



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

November 3, 2011

Mr. Lawrence J. Weber
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 PLANT, UNITS 1 AND 2 - ISSUANCE OF
AMENDMENTS TO RELOCATE CLOSURE TIME REQUIREMENTS OF
CERTAIN VALVES (TAC NOS. ME5873 AND ME5874)

Dear Mr. Weber:

The Nuclear Regulatory Commission has issued the enclosed Amendment No. 318 to Renewed Facility Operating License No. DPR-58 and Amendment No. 301 to Renewed Facility Operating License No. DPR-74 for the Donald C. Cook Nuclear Plant, Units 1 and 2, in response to your application dated March 18, 2011.

The amendments revise the TS in accordance with the previously approved Technical Specification Task Force (TSTF) Change Traveler TSTF-491, changing Surveillance Requirements 3.7.2.1, 3.7.3.1, and 3.7.3.2 by relocating the closure times for the Steam Generator Stop Valves, Main Feed Isolation Valves, and Main Feed Regulation Valves from the TS to the licensee-controlled TS Bases document.

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

Sincerely,

A handwritten signature in black ink that reads "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 Nos. 50-315 and 50-316

Enclosures:

1. Amendment No. 318 to DPR-58
2. Amendment No. 301 to DPR-74
3. Safety Evaluation

cc w/encls: Distribution via ListServ



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

INDIANA MICHIGAN POWER COMPANY

DOCKET NO. 50-315

DONALD C. COOK NUCLEAR PLANT, UNIT 1

AMENDMENT TO RENEWED FACILITY OPERATING LICENSE

Amendment No. 318
License No. DPR-58

1. The U.S. Nuclear Regulatory Commission (the Commission) has found that:
 - A. The application for amendment by Indiana Michigan Power Company (the licensee) dated March 18, 2011, 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-58 is hereby amended to read as follows:

(2) Technical Specifications

The Technical Specifications contained in Appendix A and the Environmental Protection Plan contained in Appendix B, as revised through Amendment No. 318, are hereby incorporated into this license. The licensee shall operate the facility in accordance with the Technical Specifications and the Environmental Protection Plan.

3. This license amendment is effective as of its date of issuance and shall be implemented within 120 days of issuance.

FOR THE NUCLEAR REGULATORY COMMISSION



Robert J. Pascarelli, Chief
Plant Licensing Branch III-1
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Attachment: Changes to the Renewed Facility Operating
License and Technical Specifications

Date of Issuance: November 3, 2011

ATTACHMENT TO LICENSE AMENDMENT NO. 318
TO RENEWED FACILITY OPERATING LICENSE NO. DPR-58

DOCKET NO. 50-315

Replace the following page of Renewed Facility Operating License DPR-58 with the attached revised page. The revised page is identified by amendment number and contains a marginal line indicating the areas 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 marginal lines indicating the areas of change.

REMOVE

3.7.2-2
3.7.3-2

INSERT

3.7.2-2
3.7.3-2

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, 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 and equipment calibration or associated with radioactive apparatus or components; and
 - (5) Pursuant to the Act and 10 CFR Parts 30 and 70, to possess, but not separate, such byproduct and special nuclear materials as may be produced by the operation of the facility.
- C. This renewed operating license shall be deemed to contain and is subject to the conditions specified in the following Commission regulations in 10 CFR Chapter I: Part 20, Section 30.34 of Part 30, Section 40.41 of Part 40, Section 50.54 and 50.59 of Part 50, and Section 70.32 of Part 70; 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

The licensee is authorized to operate the facility at steady state reactor core power levels not to exceed 3304 megawatts thermal in accordance with the conditions specified therein.

(2) Technical Specifications

The Technical Specifications contained in Appendix A, and the Environmental Protection Plan contained in Appendix B, as revised through Amendment No. 318, are hereby incorporated into this license. The licensee shall operate the facility in accordance with the Technical Specifications and the Environmental Protection Plan.

