

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Genesys Hurley Cancer Institute 302 Kensington Avenue Suite 114 Flint, MI 48503 REPORT NUMBER(S) 2018001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-36106	4. LICENSE NUMBER(S) 21-32322-01	5. DATE(S) OF INSPECTION March 29, 2018	

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)
Contrary to 10 CFR 35.643(d)(6), on March 28 and March 29, 2018, the licensee failed to assure proper timer accuracy of the licensee's high dose-rate remote afterloader (HDR) unit prior to patient treatment, which is required to be performed before the first use of the HDR on a given day in accordance with 10 CFR 35.643(a)(1). This is a Severity Level IV violation.

As corrective action, on March 29, 2018, the licensee updated its HDR start-up procedure and daily quality assurance checklist to include a timer accuracy test.

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	Ibrahim Abdulkay, Ph.D	<i>Ibrahim Abdulkay</i>	4/16/18
NRC INSPECTOR	Edward F. Harvey	<i>Edward F. Harvey</i>	4/16/18
BRANCH CHIEF	Aaron T. McCraw	<i>Aaron T. McCraw</i>	04/16/2018

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Genesys Hurley Cancer Institute 302 Kensington Avenue Suite 114 Flint, MI 48503 REPORT NUMBER(S) 2018001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
---	---

3. DOCKET NUMBER(S) 030-36106	4. LICENSE NUMBER(S) 21-32322-01	5. DATE(S) OF INSPECTION March 29, 2018
--------------------------------------	---	--

6. INSPECTION PROCEDURES USED 87131 & 87132	7. INSPECTION FOCUS AREAS All
--	--------------------------------------

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Ibrahim Abdulhay, PhD - RSO	4. TELEPHONE NUMBER (810) 762-8490
---------------------------------	----------------------	--	---

Main Office Inspection Next Inspection Date: March 29, 2020

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a cancer center authorized to use byproduct material for therapeutic medical procedures under 10 CFR 35.300 and 35.600 at its facility in Flint, Michigan. At the time of the inspection, the licensee treated a wide variety of cancers using its HDR unit at a frequency of four to five patients per month. The licensee also administered approximately one therapeutic dose of iodine-131 (I-131) per month and treated two patients with radium-223 dichloride (Xofigo®) since the last inspection. The licensee retained the services of a medical physics consultant to audit the use of unsealed material.

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 all scheduled procedures had been completed prior to the start 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 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.

One violation of NRC requirements, described in Part 1 of this report, was identified during this inspection.