

## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

## 1. LICENSEE/LOCATION INSPECTED:

QHG of Indiana, Inc.  
7950 West Jefferson Blvd.  
Fort Wayne, IN 46804-1677

REPORT NUMBER(S) 2016002

## 2. NRC/REGIONAL OFFICE

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

## 3. DOCKET NUMBER(S)

030-01594

## 4. LICENSE NUMBER(S)

13-01535-01

## 5. DATE(S) OF INSPECTION

Oct. 21, 2016

## 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.

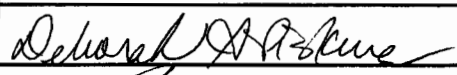
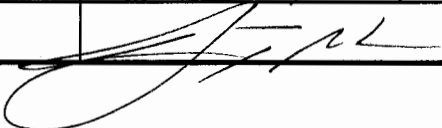
Non-cited violation(s) were discussed involving the following requirement(s):

- ☐ 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	Deborah A. Piskura, Senior Health Physicist		10/21/16
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		10/31/16

**Docket File Information**

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3. DOCKET NUMBER(S)

030-015944

4. LICENSE NUMBER(S)

13-01535-01

5. DATE(S) OF INSPECTION

Oct. 21, 2016

6. INSPECTION PROCEDURES USED

87132

7. INSPECTION FOCUS AREAS

03.01, 03.02, 03.06, 03.07, and 03.08 limited to Y-90 admin

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)

02240

2. PRIORITY

2

3. LICENSEE CONTACT

Randall J. Phillips, M.D., RSO

4. TELEPHONE NUMBER

(260) 435-7291



Main Office Inspection

Next Inspection Date: unchanged



Field Office Inspection



Temporary Job Site Inspection

**PROGRAM SCOPE**

This was a followup inspection conducted to review the licensee's corrective actions to escalated enforcement involving a violation of 10 CFR 35.41(a)(2)/35.41(b)(2). The licensee was cited for the failure to develop written procedures to provide high confidence that each yttrium-90 (Y-90) administration was in accordance with the written directive. The licensee's procedures for Y-90 treatments did not specify the survey instrumentation to be used to measure the quantity of the Y-90 remaining in the treatment vial in order to determine/calculate the dosage administered to the patient. For two dosages, the licensee used a survey instrument that was not capable of measuring residual Y-90 in the delivery set in order for the staff to calculate the final dosage administered. The licensee's corrective actions included: (1) designating the type of survey instrument to be used for Y-90 procedures; (2) revising its procedures (effective 1/29/2016) to specify the type of survey instrument to be used for Y-90 procedures; (3) provided training to the nuclear medicine staff on the change to survey instrumentation and the revised procedure; and (4) discussing these changes during the 8/26/2016 radiation safety committee meeting.

This inspection consisted of interviews with licensee personnel, a review of selected records (written directives, surveys and treatment worksheets), a tour of the nuclear medicine department, and observations of survey instrumentation. No Y-90 patient cases were administered on the day of this followup inspection and the inspector was unable to observe the licensee's implementation of its corrective actions described above. No violations of NRC requirements were identified during this followup inspection and the previous violation involving Sections 35.41(a)(2)/35.41(b)(2) is considered closed.