NRC FORM 591M PART 1
(07-2012)
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, IN 47802 REPORT NUMBER(S) 2017001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-09540	13-09649-02	10/30/17, with continued in-office review through 11/16/17

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)

Contrary to Title 10, Code of Federal Regulations (CFR), 35.67(b)(2), between June 26, 2015, and October 30, 2017, the licensee failed to test five sealed brachytherapy sources of cesium-137 (Cs-137) for leakage at intervals not to exceed 6 months, as specified in SS&D Certificate NR-460-S-906-S.

The inspector determined that the root cause of the violation was a misunderstanding by the Radiation Safety Officer (RSO) of the required leak test interval for these particular manufacturer/model sources, in that the instructions for similar brachytherapy sources, differing in manufacturer and model number, possessed by the

(cont'd. on next page)

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	JEREMY GALLMAN		12/4/17
NRC INSPECTOR	Dennis P. O'Dowd	Dennis P. O'Dowd	11/22/17
BRANCH CHIEF	Aaron T. McCraw		11/22/17

NRC FORM 591M PART 2
(07 2012)
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, IN 47802 REPORT NUMBER(S) 2017001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5 DATE(S) OF INSPECTION
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(Continued)

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licensee specified a leak test frequency of every three years. As corrective action, the licensee committed to having the sources tested for leakage within 30 days of the date of the inspection exit. For long-term corrective action, the licensee committed to updating its calendar to ensure that these sources are scheduled for leak testing at intervals not to exceed every six months.

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Terre Haute Regional Hospital 3901 South 7th Street Terre Haute, IN 47802 REPORT NUMBER(S) 2017001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

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030-09540	13-09649-02	10/30/17, with continued in-office review through 11/16/17

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131	3.01-3.07

SUPPLEMENTAL INSPECTION INFORMATION

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

☑ Main Office Inspection Next Inspection Date: 10/30/2020

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection of a large community hospital (270 beds) authorized under NRC license to use byproduct materials for medical uses permitted by 10 CFR 35.100, 35.200, 35.300, and 35.400. The nuclear medicine department was staffed with two full-time nuclear medicine technologists who performed approximately 160 diagnostic nuclear medicine procedures monthly. The licensee work hours were from 7 AM- 4 PM, Monday through Friday. The licensee no longer used materials at the Premier Diagnostic Imaging office, and that location was removed from the license (Amendment 68, issued 03/22/17). The licensee retained a consulting physicist who audited the nuclear medicine radiation safety program on a quarterly basis. The licensee received both unit and bulk doses at the nuclear medicine department. The licensee maintained an active Iodine-131 (I-131) therapy program. Typically in a year, the licensee administered about 20 I-131 treatments for hyperthyroidism, and approximately 10 thyroid ablations. The licensee's Cancer Center was staffed with one oncologist, one medical physicist and one dosimetrist, who administered one to two Cs-137 temporary implants annually and approximately 12 I-125 permanent prostate implants annually. The licensee had not used Ir-192 source for the manual brachytherapy program since 2011.

Performance Observations

This inspection consisted of interviews with select licensee personnel; tours of the nuclear medicine and radiation oncology departments, and the radioactive material storage area; independent measurements; and a review of select records. No patient administrations were performed at the time of the inspection. Interviews with licensee personnel indicated an adequate level of understanding of emergency and material handling procedures and techniques, and knowledge of radiation safety concepts. The licensee's staff discussed and/or successfully demonstrated the following: (1) package receiving and check-in procedures (including receipt surveys); (2) security of licensed material; (3) dose prep and safe use; (4) daily surveys and weekly wipe tests; (5) survey meter use and calibrations; (6) waste handling; (7) sealed source inventories and leak tests; (8) dose calibrator tests; (9) radiation safety program audits; (10) HAZMAT refresher training; (11) contamination events (none); and (12) dosimetry. The inspector reviewed (with no issues identified): written directives those materials and uses requiring a written directive; patient release calculations; and gynecological and prostate pre- and post- treatment plans.

