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Indiana Michigan Power
Cook Nuclear Plant
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Bridgman, MI 49106
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October 10, 2005

AEP:NRC:2201-04
10 CFR 50.4
EA-05-171

Docket No.: 50-315
50-316

U. S. Nuclear Regulatory Commission,
ATTN: Document Control Desk
Mail Stop O-P1-17
Washington, DC 20555-0001

Donald C. Cook Nuclear Plant Units 1 and 2
RESPONSE TO APPARENT VIOLATIONS
IN INSPECTION REPORT NO.
05000315/2005006 (DRS); 05000316/2005006 (DRS); EA-05-171

Indiana Michigan Power Company (I&M), the licensee for Donald C. Cook Nuclear Plant (CNP), Units 1 and 2, is submitting the attached response to the apparent violations identified in Nuclear Regulatory Commission (NRC) Inspection Report 05000315/2005006 (DRS); 05000316/2005006 (DRS) and Enforcement Action (EA) EA-05-171.

The inspection report identified four apparent violations of 10 CFR 50.9 and two apparent violations of 10 CFR 55.25 that are being considered for escalated enforcement. The inspection report stated that the final decision regarding escalated enforcement is contingent on I&M confirming that the corrective actions described to the NRC Staff, in an August 11, 2005, meeting and in an August 26, 2005 telephone call, have been or are being taken. Attachment 1 to this letter provides I&M's response to the apparent violations, including the corrective actions described to the NRC staff that have been taken or are being taken.

Attachment 2 describes commitments contained in Attachment 1 of this submittal.

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If you have any questions or desire additional information, please contact Mr. Michael K. Scarpello, Regulatory Affairs Supervisor, at (269) 466-2649.

Sincerely,

Lawrence J. Weber
Plant Manager

HLE/jn

Attachments

c: J. L. Caldwell – NRC Region III
K. D. Curry – AEP Ft. Wayne
J. T. King – MPSC
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ATTACHMENT 1 TO AEP:NRC:2201-04

RESPONSE TO APPARENT VIOLATIONS
IN INSPECTION REPORT NO.
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Restatement of Apparent Violations:

The apparent violations listed below have been assigned numbers corresponding to the order in which they appear in the inspection report.

1. "The licensee provided incomplete and inaccurate information in a letter to the NRC dated August 2, 2004. Specifically, the licensee, in its response to an apparent violation, which was subsequently issued as a Severity Level III Notice of Violation issued on September 29, 2004, incorrectly stated that: "a 100 percent review (self-assessment) of all operator medical records was performed in February and March of 2004;" and that full compliance was achieved on April 8, 2004. During an April 2005 followup review of the licensee's corrective actions for the Severity Level III violation, the NRC identified three additional examples of licensed operators with a potentially disqualifying medical condition that existed prior to the licensee's February and March 2004 review of its medical records, that had not been reported to the NRC. The licensee made changes to their administrative procedures to ensure clarity in regard to medical reporting requirements and required an annual medical file review in addition to an annual discussion with their medical review official to ensure a mutual understanding of the appropriate regulatory requirements.

   "Because the issue affected the NRC's ability to perform its regulatory function, it was evaluated using the traditional enforcement process. The regulatory significance was important because the incorrect information was provided under a signed statement to the NRC and impacted an enforcement decision. The issue was preliminarily determined to be an apparent violation of 10 CFR 50.9."

2. "The NRC identified that on May 5, 2004, a senior licensee representative submitted to the NRC a Form NRC-396 to support an application for renewal of an SRO license, that was not complete and accurate in all material respects. The Form NRC-396 certified that the applicant met the medical requirements of ANSI/ANS 3.4-1983 and that the applicant would not require any restrictions to the individual's license. In fact, the applicant had a potentially disqualifying medical condition dating back to October 30, 1998. [Note: The information concerning the individual's specific medical condition is considered medical privacy information under 10 CFR 2.390(2)(6) and is not specifically discussed here.] The medical condition was potentially disqualifying in accordance with ANSI/ANS 3.4, 1983, and required that the individual's license be amended to include an operating restriction. The information is material to the NRC because the NRC relies on this certification to determine whether the applicant meets the requirements to operate the controls of a nuclear power plant pursuant to 10 CFR Part 55. The licensee made changes to their administrative procedures to ensure clarity in regard to medical reporting requirements and required an annual medical file

review in addition to an annual discussion with their medical review official to ensure a mutual understanding of the appropriate regulatory requirements.

