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 |
|---|---|
| St. Luke's Hospital of Kansas City<br>4401 Wornall Road<br>Kansas City, Missouri 64111<br>REPORT NUMBER(S): 2011-001 | U.S. Nuclear Regulatory Commission, Region III<br>2443 Warrenville Road, Suite 210<br>Lisle, Illinois 60532 |

| 3. DOCKET NUMBER(S) | 4. LICENSEE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-02286 | 24-00889-01 | August 9 - 11 , 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

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

See Part 2

☐ 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 | Kevin Thorp, Senior Vice President | | 8/11/2011 |
| NRC INSPECTOR | Geoffrey M. Warren | | 8/11/11 |
| Branch Chief | Tamara E. Bloomer | | 8/22/11 |

NRC FORM 591M PART 2
(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 |
|---|---|
| St. Luke's Hospital of Kansas City<br>Kansas City, Missouri<br>REPORT NUMBER(S) 2011-001 | U.S. Nuclear Regulatory Commission, Region III<br>2443 Warrenville Road, Suite 210<br>Lisle, Illinois 60532 |

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(Continued)

10 CFR 30.3 requires, in part, that except for persons exempted, no person shall possess or use byproduct material except as authorized by a specific or general license issued pursuant to Title 10, Chapter 1, Code of Federal Regulations

Contrary to the above, between June 2010 and January 2011, the licensee possessed an americium-241 source, ~~which was~~ that was not authorized by either NRC License No. 24-00889-01, Amendment No. 80, or by a general license.

As corrective action, the licensee, upon discovering the source, requested a license amendment authorizing possession of the source for storage incident to disposal. Amendment 81 to the license was issued January 11, 2011. ~~The~~ The licensee has begun determining how to dispose of the source to an authorized recipient.

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 |
|---|---|
| St. Luke's Hospital of Kansas City<br>Kansas City, MO<br>REPORT NUMBER(S) 2011-001 | U.S. Nuclear Regulatory Commission, Region III<br>2443 Warrenville Road, Suite 210<br>Lisle, Illinois 60532 |

| 3. DOCKET NUMBER(S) | 4. LICENSEE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-02286 | 24-00889-01 | August 9 – 11, 2011 |

| 6. INSPECTION PROCEDURES | 7. INSPECTION FOCUS AREAS |
|---|---|
| 87134 | 03.01 – 03.08 |

**SUPPLEMENTAL INSPECTION INFORMATION**

| 1.PROGRAM | 2. PRIORITY | 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |
|---|---|---|---|
| 02110 | 2 | Gregory D. Sackett, M.S., RSO | 816-932-6296 |

☒ Main Office Inspection — Next Inspection Date: August 2013

☒ Field Office Inspection — 5830 NW Barry Rd and 5844 NW Barry Rd., Kansas City, MO

☒ Temporary Job Site Inspection — mobile van (PET/CT) at 4401 Wornall Rd., Kansas City, MO

**PROGRAM SCOPE**

The licensee operated the main hospital, an outpatient nuclear medicine clinic, two smaller hospitals, four cardiology clinics, and a mobile PET/CT service in the Kansas City, Missouri, area under this license. The licensee performed activities under Sections 35.100, 35.200, 35,300, 35,400, and 35.500, as well as operating a high dose rate (HDR) remote afterloader and a blood irradiator. While authorized to perform research activities, the licensee had not performed such activities in several years. The radiation safety staff consisted of two full-time employees, including the radiation safety officer and an assistant.

At the main hospital, a 400-bed hospital, the nuclear medicine department was staffed with two full-time technologists. The staff performed approximately 120 diagnostic procedures monthly, including a wide spectrum of procedures excluding cardiac procedures, and approximately two therapy procedures monthly, primarily iodine-131 therapies (hyperthyroid and thyroid cancer) with the iodine in capsule form. The licensee received unit doses and bulk technetium-99m from a licensed nuclear pharmacy. The radiation oncology department was staffed with three radiation oncologists, three physicists, three dosimetrists, and six therapists that assisted with procedures. The oncology staff performed approximately 30 HDR fractions and 4 to 5 temporary implants with cesium-137 and iridium-192 sources monthly, and occasional eye plaques using iodine-125 sources. In addition, licensee personnel performed 1 – 2 microspheres treatments monthly in interventional radiology, with radiation safety staff assisting during the procedures.

At St. Luke's North (5830 NW Barry Rd.), a 95-bed hospital, the nuclear medicine department was staffed with two full-time technologists who performed approximately 80 diagnostic procedures annually and 5 to 10 iodine-131 therapy procedures quarterly.

At the cardiology clinic at 5844 NW Barry Rd., one technologist administered approximately 140 cardiac doses monthly; the technologists rotated through the cardiology facilities. The cardiology clinic had used a rubidium-82 generator, but rubidium procedures were on hold until the generator issues were resolved.

The mobile PET/CT service provided services at multiple St. Luke's Hospital locations and at North Kansas City Hospital. Two full-time technologists performed approximately 120 procedures using fluorine-18 monthly. Doses were delivered to the licensee's mobile van at each site by a licensed nuclear pharmacy.

**(continued)**

**Performance Observations**

The inspector observed two diagnostic administrations of licensed material, including dose preparation and disposal, an HDR treatment, preparation and selection of sources for a temporary cesium-137 implant, and a microsphere treatment. Licensee personnel demonstrated dose calibrator constancy, package receipt surveys and wipe tests, survey meter and wipe counter QC, daily and weekly contamination surveys, daily HDR checks, blood irradiator use, and planning for oncology treatments, and described a variety of diagnostic and therapeutic nuclear medicine procedures including in-house I-131 therapies, spill procedures, and audit and leak test procedures. The inspector noted no concerns with these activities. The inspector reviewed radiation safety committee minutes, audit records, dosimetry records, and written directives for radiopharmaceutical therapies, HDR treatments, temporary implants, and microspheres treatments. 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.

The inspector reviewed the licensee's discovery of an americium-241 source while performing the initial audit at a cardiology facility after the site had been added to the St. Luke's license. The four cardiology facilities had been added to the license since the previous inspection. The source was added to the license and placed in secured storage. Because the licensee identified and corrected the violation, it was documented as a non-cited violation. According to the licensee, they cannot identify how or why the facility acquired the source, but plan to dispose of it properly.

Two violations were cited from the previous inspection. The first violation concerned licensee personnel filling out the removal time of sources on a written directive for temporary implants prior to removal of the sources, contrary to licensee procedures. The inspector noted that the form had been changed to clarify that this section was not to be filled out until the sources were actually removed and to add a separate section for projected time of removal. Written directives for three patients being treated at the time of the inspection indicated that the time of removal had not been filled out. Based on this determination, the violation is considered closed.

The second violation concerned licensee personnel not selecting millicurie or microcurie on written directives for iodine-131 therapies. The inspector noted that the written directive form had been updated to remove the option for microcuries, and the units of the prescribed dosage were clear on all written directive forms reviewed at multiple locations. Based on this determination, the violation is considered closed.