September 8, 2005

EA-05-171

Mr. M. Nazar Senior Vice President and Chief Nuclear Officer Indiana Michigan Power Company Nuclear Generation Group One Cook Place Bridgman, MI 49106

SUBJECT: DONALD C. COOK NUCLEAR POWER PLANT, UNITS 1 AND 2 NRC INSPECTION REPORT 05000315/2005006(DRS); 05000316/2005006(DRS)

Dear Mr. Nazar:

On August 26, 2005, the U. S. Nuclear Regulatory Commission (NRC) completed a baseline inspection at your Donald C. Cook Nuclear Power Plant, Units 1 and 2. The enclosed report documents the inspection findings which were discussed on August 11, 2005, and a subsequent meeting via telephone on August 26, 2005, with Mr. L. Weber and Mr. J. Jensen, respectively, and other members of your staff.

The inspection examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, and interviews with personnel.

Based on the results of this inspection, four apparent violations involving 10 CFR 50.9 and two apparent violations involving 10 CFR 55.25 were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/reading-rm/adams.html.

On March 24, 2004, your staff provided information to the NRC regarding the medical status of a licensed senior reactor operator (SRO) at your facility. That information indicated the SRO had a pre-existing medical condition since 1996 that was considered a potentially disqualifying condition in accordance with American National Standards Institute/American Nuclear Society (ANSI/ANS)-3.4 - 1983, "American National Standard Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," and the SRO license should have required the presence of another qualified individual when the SRO was performing licensed duties.

A Severity Level III Notice of Violation was issued for the above event on September 29, 2004. In a letter to the NRC dated August 2, 2004, you stated that in response to this apparent violation, "A 100 percent review (self-assessment) of all operator medical records was performed in February and March of 2004." This response implied that there were no further problems identified with licensed operator medical records. On April 19, 2005, during a follow-up review of the corrective actions for the September 2004 violation, the NRC identified that another licensed operator had a potentially disqualifying medical condition that had not been reported to the NRC that existed prior to the licensee's review in March 2004. In response to the inspector's findings, your staff performed another medical record review and found another example of a licensed operator that had a potentially disqualifying medical condition that had not been reported to the NRC and existed prior to the March 24, 2004, medical record review. In addition, you found an example of where you failed to report that an SRO required a restriction on his license prior to being issued his SRO license. In the above cases, there was one example where you provided inaccurate information to NRC in response to a previous Severity Level III violation; three examples where you provided inaccurate information that the NRC depended on to make decisions regarding individual operator licenses; and two examples where you failed to report permanent changes to licensed operators medical conditions that would have resulted in a change to the operators' licenses.

The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with members of your staff at the inspection exit meeting on August 11, 2005, and a subsequent exit meeting via telephone on August 26, 2005. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violations addressed in this inspection report within 30 days of the date of this letter; or (2) request a predecisional enforcement conference. If a conference is held, it will be open for public observation. The NRC will also issue a press release to announce the conference. Please contact Mr. Hironori Peterson at (630) 829-9707 within seven days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to An Apparent Violation in Inspection Report No 05000315/2005006(DRS); 5000316/2005006(DRS); EA-05-171," and should include for the apparent violations: (1) the reason for the apparent violations, or, if contested, the basis for disputing the apparent violations; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

M. Nazar

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), accessible from the NRC Web site at <u>http://www.nrc.gov/readingrm/adams.html</u> (the Public Electronic Reading Room).

Sincerely,

/**RA**/

Cynthia D. Pederson, Director Division of Reactor Safety

Docket Nos. 50-315; 50-316 License Nos. DPR-58; DPR-74

- Enclosure: Inspection Report 05000315/2005006(DRS); 05000316/2005006(DRS) w/attachment: Supplemental Information
- cc w/encl: J. Jensen, Site Vice President
 - L. Weber, Plant Manager
 - G. White, Michigan Public Service Commission
 - L. Brandon, Michigan Department of Environmental Quality -
 - Waste and Hazardous Materials Division
 - Emergency Management Division
 - MI Department of State Police
 - D. Lochbaum, Union of Concerned Scientists
 - S. Stewart, Training Manager

M. Nazar

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), is accessible from the NRC Web site at <u>http://www.nrc.gov/reading-rm/adams.html</u> (the Public Electronic Reading Room).