(3) Less Than Four Loop Operation

The licensee shall not operate the reactor at power levels above P-7 (as defined in Table 3.3.1-1 of Specification 3.3.1 of Appendix A to this renewed operating license) with less than four reactor coolant loops in operation until (a) safety analyses for less than four loop operation have been submitted, and (b) approval for less than four loop operation at power levels above P-7 has been granted by the Commission by amendment of this license.

- (4) Indiana Michigan Power Company shall implement and maintain, in effect, all provisions of the approved Fire Protection Program as described in the Final Safety Analysis Report for the facility and as approved in the SERs dated December 12, 1977, July 31, 1979, January 10, 1981, February 7, 1983, November 22, 1983, December 23, 1983, March 16, 1984, August 27, 1985

SURVEILLANCE REQUIREMENTS

SURVEILLANCE		FREQUENCY
SR 3.7.2.1	<p>-----NOTE----- Only required to be performed in MODES 1 and 2. -----</p> <p>Verify the isolation time of each SGSV is within limits.</p>	In accordance with the Inservice Testing Program
SR 3.7.2.2	<p>-----NOTE----- Only required to be performed in MODES 1 and 2. -----</p> <p>Verify each SGSV actuates to the isolation position on an actual or simulated actuation signal.</p>	24 months

ACTIONS (continued)

CONDITION	REQUIRED ACTION	COMPLETION TIME
D. Required Action and associated Completion Time not met.	D.1 Be in MODE 3.	6 hours
	<u>AND</u>	
	D.2 Be in MODE 4.	12 hours

SURVEILLANCE REQUIREMENTS

SURVEILLANCE		FREQUENCY
SR 3.7.3.1	Verify the isolation time of each MFIV is within limits.	In accordance with the Inservice Testing Program
SR 3.7.3.2	Verify the isolation time of each MFRV is within limits.	In accordance with the Inservice Testing Program
SR 3.7.3.3	Verify each MFIV and MFRV actuates to the isolation position on an actual or simulated actuation signal.	24 months



UNITED STATES
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INDIANA MICHIGAN POWER COMPANY

DOCKET NO. 50-316

DONALD C. COOK NUCLEAR PLANT, UNIT 2

AMENDMENT RENEWED FACILITY OPERATING LICENSE

Amendment No. 301
License No. DPR-74

1. The U.S. Nuclear Regulatory Commission (the Commission) has found that:
 - A. The application for amendment by Indiana Michigan Power Company (the licensee) dated March 18, 2011, 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-74 is hereby amended to read as follows:

(2) Technical Specifications

The Technical Specifications contained in Appendix A and the Environmental Protection Plan contained in Appendix B, as revised through Amendment No. 301, are hereby incorporated into this license. The licensee shall operate the facility in accordance with the Technical Specifications and the Environmental Protection Plan.

3. This license amendment is effective as of its date of issuance and shall be implemented within 120 days of issuance.

FOR THE NUCLEAR REGULATORY COMMISSION



Robert J. Pascarelli, Chief
Plant Licensing Branch III-1
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Attachment: Changes to the Renewed Facility Operating
License and Technical Specifications

Date of Issuance: November 3, 2011

ATTACHMENT TO LICENSE AMENDMENT NO. 301
TO RENEWED FACILITY OPERATING LICENSE NO. DPR-74
DOCKET NO. 50-316

Replace the following page of Renewed Facility Operating License DPR-74 with the attached revised page. The revised page is identified by amendment number and contains a marginal line indicating the area of change.

REMOVE

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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 marginal lines indicating the areas of change.

REMOVE

3.7.2-2

3.7.3-2

INSERT

3.7.2-2

3.7.3-2

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, 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 and equipment calibration or associated with radioactive apparatus or components; and
 - (5) Pursuant to the Act and 10 CFR Parts 30 and 70, to possess, but not separate, such byproduct and special nuclear materials as may be produced by the operation of the facility.
- C. This renewed operating license shall be deemed to contain and is subject to the conditions specified in the following Commission regulations in 10 CFR Chapter I: Part 20, Section 30.34 of Part 30, Section 40.41 of Part 40, Section 50.54 and 50.59 of Part 50, and Section 70.32 of Part 70; 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

The licensee is authorized to operate the facility at steady state reactor core power levels not to exceed 3468 megawatts thermal in accordance with the conditions specified therein and in attachment 1 to the renewed operating license. The preoperational tests, startup and other items identified in Attachment 1 to this renewed operating license shall be completed. Attachment 1 is an integral part of this renewed operating license.

