

February 23, 2010

Mr. Tyler Hedden
Vice President of Clinical Services
Lester E. Cox Medical Center
1423 N. Jefferson
Springfield, Missouri 65802

SUBJECT: NRC INSPECTION REPORT 030-09784/11-01(DNMS) – LESTER E. COX
MEDICAL CENTER AND NOTICE OF VIOLATION

Dear Mr. Hedden:

On January 4, 2011, the U.S. Nuclear Regulatory Commission (NRC) conducted an on-site inspection at your Lester E. Cox Medical Center facility in Springfield Missouri, with continued NRC in-office review through January 27, 2011. The continuing NRC in-office review related to additional information regarding the permanent seed implant program at your facility. A telephonic exit meeting was conducted between members of your staff and Michael LaFranzo of my staff on January 27, 2011.

This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with 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 the inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The first violation involved the failure to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the inspector identified two administrations of Iodine-125 (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 indicated 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. Subsequent to the inspection, 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. As corrective action, the licensee agreed to develop and implement written procedures to provide high confidence that each administration will be in accordance with written directives. Your staff forwarded the developed

procedures to the NRC for review and it was deemed adequate to comply with NRC requirements. This corrective action was completed prior to the telephonic exit meeting on January 27, 2011.

The second violation involved the failure to conduct leak tests and inventory of all sealed sources. As corrective action, the licensee agreed to conduct leak tests and inventory of all sealed sources and develop procedures to ensure leak tests and source inventory are conducted at the required frequencies in the future. The licensee also agreed to perform the leak tests of the sealed source that it had failed to conduct within two weeks from the inspection date of January 4, 2011. The corrective action to inventory the sealed source was completed on January 4, 2011. The corrective action to develop procedures to ensure leak tests and inventory of all sealed sources as stated was completed on January 4, 2011.

These violations are cited in the enclosed Notice of Violation (Notice). The violations are being cited in the Notice because the NRC identified them.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect all of your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

Based on the results of this inspection, the NRC has also determined that one additional Severity Level IV violation of NRC requirements occurred. The violation concerned the failure to ensure that no observers were present in the high dose-rate remote afterloader (HDR) treatment room during a treatment on February 18, 2009. This violation was identified by your staff on February 18, 2009. Corrective actions that were taken to address the violation included calling out the word "cleared" before any radiation is administered in the HDR room. Additionally, your staff developed a radiation safety education sheet that all staff observing an HDR treatment must read and sign. This violation is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy.

If you contest the violation or the significance of the NCV, you should provide a response within 30 days of the date of this letter, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region III; and (2) the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with Title 10 of the Code of Federal Regulations (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management Systems (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

T. Hedden

-3-

To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Material Safety

Docket No. 030-09784
License No. 24-01143-06

Enclosure:
Notice of Violation

cc w/encl: Dr. Peter Situ, Chief Medical Physicist
Dr. John Clouse, Radiation Safety Officer
State of Missouri

T. Hedden

-3-

To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-09784
License No. 24-01143-06

Enclosure:
Notice of Violation

cc w/encl: Dr. Peter Situ, Chief Medical Physicist
Dr. John Clouse, Radiation Safety Officer
State of Missouri

DISTRIBUTION:

Cynthia Pederson
Anne Boland
Patrick Loudon
Steven Orth
Carole Ariano
Paul Pelke
Patricia Buckley
Tammy Tomczak
MIB Inspectors

DOCUMENT NAME: G:\DNMS\Work in progress\IR - Lester Cox 030-09784 Letter2.docx

Publicly Available Non-Publicly Available Sensitive Non-Sensitive

To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RIII DNMS	C	RIII DNMS		RIII DNMS		RIII DNMS	
NAME	MMLaFranzo: jm*		TEBloomer					
DATE	02/23/2011		02/23/11.					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Lester E. Cox Medical Center
Springfield, Missouri

Docket No. 030-09784
License No. 24-01143-06

During an U.S. Nuclear Regulatory Commission (NRC) inspection conducted on January 4, 2011, with continuing NRC in-office review through January 27, 2011, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Title 10 of the Code of Federal Regulations (CFR) 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.

Contrary to the above, as of January 4, 2011, the licensee failed to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's written procedures failed to properly address the actions to be taken when two significant administration deviations requiring a written directive were identified between the post-administration calculated dose and the prescribed dose.

This is a Severity Level IV violation (Section 6.3).

- B. Title 10 CFR 35.67(b)(2) states, in part, that, a licensee in possession of a sealed source shall test the source for leakage at intervals not to exceed six months. Title 10 CFR 35.67(g) states, in part, that a licensee in possession of sealed sources or brachytherapy sources shall conduct a semi-annual physical inventory of all such sources in its possession.

Contrary to the above, on January 4, 2011, the licensee possessed a Sr-90 sealed source and failed to: (1) test the source for leakage since December 2009, a period exceeding six months; and (2) conduct semi-annual physical inventory since December 2009.

This is a Severity Level IV violation (Section 6.3).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in the letter transmitting this notice. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect all of your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, Inspection Report No. 030-09784/11-01(DNMS)" and send it to the U.S. Nuclear Regulatory Commission,

Enclosure

Notice of Violation

-2-

ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your response will be made available electronically for public inspection in the NRC's Agencywide Documents Access and Management Systems (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/readingrm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 23rd day of February 2011.

Enclosure

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