



Indiana University Health

December 9, 2011

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

Re: Reply to a Notice of Violation
Docket No. 030-35485
License No. 13-15399-02

Dear Sir or Madam:

This letter and its enclosures are in response to the above-indicated Notice of Violation dated November 14, 2011.

1. Reason for Violation. The failure to seek advanced approval for the change in ownership of the Starke Memorial Hospital was due to inadvertent oversight.
2. Corrective Steps. The documents submitted with this letter, and previously provided in response to this investigation, constitute the corrective steps for this violation.
3. Timing. These corrective steps are effective as of the acceptance of this letter and its enclosures by the NRC.
4. Full Compliance. The date of the NRC's acceptance of this response is the effective date of full compliance.

Please accept this submission on behalf of Indiana University Health Starke Hospital f/k/a Starke Memorial Hospital. Please contact the undersigned or David W. Hyatt, MHA, Vice President of Operations at (574) 772-1118 if there are further questions.

Very truly yours

IU HEALTH STARKE HOSPITAL

A handwritten signature in black ink that reads "Linda L. Satkoski".

Linda L. Satkoski, MSA, RN
President, CEO/CNO

cc: Regional Administrator, Region III

Enclosure

IU Health Starke Hospital
PO Box 339
102 East Culver Road
Knox, IN 46534

T 574.772.6231 800.223.6231 F 574.772.5948

iuhealth.org

Handwritten initials "JED" above the words "REGION III" written in a stylized, blocky font.

Change of Control Information

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who NRC may contact if more information is needed.

As fully described in the communication forwarded by David W. Hyatt, Vice President of Operations at Indiana University Health Starke Hospital (the "Hospital") to Robert G. Gattone, Jr., on August 25, 2011 and the enclosed memorandum from James Kaminski, Esq., outside counsel for the Hospital, the Hospital assumed the operations from the previous licensee at that location. The previous licensee's name was Principal Knox, LLC (the "Seller"). The name of the legal entity assuming the lease was CNI Starke, LLC (the "LLC").

The LLC, as of July 1, 2009, took operations control from the Seller. Due to inadvertent oversight, the US NRC did not receive specific notice of this change of control at that time.

The LLC continued to operate the Hospital under the lease with Starke County (the "County") and the operations under Byproduct Materials License, #13-15399-01 continued undisturbed. Personnel were the same and, of course, the facilities, equipment, and procedures were unchanged.

In the summer of 2011, there were a number of changes that affected BML #13-15399-01. First, the corporate name of the Hospital/LLC was changed to the current name, Indiana University Health Starke Hospital, LLC, effective as of November 1, 2011. Second, a new group of physicians (the group previously also serving LaPorte Regional Health System, Inc., the parent entity of the Hospital/LLC) were added as authorized users on the BML #13-15399-01. The previous physicians listed on that license were also deleted. Finally, Stan Buhr was added as the Radiation Safety Officer in lieu of Maximo Bleza, D.O.

The subsequent site visit and correspondence between the Hospital/LLC and the NRC staff brought to light the mistake in failing to notify the change in ownership at the Starke facility. In turn, the NRC issued its Notice of Violation dated November 14, 2011. This Change of Control information sheet responds to that Notice.

2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.

As mentioned above and in the previous correspondence on this matter, Mr. Buhr has been appointed as the new Radiation Safety Officer and the physician group has been replaced. The training and experience of both Mr. Buhr and the physicians were previously provided or incorporated by reference from the Indiana University Health LaPorte Hospital filings.

3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.

Other than as set forth above, there were no changes to the organization, location, facilities, equipment or procedure related to the licensed program.

4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

There were no changes in the surveillance program.

5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

All records concerning the site and effective decommissioning of the facility were transferred by the Seller to the Hospital/LLC.

6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

The Hospital/LLC will abide by and has abided with all constraints, conditions, requirements and commitments of the Seller.

7. Provide documentation the transferor and transferee agree to the change in ownership or control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for resulting enforcement actions.

Enclosed herewith are copies of the change in ownership documents including the agreement between the Seller and the Hospital/LLC to that effect and that the Hospital/LLC was aware of all open inspection items and its responsibilities for resulting enforcement actions.