"Because the issue affected the NRC's ability to perform its regulatory function, it was evaluated using the traditional enforcement process. The regulatory significance was important because the incorrect information was provided under a signed statement to the NRC and impacted a licensing decision for the individual. The issue was preliminarily determined to be an apparent violation of 10 CFR 50.9."

3. "The NRC identified that from November 29, 1998, until May 18, 2005, the licensee did not report the change in medical status of an SRO that acquired a potentially disqualifying medical condition as required by 10 CFR 55.25. The medical condition was potentially disqualifying in accordance with ANSI/ANS 3.4, 1983, and required that the individual's license be amended when it was finally reported on May 18, 2005, to include an operating restriction. [Note: The information concerning the individual's specific medical condition is considered medical privacy information under 10 CFR 2.390(2)(6) and is not specifically discussed here.] The issue was more than minor because the NRC relies on this certification to determine whether the applicant meets the requirements to operate the controls of a nuclear power plant pursuant to 10 CFR Part 55. The licensee made changes to their administrative procedures to ensure clarity in regard to medical reporting requirements and required an annual medical file review in addition to an annual discussion with their medical review official to ensure a mutual understanding of the appropriate regulatory requirements.

   "Because the issue affected the NRC's ability to perform its regulatory function, it was evaluated with the traditional enforcement process. The regulatory significance was important because information was not provided that would have resulted in a licensing decision for the individual. The issue was preliminarily determined to be an apparent violation of 10 CFR 55.25."

4. "On April 26, 2004, a senior licensee representative submitted to the NRC a Form NRC-396 to support an amendment request of a Senior Reactor Operator (SRO) license, that was not complete and accurate in all material respects. The Form NRC-396 certified that the applicant met the medical requirements of ANSI/ANS 3.4-1983 and that the applicant would not require any restrictions to the individual's license. In fact, the applicant had a potentially disqualifying medical condition dating back to 2003. The medical condition was potentially disqualifying in accordance with ANSI/ANS 3.4-1983, and required that the individual's license be amended to include an operating restriction. [Note: The information concerning the individual's specific medical condition is considered medical privacy information under 10 CFR 2.390(2)(6) and is not specifically discussed here.] The issue was more than minor because the NRC relies on this certification to determine whether the applicant meets the requirements to operate the controls of a nuclear power plant pursuant to 10 CFR Part 55. The licensee made changes to their administrative procedures to ensure clarity in regard to medical reporting requirements and required an annual medical file review in addition to an

annual discussion with their medical review official to ensure a mutual understanding of the appropriate regulatory requirements. Since NRC intervention was required to identify the requirement for the operator to have a license restriction, this issue was considered NRC-identified.

"Because the issue affected the NRC's ability to perform its regulatory function, it was evaluated with the traditional enforcement process. The regulatory significance was important because the incorrect information was provided under a signed statement to the NRC and impacted a licensing decision for the individual. The issue was preliminarily determined to be an apparent violation of 10 CFR 50.9."

5. "The NRC identified that from January 6, 2003, until May 18, 2005, the licensee did not report the change in medical status of an SRO that acquired a potentially disqualifying medical condition as required by 10 CFR 55.25. The medical condition was potentially disqualifying in accordance with ANSI/ANS 3.4, 1983, and required that the individual's license be amended when it was finally reported on May 18, 2005, to include an operating restriction. [Note: The information concerning the individual's specific medical condition is considered medical privacy information under 10 CFR 2.390(2)(6) and is not specifically discussed here.] The issue was more than minor because the NRC relies on this certification to determine whether the applicant meets the requirements to operate the controls of a nuclear power plant pursuant to 10 CFR Part 55. The apparent violation was determined to be of significant regulatory concern because a licensing action was not taken because information was not provided by the licensee. Since NRC intervention was required to identify the requirement for the operator to have a license restriction, this issue was considered NRC identified.

