

ENCLOSURE 6

INSPECTION RECORD

Region III

Inspection Report No. 2007-001

License No. 24-02490-03

Licensee (Name and Address):

Docket No. 030-02308

SSM DePaul Health Center
Department of Nuclear Medicine
12303 DePaul Drive
Bridgeton, MO 63044

Location (Authorized Site) Being Inspected: 12303 DePaul Drive, Bridgeton, MO

Licensee Contact: Thomas Phillip Bocchini, M.D., RSO Telephone No. 314-344-6350

Priority: 2 Program Code: 02230

Date of Last Inspection: 9/21/2005

Date of This Inspection: 7/23/2007

Type of Inspection: ☐ Announced ☒ Unannounced
☒ Routine ☐ Special
☐ Initial

Next Inspection Date 7/2009 ☒ Normal ☐ Reduced


Justification for reducing the routine inspection interval:

Summary of Findings and Actions:

- ☐ No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- ☐ Non-cited violations (NCVs)
- ☐ Violation(s), Form 591 issued
- ☒ **Violation(s), regional letter issued**
- ☐ Followup on previous violations

Inspector(s) 
Deborah A. Piskura

Date 8/10/2007

Approved 
John R. Madera, Chief, MIB

Date 8/15/07

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

(License amendments issued since last inspection, or program changes noted in the license)

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
49	11/29/2005	RSO change, new AU, new AMP
50	06/05/2006	license renewal
51	03/02/2007	new AMP, verbiage changes to various items in license

2. INSPECTION AND ENFORCEMENT HISTORY:

(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

No violations of NRC requirements were identified during the last inspection on 9/21/2005.

3. INCIDENT/EVENT HISTORY:

(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.) **NONE**

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

This licensee was a large hospital authorized to use licensed material permitted by Sections 35.100, 35.200, 35.300, 35.400 and Ir-192 in an HDR unit. The nuclear medicine department was staffed with four full-time technologists who performed approximately 20-30 diagnostic nuclear medicine procedures daily. The majority of the studies were bone, and gall bladder imaging. The department was open daily and on weekends for emergency on-call cases. The licensee received unit doses and bulk Tc-99m from a licensed radiopharmacy. The licensee had a separate nuclear cardiology group which was staffed with technologists who worked in the cardiology department on a rotating basis. The cardiology department performed approximately 10-15 cardiac studies daily. Typically, in a year the hospital treated 30-50 cases of hyperthyroidism using I-131 (capsule form). The licensee retained the services of a consulting physicist to audit the nuclear medicine radiation safety program on a quarterly basis.

The radiation therapy department was staffed with 1 contract medical physicist, one physician authorized user, and 1 dosimetrists. The department possessed an HDR unit and administered approximately 20 patient treatments per year; the majority of these treatments were for breast, and gynecological cancers. All HDR patient treatments were administered by the attending radiation oncologist and the medical physicist. Source exchange, maintenance, and repairs on the HDR unit were performed by the manufacturer. Typically in a year, the department

administered 5-10 treatments for thyroid carcinoma using NaI-131. Radioiodine was obtained from a licensed nuclear pharmacy in capsule form. The department also administered an average of 1-2 beta-emitting radiopharmaceutical dosages annually.

During this inspection, the inspector toured the nuclear medicine and radiation oncology departments, interviewed licensee personnel, observed activities in progress, performed radiation surveys around the hot lab and the HDR unit, and reviewed select records.

One violation of NRC requirements was identified concerning the licensee's failure to determine the TEDE to any other individuals (members of the public) from 12 patients whom the hospital released under the provisions of Section 35.75. The licensee released 12 patients between 11/28/2005 and 6/25/2007 who were each administered I-131 in quantities between 94.8 to 154.4 mCi. The inspector's review of written directives and dosage administration forms revealed that the licensee appeared to release these patients on the basis of survey results. Survey readings were recorded at the surface of the patient's abdomen and at 1 meter from the patient; maximum survey readings were recorded as 2-4 R/hr at the patient abdomen and 100-400+ mR/hr at 1 meter. Further interviews with members of the radiation oncology department confirmed that the licensee failed to determine the TEDE (by calculations) to any other individuals from exposure to these released patients was not likely to exceed 0.5 rem as required by Section 35.75(a). The licensee committed to develop a worksheet for determining/calculating the TEDE from released patients and provide instruction to the radiation oncology staff on Section 35.75 patient release requirements. Based on the inspector's calculations, the TEDEs for these released patients was between 215 millirem and 349 millirem; therefore the release of each of these patients would not likely exceed the 500 millirem TEDE limit in Section 35.75.

2. INSPECTION SCOPE

INSPECTION PROCEDURE(S) USED: 87130, 87131, 87132

INSPECTION FOCUS AREAS: 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, 03.08

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

The inspector performed direct radiation measurements in and around the licensee's hot labs and dose prep areas, and the HDR unit which indicated similar results as noted in the licensee's survey records, <2 mR/hour. Maximum levels were measured at the surface of the hospital's L-block, 0.4 mR/hr. Radiation levels in the unrestricted areas outside the hot lab and the scan rooms were at background (<0.02 mR/hr). These surveys confirmed that the licensee complied with Part 20 limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

(State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

A regional letter was issued to the licensee containing a notice of violation with the following citation:

10 CFR 35.75(a) states 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 0.5 rem.

Contrary to the above, between November 28, 2005, and June 25, 2007, the licensee administered unsealed sodium iodine-131 to twelve patients in quantities ranging from 94.9 millicuries to 154.4 millicuries and released these individuals from its control without determining or verifying that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem.

5. PERSONNEL CONTACTED:

[Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).

***#Patty Karfs, CMD, Dosimetrist**

+Chad W. Gerber, M.S, Medical Physicist

***Wally Fuhrman, CNMT, Supervisor, Nuclear Medicine**

Jerry Rump, Director, Inpatient Radiology

Joe Pekala, CNMT

#*Heather Raines, Interim Director, Oncology

***#Edwin Ernest, M.D., Clinical Director, acting for RSO who was on vacation**

+Corey Elliott, VP, Ambulatory Services

***Denise Larosa, Manager, Oncology**

***Debbie Daniels-Ellis, Director, Administrative Services and Risk Management**

Use the following identification symbols:

Individual(s) present at entrance meeting

* Individual(s) present at exit meeting

+Individual contacted by telephone