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
QHG of Indiana, Inc. 7950 West Jefferson Blvd. Fort Wayne, IN 46804-1677 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
030-01594	13-01535-01	March 7, 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	03/07/2018
BRANCH CHIEF	Aaron T. McCraw		3/22/18

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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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
02240	2	Randall J. Phillips, M.D., RSO	(260) 435-7291

☑ Main Office Inspection Next Inspection Date: 03/07/2020

☑ Field Office Inspection 7916 West Jefferson Boulevard, Fort Wayne, IN

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection of a regional hospital authorized to use byproduct material for medical purposes at its campus in Fort Wayne, Indiana. The licensee was authorized to perform Y-90 microspheres, temporary brachytherapy implants, and a full spectrum of therapeutic and diagnostic radiopharmaceutical administrations at the main hospital, and diagnostic uses only at its heart clinic, in another building on its campus. The licensee has not performed brachytherapy implants since 2012. The licensee retained the services of a medical physics consultant to review the content and implementation of its program on a quarterly basis, and its Radiation Safety Committee met quarterly.

PERFORMANCE OBSERVATIONS: The inspector toured the facilities at 7950 and 7916 West Jefferson Boulevard to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector observed the preparation and administration of numerous diagnostic procedures at both facilities, including PET, a HIDA study, and cardiac studies at the main hospital, and cardiac studies at the heart clinic. The inspector also observed the receipt of packages containing radioactive material and handling of radioactive waste by nuclear medicine staff. The inspector found that the licensee's staff handled material safely and wore appropriate personal protective equipment and dosimetry. The staff also demonstrated the implementation of procedures for area surveys and spill response. In addition, as no therapeutic procedures took place on the day of the inspection, the staff demonstrated its procedure for preparation, use, and follow-up of Y-90 Sir-Spheres treatments. The inspector found through these observations, demonstrations, and various discussions that the licensee's staff was knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed a selection of written directives for Y-90 Sir-Spheres, and I-131 and Ra-223 therapies, as well as routine nuclear medicine records, dosimetry reports, quarterly audits, RSC meeting minutes, and documentation of relevant staff training. The inspector did not identify any issues in the records reviews. The inspector conducted independent surveys of the licensee's areas of use and found no evidence of residual contamination or exposures to members of the public in excess of regulatory limits.

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