

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED

Owlstone, Inc.
19 Ludlow Road
Suite 202
Westport, CT 06880

2. NRC/REGIONAL OFFICE

Region 1
2100 Renaissance Blvd
Suite 100
King of Prussia, PA 19406-2713

REPORT NUMBER(s) 2021001

3. DOCKET NUMBER(S)

030-38060

4. LICENSE NUMBER(S)

31-23978-01E

5. DATE(S) OF INSPECTION

08/03/2021 - 08/16/2021

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 the 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)

10 CFR 32.29(c)(4)(i) requires, in part, that the licensee shall file a report with the Director of the Office of Nuclear Materials Safety and Safeguards, covering the preceding year, on or before January 31 of each year.


Contrary to the above, since January 31, 2017, the licensee failed to file a report with the Director, NMSS, covering the preceding year, on or before January 31 of each year. Specifically, no report was received for the year 2017 and the reports for 2018 to 2020 were dated February 4, February 11, and February 10, respectively.

This is a Severity Level IV violation (Enforcement Policy Section 6.9).

The licensee indicated that they were unaware of the January 31 requirement and would set up a reminder system so that future reports would be submitted on time. The licensee also submitted a report for the distributions in Calendar Year 2017.

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	Mikaela Abraham		9/8/2021
NRC INSPECTOR	Steven Courtemanche	Steven R. Courtemanche <small>Digitally signed by Steven R. Courtemanche Date: 2021.09.07 10:06:45 -04'00'</small>	
BRANCH CHIEF	Christopher Cahill	Christopher G. Cahill <small>Digitally signed by Christopher G. Cahill Date: 2021.09.07 11:24:43 -04'00'</small>	