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- ☐ A.3 Sensitive Security Related
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Department of Health and Humans Services

Reviewer: *MP* *9/2/14*
~~DHHS/HHS/Healthcare System Bureau~~
Division of National Hansen's Disease Programs
Louisiana State University
School of Veterinary Medicine
Skip Bertman Drive
Baton Rouge, La. 70803
DATE: August 28, 2014

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AUG 28 2014

DNMS

TO: Jack E. Whitten
Chief, Nuclear Material Safety Branch B,
Division of Nuclear Materials Safety.

FROM: Ramanuj Lahiri, Ph.D., RSO,
Laboratory Research Branch, NHDP.
And
Richard W. Truman, Ph.D., Chief,
Laboratory Research Branch, NHDP.

R. Lahiri
R. W. Truman

RE: Response to Notice of Violation
Docket No. 030-08380
License No. 17-14996-01

The following narrative describes National Hansen's Disease Programs' (NHDP) response to NRC INSPECTION REPORT 030-08380/2014-001 AND NOTICE OF VIOLATION. The U. S. Nuclear Regulatory Commission (NRC) identified two Severity level IV violations during their routine unannounced inspection of NHDP; Laboratory Research Branch facilities conducted on May 19, 2014. They were:

- A. 10 CFR 20.1101(c) requires that the licensee shall periodically (at least annually) review the radiation protection program content and implementation. Contrary to the above, the licensee failed to 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 the calendar years 2009-2013.

RESPONSE: NHDPs' failure to review the radiation protection program content and implementation during the calendar years 2009-2013 may be attributed to insufficient understanding of the radiation protection program and NRC license requirements. The program was reviewed annually by the user group during annual radiation safety training, although no systematic annual internal audits for the LRB radiation protection program were conducted. The management was made aware of this deficiency. As an immediate corrective action we have audited our radiation protection program in May 2014. It has been decided to review the radiation protection program semi-annually coinciding with the semi-annual



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review of the Institutional Animal Care and Use Committee (IACUC) for which mature procedures are already in place. This review process will prevent future violations of 10 CFR 20.1101(c) requirement that the licensee shall periodically (at least annually) review the radiation protection program content and implementation. As of now we are in compliance with NRC regulation and expect to at least annually review the radiation protection program content and implementation in future.

- B. License Condition 16 of Amendment 24, to NRC Materials License 17-14996-01, states, in part, that the licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the Commission to account for all sources received and possessed under the license.

Contrary to the above, licensee failed to conduct a physical inventory every 6 months to account for all sources received and possessed under the license. Specifically, the licensee had not conducted a physical inventory during the calendar years 2010-2013.

RESPONSE: NHDP failed to produce documentation of inventory during calendar years 2010-2013 during NRC inspection. However, to the best of management's knowledge inventories were taken every 6 months and the total amount of different radio-isotopes never exceeded their individual limits as per LRB license. Inspection of our order and receipt history of radioactive materials confirms that our holdings could not have exceeded the allowable maximum at any time during this period. The loss of inventory documents may be attributed to inefficient administrative handover procedures to the current RSO from the previous individual who retired from service in January 2014. As an immediate corrective action we conducted a physical inventory in April 2014 and have scheduled another for September 2014. We are also in the process of implementing a digital inventory tracking system, so that we can track radio-isotopes from procurement to disposal in 'real time'. The digital system will also ensure that documentation is not lost as a result of attrition or improper handover of duties. We will evaluate the effectiveness of this system specifically during our annual Radiation Safety Program review, and reconsider any deficiencies and corrective actions that may be needed in overall implementation of NRC regulations during the next annual audit of the radiation protection program. Currently we are in full compliance with NRC regulation and expect to conduct a physical inventory at least every 6 months to account for all sources received and possessed under the license.

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 Dr. Lahiri (225-578-9844) or Dr. Truman (225-578-9848).