

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Detroit Medical Center Children's Hospital of Michigan 3901 Beaubien Boulevard Detroit, MI 48201 REPORT NUMBER(S) 2014-001	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 December 19, 2014

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:


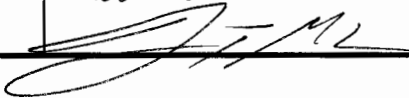
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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		12/19/14
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		12/24/14

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Detroit Medical Center Children's Hospital of Michigan 3901 Beaubien Boulevard Detroit, MI 48201</p> <p>REPORT NUMBER(S) 2014-001</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>
---	---

<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>December 19, 2014</p>
---	--	--

<p>6. INSPECTION PROCEDURES USED</p> <p>87125</p>	<p>7. INSPECTION FOCUS AREAS</p> <p>03.01-03.07</p>
---	---

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 J. Mangner, Ph.D., RSO</p>	<p>4. TELEPHONE NUMBER</p> <p>(313) 993-0820</p>
--	-----------------------------	---	--

Main Office Inspection Next Inspection Date: Dec. 2016

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a cyclotron production licensee. The licensee operated two cyclotron units: one older unit was used to produce C-11, and O-15 (research products) and one new unit (PET Trace 880 Self-shielded Cyclotron) was used to produce F-18 FDG. Two individuals served as cyclotron engineers. 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 (License No. 21-03298-05); therefore, the licensee did not operate a license for commercial distribution. Typically, the licensee initiated production activities at 5:00 am and produced 8-10 patient dosages of F-18 FDG. The licensee retained the services of a consulting physicist who audited the radiation safety program on a quarterly basis (last 11/11/2014, with minor findings).

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 2014	2013	2012
TEDE	270	305	384
SDE	4,010	8,620	5,630

This inspection consisted of interviews with select licensee personnel; a review of select records; and independent measurements. The inspector toured the facility and observed production operations, use of personnel monitoring, personnel surveys, product QA/QC, dose dispensing and assays. During early morning hours staff may be reached at 313-993-0820 or 313-993-6086. No violations of NRC requirements were identified during this inspection.