



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I**
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

April 10, 2015

EA-14-192

Mr. Peter Orphanos
Site Vice President
Nine Mile Point Nuclear Station, LLC
Exelon Generation Company, LLC
P.O. Box 63
Lycoming, NY 13093

SUBJECT: NINE MILE POINT NUCLEAR STATION – NOTICE OF VIOLATION –
SEVERITY LEVEL III PROBLEM - NRC INSPECTION REPORT NO.
05000220/2015008 AND 05000410/2015008

Dear Mr. Orphanos:

This letter provides you the NRC enforcement decision for the apparent violations documented in Inspection Report No. 05000220/2014005 and 05000410/2014005, issued to Exelon Generation Company's (Exelon's) Nine Mile Point Nuclear Station (NMP) on February 5, 2015 (ML15037A047)¹. The apparent violations, associated with licensed reactor operator medical examinations and related NRC reporting requirements, were discussed with Exelon representatives at an inspection exit meeting on January 8, 2015, and documented in the subject inspection report.

In the letter transmitting the inspection report, we requested that you address the apparent violations identified in the report by either attending a pre-decisional enforcement conference, providing a written response, or requesting Alternative Dispute Resolution, before we made our final enforcement decision. Specifically, we requested additional information from Exelon regarding long-term corrective actions to prevent recurrence of the issue, such as information related to any plans by Exelon to provide continuing training on NRC regulatory requirements and ANSI standards for both site medical staff and licensed operators. In a letter dated March 5, 2015 (ML15091A281), you provided a response to the apparent violations that accepted the violations, described the results of a root cause evaluation of the issue (including the identification of additional violation examples which the NRC determined to be bounded and encompassed by the identified apparent violations), and summarized the corrective actions both taken and planned. In a subsequent telephone conversation on March 11, 2015, Bill Trafton and Terry Syrell of your staff reiterated the contents of the March 5, 2015 letter with Donald Jackson, Chief, NRC Region I Operations Branch, and other members of my staff.

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

Based on the information developed during the inspection, and that you provided in your March 5, 2015, letter, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding them are described in detail in the subject inspection report and in the NRC's February 5, 2015, letter.

The first violation involved multiple instances between June 2002 and August 2014, in which NMP did not notify the NRC within 30 days of learning of changes in the medical conditions of licensed reactor operators (ROs) and senior reactor operators (SROs) that involved permanent disabilities/ illnesses, as required by Title 10 of the Code of Federal Regulations (CFR) Section 50.74. Specifically, the operators, during biennial medical examinations, informed the NMP medical review officer (MRO) that they had been prescribed medications for such conditions as hypertension, post-traumatic stress disorder, attention deficit disorder, and asthma. However, the MRO did not recognize that these conditions constituted permanent disabilities or illnesses that required NRC notification and, therefore, did not provide the required notification. Additionally, between June 2002 and September 2014, NMP did not restrict licensed ROs and SROs from performing licensed duties when the individuals had disqualifying medical conditions, in accordance with 10 CFR 55.25. Specifically, the operators performed licensed duties while they had permanent disabilities or illnesses that caused them to not meet the requirements of 10 CFR 55.33(a)(1), since each had medical issues that were defined by ANSI/ANS 3.4-1983 as disqualifying conditions, and the NRC licenses for these operators were not conditioned to accommodate the medical concerns.

The second violation involved the licensee, between September 2002 and February 2012, submitting various licensing applications for the operators referenced above (including applications for RO and SRO initial and/or renewed licenses and RO and SRO license amendments), each of which included NRC Form 396s that certified the medical fitness of these applicants and that did not identify any needed license operator restrictions regarding disqualifying medical conditions or related prescribed medication. However, each of these applicants had medical conditions that did not meet the minimum standards of 10 CFR 55.33(a)(1) and, therefore, required specific license conditions in order to perform licensed activities. Based, in part, on this inaccurate information, the NRC issued operator license documents without proper evaluation of disqualifying medical conditions and application of license operator restrictions.

