

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Housey Pharmaceutical Research Laboratories, LLC 16800 West Twelve Mile Road Southfield, MI 48076</p> <p>REPORT NUMBER(S) 2018001</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>	
<p>3. DOCKET NUMBER(S)</p> <p>030-36425</p>	<p>4. LICENSE NUMBER(S)</p> <p>21-32481-01</p>	<p>5. DATE(S) OF INSPECTION</p> <p>March 9, 2018</p>

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

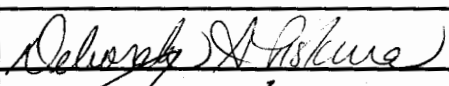
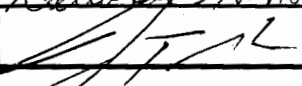
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s):

- 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Deborah A. Piskura, Senior Health Physicist		3/13/18
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		3/14/18

Docket File Information

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6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS 03.01 - 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03810	2. PRIORITY 3	3. LICENSEE CONTACT Gerald M. Housey, M.D., Ph.D., RSO	4. TELEPHONE NUMBER (248) 663-7000
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Main Office Inspection Next Inspection Date: March 9, 2021

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine, unannounced inspection of a small laboratory R&D firm authorized for H-3, C-14, P-32, and S-35 "for storage only." The licensee's prior use of material was limited to P-32 (last project approximately 10-15 years ago). However, the licensee maintained its license for future use of material to support product development and FDA approval. The licensee employed 6 individuals at its site. All laboratories and equipment were maintained and in use for other non-radioactive studies.

This inspection consisted of interviews with licensee personnel, a review of select records, a tour of the laboratories, and independent measurements.

No violations of NRC requirements were identified during this inspection