

April 27, 2010

EA-09-286

Mr. Jack Davis
Chief Nuclear Officer
Detroit Edison Company
One Energy Plaza
Detroit, MI 48226-1279

SUBJECT: NRC RESPONSE TO DETROIT EDISON REPLY TO A NOTICE OF VIOLATION
05200033/2009-201-01, 02, and 03 AND REVISED NOTICE OF VIOLATION TO
DETROIT EDISON COMPANY

Dear Mr. Davis:

This refers to your letter dated November 9, 2009 (ML093160318), from Peter W. Smith, Nuclear Development – Licensing & Engineering Director, in reply to our letter dated October 5, 2009 (ML092740064), which transmitted Inspection Report 05200033/2009-201 and Notice of Violation (Initial Notice). The Initial Notice described three Severity Level IV violations identified during an inspection conducted at your Detroit, Michigan, facility August 18-21, 2009. Your correspondence provided clarifying information and denied that the violations occurred.

Violation A in the Initial Notice (05200033/2009-201-01) involved the failure, between March 2007 and February 2008, to establish and implement a Fermi Unit 3 (Fermi 3) quality assurance (QA) program and retain overall control of safety-related activities performed by Black & Veatch (B&V), the Fermi 3 combined license (COL) application contractor. You disputed the violation based on two assertions. First, that the requirements of 10 CFR Part 50, Appendix B (Appendix B) were not applicable to Detroit Edison prior to September 18, 2008, because Detroit Edison was not yet an applicant, and second, that Detroit Edison had contractually delegated the work of establishing and executing the QA program to B&V.

The NRC has reviewed your letter and has determined that Detroit Edison was not an applicant for Fermi 3 prior to September 18, 2008. While Detroit Edison must demonstrate compliance with Appendix B in order to receive a COL from the Nuclear Regulatory Commission (NRC), the NRC cannot issue a Notice of Violation for actions or omissions occurring before it submitted the Fermi 3 COL application to the NRC. Therefore, Violation A of the Initial Notice dated October 5, 2009, is withdrawn and the NRC records will be amended to reflect this change.

Violation B in the Initial Notice (05200033/2009-201-02) involved the failure to complete internal audits of QA programmatic areas implemented for Fermi 3 COL application activities prior to August 21, 2009 (the date of the inspection). Violation C in the Initial Notice (05200033/2009-201-03) involved the failure to document trending of corrective actions to identify recurring conditions adverse to quality since the beginning of the Fermi 3 project in March 2007. For both violations, your November 9, 2009, letter asserts that these requirements are not specifically

stated in Appendix B, and are not enforceable because the NRC has not approved and incorporated into a condition of a license the Fermi 3 Quality Assurance Program Description (QAPD) or Detroit Edison implementing procedures. Additional Detroit Edison amplifying information is provided in Enclosure 1, "NRC Response to Detroit Edison Reply to a Notice of Violation 05200033/2009-201-01, 02, and 03."

After evaluation of your assertions and consultation with the NRC Office of Enforcement and Office of the General Counsel, we have determined that the violations of Appendix B cited in Violations B and C remain valid. However, Violations B and C of the Initial Notice will be revised to remove references to the Fermi 3 QAPD. NRC records will be amended to reflect this change. The revised Violation B combines Violations B and C from the Initial Notice and is cited in the Notice of Violation included as Enclosure 2 to this letter (Revised Notice). Enclosure 1 provides the details of our evaluation and supporting analysis of your assertions.

Additionally, we have reviewed your corrective actions relating to Violations B and C of the Initial Notice and find them responsive to the Initial Notice. We have no further questions or comments at this time and you are not required to respond further to these two violations, or to Violation B of the Revised Notice. We may review the implementation of your corrective actions during a future NRC staff inspection to determine that full compliance has been achieved and maintained.

As a result of further evaluation of the facts associated with Violation A of the Initial Notice, the NRC has determined that a violation involving failure to adhere to the requirements of Criterion VII of Appendix B did occur. This new violation is cited in the Revised Notice. The circumstances surrounding the violation are described in detail in NRC Inspection Report 05200033/2009-201, Section 3, "Control of Purchased Material, Equipment, and Services."