Each violation was assessed at Severity Level III (SL III), because each was similar to the Enforcement Policy SL III example violation 6.4.c.4 for inaccurate or incomplete information inadvertently provided to the NRC, subsequently contributing to the NRC making an incorrect regulatory decision (such as granting an RO or SRO license, contributing to an individual being permitted to perform the function of an RO or SRO, or contributing to a medically unqualified individual performing the functions of a licensed RO or SRO). However, the NRC has concluded that both violations resulted from the licensee's failures to: 1) oversee the licensed operator medical examination process and 2) train the medical staff involved with the process on the requirements of ANSI/ANS-3.4-1983 and 10 CFR Part 55. Accordingly, these violations have been categorized collectively as one Severity Level III (SL III) problem to emphasize the importance of providing suitable training, oversight, and focus on licensed operator medical requirements.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$70,000 is considered for a SL III problem involving a power reactor licensee. Because Exelon's NMP facility has not been the subject of escalated traditional enforcement action within the last two years or two inspections, the NRC considered only whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC has concluded that credit is warranted for Exelon's corrective actions. Specifically, in addition to requesting that the NRC amend or terminate, as appropriate, each impacted operators' license to account for any disqualifying conditions, thereby restoring compliance, Exelon has, in part: (1) conducted a root cause evaluation that included an extent of condition review to determine if other operators had disqualifying medical conditions; (2) implemented standard Exelon procedures, new to NMP, that resulted in the site instituting a multi-disciplinary oversight committee, that is currently meeting monthly, and that discusses upcoming license submittals, training, and other methods to ensure licensed operators are maintaining their medical qualifications; (3) instituted an independent review of operators' medical examinations by Exelon corporate staff; (4) provided read-and-sign training of all licensed operators on the process and requirements for reporting changes in medical conditions, and developed plans to perform more formal training; (5) trained the NMP nurse practitioner on NRC medical restriction requirements and instituted annual training requirements for all site medical personnel; (6) instituted an annual, full audit of all operator medical charts as well as quarterly peer-to-peer audits; and (7) committed to revising its fleet procedure to improve the review and approval process of NRC Form 396s by providing site senior management the opportunity to compare the form to the operator's medical file.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated traditional 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.

The NRC has concluded that information regarding: (1) the reasons for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 05000220/2014005 and 05000410/2014005, in your letter dated March 5, 2015, and in this letter. 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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room and in 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, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, 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 information, 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).

The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

/RA/

Daniel H. Dorman
Regional Administrator

Docket Nos. 50-220; 50-410
License Nos. DPR-63; NPF-69

Enclosure: Notice of Violation

cc w/enclosure: Distribution via ListServ

If you request withholding of such information, 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).

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Docket Nos. 50-220; 50-410
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ENCLOSURE
NOTICE OF VIOLATION

Exelon Generation Company, LLC
Nine Mile Point Nuclear Station

Docket Nos. 50-220; 50-410
License Nos. DPR-63; NPF-69
EA-14-192

During an NRC inspection conducted between October 13, 2014, and December 30, 2014, for which an exit meeting was conducted on January 8, 2015, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 55.3 requires, in part, that a person must be authorized by a license issued by the Commission to perform the function of a licensed operator or a licensed senior operator as defined in Part 55.

10 CFR 55.21 requires, in part, that individual licensed operators and senior operators shall have a medical examination by a physician every two years, and that the physician shall determine that the operator meets requirements of Section 55.33(a)(1). 10 CFR 55.33(a)(1) requires, in part, that an applicant's medical condition and general health will not adversely affect the performance of assigned operator job duties or cause operational errors endangering public health and safety. 10 CFR 55.33(b) states, in part, that if the general medical condition of an applicant does not meet the minimum standards under 10 CFR 55.33(a)(1), the Commission may approve the application and include conditions in the license to accommodate the medical defect.

10 CFR 55.23 requires, in part, that an authorized representative of the facility licensee shall certify the medical fitness of an applicant by completing and signing an NRC Form-396, "Certification of Medical Examination by Facility Licensee." On its Form 396, facility licensees must certify, in part, the guidance that was used to determine the medical fitness of its applicants. NMP certified on its Form 396s that it used the guidance in American National Standards Institute/American Nuclear Society (ANSI/ANS) 3.4-1983, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants."

