FAX NUMBER: 313-436-2042 ☐ **VERIFY BY CALLING SENDER**

FROM: (SENDER) Debbie Pickura

TELEPHONE NUMBER: 630-829-9867 FAX NUMBER: 630-515-1259

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE

Dear Mr. Hillborn,

Please sign & review the attached Form 591 (Inspection report) and return the signed copy to me. Note that your license requires a weekly survey of the brachy storage room. This is more restrictive than other commitments I've seen. Your medical physicist can discuss this with me.

Best Regards,

Debbie Pickura

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address , by U.S. Mail. Thank you.

DATE,TIME	10/09 14:12
FAX NO./NAME	13134362042
DURATION	00:01:05
PAGE(S)	03
RESULT	OK
MODE	STANDARD ECM

TRANSMISSION VERIFICATION REPORT

TIME : 10/09/2008 14:13
NAME : USNRC REGION3 DNMS
FAX : 6305151259
TEL :
SER.# : 000A7J925770

18101 Oakwood Blvd.
Dearborn, MI 48123
Phone: 313-593-7125
Fax: 313-436-2042

OHMC-Dearborn

Fax

ph 313.593.7125

To: Debbie Piskura **From:** Richard Hillson

Fax: 630-515-1259 **Date:** 10-10-08

Phone: 630-829-2042 **Pages:** 2

Re: Attached Compliance Dnsp. Sheet **CC:**

☒ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

Debbie

I've signed the commitment form (see attached) also, PVI, I did validate that the instrument was removed from service & the corrective actions were implemented. If you need anything else, please don't hesitate to call. Rich Hillson

NRC FORM 591M PART 1
(10-2003) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Oakwood Hospital and Medical Center 18101 Oakwood Blvd. Dearborn, MI 48123-2500 REPORT NUMBER(S) 2008-001	U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-02051	21-04515-01	September 25-26, 2008

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. This 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.

_____ 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.
(Violations and Corrective Actions)

10 CFR 35.61(a) requires, in part, that a licensee calibrate the survey instrument used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following a repair that affects the calibration.

Contrary to the above, as of September 26, 2008, the licensee was using a Victoreen Model 290 survey instrument to show compliance with this part and 10 CFR Part 20, and this survey instrument had not been calibrated from July 10, 2007, through September 26, 2008 a period which exceeds annually. Specifically, this meter was used to perform patient surveys in accordance with Section 35.604(a) and was last used following an HDR treatment on September 23, 2008.

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	RICHARD HILLBOM	Richard Hillbom	10/10/2008
NRC INSPECTOR	Deborah A. Piskura	Deborah A. Piskura	10/09/2008

NRC FORM 591M PART 1 (10-2003)

NRC FORM 591M
PART 2
(10-2003) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Oakwood Hospital and Medical Center REPORT NUMBER(S) 2008-001	**Region III** **2443 Warrenville Road, Suite 210** **Lisle, Illinois 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-02051	21-04515-01	September 25-26, 2008

(Continued)

10 CFR 35.67(g) requires a licensee in possession of brachytherapy sources shall conduct a semi-annual physical inventory of all such sources in its possession.

Contrary to the above, the licensee failed to conduct semi-annual physical inventories of its brachytherapy sources since August 22, 2007.

Condition 22.A. of License No. 21-04515-01 requires in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application, dated July 25, 2001, with attachments.

Item 10.12, "Area Survey Procedures" of the application dated July 25, 2001, states that surveys for contamination and ambient exposure rates will be perfume in accordance with 10 CFR 35.70.

Number 2. states that all areas where radioactive materials are stored will be surveyed weekly for ambient exposure rates and for removable contamination.

Contrary to the above, ambient exposure rate surveys have not been performed of the bracytherapy source storage room, an area where radioactive materials are stored, since August 22, 2007, an interval exceeding weekly.

