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
American Oncologic Associates of michigan, P.C. d/b/a 21st Century of michigan REPORT NUMBER(S) 2019001	Region III 2443 Warrenville Rd., Suite 210 Lisle, IL 60532 Select a location (Use keyboard arrows to select). . .

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-33134	21-26488-01	4/1 and 2/19

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.	4/2/19
BRANCH CHIEF	Aaron T. McClean		4/9/19

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
American Oncologic Associates of Michigan, P.C. d/b/a 21st. Century Oncology of Michigan 70 Fulton St., Pontiac, 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
030-33134	21-26488-01	4/1&2/2019

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87132 & 87131	03.01 through 03.08 & 03.01 through 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230, 02200	2	Teamour Nurus	(248) 410-8011

☑ Main Office Inspection Next Inspection Date: 04/01/2021

☑ Field Office Inspection 4550 Investment Dr., #B111, Troy, MI

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection of the licensee's radiation protection program with facilities in Pontiac and Troy, Michigan. The licensee's work hours were Monday through Friday 8:00 am to 5:00 pm for both locations. The licensee performed high dose rate remote afterloader (HDR) brachytherapy under 10 CFR 35.600 at both locations. In March of 2019, the licensee began administering Lutathera Lutetium -177 at the Troy facility. The licensee had not administered Samarium-153 yet. The licensee was staffed with one full-time oncologist, a dosimetrist, and an authorized medical physicist (AMP) at each location. At the Troy facility, the licensee performed about five Xofigo treatments per year. At the Pontiac location, the licensee conducted about 14 HDR gynecological, breast, and superficial skin cancer treatments.

Performance Observations

The inspector: (1) noted that the licensee implemented corrective actions to prevent the two violations that were identified during the last inspection (i.e., the licensee modified the current electronic written directive form and separated the written directive section from the rest of the medical physics procedures section of the form and trained the users on the new work flow with verification of the mandatory signature by the authorized user and the AMP before the procedure); (2) used an NRC-owned, calibrated survey instrument to conduct a comparative ambient exposure rate survey, and the licensee and the inspector measured 0.3 milliRoentgen per hour at selected surfaces of the HDR unit at the Pontiac location; (3) noted that the licensee had 2 calibrated survey meters at the Pontiac location; (4) observed that the licensee had emergency equipment for the HDR unit at the Pontiac facility, including a lead pig and forceps; (5) observed an AMP demonstrate how he conducted post administration radiation surveys of the HDR unit and the patient to ensure that the patient does not have the source in the patient's body and to ensure that the sealed source is fully shielded in the HDR unit; (6) observed that the licensee's Elekta Oncentra software was Version 4.5.3 at both locations; (7) observed that the licensee secured licensed material; (8) reviewed selected records regarding HDR treatments and there were no concerns; (9) reviewed selected records regarding Lutathera and Xofigo treatments and there were no concerns; (10) reviewed records of the licensee's annual audits of its radiation protection program for both locations, and there were no concerns; (11) reviewed dosimeter badge records, and the doses were well below the annual regulatory limits; and (12) observed a complete prostate HDR treatment, and there were no concerns.