

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Mid Michigan Medical Center

Midland, MI 48670

REPORT NUMBER(S) 2006-00/ mid-002

2. NRC/REGIONAL OFFICE

U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4351

3. DOCKET NUMBER(S)

030-02013

4. LICENSEE NUMBER(S)

21-01549-02

5. DATE(S) OF INSPECTION

Oct. 16-18, 2006

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

- ☒ 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, 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)

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

NRC INSPECTOR

Deborah A. Piskura



10/18/06

Docket File Information
SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION

1. LICENSEE MidMichigan Medical Center REPORT 2006-001 & 2006-002		2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532					
3. DOCKET NUMBER(S) 030-02013		4. LICENSE NUMBER(S) 21-01549-02		5. DATE(S) OF INSPECTION Oct. 16-18, 2006			
6. INSPECTION PROCEDURES USED 87130, 87131, 87132 & 87133		7. INSPECTION FOCUS AREAS 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, and 03.08					
SUPPLEMENTAL INSPECTION INFORMATION							
1. PROGRAM CODE(S) 02231		2. PRIORITY G 2		3. LICENSEE CONTACT Larry Langrill, M.S., RSO		4. TELEPHONE NUMBER 989.849.3452	
<input checked="" type="checkbox"/> Main Office Inspection						Next Inspection Date: Oct. 2008	
<input type="checkbox"/> Field <u>Jeppesen Rad. Onc. Ctr. 3180 E. Midland Road, Bay City, MI</u>							
<input type="checkbox"/> Temporary Job Site _____							

PROGRAM SCOPE

This licensee was a large medical center, authorized to use licensed material permitted by Sections 35.100, 35.200, 35.300, 35.400, Ir-192 within HDR units, and Co-60 within a "Gamma Knife" unit. The nuclear medicine department was staffed with seven technologists who performed approximately 300-400 diagnostic nuclear medicine procedures per month. The licensee received unit doses from a licensed radiopharmacy. The hospital performed a full spectrum of nuclear diagnostic imaging studies. Typically, in a year the hospital administered 10 iodine-131 thyroid carcinoma therapies, 40-50 hyperthyroidism treatments, and 20-25 whole body CA follow up studies. The hospital obtained its I-131 in capsule form only. The department had not administered any beta-emitting radiopharmaceuticals since the previous inspection. The licensee retained the services of a consulting physicist to audit the nuclear medicine radiation safety activities on a quarterly basis.

The radiation therapy department was staffed with 3 medical physicists, 15-20 therapy technologists, and 5 physicians (authorized users). Cesium-137 sources were maintained in secured storage and had not been used since the previous inspection. The department also used I-125 and Pd-103 for permanent prostate implants to treat approximately 4-5 cases per year. The oncology department possessed two HDR units containing Ir-192 sources; one unit was based at the main hospital and the other unit transported to two customer locations on a weekly basis. The department administered approximately 250-300 patient HDR treatments per year; the majority of these treatments were for gynecological, lung and breast cancers. All HDR patient treatments were administered by the attending physician authorized user, the medical physicist, and a therapist (note that the physicist operated the controls to the HDR unit). All source exchange, maintenance, and repairs on the HDR unit were performed by the manufacturer.

The licensee also possessed a Leksell Gamma System Model 24001 Type C (gamma knife). The unit was used daily for treatment of various brain tumors and diseases. The Gamma Knife center was staffed with two medical physicists, three authorized users, 1 neurosurgeon, and three nurses. The licensee expected to replace the unit with the latest model in 2007. All source exchange, maintenance, and repairs on the gamma knife were performed by the manufacturer.

This inspection consisted of interviews with licensee personnel, a review of selected records, tours of the nuclear medicine and radiation oncology departments, and independent measurements. The inspector observed licensee nuclear medicine personnel prepare, assay and administer several unit doses for various imaging procedures. The inspection included observations of dose calibrator QA checks, package receipts and surveys, and area surveys. The inspector observed one HDR brachytherapy treatment at a field location and three patient treatments utilizing the gamma knife unit. The inspector reviewed the written directive for each procedure; observed the licensee performing daily QA checks and treatment planning; and observed the patient treatments and patient survey at the conclusion of the HDR treatment. The inspector also interviewed the physician authorized users and nurses who attended the patients.

The inspection included a review of the licensee's actions in response to the Order for Increased Controls (EA-05-090), dated Nov. 14, 2005. The results of the IC inspection were documented in IR 030-02013/2006003.