

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

BioStorage Technologies, Inc.
2910 Fortune Circle West, Suite E
Indianapolis, IN 46241

REPORT NUMBER(S) 2016001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-37223

4. LICENSE NUMBER(S)

13-32622-01

5. DATE(S) OF INSPECTION

OCTOBER 14TH 2016

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.

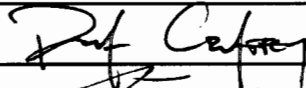

Non-cited violation(s) were discussed involving the following requirement(s):

- ☐ 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	Ryan Craffey		10/14/16
BRANCH CHIEF	Aaron McCraw		10/19/16

Docket File Information

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3. DOCKET NUMBER(S) 030-37223	4. LICENSE NUMBER(S) 13-32622-01	5. DATE(S) OF INSPECTION October 14, 2016
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6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS All
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03225	2. PRIORITY 5	3. LICENSEE CONTACT Thomas Schumacher, MS, CHP - RSO	4. TELEPHONE NUMBER (317) 902-9868
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☒ Main Office Inspection Next Inspection Date: 10/14/2021

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a biorepository authorized to store radiolabeled biological samples as a commercial service at its facility in Indianapolis, Indiana. At the time of the inspection, a small fraction of the licensee's total inventory in cold storage contained trace amounts of tritium and carbon-14. The licensee received radiolabeled samples infrequently (once a month or less), and shipped them back upon request even more infrequently (once a year or less). The licensee had 16 staff (out of approximately 260 in total), who were trained in the safe handling of radioactive material. The licensee retained the services of a health physics consultant to serve as RSO and perform quarterly audits of the program.

PERFORMANCE OBSERVATIONS

The inspector toured the facility in Indianapolis to evaluate the licensee's measures for materials security, hazard communication and contamination control. The inspector conducted independent surveys in the vicinity of the designated radioactive material storage locations, and found no evidence of residual contamination. With the assistance of licensee staff, the inspector accounted for a random selection of the licensee's inventory of radiolabeled samples. The licensee's staff also demonstrated and discussed implementation of procedures for safe handling of radioactive materials, use of survey instruments, sample disposal, and others. Through these demonstrations and discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements. The inspector also reviewed a selection of recent package receipt, inventory, training, and audit records.

The inspector also reviewed the licensee's corrective actions for a violation identified during the previous inspection (IR 03037223/2015001(DNMS)) regarding the inadvertent transfer of radioactive material to a facility that was not authorized to receive or possess byproduct material. The inspector found the licensee's corrective actions to be effective, and identified no additional examples of this violation. Therefore, the NRC considers this violation to be closed.

No violations of significance were identified as a result of this inspection.