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

November 14, 2011

Ms. Linda Satkoski
Chief Executive Officer
Starke Memorial Hospital
102 East Culver Road
Knox, IN 46534

**SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-35485/11-001(DNMS) AND
NOTICE OF VIOLATION – STARKE MEMORIAL HOSPITAL**

Dear Ms. Satkoski:

This refers to the U. S. Nuclear Regulatory Commission (NRC) letter to you dated September 16, 2011, regarding an Open Item. During a NRC inspection conducted at Starke Memorial Hospital in Knox, Indiana on August 3, 2011, the inspector identified a potential transfer of control of your license. We have completed our review of the Open Item: the information provided below closes the Open Item, and presents the final results of this inspection. On November 3, 2011, Robert Gattone of my staff discussed the final results of the inspection with Stan Buhr of your staff.

Based on our review, the NRC has determined that a 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 Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation involved failure to secure the NRC's consent in writing prior to a change in control of licensed activities. Specifically, on or about July 1, 2009, Principal Knox, LLC, a holder of NRC License No. 13-15399-02 under the assumed name of Starke Memorial Hospital, failed to secure the NRC's consent in writing prior to transfer of control of the materials license to a new person, CNI Starke, LLC. CNI Starke, LLC, commenced business activities under the assumed name of Starke Memorial Hospital and became responsible, in part, for: (1) the day-to-day operations of the hospital, including providing personnel, overseeing regulatory compliance, and providing and paying for any capital improvements, expenditures, equipment and supplies; and (2) final decisions on budgets, capital purchases, repairs, and maintenance of the physical facility.

The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in this inspection report. 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. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC's review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

L. Satkoski

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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 enclosures, 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 Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

Please feel free to contact Mr. Robert Gattone of my staff if you have any questions regarding this inspection. Mr. Gattone can be reached at (630) 829-9823.

Sincerely,

A handwritten signature in black ink, appearing to read "Tamara Bloomer". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

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

Docket No. 030-35485
License No. 13-15399-02

Enclosure:
Notice of Violation

cc w/encl: Stan Buhr, Radiation Safety Officer
State of Indiana

NOTICE OF VIOLATION

Starke Memorial Hospital
Knox, Indiana

Docket No. 030-35485
License No. 13-15399-02

During a U.S. Nuclear Regulatory Commission inspection conducted on August 3, 2011, with continued in office review through November 4, 2011, a 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) Section 30.34(b) states that no license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

Contrary to the above, on or about July 1, 2009, Principal Knox, LLC, holder of NRC License No. 13-15399-02 under the assumed name of Starke Memorial Hospital, transferred control of the license to CNI Starke, LLC, without prior written consent from the Commission.

This is a Severity Level IV violation (Section 6.3.d.7.).

Pursuant to the provisions of 10 CFR 2.201, Starke Memorial 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 for each violation: (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 previous 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, United States 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 document system (ADAMS), accessible from the NRC Web site 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

Enclosure

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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21. If classified information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR Part 95.

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

Dated this 14th day of November 2011.

**Indiana University Health Starke Hospital
102 East Culver Road
Knox, IN 46534**

August 3, 2011

U.S. Nuclear Regulatory Commission
Region III
Nuclear Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4351

Re: License #13-15399-01

To Whom It May Concern:

We request that our Byproduct Materials License, #13-15399-01 be amended for the following items:

1. Please change the name of our facility from Starke Memorial Hospital to Indiana University Health Starke Hospital.

2. Please add the following physicians as authorized users on our license:

Hester Muller, M.D.; Smari Thordarson, M.D.; John E. DePersio, M.D.; Krishna R. Pillai, M.D.

Each of these physicians is to be authorized for 10 CFR 35.100 and 35.200

For training and experience on these physicians, please reference license # 13-15151-01, for Indiana University Health LaPorte Hospital.

3. Please delete the following physicians as authorized users on our license:

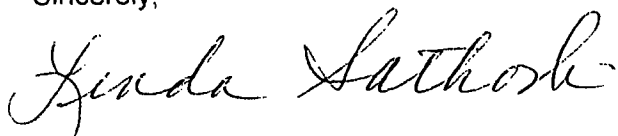
Anil Kotheri, M.D.; Maximo Bleza, D.O.; James Forde, M.D.; Jeffrey Huth, M.D.

4. Please list Stan Buhr rather than Maximo Bleza, D.O. as Radiation Safety Officer for the hospital, effective June 30, 2011. Attached is a copy of license # IL-01612-01, which identifies Stan Buhr as Radiation Safety Officer. We confirm that we have established, in writing the authority, duties and responsibilities of the RSO as required by 10 CFR 35.24 (b).

Please contact us if additional information is required.

Thank you.

