

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Advion BioServices, Inc.
d/b/a Advion Bioanalytical Labs, a Quintiles Company
5225 Exploration Drive
Indianapolis, Indiana 46241

REPORT NUMBER(S) 12-01

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-38468

4. LICENSE NUMBER(S)

13-32830-01

5. DATE(S) OF INSPECTION

May 10, 2012

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	Andrew M. Bramnik	<i>Andrew M. Bramnik</i>	5/10/12
BRANCH CHIEF	<i>Hironali Peterson</i>	<i>[Signature]</i>	5/25/12

Docket File Information

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3. DOCKET NUMBER(S) 030-38468	4. LICENSE NUMBER(S) 13-32830-01	5. DATE(S) OF INSPECTION May 10, 2012
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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 Natalie Russel, RSO	4. TELEPHONE NUMBER (317) 548-5105
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Main Office Inspection Next Inspection Date: 05/01/2017
 Field Office Inspection
 Temporary Job Site Inspection

PROGRAM SCOPE

This was an initial inspection of a research and development laboratory. The licensee received and analyzed samples of human or animal plasma, bile, urine, and feces that contained microcurie quantities of either carbon-14 or hydrogen-3. Since the facility opened in October 2011, the licensee had only received samples containing carbon-14. Two authorized users and seven individuals working under supervision, including the Radiation Safety Officer (RSO), handled or used radioactive materials. Over 150 individuals worked at the licensee's corporate office in Ithica, New York, and 40 individuals worked at the address authorized on the NRC license. The laboratory group had been started under a different NRC licensee in May 2011, and was now working independently.

PERFORMANCE OBSERVATIONS

Interviews conducted with available staff revealed an adequate level of understanding of emergency and materials handling procedures and techniques. All licensed material was required to be ordered through the RSO, who verified that the amount and proposed use had been approved prior to delivery. The licensee demonstrated their process for surveying and delivering incoming packages containing licensed material to individual users. The inspector observed the licensee's staff conduct package receipt surveys using a GM meter, followed by wipe samples of package exteriors, interiors, and individual sample boxes; however, the licensee did not analyze the wipe samples in a liquid scintillation counter until after packages were opened and the samples were placed into temporary storage locations. The inspector informed the licensee's staff and management that this practice could result in missed opportunities to identify contamination before package contents were moved to different areas of the laboratory. The inspector also observed that a GM meter with a pancake probe would not accurately detect hydrogen-3 contamination. The licensee committed to revise its procedures for package receipt to analyze samples in a more timely manner and better assess potential hydrogen-3 contamination.

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PROGRAM SCOPE

The licensee possessed multiple survey meters that were operational, calibrated, and performed well in side-by-side comparisons with an NRC survey meter. The licensee conducted monthly wipe tests for contamination and analyzed them in a liquid scintillation counter. The licensee also maintained records of licensed material uses and disposals to a waste storage room. At the time of the inspection, the licensee was finalizing a contract with a waste management company to remove contaminated waste. The licensee had not transferred or disposed-of waste items since beginning operations.

The licensee received packages that contained between 2 and 40 samples for each experimental analysis. Although the licensee conducted a physical inventory to account for all sources possessed under their license at six month intervals, the licensee did not track the location of each individual sample. Instead, the licensee tracked its material by experiment lot number. The inspector informed the licensee's staff and management that this practice could result in missed opportunities to identify lost radioactive materials, because the inventory only listed the refrigerator or laboratory where unused samples were stored in addition to the original quantity of radioactive material in that experimental lot. The licensee's inventory did not accurately report the location of each individual sample or whether it had been used and/or disposed as waste. The licensee committed to revise their inventory process to better reflect the quantity and location of radioactive sources it possessed under its license. In addition to the semi-annual physical inventories, the RSO kept a running total of the quantity of radioactivity possessed by the laboratory, to ensure compliance with the possession limit in Condition 8 of the NRC license.

The inspector observed that all licensed material was adequately secured and not readily accessible to members of the general public. Independent measurements did not indicate readings in excess of 10 CFR Part 20 limits in restricted or unrestricted areas. Individual whole body and extremity dosimetry badges were observed being worn by the licensee's staff during the inspection, even though the licensee had performed an assessment and determined that dosimetry badges were not required.

No violations were identified during this inspection.