



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

TELEFAX TRANSMITTAL

DATE May 27, 2014

NUMBER OF PAGES 3

SEND TO Luz Santa Maria- Office Manager- Sterling Diagnostics, Inc. NRC
License 21-26030-01

LOCATION -Sterling Heights, Michigan

FAX NUMBER (586) 979-4971

VERIFY BY CALLING

FROM: Bill Reichhold
(Sender)

TELEPHONE NUMBER (630) 829-9839

FAX NUMBER (630) 515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE See accompanying documents.

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank You.

Thank you for your response to our request for additional information. We still need you to clarify the following information so that we can complete our review of your renewal request.

Authorized User

Please specify if you still wish Debra Watson authorized as an authorized user for radioactive materials as shown in License Condition 11.A.

Training for Individuals Working In or Frequenting Restricted Areas (Occupationally Exposed Individuals and Ancillary Personnel)

1. Please specify the frequency of training for individuals working in or frequenting restricted areas where radionuclides are used or stored. For example, training for individuals working in or frequenting restricted areas where radionuclides are used or stored will be given radiation safety training (1) when the individual is initially hired, or (2) when there are new NRC requirements or regulations, and (3) an annual refresher.

2. Please submit a copy of your radiation safety training program, OR you may wish to state, " We will develop, implement, and maintain a written training program with the applicable Radiation Safety Topics training topics in Appendix J of NUREG-1556, volume 7".

Facility diagram

1. Please identify the area on the facility diagram where in-vitro kits are received.

2. Please describe your security precautions to prevent unauthorized removal of in-vitro kits from your facility. For example, (1) unauthorized individuals are not allowed in areas where in-vitro kits are received, stored, or re-packaged for distribution. (2) The door to the in-vitro storage area is kept locked and only the authorized users have keys to this lock. (3) After working hours the building is kept locked and is monitored by a security company, etc.

3. Please provide the scale of the facility diagram OR please specify the storage room dimensions (such as 12 feet by 10 feet) of the in-vitro storage area.

Radiation Monitoring Instruments

Your response to this section has a typographical error. Please correct this section to read, "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to **NUREG-1556**, Volume 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope" dated December 1999".

Occupational Dose

Please state that "We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20"

Safe Use of Radionuclides and Emergency Procedures

Please state that "We have developed, will implement, and will maintain procedures for safe use of radioactive materials, security of radioactive materials and emergencies involving radioactive materials".

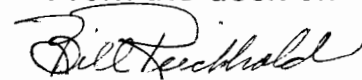
Radiation Surveys

A periodic radiation survey is too general of a term. Please specify a survey frequency, such as at least monthly, weekly, etc. For example, radiation surveys will be performed at least monthly.

Please send a facsimile (630- 515-1078) of your response to the above within 7 days and state, Response to Control 583481. Please include a cover letter on company letterhead, dated and signed (signed by an individual who is authorized to sign official documents on behalf of the licensee) with your response letter. Please call me at 630-829-9839 if you have any questions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this facsimile and the attached documents will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

From the desk of:



Bill Reichhold