Specifically, Detroit Edison's activities related to Fermi 3 became subject to NRC regulations and NRC enforcement upon filing the Fermi 3 COL application on September 18, 2008. Since B&V was a Detroit Edison contractor performing safety-related activities after the Fermi 3 COL application was filed on September 18, 2008, Detroit Edison was required to ensure these B&V activities complied with NRC requirements as of September 18, 2008. Compliance, in part, with Criterion VII of Appendix B to 10 CFR Part 50 would require a documented evaluation of the B&V quality assurance program. This documentation forms the basis for supplier selection and qualification as a safety-related Fermi 3 supplier. The Revised Notice cites Detroit Edison for failure to perform an evaluation of the B&V quality assurance program and adequately document the basis for the qualification of B&V to perform safety-related Fermi 3 COL activities after September 18, 2008.

The violation was evaluated in accordance with the NRC Enforcement Policy and is categorized at Severity Level IV. The NRC Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

You are required to provide a written explanation to Violation A in the Revised Notice within 30 days of this letter in accordance with the instructions specified in Enclosure 2. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390, "Public Exemptions, Requests for Withholding," the agency will make a copy of this letter, its enclosures, and your response available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible at

<http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

Sincerely,

/RA for/

Richard Rasmussen, Chief
Quality and Vendor Branch B
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No. 052-00033

Enclosure:

1. NRC Response to Detroit Edison Reply to a Notice of Violation 05200033/2009-201-01, 02, and 03
2. Notice of Violation

cc:

See next page

J. Davis

- 3 -

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Sincerely,

/RA for/

Richard Rasmussen, Chief
Quality and Vendor Branch B
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No. 052-00033

Enclosure:

1. NRC Response to Detroit Edison Reply to a Notice of Violation 05200033/2009-201-01, 02, and 03
2. Notice of Violation

cc:

See next page

DISTRIBUTION: Cqvb/RF RidsNroCqvb RidsNroDcip MCarpentier
KKavanagh MTonacci JHale AJohnson JJimenez
staseks@dteenergy.com mayr@dteenergy.com

ADAMS Accession Number: **ML100330687**

NRO-002

OFFICE	NRO/DCIP/CQVB	NRO/DCIP/CQVB	NRO/DCIP
NAME	GLipscomb	RMclntyre	ARivera-Varona
DATE	4/13/2010	4/16/2010	4/16/2010
OFFICE	OE/EB	OGC/GCHEA/AGCMLE	NRO/DCIP/CQVB:BC
NAME	JWray	MBarkman	RRasmussen (RMclntyre for)
DATE	4/13/2010	4/27/2010	04/27/2010

OFFICIAL AGENCY RECORD

Fermi - Mailing List

cc:

Wayne County Department of Homeland
Security & Emergency Management
10250 Middlebelt Road
Detroit, MI 48242

Supervisor-Electric Operators
Michigan public Service Commission
P.O. Box 30221
Lansing, MI 48909

U. S. Nuclear Regulatory Commission
Resident Inspectors' Office
6450 North Dixie Highway
Newport, MI 48166

Michigan Department of Environmental
Waste and Hazardous Materials Division
Radiological Protection & Medical Waste
Sec.
Nuclear Facilities Unit - Constitution Hall
525 West Allegan Street
P.O. Box 30241
Lansing, MI 48909-7747

Mr. Jack M. Davis
Senior Vice President
and Chief Nuclear Officer
Detroit Edison Company
Fermi 2 - 210 NOC
6400 North Dixie Highway
Newport, MI 48166

Mr. Bruce R. Maters
Director - Legal
Detroit Edison Company
688 WCB
2000 2nd Avenue
Detroit, MI 48226-1279

Mr. Ronnie A. May
Senior Vice President-Major Enterprise Proj.
Detroit Edison Company
2402 WCB
2000 2nd Avenue
Detroit, MI 48226-1279

Email

greenl@dteenergy.com (LaShawn G.
Green)

hardwoodd@dteenergy.com (David B.
Harwood)

smithpw@dteenergy.com (Peter W. Smith)
Stephan.moen@ge.com

(Revised 07/13/2009)

**NRC Response to Detroit Edison Reply to a
Notice of Violation 05200033/2009-201-01, 02, and 03**

STATEMENT OF VIOLATION A (05200033/2009-201-01)

Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50 states, in part, that "The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this appendix. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions."

Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50 states, in part, that "Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix."

Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 states, in part, that "Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."

