

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Community Hospital Anderson Radiation Oncology Department 1340 North Madison Avenue Anderson, Indiana 46011 REPORT NUMBER(S) 2017001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-36525	4. LICENSE NUMBER(S) 13-32500-01	5. DATE(S) OF INSPECTION January 26, 2017	

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, 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)

A. Title 10 CFR 35.24(f) requires, in part, that licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of 10 CFR Part 35 establish a Radiation Safety Committee (RSC) to oversee all uses of byproduct material permitted by the license.

Contrary to the above, as of January 26, 2017, the licensee failed to establish an RSC to oversee all uses of byproduct material permitted by the license, and the licensee is authorized for two different types of uses of byproduct material under Subparts E, F, and H of 10 CFR Part 35. Specifically, the licensee is authorized to use unsealed byproduct material - written directive required, under Subpart E, and to operate a high dose-rate remote afterloader (HDR) unit, under Subpart H.

(Continued on Part 2)

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	Marsha Sherrell, Director	<i>Marsha Sherrell</i>	2/9/17
NRC INSPECTOR	Geoffrey M. Warren	<i>Geoffrey M. Warren</i>	2/9/17
BRANCH CHIEF	Aaron T. McCraw	<i>Aaron T. McCraw</i>	2/7/17

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Community Hospital Anderson Radiation Oncology Department 1340 North Madison Avenue Anderson, Indiana 46011 REPORT NUMBER(S) 2017001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-36525	4. LICENSE NUMBER(S) 13-32500-01	5. DATE(S) OF INSPECTION January 26, 2017	

(Continued)

The root cause of the violation was that the licensee was unaware of this requirement. As corrective action, the licensee will work with Community Hospital of Anderson and Madison County, NRC License No. 13-10205-01, and begin attending RSC meetings there. The RSC for that license will also oversee all uses of byproduct material performed under this license. The next RSC meeting is scheduled for February 7, 2017.

B. Title 10 CFR 35.643(a)(1) requires, in part, that a licensee authorized to use a remote afterloader unit for medical use perform spot-checks of each remote afterloader facility and on each unit before the first use of an HDR unit on a given day. Title 10 CFR 35.643(d)(6) states that to satisfy this requirement, spot-checks must, at a minimum, assure proper operation of timer accuracy.

Contrary to the above, as of January 26, 2017, the licensee failed to include timer accuracy in the spot-checks performed on the HDR unit before the first use of the unit on a given day. Specifically, instead of performing this check each day, licensee staff performed this check weekly.

The root cause of this violation was that the licensee was unaware that this check was required to be performed each day of use. As corrective action, the physicist will immediately begin checking timer accuracy before the first use of the HDR unit each day and will notify other physicists who may perform the spot-checks for the HDR unit about this requirement.

Warren, Geoffrey

From: Sherrell, Marsha <Marsha.Sherrell@ecommunity.com>
Sent: Friday, February 10, 2017 7:28 AM
To: Warren, Geoffrey
Cc: Real, Lori A; Mihail, Ana
Subject: [External_Sender] RE: External: RE: Community Hospital Radiation Oncology
Attachments: CHA NRC 2017 INSPECTION REPORT.pdf

Good Morning,

Please find attached the scanned, signed safety inspection report and compliance. Please let us know if there is anything else you need from us. Thank you for your time and patience with us.

Marsha Sherrell | Director of Cancer Services
Community Hospital Anderson | 1515 N Madison Ave | Anderson, IN 46011
765.298.1621 *office* | 765.641.1340 *fax* | marsha.sherrell@ecommunity.com

From: Warren, Geoffrey [mailto:Geoffrey.Warren@nrc.gov]
Sent: Thursday, February 09, 2017 9:47 AM
To: Sherrell, Marsha
Cc: Real, Lori A; Mihail, Ana
Subject: External: RE: Community Hospital Radiation Oncology

Attached is the inspection report for the inspection on January 26. Please print your name and title in the box at the bottom of the first page for Printed Name of Licensee Representative, then sign and date in the appropriate boxes. Your signature represents a commitment to the corrective actions described. Once this is complete, please scan and send back both pages.

Please contact me if you have any questions.

