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
Elkhart General Hospital P.O. Box 1329 Elkhart, IN 46515-1111 REPORT NUMBER(S) 2018001	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
030-17305	13-18879-01	08/30/2018

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	Dennis P. O'Dowd	Dennis P. O'Dowd	08/30/2018
BRANCH CHIEF	~~Geoffrey Warren, Acting Chief~~ Daniel L. McGrath		9/24/18

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
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3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-17305	13-18879-01	August 30, 2018

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87132	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Liang (Larry) Q. Wang, M.S.	(574) 389-7374

☑ Main Office Inspection Next Inspection Date: 8/30/2020

☑ Field Office Inspection cardiac suite, Arcade St, Elkhart, IN &

☐ Temporary Job Site Inspection cardiac clinic, S. Napponee St., Elkhart, IN

PROGRAM SCOPE

This was an unannounced routine inspection of a 180-bed hospital authorized to use byproduct material under 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600 and 35.1000 at its main facility and 35.200 (for cardiac imaging) at two satellite locations in Elkhart, Indiana. A staff of five nuclear medicine technologists performed a full spectrum of approximately 8-10 diagnostic administrations per day of radiopharmaceuticals at its main facility, 6 diagnostic administrations daily at the South Nappanee location, and 4 diagnostic administrations daily at the Arcade location. The licensee performed approximately 2-3 therapeutic administrations a month using I-131 capsules at the main facility. Since the last inspection, only one Y-90 microsphere treatment was administered. The licensee discontinued its brachytherapy program in 2015 (with all sources transferred in February 2018). The licensee's radiation oncology department performed 2 fractionated HDR since the last inspection, and discontinued its HDR program as of August 2017. The licensee maintained a quarterly Radiation Safety Committee, and the RSO reviewed the content and implementation of the radiation safety program annually.

PERFORMANCE OBSERVATIONS

The inspector toured all locations listed on the license to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector observed several diagnostics studies at the main facility and at the South Nappanee clinic; no therapeutic administrations or procedures were performed during the inspection. The inspector conducted independent and confirmatory surveys, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The licensee's nuclear medicine staff demonstrated the implementation of procedures for use of radiopharmaceuticals, as well as procedures for package receipt, dose preparation, waste handling, and spill response. The licensee's staff demonstrated and discussed preparation for and administration of Y-90 SIR-Sphere. The inspector reviewed the licensee's records for administrations of byproduct material requiring a written directive, including the two HDR treatments administered during the review period, numerous I-131 treatments, and the one SIR-Sphere therapy, and reviewed records of brachytherapy source transfers and disposals during the review period. The inspector also reviewed a selection of nuclear medicine records, personnel dosimetry, and quarterly audits.

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