NRC FORM 591M PART 1
(4-2008)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Terre Haute Regional Hospital 3901 South 7th Street Terre Haute, Indiana 47802 REPORT NO: 2011-001	U.S. Nuclear Regulatory Commission Region IV, 612 East Lamar Blvd, Suite 400 Arlington, Texas 76011-4125

3. DOCKET NUMBER	4. LICENSE NUMBER	5. DATE OF INSPECTION
030-09540	13-09649-02	September 22 & October 6, 2011

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) 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.

10 CFR 35.75(a), requires, in part, that a licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 millirem. 10 CFR 35.75(c), requires, in part, that a licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with § 35.2075(a).

Contrary to the above, the licensee failed to document in writing a calculation demonstrating that patients administered I-131 could be released in accordance with 10 CFR 35.75. Specifically, written calculations demonstrating that patients could be released in accordance with 10 CFR 35.75 were not documented in 20 of the 32 cases involving the administration of I-131 in dosages greater than 150 millicuries. This is a Severity Level IV violation.

During the inspection, the licensee's radiation safety officer (RSO) performed the calculation for up to 175 millicuries of I-131 and the inspector determined that there was no safety concern and that all 20 patients met the release criteria. The RSO formally submitted an updated patient release calculation form to include dosages up to 175 millicuries.

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	Dale F. Alward, COO		10/11/2011
NRC INSPECTOR	Lizette Roldán-Otero, Ph.D.	Lizette Roldán-Otero	10/11/2011
BRANCH CHIEF	TAMARA Bloomer	TC Bloomer	10/27/11

☐ Non-Public ☐ Sensitive – Security-Related ☒ Public ☒ Non-Sensitive

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-09540	13-09649-02	9/22/11 & 10/6/11

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131 &87132	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02120	3	Edward Johnston, III	(812) 251-6797

☑ Main Office Inspection Next Inspection Date: 10/2014

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

Terre Haute Regional Hospital operates Monday through Friday from 06:00 A.M. to 4:00 P.M. and is licensed for 35.100, 35.200, 35.300, and 35.400 uses. The licensee employs two full-time and two part-time nuclear medicine technologists. The licensee conducts about 30 to 40 diagnostic studies per week, mainly bone scans, HIDA, and cardiac studies. Tc-99m unit and bulk dosages are received from a local nuclear pharmacy. No Mo-99/Tc-99m generator or PET materials are used. The licensee has two gamma cameras. The licensee administers I-131 in capsule form for diagnostic and therapeutic procedures. 35.100, 35.200, and I-131 less than 33 millicuries are performed in the nuclear medicine department, while I-131 procedures greater 33 millicuries and manual brachytherapy are performed in the oncology center. Both sites are located in the same floor. Most of the manual brachytherapy involves I-125 prostate permanent implant procedures. The licensee hires a radiation safety consultant for services such as wipe tests for seal sources, records review, inventory, internal audits, training and instrument calibration.

Performance Observation

About 66 procedures involving the administration of I-131 (4 mCi to 30 mCi range) were performed from 2009 to 2011. The inspector reviewed all the written directives and found them containing all the regulatory required information. No medical events were identified. Patients were released in accordance with Table U.1. of NUREG-1556. volume 9, revision 2.

About 32 procedures involving the administration I-131 (50mCi to 175 mCi range) were performed from 2009 to 2011. The inspector reviewed all the written directives and found them containing all the regulatory required information. No medical events were identified. Special instructions were provided to the patients. The licensee has a specific room designated for those patients that cannot be released in accordance with Title 10 Code of Federal Regulations (CFR) 35.75. This room was used once within the last four to five years. Patients receiving I-131 in the range of 50 mCi to 150 mCi are released after the licensee demonstrates by calculation that no member of the public will receive more than 500 millirem from the released individual. The inspector noted that for 20 out of the 32 procedures, the licensee failed to have written documented calculation to demonstrate that patients administered I-131 in quantities greater than 150 millicuries could be released in accordance with 10 CFR 35.75.

NRC FORM 591 PART 2
(10-2011)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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(Continued)

At the request of the inspector, the licensee's radiation safety officer (RSO) performed the calculation for up to 175 mCi and the inspector determined that there was no safety concern and that all 20 patients met the release criteria. The RSO committed to update the patient release calculation form to include dosages up to 175 mCi.

About 57 manual brachytherapy procedures (48 I-125 prostate permanent implants and 9 Cs-137 temporary implants) were performed from 2009 to 2011. The inspector reviewed all the written directives and found them containing all the regulatory required information. The inspector reviewed the D90 values for all procedures. No medical events were identified. Special instructions were provided to the patients.

The inspector observed the administration of I-131 to a patient and no safety concerns were identified. The inspector interviewed the following licensee personnel: nuclear medicine technologist, the authorized user, the dosimetrist, the Radiation Oncology Director, RSO, as well as other supporting personnel. These individual demonstrated knowledge of operating and emergency procedures, and NRC radiation safety requirements.

The inspector reviewed the dosimetry records of the nuclear medicine department and oncology center and no whole body or ring badge overexposures or abnormal readings were identified. Dose calibrator tests, leak test results, calibration of survey meters, area surveys and wipe tests, radiation safety training, internal audits, and dosimetry records were reviewed and found adequate. Ambient radiation surveys were performed to confirm that area where radioactive material are used or stored were less than 2 mrem in any hour. Security of radioactive material was adequate meeting 10 CFR 20.1801 and 1802 requirements. Area posting was adequate. The inspector determined that the licensee examines licensed activities performed by the consultant and follows up on the consultant's recommendations regarding the licensee's radiation safety program.

The inspector identified one SL-IV violation during this inspection. The licensee had performed a release calculation up to 150 millicuries for I-131 treatments. The licensee failed to have written documentation to demonstrate that patients administered I-131 in quantities greater than 150 millicuries were released in accordance with 10 CFR 35.75. The licensee submitted their calculation to the NRC to release patients for treatments up to 175 millicuries of I-131.