UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

May 10, 2016

EA-16-074

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

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

Dear Mr. Earnest:

On January 27-28, 2016, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection 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 activities were being performed in accordance with NRC requirements. The in-office review included an evaluation of survey instrument data that was not available at the time of the inspection. On April 8, 2016, Mr. Ryan Craffey of my staff conducted a final exit meeting by telephone with you, Mr. Jim Ruschmeyer, and Dr. Randall Phillips to discuss the inspection findings. The enclosed inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, one apparent violation of NRC requirements was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation concerned the apparent failure to develop, implement, and maintain written procedures to provide high confidence that yttrium-90 microsphere administrations were in accordance with written directives, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 35.41(b)(2).

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for this inspection finding at this time. The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with you, Mr. Ruschmeyer, and Dr. Phillips at the inspection exit meeting on April 8, 2016.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violation addressed in this inspection report within 30 days of the date of this letter, (2) request a Predecisional Enforcement Conference (PEC), or (3) request Alternative Dispute Resolution (ADR). **Please contact Aaron McCraw at 630-829-9650 within ten days of the date of this letter to notify the NRC of your intended response.**

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03001594/2016001(DNMS); EA-16-074," and should include, for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

The NRC identified the failure to fully evaluate the impact of a change in instrumentation as a contributing cause of the apparent violation. In addition to the items listed in the preceding paragraph, your written response should also include a discussion of what measures you have implemented or will implement to evaluate the potential regulatory and safety impacts of future changes to your radiation safety program. The NRC also noted that members of your staff raised a concern regarding the appropriateness of the new survey instrument and that your management acknowledged the concern but did not implement corrective actions to restore compliance until prompted by the NRC inspection. Had these actions been implemented earlier, the apparent violation might have been prevented or proactively corrected. Your response should also therefore address the measures you have implemented or will implement to ensure that employee safety concerns are evaluated and resolved promptly and effectively.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation

occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. If a PEC is held, it will be open for public observation; the NRC will issue a press release to announce the time and date of the conference.

In lieu of a PEC, you may also request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a third party neutral. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Mr. Craffey or Mr. Nieves of my staff if you have any questions regarding this inspection. Mr. Craffey can be reached at 630-829-9655, and Mr. Nieves can be reached at 630-829-9571.

Sincerely,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

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

Enclosure:
IR 03001594/2016001(DNMS)

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

Please feel free to contact Mr. Craffey or Mr. Nieves of my staff if you have any questions regarding this inspection. Mr. Craffey can be reached at 630-829-9655, and Mr. Nieves can be reached at 630-829-9571.

Sincerely,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

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

Enclosure:
IR 03001594/2016001(DNMS)

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

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NAME	RCraffey:ps		LNieves		AMcCraw		PHolahan **1**	
DATE	5/1/2016		5/2/2016		5/2/2016		5/9/2016	
OFFICE	RIII-EICS		RIII-DNMS		RIII		RIII	
NAME	RSkokowski KLambert for		JGiessner					
DATE	5/9/2016		5/10/2016					

1 – (OE) review and concurrence received via e-mail from Kerstun Norman on 5/9/2016

OFFICIAL RECORD COPY

Letter to Thomas Earnest from John Giessner dated May 10, 2016

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

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-01594
License No.	13-01535-01
Report No.	03001594/2016001(DNMS)
EA No.	EA-16-074
Licensee:	QHG of Indiana, Inc.
Facilities Inspected:	7916 and 7950 West Jefferson Blvd. Fort Wayne, IN 46804
Inspection Dates:	January 27-28, 2016, with in-office review through March 18, 2016
Exit Meeting Date:	April 15, 2016
Inspectors:	Ryan Craffey, Health Physicist Luis Nieves, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

QHG of Indiana, Inc.
NRC Inspection Report 03001594/2016001(DNMS)

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 inspection included a review of the radiation safety program on-campus, including observations of licensed activities, interviews with staff members, and the review of relevant records.