Contrary to the above, DECo failed to establish and implement a Fermi Unit 3 quality assurance (QA) program between March 2007, when the initial contract was placed with Black and Veatch (B&V) for the conduct of safety-related combined license (COL) activities, until February 2008, and retain overall control of safety-related activities performed by B&V.

DECo's failure to establish and implement a Fermi 3 QA program resulted in:

1. Failure to classify safety-related B&V COL application and OE contracts as safety-related.
2. Failure to impose adequate QA requirements and a sufficient statement of work in the OE Contract for QA oversight activities performed by B&V.
3. Failure to adequately document the qualification of B&V to perform safety-related COL application activities.
4. Failure to adequately document an annual supplier evaluation of B&V.

5. SUMMARY OF DETROIT EDISON RESPONSE TO VIOLATION A

Detroit Edison is contesting that a violation of the cited requirements from Criterion II, "Quality Assurance Program," Criterion IV, "Procurement Document Control," or Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 or the conditions of a license or an order issued by the Commission occurred. Detroit Edison's basis for disputing the violation is presented below.

First, Appendix B to 10 CFR Part 50, Criterion I states that the "applicant" shall be responsible for the establishment and execution of the quality assurance program. Detroit Edison tendered the COLA to the NRC on September 18, 2008. Under a plain reading of Appendix B, Criterion I, the requirements of Appendix B to 10 CFR Part 50 were not applicable to Detroit Edison prior to September 18, 2008, because Detroit Edison was not yet an applicant. In the absence of a regulatory requirement to have a QA program in place, there can be no regulatory violation.

Second, even if one concluded that there was an operative requirement for Detroit Edison to establish a QA program prior to becoming an applicant on September 18, 2008, Detroit Edison did in fact establish a QA program, by contractually delegating the work of establishing and executing the QA program to the COLA contractor for COLA development related activities, as permitted by Appendix B to 10 CFR Part 50, Criterion I.

The full text of the Detroit Edison response to Violation A is contained in Attachment 1 to "Detroit Edison Reply to a Notice of Violation 05200033/2009-201-01, 02, and 03," (ML092740064). This document is available for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible at <http://www.nrc.gov/reading-rm/adams.html>.

NRC EVALUATION OF DETROIT EDISON RESPONSE TO VIOLATION A

The Nuclear Regulatory Commission (NRC) has reviewed your response and has determined that Detroit Edison (DECo) was not an applicant prior to September 18, 2008. While DECo must demonstrate compliance with Appendix B in order to receive a COL from the NRC, the NRC cannot issue a Notice of Violation for actions or omissions occurring before it submitted the Fermi Unit 3 (Fermi 3) COL application to the NRC. Therefore, Violation A of the Notice of Violation dated October 5, 2009 (Initial Notice) is withdrawn and the NRC records will be amended to reflect this change.

However, once DECo became an applicant on September 18, 2008, DECo became subject to NRC regulations (10 CFR Part 52 and Appendix B, as invoked by Part 52, in this particular case) and NRC enforcement. The regulations of 10 CFR 2.201, "Notice of violation," state that "In response to an alleged violation of any provision of the Act or this chapter or the conditions of a license or an order issued by the Commission, the Commission may serve on the licensee or other person subject to the jurisdiction of the Commission a written notice of violation." As an applicant, DECo is subject to the jurisdiction of the Commission and must comply with all applicable requirements of Chapter I of Title 10, "Energy," of the *Code of Federal Regulations*. Chapter I includes Parts 1-199 of Title 10 of the *Code of Federal Regulations*.

The Introduction of Appendix B states, in part:

Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

Specifically, compliance includes meeting the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B, which states, in part, that "Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery." The source evaluation of the supplier quality assurance program, in this case B&V, forms the basis for supplier selection and qualification as a safety-related Fermi 3 supplier.

Since B&V was a DECo contractor performing safety-related activities after the Fermi 3 COL application was filed on September 18, 2008, DECo was required to ensure these B&V activities complied with NRC requirements as of September 18, 2008.

As a result of further evaluation of the facts associated with Violation A, the NRC has determined that a violation involving failure to adhere to the requirements of Criterion VII of Appendix B did occur. This new violation (05200033/2009-201-04) is cited in the Notice of Violation included as Enclosure 2 to this letter (Revised Notice). The new violation relates to an example given in Violation A of the Initial Notice, and the circumstances surrounding the violation are described in detail in NRC Inspection Report 05200033/2009-201, Section 3, "Control of Purchased Material, Equipment, and Services."

