

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Analytical Bio-Chemistry Laboratories, Inc.
4780 Discovery Drive
Columbia, MO 65201

REPORT NUMBER(S) 2018001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-05154

4. LICENSE NUMBER(S)

24-13365-01

5. DATE(S) OF INSPECTION

August 16, 2018

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):

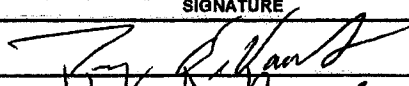
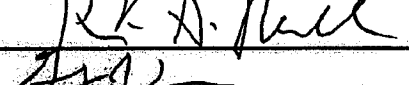
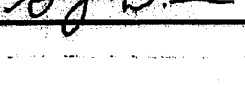
- ☒ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations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

License condition 22.A. requires, in part, that the licensee conduct its program in accordance with application dated May 23, 2017. Item 9 of the application requires that the radiation safety office staff conduct surveys for contamination in 6 rooms in building J on a weekly basis. Contrary to the above, from 11/30/17 through 8/16/18, the licensee failed to conduct surveys for contamination in 5 rooms in building J on a weekly basis.

As immediate corrective action, the RSO committed to begin conducting the weekly surveys in the five synthesis labs beginning immediately after the date of this inspection. The RSO and licensee management plan to consider requesting an amendment to their license to adjust the survey frequency of the synthesis labs based on a laboratory classification system.

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	Troy DeVault		05 SEP 2018
NRC INSPECTOR	Kevin G. Null		09/05/2018
BRANCH CHIEF	Geoffrey Warren, Acting Chief		9/5/18

Docket File Information**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:

Analytical Bio-Chemistry Laboratories, Inc.
4780 Discovery Drive
Columbia, MO 65201

REPORT NUMBER(S) 2018001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-05154

4. LICENSE NUMBER(S)

24-13365-01

5. DATE(S) OF INSPECTION

August 16, 2018

6. INSPECTION PROCEDURES USED

87125 and 87126

7. INSPECTION FOCUS AREAS

03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

3610

2. PRIORITY

3

3. LICENSEE CONTACT

Mark Gilliland, RSO

4. TELEPHONE NUMBER

(573) 777-6242

☒ Main Office Inspection Next Inspection Date: 08/16/2021

☒ Field Office Inspection 7200 East ABC Lane, Columbia, MO

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of an industrial broad scope program. The licensee primarily conducted research using millicurie (mci) quantities of carbon-14 (C-14) and hydrogen-3 (H-3) to label various organic and pharmaceutical compounds with C-14 and H-3 for customers who performed independent research studies. The licensee's inventory (including material being used and waste in storage) at the time of the inspection was approximately 7 curies of C-14, and 3 mci of H-3. The licensee had a radiation safety committee (RSC) that approved research studies, laboratories, authorized users, and had 2 locations of use listed on the NRC license.

PERFORMANCE OBSERVATIONS

The inspector toured several RSC-approved laboratories and radioactive waste storage areas at both locations of use listed in license condition number 10, and interviewed the radiation safety officer (RSO) and a random selection of authorized users (AU's) and radiation workers. The inspector observed AU's and radiation workers handling mci quantities of C-14 in synthesis labs and noted that each worker was wearing a lab coat, gloves, and eye protection. The inspector also interviewed package receiving staff in the loading dock. The staff members described radioactive material package receipt procedures and how they would handle packages that appeared to be damaged. The inspector reviewed a random sampling of incoming package survey records, records of initial and annual refresher training, weekly and monthly results of areas surveys for contamination conducted by the radiation safety staff (RSS), and radiation program protection program reviews conducted by the licensee for calendar years 2016 and 2017.

Item 9 of the licensee's application dated May 23, 2017 (tied down in license condition 22.A.) required that the RSS conduct weekly surveys for contamination in 6 specific laboratory suites located in building J. These suites were used to perform C-14 synthesis using 10 - 20 mci per study. From 11/30/17 (date license was renewed) through 8/16/18, the RSS staff had not conducted weekly surveys for contamination in 5 of the 6 laboratory suites.

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Analytical Bio-Chemistry Laboratories, Inc. 4780 Discovery Drive Columbia, MO 65201 REPORT NUMBER(S) 2018001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-05154	4. LICENSE NUMBER(S) 24-13365-01	5. DATE(S) OF INSPECTION August 16, 2018	
6. INSPECTION PROCEDURES USED 87125 and 87126	7. INSPECTION FOCUS AREAS 03.01 - 03.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 3610	2. PRIORITY 3	3. LICENSEE CONTACT Mark Gilliland, RSO	4. TELEPHONE NUMBER (573) 777-6242
<input checked="" type="checkbox"/> Main Office Inspection Next Inspection Date: 08/16/2021			
<input checked="" type="checkbox"/> Field Office Inspection 7200 East ABC Lane, Columbia, MO			
<input type="checkbox"/> Temporary Job Site Inspection			

PROGRAM SCOPE

These synthesis laboratory suites were good manufacturing practice (GMP) labs, and the process and procedures being implemented were strictly regulated by FDA because the material was being developed for use in humans by the licensee's clients. The RSO stated that the 1 suite which the RSS surveyed for contamination on a weekly basis was a transition area between the 5 synthesis labs and an unrestricted area. The 5 synthesis labs were surveyed for contamination by the RSS on demand by the AU's after synthesis studies were completed.

Based on interviews of licensee staff, the failure to conduct surveys of the 5 suites appears to be the result of not fully understanding commitments made in the licensee's 5/23/17 application for license renewal. Failure to conduct the weekly surveys in the 5 suites was a violation of license condition 22.A.

As immediate corrective action, the RSO committed to begin conducting the weekly surveys in the 5 synthesis labs beginning immediately after the date of this inspection. The RSO and licensee management plan to consider requesting an amendment to their licensee to adjust the survey frequency of the synthesis labs based on a laboratory classification system.

One Severity Level IV violation was identified as described on NRC Form 591 Part 1.