



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

May 17, 2016

EA-16-022

Mr. Brian D. Boles
Site Vice President
FirstEnergy Nuclear Operating Co.
Davis-Besse Nuclear Power Station
5501 N. State Rte. 2, Mail Stop A-DB-3080
Oak Harbor, OH 43449-9760

SUBJECT: DAVIS-BESSE NUCLEAR POWER STATION – NRC INSPECTION REPORT
05000346/2016008; INVESTIGATION REPORT NO. 3-2015-009 AND
APPARENT VIOLATION

Dear Mr. Boles:

This letter refers to the investigation completed on January 29, 2016, by the U.S. Nuclear Regulatory Commission's (NRC's) Office of Investigations (OI) at your Davis-Besse Nuclear Power Station facility. The purpose of the investigation was to determine whether a licensed operator deliberately failed to comply with a condition of his license that required him to take medications as prescribed by his physician to maintain medical qualifications. Based on the results of its investigation, the NRC preliminarily determined that the licensed operator deliberately failed to comply with a condition of his license, and failed to provide the facility licensee with information, that was complete and accurate in all material respects, for the submittal of required updates on the operator's medical condition.

Based on results of the investigation, the NRC identified an apparent violation that is being considered for escalated enforcement action in accordance with the NRC's Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violation involved the failure to provide information that was complete and accurate in all material respects on an NRC Form 396 submitted to the Commission in accordance with a licensed operator's license condition, as required by Title 10 of the *Code of Federal Regulations* (CFR) 50.9(a). A Factual Summary, included as an Enclosure to this letter, provides a summary of the factual basis for the apparent violation.

Before the NRC makes its enforcement decision, we are providing you with the opportunity to: (1) provide a written response to the NRC; (2) request a Predecisional Enforcement Conference (PEC), or (3) request Alternative Dispute Resolution (ADR). If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however, the PEC will be closed to public observation since information related to an OI report will be discussed and the report has not been made public. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you decide to submit a written response to this apparent violation, it should be clearly marked as a "Response to Apparent Violation in NRC Inspection Report 05000346/2016008; EA-16-022," and should include: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (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. Additionally, your response should be sent to the NRC's Document Control Center, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, with a copy mailed to Kenneth G. O'Brien, Director, Division of Reactor Safety, Region III, U.S. Nuclear Regulatory Commission, Suite 210, 2443 Warrenville Road, Lisle, IL 60532-4352, within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include: (1) information to determine whether the violation occurred; (2) information to determine the significance of the violation; (3) information related to the identification of the violation; and (4) information related to any corrective actions taken or planned. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions would be considered in assessing any civil penalty for the apparent violation.

You may also request ADR with the NRC in an attempt to resolve the willful apparent violation. The term ADR generally encompasses various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact ICR, at 877-733-9415, within 10 days of the date of this letter, along with notifying Mr. Orlikowski, if you are interested in pursuing resolution of this issue through ADR. The ADR mediation session is normally held within 30 to 45 days of receipt of this letter, dependent upon availability of a mediator.

Please contact Mr. Robert Orlikowski, at 630-829-9834, within 10 days from the issue date of this letter to notify the NRC of how you intend to respond to the apparent violation.

B. Boles

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Please be advised that the number and characterization of apparent violations may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response (if any) will be available electronically for public inspection in the NRC's Public Document Room or from the Publicly Available Records (PARS) component of the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

If you have any questions concerning this matter, please contact Mr. Robert Orlikowski of my staff at 630-829-9834.

Sincerely,

/RA/

Kenneth G. O'Brien, Director
Division of Reactor Safety

Docket No. 50-346
License No. NPF-3

Enclosure:
Factual Summary of NRC Investigation

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FACTUAL SUMMARY OF OFFICE OF INVESTIGATIONS REPORT 3-2015-009

On February 9, 2015, the U.S. Nuclear Regulatory Commission (NRC) Office of Investigations (OI), Region III Field Office, initiated an investigation to determine whether a licensed reactor operator at the Davis-Besse Nuclear Power Station deliberately failed to comply with a condition of his license and to report a change in a medical condition. The NRC completed its investigation on January 29, 2016.

The licensed reactor operator received his reactor operator license in January 2012. Pursuant to 10 CFR 55.33(b), the license included conditions to take all medications as prescribed by the licensed operator's physician to maintain medical qualifications and to wear corrective lenses when performing licensed duties. In March 2012, the NRC amended the operator's license to include a condition to provide 3-month updates to the NRC on his medical condition, prognosis, treatment, and ability to perform licensed activities. The operator was taking two medications to control diabetes at the time the original license was issued.