ANSI/ANS 3.4-1983, states, in part, that the primary responsibility for assuring that qualified personnel are on duty rests with the facility licensee. In addition, the health requirements set forth within the standard provide the minimum necessary to determine that the physical condition and general health of the individuals are not such as might cause operational errors endangering public health and safety. The specific health requirements and disqualifying conditions are described in Section 5.3, "Disqualifying Conditions," and Section 5.4, "Specific Minimum Capacities Required for Medical Qualifications."

10 CFR 50.74(c) requires, in part, that each facility licensee notify the appropriate NRC Regional Administrator within 30 days of a permanent disability or illness as described in 10 CFR 55.25 involving a licensed operator or senior operator.

10 CFR 55.25 requires, in part, that if a licensed operator or licensed senior operator develops a permanent physical condition that causes the licensee to fail to meet the requirements of 10 CFR 55.21, the facility must notify the NRC within 30 days of learning of the diagnosis. For conditions where a license condition is required, the facility licensee must

provide medical certification on NRC Form 396, "Certification of Medical Examination by Facility Licensee."

Contrary to the above, between June 2002 and September 2014, reactor operators performed licensed duties when they had permanent disabilities or illnesses that caused them to not meet the requirements of 10 CFR 55.33(a)(1), since each had medical issues that were defined by ANSI/ANS 3.4-1983 as disqualifying conditions. The facility did not notify the NRC within 30 days of learning of these medical concerns and did not provide medical certification on NRC Form 396 to request conditions in the licenses to accommodate the medical defects. Specifically, the operators, during initial and biennial medical examinations, informed the NMP medical review officer (MRO) that they had been prescribed medications for such conditions as hypertension, post-traumatic stress disorder, attention deficit disorder, and asthma. However, NMP did not restrict these licensed operators from performing licensed operator duties, report these changes in permanent medical condition to the NRC within 30 days, or request amended licenses with conditions to account for the disqualifying medical issues.

- B. 10 CFR 50.9 requires, in part, that information provided to the Commission by a licensee shall be complete and accurate in all material respects.

10 CFR 55.3 requires, in part, that a person must be authorized by a license issued by the Commission to perform the function of a licensed operator or a licensed senior operator as defined in Part 55.

10 CFR 55.21 requires, in part, that individual licensed operators and licensed senior operators shall have a medical examination by a physician every two years, and that the physician shall determine that the licensee meets requirements of Section 55.33(a)(1). 10 CFR 55.33(a)(1) requires, in part, that an applicant's medical condition and general health will not adversely affect the performance of assigned operator job duties or cause operational errors endangering public health and safety. 10 CFR 55.33(b) states, in part, that if the applicant's general medical condition does not meet the minimum standards under 10 CFR 55.33(a)(1), the Commission may approve the application and include conditions in the license to accommodate the medical defect.

10 CFR 55.23 requires, in part, that an authorized representative of the facility licensee shall certify the medical fitness of an by completing and signing an NRC Form-396, "Certification of Medical Examination by Facility Licensee." NRC Form-396, when signed by an authorized representative of the facility licensee, certifies that, based on the results of the physical examination, including information furnished by the applicant, the physician has determined that the applicant's physical condition and general health are such that the applicant would not be expected to cause operational errors endangering public health and safety, and documents whether the applicant's license should be conditioned with restrictions.

Contrary to the above, on multiple occasions between September 2002 and February 2012, the licensee provided information to the NRC that was not complete and accurate in all material respects. Specifically, NMP submitted applications for operators (including applications for RO and SRO initial and/or renewed licenses and RO and SRO license amendments), each of which included NRC Form 396s that certified the medical fitness of the applicants and that did not identify any needed license operator restrictions regarding

disqualifying medical conditions or related prescribed medication. However each of the applicants had medical conditions that did not meet the minimum standards of 10 CFR 55.33(a)(1) and, therefore, required specific license conditions in order to perform licensed activities. Based, in part, on this inaccurate information, the NRC issued the license documents without the required restricting license conditions.

These two violations represent a Severity Level III problem (Section 6.4)

The NRC has concluded that information regarding: (1) the reasons for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 05000220/2014005 and 05000410/2014005, in your letter dated March 5, 2015, and in this letter. Therefore, you are not required to respond to this Notice. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation EA-14-192," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406, and a copy to the NRC resident inspector at Nine Mile Point Nuclear Station, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, 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>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 10th day of April, 2015