   "Because the issue affected the NRC's ability to perform its regulatory function, it was evaluated with the traditional enforcement process. The regulatory significance was important because information was not provided that would have affected a licensing decision for the individual. The issue was preliminarily determined to be an apparent violation of 10 CFR 55.25."

6. "On November 4, 2002, a senior licensee representative submitted to the NRC a Form NRC-396 to support an application for an SRO license, that was not complete and accurate in all material respects. The Form NRC-396 certified that the applicant met the medical requirements of ANSI/ANS 3.4-1983 and that the applicant would not require any restrictions to the individual's license. In fact, the applicant had a potentially disqualifying medical condition in accordance with ANSI/ANS 3.4-1983. The medical condition required that the individual's license be amended to include an operating restriction. [Note: The information concerning the individual's specific medical condition is considered medical privacy information under 10 CFR 2.390(2)(6) and is not specifically discussed here.] The issue is more than minor because the NRC relies on this certification to determine whether the applicant meets the requirements to operate the controls of a nuclear power plant pursuant

to 10 CFR Part 55. The licensee made changes to their administrative procedures to ensure clarity in regard to medical reporting requirements and required an annual medical file review in addition to an annual discussion with their medical review official to ensure a mutual understanding of the appropriate regulatory requirements. Since NRC intervention was required to identify the requirement for the operator to have a license restriction prior to his initial license being issued, this issue was considered NRC-identified.

"Because the issue affected the NRC's ability to perform its regulatory function, it was evaluated with the traditional enforcement process. The regulatory significance was important because the incorrect information was provided under a signed statement to the NRC and impacted a licensing decision for the individual. The issue was preliminarily determined to be an apparent violation of 10 CFR 50.9."

Admission/Denial of the Apparent Violations:

Indiana Michigan Power Company (I&M) acknowledges the apparent violations described above.

Reasons for the Apparent Violations:

The reason for the first apparent violation was the crediting by I&M personnel of a review of operator medical records conducted as part of a Quick Hit Self-Assessment of operator medical records. Although this assessment reviewed each licensed operator medical file, it did not review all information contained in those files.

The reason for the remaining apparent violations is that I&M's procedures and processes were such that personnel relied upon the designated medical review officer for operator license restriction recommendations. This reliance was cultivated by I&M's interpretation of the ANSI 3.4-1983, "American National Standard Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," guidance that the designated medical review officer had the responsibility to evaluate the condition, and any compensatory measures used to control the condition, to determine the medical qualification of the licensed operator. As a result of the interpretation and reliance, I&M only submitted the NRC Form 396, "Certificate of Medical History by Facility Licensee," marked to reflect the designated medical review officer's recommendation without including the physical examination documentation with the license renewal application.

Corrective Actions Taken and Planned to Avoid Further Violations:

1. I&M has developed guidance for validation of information that is provided on NRC forms 396 and 398, including the source documents to be used for validation. This guidance has been incorporated into the applicable Training Department administrative procedure.

2. The applicable Training Department administrative procedure was revised to require a discussion of requirements, specified in ANSI 3.4-1983, with the designated medical review officer prior to the performance of the annual medical records review.

3. The applicable Training Department administrative procedure was changed to include two new requirements. One new requirement is to submit completed physical examination forms to Regulatory Affairs for inclusion with initial or renewal license applications. This will ensure complete and accurate information is provided to the NRC when communicating medical issues regarding operator licenses. The other new requirement is to include a review by Regulatory Affairs of any new or changing medical condition that is being reported by a licensed operator. This will provide for an additional review to identify potential notification requirements for medical conditions of licensed operators.

