



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 7, 2012

Mr. Mark A. Schimmel
Site Vice President
Monticello Nuclear Generating Plant
Northern States Power Company - Minnesota
2807 West County Road 75
Monticello, MN 55362-9637

SUBJECT: MONTICELLO NUCLEAR GENERATING PLANT - ISSUANCE OF AMENDMENT
REGARDING THE AUTOMATIC DEPRESSURIZATION SYSTEM BYPASS
TIMER (TAC NO. ME8345)

Dear Schimmel:

The U.S. Nuclear Regulatory Commission (NRC) has issued the enclosed Amendment No. 170 to Renewed Facility Operating License No. DPR-22 for the Monticello Nuclear Generating Plant. The amendment consists of changes to the technical specifications (TSs) in response to your application dated April 5, 2012.

The amendment revises TSs to eliminate the lower allowable value limit of "≥ 18 minutes" for Functions 1.e and 2.e, "Reactor Steam Dome Pressure Permissive – Bypass Timer (Pump Permissive)," in Table 3.3.5.1-1, "Emergency Core Cooling System Instrumentation."

Please note that the NRC staff declined to issue this amendment by the licensee's requested issuance date of June 6, 2012; the application did not provide any reason for shortening the regulatory 60-day notice period during which interested parties may petition for a hearing.

A copy of our related safety evaluation is also enclosed. The Notice of Issuance will be included in the Commission's biweekly *Federal Register* notice.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter S. Tam".

Peter S. Tam, Senior Project Manager
Plant Licensing Branch III-1
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Docket No. 50-263

Enclosures:

1. Amendment No. 170 to DPR-22
2. Safety Evaluation

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
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NORTHERN STATES POWER COMPANY

DOCKET NO. 50-263

MONTICELLO NUCLEAR GENERATING PLANT

AMENDMENT TO RENEWED FACILITY OPERATING LICENSE

Amendment No. 170
License No. DPR-22

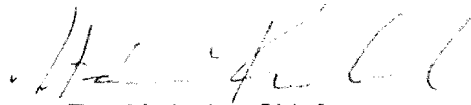
1. The U.S. Nuclear Regulatory Commission (the Commission) has found that:
 - A. The application for amendment by Northern States Power Company (NSPM, the licensee), dated April 5, 2012, complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in 10 CFR Chapter I;
 - B. The facility will operate in conformity with the application, the provisions of the Act, and the rules and regulations of the Commission;
 - C. There is reasonable assurance (i) that the activities authorized by this amendment can be conducted without endangering the health and safety of the public, and (ii) that such activities will be conducted in compliance with the Commission's regulations;
 - D. The issuance of this amendment will not be inimical to the common defense and security or to the health and safety of the public; and
 - E. The issuance of this amendment is in accordance with 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.
2. Accordingly, the license is amended by changes to the Technical Specifications as indicated in the attachment to this license amendment, and paragraph 2.C.2 of Renewed Facility Operating License No. DPR-22 is hereby amended to read as follows:

Technical Specifications

The Technical Specifications contained in Appendix A, as revised through Amendment No. 170, are hereby incorporated in the license. NSPM shall operate the facility in accordance with the Technical Specifications.

3. This license amendment is effective as of its date of issuance and shall be implemented within 14 days of issuance.

FOR THE NUCLEAR REGULATORY COMMISSION



Istvan Frankl, Acting Chief
Plant Licensing Branch III-1
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Attachment: Changes to Renewed Operating License DPR-22
and Technical Specifications

Date of Issuance: September 7, 2012

ATTACHMENT TO LICENSE AMENDMENT NO. 170

RENEWED FACILITY OPERATING LICENSE NO. DPR-22

DOCKET NO. 50-263

Replace the following page of Renewed Facility Operating License DPR-22 with the attached revised page. The revised page is identified by amendment number and contains a marginal line indicating the area of change.

REMOVE

3

INSERT

3

Replace the following pages of Appendix A, Technical Specifications, with the attached revised pages. The revised pages are identified by amendment number and contain a marginal line indicating the area of change.

