

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Sterling Diagnostics, Inc. 36645 Metro Court Sterling Heights, MI 48310		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351	
3. DOCKET NUMBER(S) 030-31055		4. LICENSEE NUMBER(S) 21-26030-01	
		5. DATE(S) OF INSPECTION January 21, 2010	

LICENSEE:
The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

License Condition 11.B. Radiation Safety Officer.
Contrary to License Condition 11.B., the Radiation Safety Officer, David Callender, was no longer working as the Radiation Safety Officer and the license has not been amended to indicate a replacement Radiation Safety Officer.

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE	LUZ STA. MARIA	<i>[Signature]</i>	01/21/2010
NRC INSPECTOR	Robert P. Hays	<i>[Signature]</i>	1/21/2010

[Handwritten initials]

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6. INSPECTION PROCEDURES USED 87126 (9/28/2005))	7. INSPECTION FOCUS AREAS 03.01-03.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03244	2. PRIORITY 5	3. LICENSEE CONTACT Lou Icasas	4. TELEPHONE NUMBER 800-637-2661
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Main Office Inspection Next Inspection Date: **January 2015**

Field Office _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

The licensee is authorized by the license for redistribution of prepackaged iodine-125 in vitro test kits which involves shipping radioimmunoassay (RIA) medical kits containing I-125 with each kit averaging 3-10 microcuries per kit as ordered by customers pursuant to 10 CFR 32 to persons generally licensed pursuant to 31.11. The kits are not opened or manipulated. No waste is generated by the licensee. Current inventory was well below the license limit. There are 2-3 staff involved with licensed activities. The inspector performed independent and confirmatory radiation measurements which indicated no concerns with licensed material. The inspection determined that the RSO listed on the license had died during November 2009, and the license had not been amended to name a replacement RSO, a SL IV violation. Two additional licensee staff listed as authorized users on the license were available. The review of licensed activities and procedures did not identify any concerns because of the loss of the RSO.

Performance Observations

During the inspection, the licensee's staff demonstrated/discussed: (1) inventory and license activity limits; (2) package handling and shipping procedures; (3) receipt, storage and security of licensed material; (4) authorized users; (5) any minor contamination events (none); and (6) corrective actions for the SL IV violation for failure to change the RSO. The licensee will submit a license amendment request to change the RSO.

JEP