(2) Technical Specifications

The Technical Specifications contained in Appendix A, and the Environmental Protection Plan contained in Appendix B, as revised through Amendment No. 301, are hereby incorporated into this license. The licensee shall operate the facility in accordance with the Technical Specifications and the Environmental Protection Plan.

(3) Additional Conditions

- (a) Deleted by Amendment No. 76
- (b) Deleted by Amendment No. 2
- (c) Leak Testing of Emergency Core cooling System Valves

Indiana Michigan Power Company shall prior to completion of the first inservice testing interval test each of the two valves in series in the

SURVEILLANCE REQUIREMENTS

SURVEILLANCE		FREQUENCY
SR 3.7.2.1	<p style="text-align: center;">NOTE</p> <p>Only required to be performed in MODES 1 and 2.</p> <hr/> <p>Verify the isolation time of each SGSV is within limits.</p>	In accordance with the Inservice Testing Program
SR 3.7.2.2	<p style="text-align: center;">NOTE</p> <p>Only required to be performed in MODES 1 and 2.</p> <hr/> <p>Verify each SGSV actuates to the isolation position on an actual or simulated actuation signal.</p>	24 months

ACTIONS (continued)

CONDITION	REQUIRED ACTION	COMPLETION TIME
D. Required Action and associated Completion Time not met.	D.1 Be in MODE 3.	6 hours
	<u>AND</u> D.2 Be in MODE 4.	12 hours

SURVEILLANCE REQUIREMENTS

SURVEILLANCE		FREQUENCY
SR 3.7.3.1	Verify the isolation time of each MFIV is within limits.	In accordance with the Inservice Testing Program
SR 3.7.3.2	Verify the isolation time of each MFRV is within limits.	In accordance with the Inservice Testing Program
SR 3.7.3.3	Verify each MFIV and MFRV actuates to the isolation position on an actual or simulated actuation signal.	24 months



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

SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

RELATED TO

AMENDMENT NO. 318 TO RENEWED FACILITY OPERATING LICENSE NO. DPR-58

AMENDMENT NO. 301 TO RENEWED FACILITY OPERATING LICENSE NO. DPR-74

INDIANA MICHIGAN POWER COMPANY

DONALD C. COOK NUCLEAR PLANT, UNITS 1 AND 2

DOCKET NOS. 50-315 AND 50-316

1.0 INTRODUCTION

By letter dated March 18, 2011 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML110880107), Indiana Michigan Power Company (the licensee), submitted a request for changes to the Technical Specifications (TS) for Donald C. Cook Nuclear Plant (CNP) Units 1 and 2. The requested changes are the adoption of TSTF-491, Revision 2, "Removal of Main Steam and Feedwater Valve Isolation Times," which was proposed by the Technical Specification Task Force (TSTF) by letter on May 18, 2006 (ADAMS Accession No. ML061500078). The proposed changes would revise TS Surveillance Requirements (SRs) 3.7.2.1, 3.7.3.1 and 3.7.3.2 by relocating the closure times for the Steam Generator Stop Valves (SGSVs), Main Feed Isolation Valves (MFIVs) and Main Feed Regulation Valves (MFRVs), respectively, from the CNP TS to the TS Bases document. TSTF-491 was announced for availability in the *Federal Register* on December 29, 2006 (71 FR 78472, as part of the Consolidated Line Item Improvement Process (CLIIP) of the Nuclear Regulatory Commission (NRC).