The Revised Notice cites DECo for failure to perform an evaluation of the B&V quality assurance program and adequately document the basis for the qualification of B&V to perform safety-related Fermi 3 COL activities as of September 18, 2008, the date the Fermi 3 COL application was filed.

STATEMENT OF VIOLATION B (05200033/2009-201-02)

Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50 states, in part, that "A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program."

Fermi 3 Policy: COL Quality Assurance Program Description (QAPD) During Construction and Operation, Section 18, "Audits," Revision 1, states that "Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed at least once each year or at least once during the life of the activity, whichever is shorter." This requirement is restated in Detroit Edison Company (DECo) Procedure Number NP 18.1, "Audits (Internal)," Revision 1, dated August 7, 2009.

Contrary to these requirements, as of August 21, 2009, DECo QA personnel had not completed any internal audits of QA programmatic areas implemented for Fermi 3 COL application activities performed to date.

DETROIT EDISON RESPONSE TO VIOLATION B

Detroit Edison is contesting that a violation of the cited requirements from Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50 or the conditions of a license or an order issued by the Commission occurred. Detroit Edison disagrees that any of the cited requirements from the QAPD or Procedure Number NP 18.1 are enforceable. Detroit Edison's basis for disputing the violation is presented below.

Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50 states:

A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas shall be taken where indicated.

Criterion XVIII does not state a frequency of internal audits.

The Fermi 3 Policy: ND Quality Assurance Program Description (ND QAPD), Revision 0 (applicable from February 2008 through August 2008) implemented Criterion XVIII of Appendix B to 10 CFR Part 50 in Section 18, "Audits," and prescribed that internal audits be "performed with a frequency commensurate with safety significance and in a manner which assures that audits of safety-related activities are completed." Under the ND QAPD, there was no requirement that audits be conducted at "least once a year or at least once during the life of the activity, whichever is shorter."

Fermi 3 Policy: COL Quality Assurance Program Description (Fermi 3 QAPD) During Construction and Operation, Section 18, "Audits," Revision 0 and Revision 1 (applicable from

September 2008 through the present), also implements Criterion XVIII of Appendix B to 10 CFR Part 50 and states, in part, that "Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter."

Detroit Edison notes, that neither the ND QAPD, provided as an enclosure to RAI 17.5-3 in Detroit Edison's letter to the NRC dated September 2009 (MP092790561), nor the Fermi 3 QAPD, provided as Part 2, Chapter 17, Appendix 17AA to the Fermi 3 COLA, have been accepted by the NRC and incorporated into a condition of a license. Therefore, requirements from these documents are not enforceable under 10 CFR 2.201, "Notice of Violation." Further, while the NRC did review the implementation of portions of these QAPDs, the NRC inspection report states "this NRC inspection report does not constitute NRC the *[sic]* approval, of your QA program."

The procedural requirement of Criterion XVIII of Appendix B to 10 CFR Part 50 for audits to "be performed in accordance with written procedures or checklists by appropriately trained personnel" is implemented in the cited Detroit Edison Procedure Number NP-18.1, "Audits (Internal)", Revision 1 (applicable from August 2009 through present). As scheduled in the cited Audit Schedule dated August 6, 2009, the October 2009 internal audit was conducted during the week of October 26, 2009. Consistent with the Fermi 3 QAPD, Section 18, "Audits," appropriately trained Detroit Edison personnel conducted the internal audit of applicable QA program elements for Fermi 3 COL application activities (functional area).

During the inspection, Detroit Edison personnel acknowledged that Detroit Edison Procedure Number NDP-NP- 18.1, "Audits", Revision 0, dated March 24, 2008, (applicable from March 2008 through July 2009) does require that "Internal audits of all elements of the Nuclear Development Project quality program should be conducted at least once every calendar year or at least once during the project if the duration is less than once per year." Detroit Edison initiated the required Corrective Action Report (CAR 1544905).

The full text of the Detroit Edison response to Violation 05200033/2009-201-02, including Detroit Edison corrective actions, is contained in Attachment 2 to "Detroit Edison Reply to a Notice of Violation 05200033/2009-201-01, 02, and 03," (ML092740064). This document is available for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible at <http://www.nrc.gov/reading-rm/adams.html>.

