NRC FORM 591M PART 1
(10-2011)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

# SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| 1. LICENSEE/LOCATION INSPECTED: | 2. NRC/REGIONAL OFFICE |
|---|---|
| Thyroid & Diabetes Management Center<br>8939 Broadway<br>Merrillville, IN 46410<br><br>REPORT NUMBER(S) 12-01 | Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-35963 | 13-32380-01 | March 1, 2012 |

**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 violations(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, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(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 in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

## Statement of Corrective Actions

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 | | 3/1/12 |
| BRANCH CHIEF | Tamara E. Bloomer | | 3/9/12 |

NRC FORM 591M PART 3
(10-2011)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

*Docket File Information*

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| 6. INSPECTION PROCEDURES USED | 7. INSPECTION FOCUS AREAS |
|---|---|
| 87131 | 03.01-03.07 |

## SUPPLEMENTAL INSPECTION INFORMATION

| 1. PROGRAM CODE(S) | 2. PRIORITY | 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |
|---|---|---|---|
| 2200 | 3 | R. S. Longley, M. D., RSO | (219) 736-5077 |

☑ Main Office Inspection  Next Inspection Date: 02/27/2015

☐ Field Office Inspection

☐ Temporary Job Site Inspection

## PROGRAM SCOPE

The licensee was a medical clinic authorized by the license to use iodine-131 for any iodine-131 procedure permitted by 10 CFR 35.300 in capsule form. The licensee averages from none to one or two procedures each year for hyperthyroid therapy. Licensed activities are scheduled on Fridays when a procedure has been prescribed. I-131 dosages are ordered as needed form a local nuclear pharmacy. Recent written directives indicated that only dosages prescribed for hyperthyroidism were administered in November and December 2011. The licensee also uses generally-licensed iodine-125 in vitro kits for patient tests. No waste is returned to the nuclear pharmacy.

Performance Observations

During the inspection, the authorized user/RSO demonstrated/discussed: (1) survey meter use and calibrations; (2) package check-in procedures; (3) wipe test counting; (4) dosage preparation and safe use; (5) waste handling; (6) sealed source inventories and leak tests; (7) routine security of licensed material; (8) dose calibrator tests; (9) dosimetry [< 10% of annual regulatory limits]; (10) 10 CFR 35.75 patient release and instructions; and (11) corrective actions pertaining to a violation of 10 CFR 30.36(d)(3) that was identified for the failure of the licensee to notify the NRC that no principal activities occurred for a time period between August 2008 and October 2011. The licensee submitted the required written notification and the violation is now considered closed. The authorized user/RSO also informed the inspector that he plans to use iodine-131 on a more frequent basis to prevent another violation of 10 CFR 30.36(d)(3). The inspector performed independent and confirmatory radiation measurements, which determined that there was no contamination in areas of administration and use and results were consistent with licensee survey records and postings.