

Brian D. Boles  
Vice President, Nuclear

419-321-7676

December 1, 2016  
L-16-347

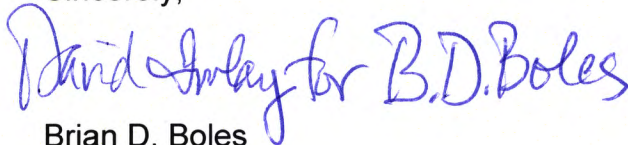
Kenneth O'Brien  
Director, Division of Reactor Safety  
U.S. Nuclear Regulatory Commission Region III  
2443 Warrenville Road, Suite 210  
Lisle, Illinois 60532-4352

SUBJECT:  
Davis-Besse Nuclear Power Station, Unit 1  
Docket Number 50-346, License Number NPF-3  
Action for Confirmatory Order EA-16-022

On September 1, 2016, the NRC issued a Confirmatory Order to the FirstEnergy Nuclear Operating Company (FENOC) modifying the Davis-Besse Nuclear Power Station (DBNPS) license. This Confirmatory Order was the result of an agreement reached during an alternative dispute resolution (ADR) mediation session conducted on July 21, 2016. One of the actions agreed upon during this ADR mediation session was that no later than December 31, 2016, FENOC would submit an article to a widespread trade publication based on the facts and lessons learned from the event that gave rise to the Confirmatory Order. FENOC would also provide a draft of the article to you 30 days prior to the submittal to the trade publication. The draft of this article is attached for your review.

There are no regulatory commitments contained in this letter. If there are any questions or if additional information is required, please contact Mr. Gerald M. Wolf, Supervisor, Regulatory Compliance, at (419) 321-8001.

Sincerely,



Brian D. Boles

GMW

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Enclosure: Draft Article for Trade Publication

Davis-Besse Nuclear Power Station, Unit 1  
L-16-347  
Page 2 of 2

cc: NRC Document Control Desk  
DB-1 Senior Resident Inspector



Draft Article for Trade Publication  
Page 1 of 3

The Importance of Maintaining Medical Qualifications by a Licensed Operator

The importance of an operator meeting conditions of his Nuclear Regulatory Commission (NRC) license was recently emphasized at the Davis-Besse Nuclear Power Station, operated by the FirstEnergy Nuclear Operating Company (FENOC), when a licensed reactor operator was issued an individual violation for intentionally violating his license condition requirements.

Reactor Operator and Senior Reactor Operators are licensed by the NRC in accordance with Title 10 of the Code of Federal Regulations, Part 55 (10 CFR 55). One of the requirements to receive a license is that the operator's medical condition and general health will not adversely affect the performance of assigned duties or cause operational errors endangering public health and safety. If an operator's general medical condition does not meet the minimum standards (such as those specified in American Nuclear Society Standard ANSI/ANS 3.4 or ANSI/ANS 15.4), the NRC may still grant a license; however, the license will include conditions in the license to accommodate the medical "defect." These conditions include items such as wearing corrective lenses, wearing a hearing aid, taking medication as prescribed, and use of a therapeutic device as prescribed. The NRC can also request more frequent monitoring and reporting of the operator's medical condition if necessary to ensure compliance with the applicable ANSI standard.

An operator at Davis-Besse was issued a Reactor Operator License that contained a restriction to "take medication as prescribed" in order to control a medical condition. Soon after his license was issued, it was amended to include another condition to provide 3-month status updates to the NRC on his medical condition, prognosis, treatment, and ability to perform licensed activities.

In July 2014, during a Fire Brigade physical, a Health Center nurse noted discrepancies between the operator's prescribed medications listed in his medical record and those he reported during his physical that he was actually taking. The operator's medical qualifications were immediately placed on hold to prevent him from standing watch until the issue was resolved and an internal investigation was initiated. After receiving information from the operator's personal physician, FENOC notified the NRC of the deficiency and updated the NRC on the operator's medical status. FENOC ultimately determined the operator had stopped certain prescribed medications without his doctor's prior approval. . As such, the Operator was not compliant with the condition of his license requiring him to "take medication as prescribed."

Throughout the period of non-compliance, the NRC license requirement for the operator to submit 3-month status updates remained in effect. All of the status updates, along with any changes to his medical condition during this time were prepared based on information supplied by the operator. In addition, the operator signed correspondence review and



approval forms prior to submittal indicating that to the best of his knowledge, the information contained in the submittal was accurate and complete.

In February 2015, the NRC Office of Investigation (OI) initiated an investigation. Following their investigation of the matter, the NRC determined that four status updates submitted for the operator contained inaccurate information regarding the prescribed medications listed. As a result, the NRC issued two deliberate violations to the licensed operator for:

1. Performing licensed duties without complying with the conditions imposed on his license for taking medication as prescribed to maintain medical qualifications,
2. Knowingly providing incomplete or inaccurate information regarding his medical condition, specifically, the prescribed medications being taken to the facility licensee (FENOC).

The NRC determined this to be a Severity Level III problem.

The NRC also issued an Apparent Violation of 10 CFR 50.9 to FENOC for submittal of inaccurate information to the NRC regarding the operator's medical qualification. FENOC attended an Alternative Dispute Resolution (ADR) session in July of 2016 for the Apparent Violation. Corrective Actions that had been taken prior to the ADR session included:

1. Performance Management actions with the individual licensed operator;
2. Provided required reading to all licensed operators at Davis-Besse on requirements for maintaining medical qualifications and reporting changes in medical conditions;
3. Reinforced expectations and requirements for medical reporting and completeness and accuracy of information;
4. Verified through an independent operator survey the effectiveness of communications to licensed operators regarding this issue; and
5. Completed a review of corrective action program documents to identify potential trends in medical reporting.

During the ADR session, the following actions were agreed to be taken (unless specified as plant specific, these actions are being taken throughout the FENOC Fleet):

1. At Davis-Besse, operations management will discuss with each licensed operator the facts and lessons learned from this event;
2. Operator requalification training materials will be revised to incorporate the facts and lessons learned from this event;
3. Management will communicate expectations and requirements for complete and accurate medical reporting to operations and site protection personnel subject to those requirements;
4. Plant access training will be revised and administered fleet-wide to address the provisions of 10 CFR 50.9 regarding completeness and accuracy of information, incorporating the facts and lessons learned from this event;
5. Upon completion of items 3 and 4 to strengthen communications and training, FENOC will complete an effectiveness review of those items;

6. Fleet procedures will be revised governing the update of licensed operator's medical reports to state that the company physician may request the operator submit prescription purchase records or receipts if the physician deems appropriate;
7. A presentation will be made at the Nuclear Medical Resources Professionals User Group to engage industry personnel from across the United States on the facts and lessons learned from this event;
8. An article will be submitted to a widespread trade publication based on the facts and lessons learned from this event (This article is fulfilling this action); and
9. Upon completion of various portions of these actions FENOC will provide written notification of the completed actions, with the final notification to be completed no later than December 31, 2018.

Key lessons learned from this Davis-Besse event include the following:

- A. Licensed operators must comply with the conditions of their license. For medication restrictions, the operator must follow the direction of their personal physician, and be forthright and deliberate with information on any potential change to their medical condition.
- B. When submitting information to the NRC, completeness and accuracy are essential.

Even though lessons A and B above seem to be basic rules that any nuclear power plant employee should know, there may still be employees that are unaware of the consequences of not following these or similar rules. The importance of following regulations should be reinforced to the applicable population on a frequent interval to ensure seemingly minor problems do not end up as much larger issues.