NRC FORM 591M PART 1
(10-2003) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Elkhart Clinic **303 South Nappanee Street** **Elkhart, IN 46514** **REPORT NUMBER(S)** **2010-01**	**U.S. Nuclear Regulatory Commission** **Region III** **2443 Warrenville Road** **Suite 210** **Lisle, Illinois 60532-4351**

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36581	**13-32515-01**	MAY 20, 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)

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	**Robert P. Hays**		5/20/10

NRC FORM 591M PART 1 (10-2003)

RPH

NRC FORM 591M PART 3
(10-2003) 10 CFR 2.201

Docket File Information

U.S. NUCLEAR REGULATORY COMMISSION

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1. LICENSEE	2. NRC/REGIONAL OFFICE
Elkhart Clinic REPORT NUMBER(S) **2010-01**	**Region III** **2443 Warrenville Road, Suite 210** **Lisle, IL 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
03034876	**24-32116-01**	**May 21, 2010**

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87124 (11/25/03)	**03.01-03.07**

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02201	**5**	**L. Gonzales, M.D., RSO**	**574-296-3449**

[X] Main Office Inspection — Next Inspection Date: **May 2015**

[ ] Field Office

[ ] Temporary Job Site Inspection — **Phil Hickman, CNMT, Cardiac Diagnostic Manager**

PROGRAM SCOPE

The licensee was a cardiac clinic authorized by the license to use any byproduct material as needed for any imaging and localization study permitted by 10 CFR 35.200 at the location specified on the license. The nuclear medicine department was staffed with one nuclear medicine technologist (NMT) who routinely conducted an average of 3-4 patient studies, rest and stress tests, each weekday. Patient studies are currently limited by available supply from the nuclear pharmacy. The licensee received unit doses as ordered from a local nuclear pharmacy. All waste was held for decay-in-storage (DIS) or returned to the nuclear pharmacy as a limited quantity shipment. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings. The licensee's survey meter response was within 5% of the inspector's survey instrument.

Performance Observations

During the inspection, the licensee's NMT demonstrated/discussed: (1) package check-in procedures and wipe test counting; (2) dosimetry (<10% of Part 20 limits); (3) dose calibrator tests; (4) unit dose handling procedures; (5) security of licensed material; (6) radiation safety program audits; (7) rad waste procedures; (8) sealed source inventory and leak tests; and (9) any contamination events (none).