Sincerely,

/RA/

Cynthia D. Pederson, Director Division of Reactor Safety

Docket Nos. 50-315; 50-316 License Nos. DPR-58; DPR-74

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- D. Lochbaum, Union of Concerned Scientists
- S. Stewart, Training Manager

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M. Nazar

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket Nos: License Nos:	50-315; 50-316 DPR-58; DPR-74
Report No:	05000315/2005006(DRS); 05000316/2005006(DRS)
Licensee:	American Electric Power Company
Facility:	Donald C. Cook Nuclear Power Plant, Units 1 and 2
Location:	1 Cook Place Bridgman, MI 49106
Dates:	April 18, 2005 through August 26, 2005
Inspectors:	C. Phillips, Senior Operations Engineer
Approved by:	H. Peterson, Chief Operations Branch Division of Reactor Safety

SUMMARY OF FINDINGS

IR 05000315/2005006(DRS); 05000316/2005006(DRS); 04/18/2005 - 04/21/2005 and 08/11/2005 (on-site) and 04/22/2005 - 08/26/2005 (periodic in-office review); D. C. Cook Nuclear Power Plant, Units 1 and 2; Licensed Operator Requalification.

This report covers an approximate five-month period of periodic on-site and in-office review of baseline announced inspection in the area of licensed operator requalification. The inspection was conducted by one regional specialist inspector. Six apparent violations were identified during the inspection. The significance of most findings is indicated by their color (Green, White, Yellow, Red) using Inspection Manual Chapter (IMC) 0609, "Significance Determination Process" (SDP). Findings for which the SDP does not apply may be "Green" or be assigned a severity level after NRC management review. The NRC's program for overseeing the safe operation of commercial nuclear power reactors is described in NUREG-1649, "Reactor Oversight Process," Revision 3, dated July 2000.

A. Inspector-Identified and Self-Revealed Findings

Cornerstone: Mitigating Systems

• To Be Determined (TBD). 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 (AV 05000315/2005006-01; AV 05000316/2004007-01). (Section 1R11)

TBD. 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 (AV 05000315/2005006-02; AV 05000316/2005006-02). (Section 1R11)

TBD. 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 (AV 05000315/2005006-03; AV 05000316/2005006-03). (Section 1R11)

TBD. 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 (AV 05000315/2005006-04; AV 05000316/2005006-04). (Section 1R11)

TBD. 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 (AV 05000315/2005006-05; AV 05000316/2005006-05). (Section 1R11)

TBD. 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 (AV 05000315/2005006-06; AV 05000316/2005006-06). (Section 1R11)

B. Licensee-Identified Violations

None.

REPORT DETAILS

1. **REACTOR SAFETY**

Cornerstone: Mitigating Systems

- 1R11 Licensed Operator Requalification (71111.11)
- .1 <u>Conformance With Operator License Conditions</u>
- a. Inspection Scope

The inspector reviewed the licensee's corrective actions for a Severity Level III violation dated September 29, 2004. The corrective actions were documented in a letter from the licensee to the NRC dated August 2, 2004. The inspector also reviewed 19 licensed operators' medical records maintained by the facility licensee and assessed compliance with the medical standards delineated in ANSI/ANS 3.4 -1983, "American National Standard Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," and with 10 CFR 55.21 and 10 CFR 55.25. The inspector reviewed associated corrective action documents and interviewed individuals that were involved with these issues.

b. Findings

Introduction: In 2004, the licensee received a Severity Level III Violation because the NRC took a licensing action on an individual without knowing about a pre-existing potentially disqualifying medical condition. The licensee informed the NRC on August 2, 2004, that they had completed their corrective actions for this violation. When the inspector followed up on the violation on April 19, 2005, he identified there was another example of the NRC taking a licensing action (license renewal) for an operator that had a pre-existing potentially disqualifying medical condition where the licensee had not previously notified the NRC. In response to the NRC's concerns, the licensee looked again and found two additional examples where pre-existing medical conditions were not reported to the NRC prior to the NRC taking licensing actions.

