

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

ARK Cardiovascular & Arrhythmia Center, PLC
6050 Greenfield Road
Suite 101
Dearborn, MI 48126

REPORT NUMBER(S) 2020001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-38647

4. LICENSE NUMBER(S)

21-35069-01

5. DATE(S) OF INSPECTION

February 24, 2020;
Exit March 25, 2020

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)

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	Edward F. Harvey	Edward Harvey Digitally signed by Edward Harvey Date: 2020.03.26 07:23:02 -04'00'	3/26/2020
BRANCH CHIEF	Robert Ruiz	 Digitally signed by Robert Ruiz Date: 2020.03.26 07:35:51 -05'00'	

Docket File Information

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3. DOCKET NUMBER(S) 030-38647	4. LICENSE NUMBER(S) 21-35069-01	5. DATE(S) OF INSPECTION February 24, 2020; Exit March 25, 2020	
6. INSPECTION PROCEDURES USED 87130	7. INSPECTION FOCUS AREAS All		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02220	2. PRIORITY 3	3. LICENSEE CONTACT Ray Carlson, RSO	4. TELEPHONE NUMBER (734) 395-7361
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☒ Main Office Inspection Next Inspection Date: February 24, 2023

☒ Field Office Inspection 29201 Telegraph Road, Southfield, MI

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of a private cardiology clinic authorized to possess and use unsealed byproduct material for diagnostic medical procedures at their locations in Dearborn and Southfield, Michigan. The in-office review included an evaluation of the licensee's well counter quality assurance procedures. The licensee employed one nuclear medicine technologist (NMT) who performed approximately five nuclear stress tests per day, on Mondays through Thursday at the office in Dearborn. Although authorized, the inspector verified that the licensee had not yet conducted licensed activities at neither the location in Southfield, nor temporary job sites. The radiation safety officer (RSO) stated that an amendment request will be filed to have the Southfield location removed from the license because the licensee abandoned their plans to use that building. The licensee retained the services of a medical physics consultant for instrument calibrations, quarterly program audits, and RSO oversight.

The inspector toured the licensee's facility in Dearborn to evaluate the licensee's measures for material security, hazard communication, and exposure control. The inspector observed one diagnostic administration of licensed material for a stress test and noted that the NMT wore dosimetry and appropriate personal protective equipment, assayed the dose, and verified patient identity prior to the administration. The inspector observed the NMT demonstrate package receipt procedures, dose calibrator quality control, and area survey procedures. The NMT also demonstrated adequate knowledge of radiation protection principles and emergency procedures through interviews with the inspector.

The inspector reviewed a selection of licensee records, including quarterly audits, source inventories, survey meter calibration records, package receipt logs, and dosimetry with no issues noted. In addition, the inspector performed independent surveys, which revealed no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits. In addition, the inspector confirmed that no licensed activities were conducted in Southfield by a site visit, which included surveys of pertinent areas included on the facility diagram submitted to the NRC.

No violations of NRC requirements were identified during this inspection.