Sincerely,



Linda Satkoski, CEO



Delegation of Authority to Radiation Safety Officer

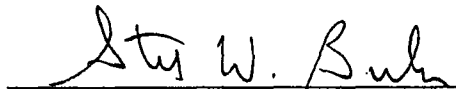
Authority, Duties and Responsibilities of Radiation Safety Officer

You, Stan Buhr, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program, identifying radiation safety problems, initiating recommending or providing corrective actions, stopping unsafe operations, and verifying implementation of corrective actions.

You have been delegated the authority needed to meet those responsibilities, including prohibiting the use of radioactive materials by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the U.S. Nuclear Regulatory Commission at anytime.


Linda Satkoski, CEO

Signature of Management Representative,


Stan Buhr

Signature of Radiation Safety Officer



Indiana University Health

August 25, 2011

Mr. Robert G. Gattone, Jr.
Senior Health Physicist
Materials Inspection Branch
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Mr. Gattone, Jr.

Attached you will find a memo from IU Health Starke Hospital's attorney regarding the issue of change of control from Principal Knox, LLS to CNI-Starke, LLC on July 1, 2009. If you should have any further questions please do not hesitate to contact me or Stan Buhr, our RSO, for more information.

Sincerely,

David W. Hyatt, MHA
Vice President of Operations
IU Health Starke Hospital
574.772.1118

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Indiana University Health

MEMO

TO: Dave Hyatt
FROM: Jim Kaminski
DATE: August 25, 2011
RE: Nuclear Regulatory Inspection Issue

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The Starke Memorial Hospital real estate and facility are owned by the Starke County Government. The facility was leased to Principal Knox, LLC, and the lease was then assigned in July, 2009, from Principal Knox, LLC, to CNI Starke, LLC.

Under the terms of the Lease of the hospital facility, Starke County, as the landlord, retained the right to appoint a Community Board of Directors which was to provide the continued support and involvement of community leaders so that Starke County, as the landlord, would be reasonably informed as to the services provided by the hospital as well as provide the hospital with a meaningful opportunity to continue to influence the operation of the hospital. The "Community Board of Directors" remains appointed by the Starke County Council and Board of Commissioners as the landlord of the facility. The Community Board retains certain rights, including the appointment of the CEO, the discontinuance, sale or subcontracting of major hospital service lines, such as emergency care, imaging, radiology and diagnostic services, and accreditations of the hospital. The Community Board, which has not changed since CNI Starke, LLC, became the lessee, also has consultation rights with respect to capital and operating budgets of the hospital, Medical Staff credentialing and the termination of the CEO of the hospital. Accordingly, those functions were in place and have remained in place for a number of years at the hospital.

CNI Starke, LLC, is the active tenant and is responsible for the day-to-day operations of the hospital, including providing personnel, overseeing regulatory compliance, non-officer personnel issues, and providing and paying for any capital improvements, expenditures, equipment and supplies. As the tenant, it has final decision on budgets, capital purchases, and repairs and maintenance of the physical facility in addition to providing the personnel. The Board of CNI Starke, LLC, is appointed by the La Porte Regional Health System, Inc., and a majority of its members reside in Starke County, but are separate from the "Community Board" appointed by Starke County. Accordingly, the radiation safety program and its day-to-day operations would be administered through CNI Starke, LLC, which is providing the personnel for hospital administration and operation of the facility. It will certainly immediately comply with any notices, acknowledgment or permitting changes consistent with the current hospital relationship required by the Nuclear Regulatory Commission.

James W. Kaminski

JWK:d/s

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Indiana University Health

October 7, 2011

Nuclear Regulatory Commission
Region III
2443 Warrenville Rd., Ste. 210
Lisle, IL 60532-4352

Re: Legal Name Change from CNI Starke, LLC to
Indiana University Health Starke Hospital, LLC

Dear Sir or Madam:

As you may know, on January 22, 2011, CNI Starke, LLC ("Starke") began using the d/b/a **Indiana University Health Starke Hospital, LLC** to promote Starke's relationship and shared mission with the Indiana University School of Medicine. On November 1, 2011, an amendment to Starke's Articles of Incorporation will be effective and will change Starke's legal name to **Indiana University Health Starke Hospital, LLC**. A Certificate of Amendment from the Indiana Secretary of State documenting the name change described above is attached. Please note that this is only a name change. There has been no change in ownership or governance. Our Federal Tax ID number of 27-0328204 will remain the same.

We request that effective November 1, 2011, you change your records to reflect our new legal name of Indiana University Health Starke Hospital, LLC.

We very much appreciate your cooperation in this matter. Please feel free to contact me if you have any questions.

Sincerely,

Linda L. Satkoski, MSA, RN
President, CEO/CNO
IU Health Starke Hospital

Encl.

IU Health Starke Hospital
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