 314.

Thank you again for all your help, and please let me know if anything further is needed.

Please confirm receipt of this e-mail.

Thank you and best regards,

Monica

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Monica Balash
Sr. Research Scientist
Housey Pharmaceutical Research Laboratories
16800 West Twelve Mile Road, Suite 201
Southfield, MI 48076
(office) (248) 663-7000, ext. 223
E-mail: MBalash@housey.com

Housey Pharmaceutical Research Laboratories

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From: Tran, Frank
Sent: Thursday, September 19, 2019 5:10 PM
To: Monica Balash <mbalash@housey.com>
Subject: RE: RE: Regarding NRC License No. 21-32481-01

Ms. Monica,

At the time the license be terminated, we will review the history of all licensed material which the licensee had ever possessed; it is back to the original license regardless of time. If the licensee possessed licensed material, they must check box #2.

Thanks,

Frank Tran

From: Monica Balash <mbalash@housey.com>
Sent: Thursday, September 19, 2019 3:10 PM
To: Tran, Frank <Frank.Tran@nrc.gov>
Subject: [External_Sender] RE: Regarding NRC License No. 21-32481-01

Dear Mr. Tran,

Following up on our discussion regarding Form 314, for Section B #1, is it asking in regards to the length of this license (meaning a 2 yr. possession and storage only), or from when we originally applied for and was granted a license? Meaning that if we have not had any radioactive materials on-site since 2010, should we check box #1 and leave #2 blank?

Thanks in advance for your help!

Best regards,

Monica

Monica Balash
Sr. Research Scientist
Housey Pharmaceutical Research Laboratories
16800 West Twelve Mile Road, Suite 201
Southfield, MI 48076
(office) (248) 663-7000, ext. 223
E-mail: MBalash@housey.com

Housey Pharmaceutical Research Laboratories

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From: Tran, Frank
Sent: Thursday, July 11, 2019 9:14 AM
To: info@housey.com; Monica Balash <mbalash@housey.com>; Gerard Housey <ghousey@housey.com>
Subject: Regarding NRC License No. 21-32481-01

Dear Dr. Housey:

This is Frank Tran, License Reviewer, with the U.S. Nuclear Regulatory Commission (NRC) in Region III. It has come to my attention that your NRC License No. 21-32481-01 expired in October 2018. Based on the NRC regulations, your license cannot be terminated until you submitted NRC Form 314 (a copy is attached for your reference) or equivalent license termination request and the NRC reviewed and approved your request. Until the license is terminated by the NRC, the licensee will still be responsible for the annual fee listed in Tittle 10 of the Code of Federal Regulations (10 CFR) Section 171. If you would like to keep your license, please submit a renewal application in accordance with NUREG-1556, Volume 7, Revision 1. An electronic copy of this guidance can be obtained at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/>.

If you have any questions or need any assistance with Form 314 or the renewal application, please reply to this email.

Thank you,

Frank Tran

Health Physicist/License Reviewer
NRC Region III/Division of Nuclear Materials Safety
Phone: 630-829-9623
Fax: 630-515-1078
Email: Frank.Tran@nrc.gov

