



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

September 1, 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: CONFIRMATORY ORDER RELATED TO NRC REPORTS  
05000346/2016008; INVESTIGATION REPORT NO. 3-2015-009;  
DAVIS-BESSE NUCLEAR POWER STATION**

Dear Mr. Boles:

The enclosed Confirmatory Order is being issued to First Energy Nuclear Operating Company, Ohio, (FENOC) as a result of a successful Alternative Dispute Resolution (ADR) session. As the representative of the licensee, you made the enclosed commitments as part of a settlement agreement between FENOC and the U.S. Nuclear Regulatory Commission (NRC) concerning apparent violations of NRC requirements. The apparent violations are discussed in the enclosure to our letter dated May 17, 2016.

Our May 17, 2016 (ML16138A562) letter provided you with the results of an investigation conducted by the NRC's Office of Investigations 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.

Our letter also informed you that the apparent violations were being considered for enforcement action in accordance with the NRC's Enforcement Policy, and provided you with the option of: (1) providing a written response to the violation; (2) attending a Predecisional Enforcement Conference; or (3) requesting ADR with the NRC.

In response to our letter, you requested ADR. An ADR mediation session was held on July 21, 2016, and a preliminary settlement agreement was reached. The elements of the preliminary agreement were formulated and agreed to at the mediation session. At the session, you agreed that a Confirmatory Order would be issued in settlement of a disputed claim in order to avoid further action by the NRC. In light of the corrective actions you took or agreed to take, as described in the Confirmatory Order (Enclosure 1), the NRC is satisfied that its concerns will be addressed by making your commitments legally binding. As evidenced by your signed "Consent

and Hearing Waiver Form” (Enclosure 2), dated August 29, 2016, you agreed to the issuance of the Confirmatory Order.

Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of this Confirmatory Order shall be subject to criminal prosecution, as set forth in that section. Violation of this Confirmatory Order may also subject the person to civil monetary penalties.

In accordance with 10 CFR 2.390 of the NRC’s “Rules of Practice,” a copy of this letter, along with its enclosures, 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>. The Confirmatory Order will be published in the Federal Register. The NRC also publishes Confirmatory Orders on its Web site under Significant Enforcement Actions at <http://www.nrc.gov/about-nrc/regulatory/enforcement.html>.

Sincerely,

***/RA by Darrell J. Roberts acting for/***

Cynthia D. Pederson  
Regional Administrator

Docket Nos. 50-346; 72-014  
License No. NPF-3

Enclosures:

1. Confirmatory Order
2. Consent and Hearing Waiver

cc: Distribution via LISTSERV®

**UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION**

<b>In the Matter of</b>	)	
	)	
<b>ALL POWER REACTOR LICENSEES</b>	)	
<b>OWNED AND OPERATED BY</b>	)	<b>Docket Nos. (Attachment 1)</b>
<b>FIRST ENERGY NUCLEAR OPERATING</b>	)	<b>Licensed Nos. (Attachment 1)</b>
<b>COMPANY; AND FIRST ENERGY CORP</b>	)	
	)	<b>EA-16-022</b>

**CONFIRMATORY ORDER MODIFYING LICENSE**

I

First Energy Nuclear Operating Company (FENOC), is the holder of Reactor Operating License No. NPF-3 issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 on April 22, 1977. The license authorizes the operation of the Davis-Besse Nuclear Power Station (Davis-Besse) in accordance with conditions specified therein. The facility is located on FENOC's site in Oak Harbor, Ohio.

This Confirmatory Order is the result of an agreement reached during an alternative dispute resolution (ADR) mediation session conducted on July 21, 2016.

II

On February 9, 2015, the NRC Office of Investigations (OI), Region III Field Office, initiated an investigation to determine whether a licensed reactor operator at Davis-Besse 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.