<u>Description</u>: On March 24, 2004, the licensee provided information to the NRC regarding the medical status of a licensed senior reactor operator (SRO) at D.C Cook. That information indicated the SRO had a pre-existing medical condition since 1996 that was considered a potentially disqualifying condition in accordance with American National Standards Institute/American Nuclear Society (ANSI/ANS)-3.4 - 1983, "American National Standard Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," and the SRO license should have required the presence of another qualified individual when the SRO was performing licensed duties.

A Severity Level III Notice of Violation was issued to the licensee for the above event on September 29, 2004. In a letter to the NRC dated August 2, 2004, the licensee stated that in response to this violation, "A 100 percent review (self-assessment) of all operator

medical records was performed in February and March of 2004." This response implied that there were no further problems identified with licensed operator medical records. On April 19, 2005, during a follow-up review of the corrective actions for the September 2004, violation and a sample of operator medical records the inspector identified that another licensed operator had a potentially disqualifying medical condition that had not been reported to the NRC that existed prior to the licensee's review in March 2004. In response to the inspector's findings, the licensee performed another medical record review and found another example of a licensed operator that had a potentially disqualifying medical condition that had not been reported to the NRC and existed prior to the March 24, 2004, medical record review. In addition, the licensee found an example of where they failed to report that an SRO required a restriction on his license prior to being issued his SRO license.

On May 18, 2005, the licensee provided information to the NRC regarding the medical status of two of the three SROs mentioned above. That information indicated the SROs had pre-existing medical conditions since 2003 and 1998, respectively, which were considered potentially disqualifying conditions in accordance with American National Standards Institute/American Nuclear Society (ANSI/ANS)-3.4 - 1983, "American National Standard Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants." The SROs' licenses should have required an operating restriction usage when performing licensed duties.

On July 15, 2005, the licensee provided information to the NRC regarding the medical status of an additional SRO. His initial physical report stated that there were no physical restrictions required on his license. He was issued a license without restrictions. When in fact, at the time it was issued, his license should have been restricted due to a potentially disqualifying medical condition.

Details of the First SRO Medical Condition: On April 26, 2004, the licensee provided information to the NRC regarding the medical status of one of the SROs. The licensee requested to have a medical restriction removed from the SRO's license. Information provided in that amendment request did not describe the individual's pre-existing medical condition from January 2003. The individual's license was amended by the NRC on April 30, 2004, based on the information the licensee provided on April 26, 2004. Therefore, the information provided to the NRC on April 26, 2004, was material to an NRC licensing action. The failure to provide accurate and complete information to the NRC regarding a pre-existing medical condition of an SRO is a significant regulatory issue. If the information had been complete and accurate at the time provided, the NRC would have taken a different regulatory position and would not have renewed the license without an operating restriction.

The SRO had a potentially disqualifying medical condition dating back to January 6, 2003. Part 5.3 of ANSI/ANS 3.4-1983, states that, "a history or other indication of any disqualifying condition shall be considered disqualifying unless adequate supplemental findings demonstrate that no disqualifying condition exists." The individual did not have adequate supplemental findings to demonstrated that no disqualifying condition existed.

