

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: <i>Leid Hospital & Health Care Services</i> <i>Richmond, IN</i> REPORT NUMBER(S)	2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351
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3. DOCKET NUMBER(S) <i>030-01614</i>	4. LICENSEE NUMBER(S) <i>13-03284-02</i>	5. DATE(S) OF INSPECTION <i>July 22, 2008</i>
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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) was/were discussed involving the following requirement(s) and Corrective Action(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.
 (Violations and Corrective Actions)



Licensee's Statement of Corrective Actions for Item 4, above.

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	<i>Deborah A. Piskura</i>	7/22/08

SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION

1. LICENSEE Reid Hospital and Health Care Services REPORT NUMBER(S) 2008-002		2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532	
3. DOCKET NUMBER(S) 030-01614	4. LICENSE NUMBER(S) 13-03284-02	5. DATE(S) OF INSPECTION July 22, 2008	
6. INSPECTION PROCEDURES USED 87132		7. INSPECTION FOCUS AREAS 03.01 – 03.08	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02120	2. PRIORITY 2	3. LICENSEE CONTACT Eugene DiTillio, Radiology Manager	4. TELEPHONE NUMBER 765-983-3166
<input checked="" type="checkbox"/> Main Office Inspection		Next Inspection Date: Feb. 2009* unchanged	
<input checked="" type="checkbox"/> Field Office 1100 Reid Parkway, Richmond, IN (new hospital site)			
<input type="checkbox"/> Temporary Job Site Inspection			

PROGRAM SCOPE

This licensee was a 200+-bed hospital, authorized to use licensed material permitted by Sections 35.100, 35.200, 35.300, 35.400 (prostate implants) and Ir-192 in an HDR unit (not possess at the time of this inspection). This inspection was a review and verification of the licensee's corrective actions following an escalated enforcement action (IR No. 03001614/2008-001 (DNMS) concerning a medical event which had occurred during prostate seed implant procedure on February 27, 2008. The hospital has not performed any prostate implants since the medical event. These activities will resume as eligible candidates are referred to the hospital. Two apparent violations were identified during the March 5-6, 2008 inspection: (1) failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive for I-125 seed prostate implants as required by 10 CFR 35.41; and (2) failure to report a medical event to the NRC Operations Center no later than the next calendar day after discovery as required by 10 CFR 35.3045(c).

The inspector verified that the licensee implemented its corrective actions regarding the medical event described in its letter dated March 11, 2008 which included: (1) halting prostate seed implant procedures until all corrective actions were completed; (2) revising the prostate seed implant procedure policy to require that the location of the needle in the prostate be verified with certainty by x-ray and ultrasound imaging prior to any seeds being deposited, and to require that the procedure be stopped before any seeds are implanted if the location of the needle in the prostate cannot be verified with certainty; and (3) providing education and training on the ultrasound machine and stepper for physicians and other personnel (on May 22, 2008).

For the violation involving the licensee's failure to timely report a medical event the inspector verified the licensee's corrective actions: (1) discussing NRC regulations requiring reporting of a medical event with physicians, authorized users, the Radiation Safety Officer, physicists, and other personnel (on March 3 and May 29, 2008); (2) reviewing on an annual basis NRC reporting requirements regarding medical events with authorized users, the Radiation Safety Officer, physicists, and other Radiology/Radiation Oncology/Nuclear Medicine personnel involved in procedures using NRC-licensed materials; and (3) revising their administrative policy to state that the requirement is to report medical events to the NRC no later than the next calendar day.

The licensee's corrective actions appeared adequate and the violations are considered closed.