

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Arch Cancer Care
12855 N Forty Dr
Ground Level
St. Louis MO 63141

REPORT NUMBER(S) 2021001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-39196

4. LICENSE NUMBER(S)

24-35567-01

5. DATE(S) OF INSPECTION

April 14, 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)

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	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman <small>Digitally signed by Zahid M. Sulaiman Date: 2021.04.16 13:19:20 -05'00'</small>	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski <small>Digitally signed by Michael A. Kunowski Date: 2021.04.19 06:37:50 -05'00'</small>	



Materials Inspection Record

1. Licensee Name: Arch Cancer Care		2. Docket Number(s): 030-39196		3. License Number(s) 24-35567-01	
4. Report Number(s): 2021001			5. Date(s) of Inspection: April 14, 2021		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 2200		8. Priority: 3	9. Inspection Guidance Used: 87131
10. Licensee Contact Name(s): Edward Kline, ARSO		11. Licensee E-mail Address: ed@uscancertherapies.com		12. Licensee Telephone Number(s): 505-980-1314	
13. Inspection Type: <input checked="" type="checkbox"/> Initial <input type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input checked="" type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 04/14/2024 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was an announced remote initial inspection of a cancer care clinic authorized to use of radium-223 dichloride (Ra-223), Xofigo for medical purposes permitted by 10 CFR 35.300. The licensee was staffed with an authorized user/RSO and an associate radiation safety officer (ARSO). The licensee administers therapy dose one week a month. Since February 23, 2021, licensee administered Ra-223, Xofigo to three patients. Recommend next inspector contact the ARSO to schedule for a routine inspection, since the RSO/ARSO are only available at the cancer care clinic when the patient treatment is scheduled.

PERFORMANCE OBSERVATIONS

This inspection was conducted virtually through the Microsoft Team meeting and consisted of interview with select licensee personnel, a review of select records, and an observation of security of the materials. Through Microsoft Team meeting, the inspector observed the ARSO conduct a physical inventory of sealed sources, and all sources were accounted for. The inspector had the ARSO demonstrate the dose calibrator constancy check, package receipt procedures, the area surveys, proper handling of radioactive waste and disposal procedures, and spill response, with no issue noted. The inspector had the ARSO described the Ra-223 treatment procedures. The inspector reviewed selected written directives and therapy procedures. Through these demonstrations and other discussion, the inspector found that the licensee personnel was knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

The inspector reviewed the following records: annual audit, package receipts, waste disposal records, radiation safety training, linearity, accuracy, and geometry test of the dose calibrator, instrument calibration, sealed source leak tests and inventory, area surveys, wipe tests, and dosimetry record.

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