



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

July 17, 2013

EA-11-260

Mr. John Dent, Jr.
Site Vice President
Entergy Nuclear Operations, Inc.
Pilgrim Nuclear Power Station
600 Rocky Hill Road
Plymouth, MA 02360-5508

SUBJECT: PILGRIM NUCLEAR POWER STATION – NRC INVESTIGATION REPORT NO. 1-2012-013; NRC INSPECTION REPORT NO. 05000293/2013007; AND NOTICE OF VIOLATION

Dear Mr. Dent:

This letter provides you the U.S. Nuclear Regulatory Commission (NRC) enforcement decision for the apparent violations documented in Inspection Report No. 05000293/2011005, issued to Entergy Nuclear Operations, Inc.'s (ENO's) Pilgrim Nuclear Power Station (PNPS) on February 2, 2012 (ML12033A229)¹. The apparent violations, associated with licensed reactor operator medical examinations and NRC reporting requirements, were discussed with PNPS representatives at an inspection exit meeting on December 20, 2011, and documented in the February 2, 2012, inspection report. In addition, a related investigation by the NRC Office of Investigations (OI) was completed on February 1, 2013, to determine whether any of the apparent violations were deliberate. In a letter dated May 21, 2013 (ML13143A528), the NRC informed you that based on the results of the investigation; the NRC did not identify any wrongdoing associated with the apparent violations.

The May 21, 2013, NRC letter also: (1) notified you that two of the apparent violations were being considered for escalated enforcement in accordance with the NRC Enforcement Policy; and, (2) provided you with the opportunity to address these apparent violations by either attending a pre-decisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated June 20, 2013 (ML13190A311), you provided a response which did not deny the violations and described corrective actions taken in response to these concerns.

Based on the information developed during the inspection and investigation and the information that you provided in your June 20, 2013, letter, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice)

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.

and the circumstances surrounding them are described in detail in the subject inspection report and in the NRC's May 21, 2013, letter.

The first violation involved multiple occurrences from March 2008 through October 11, 2011, of certain ENO licensed operators at PNPS not meeting certain medical prerequisites, and the licensed operators nonetheless engaging in NRC-licensed activities without ENO first obtaining prior NRC approval. In one case, a licensed reactor operator (RO), during a medical exam on December 1, 2010, had a blood pressure reading that exceeded limits. The Pilgrim Medical Examiner (ME) who conducted the exam was not knowledgeable of the standard or the minimum acceptable criteria contained therein. As a result, in spite of the RO's high blood pressure reading, the ME determined the operator to be medically qualified to continue to conduct licensed activities based on the ME's medical opinion, although the ME did not document a basis for this determination. The ME also failed to notify ENO of the RO's medical condition. Therefore, ENO did not obtain from the NRC a conditional license for the RO indicating that, in order to continue to conduct licensed activities, the RO must take medication as prescribed to meet the minimum medical requirements.

The NRC also identified examples where the required biennial medical examinations administered to three ENO ROs and two senior reactor operators at various times from March 2008 through October 11, 2011, did not include the required stamina tests. The stamina tests should have been conducted to assure the operators met respiratory and cardiovascular requirements that licensed operators respectively have the capacity and reserve to perform strenuous physical exertion in emergencies and have a tolerance to postural changes and capacity for exertion during emergencies. However, the ME did not administer the stamina tests to these licensed operators at the time of their biennial examinations because of various ailments and disabilities reported to him by the operators at the time of the exams. The ME did not document the basis for these decisions or notify ENO of the operators' conditions.

The second violation involved ENO's submittal of information to the NRC that was not complete and accurate in all material respects. Specifically, on May 17, 2011, ENO submitted renewal applications for the reactor operator licenses for two of the PNPS ROs that did not receive stamina tests, and the applications certified that the applicants met the medical requirements for license renewal when in fact they did not. Based, in part, on this inaccurate information, the NRC issued both ROs their renewed licenses on June 23, 2011.

The NRC has concluded that both violations occurred as a result of the ME's lack of knowledge of NRC requirements and the existence and content of the related ANSI/ANS standard. The NRC inspectors found that Pilgrim had experienced turnover in the ME position and in the Operations Department management shortly before the violations occurred. It appeared that there was insufficient and inadequate turnover to, and training of, the new ME, as well as insufficient oversight of this ME position by the site Operations Department. Accordingly, these violations have been categorized collectively as a 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 Severity Level III problem. Because PNPS has not been the subject of escalated traditional enforcement action within the last two 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 ENO's corrective actions. Specifically, ENO: (1) performed an extent of condition evaluation for all medical exams conducted from 2009 to 2011 to identify any additional issues; (2) performed an assessment of the medical practices across the ENO fleet to ensure a consistent approach to medical testing and regulatory compliance; (3) implemented a standardized fleet form for medical exams; (4) contracted new medical staff to conduct the exams and trained the new medical personnel on regulatory requirements, applicable medical standards, procedure use, documentation and peer checking; (5) developed and implemented an independent verification process to ensure that conditions for operator licenses are accurately documented and tracked; and, (6) established an expectation that licensed operators certify that their medical exams were performed properly and that any restrictions due to medical conditions imposed on their individual licenses were accurate. 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.

