NRC FORM 591M PART 1
(06-2010)
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, Indiana 46804 REPORT NUMBER(S): 2011-001	U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-01594	13-01535-01	Aug. 29-30, 2011

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, NUREG-1600, 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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

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	Brian M. Bauer - CEO		8/30/11
NRC INSPECTOR	Geoffrey M. Warren		8/30/11
Branch Chief	Tamara E. Bloomer		9/19/11

NRC FORM 591 M PART 3 (06-2010) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
QHG of Indiana, Inc. Fort Wayne, Indiana REPORT NUMBER(S) 2011-001	U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-01594	13-01535-01	Aug. 29-30, 2011

6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS
87131, 87132	03.01 – 03.08, 03.01 – 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1.PROGRAM	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: August 2013

☒ Field Office Inspection — 7916 W. Jefferson Blvd., Fort Wayne, IN

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

The licensee operated a 350-bed medical facility (Lutheran Hospital) located in Fort Wayne, Indiana, with authorization to use byproduct materials in Sections 35.100, 35.200, 35.300, 35.400, and 35.500, as well as a nearby cardiology clinic. While authorized to use yttrium-90 as microspheres, the licensee had not yet performed any such procedures, but stated that all personnel would be trained on such procedures prior to performing them. Licensed activities were conducted only at the facilities identified on the license.

At the main hospital, the nuclear medicine department was staffed with three full-time nuclear medicine technologists. The licensee's nuclear medicine staff typically administered 420 diagnostic doses and 10 iodine-131 therapy doses monthly, with the iodine-131 in capsule form. The diagnostic procedures included a variety of procedures, mostly using technetium-99m unit doses. The nuclear medicine technologists also performed approximately 50 PET imaging procedures monthly using fluorine-18 unit doses, using a dedicated hot lab and camera in the nuclear medicine area. While the licensee possessed a rubidium generator, they had not used it since the breakthrough issue was identified. When the generator was in use, the nuclear medicine staff performed approximately 50 such procedures monthly. The department received unit doses and bulk technetium-99m from licensed nuclear pharmacies.

Prostate implant procedures were performed at the hospital by personnel from Radiation Oncology Associates (ROA), a separate licensee that maintained their own treatment facilities near the hospital. One oncologist and two physicists were involved in the implant procedures, performing approximately five such procedures annually. Seeds were delivered to nuclear medicine; ROA never possessed them at their facility. Patient files were maintained at the ROA offices.

The licensee also operated a cardiology clinic at 7916 W. Jefferson Blvd. This facility was staffed with three full-time technologists who performed approximately 400 cardiac procedures monthly. Doses were received as unit doses from a licensed radiopharmacy.

(continued)

NRC 591M Part 3 – continued

QHG of Indiana, Inc.
Report No. 2011-001
Docket No. 030-01594
License No. 13-01535-01
Dates of Inspection: Aug. 29-30, 2011

Performance Observations

The inspector observed five diagnostic administrations of licensed material, as well as a package receipt survey. Licensee personnel demonstrated dose calibrator constancy, daily and weekly contamination surveys, and survey meter and wipe counter QC. No issues were identified with these activities. The inspector reviewed written directives for radiopharmaceutical and implant procedures and noted no issues. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

In the January 2010 reactive inspection, the licensee was cited for the failure to have adequate procedures to prevent a medical event, in that the procedures in place did not prevent a patient from receiving the wrong dose. The inspector determined that licensee personnel used a "time-out" sheet for therapeutic doses in nuclear medicine, with the authorized user and technologist verifying the patient and dosage prior to administration, and maintained these sheets in their files. Based on this determination, the violation is considered closed.