

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Confluence Life Sciences, Inc.
4320 Forest Park Avenue, Suite 303
St. Louis, MO 63108

REPORT NUMBER(S) 2017001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-38464

4. LICENSE NUMBER(S)

24-32829-01

5. DATE(S) OF INSPECTION

January 11, 2017

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:

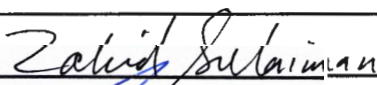
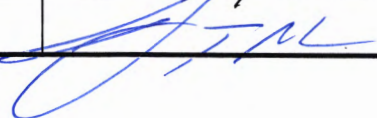
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Zahid Sulaiman, Health Physicist		1/11/2017
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		1/27/17

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(Continued)

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) 03620	2. PRIORITY 5	3. LICENSEE CONTACT Jeffrey Hirsch, RSO	4. TELEPHONE NUMBER (314) 932-4032
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Main Office Inspection Next Inspection Date: 06/21/2018

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a research and development licensee authorized to use a variety of radionuclides for in-vitro binding assays and cellular labeling studies. The licensee had five authorized user's (AU) who were authorized to use millicurie quantities of byproduct materials for non-human research studies. The licensee has submitted a license amendment request, to change the licensee name to Confluence Discovery Technologies, Inc.

Performance Observations

The inspection consisted of interviews with select licensee personnel; review of select records; tours of research laboratories (Suite 303), waste storage area, and conducted independent measurement to verify compliance with public dose limits. The inspector interviewed the RSO, an AU, and the technician who uses byproduct materials; all demonstrated adequate knowledge of radiological principles and practices. The inspector: (1) had the AU demonstrate the survey instrument battery check, the use of instrument, and package check-in procedure; (2) observed the AU conduct a physical inventory of licensed material, and all the licensed material was accounted for; (3) had the technician perform weekly wipes and surveys; (4) observed the AU and the technician wearing the proper PPE; (5) reviewed security of licensed materials and access to the research lab. The licensee stored waste in the storage closet for decay-in-storage and disposed of the solid waste as ordinary trash after determining the radioactivity of the waste cannot be distinguished from background and the labels are removed or obliterated. The inspector reviewed the following records: annual program audits, spill procedures, dosimetry records, package receipt, licensed materials inventory tracking document, records of licensed materials usage, and waste disposal records, with no issues noted.

No violations of NRC requirements were identified as a result of this inspection.