2.0 REGULATORY EVALUATION

Section 182a of the Atomic Energy Act (the Act) requires applicants for nuclear power plant operating licenses to include TS as part of the license. The TS ensure the operational capability of structures, systems, and components that are required to protect the health and safety of the public. The Commission's regulatory requirements related to the content of the TS are contained in 10 CFR Section 50.36. That regulation requires that the TS include items in the following specific categories: (1) safety limits, limiting safety systems settings, and limiting control settings (50.36(c)(1)); (2) Limiting Conditions for Operation (50.36(c)(2)); (3) SRs (50.36(c)(3)); (4) design features (50.34(c)(4)); and (5) administrative controls (50.36(c)(5)).

In general, there are two classes of changes to TS: (1) changes needed to reflect modifications to the design basis (TS are derived from the design basis), and (2) voluntary changes to take advantage of the evolution in policy and guidance as to the required content and preferred format of TS over time. This amendment deals with the second class of changes.

Enclosure

In determining the acceptability of revising CNP TSs, the NRC staff used the accumulation of generically approved guidance in NUREG-1431, Revision 3, "Standard Technical Specifications [STS], Westinghouse Plants," dated June, 2004. Licensees may revise the TS to adopt current improved STS format and content provided that plant-specific review supports a finding of continued adequate safety because: (1) the change is editorial, administrative or provides clarification (i.e., no requirements are materially altered), (2) the change is more restrictive than the licensee's current requirement, or (3) the change is less restrictive than the licensee's current requirement, but nonetheless still affords adequate assurance of safety when judged against current regulatory standards. The detailed application of this general framework, and additional specialized guidance, are discussed in Section 3.0 below in the context of specific proposed changes.

3.0 TECHNICAL EVALUATION

The NRC staff reviewed the justification for TSTF-491 as described in the TSTF submittal dated September 13, 2005 (ADAMS Accession No. ML052590343), transmitting Rev. 0 of TSTF-491. The licensee stated in its application that the proposal presented in the TSTF-491, Rev. 2, and the model Safety Evaluation prepared by the NRC staff are applicable to CNP for the incorporation of the changes to CNP TS. The detailed evaluation below will support the conclusion 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) 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.

3.1 Steam Generator Stop Valves (SGSVs)

The SGSVs protect the reactor core from being damaged following a high energy line break (HELB). One SGSV is located in each main steam line outside of the containment. Closing the SGSVs isolates each steam generator from the others and isolates the turbine, steam bypass system and other auxiliary steam supplies from the steam generator. By isolating the steam flow from the secondary side of the steam generator the SGSVs prevent over cooling the reactor core following an HELB. By preventing core overcooling the SGSVs protect the reactor core from being damaged.

TSTF-491 relocated the required closure times to a licensee-controlled document that is referenced in the STS Bases. The NRC staff approved TSTF-491 on the basis that changes to licensee-controlled documents are subject to the 10 CFR 50.59 process. This regulatory requirement provides adequate assurance that prior NRC staff review and approval will be requested by a licensee for changes to the licensee-controlled document with the potential to affect the safe operation of the plant. The licensee proposed relocating the required closure times for the SGSVs to the CNP TS Bases. CNP has a TS Bases Control Program that requires that proposed changes to the Bases are subject to the 10 CFR 50.59 process. The NRC staff reviewed the CNP TS Bases Control Program and determined that it provides adequate assurance that prior NRC staff review and approval will be requested by the licensee for changes to the TS Bases with the potential to affect the safe operation of the plant. Furthermore, the SGSVs are subject to periodic testing and acceptance criteria in accordance with the Inservice Testing (IST) Program. Compliance with the IST Program is required by TS Section 5.5.6 and 10 CFR 50.55a. The IST Program includes specific reference value baseline operating times for valves that are not subject to arbitrary changes.

The provisions of 10 CFR 50.36 require the inclusion of the periodic testing of the SGSVs in the SRs, but not the actual closure time of the valves. Thus the licensee's adoption of TSTF-491 changes will maintain the periodic testing requirements for SGSVs in accordance with 10 CFR 50.36.

Based on the requirements of 10 CFR 50.36, 10 CFR 50.59, and the IST Program, the NRC staff concludes that relocating the SGSV closure time to the licensee-controlled CNP TS Bases document is acceptable.