--

Geoffrey Warren
Senior Health Physicist
NRC Region III
630-829-9742

From: Sherrell, Marsha [mailto:Marsha.Sherrell@ecommunity.com]
Sent: Tuesday, January 31, 2017 2:48 PM
To: Warren, Geoffrey <Geoffrey.Warren@nrc.gov>
Cc: Real, Lori A <Lori.Real@ecommunity.com>; Mihail, Ana <Ana.Mihail@ecommunity.com>
Subject: [External_Sender] Community Hospital Radiation Oncology

Hi Geoff,

In follow-up from our survey last week, I have spoken with the radiation safety officer at the hospital, and they are good with Ana Mihail or myself reporting to their radiation safety committee, which meets quarterly. I have let him know we need to have our HDR as an agenda item to report. Below is a screen shot of the e-mail received from Joe Rastetter regarding the meetings. If you have any questions, please do not hesitate to contact me. Thank you!

Radiation Safety Meetings for 2017 - Message (HTML)

FILE

MESSAGE

Ignore

Junk

Delete

Reply

Reply All

Forward

More

Meeting

More

jcaho

To Manager

Team Email

Move

Rules

OneNote

Actions

Mark Unread

Categorize

Follow Up

Delete

Respond

Quick Steps

Move

Tags

Mon 1/30/2017 7:58 AM

Rastetter, Joseph

Radiation Safety Meetings for 2017

To Sherrell, Marsha

You replied to this message on 1/30/2017 8:10 AM.

Marsha,

All meeting are held in the lab conference room at 11:00am. If it is occupied, our alternative meeting site is the radiology of any changes prior to meeting. The meetings are as follows:

February 7th
 May 2nd
 August 1st
 November 7th

Rastetter, Joseph

Nuclear Medicine Su...

Sherrell, Marsha

Administrative Direct...

Marsha Sherrell | Director of Cancer Services

Community Hospital Anderson | 1515 N Madison Ave | Anderson, IN 46011

765.298.1621 *office* | 765.641.1340 *fax* | marsha.sherrell@ecomunity.com

CONFIDENTIALITY NOTE: This e-mail contains information that may be privileged, confidential and subject to legal restrictions and penalties regarding its unauthorized disclosure or other use. You are prohibited from copying, distributing or otherwise using this information if you are not the intended recipient or the employee or agent to deliver to the intended recipient. If you have received this e-mail in error, please notify us immediately by return e-mail and delete this e-mail and all attachments from your system. Thank you.

CONFIDENTIALITY NOTE: This e-mail contains information that may be privileged, confidential and subject to legal restrictions and penalties regarding its unauthorized disclosure or other use. You are prohibited from copying, distributing or otherwise using this information if you are not the intended recipient or the employee or agent to deliver to the intended recipient. If you have received this e-mail in error, please notify us immediately by return e-mail and delete this e-mail and all attachments from your system. Thank you.

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Community Hospital Anderson Radiation Oncology Department 1340 North Madison Avenue Anderson, Indiana 46011 REPORT NUMBER(S) 2017001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-36525	4. LICENSE NUMBER(S) 13-32500-01	5. DATE(S) OF INSPECTION January 26, 2017	
6. INSPECTION PROCEDURES USED 87132	7. INSPECTION FOCUS AREAS 03.01 - 03.09		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Ana Mihail, M.S., RSO	4. TELEPHONE NUMBER (765) 298-4770
<input checked="" type="checkbox"/> Main Office Inspection Next Inspection Date: January 2019			
<input type="checkbox"/> Field Office Inspection _____			
<input type="checkbox"/> Temporary Job Site Inspection _____			

PROGRAM SCOPE

This was an unannounced routine inspection of the radiation oncology center associated with Community Hospital of Anderson and Madison County in Anderson, Indiana. The licensee operated a high dose-rate remote afterloader (HDR) unit under 10 CFR 35.600. While authorized to perform activities under 10 CFR 35.300, no such activities had been performed to date and the licensee had no plans to do so. Licensed activities were conducted only at the facility identified on the license. The licensee was staffed with one physician authorized user and one medical physicist and performed around 180 HDR fractions annually. HDR procedures were primarily breast cancer therapy procedures, with occasional prostate interstitial and gynecological cylinder procedures.

Performance Observations: The inspector observed daily HDR spot checks and one HDR administration. Licensee personnel described planning and approving HDR plans and source exchange and verification procedures. The inspector noted that the daily HDR spot checks did not include timer accuracy; instead, this test was performed weekly. The inspector reviewed written directives for HDR treatments and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of regulatory concern. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings. The inspector noted that the licensee did not maintain a radiation safety committee (RSC).

The inspector identified two violations of NRC requirements during this inspection. The licensee (1) failed to have a radiation safety committee to oversee all use of licensed materials as required by 10 CFR 35.24(f) and (2) failed to include timer accuracy in the daily HDR spot checks as required by 10 CFR 35.643(a)(1) and 10 CFR 35.643(d)(6). The licensee committed to corrective actions as described on Part 1 of this report.