



July 23, 2007

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

RE: Reply to a Notice of Violation

Dear Sir/Madam:

This letter is in response to NRC Inspection Report 030-37312/07-001 and Notice of Violation dated June 27, 2007. Lovelace Respiratory Research Institute (LRRI) is committed, at a minimum, to adhering strictly to NRC requirements, and appreciates the opportunity to respond to the NOV.

A. The NRC licensee had not been amended to designate Mr. Fitch as LRRI's Radiation Safety Officer (RSO) prior to Mr. Mauser leaving its employment.

Shortly after Mr. Mauser rather abruptly left LRRI, the Institute began searching for a replacement RSO. Mr. Mauser had agreed to serve as an RSO on a consulting basis until a new RSO was found. Before we were able to bring Mr. Fitch on board, Mr. Mauser unexpectedly ended the consulting arrangement.

If this situation should reoccur, we will identify one of our scientists with extensive experience in handling radioactive materials as an interim RSO. We will amend our license to reflect this change and amend the license again when a permanent RSO is hired.

B. Contrary to requirements of 10 CFR 20.1101(c), the licensee failed to review periodically (at least annually) the radiation protection program content and implementation.

LRRI interpreted 10 CFR 20.1101(c) to mean that the annual program review was to be conducted each year no later than the anniversary date of original license issuance, which fell on August 21. We had therefore planned to complete the first program prior to August 21, 2007. In our review of NRC regulations and guidance, we noted that the program must be reviewed at least annually; however, nowhere in the regulations or guidance is it stated that the first program review shall be conducted before December 31.

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Nevertheless, LRRRI will soon complete its 2007 annual program review, which will include a review of the program activities in calendar year 2006.

LRRRI regrets any confusion on this matter, and will conduct its subsequent reviews at least annually in accordance with 10 CFR 20.1101(c).

C. The licensee used byproduct material (i.e., a 10 millicurie Cesium-137 sealed source used to calibrate survey instruments) that was not authorized on the license in License Condition 6., and for a use not in License Condition 9.

The cause of this oversight was related to the long and extensive experience of LRRRI working with radioactive materials under its relationship with the US Department of Energy (DOE). The vast majority of the radioactive material on site and the locations needed to be surveyed are related to DOE work. The instrument in question had been used extensively to survey DOE-related spaces and radioactive materials. When it was used to evaluate activities under our NRC license, the technician recalibrated the survey equipment, as has been standard practice, by using the DOE source.

The Institute will cease using the source to calibrate equipment when used to survey materials covered by our NRC license. The Institute will, for the immediate future, have its instrumentation calibrated off-site by a third party authorized to perform calibrations under an NRC or Agreement State license. The Institute will subsequently evaluate whether it should request a license amendment to enable the Institute to calibrate such equipment on site.

D. The licensee failed to monitor for radioactive contamination the external surfaces of a labeled package as required by 10 CFR 20.1906(b)(1).

In a review of the violation, LRRRI determined that the provisions of 10 CFR 20.1906(b)(1) were not suitably integrated to our procedure for receiving shipments of radioactive material. LRRRI also noted that the Radiological Control Technician (RCT) who receives radioactive material shipments has not been properly trained on the provisions of 10 CFR 20.1906(b)(1). Our corrective actions to address this issue include: revising our procedure to meet the provisions of 10 CFR 20.1906(b)(1), and training all Radiological Control Technicians on the revised procedure.

E. Contrary to License Conditions 9 and 16 of NRC Byproduct Materials License 30-29237-01, the licensee used radioactive material in locations that were not indicated on the drawings provided.

The cause of this oversight was related to the long and extensive experience of LRRRI working with radioactive materials under its relationship with the US Department of Energy (DOE). Under DOE, the Institute conducted its radiological operations in a manner quite similar to NRC broad-scope licenses wherein operations were started in alternative spaces following approval by LRRRI management. However, after receiving the NRC license, LRRRI's ES&H program failed to implement the space usage limitations required by the NRC limited-scope license. Hence the actual usage locations did not reflect those submitted in the original license application.

LRRRI has undertaken corrective actions in response to the violation. The Institute has performed a gap analysis to determine the spaces in which radioactive materials are used or stored versus what was indicated in the license. The Institute has requested to amend its license to reflect all current use spaces as well as locations where such materials may be used in the near future.

In addition to the above, all areas in which radioactive materials may be used have signage posted. No other areas will be permitted to have radioactive materials. This requirement has been communicated in writing by the Institute's CEO to all Institute personnel. Furthermore, additional scrutiny will be placed on the specific location of intended use during the RSO's review of radioactive material purchases and the RSO's review of specific experimental protocols.

F. ES&H Technicians had not, from August 2006 until the inspection date, performed areas surveys as specified in the licensee's procedure RP-11 dated January 2002. As stated in the procedure, ES&H technicians were to perform surveys in class A and B labs bi-monthly; in alpha and beta/gamma labs annually; on floors in hallways for A, B and C labs annually; and non-radiological areas annually.

LRRRI agrees in principal with the violation as noted. A facility-wide survey will be completed by August 31, 2007. We would also like to offer a point of clarification: At the time of the inspection, LRRRI's class A laboratories contained DOE-regulated materials and were therefore not subject to NRC jurisdiction.

The Institute is committed to conducting all its activities in accordance with established procedures. This includes our procedures for radiation and contamination surveys. To address some of the factors that led to disuse of the survey procedure RP-11, LRRRI will take the following actions:

1. Augment the resources of the radiation protection program by hiring two additional full-time RCT positions.
2. Improve management oversight regarding completion of routine surveys through implementation of a survey tracking system. The RSO will communicate pending surveys to the technicians and the ES&H Manager. If the surveys are not completed on time, the RSO will communicate the deficiency to the ES&H Manager who will undertake appropriate corrective actions.

Lovelace Respiratory Research Institute is fully committed to improving its compliance with NRC regulatory requirements and increasing management oversight of the program. As part of this commitment, LRRRI will establish a radiation safety committee (RSC), consistent with the requirements of 10 CFR 33.13. This RSC will help ensure that all possession, use and disposition of radioactive materials by personnel at LRRRI complies with NRC regulations as well as the specific conditions of licenses issued to the Institute.

If you questions or comments, please contact our ES&H Manager, Scott Weiner, at (505) 348-9672.

Sincerely,



Dr. Robert Rubin
President and CEO

cc: Regional Administrator
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US Nuclear Regulatory Commission
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