

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Howard Regional Health System Kokomo, Indiana		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351	
REPORT NUMBER(S)	2010-001		
3. DOCKET NUMBER(S) 030-13342	4. LICENSEE NUMBER(S) 13-13028-02	5. DATE(S) OF INSPECTION 5/11/10 through 5/26/10	

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.

One

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

10 CFR 35.63(d) states, in part, that the licensee may not use a dosage if the dosage differs by more than 20%. Corrective Actions: Retrain all individuals signing written directives to ensure the doses on the written directive were given and, if changes occur, modify the written directive.

- 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	Michael LaFranzo		6/16/10

Handwritten initials

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AND COMPLIANCE INSPECTION**

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6. INSPECTION PROCEDURES USED 87130 and 87131	7. INSPECTION FOCUS AREAS 03.01-03.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 2120	2. PRIORITY 3	3. LICENSEE CONTACT Dr. Rik Stephens - RSO	4. TELEPHONE NUMBER 765-453-0702
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Main Office Inspection Next Inspection Date: 5/2013

Field Office _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

The licensee is a small medical facility performing approximately 30-50 diagnostic administrations per week. The licensee performs approximately 12-16 iodination therapies per year. The licensee had one hot lab, a Radiation Safety Officer, a full time nuclear medicine technician and a part time nuclear medicine technician. The licensee received unit and bulk doses only from a local pharmacy; the licensee did not possess moly-tc generators.

Observations and Findings

The inspector observed the licensee administer licensed material and the technician had all radiation safety equipment available and implemented proper radiation safety practices. The inspector interviewed licensee staff and determined that they were aware of radiation safety practices and were implementing the radiation safety program adequately. The inspector reviewed selected documents which included: dosimetry records, radiation safety committee meeting minutes, dose administration records, dose calibrator records and radiological surveys; no abnormal issues were identified. The inspector performed independent radiological surveys and did not identify an abnormal radiation or contamination levels.

On January 21, 2008, the licensee identified that on November 5, 2007, a written directive to administer 5 millicuries of I-131 was approved by an authorized user but 6.5 millicuries of I-131 was administered to the patient. The licensee performed an evaluation and determined that the issue was not defined as a medical event. The NRC reviewed the licensee's analysis and determined that a medical event did not occur. However, the licensee identified that a violation of 10 CFR 35.63(d) did occur; 10 CFR 35.63(d) states, in part, that the licensee may not use a dosage if the dosage differs by more than 20%. In this case, the licensee believes that a written directive was signed by the authorized user for 5 millicuries but 6.5 millicuries of iodine-131 arrived from the pharmacy. According to the licensee, the authorized user, not noting the difference between the prescribed and received dose, administered the dosage to the patient. The licensee's corrective actions were to retrain all individuals signing written directives to ensure the doses on the written directive were given and, if changes occur, modify the written directive. The NRC did not identify any further instances of dosages differing by more than 20%. The NRC is classifying this violation as a Non-Cited Violation.