NRC EVALUATION OF DETROIT EDISON RESPONSE TO VIOLATION B

The NRC rejects DECo's assertion that the violation of the cited requirements of Appendix B did not occur. However, NRC records will be revised to reflect this violation is written against Appendix B, not the Fermi 3 QAPD. The revised Violation B is cited in the Revised Notice included as Enclosure 2 to this letter.

Even though Fermi 3 QAPD is currently not an enforceable NRC regulatory requirement, as of the date on which the Fermi 3 COL application was submitted to the NRC, DECo became an applicant and, as such, was subject to the requirements of NRC regulations (10 CFR Part 52 and Appendix B, as invoked by Part 52, in this particular case). The regulations of 10 CFR

2.201, "Notice of violation," state that "In response to an alleged violation of any provision of the Act or this chapter or the conditions of a license or an order issued by the Commission, the Commission may serve on the licensee or other person subject to the jurisdiction of the Commission a written notice of violation." As an applicant, DECo is subject to the jurisdiction of the Commission and must comply with all applicable requirements of Chapter I of Title 10, "Energy," of the *Code of Federal Regulations*. Chapter I includes Parts 1-199 of Title 10 of the *Code of Federal Regulations*.

The Introduction of Appendix B states, in part:

Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

Criterion XVIII, "Audits," of Appendix B states:

A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas shall be taken where indicated.

Criterion V, "Instructions, Procedures, and Drawings," of Appendix B states, in part:

Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.

DECo Procedure Number NP 18.1, "Audits (Internal)," Revision 0, dated March 24, 2008, and Revision 1, dated August 7, 2009, stated that internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed at least once each year or at least once during the life of the activity, whichever is shorter.

Upon submitting its COL application in September 2008, DECo was required to implement a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. All audits were required to be accomplished in accordance with documented procedures. DECo Procedure Number NP 18.1 required internal audits of

all applicable QA program elements be completed at least once each year or at least once during the life of the activity, whichever is shorter.

At the time of the NRC inspection on August 18-21, 2009, no internal audits had been completed and the audit schedule indicated that the earliest audits would take place in October and November of 2009. As stated above, the first internal audit was conducted during the week of October 26, 2009, over a year after Fermi 3's obligation to maintain compliance with Appendix B began.

Specifically, DECo failed to conduct an internal audit within the DECo Procedure Number NP 18.1 prescribed timeframe for all safety-related activities affecting the Fermi 3 structures, systems, and components, and therefore did not satisfy Appendix B, Criterion V. Accordingly, the NRC staff has determined that a violation of Appendix B, Criterion V, occurred.

The NRC notes that the ND QAPD was in effect prior to September 2008, and was not cited in Violation 05200033/2009-201-02. As a result, the NRC staff did not respond to the ND QAPD information presented in your response. However, the ND QAPD information has been made available to the NRC personnel conducting the Fermi 3 QAPD licensing review.

Furthermore, we have reviewed your corrective actions relating to Violation B and find them responsive to the Initial Notice. We have no further questions or comments at this time and you are not required by the Revised Notice to respond further to this violation. We may review the implementation of your corrective actions during a future NRC staff inspection to determine that full compliance has been achieved and maintained.

STATEMENT OF VIOLATION C (05200033/2009-201-03)

Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 states, in part, that "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected."

Fermi 3 Policy: COL Quality Assurance Program Description (QAPD) During Construction and Operation, Section 16, "Corrective Action," Revision 1, sets forth the requirement that "Reports of conditions adverse to quality are analyzed to identify trends."

DECo Procedure Number NP 16.1, "Corrective Action Program," Revision 1, dated August 4, 2009, stated that the Director of Quality Management "is responsible for trending corrective actions to determine if there are adverse trends that require management attention."

Contrary to these requirements, as of August 21, 2009, DECo had not documented trending of corrective actions to identify recurring conditions adverse to quality since the beginning of Fermi 3 project in March 2007.

DETROIT EDISON RESPONSE TO VIOLATION C

Detroit Edison is contesting that a violation of the cited requirements from Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 or the conditions of a license or an order issued by the Commission occurred. Detroit Edison disagrees that any of the cited requirements from the QAPDs or Procedure Number NP-16.1 were enforceable. Detroit Edison's basis for disputing the violation is presented below.

Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 states:

Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

Criterion XVI does not require the trending of corrective actions.

