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Laboratories

September 16, 2008

Nuclear Regulatory Commission
Materials Inspection Branch
US Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

ATTN: Patrick L. Louden

RE: NRC Inspection Report 030-05154/08-01(DNMS) and Notice of Violation – Analytical Bio-Chemistry Laboratories, Inc.

Dear Mr. Louden:

Please find enclosed the "Reply to a Notice of Violation" which pertains to the "Notice of Violation" sent to Scott Ward on 22 August 2008. The reply contains the violation reprinted with our corrective actions taken listed.

If you have any questions or need further information, please feel free to contact me at 573-777-6070.

Sincerely,

Sheila C Hecht

Sheila C. Hecht
Director, Safety and Occupational Health

Notice of Violation

1. **Title 10 CFR 20.2001(a) requires that the licensee dispose of licensed material only by specified procedures.**

   Contrary to the above, on June 25, 2008, the licensee disposed of approximately 1700 becquerels of carbon-14 by releasing this material to a non-radioactive trash container, a method not authorized by §20.2001.

Reply to the Notice of Violation

REASON FOR VIOLATION

The licensee determined that the above violation occurred because personnel did not properly follow established laboratory safety and waste handling procedures. This may have occurred as a result of inadequate instructions from laboratory managers and/or radiation safety staff or a lack of understanding by the personnel of the importance of compliance with proper radioactive waste disposal procedures.

CORRECTIVE ACTIONS

In order to raise the awareness of proper radiation handling procedures and to prevent any reoccurrence of this situation, the following corrective actions have been taken:

1) Refresher training has been given to all staff in the Synthesis Department. This training included demonstrations and discussions on the proper handling of radioactive materials, the proper procedure for removal of disposable labcoats and gloves, the operation and use of the G-M survey meter and the new foot monitors, the procedure for surveying hands and feet before exiting the laboratory, and the proper disposal of radioactive materials..

2) New signage has been placed directly above the waste receptacles designating "Hot Rad Waste" from "Cold Waste". Signs have also been placed on the three doors exiting the laboratory reminding personnel that they must survey their hands, feet, and any item that they are going to remove from the laboratory..

3) Staff have been reminded that all items being removed from the Synthesis laboratory must be checked with a G-M survey meter before removal. All hot waste will be placed into either a plastic lined waste receptacle, a cardboard container lined with a plastic bag, or appropriate type drum container. For transferring hot liquid waste to the appropriate drum container, a spill-control drum funnel has been obtained and will be used. This will aid in keeping the top of the drum from becoming contaminated. When a plastic lined waste receptacle is full, it will be transferred to a cardboard container lined with a plastic bag which will be taped closed when full. The appropriate radiation waste label will be affixed to the outside of the closed box or drum and the outside of the container will be swiped to verify that there is no external contamination. The swipe report will be taped to the side of the container by laboratory personnel for verification purposes. After the container has been deemed free of external contamination, Radiation Safety will be contacted to collect the box or drum and place in the Waste Storage Facility. As an additional precaution, Radiation Safety will again survey the box or container with a G-M survey meter to verify that there is no external radiation contamination present before removing it from the laboratory and transferring it to the Waste Storage Facility.

CORRECTIVE STEPS TO AVOID FURTHER VIOLATIONS

1) In order to monitor compliance, the Radiation Safety staff will conduct random visual inspections to see that staff follows prescribed procedures, as well as, perform both visual and G-M monitoring of laboratory and office areas outside of the main Synthesis laboratory for any potential movement of radioactive materials or contamination.

DATE FOR ACHIEVEMENT OF FULL COMPLIANCE

10 September 2008.

2.. 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. Title 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.

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

Contrary to the above, as of June 25, 2008, the licensee did not make surveys to assure compliance with 10 CFR 20.1201, which limits annually the total effective dose equivalent to 5 rems. Specifically, the licensee used incorrect bioassay dose calculations values concerning internal intakes of carbon-14 which resulted in the underestimated dose to occupational workers.

Reply to the Notice of Violation

REASON FOR VIOLATION

The licensee confirms that the above violation occurred because of the utilization of a bioassay dose calculation formula that had been previously used without verifying that it was the correct formula.

CORRECTIVE ACTIONS

The following corrective actions have been taken to obtain the proper bioassay dose calculation formula and to insure that licensee personnel are adequately monitored in a timely manner:

1) An outside consultant was hired to review the current bioassay dose calculation formula to determine if it was correct and if not, to research and provide the correct formula. After researching the data, it was found that each C-14 compound that we utilize (a total of four) would need it's own bioassay dose calculation formula based on different body excretion values. The licensee admits that It took longer than expected for the consultant to research each compound and to develop new calculation formulas for each compound with the licensee based on the number of days post exposure. The consultant wanted to make sure that each formula was correct before releasing them to be used for the licensee's radiation workers.

2) Each radiation worker in the Synthesis Department that used one of the four C-14 compounds during the years 2006, 2007 and 2008 and had a bioassay performed had the results recalculated to verify that no individual exceeded the 5 rem limit for that calendar year. One individual seems to flush the C-14

through his system faster than a normal reference man so the consultant has modified the formulas to correct for the higher flushing by this individual.

3) Bioassay (urine) samples are collected weekly and analyzed on a Liquid Scintillation Counter. The results are then calculated by the Radiation Safety Officer using the appropriate formula for the compound the worker used that week. These results are then entered into a spreadsheet which keeps track of the total exposure received up to that date and used to ensure that no worker exceeds the allowable exposure limit. The licensee is committed to insuring timely dose assessments in order to insure that it's staff does not receive additional dose and that general members of the public receive no dose that would exceed NRC regulatory dose limits.

CORRECTIVE STEPS TO AVOID FURTHER VIOLATIONS

1) All bioassay sample results will be closely monitored to insure that no staff member receives a dose that would exceed NRC regulatory guidelines. If new C-14 compounds are utilized in the laboratory, bioassay dose calculation formulas will be researched and developed for each new compound.

DATE FOR ACHIEVEMENT OF FULL COMPLIANCE

10 September 2008.

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