



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

July 23, 2016

EA-16-074

Mr. Thomas Earnest
Director of Radiology
QHG of Indiana, Inc.
7950 West Jefferson Boulevard
Fort Wayne, IN 46804

SUBJECT: NOTICE OF VIOLATION – QHG OF INDIANA, INC.;
NRC ROUTINE INSPECTION REPORT NO. 03001594/2016001(DNMS)

Dear Mr. Earnest:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted January 27–28, 2016, at your facilities in Fort Wayne, Indiana, with continued in-office review through March 18, 2016. The purpose of the inspection was to review activities performed under your NRC license to ensure that those activities were being performed in accordance with NRC requirements. During the inspection, an apparent violation of NRC requirements was identified. The significance of the issue and the need for lasting and effective corrective actions were discussed with you and members of your staff during the telephonic exit meeting that was held on April 8, 2016. Details regarding the apparent violation were provided in NRC Inspection Report No. 03001594/2016001(DNMS) dated May 10, 2016. The inspection report is available electronically in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML16131A748.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by: (1) providing a written response; (2) requesting a Predecisional Enforcement Conference; or (3) requesting Alternative Dispute Resolution. In a letter dated June 13, 2016, you provided a written response to the apparent violation.

Based on the information developed during the inspection, and the information you provided in your response dated June 13, 2016, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation involved the failure to develop, implement, and maintain written procedures that would specify the instrumentation needed to provide high confidence that yttrium-90 (Y-90) microsphere administrations were performed in accordance with a written directive, as required by Title 10 of the *Code of Federal Regulations* (CFR) 35.41 (a)(2). Specifically, on January 7, 2016, during two separate procedures, the licensee used a hand-held ion chamber that was not capable of measuring with high confidence the amount of Y-90 remaining in the equipment used to deliver the dose. Therefore, the licensee could not determine with high confidence that the two administrations were in accordance with the written directive.

The root cause of the apparent violation was an oversight by the licensee's consultant in failing to recognize that the instrument was not able to measure readings below 0.05 mR/hr. Contributing factors included the lack of procedural guidance for selection of a survey meter to determine pre-administration and post-administration dose measurements and failure to evaluate the impact of the new survey instrument on the licensee's process. This violation is of concern to the NRC because of the potential consequences to patients and for medical events to occur and not be reported. In addition, because the licensee was not able to determine with high confidence that the two treatments involving low-dose Y-90 were not medical events and would not have been able to do so for any similar low-dose microsphere administration with the use of the hand-held ionization chamber, the violation had the potential to impact the regulatory process. Specifically, the NRC would not be afforded the opportunity to conduct a reactive inspection if the licensee were not able to determine that a medical event occurred. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a Severity Level III violation. Because your facility has not been the subject of an escalated enforcement action within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC considered the information that you provided to the inspector at the time of the inspection, and your response dated June 13, 2016. Your corrective actions included revising your procedure for Y-90 microsphere administrations to require the use of a Geiger Mueller (GM) counter, an instrument with the required sensitivity, to determine if the low-dose administrations (15 mCi or less of Y-90) are performed in accordance with the written directive. You also discussed the new requirement to use the GM counter with all nuclear medical technologists. Further, you committed to present each proposed change or addition associated with the Nuclear Medicine program services to the Radiation Safety Committee (RSC) for evaluation and consideration of any potential safety and regulatory impacts.

As requested in our letter dated May 10, 2016, you acknowledged that your staff raised a concern to a manager regarding the hand-held ion chamber not being adequate for low-dose Y-90 administrations. You explained that the manager reviewed the concern and determined that the Y-90 procedure, established at the time, was followed. The manager placed the concern on an agenda to be reviewed with its medical physics consultant during his next quarterly audit. You concluded that the manager's review, acknowledgement, and development of an action plan was acceptable. On June 30, 2016, during a telephone discussion with Mr. Ryan Craffey of U.S. NRC, you clarified that QHG will initiate its review of any safety concerns immediately (no later than by next business day), and will address them at a management level commensurate with the potential risk. You stated that changes to the program will not be made until the RSC and the Radiation Safety Officer have reviewed and approved them. You added that if a change needs to be addressed sooner (i.e., for worker or patient safety), then QHG will hold an ad-hoc RSC meeting to review and approve the change. On the basis of these corrective actions, the NRC determined that *Corrective Action credit* is warranted.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance

T. Earnest

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of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in the inspection report, in your response dated June 13, 2016, and this letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-01594
License No. 13-01535-01

Enclosure:
Notice of Violation

cc: State of Indiana
Dr. Randall Phillips,
Radiation Safety Officer

of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in the inspection report, in your response dated June 13, 2016, and this letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-01594
License No. 13-01535-01

Enclosure:
Notice of Violation

cc: State of Indiana
Dr. Randall Phillips,
Radiation Safety Officer

Distribution:
See next page

ADAMS Accession Number ML16208A064

OFFICE	RIII	RIII	RIII	D:OE	RIII	RIII
NAME	MGryglak	AMcCraw DAP for	JGiessner CAL for	PHolahan ¹	RSkokowski	CPederson
DATE	07/07/16	07/08/16	07/11/16	07/18/16	07/22/16	07/23/16

OFFICIAL RECORD COPY

¹ OE concurrence provided via e-mail from Kerstun Norman on July 18, 2016.

Letter to T. Earnest from Cynthia D. Pederson dated July 23, 2016

SUBJECT: NOTICE OF VIOLATION – QHG OF INDIANA, INC.;
NRC ROUTINE INSPECTION REPORT NO. 03001594/2016001(DNMS)

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NOTICE OF VIOLATION

QHG of Indiana, Inc.
Fort Wayne, IN

Docket No. 030-01594
License No. 13-01535-01
EA-16-074

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted January 27–28, 2016, at your facilities in Fort Wayne, Indiana, with continued in-office review through March 18, 2016, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (CFR) 35.41(a)(2) states, that for any administration requiring a written directive, the licensee shall develop, implement and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Title 10 CFR 35.41(b)(2) states, in part, that at a minimum, the procedures required by 10 CFR 35.41(a) must address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.

Contrary to the above, between June 2015 and January 27, 2016, the licensee did not develop written procedures to provide high confidence that each yttrium-90 (Y-90) administration was in accordance with the written directive. Specifically, the licensee's written procedures for Y-90 administrations did not specify requirements for the instrumentation to be used to measure the quantity of the material remaining. As a result, during two low-dose administrations of Y-90 on January 7, 2016, the licensee used a hand-held ion chamber that was not capable of measuring with high confidence the amount of Y-90 remaining in the equipment used to deliver the dose. Therefore, the licensee could not determine with high confidence that the two administrations were in accordance with the written directive.

This is a Severity Level III violation (Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03001594/2016001(DNMS) dated May 10, 2016, in your response dated June 13, 2016, and the letter transmitting this Notice of Violation (Notice). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-16-074" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, Suite 210, 2443 Warrenville Rd, Lisle IL, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

Enclosure

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 23rd day of July, 2016.