The Fermi 3 Policy: ND Quality Assurance Program Description (ND QAPD), Revision 0 (applicable from February 2008 through August 2008) implements Criterion XVI of Appendix B to 10 CFR Part 50 in Section 16, "Corrective Action" and prescribes that procedures "assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with this QAPD, regulatory requirements and applicable quality standards." A "trend" requirement was *not specified* in the ND QAPD.

Fermi 3 Policy: COL Quality Assurance Program Description (Fermi 3 QAPD) During Construction and Operation, Section 16, "Corrective Action," Revision 0 and Revision 1

(applicable from September 2008 through the present), also implements Criterion XVI of Appendix B to 10 CFR Part 50 and states, in part that "Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management."

Detroit Edison notes that neither the ND QAPD, provided as an enclosure to RAI 17.5-3 in Detroit Edison's letter to the NRC dated September 2009 (MP092790561), nor the Fermi 3 QAPD, provided as Part 2, Chapter 17, Appendix 17AA to the Fermi 3 COLA, have been accepted by the NRC and incorporated into a condition of a license. Therefore, requirements from these documents are not enforceable under 10 CFR 2.201, "Notice of Violation." Further, while the NRC did review the implementation of portions of these QAPDs, the NRC inspection report states "this NRC inspection report does not constitute NRC the *[sic]* approval of your QA program."

The procedural requirement of the ND QAPD and the Fermi 3 QAPD is implemented in the cited Detroit Edison Procedure Number NP-16.1, "Corrective Action," Revision 0 and Revision 1 (applicable from February 2008 through present).

Detroit Edison acknowledges that trending of corrective actions is a valuable practice and as such has included it as part of Detroit Edison's quality practices, but there is no enforceable requirement for the trending of corrective actions.

As cited in the inspection report, Detroit Edison's Director of Quality Management identified that Detroit Edison had performed the corrective action trending required by Detroit Edison Procedure Number NP-16.1 and that no trends adverse to quality were identified in the 29 corrective actions initiated as of the date of the inspection. Additionally, during the inspection, the NRC verbally acknowledged to the Director of Quality Management that there were no trends adverse to quality identified.

The full text of the Detroit Edison response to Violation 05200033/2009-201-03, including Detroit Edison corrective actions, is contained in Attachment 3 to "Detroit Edison Reply to a Notice of Violation 05200033/2009-201-01, 02, and 03," (ML092740064). This document is available for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible at <http://www.nrc.gov/reading-rm/adams.html>.

NRC EVALUATION OF DETROIT EDISON RESPONSE TO VIOLATION C

The NRC rejects DECo's assertion that the violation of the cited requirements of Appendix B did not occur. However, NRC records will be revised to reflect this violation is written against Appendix B, not the Fermi 3 QAPD. The revised violation is cited in the Revised Notice included as Enclosure 2 to this letter.

Even though Fermi 3 QAPD is currently not an enforceable NRC regulatory requirement, as of the date on which the Fermi 3 COL application was submitted to the NRC, DECo became an applicant and, as such, was subject to the requirements of NRC regulations (10 CFR Part 52 and Appendix B, as invoked by Part 52, in this particular case). The regulations of 10 CFR 2.201, "Notice of violation," state that "In response to an alleged violation of any provision of the Act or this chapter or the conditions of a license or an order issued by the Commission, the

Commission may serve on the licensee or other person subject to the jurisdiction of the Commission a written notice of violation.” As an applicant, DECo is subject to the jurisdiction of the Commission and must comply with all applicable requirements of Chapter I of Title 10, “Energy,” of the *Code of Federal Regulations*. Chapter I includes Parts 1-199 of Title 10 of the *Code of Federal Regulations*.

The Introduction of Appendix B states, in part:

Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

Criterion XVI, "Corrective Action," of Appendix B states:

Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

Criterion V, “Instructions, Procedures, and Drawings,” of Appendix B states, in part:

Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.

DECo Procedure Number NP 16.1, “Corrective Action Program,” Revision 1, dated August 4, 2009, states that the Director of Quality Management “is responsible for trending corrective actions to determine if there are adverse trends that require management attention.”

Upon submitting its COL application in September 2008, DECo was required to establish measures to assure that conditions adverse to quality were promptly identified and corrected, and for significant conditions adverse to quality, that the cause of the condition was determined and corrective action was taken to preclude repetition. Additionally, DECo was required to maintain sufficient records to furnish evidence of activities affecting quality in accordance with documented procedures. DECo Procedure Number NP 16.1 required trending corrective actions to determine if there were adverse trends that require management attention.

