



DATE: June 12, 2009

TO: Vivian H. Campbell
Chief, Nuclear Materials Safety Branch-A

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RE: Response to NOTICE OF VIOLATION
Docket No. 030-08380
License No. 17-14996-01

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DNMS

The following narrative describes the National Hansen's Disease Programs' response to the NRC INSPECTION REPORT 030-08380/09-011 AND NOTICE OF VIOLATION. We describe our understanding of the violations cited as a result of the routine, unannounced inspection conducted on April 22, 2009 and our proposed corrective actions to bring our program into full compliance with NRC regulations.

The NRC inspection cited three Severity Level IV violations of NRC requirements. They were:

- A. 10 CFR 20.1801 requires, in part, that the licensee shall secure from unauthorized removal or access licensed materials that are stored in control or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, a controlled area is an area outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason. An unrestricted area is defined as an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on April 22, 2009, the licensee did not secure from unauthorized removal or limited access to licensed material stored in lab No. 3520 in an unlocked container containing 2 millicuries of carbon-14, which was in a controlled area. Specifically, the licensee did not control access to the lab by locking the lab door during normal working hours, and routinely the lab door was propped open during periods of use with access by non-licensee individuals.

RESPONSE: The lab doors to 3520 are routinely kept closed but not locked. We do not lock the doors to 3520 because the building has security measures in place allowing only authorized individuals into the building as well as restricting individuals with appropriate clearances to certain floors. The security program is maintained by the LSU police department. Lab 3520 is a core lab that accommodates approximately 20 technical staff of the NHDP who may frequent the lab 10-20 times per day. Often individuals carry specimens to and from the lab for specialty monitoring or treatment. For ease of entry and to avoid accidents that could result from unlocking/locking entry doors upon each entry/exit, the doors to 3520 are kept unlocked during working hours. All doors are locked during nonworking hours and continued security is monitored overnight by the police on duty. It was our impression that this level of security was sufficient to maintain control of the radioactive material in our possession.

Based on the security deficiency cited during our recent inspection, we propose to enhance security in 3520 by moving all radioactive materials into two cabinets and one refrigerator within 3520. We plan to have the refrigerator and cabinets retrofitted with locking devices to secure the radioactive materials and, until the locks are in place, lab 3520 will remain locked 24-hours a day. This should avoid unauthorized removal and limit unauthorized access to licensed material in 3520.

- B. 10 CFR 20.1101.(c) requires that the licensee shall periodically (at least annually) review the radiation protection program content and implementation. Specifically the licensee had not reviewed the radiation protection program content and implementation during calendar years 2005-2008

RESPONSE: To bring our review of radiation protection program content into compliance we plan to integrate a radiation safety and procedures training component into our annual Biosafety training program offered once per year. The one hour lecture and Q and A session is mandatory for all technical employees of the Laboratory Research Branch. The discussion on radiation safety will be managed by Dr. Gillis, Chief of Laboratory Research Branch, and will cover SOP's for acquiring, storing, disposing of radioactive material as well as required safety precautions used when working with radioisotopes. Dr. Gillis has training in radiation biology and over 30 years of experience using radionuclides in a biological setting. We will have scheduled this training session for June 26, 2009. It is our understanding that the NRC has training materials useful for this type of workshop and we will avail ourselves of these materials to organize and implement our training session.

- C. 10 CFR 20.1902(e) requires that the licensee post each area or room in which certain amounts of licensed material, specified in 20.1902(e), are used or stored, with conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

Contrary to the above, on April 22, 2009, a caged-in compound on the Diagnostics Services Loading Dock (outside of the SVM building), an area or

room in which 8.5 millicuries of carbon-14 was stored, was not posted with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

RESPONSE: Permanent signs with the appropriate warning have been ordered and will be in place by the end of June, 2009. Until that time, temporary signage has been placed in the area indicated in the above statement of violation.

We appreciate the professional manner in which the inspection was managed and hope that our actions as stated above will bring our program into full compliance with NRC regulations. If there are questions regarding our proposed actions or further discussions needed, please contact Mr. Pasqua (225-578-9855), Dr. Gillis (225-578-9836) or Dr. Krahenbuhl (225-756-3776).