NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
VHS Children's Hospital of Michigan, Inc. 3901 Beaubien Street Detroit, MI 48201 REPORT NUMBER(S) 2017001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38328	21-03298-06	MARCH 3RD, 2017

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 violations(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	Ryan Craffey	Ryan Craffey	3/3/17
BRANCH CHIEF	Aaron McCraw		3/9/17

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38328	21-03298-06	March 3, 2017

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87127	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
03210	2	Thomas Magner - RSO	(313) 993-2618

☑ Main Office Inspection Next Inspection Date: 03/03/2019

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a cyclotron facility authorized for the production of PET radiopharmaceuticals using one of two cyclotrons at the DMC Children's Hospital PET Center in Detroit, Michigan. The licensee used its newer unit, a GE PETtrace 880, to produce around 500 mCi F-18 FDG daily exclusively for administration under the hospital's other byproduct materials license (21-03298-05 / 030-13166). The licensee used the older unit to produce C-11 and O-15 for research and development. Four individuals were involved in the production of PET isotopes, and began production of F-18 around 5:00 am each morning, with doses transferred to the PET Center around 7:30 am. The staff can be contacted at 313-993-0820 or 313-993-6086 during these early morning hours. The licensee contracted with the cyclotron manufacturer for equipment maintenance, and a medical physics consultant to review the content and implementation of the radiation safety program.

PERFORAMNCE OBSERVATIONS

The inspector toured the PET Center in Detroit to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector observed the production of F-18 FDG, and conducted independent surveys of restricted and unrestricted areas during and after production. The inspector interviewed the licensee's staff to discuss implementation of licensee procedures for radiopharmaceutical production and QA, survey instrument and radiation monitor use, and radioactive waste handling. The inspector found that the staff were knowledgeable and conscientious of radiation protection principles, and implemented adequate engineering and process controls to minimize occupational radiation exposures.

The inspector reviewed a selection of records, including dose calibrator quality control records, area monitor and survey instrument calibrations, air effluent monitoring data, quarterly program audits, refresher training materials, and personnel dosimetry, which indicated annual exposures of 450 mrem whole-body and 2916 mrem extremity in 2015, and 313 mrem whole-body and 2428 mrem exremity in 2016 through November 30 (the latest date for which dosimetry reports were available from the provider).

No violations of NRC requirements were identified as a result of this inspection.