

NRC FORM 591M PART 1
(1-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Analytical Bio-Chemistry Laboratories, Inc. 7200 E. ABC Lane Columbia, Missouri 65202</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>REPORT NUMBER(S) 2012-001</p>		
<p>3. DOCKET NUMBER(S)</p> <p>030-05154</p>	<p>4. LICENSE NUMBER(S)</p> <p>24-13365-01</p>	<p>5. DATE(S) OF INSPECTION</p> <p>May 22 - 30, 2012</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)

10 CFR 31.5(c)(2) requires, in part, with the exception of the devices listed in subparagraphs (i) and (ii), that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall assure that the device is tested for leakage of radioactive material, at no longer than six month intervals or at such other intervals as are specified in the label. Contrary to the above, the licensee did not test three devices possessed pursuant to a general license, each device containing a nominal 15 millicuries of nickel-63, which are not subject to the exemptions specified in subparagraphs (i) and (ii), for leakage between August 16, 2010, and May 22, 2012, an interval greater than six months, the interval specified in the regulations. As corrective action, the licensee leak tested the sources before May 26, 2012, and submitted the samples for analysis. In addition, the licensee will track leak tests through a reminder system and will ask for reminders from the leak test company.

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, RA of Corporate Services		6/14/12
NRC INSPECTOR	Geoffrey M. Warren		6/14/12
BRANCH CHIEF	Hironori Peterson		6/14/12

Docket File Information

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3. DOCKET NUMBER(S) 030-05154	4. LICENSE NUMBER(S) 24-13365-01	5. DATE(S) OF INSPECTION May 22 - 30, 2012	
6. INSPECTION PROCEDURES USED 87125, 87126	7. INSPECTION FOCUS AREAS 03.01 - 03.07; 03.01 - 03.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03610	2. PRIORITY 3	3. LICENSEE CONTACT Bradly Keck, Ph.D., RSO	4. TELEPHONE NUMBER (573) 777-6070
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☒ Main Office Inspection Next Inspection Date: May 2015

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This inspection included in-office review through May 30, 2012; this review included review of licensee inventory, leak test, waste shipment, and audit records.

ABC Labs (licensee) was a company located in Columbia, Missouri, that performed contract research for clients, primarily in the pharmaceutical and agricultural industries. The licensee employed 150 personnel at the ABC Lane address and 250 at the Discovery Drive address. No radioactive material was in use at the Discovery Drive address, though small quantities remained in secured storage. At the ABC Lane address, ten employees in two labs (Building J) were involved in the production of radiochemicals using carbon-14 and tritium. These radiochemicals were prepared and shipped to clients or used on site. Approximately 30-35 employees used microcurie to millicurie quantities of carbon-14 and tritium for research, including aquatic animal studies, in eight labs (Buildings E and J). Three generally-licensed gas chromatographs (GC) using nickel-63 sources were in use in one lab, and additional GC sources were in storage pending disposal. The radiation safety program was staffed with two individuals including the radiation safety officer (RSO) and one safety technician; the RSO also serves as the company's environmental health and safety manager.

Performance Observations

The inspector toured five research labs and two production labs and observed laboratory use of carbon-14 and tritium, including use of personal protective equipment, personal surveys, and instrumentation. Licensee personnel demonstrated radiochemical analysis and synthesis, quality control, surveys of lab areas, package receipt surveys and wipes, and package shipment (limited quantity); and described inventory, bioassay, and training programs. The inspector noted no concerns with these activities except leak testing. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of the bioassay program and survey records indicated no concerns with dose to radiation workers or general public. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

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(Continued)

The inspector identified one violation concerning the licensee's failure to perform leak tests on three generally-licensed gas chromatograph sources, as described in the notice of violation. The leak test results indicated no evidence of contamination.

The inspector reviewed two open violations from Inspection Report No. 08-01 and six from No. 08-02:

- 08-01 - 1. The inspector found no evidence of licensed materials being disposed through regular trash, and licensee personnel stated that all licensed materials would be disposed as radioactive materials.
2. The licensee used bioassay calculations and dose factors as described in the procedure reviewed and approved by NRC in Amendment No. 34, issued in December 2008.
- 08-02 - 1: The license had been amended to authorize processing incident to the synthesis of radiochemicals.
2.A: The licensee used bioassay calculations and dose factors as described in the procedure reviewed and approved by NRC in Amendment No. 34, issued in December 2008.
2.B: Licensee procedures required personnel to determine the solubility of materials before disposing through sanitary sewerage, and licensee personnel described the same process.
3: The licensee documented the carbon-14 intakes of all individuals for whom the bioassay program indicated intakes requiring such documentation. All personnel required to be in the bioassay program were tracked through that program.
4: The RSO maintained an inventory of carbon-14 and tritium materials at the facility and physically reconciled this inventory annually with the actual materials possessed in in each laboratory.
5: The inspector found no evidence of food or drink in radioactive materials use areas, and licensee personnel stated that they would eat or drink only outside those areas.
6: The licensee performed program audits, used those audits to identify problems in the program, and took steps to correct those problems.

Based on these observations, the violations are considered to be closed.