

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Harper University Hospital 3990 John R Street Detroit, MI 48201		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351	
REPORT NUMBER(S) 2006-001			
3. DOCKET NUMBER(S) 030-02045	4. LICENSEE NUMBER(S) 21-04127-02	5. DATE(S) OF INSPECTION March 29, 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 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)

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	<i>[Signature]</i>	3/29/06

[Handwritten initials]

Docket File Information
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1. LICENSEE Harper University Hospital REPORT 2006-001		2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532	
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6. INSPECTION PROCEDURES USED 87130, 87131, 87132, and 87122		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) 02240	2. PRIORITY G 2	3. LICENSEE CONTACT Richard N, Joyrich, M.D., RSO	4. TELEPHONE NUMBER 313.745.8585
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Main Office Inspection Next Inspection Date: Mar. 2008

Field _____

Temporary Job Site _____

PROGRAM SCOPE

This licensee was a 400-bed hospital, authorized to use licensed material permitted by Sections 35.100, 35.200, 35.300, 35.500. Although the hospital was authorized for 35.1000 material, limited to the GlinSite radiotherapy system, the hospital had not used this material to date. The hospital was also authorized to use various isotopes for R&D purposes and Cs-137 in a self-contained irradiator. The radiation therapy activities previously authorized under this licensee (35.400 and 35.1000) had been transferred to the radiation therapy department now operating under a separate NRC license as the Karmanos Cancer Center, License No. 21-04127-06.

The nuclear medicine department was staffed with eight full-time technologists who performed approximately 500-600+ diagnostic nuclear medicine procedures per month. Nuclear medicine activities were performed in two separate areas within the main hospital (diagnostic studies within the radiology department, and cardiac studies in the cardiac department). The licensee received unit doses and bulk Tc-99m from a licensed radiopharmacy. The hospital performed a full spectrum of nuclear diagnostic imaging studies. Typically, in a year the hospital administered 35+ iodine-131 thyroid carcinoma therapies and 100+ hyperthyroidism treatments. The hospital obtained its I-131 in capsule form only. The department administered 1-2 Sr-89 and Sm-153 dosages annually for treatment of metastatic bone disease. Occasionally, the department administered Bexstar and Zevalin treatments. The licensee retained the services of a consulting physicist to serve as a alternate RSO and to audit the radiation safety program on a quarterly basis.

This inspection consisted of interviews with licensee personnel; a review of selected records; tours of the nuclear medicine, nuclear cardiology, blood bank, and R&D labs; and independent measurements. The inspector observed licensee nuclear medicine personnel prepare, assay and administer several unit doses for various imaging procedures; the inspector also observed the administration of a Y-90 Zevalin therapeutic dosage. The inspection included observations of dose calibrator QA checks, security of byproduct material, use of personnel monitoring package receipts and surveys, and area surveys.