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
Radiation Oncology Associates, P.C. 7910 W Jefferson Blvd. Ste. 110 Fort Wayne, IN 46804 REPORT NUMBER(S) 2021001	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
030-36814	13-32551-01	June 24, 2021, with in-office review through July 15, 2021

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)

Contrary to 10 CFR 35.40(a), on January 6, 2020, the licensee treated a patient with a therapeutic dose from a high dose-rate remote afterloader (HDR) containing an Ir-192 sealed source, but the Authorized User failed to sign and date the written directive before the administration. As corrective action, the licensee will ensure that relevent documents, including written directives are signed prior to starting treatments.

Contrary to 10 CFR 20.1101(c), in 2019 and 2020, the licensee failed to perform a review of radiation safety program content and implementation at least annually. As corrective action, the licensee plans to adopt applicable portions of the model audit in Appendix L of NUREG-1556, Volume 9, and perform an audit by September 2021.

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	J. JAMES GORDON DABR		7/28/2021
NRC INSPECTOR	Jason D. Draper, Health Physicist	Jason D. Draper Digitally signed by Jason D. Draper Date: 2021.07.19 14:33:24 -05'00'	
BRANCH CHIEF	Michael A. Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.07.20 06:44:32 -05'00'	

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Radiation Oncology Associates, P.C.	030-36814	13-32551-01

4. Report Number(s):	5. Date(s) of Inspection:
2021001	June 24, 2021, through July 15, 2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Jason Draper	02230	2	IP 87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
James Gordon, Ph.D., RSO	james.gordon@usa.genesiscare.com	313-718-1227

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☑ Announced ☐ Non-Routine ☐ Unannounced	☑ Main Office ☐ Field Office ☐ Temporary Job Site ☐ Remote	June 24, 2023 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced, routine inspection of an oncology center in Fort Wayne, Indiana, authorized to use Ir-192 sealed sources in an Elekta, Inc. microSelectron 106.990 high dose rate (HDR) remote afterloading brachytherapy device. The licensee had three authorized users (AUs) and three authorized medical physicists (AMPs) who routinely performed work under the license. The licensee treated approximately 25-30 gynecological cancer patients per year using the HDR with tandem and ovoid (T&O), cylinder, and interstitial applicators. There were no treatments occurring at the time of the inspection.

Due to the Covid-19 public health emergency, the inspector contacted the licensee prior to the inspection to ensure an on-site inspection could be performed safely. The inspector observed the AMP demonstrate HDR daily spot checks and security of the material. The inspector also interviewed two AMPs with respect to written directives, applicator setup and use, HDR maintenance and testing, emergency procedures, and training, and determined that the AMPs were knowledgeable with respect to their duties. The inspector reviewed a sample of six written directives covering uses of each of the three types of applicators. Through this review, the inspector identified that on January 6, 2020, the licensee failed to have a signed and dated written directive prior to administering the first fraction of an HDR therapy using a T&O applicator. Specifically, the written directive, as well as the treatment plan, were prepared and the patient was treated, but the written directive was not signed and dated until January 13, 2020. This constituted a violation of 10 CFR 35.40(a). As a corrective action, the RSO stated that his staff will ensure that all relevant documents, including written directives, are signed prior to starting treatments.

The inspector also reviewed a selection of records including source receipt and exchange, HDR maintenance and testing, and dosimetry. The inspector identified that the licensee had not performed any periodic reviews of radiation safety program content and implementation since the last inspection in 2018. This constituted a violation of 10 CFR 20.1101(c). As a corrective action, the RSO stated that he will adopt applicable portions of the model audit found in NUREG-1556, Volume 9, Appendix L, and perform the 2021 audit by September 30, 2021.

Two Severity Level IV violations were identified as a result of this inspection.