



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

February 24, 2015

EA-14-235

Joseph E. Pacher  
Site Vice President  
R.E. Ginna Nuclear Power Plant, LLC  
Exelon Generation Company, LLC  
1503 Lake Road  
Ontario, NY 14519

**SUBJECT: R. E. GINNA NUCLEAR POWER PLANT – NOTICE OF VIOLATION –  
SEVERITY LEVEL III PROBLEM - NRC INSPECTION REPORT  
05000244/2015007**

Dear Mr. Pacher:

This letter provides you the NRC enforcement decision for the apparent violations documented in Inspection Report 05000244/2014005, issued to R.E Ginna Nuclear Power Plant, LLC (Ginna) on February 4, 2015 (ML15035A166)<sup>1</sup>. The apparent violations, associated with licensed reactor operator medical examinations and related NRC reporting requirements, were discussed with Ginna representatives at an inspection exit meeting on January 14, 2015, and documented in the subject inspection report.

The February 4, 2015, NRC letter transmitting the inspection report notified you that the apparent violations were being considered for escalated enforcement in accordance with the NRC Enforcement Policy, and provided you the opportunity to address the apparent violations by attending a pre-decisional enforcement conference (PEC), or by providing a written response before we made our final enforcement decision. In the letter we also informed you that we had sufficient information regarding the apparent violations and Ginna's corrective actions to make an enforcement decision without the need for a PEC or a written response. In a telephone call on February 9, 2015, Tom Harding, Manager, Site Regulatory Assurance informed Dan Schroeder, Branch Chief that Ginna did not require a PEC nor intend to send a written response.

Therefore, based on the information developed during the inspection, 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 4, 2015, letter.

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<sup>1</sup> 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.

The first violation involved Ginna's submittal of information to the NRC in an October 8, 2008, NRC licensed senior operator application that was not complete and accurate in all material respects. Specifically, the application did not specify that the applicant had a medical condition that required a restriction to take medication for hypertension. Based, in part, on this inaccurate information, the NRC issued an initial license that did not contain the necessary restriction.

The second violation involved Ginna's failure to notify the NRC within 30 days of a permanent disability of a licensed senior operator. Specifically, Ginna's staff was informed in July 2008 that the operator was taking medication for hypertension. Ginna did not report this condition to the NRC when they submitted NRC Form 396 as part of the licensed senior operator application in October 2008, and during subsequent biennial requalification medical examinations in 2010 and 2012. Ginna also did not request an amended license with a condition to account for the medical issue until July 2014.

The NRC has concluded that both violations occurred as a result of the contract medical personnel's failing to follow Ginna's prescribed processes. Accordingly, these violations have been categorized collectively as a Severity Level (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 your facility has not been the subject of escalated traditional enforcement actions within the last 2 years, 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. The NRC has concluded that credit is warranted for Ginna's corrective actions. Specifically, the inspectors confirmed during the inspection that Ginna: (1) requested the NRC amend the operator's license to include a restriction for the use of prescribed medication for hypertension (on August 28, 2014, the NRC issued the amended license with the new restriction); (2) initiated a Root Cause Evaluation that included an extent of condition review of all operators to determine if there are any further unknown medical conditions; (3) trained licensee medical personnel on NRC medical restriction requirements; and (4) implemented a process to audit medical records annually.

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 either Inspection Report 05000244/2014005 or 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 No. 50-244  
License No. DPR-18

Enclosure: Notice of Violation

cc w/enclosure: Distribution via ListServ

J. Pacher

3

(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.

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Sincerely,

*/RA/*

Daniel H. Dorman  
Regional Administrator

Docket No. 50-244  
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DOC NAME: S:\Enf-allg\Enforcement\Proposed-Actions\Region1\Ginna Operator Medical NOV-III EA-14-235.docx  
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ENCLOSURE  
NOTICE OF VIOLATION

Exelon Generation Company, LLC.  
R. E. Ginna Nuclear Power Plant, LLC

Docket No. 50-244  
License No. DPR-18  
EA-14-235

During an NRC inspection conducted between November 17, 2014, and November 21, 2014, for which an exit meeting was conducted on January 14, 2015, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 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 55.21 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 applicant by completing and signing an NRC Form-396, "Certification of Medical Examination by Facility Licensee." The 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 October 8, 2008, Ginna staff provided information to the NRC that was not complete and accurate in all material respects. Specifically, Ginna submitted an NRC licensed senior operator application with an NRC Form 396 that certified the medical fitness of the applicant and that the only necessary restricting license condition was for corrective lenses. This information was inaccurate in that the applicant had hypertension, a medical condition that does not meet the minimum standards of 10 CFR 55.33(a)(1), and that requires a restricting license condition to take medication as prescribed, to maintain medical qualifications.

- B. 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 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."

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.

Contrary to the above, from January 4, 2009, (this date is 30 days from the date of the initial license) until July 16, 2014, Ginna failed to notify the NRC of a permanent disability of a licensed senior operator. Specifically, Ginna staff was informed in July 2008 that the operator was taking prescribed medication for hypertension. Ginna did not report this permanent medical condition to the NRC when they submitted NRC Form 396 as part of the senior operator license application in October 2008, during subsequent biennial requalification medical examinations in 2010 and 2012, nor did they request an amended license with a condition to account for the medical issue until July 16, 2014.

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 either Inspection Report 05000244/2014005 or 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-14-235," 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 the R. E. Ginna Nuclear Power Plant, LLC, 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 24<sup>th</sup> day of February, 2015