Based on the evidence gathered in the OI investigation, a licensed reactor operator deliberately provided false information to the facility licensee. This inaccurate information was used by the facility licensee to complete NRC 396 forms that were submitted to the NRC. Specifically, the operator signed forms validating the accuracy of the list of prescription medication he was taking when he knew the list was inaccurate. The information in the document, which was material to the NRC because it provided the basis for the operator's medical qualification, was submitted to the NRC by the facility licensee causing a violation of 10 CFR 50.9(a).

FENOC accepted the NRC's offer of Alternative Dispute Resolution (ADR) to resolve the dispute with the NRC over the results of the investigation and the apparent violation. ADR is a process in which a neutral mediator with no decision-making authority assists the parties in reaching an agreement to resolve differing views on the dispute. On July 21, 2016, FENOC and the NRC met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution.

Prior to the NRC's offer to engage in ADR, FENOC had already taken several corrective actions, including (but not limited to):

1. Took 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 with Davis-Besse and FENOC management through routine

Operations Leadership meetings, and Operations and Regulatory Compliance Peer Team calls;

4. Verified through an Independent Operator Survey the effectiveness of communications to licensed operators regarding the requirements for medical reporting and completeness and accuracy of information; and
5. Completed a review of corrective action program documents to identify potential trends in medical reporting.

### III

During the ADR session held on July 21, 2016, a preliminary settlement agreement was reached. This Confirmatory Order is issued pursuant to the agreement reached during the ADR process. The elements of the agreement, as signed by both parties, consisted of the following:

1. To reinforce knowledge of and compliance with requirements for medical qualifications and completeness and accuracy of reported information, FENOC will take the following actions related to licensed operator requalification training at Davis-Besse:
  - a. Within 60 days of the effective date of the Confirmatory Order, Davis-Besse operations management will complete discussions with each licensed operator regarding the facts and lessons learned from the event that gave rise to the Confirmatory Order.

- b. No later than December 31, 2016, FENOC will revise operator requalification training materials to incorporate facts and lessons learned from the event that gave rise to the Confirmatory Order.
2. To reinforce knowledge of and compliance with requirements for ensuring the completeness and accuracy of reported information across the fleet, FENOC will take the following actions:
  - a. No later than December 31, 2016, appropriate FENOC management will communicate expectations and requirements for complete and accurate medical reporting to operations and security personnel subject to those requirements;
  - b. No later than December 31, 2017, FENOC will revise and administer fleetwide plant access training. The revised training shall address the provisions of 10 CFR 50.9 and incorporate facts and lessons learned from the event that gave rise to the Confirmatory Order.
3. Upon completion of actions taken under items 1 and 2 to strengthen communications and training, but in no event later than two years from the effective date of the Confirmatory Order, FENOC shall complete an effectiveness review of those actions.
4. No later than December 31, 2016, FENOC will revise existing fleet procedures governing the update of licensed operators' medical reports. The revised procedure will state that the licensed medical physician may request that the operator submit prescription purchase records or receipts, if the physician deems appropriate.

5. To ensure dissemination of the facts and lessons learned across the nuclear industry, FENOC will take the following actions:
  - a. Within 30 days of the Agreement in Principle, FENOC will make a presentation at the Nuclear Medical Resources Professionals User Group to engage industry personnel from across the entirety of the United States on the facts and lessons learned from the event that gave rise to the Confirmatory Order.
  - b. No later than December 31, 2016, FENOC shall 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 shall provide to the Director, Division of Reactor Safety, NRC Region III, a draft of the article 30 days prior to the submittal.
  
6. To ensure communication of actions completed and to enable NRC inspection, FENOC will make the following notifications to the Director, Division of Reactor Safety, NRC Region III:
  - a. No later than March 1, 2017, FENOC will provide written notification of the completion of actions taken under items 1a., 1b., 2a., 4, 5a., and 5b.
  - b. No later than December 31, 2018, FENOC will provide written notification of the completion of actions taken under items 2b. and 3.