During the inspection, the inspectors identified one apparent violation of Title 10 of the *Code of Federal Regulations* (CFR) Section 35.41(b)(2) for the apparent failure to develop, implement, and maintain written procedures for the administration of yttrium-90 (Y-90) microspheres that provide high confidence that each administration is accordance with the written directive. Specifically, the procedure did not provide high confidence for low-dose administrations of Y-90 microspheres because it did not specify any requirements for the instrumentation used to determine the quantity of material administered As such, the procedure did not prohibit the use of an ionization chamber that, on January 7, 2016, was unable to provide high confidence that the quantity of material injected during two administrations of Y-90 microspheres was within acceptable limits of variance, as that limit was too small to be measured accurately and with certainty by the instrument.

As corrective action, the licensee committed to revise its procedure to require the use of an instrument with sufficient visual resolution to determine with high confidence that low-dose administrations were in accordance with the written directive, and to immediately begin using such an instrument to perform the pre- and post-administration dose measurements for any subsequent low-dose treatments. The licensee also committed to discuss the matter with its medical physics consultant during his next quarterly audit.

REPORT DETAILS

1 Program Overview and Inspection History

QHG of Indiana, Inc., which operated as Lutheran Hospital, was authorized to use byproduct material for medical purposes at its campus in Fort Wayne, Indiana. At the time of the inspection, the licensee performed 2-3 Y-90 microsphere administrations and 15-20 iodine (I-131) therapies monthly, as well as 20-25 diagnostic radiopharmaceutical administrations (including 4-6 PET injections) daily at its main facility. The licensee also performed 6-12 cardiac stress tests at a second facility adjacent to the main hospital. The licensee had performed several administrations of radium-223 (Ra-223) dichloride since the last inspection, but none recently. The licensee performed manual brachytherapy on site; however, records of the treatments were maintained at a partner site for Radiation Oncology Associates, P.C. (NRC License No. 13-32551-01). The licensee retained the services of a medical physics consultant to review the content and implementation of the various facilities quarterly, and its Radiation Safety Committee (RSC) met quarterly.

The NRC last conducted routine inspections of this licensee on September 25-26, 2013 and August 29-30, 2011. No violations of NRC requirements were identified as a result of either inspection.

2 Administrations of Yttrium-90 Microspheres

2.1 Inspection Scope

During preliminary discussions of the status of the radiation safety program, the inspectors learned that, starting in 2014, the licensee routinely performed several Y-90 microsphere administrations per month under an authorization originally obtained in 2009. The inspectors therefore reviewed the licensee's procedures for the administration of Y-90 microspheres, through an evaluation of the licensee's facilities and equipment, interviews with involved staff, and an examination of relevant records.

2.2 Observations and Findings

The inspectors toured areas of the licensee's facility at 7950 West Jefferson where Y-90 microsphere doses were stored and prepared. The licensee did not have any administrations of Y-90 scheduled during the time that the inspectors were on-site. Instead, the licensee's staff demonstrated the implementation of procedures for the preparation and administration of microspheres, including specific measures for dose measurement, contamination control and waste handling.

During these discussions, the inspectors identified an apparent violation of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35.41(b)(2) for the apparent failure to develop, implement and maintain written procedures to provide high confidence that each Y-90 microsphere administration is in accordance with the written directive.

The inspectors found that, beginning in June 2015, the licensee's technologists routinely determined the quantity of Y-90 microspheres administered using a hand-held ionization chamber that was not able to measure with confidence whether administrations of low-dose cases of Y-90 (i.e., less than around 15 millicuries (mCi)) were within

20 percent of what had been prescribed on the written directive, because the instrument's display did not provide the visual resolution necessary to determine with confidence whether 80 percent or more of the prescribed amounts had actually been injected.

By procedure, the technologists measured each Y-90 microspheres dose using the meter in a setup that ensured consistent geometry before and after administration. Once drawn and assayed, the technologists placed the dose in an empty waste container, and measured that container on four sides using the meter at a predetermined distance. The four measurements were then averaged to determine a pre-administration exposure reading.

Following administration, the vial and all potentially contaminated equipment were placed in the waste container, which the technologists then measured as before. These measurements were also averaged to then determine a post-administration reading, which, when compared to the pre-administration reading, could be used to approximate the amount of material which had not been injected into the patient. By subtracting this amount from the original assayed activity, the licensee could then determine how much material was administered, and therefore determine whether the administration was performed in accordance with the written directive and treatment plan.

