

INSPECTION RECORD

Region III Inspection Report No. 030-09784/11-01(DNMS)
License No. 24-01143-06 Docket No. 030-09784

Licensee (Name and Address):

Lester E. Cox Medical Center
1423 N. Jefferson
Springfield, Missouri 65802

Licensee Contact: Jeff S. Robinson, BA, R.T.(R)(N), CNMT
Director, Radiation Oncology

Telephone No. (417) 269-6991

Priority: 2 Program Code: 2230

Date of Last Inspection: August 7, 2008

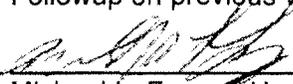
Date of This Inspection: January, 4, 2011 with continuing NRC in-office review
Through January 27, 2011

Type of Inspection: () Initial () Announced (X) Unannounced
(X) Routine () Special

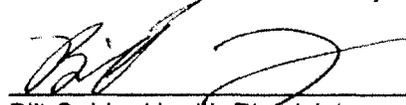
Next Inspection Date: 01/2013 (X) Normal () Reduced

Summary of Findings and Actions:

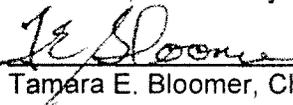
- () No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- (X) Non-cited violations (NCVs)
- () Violation(s), Form 591 issued
- (X) Violation(s), regional letter issued
- () Followup on previous violations

Inspector 
Michael LaFranzo, Health Physicist

Date 2/24/11

Inspector 
Bill C. Lin, Health Physicist

Date 2/23/11

Approved 
Tamara E. Bloomer, Chief, MIB

Date 2/23/11

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

<u>Amendment No.</u>	<u>Date</u>	<u>Subject</u>
74	11/3/08	Addition of radioactive type seed sources for brachytherapy treatments
75	6/14/10	Addition of Medical Physicist and a change of Radiation Safety Officer
76	9/15/10	Addition of Medical Physicist

2. INSPECTION AND ENFORCEMENT HISTORY:

The last U.S. Nuclear Regulatory Commission (NRC) routine inspection was conducted on 08/07/08. There were two SL IV violations identified. They included:

The licensee failed to conduct semi-annual inventories of all brachytherapy sources. Specifically, the licensee failed to inventory unused Iodine-125 (I-125) permanent implant seeds that were being kept by the licensee after treatment occurred. As corrective action, the licensee placed all I-125 seeds within their possession in a tamper proof container until properly disposed. The licensee completed the corrective action on August 12, 2008.

The licensee failed to conduct all of the necessary spots checks on the high dose rate afterloader (HDR) unit before its first use on any given day. Specifically, the licensee did not perform spot checks of the electrical interlock on the patient door leading into the room. The licensee was performing the required spot check on the licensee staff entrance door. As corrective action, the licensee retrained all operators who perform those spot checks and added the checking of the patient door interlocks on the HDR daily check list. The licensee completed the corrective actions on August 7, 2008.

A previous special inspection was conducted on August 2, 2007 as the result of a reported medical event. During the inspection, a SL IV violation was identified regarding the failure to ensure each administration is in accordance with the written directive prior to patient treatment. Specifically, the licensee's procedures for the implementation of treatment plans with its HDR unit as required by 10 CFR 35.41 did not require a check and verification of the treatment plan parameters prior to the treatment.

3. INCIDENT/EVENT HISTORY:

None

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Vice President of Clinical Services
Administrative Directors
Radiation Safety Officer

The licensee was authorized to perform licensed operations at four locations of use. Between all four facilities, the licensee had performed approximately 30-40 diagnostic administrations using Tc-99m/day, 10-15 diagnostic administrations/day using PET, 10-20 cases of I-131 therapy administrations/year, 50-80 administrations via permanent seed implants/year, and 10-15 administrations of low dose brachytherapy/year. The licensee's operations are primarily Monday through Friday with occasional on-call activities on the weekends. The licensee has numerous technicians at each locations of use to administer licensed material and implement the radiation safety program, 20 authorized users and three authorized medical physicists.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: IP 87130, IP 87125, and IP 87132

Focus Areas Evaluated: 03.01 through 03.07

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors performed radiological surveys of restricted and unrestricted areas of the licensee's facility; no abnormal radiation levels were identified. The inspectors performed a side-by-side radiation level comparison between NRC and licensee survey instruments; the radiation levels measured were within acceptable ranges.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Three violations of NRC requirements were identified. There were two SL IV violations and one non-cited violation. The violations were the following:

Violation 1:

Title 10 of the Code of Federal Regulations (CFR) Section 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) The patient's or human research subject's identity is verified before each administration; and (2) Each administration is in accordance with the written directive.

During the inspection, the inspector identified two administrations of I-125 permanent seed implants where the dose delivered differed from the prescribed dose by more than 20 percent and the licensee had not identified the difference and recognized that a medical event could have occurred. The licensee explained to the inspectors that the post administration review did not necessarily include a review to determine if a medical event occurred as defined by NRC regulations; rather the post administration review was

primarily concerned with the placement and number of I-125 seeds in or near the target organ.

