

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Detroit Medical Center
Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, MI 48201

REPORT NUMBER(S) 2012-001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-38328

4. LICENSE NUMBER(S)

21-03298-06

5. DATE(S) OF INSPECTION

October 19, 2012

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, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(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 in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

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, Health Physicist	<i>Deborah A. Piskura</i>	10/19/2012
BRANCH CHIEF	Tamara E. Bloomer, Chief, MIB	<i>Tamara Bloomer</i>	10/25/12

Docket File Information

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<p>3. DOCKET NUMBER(S)</p> <p>030-38328</p>	<p>4. LICENSE NUMBER(S)</p> <p>21-03298-06</p>	<p>5. DATE(S) OF INSPECTION</p> <p>October 19, 2012</p>
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<p>6. INSPECTION PROCEDURES USED</p> <p>87125 & 87126</p>	<p>7. INSPECTION FOCUS AREAS</p> <p>03.01 - 03.07</p>
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SUPPLEMENTAL INSPECTION INFORMATION

<p>1. PROGRAM CODE(S)</p> <p>03210</p>	<p>2. PRIORITY</p> <p>2</p>	<p>3. LICENSEE CONTACT</p> <p>Thomas Mangner, Ph.D., RSO</p>	<p>4. TELEPHONE NUMBER</p> <p>(313) 993-2618</p>
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Main Office Inspection Next Inspection Date: Oct. 2014

Field Office Inspection

Temporary Job Site Inspection

PROGRAM SCOPE

This was the initial inspection performed in accordance with MC 2800 for DMC's -06 license authorizing the production and handling of radiochemicals. The licensee operated two cyclotron units, one older unit was used to produce C-11, and O-15 (research products) and one new unit was used to produce F-18 FDG. Four individuals serving as cyclotron engineers operated the cyclotrons. The cyclotrons were located within the DMC Children's Hospital PET center. As material was produced, it was transferred via shielded lines to hot cells. This licensee only produced materials for use by Children's Hospital; therefore, the licensee did not operate a license for commercial distribution.

Individuals operating the cyclotron as well as the individuals handling the materials wore whole body and extremity (right and left rings) dosimetry. The maximum whole body and extremity exposures were reported (in millirem) as follows:

	YTD 2012
Whole body	218
Extremity	4,840

This inspection consisted of interviews with select licensee personnel; a review of select records; and independent measurements. The inspector toured the facility and observed operations. Licensee personnel demonstrated cyclotron operations and maintenance, F-18 chemistry, purification, and QA/QC.