REMOVE

3.3.5.1-6

3.3.5.1-8

INSERT

3.3.5.1-6

3.3.5.1-8

2. Pursuant to the Act and 10 CFR Part 70, NSPM to receive, possess, and use at any time special nuclear material as reactor fuel, in accordance with the limitations for storage and amounts required for reactor operations, as described in the Final Safety Analysis Report, as supplemented and amended, and the licensee's filings dated August 16, 1974 (those portions dealing with handling of reactor fuel) and August 17, 1977 (those portions dealing with fuel assembly storage capacity);
 3. Pursuant to the Act and 10 CFR Parts 30, 40 and 70, NSPM to receive, possess, and use at any time any byproduct, source and special nuclear material as sealed neutron sources for reactor startup, sealed sources for reactor instrumentation and radiation monitoring equipment calibration, and as fission detectors in amounts as required;
 4. Pursuant to the Act and 10 CFR Parts 30, 40 and 70, NSPM to receive, possess, and use in amounts as required any byproduct, source or special nuclear material without restriction to chemical or physical form, for sample analysis or instrument calibration or associated with radioactive apparatus or components; and
 5. Pursuant to the Act and 10 CFR Parts 30 and 70, NSPM to possess, but not separate, such byproduct and special nuclear material as may be produced by operation of the facility.
- C. This renewed operating license shall be deemed to contain and is subject to the conditions specified in the Commission's regulations in 10 CFR Chapter I and is subject to all applicable provisions of the Act and to the rules, regulations, and orders of the Commission, now or hereafter in effect; and is subject to the additional conditions specified or incorporated below:
1. Maximum Power Level

NSPM is authorized to operate the facility at steady state reactor core power levels not in excess of 1775 megawatts (thermal).
 2. Technical Specifications

The Technical Specifications contained in Appendix A, as revised through Amendment No. 170, are hereby incorporated in the license. NSPM shall operate the facility in accordance with the Technical Specifications.
 3. Physical Protection

NSPM shall implement and maintain in effect all provisions of the Commission-approved physical security, guard training and qualification, and safeguards contingency plans including amendments made pursuant to provisions of the Miscellaneous Amendments and Search

Table 3.3.5.1-1 (page 1 of 6)
Emergency Core Cooling System Instrumentation

FUNCTION	APPLICABLE MODES OR OTHER SPECIFIED CONDITIONS	REQUIRED CHANNELS PER FUNCTION	CONDITIONS REFERENCED FROM REQUIRED ACTION A.1	SURVEILLANCE REQUIREMENTS	ALLOWABLE VALUE
1. Core Spray System					
a. Reactor Vessel Water Level - Low	1, 2, 3, 4 ^(a) , 5 ^(a)	4 ^(b)	B	SR 3.3.5.1.1 SR 3.3.5.1.2 SR 3.3.5.1.3 SR 3.3.5.1.7 SR 3.3.5.1.8	≥ -48 inches
b. Drywell Pressure - High	1, 2, 3	4 ^(b)	B	SR 3.3.5.1.2 SR 3.3.5.1.4 SR 3.3.5.1.8	≤ 2 psig
c. Reactor Steam Dome Pressure - Low (Injection Permissive)	1, 2, 3	2	C	SR 3.3.5.1.2 SR 3.3.5.1.4 ^{(c)(d)} SR 3.3.5.1.8	≥ 397 psig and ≤ 440 psig
d. Reactor Steam Dome Pressure Permissive - Low (Pump Permissive)	4 ^(a) , 5 ^(a)	2	B	SR 3.3.5.1.2 SR 3.3.5.1.4 ^{(c)(d)} SR 3.3.5.1.8	≥ 397 psig and ≤ 440 psig
d. Reactor Steam Dome Pressure Permissive - Low (Pump Permissive)	1, 2, 3	2	C	SR 3.3.5.1.2 SR 3.3.5.1.4 ^{(c)(d)} SR 3.3.5.1.8	≥ 397 psig
e. Reactor Steam Dome Pressure Permissive - Bypass Timer (Pump Permissive)	4 ^(a) , 5 ^(a)	2	B	SR 3.3.5.1.2 SR 3.3.5.1.4 ^{(c)(d)} SR 3.3.5.1.8	≥ 397 psig
e. Reactor Steam Dome Pressure Permissive - Bypass Timer (Pump Permissive)	1, 2, 3	2	C	SR 3.3.5.1.7 SR 3.3.5.1.8	≤ 22 minutes
e. Reactor Steam Dome Pressure Permissive - Bypass Timer (Pump Permissive)	4 ^(a) , 5 ^(a)	2	B	SR 3.3.5.1.7 SR 3.3.5.1.8	≤ 22 minutes

(a) When associated ECCS subsystem(s) are required to be OPERABLE per LCO 3.5.2, "ECCS - Shutdown."

