

INSPECTION RECORD

Region III

Inspection Report No. 030-05154/2008-002

License No. 24-13365-01

Docket No. 030-05154

Licensee (Name and Address):

Analytical Bio-Chemistry Laboratories, Inc.
7200 E. ABC Lane
Columbia, Missouri 65202

Licensee Contact: Shiela Hecht – RSO Telephone No. 573-443-9070

Priority: K3 Program Code: 3610

Date of Last Inspection: _____

Date of This Inspection: September 29 – October 2, 2008

Type of Inspection: () Initial (X) Announced () Unannounced
 () Routine () Special

Next Inspection Date: October 2010 () Normal (X) Reduced

Justification for reducing the routine inspection interval:

The lack of the licensee's management oversight of the radiation safety program which included continued contamination outside of restricted areas, continued lack of a completed internal dosimetry program and other findings were of a sufficient NRC management concern to warrant a reduced inspection frequency; in accordance with M2800 (section 06.04).

Summary of Findings and Actions:

- () No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- () Non-cited violations (NCVs)
- () Violation(s), Form 591 issued
- (X) Violation(s), regional letter issued
- (X) Followup on previous violations

Inspector(s) 
Michael LaFranzo, Materials Inspector

Date 10-14-08

Approved 
Patrick Loudon, Chief, MIB

Date 10-14-08

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

<u>Amendment No.</u>	<u>Date</u>	<u>Subject</u>
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None since the last inspection conducted from May to August 2008.

2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine NRC inspection was a joint inspection between staff of the decommissioning branch and materials inspection branch. Two violations of NRC requirements were identified. The first violation concerned the unauthorized disposal of licensed material. The second violation concerned the licensee's lack of a bioassay program. The inspection also identified radiological contamination within and outside of the unrestricted areas which caused the contamination of a radiation worker and some unnecessary radiation exposures to others on the sight. The inspection frequency was reduced to address those concerns and further review other areas of the licensee's program to ensure compliance with NRC requirements.

During a subsequent NRC inspection on March 29, 2006, a single violation of NRC requirements was identified regarding the licensee's failure to conduct quarterly wipe surveys.

3. INCIDENT/EVENT HISTORY:

None

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

G Scott Ward – Vice President, General Manager, Chemical Services
Sheila Hecht – Radiation Safety Officer

The licensee had two locations of use. The primary location was at 7200 E. ABC Lane. The licensee performs licensed activities with, primarily, carbon-14. The licensee used the carbon-14 for experimental purposes in microcurie or low millicurie quantities but also uses carbon-14, in several chemical forms, as part of a manufacturing/distribution process using hundreds of millicuries. The licensee primarily used licensed material Monday through Friday. The licensee had one radiation safety officer and two technicians.

The licensee's new location of use started in June 2008 and uses microcurie quantities of licensed material for research and development purposes.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87126

Focus Areas Evaluated: 03.01-03.07

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

During the inspection, the inspector performed independent radiation measurements and found contaminated clothing (8,000 dpm) in a restricted area the licensee was not aware of and a contaminated pen (approximately 24,000 dpm) outside of the restricted area. Since the last inspection, the licensee has placed additional emphasis on contamination control by additional training of the staff, providing additional protective clothing and adding more radiological survey instruments for use by the staff.

In addition, the inspector identified contamination on the exterior of a bottle that was used to store liquid radioactive waste and on a hand cart used to transport waste throughout the facility. These items that were contaminated were within the waste storage building; a restricted area, but, through interviews with the licensee staff, they were not expected to be contaminated. During the last routine inspection, a technician was contaminated from a container that he had not expected to be contaminated resulting in an unintended dose. The licensee committed to provide additional training to the technician to ensure contamination within restricted areas is known and protective equipment is used to limit exposure to licensed material.

The inspector found no additional contamination in other licensee areas or equipment that was not expected.

