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
Genesys Hurley Cancer Institute 302 Kensington Avenue Flint, MI 48503 REPORT NUMBER(S) 2016-001	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
030-36106	21-32322-01	APRIL 28TH 2016

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	4/28/16
BRANCH CHIEF	Aaron McCraw		5/2/16

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
030-36106	21-32322-01	April 28, 2016

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87132	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Ahmed Akl, MD - RSO	(810) 762-8490

☑ Main Office Inspection Next Inspection Date: 04/28/2018

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a standalone cancer center authorized to use byproduct material for therapeutic purposes at its facility in Flint, Michigan. At the time of the inspection, the licensee treated a wide variety of cancers using its HDR unit, averaging two to three patients monthly. The licensee administered I-131 capsules for thyroid cancer a few times a year, and had performed nine Ra-223 Xofigo injections since the last inspection, though none since September 2014. The licensee's staff performed manual brachytherapy at the main hospital (under the hopsital's license), and participated in the hospital's quarterly Radiation Safety Committee. The licensee also retained the services of a medical physics consultant to audit the use of unsealed material on-site.

PERFORMANCE OBSERVATIONS

The inspector toured the cancer center in Flint to evaluate the licensee's implementation of measures for materials security, hazard communication, and exposure control. The inspector performed independent surveys of the facility and found no evidence of residual contamination or exposures to members of the public in excess of regulatory limits. The inspector was unable to observe the conduct of any licensed activities, as none were scheduled for the day of the inspection. Instead, the licensee's staff demonstrated the implementation of procedures for the receipt of packages containing radioactive material, I-131 dose preparation, administration and waste handling, area surveys, HDR daily, monthly and quarterly checks, HDR treatment planning and administration, and procedures for emergencies involving the HDR unit. Through these demonstrations and discussions, the inspector found that the licensee's staff was knowledgeable of radiation protection principles and regulatory requirements.

The inspector also reviewed a selection of relevant records, including written directives, treatment plans and verifications for I-131 administrations, Xofigo injections, and a variety of HDR cases performed since the last inspection. The inspector also reviewed a selection of quarterly consultant audits, training documentation including HDR emergency drills, and personnel dosimetry, which indicated that annual occupational exposures were well below regulatory limits.

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