



Entergy Nuclear Operations, Inc.
Pilgrim Nuclear Power Station
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Stephen J. Bethay
Director, Nuclear Assessment

March 4, 2010

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

SUBJECT: Entergy Nuclear Operations, Inc.
Pilgrim Nuclear Power Station
Docket No. 50-293
License No. DPR-35

Reply to Notice of Violation; EA-10-03

REFERENCE: Letter, U.S. NRC to Entergy, PNPS – NRC Integrated Inspection Report
05000293/2009005 and Notice of Violation, dated February 2, 2010

LETTER NUMBER: 2.10.012

Dear Sir or Madam:

The referenced letter identified a Level IV violation resulting from NRC inspection of the Licensed Operator Requalification Program conducted at Pilgrim Station on October 5 – 12, 2009.

Entergy acknowledges the violation and has corrected the condition. The enclosure to this letter provides the reply to the Notice of Violation (NOV) and the information sought in the inspection report cover letter.

This letter contains no commitments.

Please contact the Licensing Manager, Joseph Lynch, at 508-830-8403, if there are any questions regarding the reply.

Sincerely,

Stephen J. Bethay
Director, Nuclear Safety Assurance

MJG/mg

Enclosure: Reply to Notice of Violation; EA-10-003 (5 pages)

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Entergy Nuclear Operations
Pilgrim Nuclear Power Station

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cc: with Enclosure

Mr. Samuel J. Collins
Regional Administrator, Region I
U.S. Nuclear Regulatory Commission
475 Allendale Street
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NRC Resident Inspector

**Enclosure to Letter No. 2.10.012
(5 pages)**

Reply to Notice of Violation; EA-10-003

Notice of Violation

During an NRC inspection conducted from October 5 through October 12, 2009, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 50.9 requires, in part, that information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, Orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

10 CFR 55.21 requires, in part, that an applicant for a license shall have a medical examination by a physician, and the licensee shall have a medical examination by a physician every two years. The physician shall determine that the applicant or 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 55.23 requires, in part, that to certify the medical fitness of the applicant, 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 American National Standards Institute/American Nuclear Society (ANSI/ANS) Standard 3.4-1983, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," was followed in conducting the examination and making the determination of medical qualification.

ANSI/ANS 3.4-1983, Section 5.4 provides specific minimum capacities required for medical qualifications. Section 5.4.2 requires, in part, the ability to detect odor of products of combustion.

Contrary to the above, from April 29, 1999 to October 13, 2009, Entergy Nuclear Operations, Inc. (Entergy) provided information to the NRC that was not complete and accurate in all material respects. Specifically, Entergy had not completed medical examinations of licensed operators in accordance with ANSI/ANS 3.4-1983. The licensee submitted numerous NRC Form 396s for renewal of Senior Reactor Operator and Reactor Operator licenses, and for initial license applicants that certified that the applicants met the medical requirements of ANSI/ANS 3.4-1983 when, in fact, olfactory (combustion product odor) testing had not been conducted.

This is a Severity Level IV violation (Supplement VII)

In addition to the Notice of Violation, NRC requested the following information in the Inspection Report Number 05000293/2009005 Cover Letter:

Although this violation has been placed in your corrective action program, a Notice of Violation is being issued and a response is being required to better understand: 1) what actions were taken in 2004 in response to NRC Information Notice (IN) 2004-20, "Recent Issues Associated with NRC Medical Requirements for Licensed Operators," which, in part, reminded facility licensees that licensed operators and the personnel who perform and interpret their medical examinations need to be familiar with the regulatory requirements and guidelines (it should be noted that this IN specifically described an instance in which a facility licensee had not conducted some tests required in the ANSI standard for any of its licensed operators); 2) why action was not taken in response to IN 2004-20 to assure appropriate olfactory testing was being conducted; and 3) the corrective actions taken and planned at this time to assure all information submitted to the NRC is complete and accurate in all material respects.

Reason for the violation.

Failure to perform olfactory testing for products of combustion in accordance with ANSI Standard 3.4-1983 "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants", Section 5.4.2 "Nose" for licensed operators (both initial and renewal licensees) at Pilgrim Nuclear Power Station (PNPS) occurred because the procedures in use during the time period provided only general guidance to the site Medical staff in regards to the administration of the olfactory test. Specifically, the procedures did not provide complete testing details as specified in the ANSI Standard or clear acceptance criteria. The PNPS licensed physician's interpretation of the ANSI Standard did not include testing the licensed operators for the ability to detect products of combustion. The physician was not aware of the precise ANSI standard requirement for the olfactory testing. He believed that his method of evaluation, testing only for detection of tracer gases, provided him with sufficient information to make a determination of the olfactory discrimination capability of the licensed operator.

Corrective steps which have been taken and the results achieved.

Immediately following the identification of the violation, Entergy took prompt corrective action. Entergy tested all licensed operators for their capability of detecting both tracer gases and products of combustion; all licensed operators passed. Full compliance with ANSI Standard 3.4-1983 "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants", Section 5.4.2 "Nose" for licensed operators (both initial and renewal licensees) was achieved on October 31, 2009.