After further review, the licensee had decided that the doses documented during the post-planning procedure were not accurate and performed a re-evaluation of the doses to the target organ; the additional re-evaluation determined that each administration was within 20 percent of the prescribed dose.

The NRC reviewed the licensee's procedures and determined that the procedures did not provide high confidence that each administration was in accordance with the written directive. Specifically during the on-site inspection, the inspector noted that the two administrations deviated from the written directive by 21.86% and 31.48% and the licensee failed to notice and procedures failed to address the significant deviation at the time after the administration. As a result, an NRC inspection was required to ensure that the licensee determined whether or not a medical event occurred in accordance with NRC regulatory requirements. The fact that the licensee subsequently determined that no medical events occurred after identification of the issues by the NRC highlights the deficiency in the written procedures for identifying whether each administration was in accordance with its corresponding written directive. Prior to the telephonic exit meeting, the licensee had developed a written procedure to address the deficiencies noted above. The NRC reviewed the written procedure and determined it was adequate to comply with NRC requirements.

The NRC had determined that a violation of 10 CFR 35.41(a) occurred. However, the NRC had determined that the licensee's procedural non-compliance was limited to the determination of post-treatment evaluation and whether further evaluations were necessary or if a medical event occurred and was required to be reported. Therefore and in conjunction that a medical event did not occur, the NRC has decided to characterize this violation at a Severity Level IV. As corrective actions, the licensee modified its procedures to ensure that deviation noted during treatment or identified post treatment are either re-evaluated or reported to the NRC. These modifications will be reviewed during a future inspection to ensure compliance with NRC requirements.

Violation 2:

Title 10 CFR 35.67(b)(2) states that, a licensee in possession of a sealed source shall test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry. Also, Title 10 CFR 35.67(g) states that a licensee in possession of sealed source or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with 10 CFR 35.2067(b).

During the inspection, the inspectors noted that the licensee had not performed an inventory or leak test of a Sr-90 source since December 2009. The licensee explained the reason was a change in the individual responsible for inventory and leak tests. The new individual explained that he was unaware of the Sr-90 source. The licensee immediately inventoried the source and committed to conduct a leak test within 2 weeks of the inspection. A review of previous leak test records by the inspectors did not identify the Sr-90 source was leaking. As long term corrective actions, the licensee plans to dispose of the Sr-90 source as it had not been used in over 10 years. The

licensee modified its procedures to ensure all sealed sources are appropriately inventoried and leak tested.

As a result of the licensee's adequate corrective actions, the NRC will not request a response to the Notice of Violation but will review the licensee's corrective action implementation during the next routine inspection.

Non-Cited Violation

Title 10 CFR 35.610(a)(2) states that, a licensee shall permit only individuals approved by the authorized user, Radiation Safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source.

On February 18, 2009, the licensee identified that a visiting student was in the HDR treatment room while a patient treatment was on-going without the approval of an authorized user, Radiation Safety Officer or authorized medical physicist. The licensee determined that during an HDR brachytherapy treatment, the student remained inside the room for a total of 9 minutes and 2 seconds, the total treatment time. The student was inside the room behind a lead viewing glass window and was unnoticed by the licensee's staff. As soon as it was discovered that there was an accidental exposure, the RSO sent the student's Landauer badge for processing and duplicated the exposure with three unused Landauer badge. Based on the badge readings, the individual's exposures were determined to be less than 100 millirem (whole body). The student was considered a radiation worker as part of the licensee's radiation safety program. As corrective actions, the licensee performed the following: The licensee required that "cleared" be called out before any radiation is administered in the HDR room, this corrective action was completed on February 18, 2009. Furthermore on May 28, 2010, the licensee took additional corrective action by developing a radiation safety education sheet that all staff observing an HDR treatment must read and sign. The inspectors noted that the licensee's corrective action program was in place and operational during the inspection.

The NRC is classifying this violation as a Non-Cited Violation because the licensee; (1) identified the violation; (2) initiated corrective actions; (3) no recurring violations were noted; (4) the violation was non-willful; and (5) the NRC would have normally classified the violation at a Severity Level IV.

PARTIAL LIST OF PERSONNEL CONTACTED:

- #*& Tyler Hedden – Vice President of Clinical Services
- * Ron Prenger – Vice President of Clinical and Support Services
- * June Johnson – Administrative Director, Hulston Cancer Center
- #*& Jeff Robinson – Director of Radiation Oncology
- *& Dr. Peter Situ – Chief Medical Physicist
- * Victor Jacome – Authorized Medical Physicist
- *& Dr. John Clouse – Radiation Safety Officer

Use the following identification symbols:

Individual(s) present at entrance meeting

* Individual(s) present at site preliminary exit meeting

& Individual present at telephonic exit meeting on January 27, 2011