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
Karmanos Cancer Center 4100 John R Street Detroit, MI REPORT NUMBER(S) 2019001	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
030-09376	21-04127-06	4/2&3/19

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	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	4/11/19
BRANCH CHIEF	Aaron T. McCraw		4/12/19

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87133 & 87137	03.01 through 03.07 & 03.02.01 through 03.02.06

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02310	2	Joseph Rakowski, Ph.D., RSO	(419) 324-6748

☑ Main Office Inspection Next Inspection Date: 04/02/2021

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of the licensee's radiation protection program. At the time of the inspection, the licensee actively used a gamma stereotactic radiosurgery (GSR) unit, a teletherapy unit for total body irradiations, and a high dose-rate remote afterloader (HDR) unit. The licensee treated two to three patients per week with each unit, on average. The licensee also performed around six prostate seed implants per year, and actively administered radium-223 Xofigo to prostate cancer patients, and technetium-99m for breast lymphoscintigraphy. The licensee also possessed a GammaBeam panoramic irradiator for the irradiation of biological materials and radiation biology studies. However, the unit, which remained in storage pending disposal, had not been used since July 6, 2010. The licensee began to conduct Lutathera Lu-177 treatments in April 2018. In addition, the licensee conducted Lu-177 anti-prostate specific membrane antigen clinical trials.

Performance Observations

The inspector: (1) observed that the licensee secured licensed material; (2) noted that the licensee stopped using manual brachytherapy (10 CFR 35.400) in September 2018; (3) observed licensee survey meters that were calibrated; (4) noted that the licensee took action to prevent a similar medical event that occurred on 11/9/18 involving a Lutathera treatment (i.e., the licensee uses a pump to move the Lutathera into the patient rather than the force of gravity); (5) used an NRC-owned, calibrated survey meter to conduct independent ambient exposure rates at selected surfaces in a hot lab and there were no concerns; (6) reviewed records for selected Lutathera treatments including, in part, dual independent means to verify the identity of patients prior to administration, post treatment patient ambient exposure rates to determine if the patient is releasable, and use of a dose calibrator to measure the residual activity as a means of determining how much Lutathera went into the patient; (7) observed preparation and administration of Lutathera; (8) observed an authorized person demonstrate how he would respond to a Lutathera spill based on a scenario posed by the inspector and there were no concerns; (9) reviewed dosimeter badge records for 2017 through 2019 to date, and the whole body and extremity badge results were well below the annual dose limits; (10) reviewed selected records for GSR treatments and there were no concerns; (11) noted that the GSR unit was maintained, adjusted, and repaired by the manufacturer; (12) reviewed selected records for HDR treatments and there were no concerns; and (13) observed a total body teletherapy treatment using a Gammabeam 500 Total Body Irradiator and there were no concerns. No violations of NRC requirements were identified as a result of this inspection.