(b) Also required to initiate the associated emergency diesel generator (EDG).

(c) If the as-found channel setpoint is conservative with respect to the Allowable Value but outside its predefined as-found tolerance, then the channel shall be evaluated to verify that it is functioning as required before returning the channel to service.

(d) The instrument channel setpoint shall be reset to a value that is within the as-left tolerance of the nominal trip setpoint; otherwise, the channel shall be declared inoperable. The nominal trip setpoint and the methodology used to determine the as-found tolerance and the as-left tolerance are specified in the Technical Requirements Manual (TRM).

Table 3.3.5.1-1 (page 3 of 6)
Emergency Core Cooling System Instrumentation

FUNCTION	APPLICABLE MODES OR OTHER SPECIFIED CONDITIONS	REQUIRED CHANNELS PER FUNCTION	CONDITIONS REFERENCED FROM REQUIRED ACTION A.1	SURVEILLANCE REQUIREMENTS	ALLOWABLE VALUE
2. LPCI System					
e. Reactor Steam Dome Pressure Permissive - Bypass Timer (Pump Permissive)	1, 2, 3	2	C	SR 3.3.5.1.7 SR 3.3.5.1.8	≤ 22 minutes
	4 ^(a) , 5 ^(a)	2	B	SR 3.3.5.1.7 SR 3.3.5.1.8	≤ 22 minutes
f. Low Pressure Coolant Injection Pump Start - Time Delay Relay	1, 2, 3, 4 ^(a) , 5 ^(a)	4 per pump	B	SR 3.3.5.1.7 SR 3.3.5.1.8	
Pumps A, B					≤ 5.33 seconds
Pumps C, D					≤ 10.59 seconds
g. Low Pressure Coolant Injection Pump Discharge Flow - Low (Bypass)	1, 2, 3, 4 ^(a) , 5 ^(a)	1 per pump	E	SR 3.3.5.1.2 SR 3.3.5.1.7 SR 3.3.5.1.8	≥ 360 gpm and ≤ 745 gpm
h. Reactor Steam Dome Pressure - Low (Break Detection)	1, 2, 3	4	B	SR 3.3.5.1.2 SR 3.3.5.1.7 SR 3.3.5.1.8	≥ 873.6 psig and ≤ 923.4 psig
i. Recirculation Pump Differential Pressure - High (Break Detection)	1, 2, 3	4 per pump	C	SR 3.3.5.1.2 SR 3.3.5.1.7 SR 3.3.5.1.8	≥ 63.5 inches wc
j. Recirculation Riser Differential Pressure - High (Break Detection)	1, 2, 3	4	C	SR 3.3.5.1.2 SR 3.3.5.1.7 ^{(c)(d)} SR 3.3.5.1.8	≤ 100.0 inches wc

- (a) When associated ECCS subsystem(s) are required to be OPERABLE per LCO 3.5.2.
- (c) If the as-found channel setpoint is conservative with respect to the Allowable Value but outside its predefined as-found tolerance, then the channel shall be evaluated to verify that it is functioning as required before returning the channel to service.
- (d) The instrument channel setpoint shall be reset to a value that is within the as-left tolerance of the nominal trip setpoint; otherwise, the channel shall be declared inoperable. The nominal trip setpoint and the methodology used to determine the as-found tolerance and the as-left tolerance are specified in the TRM.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