Details of the Second SRO Medical Condition: In addition, On May 5, 2004, the licensee provided information to the NRC regarding the medical status of one of the SROs in an application for renewal of the SRO's license and information provided in that renewal application did not describe the individual's pre-existing medical condition from 1998. The individual's license was renewed by the NRC on May 7, 2004, based on the information the licensee provided on May 5, 2004. Therefore, the information provided to the NRC on May 5, 2004, was material to an NRC licensing action. The failure to provide accurate and complete information to the NRC regarding a pre-existing medical condition of an SRO is a significant regulatory issue. If the information had been complete and accurate at the time provided, the NRC would have taken a different regulatory position and would not have renewed the license without an operating restriction.

The SRO had a potentially disqualifying medical condition dating back to November 23, 1998. Part 5.3 of ANSI/ANS 3.4-1983, states that, "a history or other indication of any disqualifying condition shall be considered disqualifying unless adequate supplemental findings demonstrate that no disqualifying condition exists." The individual did not have adequate supplemental findings to demonstrated that no disqualifying condition existed.

<u>Details of the Third SRO Medical Condition</u>: The initial SRO license application was submitted to the NRC with "no restrictions" on November 4, 2002. The SRO received his license from the NRC on December 27, 2002, without any medical restrictions. The SRO submitted formal notification to the licensee's operations training manager that he had a potentially disqualifying medical condition on July 15, 2003, that pre-dated his November 4, 2002, application. The licensee contacted the NRC on July 28, 2003, about the change in medical status and requested a license amendment on August 20, 2003. The NRC amended the SRO's license to include an operating restriction on August 28, 2003.

<u>Analysis</u>: Because violations of 10 CFR 50.9 and 10 CFR 55.25 are considered to be violations that potentially impede or impact the regulatory process, they are dispositioned using the NRC Enforcement Policy instead of the Significance Determination Process (SDP). Using Inspection Manual Chapter (IMC) 0612, Appendix B, "Issue Dispositioning Screening," the findings associated with 10 CFR 50.9 were determined to be more than minor because the information associated with the licenses of the individuals was provided to the NRC under a signed statement by the Site Vice President and in three of the six cases erroneously impacted an NRC licensing decision and in the fourth case erroneously impacted an NRC enforcement decision. Individuals who had pre-existing medical conditions, that at a minimum required a restriction on the individual's license, were issued a license without such a restriction. The inspector determined that two of the individuals were never required to rely upon the restriction that should have been present in their licenses and the third was in compliance with the restriction before it was placed in his license.

The findings associated with 10 CFR 55.25 were determined to be more than minor because had the information been provided to the NRC at the appropriate time the individuals' licenses would have been amended. The NRC relies upon the licensee to fulfill regulatory reporting requirements so that prompt discussions regarding operators licenses can be made.

The NRC depends upon the licensee to ensure that medical examinations are performed correctly and that the regulatory requirements and the rigors of the operator's duties are carefully explained to the medical personnel that perform these examinations. An operator that cannot perform licensed duties due to a medical condition that might be exacerbated by the stress resulting from a reactor accident scenario could be a significant distraction to the rest of the crew. Therefore, the safety significance of these issues was determined to be more than minor. However, the regulatory significance was greater because the information was material to NRC licensing decisions and NRC SRO licenses were issued without the proper medical restriction because incomplete and inaccurate information was provided to the NRC.

<u>Enforcement</u>: Title 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.

Title 10 CFR 55.25 requires, in part, if, during the term of the license, the licensee develops a permanent physical or mental condition that causes the licensee to fail to meet the requirements of 55.21 of this part, the facility licensee shall notify the Commission, within 30 days of learning of the diagnosis, in accordance with 50.74(c). For conditions for which a conditional license (as described in 55.33(b) of this part) is requested, the facility licensee shall provide medical certification on Form NRC - 396 to the Commission (as described in 55.23 of this part).

Title 10 CFR 55.23 requires that to certify the medical fitness of the applicant, an authorized representative of the facility licensee shall complete and sign Form NRC - 396, "Certification of Medical Examination by Facility Licensee."

Title 10 CFR 55.21 requires, in part, that an applicant for a license shall have a medical examination by a physician. A licensee shall have a medical examination by a physician every two years. The physician shall determine that the applicant or licensee meets the requirements of 55.33(a)(1).