4. The periodicity for operator medical records review has been changed from every two years to every year. This periodicity has been incorporated into the applicable Training Department administrative procedure.

5. A review was conducted in April 2005 of the contents of the medical files for each current license holder to ensure historical issues were identified that were not identified in the original scope of the 2004 self-assessment. The results of this review identified one additional licensed operator that had a potentially disqualifying medical condition that had not been reported to the NRC, and one operator with an existing license restriction that was not included in the initial license application but should have been included.

6. I&M administratively placed the licenses of the two operators', who had previous existing medical conditions that had not been reported to the NRC, on inactive status, and notified the NRC of the medical conditions and requested license restrictions to their licenses.

7. I&M provided an informational notification to the NRC in letter AEP:NRC:2574-101, dated July 15, 2005, informing the NRC of the operator license that was previously amended to include a restriction but should have had the restriction on the initial license.

8. Training on the requirements for reporting changes in medical conditions has been provided in licensed operator requalification continuing training. Additionally, annual refresher training will be included in the licensed operator requalification training program.

9. Although not an action to address a causal factor in the apparent violations, the procedural guidance for licensed operator requirements has been enhanced to require operator affirmation, when documenting requirements for active status as defined in 10 CFR 55.53(e), that medical conditions potentially affecting licensed duties have been reported.

The actions above will ensure a robust and rigorous program for identifying and reporting of licensed operator medical conditions that may affect performance of licensed duties.

Additionally, these actions ensure complete and accurate information is provided to the NRC in a timely manner to ensure that the appropriate information is available for licensing decisions.

Date Full Compliance Will Be Achieved:

Compliance for each apparent violation is addressed below in the order that they appear in NRC Inspection Report 05000315/2005006(DRS); 05000316/2005006(DRS).

1. A review was completed on April 27, 2005, of the contents of the medical files for each current license holder to ensure historical issues were identified that were not identified in the original scope of the February and March 2004 self-assessment. Full compliance was achieved on April 27, 2005, when the review was completed and the results documented.

2. I&M submitted letter AEP:NRC:2574-96, dated May 18, 2005, which requested that a restriction be placed on the operator's license. Full compliance was achieved on June 8, 2005, when the NRC placed the requested restriction on the license in question and issued a license amendment.

3. I&M submitted letter AEP:NRC:2574-96, dated May 18, 2005, which requested that a restriction be placed on the operator's license. In this letter I&M acknowledges the notification of restriction should have been communicated within 30 days of the initial recommendation for restriction made by the medical review officer in December of 1998, and that the notification is considered late. Full compliance was achieved on May 18, 2005, when I&M notified the NRC with the requested restriction for the license in question.

4. I&M submitted letter AEP:NRC:2574-97, dated May 18, 2005, which requested that a restriction be placed on the operator's license. Full compliance was achieved on June 8, 2005, when the NRC placed the requested restriction on the license in question and issued a license amendment.

5. I&M submitted letter AEP:NRC:2574-97, dated May 18, 2005, which requested that a restriction be placed on the operator's license. In this letter I&M acknowledges the notification of restriction should have been communicated within 30 days of the initial recommendation for restriction made by the medical review officer on January 6, 2003, and that the notification is considered late. Full compliance was achieved on May 18, 2005, when I&M notified the NRC with the requested restriction for the license in question.

6. I&M submitted letter AEP:NRC:2574-33, dated August 20, 2003, which requested that a restriction be placed on the operator's license. Full compliance was achieved on August 28, 2003, when the NRC placed the requested restriction on the license in question and issued a license amendment.

LIST OF REGULATORY COMMITMENTS

The following table summarizes the actions committed to by Indiana Michigan Power Company (I&M) in this document. Any other actions discussed in this submittal represent intended or planned actions by I&M. They are described to the Nuclear Regulatory Commission (NRC) for information and are not regulatory commitments.

Commitment	Due Date
Annual refresher training of the requirements for reporting changes in medical conditions will be included in the licensed operator requalification training program.	December 30, 2005