RELATED TO AMENDMENT NO. 170

RENEWED FACILITY OPERATING LICENSE NO. DPR-22

NORTHERN STATES POWER COMPANY

MONTICELLO NUCLEAR GENERATING PLANT

DOCKET NO. 50-263

1.0 INTRODUCTION

By letter to the U.S. Nuclear Regulatory Commission (NRC or Commission) dated April 5, 2012 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12100A011), Northern States Power Company – Minnesota, the licensee, submitted a request for amendment for Monticello Nuclear Generating Plant (MNGP). The proposed amendment involves technical specification (TS) 3.3.5.1, "Emergency Core Cooling System (ECCS) Instrumentation." Specifically, the licensee proposed to eliminate the lower allowable value limit of "≥ 18 minutes" for Functions 1.e and 2.e, "Reactor Steam Dome Pressure Permissive – Bypass Timer (Pump Permissive)" (hereafter referred to as the Automatic Depressurization System (ADS) bypass timer), in Table 3.3.5.1-1, "Emergency Core Cooling System Instrumentation."

2.0 REGULATORY EVALUATION

Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.36, "Technical specifications," requires that a facility's TS will include a section addressing limiting conditions for operation (LCO). In accordance with 10 CFR 50.36(c)(2)(ii), the LCO of a nuclear reactor must be established for each item meeting one or more the specified criteria. One of these criteria is Criterion 3 which requires an LCO for a structure, system, or component, that is a part of the primary success path, and functions or actuates to mitigate a design-basis accident or transient that either assumes the failure of or presents a challenge to the integrity of a fission product barrier. Further, paragraph (c)(3) states, "Surveillance requirements are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the limiting conditions for operation will be met."

The proposed amendment regarding the subject functions, as described in the following section, to a single-sided allowable value will remain consistent with the facility operation that will be within safety limits, and that the limiting conditions for operation will be met; and therefore, is consistent with 10 CFR 50.36(c)(3), as discussed below.

3.0 TECHNICAL EVALUATION

3.1 Evaluation of the Proposed Change

The licensee proposed to revise the TS Allowable Value for Functions 1.e and 2.e, "Reactor Steam Dome Pressure Permissive – Bypass Timer (Pump Permissive)," in Table 3.3.5.1-1, "Emergency Core Cooling System Instrumentation." The proposed change to the Allowable Value is summarized below.

The current TS Allowable Values are:

1. Core Spray System

- e. Reactor Steam Dome Pressure ≥ 18 minutes and
Permissive – Bypass Timer (Pump Permissive) ≤ 22 minutes

2. Low-Pressure Core Injection (LPCI) System

- e. Reactor Steam Dome Pressure ≥ 18 minutes and
Permissive – Bypass Timer (Pump Permissive) ≤ 22 minutes

The licensee's proposed amendment would modify the Allowable Values as follows:

1. Core Spray System

- e. Reactor Steam Dome Pressure ≤ 22 minutes
Permissive – Bypass Timer (Pump Permissive)

2. LPCI System

- e. Reactor Steam Dome Pressure ≤ 22 minutes
Permissive – Bypass Timer (Pump Permissive)

The ADS is a part of the ECCS, and is an automatic actuation logic system that through operation of selected safety/relief valves (S/RVs) provides a backup to the high-pressure injection systems (e.g., high-pressure coolant injection (HPCI) system, feedwater, and reactor core isolation cooling (RCIC) systems). Only HPCI is credited in the accident analysis. In MNGP, three S/RVs perform the ADS function. The ADS is designed to depressurize the reactor during a small-break loss-of-coolant accident (LOCA) so that the LPCI and core spray can inject if HPCI fails or is unable to maintain reactor pressure vessel (RPV) water level. The ADS monitors the discharge pressures of the four LPCI pumps and two Core Spray pumps. These signals are used as a permissive for ADS actuation, indicating there is a source of coolant available once ADS has depressurized the vessel.

The ADS (and ECCS pump start) logic activates upon signals indicating:

- (1) reactor low-low water level, and

- (2) at least one LPCI or Core Spray pump running with a nominal discharge pressure of 100 psig (blowdown permissive interlock)

The LPCI and Core Spray pumps start automatically on high drywell pressure alone, or a sustained (20 minutes) RPV low-low water level. The ADS bypass timer is monitoring the sustained RPV low-low water level.