In exchange for the commitments and corrective actions taken by FENOC, the NRC agrees to the following conditions:

1. The NRC will not issue a violation and agrees not to pursue any further enforcement action in connection with the NRC's May 17, 2016 letter to FENOC.
2. The NRC will consider the Confirmatory Order as an escalated enforcement action for a period of one year from its effective date.

This agreement is binding upon the successors and assigns of FENOC.

On August 29, 2016, FENOC consented to issuing this Confirmatory Order with the commitments, as described in Section V below. FENOC further agreed that this Confirmatory Order is to be effective 30 calendar days after issuance of the Confirmatory Order and that it has waived its right to a hearing.

#### IV

Since FENOC agreed to take additional actions to address NRC concerns, as set forth in Section III above, the NRC concluded that its concerns can be resolved through issuance of this Confirmatory Order.

I find that FENOC's commitments as set forth in Section V are acceptable and necessary and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that FENOC's commitments be confirmed by this Order. Based on the above and FENOC's consent, this Confirmatory Order is effective 30 calendar days after issuance.



Accordingly, pursuant to Sections 104b, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 10 CFR Part 50, IT IS HEREBY ORDERED THAT THE ACTIONS DESCRIBED BELOW WILL BE TAKEN AT DAVIS-BESSE NUCLEAR POWER STATION AND OTHER NUCLEAR PLANTS IN FENOC'S FLEET WHERE INDICATED AND THAT LICENSE NO. NPF-3 IS MODIFIED AS FOLLOWS WITH RESPECT TO THE ACTIONS TO BE TAKEN AT THE DAVIS-BESSE NUCLEAR POWER STATION:

1. Within 60 days of the effective date of the Confirmatory Order, Davis-Besse operations management will complete discussions with each licensed operator regarding the facts and lessons learned from the event that gave rise to the Confirmatory Order.
2. No later than December 31, 2016, FENOC will revise operator requalification training materials to incorporate facts and lessons learned from the event that gave rise to the Confirmatory Order.
3. No later than December 31, 2016, appropriate FENOC management will communicate expectations and requirements for complete and accurate medical reporting to operations and security personnel subject to those requirements.
4. No later than December 31, 2017, FENOC will revise and administer fleetwide plant access training. The revised training shall address the provisions of 10 CFR 50.9 and

incorporate facts and lessons learned from the event that gave rise to the Confirmatory Order.

5. Upon completion of actions taken under items 1, 2, 3, and 4, but in no event later than two years from the effective date of the Confirmatory Order, FENOC shall complete an effectiveness review of those actions.
6. No later than December 31, 2016, FENOC will revise existing fleet procedures governing the update of licensed operators' medical reports. The revised procedure will state that the licensed medical physician may request that the operator submit prescription purchase records or receipts, if the physician deems appropriate.
7. Within 30 days of the Agreement in Principle, FENOC will make a presentation at the Nuclear Medical Resources Professionals User Group to engage industry personnel from across the entirety of the United States on the facts and lessons learned from the event that gave rise to the Confirmatory Order.
8. No later than December 31, 2016, FENOC shall 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 shall provide to the Director, Division of Reactor Safety, NRC Region III, a draft of the article 30 days prior to the submittal.
9. No later than March 1, 2017, FENOC will provide written notification to the Director, Division of Reactor Safety, NRC Region III of the completion of actions taken under items 1, 2, 3, 6, 7, and 8.

10. No later than December 31, 2018, FENOC will provide written notification to the Director, Division of Reactor Safety, NRC Region III of the completion of actions taken under items 4 and 5.

The Regional Administrator, Region III, may, in writing, relax or rescind any of the above conditions upon demonstration by FENOC of good cause.