The licensee committed to immediately correct the above violations by performed the respective tasks ASAP. The licensee also committed to include the above items in the radiation therapy department quality report card. This mechanism requires the department to report the status of various aspects of the department's business, including survey instrument calibration, sealed source inventories, and area surveys to the hospital administration.

NRC FORM 591M PART 3
(10-2003) 10 CFR 2.201

Docket File Information

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Oakwood Hospital and Medical Center REPORT NUMBER(S) 2008-001	**Region III** **2443 Warrenville Road, Suite 210** **Lisle, IL 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-02051	21-04515-01	September 25-26, 2008

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87130, 87131, 87132	03.01 – 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	G 2	Jerry Drake, M.D., RSO	313-593-7335

[X] Main Office Inspection — Next Inspection Date: September 2010

[ ] Field Office

[ ] Temporary Job Site Inspection

PROGRAM SCOPE

This large hospital was authorized to use materials permitted in Sections 35.100, 35.200, 35.300, 35.400, 31.11, I-125 for the GliaSite system, and iridium-192 in an HDR unit. The nuclear medicine department was staffed with 9 technologists who performed approximately 700-800 diagnostic nuclear medicine procedures per month which included a full spectrum of diagnostic imaging studies. The licensee received unit doses from a licensed nuclear pharmacy and a Mo-99/Tc-99m generator for kit preparation. Typically in a year, the hospital treated 100 cases of hyperthyroidism, 10-15 cases of thyroid carcinoma, and 20 whole body CA follow up studies. Radioiodine was obtained from a licensed nuclear pharmacy in capsule form. The department retained the services of a consulting physicist to audit the radiation safety activities on a quarterly basis (last 8/20/2008).

The radiation therapy department was staffed with 4 authorized users, 2 medical physicists and 3 dosimetrists. The hospital had not used its Cs-137 sources for temporary implants since the previous inspection. Although authorized to use I-125 within the GliaSite Radiotheray System, the licensee had not used this material to date. The department used I-125 and Pd-103 for permanent prostate implants to treat approximately 30-40 cases per year. The department possessed an HDR unit and administered approximately 20 patient treatment series per year; these treatments were for gynecological cancers. All HDR patient treatments were administered by the attending AU, a dosimetrist and the medical physicist.

This inspection consisted of interviews with licensee personnel, a review of select records, tours of the, nuclear medicine, and radiation oncology departments, and independent measurements. The inspector observed the administration of several diagnostic nuclear medicine procedures. The inspection included observations of HDR safety checks, dose calibrator QA checks, security of byproduct material, use of personnel monitoring, and package receipts and surveys.

The inspector reviewed the licensee's report of a medical event (and subsequently retracted on in its letter dated August 20, 2008. The licensee initially reported to the HOO a medical event involving an I-131 dosage 35% greater than the prescribed dosage. Upon further investigation, the licensee's comparison of the initial activity of the I-131 capsule (2.17 mCi on 6/02/2008) to the time/date of administration (calculated 2.0 mCi at 11:14 am on 6/03/2008), it was not plausible to administer a dosage of 2.7 mCi on 6/03/2008 to the patient. Based on interviews with the technologist, a recording error on the paperwork is the most probable cause for the discrepancy in the dose assay results. The licensee implemented several corrective actions included retraining, dual verification of I-131 dosages, and random "time-out" audits of I-131 administrations.

Three violations of NRC requirements were identified during this inspection: (1) 35.61(a) failure to calibrate a survey meter used for HDR patient surveys annually (last 7/10/2007) (2) 35.67(g) failure to perform semi-annual inventories of Cs137 brachytherapy sources (last 8/22/2007); and (3) failure to survey the brachytherapy source room/storage area at weekly intervals as required by item,10.12 of license renewal application dated 7/25/2001 referenced in LC. 22.A. According to the RSO, these items had been forgotten. As corrective action the licensee committed during the on-site exit meeting to immediately perfume the tasks. In addition, the licensee will include these items in the Radiation Oncology Department's "quality report card" which is reported to hospital administration on a semi-annual basis.