This logic arrangement maintains the design philosophy of minimizing the potential for unnecessary ECCS pump starts at high reactor pressure. A time delay of approximately two minutes after receipt of the signals allows the operator to reset the logic and prevent an automatic blowdown if the water level in the reactor pressure vessel is being restored or if the signals are erroneous. A manual inhibit switch was added to the ADS initiation logic to provide the operators sufficient time to assess the situation and inhibit ADS actuation if reactor water level is expected to be recovered (e.g., injection systems are being restored), the event does not require rapid reactor depressurization, or depressurization by ADS should not be performed.

The logic does not affect the high drywell pressure-reactor low-low water level initiation sequence insofar as it responds to pipe breaks inside the drywell on automatic ADS response to isolation or LOCA events.

The time delay of approximately 20 minutes for the ADS bypass timer allowable value setpoint was chosen to be long enough so that HPCI has sufficient time to recover RPV water level to above low-low, yet not so long that LPCI and Core Spray are unable to adequately cool the core and limit the peak cladding temperature (PCT) to less than 2200°F if HPCI fails to maintain level.

In the "Technical Evaluation" section of its April 5, 2012, application, the licensee described that analyses were performed to determine the analytical limit for the ADS bypass timer. The licensee stated that approved ECCS evaluation models were used for these ADS bypass timer analyses. Sensitivity studies were performed to determine limiting events for the analytical limit determination. The studies included transient and LOCA events which do not result in a release of steam to the drywell but which may require depressurization of the RPV to maintain adequate core cooling. The studies assumed that all high pressure makeup systems were lost. In order to establish the maximum allowable bypass time, the ADS bypass timer setting was varied. Plant response for different bypass time settings, were determined to be similar, except that the calculated PCT increased with increasing ADS bypass timer settings, as expected. ADS bypass timer setting analytical limit was determined that would maintain the PCT less than 2200 °F for these events. The safety analysis is only concerned with the determination of maximum time delay (the upper analytical limit) that allows the calculated PCT to be maintained less than 2200 °F.

From this analytical limit, the instrument setpoint determination process establishes an acceptable TS allowable value. Maintaining the instrument setting less than the allowable value limit (the upper limit in the current TS) ensures that the PCT will remain less than 2200 °F, the safety basis for this function in the safety analyses. Hence, the TS allowable value is properly expressed as a single-sided limit and meets the safety analysis requirement.

The licensee further stated that the lower allowable value limit for the ADS bypass timer function pertains to providing adequate margin to unwanted pump starts during reactor water level transients, and is not associated with the safety analysis. The upper allowable value provides the operator sufficient time to assess the situation and inhibit ADS actuation if the event does not require rapid reactor depressurization. The licensee is not proposing any change to the evaluation of the ADS and low pressure ECCS pump start logic modifications. The licensee only proposed to remove the ADS bypass timer lower allowable value limit from the TS since it is not assumed in the safety analysis.

The application also provided a list of a number of other operating boiling-water reactors (BWRs) whose TS did not include a lower allowable value limit for the ADS bypass timer.

The NRC staff reviewed the licensee's application and related documentation, e.g., TS and updated safety analysis report for MNGP, and BWR/4 Standard Technical Specification (NUREG-1433). The NRC staff concurs with the licensee that maintaining the instrument setting less than the allowable value of the upper limit in the current TS, calculated using the NRC-approved methodologies, ensures that the PCT will remain below the 10 CFR 50.46 requirements, which is the safety basis for this function in the safety analyses. It also provides the operators sufficient time to assess the situation and inhibit the ADS actuation if the event does not require rapid reactor depressurization. The NRC staff also understands that the lower allowable value limit for the ADS bypass timer function pertains to providing adequate margin to unwanted pump starts during reactor water level transients, and it is not associated with the safety analysis, and hence, should not be a safety limit. Therefore, the NRC staff concludes that the TS allowable value can be appropriately expressed as a single-sided limit, which meets the safety analysis requirements.

The NRC staff's review has also confirmed that the proposed change is similar to changes that have previously been approved for a number of other operating BWR plants (i.e., a single-sided allowable value limit for the function in their TS corresponding to the ADS bypass timer).