The operator indicated that part of the initial training included reporting of an individual's medical issues. The operator also stated that he had received continuing training several times since he had received his license. During these continuing training sessions, it was stressed to report all new medications that were prescribed, including any changes in medications or discontinuance of any medications. The operator indicated during his interview that he understood the condition of his license, as well as the need to report any changes in medication to the licensee's health center.

In January 2013, the operator's personal physician prescribed the operator a blood pressure medication. On January 2, 2013, the operator filled the prescription, obtaining a 3-month supply. He did not refill the prescription and in August 2013, during a doctor's appointment, the operator's blood pressure was high again. The physician prescribed the same blood pressure medicine at a higher dose. The operator indicated that in August 2013, he notified the Davis-Besse Health Center by telephone that he had been prescribed the blood pressure medication. In November 2013, the operator filled the prescription for the higher dose. He stated that he stopped taking the medication at some point in either November or December of 2013 because it caused side effects. He reported the cessation to his physician on January 31, 2014, at which point his physician told him not to take it anymore.

In January of 2014, the operator's physician prescribed a third medication for controlling his diabetes. The operator stated he notified the Davis-Besse Health Center of this additional medication he was taking. The operator filled the prescription in January for a 1-month supply and then refilled the prescription again in March with a 1-month supply. The operator also indicated that due to the high cost of the medicine, he stopped taking the third diabetes medication after one month, and notified his physician on April 30, 2014.

On July 10, 2014, the operator signed a compliance package used to generate the required Form 396 stating that he was taking his medications as prescribed. The "explanation" section of the compliance package listed all four of the medications that the operator's physician had prescribed. Despite the fact that he was no longer taking two of the listed medications, the operator signed the compliance package. Davis-Besse submitted the status report required by the additional condition of the operator's license on July 11, 2014. The status report indicated that the operator was taking all of the medications that he had been prescribed when he was not actually taking all of them.

Enclosure

In the licensee's internal investigation, the operator stated that he mentioned to a licensee Regulatory Compliance staff member that the medications were not correct, but was under the impression there was not time to correct the form before it was due. The operator stated that he signed the form with the intentions of getting the medication list corrected later. A review of the NRC Form 396s submitted quarterly by the facility licensee was conducted for 2013 and 2014. This review determined that NRC Form 396s submitted by the facility licensee on February 6, 2013, October 18, 2013, and February 17, 2014, also contained inaccurate information regarding the prescribed medications listed on the Form 396 and the actual medications taken by the operator at the time the forms were submitted.

On July 31, 2014, the operator completed a physical and noted that he was taking only two medications. The medical center questioned the operator as to why he was not taking the two additional medications listed on his medical record. The operator stated that he was surprised by the questioning because he believed he had informed the medical center that he was no longer taking the two medications in question. However, there is no record that he informed the Health Center.

Based on the evidence gathered in the OI investigation, it appears a licensed reactor operator deliberately provided false information to the facility licensee. This inaccurate information was used by the facility licensee to complete NRC Form 396s that were submitted to the NRC. Specifically, the operator deliberately provided incomplete or inaccurate information by signing the forms attesting to the accuracy of the document listing the prescription medication he was taking when he knew the list was inaccurate. The information in the document was material to the NRC because it provided the basis for the operator's medical qualification. Therefore, the operator apparently violated Title 10 CFR 50.5(a)(2) that requires, in part, that an employee of a licensee may not deliberately submit to the licensee information that the person submitting the information knows to be inaccurate in some respect material to the NRC. His actions also apparently caused the facility licensee to be in violation of 10 CFR 50.9(a).

B. Boles

-3-

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In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response (if any) will be available electronically for public inspection in the NRC's Public Document Room or from the Publicly Available Records (PARS) component of the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

If you have any questions concerning this matter, please contact Mr. Robert Orlikowski of my staff at 630-829-9834.

Sincerely,

/RA/

Kenneth G. O'Brien, Director
Division of Reactor Safety

Docket No. 50-346
License No. NPF-3

Enclosure:
Factual Summary of NRC Investigation

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DATE	04/26/16		04/27/16		05/06/16		05/06/16		05/06/16	
OFFICE	RIII									
NAME	O'Brien									
DATE	05/17/16									

OFFICIAL RECORD COPY

¹ OE Concurrence received from G. Gulla on May 6, 2016.

² OGC Concurrence received from R Carpenter on May 6, 2016.

Letter to Mr. Brian B. Boles from Mr. Kenneth G. O'Brien dated May 17, 2016

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