One additional violation, also documented in the Notice, has been categorized in accordance with the NRC Enforcement Policy at SL IV. This violation, which involved the failure by ENO to notify the NRC within 30 days of learning of permanent disabilities or illnesses of two licensed ROs, is being cited because it was identified by the NRC. The circumstances surrounding this violation are documented in detail in the above-referenced inspection report.

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. 05000293/2011005, the NRC letter dated May 21, 2013, the ENO letter dated June 20, 2013, 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 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.,

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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/

William M. Dean
Regional Administrator

Docket No. 50-293
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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 [\(http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/\)](http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/).

Sincerely,

/RA/

William M. Dean
Regional Administrator

Docket No. 50-293
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ENCLOSURE
NOTICE OF VIOLATION

Entergy Nuclear Operations, Inc.
Pilgrim Nuclear Power Station

Docket No. 05000293
License No. DPR-35
EA-11-260

During an NRC inspection conducted between October 1 and December 20, 2011, for which an exit meeting was conducted on December 20, 2011, and during an NRC investigation that was completed on February 1, 2013, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

I. ESCALATED VIOLATIONS

- 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 396s, facility licensees must certify, in part, the guidance that was used to determine the medical fitness of its applicants. Entergy Nuclear Operations, Inc (ENO) 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." Section 5.4.6, Respiratory, requires, in part, that individuals have the capacity and reserve to perform strenuous physical exertion in emergencies. Section 5.4.7, Cardiovascular, requires, in part, that individuals have a tolerance to postural changes and capacity for exertion during emergencies, and also limits blood pressure to 160/100 mm Hg.

Contrary to the above, at various times from March 2008 through October 11, 2011, several Pilgrim Nuclear Power Station (PNPS) licensed operators did not meet certain medical prerequisites for performing NRC-licensed operator activities, and the licensed operators engaged in NRC-licensed activities without ENO obtaining prior NRC approval. Specifically:

- a. Between December 1, 2010, and October 11, 2011, one licensed operator performed licensed operator duties even though on December 1, 2010, a change in his medical condition existed, as found by a medical examination. The examination identified that the operator's blood pressure exceeded the limit of 160/100 mm Hg, and ENO did not obtain NRC approval for the change in medical condition by requesting a conditional license indicating that the operator shall take medication as prescribed to maintain medical qualifications.
 - b. Between March 2008 and October 11, 2011, five other licensed operators continued to perform NRC-licensed activities even though those five licensed operators did not receive a complete biennial medical examination in the prior two years. The examinations that the individuals did receive within the prior two years were not complete in that the licensed operators were not administered a stamina test that would verify: a) their capacity and reserve to perform strenuous physical exertion in emergencies; and, b) their tolerance to postural changes and capacity for exertion during emergencies. Further, ENO did not obtain prior NRC approval for the licensed operators to continue to perform NRC-licensed activities without meeting the biennial examination requirements as conditions of their licenses.
- 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 55.23 requires, in part, that to certify the medical fitness of an applicant for an operator or senior operator license, an authorized representative of the facility licensee shall complete and sign 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 a physician conducted a medical examination of the applicant and that the guidance contained in ANSI/ANS 3.4-1983 was followed in conducting the examination and making the determination of medical qualification.

Contrary to the above, on May 17, 2011, ENO provided information to the NRC that was not complete and accurate in all material respects. Specifically, on that date, ENO submitted NRC Form-396s for renewal of two operator licenses that certified that the operators met the medical requirements of ANSI/ANS 3.4-1983 when, in fact, the facility licensee had not verified, via testing, that the operators had met the requirement for stamina testing.

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

II. NON-ESCALATED VIOLATION

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 licensed 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 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 an 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.

Contrary to the above, on two occasions in 2010, ENO did not notify the NRC within 30 days of learning of permanent disabilities or illnesses of two licensed operators that caused the operators to not meet the requirements of 10 CFR 55.33(a)(1). Specifically, in January 2010, PNPS medical staff became aware that a licensed operator required corrective lenses, and then in December 2010, PNPS medical staff became aware that another licensed operator suffered from hypertension. However, ENO did not notify the NRC of these medical conditions until November 10, 2011, a period greater than 30 days.

This is a Severity Level IV Violation (Enforcement Policy Example 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. 05000293/2011005, the NRC letter dated May 21, 2013, the PNPS letter dated June 20, 2013, 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-11-260," 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 PNPS, within 30 days of the date of the letter transmitting this Notice of Violation (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 17th day of July, 2013