The NRC staff finds that the proposed license amendment is acceptable based on the following considerations:

- (a) Maintaining the instrument setting less than the allowable value of the upper limit in the current TS ensures that the PCT (a safety limit) will remain below the 10 CFR 50.46 requirements;
- (b) The upper limit also provides the operators sufficient time to assess the situation and inhibit the ADS actuation if the event does not require rapid reactor depressurization; and
- (c) The lower allowable value limit for the ADS bypass timer function pertains only to provide adequate margin to unwanted pump starts during reactor water level transients, it is not associated with the safety analysis, and hence it is not a safety limit.

The NRC staff, therefore, concludes that the TS allowable value can be appropriately expressed as a single-sided limit, as proposed, on the basis that it meets the underlying safety analysis, and it is consistent with the regulatory requirements. The proposed TS amendment is acceptable.

Furthermore, the NRC staff determined that upon approval of the requested amendment, the applicable regulatory requirements will continue to be met, adequate defense-in-depth will be maintained, and sufficient safety margins will be maintained. The NRC staff, therefore, concludes that this license amendment is acceptable.

4.0 STATE CONSULTATION

In accordance with the Commission's regulations, the Minnesota State official was notified of the proposed issuance of the amendment. The State official had no comments.

5.0 ENVIRONMENTAL CONSIDERATION

The amendment changes a requirement with respect to the use of facility components located within the restricted area as defined in 10 CFR Part 20. The NRC staff has determined that the amendment involves no significant increase in the amounts, and no significant change in the types, of any effluents that may be released offsite, and that there is no significant increase in individual or cumulative occupational radiation exposure. The Commission has previously issued a proposed finding that the amendment involves no significant hazards consideration and there has been no public comment on such finding (77 FR 25759, dated May 1, 2012). Accordingly, the amendment meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the amendment.

6.0 CONCLUSION

The Commission has concluded, based on the considerations discussed above, that: (1) there is reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner, (2) there is reasonable assurance that such activities will be conducted in compliance with the Commission's regulations, and (3) the issuance of the amendment will not be inimical to the common defense and security or to the health and safety of the public.

Principal Contributor: Muhammad M. Razzaque, NRR

Date of issuance: September 7, 2012

Mr. Mark A. Schimmel
 Site Vice President
 Monticello Nuclear Generating Plant
 Northern States Power Company - Minnesota
 2807 West County Road 75
 Monticello, MN 55362-9637

September 7, 2012

SUBJECT: MONTICELLO NUCLEAR GENERATING PLANT - ISSUANCE OF AMENDMENT REGARDING THE AUTOMATIC DEPRESSURIZATION SYSTEM BYPASS TIMER (TAC NO. ME8345)

Dear Schimmel:

The U.S. Nuclear Regulatory Commission (NRC) has issued the enclosed Amendment No. 170 to Renewed Facility Operating License No. DPR-22 for the Monticello Nuclear Generating Plant. The amendment consists of changes to the technical specifications (TSs) in response to your application dated April 5, 2012.

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Please note that the NRC staff declined to issue this amendment by the licensee's requested issuance date of June 6, 2012; the application did not provide any reason for shortening the regulatory 60-day notice period during which interested parties may petition for a hearing.

A copy of our related safety evaluation is also enclosed. The Notice of Issuance will be included in the Commission's biweekly *Federal Register* notice.

Sincerely,
/RA/
 Peter S. Tam, Senior Project Manager
 Plant Licensing Branch III-1
 Division of Operating Reactor Licensing
 Office of Nuclear Reactor Regulation

Docket No. 50-263

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OFFICE	LPL3-1/PM	LPL3-1/LA	EPTB/BC(A)*	NRR/ITSB/BC	OGC	LPL3-1/BC(A)	LPL3-1/PM
NAME	PTam	BTully/Rohrer //	SMiranda*	RElliott	BHarris	IFrankl	PTam
DATE	8/17/12	8/17/12	8/2/12	9/7/12	8/31/12	9/7/12	9/7/12

*Safety evaluation transmitted by memo (Accession No. ML12213A537) of 8/2/2012.

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