3.2 Main Feedwater Isolation Valve (MFIVs), Main Feedwater Regulation Valves (MFRVs)

The MFIVs and the MFRVs isolate the nonsafety-related portions from the safety-related portions of the system. In the event of a secondary side pipe rupture inside containment, these valves limit the quantity of high energy fluid that enters the containment through the break and provide a pressure boundary for the controlled addition of auxiliary feedwater to the intact loops. By isolating the feedwater flow from the affected steam generator the MFIVs and MFRVs prevent overcooling the reactor core and over pressurizing of the containment from feedwater pump runout.

TSTF-491 relocated the required closure times to a licensee-controlled document that is referenced in the STS Bases. The NRC staff approved TSTF-491 on the basis that changes to licensee-controlled documents are subject to the 10 CFR 50.59 process. This regulatory requirement provides adequate assurance that prior NRC staff review and approval will be requested by a licensee for changes to the licensee-controlled document with the potential to affect the safe operation of the plant. The licensee proposed relocating the required closure times for the MFIVs and MFRVs to the TS Bases document. CNP has a TS Bases Control Program that requires that proposed changes to the Bases are subject to the 10 CFR 50.59 process. The NRC staff reviewed the CNP TS Bases Control Program and determined that it provides adequate assurance that prior NRC staff review and approval will be requested by the licensee for changes to the TS Bases with the potential to affect the safe operation of the plant. Furthermore, the MFIVs and MFRVs are subject to periodic testing and acceptance criteria in accordance with the IST Program. Compliance with the IST Program is required by TS Section 5.5.6 and 10 CFR 50.55a. The IST Program includes specific reference value baseline operating times for valves that are not subject to arbitrary changes.

The provisions in 10 CFR 50.36 require the inclusion of the periodic testing of the MFIVs and MFRVs in the SRs, but not the actual closure time of the valves. The licensee's adoption of TSTF-491 changes will maintain the periodic testing requirements for MFIVs and MFRVs in accordance with 10 CFR 50.36.

Based on the requirements of 10 CFR 50.36, 10 CFR 50.59 and the IST Program, the NRC staff concludes that relocating the MFIVs and MFRVs closure times to the licensee-controlled CNP TS Bases document is acceptable.

4.0 STATE CONSULTATION

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

5.0 ENVIRONMENTAL CONSIDERATION

The amendment changes requirements 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 (76 FR 28474). 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) 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 Contributors: M. Hamm

Date: November 3, 2011

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

November 3, 2011

SUBJECT: DONALD C. COOK NUCLEAR PLANT, UNITS 1 AND 2 - ISSUANCE OF AMENDMENTS TO RELOCATE CLOSURE TIME REQUIREMENTS OF CERTAIN VALVES (TAC NOS. ME5873 AND ME5874)

Dear Mr. Weber:

The Nuclear Regulatory Commission has issued the enclosed Amendment No. 318 to Renewed Facility Operating License No. DPR-58 and Amendment No. 301 to Renewed Facility Operating License No. DPR-74 for the Donald C. Cook Nuclear Plant, Units 1 and 2, in response to your application dated March 18, 2011.

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A copy of our related safety evaluation is also enclosed. A Notice of Issuance will be included in the Commission's next 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 Nos. 50-315 and 50-316

Enclosures:

1. Amendment No. 318 to DPR-58
 2. Amendment No. 301 to DPR-74
 3. Safety Evaluation
- cc w/encls: Distribution via ListServ

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ADAMS Accession No: ML11251A227

****NLO w/comments**

OFFICE	LPL3/1/PM	LPL/3-1/LA	ITSB/BC*	OGC**	LPL3-1/BC	LPL3/1/PM
NAME	PTam	BTully	RElliott	LSubin	RPascarelli	PTam
DATE	10/12/11	10/11/11	9/14/11	10/19/11	11/03/11	10/12/11

*Safety evaluation transmitted by memo of 9/14/11 (Accession No. ML112420560).

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