An internal Operating Experience (OE) document was issued as part of Condition Report CR-HQN-2009-955. The primary objective of this OE was to identify and transfer lessons learned into actions that enhanced the reliability of the physical testing of licensed operators across the Entergy fleet to ensure that the licensed operators met the requirements of Section 55.33(a)(1).

Concurrently, Entergy Procedure EN-NS-112 "Medical Program" was revised (Revision 7) to include specific guidance on the olfactory and tactile testing of licensed operators within the Entergy Fleet in accordance with ANSI Standard 3.4-1983. The Revision 7 was issued on December 15, 2009. This revision requires that licensed operators must be able to identify both products of combustion (smoke) and tracer gases (natural gas) in order to successfully complete the ANSI Standard olfactory testing requirement.

PNPS Medical personnel who administer these tests were briefed on the revised procedure.

Corrective steps that will be taken to avoid future violations.

No additional corrective actions are planned.

Date when full compliance was achieved.

Full compliance was achieved on December 15, 2009, with the issuance of Entergy Procedure EN-NS-112, Revision 7.

Response NRC Inspection Report 05000293/2009005 Cover Letter Request

1) Actions taken in 2004 in response to the NRC Information Notice (IN) 2004-20 "Recent Issues Associated with NRC Medical Requirements for Licensed Operators."

Information Notice (IN) 2004-20 "Recent Issues Associated with NRC Medical Requirements for Licensed Operators" was issued on November 24, 2004. The Operating Experience (OE) Coordinator for PNPS issued Learning Organization (LO) Condition Report (CR) LO-NOE-2004-648 through the PNPS Corrective Action Program (CAP) requiring an evaluation of the IN 2004-20 by PNPS staff. The result of this review indicated that the processes in place were adequate to address the IN and no further action was needed. This conclusion was based on interviews with the site Medical staff, Licensing staff, and Operations Support staff. The interviews were focused on the adequacy of the process to track changes to the medical condition of licensed operators at PNPS. The review process missed the opportunity to address compliance with the ANSI Standard.

2) Why action was not taken in response to IN 2004-20 to assure appropriate olfactory testing was being conducted.

Detailed review and interviews with applicable plant staff of the actions taken indicated that PNPS did not fully address the contents of the IN. The review of the IN did not consider compliance with the criteria included in ANSI Standard 3.4-1983 because it had been in effect since 1983. The response only focused on the adequacy of the process in place for notifying the NRC of changes in Operator Status, it did not address whether or not the site licensed physician was conducting the tests in accordance with the ANSI Standard. In 2004 the Pilgrim Staff missed the opportunity to address the compliance verification issue with the ANSI Standard.

At the time the NRC IN was reviewed in 2004, Entergy Procedure EN-OE-100 "Operating Experience Program", Revision 1 was in effect. During 2004, under Revision 1, each site individually determined which departments reviewed documents such as NRC INs. There was no procedural requirement at that time to enter the NRC IN into the site CAP by issuing a CR.

3) The corrective actions taken and planned at this time to assure all information submitted to the NRC is complete and accurate in all material respect.

It is the policy of Entergy that all communication with any regulatory agency be true, accurate, and complete. Entergy has established a certification process to assure technical information included in the submittal for the regulatory agencies is complete and accurate. Information and guidance on submittal of information to the NRC by PNPS is contained in Entergy Procedure EN-LI-106 "NRC Correspondence". This procedure details the steps for processing NRC incoming and outgoing written correspondence.

At PNPS, prior to submittal to the NRC, outgoing correspondence receives the appropriate level of technical and management reviews as determined by the correspondence preparer in accordance with Entergy Procedure EN-LI-106. This includes certification for technical accuracy and a peer review in order to identify any

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editorial changes that may be needed. Finally, the correspondence preparer obtains acknowledgement of concurrence from the applicable site departments and also verifies that the correspondence meets administrative quality expectations.

In addition, the current revision (Revision 9) of EN-OE-100, "Operating Experience Program", requires that all incoming OE items such as NRC INs are screened by a team of Operating Experience (OE) Coordinators for impact on Entergy plants. Additionally, OE items that are screened by the OE Coordinators are then reviewed at the Condition Review Group (CRG) meeting. This second level in-depth review determines whether or not any OE requires additional site specific reviews. This step provides added checks and balances in the screening processes. (In the case, of the 2004 IN, it was sent to some of the fleet's Medical groups for review and not to others.)

Under the current process in place, all Entergy Medical groups would receive the NRC IN for review. The current revision of the procedure now requires that if the IN is applicable to a site, a site Condition Report is written. Upon completion of the response to the CR a closure review is now required to be completed by the Manager of Corrective Action and plant Operating Experience Coordinator to ensure that the document has had sufficient review by the site staff.

Licensing personnel involved in the preparation and submittal of NRC correspondence including communication during inspection activities, have reviewed EN-LI-106 and their responsibilities to ensure that all communications with any regulatory agency be accurate and complete.