

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED: Siemens Healthcare Diagnostics 2150 Stanley Road Plainfield, Indiana  REPORT NUMBER(S) 2009-001		2. NRC/REGIONAL OFFICE  Region III U.S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351
3. DOCKET NUMBER(S) 030-37841	4. LICENSEE NUMBER(S) 07-32714-01G	5. DATE(S) OF INSPECTION November 16, 2009

**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:

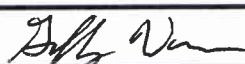
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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)

**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			
NRC INSPECTOR	Geoffrey M. Warren		11/16/09

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6. INSPECTION PROCEDURES USED 87125	7. INSPECTION FOCUS AREAS 03.01 – 03.07		

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S) 03244	2. PRIORITY 5	3. LICENSEE CONTACT Anne M. Dukehart, RSO	4. TELEPHONE NUMBER 574-262-6046
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☒ Main Office Inspection      Next Inspection Date: Nov. 2014

☐ Field Office \_\_\_\_\_

☐ Temporary Job Site  
Inspection \_\_\_\_\_

**PROGRAM SCOPE**

This was the initial inspection of activities under this license. The RSO was employed by the licensee at a facility in South Bend, Indiana, and visited the facility at least quarterly. The site contact was Andrew Nist, Health & Safety Manager, at 317-837-2292.

The facility, located in Plainfield, Indiana, was a distribution center for both generally- and specifically-licensed radioimmunoassay (RIA) kits. RIA kits were received from the production facility in Los Angeles, California, and orders were received at the licensee's facility in Atlanta, Georgia. Licensee personnel assembled orders and shipped them out, sending approximately 4000 kits monthly. Approximately 246 personnel were employed at this facility, including 210 who were trained to handle the RIA kits. All shipments in and out of the facility were performed as limited quantity shipments in accordance with DOT requirements.

**Performance Observations**

The inspector observed assembly, packaging, and shipment of orders, and licensee personnel described procedures for verifying that only authorized facilities receive specifically-licensed RIA kits, receipt of packages, inventory control, tracking of expired kits, spill procedures, and training/orientation. The inspector found no concerns with these activities. Interviews with licensee personnel indicated adequate knowledge of radiation safety procedures and concepts. Surveys indicated radiation levels consistent with licensee surveys and postings.