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
Elkhart General Hospital P. O. Box 1329 Elkhart, IN 46515-1111 REPORT 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
030-17305	13-18879-01	April 2-3, 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. 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)

Condition 18.A. of License No. 13-18879-01 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in application dated September 25, 2000. Item 10.4, of this application states that the licensee will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2. "Model Rules for Safe Use of Radiopharmaceuticals," Item 5, states do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

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	GREGORY S. LOSASSO		4/9/08
NRC INSPECTOR	Deborah A. Piskura		4/09/2008

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
Elkhart General Hospital 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
030-17305	13-18879-01	April 2-3, 2008

(Continued)

Contrary to the above, on April 3, 2008, a bottle of soda, a plastic cup and a thermal cup were found on top of a filing cabinet in the hospital's cardiac stress testing room 1, an area where radioactive material is used and radioactive waste is stored. Various dishes, silverware and tea were also found in a cabinet within Stress Room 1. Silverware and a toothbrush were found at a sink in the room. In addition chewing gum wrappers and an empty coffee cup were found in a trash bin.

Corrective actions for this violation will include providing training to the cardiology staff on the licensee's policies and procedures prohibiting eating and drinking in areas where radioactive materials are used and/or stored. Additional signs (prohibiting eating and drinking) will also be posted in the cardiology stress labs. The RSO and the cardiology manager will conduct additional unannounced audits of the cardiology stress rooms as a spot check to ensure staff do not eat/drink in the cardiac stress rooms. The RSO will also discuss this matter during the next Radiation Safety Committee meeting.

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Elkhart General Hospital REPORT **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
030-17305	13-18879-01	April 2-3, 2008

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87130, 87131, & 87132	03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, and 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	G 2	S. Lueng, Ph.D., RSO	574-423-7857

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

[ ] Field

[ ] Temporary Job Site

PROGRAM SCOPE

This licensee was a community hospital with authorization to use materials in Sections 35.100, 35.200, 35.300, 35.400, 35.500, and Ir-192 in two HDR units (however the licensee only possessed one HDR unit and transferred its late model unit to the manufacturer). The nuclear medicine department was staffed with 4 full-time and 1 temporary/agency technologists who performed approximately 200-250 diagnostic nuclear medicine procedures monthly. Nuclear medicine activities were performed in two separate areas within the main hospital (diagnostic studies within the radiology department and nuclear cardiology studies in the caridac center). The department received bulk Tc-99m and unit doses from a licensed nuclear pharmacy. Typically in a year, the hospital treated10 thyroid carcinoma cases, 50-60 cases of hyperthyroidism and 30 whole body CA follow up studies. Radioiodine was obtained from a licensed nuclear pharmacy in capsule form (only rarely, for patient-specific cases, the licensee used liquid I-131). The department had not administered any beta-emitting radiopharmaceutical dosages.

The radiation therapy department was staffed with 2 authorized medical physicists and 3 physicians (authorized users). The department used I-125 for permanent prostate implants to treat approximately 4-5 cases per year. The department possessed an HDR unit and administered approximately 200 patient treatment series per year; the majority of these treatments were for breast and gynecological cancers. All HDR patient treatments were administered by the attending radiation oncologist, the authorized medical physicist. Source exchange, maintenance, and repairs on the HDR unit were performed by the manufacturer

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

During the inspector's walk through of the hospital's cardiology department on April 3, 2008, she found gum wrappers and a coffee cup in two trash cans in cardiac stress testing room No. 1. The inspector also found a bottle of unopened diet soda, cups, dishes and silverware on or near a filing cabinet next to a container of radwaste. Additional silverware and a toothbrush were found at a sink. Nuclear cardiology patients were injected in this room on the day of the inspection; radwaste was stored in a labeled container within the room. The licensee planned to take the following corrective actions: (1) provide training for cardiology staff, (2)post additional signs prohibiting eating/drinking in the stress rooms, (3) discuss this matter at the next RSC meeting and (4) RSO/management will perform additional unannounced walk through tours.

Elkhart General

Operational/Non-Patient Information
Telecopier Transmittal Cover Sheet

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From: GREG LOSASSO

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