Title 10 CFR 55.33(a)(1) requires, in part, the 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. The Commission will base its finding upon the certification by the facility licensee as detailed in 55.23.

Form NRC - 396, when signed by an authorized representative of the facility licensee, certifies that a physician conducted a medical examination of the applicant as required in 10 CFR 55.21, and that the guidance contained in American Nuclear Standards Institute/American Nuclear Society (ANSI/ANS) 3.4-1983, was followed in conducting the examination and making the determination of medical qualification.

ANSI/ANS 3.4-1983, Part 5.3, states that, "a history or other indication of any disqualifying condition shall be considered disqualifying unless adequate supplemental findings demonstrate that no disqualifying condition exists." The licensee provided incomplete and inaccurate information in a letter to the NRC dated August 2, 2004.

Specifically, the licensee, in its response to 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. However, during an April 2005 followup review of the licensee's corrective actions for the Severity Level III violation, the NRC identified an additional example of a licensed operator, with a potentially disgualifying 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. In addition, during a subsequent review of its medical records prompted by NRC's identification of additional medical issues, the licensee found a second example of a licensed operator, with a potentially disgualifying 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 also discovered that a third operator's license was issued without a required restriction in accordance with the requirements of ANSI/ANS 3.4-1983. This is an apparent violation of 10 CFR 50.9 (AV 05000315/2005006-01; AV 05000316/2004007-01).

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 medical condition that was potentially disqualifying in accordance with ANSI/ANS 3.4-1983, dating back to October 30, 1998, 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. This is an apparent violation of 10 CFR 50.9 (AV 05000315/2005006-02; AV 05000316/2005006-02).

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. 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. This is an apparent violation of 10 CFR 55.25 (AV 05000315/2005006-03; AV 05000316/2005006-03).

On April 26, 2004, a senior licensee representative submitted to the NRC a Form NRC - 396 to support an application for amendment 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 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. 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. This is an apparent violation of 10 CFR 50.9 (AV 05000315/2005006-04; AV 05000316/2005006-04).

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 described above 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. 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. This is an apparent violation of 10 CFR 55.25 (AV 05000315/2005006-05; AV 05000316/2005006-05).

On November 4, 2002, a senior licensee representative submitted to the NRC Form NRC - 396, 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. 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. This is an apparent violation of 10 CFR 50.9 (AV 05000315/2005006-06; AV 05000316/2005006-06).

The licensee took or planned to take the following corrective actions, which were considered to be prompt and comprehensive:

- The licensee removed two of the three operators from licensed duties until the issues were resolved and the licenses were updated;
- The complete medical records of all licensed operators were reviewed to ensure compliance with applicable standards. No other issues were identified;
- A self-assessment of all licensed operator medical records will be performed every year;
- The administrative procedure governing the medical record reporting process will be changed to ensure the NRC is notified when a potentially disqualifying medical condition is identified;
- Issues regarding medical status will be discussed between members of the training department and the regulatory assurance department to ensure consistency and compliance with reporting requirements;

- On April 27, 2005, the Operations Training Manager issued an interim memo to the Operations Training Department staff assistant that outlines specific expectations for communicating information regarding changing or new medical conditions; and
- Revise administrative procedure governing the medical record reporting process to include a guideline/checklist for conducting a face-to-face review with the Medical Review Officer (MRO) that will review ANSI/ANS 3.4 - 1983 (medical certification and monitoring of personnel requiring operator licenses for nuclear power plants). The use of the checklist is to drive the appropriate discussion with the MRO to ensure a mutual understanding of the standard, communications between the MRO and the licensee's facility, and ensure the MRO understands the interface that the licensee must maintain with the NRC as medical issues are identified and evaluated.