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NRC FORM 591M PART 3
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U.S. NUCLEAR REGULATORY COMMISSION

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02120	3	Edward Johnston III, RSO	(812) 251-6797

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☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

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Licensed material was observed as adequately secured during the review and was not readily accessible to members of the general public. Survey meters were found to be calibrated and operational. The inspector performed independent and confirmatory radiation measurements that indicated results consistent with licensee survey records and postings. Independent measurements taken did not indicate readings in excess of 10 CFR Part 20 limits in restricted or unrestricted areas. Personal dosimetry was observed being worn by the staff during the inspection. Dosimetry records reviewed for the previous years since the last inspection through YTD 2017 indicated whole body and extremity exposures <10% of the annual regulatory limits.

During the inspection, the inspector identified a violation of 10 CFR 35.67(b)(2), in that the licensee failed to leak test five cesium-137 sealed brachytherapy sources since June 26, 2015, a period greater than the required period of six months. The violation and the licensee's corrective actions are described in Part 1. The licensee committed to completing the required leak tests of the sources within 30 days of the exit date of the inspection, and to maintaining a in its calendar the required dates of the leak test for these sources. The inspector determined that the root cause of the violation was the Radiation Safety Officer's misunderstanding of the required leak test frequency for these particular manufacturer/model number sources.

O'Dowd, Dennis

From: Chris.Newlin@HCAHealthcare.com
Sent: Monday, December 04, 2017 1:43 PM
To: O'Dowd, Dennis
Cc: Bruce.Adamson@hcahealthcare.com; Edward.Johnston@hcahealthcare.com
Subject: [External_Sender] FW: NRC finalized Report Terre Haute Regional Hospital
Attachments: NRC 2017 Report.pdf

Importance: High

Hello Mr. Odowd,
Attached is the signed NRC inspection report as requested. If there is anything else you need, please let us know.
Thank You,

Christiana Newlin, B.S.R.T. (R.)(T.)
Director of Radiation Oncology

PAUL SIEBENMORGEN Cancer Center
AT TERRE HAUTE REGIONAL HOSPITAL

Phone: (812) 237-9326
Fax: (812) 237-9572

Our promise is to provide the highest quality, compassionate care for every patient, every time.

HOSPITAL SAFETY SCORE

Commission on Cancer

[redacted]

O'Dowd, Dennis

From: O'Dowd, Dennis
Sent: Wednesday, November 22, 2017 11:26 AM
To: edward.johnston@hcahealthcare.com
Cc: bruce.adamson@hcahealthcare.com
Subject: Transmittal of NRC Form 591M (Part 1) "Safety Inspection Report and Compliance Inspection" for Licensee's Name, Signature, and Date
Attachments: Terre Haute Hospital NRC 591M Inspection Report (10302017-11162017)-For Signature.pdf

Edward Johnston III, Radiation Safety Officer
Terre Haute Regional Hospital
3901 South 7th Street
Terre Haute, Indiana 47802

Dear Mr. Johnston:

Please find attached Form 591M (Part 1), "Safety Inspection Report and Compliance Inspection," signed by me and Aaron T. McCraw, Chief, Materials Inspection Branch, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission (NRC), Region III, issued in response to our recent inspection of your licensed program.

As you are aware, on October 30, 2017, the NRC conducted a routine inspection at your facility in Terre Haute, Indiana. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. A telephonic exit meeting was conducted with you and Mr. Bruce Adamson, Director of Radiology, on November 16, 2017, to discuss the inspection findings. The enclosed Form 591M (Part 1) inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, interviews with personnel, and independent measurements.

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The NRC is citing the violation in the enclosed Form 591M because the inspector identified violation. The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed in the narrative on the form, and therefore, no further response is requested.

At this time, we request that a member of senior executive management date and sign his/her name in the signature block of the attached NRC Form 591M in the row "Licensee's Representative," (please include the official's printed name in the appropriate block), scan the signed and dated document, and return it to me either via email, or via fax to (630) 515-1259 (addressed to my attention), so that we can include it in your official license record.

Should you have any questions regarding this or any other related matter, please feel free to contact me. Thank you for your cooperation during this inspection.

Dennis P. O'Dowd
Health Physicist
Materials Inspection Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission

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