For two low-dose cases administered on January 7, 2016 (8 mCi and 4 mCi to the same patient, but on separate written directives), the pre-administration readings were 0.2 milliRoentgen per hour (mR/hr) and 0.15 mR/hr, respectively. The technologists would therefore have needed to determine whether the post-administration readings exceeded 0.04 mR/hr and 0.03 mR/hr in order to determine whether the administrations had been performed in accordance with the written directive. In both cases, the technologists determined that the readings were, as far as they could tell, indistinguishable from background. However, because the meter at its lowest setting (x1) had minor tick marks of just 0.2 mR/hr, the technologists admitted that they were unable to visually distinguish any readings below 0.05 mR/hr (half of a half of a tick) with any confidence, and therefore were unable to determine whether these two administrations were within 20 percent of the prescribed amount.

The treatments on January 7, 2016, did not end in stasis, and in all other respects were considered successful. The inspectors reviewed 30-40 past cases and determined that the licensee had not previously performed any other Y-90 microsphere administrations with pre-administration readings low enough to render the instrument in question inadequate to determine with confidence whether the administration was performed in accordance with the written directive.

The inspectors determined that the root cause appeared to be an oversight by the licensee's medical physicist, who ordered the instrument in question. As contributing factors, (1) the licensee's procedure did not state any requirements for the survey meter used to determine pre- and post-administration dose measurements, and (2) the licensee did not appear to have fully evaluated the impact that changing the survey instrument would have on the process.

As corrective actions, the licensee committed to revise its procedure for Y-90 microsphere administrations to require the use of an instrument with sufficient resolution to determine with high confidence that low-dose administrations (15 mCi or

less of Y-90) were in accordance with the written directive. The licensee committed to use one of its Geiger-Mueller (GM) probes instead to perform the pre- and post-administration dose measurements for any subsequent low-dose treatments. The licensee also committed to discuss the matter with its medical physics consultant during his next quarterly audit.

2.3 Conclusions

The inspectors reviewed the licensee's procedures for the administration of Y-90 microsphere administrations, and identified one apparent violation of 10 CFR 35.41(b)(2).

3 Other Areas Inspected

3.1 Inspection Scope

The inspectors reviewed other elements of the licensee's radiation safety program at both locations listed on the license. The inspectors completed this review through an evaluation of the licensee's facilities and equipment, observations of licensed activities, interviews with involved staff, and an examination of relevant records.

3.2 Observations and Findings

The inspectors 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 inspectors conducted independent surveys of these facilities and found no evidence of residual contamination or exposures to members of the public in excess of regulatory limits.

The inspectors observed the preparation and administration of numerous diagnostic procedures at both facilities. The inspectors also observed the receipt of packages containing radioactive material and handling of radioactive waste by nuclear medicine staff. The inspectors 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. The inspectors found through these observations, demonstrations, and various discussions that the licensee's staff was knowledgeable of radiation protection principles and regulatory requirements.

The inspectors reviewed a selection of written directives for recent I-131 therapies and past Ra-223 injections (the inspectors did not review any records related to manual brachytherapy treatments at this time), as well as routine nuclear medicine records, dosimetry reports, quarterly audits, RSC meeting minutes, and documentation of relevant staff training. The inspectors did not identify any issues in the records reviews.

3.3 Conclusions

The inspector reviewed other elements of the licensee's radiation program, and had no findings in these areas.

4 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on April 15, 2016. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

Mary Ellen Brill – Vice President of Quality and Transplant
John Colvin – Nuclear Medicine Technologist
Amy Davis – Nuclear Medicine Technologist
^ Tom Earnest – Director of Radiology
^ Randall Phillips, MD – Radiation Safety Officer
Panduranga "KP" Reddy – Nuclear Medicine Technologist
#^ Jim Ruschmeyer – Radiology Manager
Erica Ward – Nuclear Medicine Technologist

Attended preliminary exit meeting on January 28, 2016
^ Attended exit meeting by telephone on April 15, 2016

INSPECTION PROCEDURES USED

87131: Nuclear Medicine Programs – Written Directive Required
87132: Brachytherapy Programs