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
George J. Kelen, M. D., PLLC 913 E. Ludington Avenue Ludington, MI 49431 REPORT 2006-001	UNITED STATES NUCLEAR REGULATORY COMMISSION REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36885	21-32560-01	March 6, 2006

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**		**3/6/2006**

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
George J. Kelen, M.D., PLLC REPORT NUMBER(S) 2006-001	Region III

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
03036885	21-32560-01	March 6, 2006

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87130	03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02201	5	W. LaPenna, M.D., RSO	231-845-7677

[X] *Main Office Inspection* Next Inspection Date: March 2011

[ ] Field Office _____

[ ] Temporary Job Site _____

PROGRAM SCOPE

The licensee was a medical clinic authorized by the license to use any byproduct material as needed permitted by 10 CFR 35.100 and 35.200 (excluding aerosols and limited to cardiovascular clinical procedures) at the location specified on the license. Licensed activities were conducted in the nuclear medicine suite, as indicated in the license application. The nuclear medicine department was staffed with one part-time nuclear medicine technologist (NMT) and routinely has conducted an average of 20-22 cardiac procedures/studies per month using Cardiolite®. The licensee received unit doses as ordered from a Traverse City, MI, nuclear pharmacy. All waste was held for decay-in-storage (DIS) or returned to the nuclear pharmacy as a limited quantity shipment. Licensed activities were initiated on May 24, 2005.

Performance Observations

During the inspection, the licensee's NMT demonstrated/discussed: (1) survey meter use and calibration; (2) package check-in procedures and wipe test counting; (3) dosimetry; (4) dose calibrator checks; (5) unit dose handling procedures; (6) security of licensed material; and (7) radiation safety program audits.