The inspector made side-by-side comparisons between NRC and licensee radiation monitoring equipment; no abnormal issues were identified.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Vio. 030-05154/001

Condition 6.B and 9.B of License Number 24-13365-01 states that the licensee is authorized to use carbon-14 for research and development as defined in Title 10 CFR 30.4 involving bio-tracers studies in animals and plants and in field studies as described in application dated July 16, 2007.

Title 10 CFR 30.4 defines Research and Development, in part, as the (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes.

Contrary to the above, as of October 2, 2008, the licensee has not used carbon-14 only for research and development as defined in Title 10 CFR 30.4 involving bio-tracers studies in animals and plants and in field studies as described in application dated July 16, 2007. Specifically, the licensee is also using carbon-14 for processing incident to the synthesis of radiochemicals, an activity not authorized on the license for carbon-14.

The licensee indicated that the violation occurred because the licensee had thought that the use of carbon-14 for the synthesis of radiochemicals was already approved. The licensee's corrective actions include submitting an application to the NRC add the use of carbon-14 regarding synthesis of radiochemicals.

Vio. 030-05154/002

Title 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present. 10 CFR 20.1003 states, in part, that *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

A. Title 10 CFR 20.1201 requires, in part, that the licensee limit the annual total effective dose equivalent to 5 rems.

B. Title 10 CFR 20.1203 requires, in part, that the licensee may discharge licensed material into sanitary sewerage if: 1) the material is readily soluble (or readily dispersible biological material) in water; and 2) the quantity of licensed material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in table 3 of appendix B to part 20.

Contrary to the above, as of October 2, the licensee did not make surveys to assure compliance with:

- A. Title 10 CFR 20.1201, which limits annually the total effective dose equivalent to 5 rems. Specifically, the licensee used incorrect bioassay dose conversion values concerning internal intakes of carbon-14 which resulted in incorrect dose assessments to occupational workers.
- B. Title 10 CFR 20.2003 which allows the licensee to discharge licensed material into sanitary sewerage if: 1) the material is readily soluble (or readily dispersible biological material) in water; and 2) the quantity of licensed material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in table 3 of appendix B to part 20.

Regarding violation 2.A, the licensee is continuing to address the bioassay program to ensure compliance with NRC requirements. The licensee indicated that they would submit the procedure for NRC review and approval by October 10, 2008.

Regarding violation 2.B, the licensee had thought they were in compliance concerning the discharge of radioactive material to the sewer system. However, the licensee did not realize that they needed to ensure compliance by not assuming all radioactive material used was soluble or readily dispersible biological material in water and the amount of dilution was sufficient that the licensee did not exceed the concentrations listed in table 3 of appendix B to part 20. The licensee committed to determine the solubility or dispersibility of all radioactive material disposed of via the sewer system and ensure the average concentration does not exceed the concentration listed in table 3 of appendix B to part 20 starting immediately.

Vio. 030-05154/003

Title 10 CFR 20.2106(a) requires, in part, that each licensee maintain records of doses received by all individuals for whom monitoring was required pursuant to §20.1502. 10 CFR 20.2106(c) requires, in part, that each licensee maintain the records specified in paragraph (a) of this section on an NRC Form 5, or in clear and legible records containing all the information required by NRC Form 5.

Contrary to the above, as of October 2, 2008, the licensee did not maintain records of doses received by several radiation workers, individuals for whom monitoring was required pursuant to §20.1502. Specifically, the licensee failed to determine and document the annual intake of carbon-14 and the total radiation dose which is required by NRC Form 5.

The licensee stated the violation occurred because of a lack of attention to detail. The licensee committed to fully complete the required documentation and redo all previous documentation by November 1, 2008.

Vio. 030-05154/004

Condition 21 of License Number 33 states, in part, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 16, 2007.

Eighth bullet on page 12 of the application dated July 16, 2007 states, in part, that the Radiation Safety Officer is responsible to maintain an inventory of all radioisotopes possessed under the license.