At the time of the NRC inspection on August 18-21, 2009, there was no evidence that any trending of Corrective Action Reports (CARs), as required by DECo Procedure Number NP

16.1, beyond DECo management's verbal assertion that it had examined Fermi 3 CARs for trends. In the absence of documentation describing the performance of any CAR reviews for trending purposes, it is impossible for NRC staff to verify that DECo had performed any trending of CARs in compliance with NP 16.1. Accordingly, the NRC staff has determined that a violation of Appendix B, Criterion V, occurred.

DECo stated in its response "the NRC verbally acknowledged to the Director of Quality Management that there were no trends adverse to quality identified." While the NRC did evaluate a sample of CARs during its inspection activities and did not identify any trends at that time, the NRC inspectors did not perform a comprehensive trending review and are unable to assert that there were no trends adverse to quality in the Fermi 3's corrective action program.

The NRC notes that the ND QAPD was in effect prior to September 2008, and was not cited in Violation 05200033/2009-201-03. As a result, the NRC staff did not respond to the ND QAPD information presented in your response. However, the ND QAPD information has been made available to the NRC personnel conducting the Fermi 3 QAPD licensing review.

Furthermore, we have reviewed your corrective actions relating to Violation C and find them responsive to the Initial Notice. We have no further questions or comments at this time and you are not required by the Revised Notice to respond further to this violation. We may review the implementation of your corrective actions during a future NRC staff inspection to determine that full compliance has been achieved and maintained.

NOTICE OF VIOLATION

Detroit Edison Company
Detroit, MI 48226-1279

Docket Number 05200033
Inspection Report Number 2009-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Detroit Edison Company (DECo) in Detroit, Michigan, on August 18 – 21, 2009, and during an in-office review completed on April 7, 2010 in response to your letter dated November 9, 2009, two violations of NRC requirements were identified. Violation B revises and combines Violations B and C identified in NRC Inspection Report 05200033/2009-201 and Notice of Violation to DECo dated October 5, 2009. In accordance with the NRC Enforcement Policy, the violations are described below.

The Introduction of Appendix B to 10 CFR Part 50 (Appendix B) states, in part, that “Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.”

- A. Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B states, in part, that “Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.”

Contrary to the above, from September 18, 2008 to August 21, 2009, DECo failed to establish measures to assure that safety-related services purchased through its contractor, Black & Veatch (B&V) for Fermi 3, conformed to procurement documents. Specifically, DECo failed to assure that B&V was qualified to supply the services procured in the contract between DECo and B&V.

This is a Severity Level IV violation (Supplement II) and has been identified as Violation 05200033/2009-201-04.

- B. Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50 states, in part, that "Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings."

DECo Procedure Number NP 18.1, "Audits (Internal)," Revision 0, dated March 24, 2008 and Revision 1, dated August 7, 2009, states that internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed at least once each year or at least once during the life of the activity, whichever is shorter.

DECo Procedure Number NP 16.1, "Corrective Action Program," Revision 0, dated February 4, 2008, and Revision 1, dated August 4, 2009, states that the Director of Quality Management "is responsible for trending corrective actions to determine if there are adverse trends that require management attention."

Contrary to the above, as of August 21, 2009, DECo had not accomplished procedures for activities affecting quality as prescribed in DECo Procedure Number NP 18.1 and NP 16.1. Specifically, DECo QA personnel had not completed any internal audits of applicable QA programmatic areas for Fermi 3 COL application activities to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program in accordance with NP18.1. Additionally for conditions adverse to quality, which were entered into the corrective action program prior to the inspection, DECo had not documented any trending evaluations to identify and correct recurring conditions adverse to quality for Fermi 3 COL application activities in accordance with NP16.1.

This is a Severity Level IV violation (Supplement II) and is the combination of Violations 05200033/2009-201-02 and 05200033/2009-201-03.

Pursuant to the provisions of 10 CFR 2.201, DECo is hereby required to submit a written statement or explanation for Violation A (05200033/2009-201-04) to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to Richard Rasmussen, Chief, Quality and Vendor Branch B, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation 05200033/2009-201-04" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (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. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Dated this 27th day of April 2010.