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 cesium-137 sealed brachytherapy sources (AEA Technology Model CDC. T1) for leakage at intervals not to exceed 6 months, as specified in SS&D Certificate IL-136-S-933-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	Edward Johnston RSO	Edward Johnston	3/16/21
NRC INSPECTOR	Dennis P. O'Dowd, Health Physicist	Dennis P. O'Dowd Digitally signed by Dennis P. O'Dowd Date: 2021.02.11 16:54:35 -06'00'	
BRANCH CHIEF	Michael A. Kunowski, Branch Chief	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.02.16 10:54:57 -06'00'	

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

(Continued)

(cont'd. from previous page)

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

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

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, for 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
(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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SUPPLEMENTAL INSPECTION INFORMATION

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

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

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☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

(cont'd. from previous page)

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 (AEA Technology Model CDC.T1, Sealed Source and Device Certificate IL-136-S-933-S) 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 l. 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 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.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

March 2, 2021

Terre Haute Regional Hospital
ATTN: Edward E. Johnston, III
3901 South 7th Street
Terre Haute, IN 47802

SUBJECT: SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION, REPORT NO. 030-09540/2017001 – TERRE HAUTE REGIONAL HOSPITAL

Dear Mr. Johnston:

On October 30, 2017, the United States Nuclear Regulatory Commission (NRC) conducted an on-site inspection of the activities authorized under NRC License No. 13-09649-02, with in-office review through November 16, 2017. After the telephonic exit conference with you on November 16, 2017, an NRC Form 591M, "Safety Inspection Report and Compliance Inspection" was issued. This form listed one violation identified during this inspection for the failure to test certain sealed brachytherapy sources containing millicurie quantities of cesium-137 for leakage at intervals as prescribed in the Sealed Source and Device (SS&D) certificate for these sources. However, as identified during a recent review of your file and confirmed in several recent conversations with you, the sources involved that required leak testing at a six-month interval were those described in SS&D Certificate IL-136-S-933-S and not by SS&D Certificate No. NR-460-S-906-S as was listed in the NRC Form 591M issued to you in 2017.

As a result of this determination, and in order to be accurate in the findings of the inspection conducted in 2017 of your licensed activities, we are rescinding the NRC Form 591M dated November 22, 2017, and have issued a revised, corrected NRC Form 591M (enclosed) that references the correct SS&D Certificate number and specifically identifies the manufacturer and model number of the sealed brachytherapy sources that were required to have been leak tested at the specified six-month interval.

Please enter your name and title and sign and date the attached Form in the section marked "Licensee's Representative" and provide a copy of the signed form to the NRC by fax to 630-515-1259 or by email to Dennis.O'Dowd@NRC.gov.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and the Form with your signature will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

If you have any questions regarding this matter, please do not hesitate to contact Mr. Dennis P. O'Dowd, Health Physicist, of my staff, at 630 829-9573.

Sincerely,

Michael A. Kunowski Digitally signed by Michael A. Kunowski
Date: 2021.03.02 08:47:25 -06'00'

Michael Kunowski, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-09540
License No. 13-09649-02

Enclosure: NRC Form 591M

Letter to Edward Johnston, III from Michael Kunowski dated March 2, 2021.

SUBJECT: SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION, REPORT NO. 030-09540/2017001 – TERRE HAUTE REGIONAL HOSPITAL

ADAMS Accession Number: ML21060B372

OFFICE	RIII-DNMS	C	RIII-DNMS	C				
NAME	DO'Dowd:ps		MKunowski					
DATE	2/19/2021		3/02/2021					

OFFICIAL RECORD COPY

O'Dowd, Dennis

From: Johnston Edward <Edward.Johnston@hcahealthcare.com>
Sent: Tuesday, March 16, 2021 3:57 PM
To: O'Dowd, Dennis
Subject: [External_Sender] Re:Transmittal of Retraction Letter dated March 2, 2021 and Corrected NRC Form 591M (Parts 1 & 2) "Safety Inspection Report and Compliance Inspection" for Inspection in October - November 2017, for Licensee's Name, Signature, and Date
Attachments: Reissuance of 11-16-2017 Inspection .pdf

Follow Up Flag: Follow up
Flag Status: Completed

Dennis

See Attachment

Thanks Ed

From: O'Dowd, Dennis <Dennis.O'Dowd@nrc.gov>
Sent: Tuesday, March 16, 2021 3:08 PM
To: Johnston Edward <Edward.Johnston@hcahealthcare.com>
Subject: {EXTERNAL} FW: Transmittal of Retraction Letter dated March 2, 2021 and Corrected NRC Form 591M (Parts 1 & 2) "Safety Inspection Report and Compliance Inspection" for Inspection in October - November 2017, for Licensee's Name, Signature, and Date

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From: O'Dowd, Dennis
Sent: Thursday, March 11, 2021 4:17 PM
To: edward.johnston@hcahealthcare.com
Subject: Transmittal of Retraction Letter dated March 2, 2021 and Corrected NRC Form 591M (Parts 1 & 2) "Safety Inspection Report and Compliance Inspection" for Inspection in October - November 2017, for Licensee's Name, Signature, and Date

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

Dear Mr. Johnston:

Please find attached a Retraction Letter dated March 2, 2021, and a reissued, corrected Form 591M (Parts 1 and 2), “Safety Inspection Report and Compliance Inspection,” signed by me and Michael A. Kunowski, Chief, Materials Inspection Branch, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission (NRC), Region III, originally issued in response to our the inspection of your licensed program conducted in October – November 2017. The purpose of that inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements.

Based on the results of that inspection, the NRC had determined that a Severity Level IV violation of NRC requirements had occurred. The violation was evaluated in accordance with the NRC Enforcement Policy, and the NRC cited the violation and had provided you an NRC Form 591M, which has now been retracted, with a corrected NRC Form 591M being provided to you herein. At the conclusion of the 2017 inspection, the NRC 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 was already adequately addressed in the narrative on the form, and therefore, no further response was requested.

At this time, we request that, if you haven't already, to destroy the previous and discard the previously issued NRC Form 591M (Parts 1 & 2) that was issued to you in November 2017, and that you print your name, sign, and date the attached reissued, corrected NRC Form 591M in the row "Licensee's Representative," scan the signed and dated document, and return it to me via email, 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.

Dennis P. O'Dowd
Health Physicist
Materials Inspection Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
2443 Warrenville Road
Lisle, IL 60532
dennis.o'dowd@nrc.gov
630.829.9573 (office)
630.515.1259 (fax)

O'Dowd, Dennis

From: O'Dowd, Dennis
Sent: Thursday, March 11, 2021 4:17 PM
To: edward.johnston@hcahealthcare.com
Subject: Transmittal of Retraction Letter dated March 2, 2021 and Corrected NRC Form 591M (Parts 1 & 2) "Safety Inspection Report and Compliance Inspection" for Inspection in October - November 2017, for Licensee's Name, Signature, and Date
Attachments: Terre Haute Reg Hospital NRC591 IR Parts 1&2 reissuance of 11-16-2017 (02-11-2021).pdf; Terre Haute Reg Hospital Retraction Letter (02-11-2021).pdf

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

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Should you have any questions regarding this or any other related matter, please feel free to contact me.

Dennis P. O'Dowd
Health Physicist
Materials Inspection Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
2443 Warrenville Road
Lisle, IL 60532
dennis.o'dowd@nrc.gov
630.829.9573 (office)
630.515.1259 (fax)


UNITED STATES NUCLEAR REGULATORY COMMISSION