



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

April 20, 2016

EA-15-277

Mr. Brett Colter
Director of General Laboratory Operations
South Bend Medical Foundation, Inc.
530 North Lafayette Boulevard
South Bend, IN 46601

SUBJECT: NOTICE OF VIOLATION - SOUTH BEND MEDICAL FOUNDATION; NRC
ROUTINE INSPECTION REPORT NO. 03001582/2015001(DNMS)

Dear Mr. Colter:

This refers to the routine inspection conducted on November 18 and 19, 2015, with continued in-office review through January 7, 2016, at your South Bend, Indiana facility. The purpose of the inspection was to review activities performed under your U.S. Nuclear Regulatory Commission (NRC) license to ensure that activities were being performed in accordance with NRC requirements. During the inspection, apparent violations of NRC requirements were identified. The significance of the issues and the need for lasting and effective corrective actions were discussed with your staff during the telephonic exit meeting held on February 9, 2016. Details regarding the apparent violations were provided in NRC Inspection Report No. 03001582/2015001(DNMS), dated February 2, 2016.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either providing a written response or requesting a predecisional enforcement conference. In letters dated February 23, 2016, and March 2, 2016, you provided written responses to the apparent violations.

Based on the information developed during the inspection, and the information that you provided in your responses, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the Notice of Violation (Notice) in Enclosure 1 (Non-Public) and the circumstances surrounding them are described in detail in our inspection report dated February 2, 2016. These violations are of concern to the NRC for the reasons stated in the Final Determination of Significance in Enclosure 2 (Non-Public). Therefore, the violations have been categorized, in accordance with the NRC Enforcement Policy, as two Severity Level III problems.

Enclosures 1 and 2 contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosures 1 and 2, this transmittal letter is decontrolled.
--

B. Colter

-2-

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is normally considered for a Severity Level III problem.

Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. In NRC Inspection Report No. 03001582/2015001(DNMS), the NRC described its understanding of the corrective actions taken to correct the violations. In your responses, dated February 23, 2016, and March 2, 2016, your staff described the corrective actions taken to correct the violations and to prevent recurrence. These corrective actions are also documented in Enclosure 2. Based on these corrective actions, the NRC has determined that Corrective Action credit is warranted.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of these Severity Level III problems constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03001582/2015001(DNMS) and in your responses, dated February 23, 2016, and March 2, 2016. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect 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. Additionally, if you choose to respond, please mark your entire response "Security-Related Information – Withhold from Public Disclosure under 10 CFR 2.390." In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390(b)(1)(ii), the NRC is waiving the affidavit requirements for any response to this letter. However, to the extent possible, your response, if any, should not include any personal privacy, proprietary, or safeguards information.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter 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>. However, because of the Security-Related Information contained in the enclosures, and in accordance with 10 CFR 2.390, copies of the Enclosure 1 and 2 will not be available for public inspection.

B. Colter

-3-

Additionally, Enclosures 1 and 2 must be protected from unauthorized disclosure. Security-Related Information is discussed in Regulatory Information Summary RIS-2005-031, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information" (ML053480073), which is available on the NRC Web site or in ADAMS.

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-01582
License No. 13-00670-04

Enclosures:

1. Notice of Violation (Non-Public)
2. Final Determination of Significance (Non-Public)

cc: State of Indiana

B. Colter

-3-

Additionally, Enclosures 1 and 2 must be protected from unauthorized disclosure. Security- Related Information is discussed in Regulatory Information Summary RIS-2005-031, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information" (ML053480073), which is available on the NRC Web site or in ADAMS.

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-01582
License No. 13-00670-04

Enclosures:

1. Notice of Violation (Non-Public)
2. Final Determination of Significance (Non-Public)

cc: State of Indiana

DISTRIBUTION:
See next page

ADAMS Accession Number: ML

To receive a copy of this document, indicate in the box: "C" = Copy without enclosure "E"= Copy with enclosure "N"= No copy

OFFICE	RIII		RIII		RIII		OE		RIII	
NAME	KLambert		AMcCraw		JGiessner		PHolahan		RSkokowski	
DATE	03/28/16		03/28/16		03/28/16		04/13/16		04/19/2016	
OFFICE	RIII									
NAME	CPederson									
DATE	04/20/16									

OFFICIAL RECORD COPY

Letter to Mr. Brett Colter from Ms. Cynthia D. Pederson dated April 20, 2016

SUBJECT: NOTICE OF VIOLATION - SOUTH BEND MEDICAL FOUNDATION; NRC
ROUTINE INSPECTION REPORT NO. 03001582/2015001(DNMS)

DISTRIBUTION:

RidsSecyMailCenter
OCADistribution
Victor McCree
Glenn Tracy
Patricia Holahan
Nick Hilton
Kerstun Norman
Cynthia Pederson
Darrell Roberts
Edward Williamson
Susan Vrahoretis
Scott Moore
Daniel Collins
Michele Burgess
Brian Holian
Michael Layton
Shyrl Coker
Brice Bickett
David Gamberoni
John Kramer
Richard Skokowski

Holly Harrington
Hubert Bell
Kevin Fowler
David D'Abate
EDO Contact
John Giessner
Christine Lipa
Aaron McCraw
Robert Gattone
Allan Barker
Harral Logaras
James Lynch
Viktoria Mitlyng
Prema Chandrathil
Kenneth Lambert
Paul Pelke
Magdalena Gryglak
Sarah Bakhsh
Jim Clay
Carmen Olteanu
RidsOemailCenter
OEWEB Resource (Publicly available only)