Contrary to the above, as of October 2, 2008, the licensee's radiation safety officer did not maintain an inventory of all radioisotopes possessed under the license. Specifically, the radiation safety officer did not maintain a complete inventory of a vial containing 13.4 millicuries of carbon-14.

The licensee stated the violation occurred because the radiation safety officer was relying on authorized users to document use of the radioactive material. In this case, the authorized user apparently forgot to complete the inventory documents for which the licensee relied on to ensure inventory controls and possession limits were not exceeded. The licensee committed to performing quarterly physical audits of all unsealed licensed material under the license.

Vio. 030-05154/005

Condition 21 of License Number 33 states, in part, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 16, 2007.

Item 10 titled "Safe Use of Radionuclides and Emergency Procedures" in application dated July 16, 2007 states, in part, that the licensee will follow the model program published in Appendix R of NUREG-1556 Volume 11'

Appendix R of NUREG-1556 Volume 11 states, in part, that workers do not drink in any area where licensed material is stored or used.

Contrary to the above, on September 28, 2008, the inspector identified that a radiation worker was drinking in room 501 of Building B where licensed material was stored. Specifically, the radiation worker stated that he was drinking in the area prior to September 28, 2008 as part of decommissioning effort of the area.

The licensee stated that the radiation worker had forgot that licensed material was stored in the area while he was consuming liquids. The licensee committed to retraining the radiation worker and reemphasize to all radiation workers that consuming liquids in any area where licensed material is used or stored is a violation of policy and NRC requirements.

Vio. 030-05154/006

Condition 21 of License Number 33 states, in part, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 16, 2007.

Item 10 titled "Audit Program" states, in part, that the licensee will follow the model audit program that was established in Appendix L to NUREG-1556 Volume 7.

Contrary to the above, as of October 2, 2008, the licensee did not follow the model audit program that was established in Appendix L to NUREG-1556 Volume 7.

The licensee explained that the audit process that was being performed was a hold over from a previous radiation safety officer's audit process. The licensee committed to perform the audit as required during the next semi-annual audit of the licensee's program.

IFI 030-05154/001

As noted in Section 3, the inspector found a contaminated lab coat in a restricted area that the licensee did not recognize as contaminated, a contaminated pen in an unrestricted area and a contaminated waste bottle and hand cart within the waste storage area, a restricted area. The licensee has had significant problems in contamination control in the synthesis laboratory because of the high quantity of radioactive material used in the lab. The contaminated items were believed to come from the synthesis laboratory area. As noted in section 3, the licensee is continuing its efforts to minimize contamination both within and outside of the restricted areas.

IFI 030-05154/002

The licensee's internal bioassay program was not complete at the end of the inspection. The licensee committed to providing a procedure included in a license amendment to the NRC by October 10, 2008 to address the issues identified during the inspection as deficiencies in the procedure. These deficiencies included:

- A. No chain of custody program;
- B. No cross contamination program. Specifically, the licensee did not have procedures to ensure individuals involving the taking and processing of the bioassay samples did not accidentally contaminate the sample which would give a higher recorded dose than the individual actually received;
- C. The licensee used a factor of 1.54 mR/uCi to determine the dose to the radiation worker which was not justified in any documentation submitted to NRC;
- D. The procedure provides two tables which use different biological half-lives for the chemical compounds used but does not address when it is appropriate to use which biological half-live values;
- E. There were no formula's in the original procedure so that the licensee and NRC know how the licensee calculated the internal doses to the radiation workers;
- F. The urinary excretion factors for each of the chemical compounds were not included in the procedure.

5. PARTIAL LIST OF PERSONNEL CONTACTED:

- #* G. Scott Ward - Senior Vice President, General Manager, Chemical Services
- #* Sheila Hecht - Radiation Safety Officer
- * Pat Loudon, MIB Branch Chief

Use the following identification symbols:

Individual(s) present at entrance meeting

* Individual(s) present at exit meeting

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