February 18, 2011

NMED Nos. 100536 and 100538 (CLOSED)

Mr. Don Fesko, Administrator
Chief Executive Officer
The Community Hospital
901 MacArthur Boulevard
Munster, Indiana 46321

SUBJECT: NRC ROUTINE INSPECTION REPORT 030-09964/10-01(DNMS) AND NOTICE OF VIOLATION – THE COMMUNITY HOSPITAL

Dear Mr. Fesko:

On October 26, 2010, with continuing in-office review through January 25, 2011, a U. S. Nuclear Regulatory Commission (NRC) inspector conducted an inspection at The Community Hospital facility located in Munster, Indiana. 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 Rose Garcia and Mirel Palamaru of your staff and Michael LaFranzo of my staff on January 25, 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 one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforcement-pol.html. The 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. The violation is cited in the enclosed Notice of Violation (Notice). The violation is being cited in the Notice because it was identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the Information Notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Based on the results of this inspection, the NRC has also determined that one Severity Level IV violation of NRC requirements occurred. This violation is being treated as a Non-Cited

Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy. The NCV is described in the subject inspection report. 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 U.S. 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 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website 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.

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

Sincerely,

***/RA/***

Patrick L. Louden, Deputy Director
Division of Nuclear Materials Safety

Docket No. 030-09964
License No. 13-15882-01

Enclosure:
Notice of Violation

cc w/encl: Rose Garcia, Vice President, Diagnostic & Therapeutic Services
Mirel Palamaru, Radiation Safety Officer
State of Indiana

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| OFFICE | RIII DNMS | C | RIII DNMS | | RIII DNMS | | RIII DNMS | |
|---|---|---|---|---|---|---|---|---|
| NAME | MMLaFranzo: jm MML | | PLLouden PLL | | | | | |
| DATE | 02/18/2011 | | 02/18/2011 | | | | | |

**OFFICIAL RECORD COPY**

NOTICE OF VIOLATION

The Community Hospital
Munster, Indiana

Docket No. 030-09964
License No. 13-15882-01

During the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 26, 2010, with continuing NRC in-office review through January 25, 2011, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the Code of Federal Regulations (CFR) 35.41(a) states, in part, 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 October 26, 2010, 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 four 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).

Pursuant to the provisions of CFR 2.201, The Community Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, 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). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html to the extent possible, it should not include any personal privacy, proprietary or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response,

then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

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

Dated this 18th day of February 2011.

Enclosure

**INSPECTION RECORD**

NMED: 100536 and 100538
**Region** III **Inspection Report No.** 030-09964/210-001(DNMS)
**License No.** 13-15882-01 **Docket No.** 030-09964

**Licensee (Name and Address)**:
The Community Hospital
901 MacArthur Boulevard
Munster, Indiana 46321

**Licensee Contact:** Mirel Palamaru – RSO **Telephone No.** 219-836-7368

**Priority**: 2 **Program Code**: 2240

**Date of Last Inspection:** 4/08
**Date of This Inspection**: 10/26/2010 with continuing NRC review through 1/25/2011

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

**Next Inspection Date**: 1/2013 (X) Normal ( ) Reduced
**Justification for reducing the routine inspection interval**:

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 ***/RA/*** Date: ***02/16/2011***
Michael LaFranzo – Health Physicist

Approved ***/RA by Patrick L. Louden for/*** Date: ***02/16/2011***
Tamara E. Bloomer – Chief, MIB

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

### 1. AMENDMENTS AND PROGRAM CHANGES:

| Amendment No. | Date | Subject |
|---|---|---|
| 70 | 3/29/10 | Change in Radiation Safety Officer |
| 69 | 2/12/10 | Addition of Authorized User |
| 68 | 9/9/09 | Addition of Authorized User |
| 67 | 4/6/09 | Addition of Authorized User |
| 66 | 11/21/08 | Additional Location of Use |
| 65 | 11/10/08 | Addition of licensed activities concerning brachytherapy and HDR |

### 2. INSPECTION AND ENFORCEMENT HISTORY:

A routine U.S. Nuclear Regulatory Commission (NRC) inspection was conducted on April 1-2, 2008; no violations of NRC requirements were identified. A subsequent NRC inspection was conducted on March 21, 2006; no violations of NRC requirements were identified.

### 3. INCIDENT/EVENT HISTORY:

None

## PART II - INSPECTION DOCUMENTATION

### 1. ORGANIZATION AND SCOPE OF PROGRAM:

CEO
Vice President of Diagnostic and Therapeutic Services
Medical Director
Radiation Safety Officer

The licensee is permitted to use licensed material pursuant to Title 10 of the Code of Federal Regulations (CFR) 35.100, 35.200, 35.300, 35.400, 35.600 and 35.1000 and the possession of a sealed source. The licensee performed approximately 5-10 cases of permanent seed implants per year, 15-25 HDR cases per year, and 40-60 administrations of multi-millicurie iodine-131 concerning treatment of disease per year. The licensee performed approximately 10-20 diagnostic administrations per day – Monday through Friday. The licensee did not possess Moly-Tc generators and received only unit doses. The licensee has two locations of use. At the time of the inspection, only one location was on the license, see Section 4 for details. The licensee had several nuclear medicine technicians, 35 authorized users and two authorized medical physicists.

### 2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130, 87313, 87132

Focus Areas Evaluated: 03.01 – 03.07

### 3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector performed radiological surveys of restricted and unrestricted areas of the licensee's facility; no abnormal radiation levels were identified. The inspector 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:

Title 10 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.

During the inspection, the inspector identified four administrations of Pd-103 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 inspector 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 Pd-103 seeds in or near the target organ. On October 27 and November 1, 2010, the licensee contacted the NRC Operations Center to report the potential medical events.

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 licensee completed its dose evaluation in December 2010. The NRC reviewed the re-evaluations and determined that a medical event did not occur for any of the four administrations. On January 26, 2011, the licensee contacted the NRC Operations Center and retracted the four medical events that were reported earlier.

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 four administrations deviated from the written directive by 28%, 36%, 56% and 56%. The licensee failed to identify these significant deviations. As a result, an NRC inspection was required to ensure that the licensee determined whether or not a medical event had occurred. 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.

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, the NRC characterized this violation at a Severity Level IV. The licensee will be required to respond in writing to the violation. At the time of the exit meeting, the licensee was reviewing its procedures to ensure that each administration was in accordance with the written directive.

Title 10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized by the license. Condition 10 of License No. 13-15882-01 requires that licensed material be used only at 901 MacArthur Boulevard; Munster, Indiana.

During the inspection, the NRC identified that the licensee had not submitted an amendment to the NRC regarding licensed activities at 10020 Donald S. Powers Drive until October 2010. The inspector noted that the licensee had been administering radioactive material using F-18 at that location since August 2005. On August 7, 2009, the NRC issued Federal Register Notice No. 189, Volume 189 which stated, in part, the licensees were required to submit an amendment to the NRC for the use of byproduct (accelerator produced) material, which includes F-18, no later than February 2010. The licensee identified earlier in 2010 that a license amendment should be submitted to the

NRC; however, the licensee stated that the amendment did not get sent to the NRC until October 2010.

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:

#*& Rose Garcia – Vice President
#*& Mirel Palamaru – Radiation Safety Officer
Dr. Andrej Zajac – Authorized User
Dr. Erlinda Roque-Kerekas – Authorized User
Dr. Eric Zickgraf – Authorized Medical Physicist

Use the following identification symbols:
# Individual(s) present at entrance meeting
* Individual(s) present at on-site exit meeting
& Individuals present at telephonic exit meeting on January 19, 2011

-END-