4. OTHER ACTIVITIES

40A6 Meetings

.1 Exit Meetings

The inspectors presented the inspection results to Mr. L. Weber and other members of licensee management at the conclusion of the inspection on August 11, 2005. The inspectors asked the licensee whether any materials examined during the inspection should be considered proprietary. No proprietary information was identified. A subsequent re-exit was held with Mr. J. Jensen on August 26, 2005. The purpose of the re-exit was to convey to the licensee the changes to proposed enforcement actions that occurred after discussion with Region III management.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

KEY POINTS OF CONTACT

Licensee

- J. Jensen, Site Vice President
- L. Weber, Plant Manager
- I. Fleetwood, Training Instructor
- R. Gillespie, Operations Director
- J. Newmiller, Regulatory Compliance
- T. McCool, Operations Training Supervisor
- M. Scarpello, Regulatory Affairs Manager
- J. Zwolinski, Safety Assurance Director

<u>Nuclear Regulatory Commission</u> C. Phillips, Senior Operations Engineer

LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Opened</u>

05000315/200506-01; 05000316/200506-01	AV	Failure to Provide Complete and Accurate Information to the NRC Which Impacted A Licensing Decision. (Section 1R11)
05000315/200506-02; 05000316/200506-02	AV	Failure to Provide Complete and Accurate Information to the NRC Which Impacted A Licensing Decision. (Section 1R11)
05000315/200506-03; 05000316/200506-03	AV	Failure to Report A Change In A License Operators Medical Condition. (Section 1R11)
05000315/200506-04; 05000316/200506-04	AV	Failure to Provide Complete and Accurate Information to the NRC Which Impacted A Licensing Decision. (Section 1R11)
05000315/200506-05; 05000316/200506-05	AV	Failure to Report A Change In A License Operators Medical Condition. (Section 1R11)
05000315/200506-06; 05000316/200506-06	AV	Failure to Provide Complete and Accurate Information to the NRC Which Impacted A Licensing Decision. (Section 1R11)

<u>Closed</u>

None.

Discussed

05000315/2004007-01; AV 05000316/2004007-01 Failure to Provide Complete and Accurate Information to the NRC Which Impacted A Licensing Decision. (Section 1R11)

LIST OF DOCUMENTS REVIEWED

The following is a list of documents reviewed during the inspection. Inclusion on this list does not imply that the NRC inspectors reviewed the documents in their entirety but rather that selected sections of portions of the documents were evaluated as part of the overall inspection effort. Inclusion of a document on this list does not imply NRC acceptance of the document or any part of it, unless this is stared in the body of the inspection report.

<u>1R11</u> Licensed Operator Requalification

Nineteen Licensed Operators Medical Records; various dates

CR 05109063; On 4/19/05, the NRC Was on Site to Review Actions, to Close out a Non-Cited Violation Related to Reporting Licensed Operator Medical Conditions. The NRC Raised a Concern Regarding a Licensed Operator Medical Condition

CR 05112045; During a Review of Medical Records for Licensed Operators on April 21, 2005, it Has Been Determined That a Currently Licensed SRO Had a Medical Condition Requiring a License Restriction Which Was Not Reported at the Time of His Initial License

CR 05111059; On April 20, 2005, a Review of Medical Records Identified That a Currently Licensed Senior Reactor Operator Has a Medical Condition Which May Be a Disqualifying Condition

TI-TROP-02; Administrative Requirements for NRC License and Medical Requirements; Revision 6;

OHI-2071; Reporting Reassignment, Termination, and Conditions Potentially Affecting Performance of Licensed Duties; Revision 7

LIST OF ACRONYMS USED

- ANS American Nuclear Society
- ANSI American National Standards Institute
- CFR Code of Federal Regulations
- IMC Inspection Manual Chapter
- MRO Medical Review Officer
- NRC Nuclear Regulatory Commission
- NRR Nuclear Reactor Regulation
- ROP Reactor Oversight Process
- SDP Significance Determination Process
- SRO Senior Reactor Operator
- TBD To Be Determined