## VI

Any person adversely affected by this Confirmatory Order, other than FENOC, may request a hearing within 30 days of the issuance date of this Confirmatory Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007), as amended by 77 FR 46562; August 3, 2012 (codified in pertinent part at 10 CFR Part 2, Subpart C). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at [hearing.docket@nrc.gov](mailto:hearing.docket@nrc.gov), or by telephone at 301-415-1677, to (1) request a digital (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. System requirements for accessing the E-Submittal server are detailed in NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange (EIE), users will be required to install a Web browser plug-in from the NRC Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene through the EIE. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time (ET) on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, any others who wish to participate in the proceeding (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by e-mail at [MSHD.Resource@nrc.gov](mailto:MSHD.Resource@nrc.gov), or by a toll-free call at (866) 672-7640. The NRC Meta System Help Desk is available between 8:00 a.m. and 8:00 p.m., ET, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is available to the public at <http://ehd1.nrc.gov/ehd/>, unless excluded pursuant to an order of the Commission or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, participants are requested not to include copyrighted materials in their submission, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application.

If a person other than the licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Confirmatory Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue a separate Order designating the time and place of any hearings, as appropriate. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 30 days after issuance of the Confirmatory Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

Dated at Lisle, Illinois this 1<sup>st</sup> day of September 2016

For the Nuclear Regulatory Commission

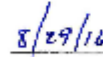
***/RA by Darrell J. Roberts acting for/***

Cynthia D. Pederson  
Regional Administrator

**CONSENT AND HEARING WAIVER FORM**

The First Energy Nuclear Operating Company hereby agrees to comply with the terms and conditions of Confirmatory Order arising out of an alternative dispute resolution process to be issued relating to enforcement action No. 2016-022. The Confirmatory Order will be immediately effective upon its issuance. By signing below, the First Energy Nuclear Operating Company consents to the issuance of the referenced Confirmatory Order effective immediately upon its issuance and, by doing so, agrees to waive the right to request a hearing on all or any part of the Confirmatory Order.

  
\_\_\_\_\_

  
\_\_\_\_\_

**Brian D. Boles**  
**Davis-Besse Site Vice President**  
**First Energy Nuclear Operating Company**

**Date**



and Hearing Waiver Form” (Enclosure 2), dated August 29, 2016, you agreed to the issuance of the Confirmatory Order.

Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of this Confirmatory Order shall be subject to criminal prosecution, as set forth in that section. Violation of this Confirmatory Order may also subject the person to civil monetary penalties.

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Sincerely,

*/RA by Darrell J. Roberts acting for/*

Cynthia D. Pederson  
Regional Administrator

Docket Nos. 50-346; 72-014  
License No. NPF-3

Enclosures:

1. Confirmatory Order
2. Consent and Hearing Waiver

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NAME	Martin <sup>1</sup> RC for	Holahan <sup>2</sup> GG for	Skokowski	Pederson DJR for	
DATE	08/18/16	08/18/16	08/31/16	09/01/16	

**OFFICIAL RECORD COPY**

<sup>1</sup> OGC concurred per e-mail from R. Carpenter dated August 18, 2016

<sup>2</sup> OE concurred per e-mail from G. Gulla dated August 18, 2016

**ALL POWER REACTOR LICENSEE OWNED AND OPERATED BY FIRST ENERGY  
NUCLEAR OPERATING COMPANY; AND FIRST ENERGY CORP**

Beaver Valley Power Station, Unit Nos. 1 and 2

Docket Nos'. 50-334 and 50-412

License Nos. DPR-66 and NPF-73

Mr. Marty Richey, Site Vice President

Pennsylvania 168

Shippingport, PA 15001

Davis-Besse Nuclear Power Station, Unit No. 1

Docket No. 50-346

License No. NPF-3

Mr. Brian Boles, Site Vice President

5501 OH-2

Oak Harbor, OH 43449

Perry Nuclear Power Plant, Unit No. 1

Docket No. 50-440

License No. NPF-58

Mr. Dave Hamilton, Site Vice President

10 Center Rd

Perry, OH 44081

Letter to Mr. Brian D. Boles from Ms. Cynthia D. Pederson dated September 1, 2016

SUBJECT: CONFIRMATORY ORDER RELATED TO NRC REPORTS  
05000346/2016008; INVESTIGATION REPORT NO. 3-2015-009;  
DAVIS-BESSE NUCLEAR POWER STATION

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