The Detroit Edison Company
One Energy Plaza, Detroit, MI 48226-1279

10 CFR 52.79
10 CFR 2.201

November 9, 2009
NRC3-09-0041

U. S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, D C 20555-0001

References: 1) Fermi 3
NRC Docket No. 52-033
2) Letter from Richard Rasmussen (NRC) to Jack M. Davis (Detroit Edison), "NRC Inspection Report 05200033/2009-201 and Notice of Violation to Detroit Edison Company," dated October 5, 2009.
3) Letter from Peter W. Smith (Detroit Edison) to U.S. Nuclear Regulatory Commission, "Detroit Edison Company Response to NRC Request for Additional Information Letter No. 10," dated September 30, 2009.
4) Letter from Mark S. Lesser (NRC) to Douglas R. Gibson (Detroit Edison), "Audit of Combined License Pre-Application Subsurface Investigation Activities at Fermi," dated August 8, 2007.

Subject: Detroit Edison Reply to a Notice of Violation 05200033/2009-201-01, 02, and 03

Pursuant to the provisions of 10 CFR 2.201, Detroit Edison is replying to the three (3) Severity Level IV violations in the Notice of Violation contained in Reference 2. The Notice of Violation relates to a limited scope inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) at Detroit Edison in Detroit, MI. The inspection focused on assessing Detroit Edison's compliance with the provisions of selected portions of Appendix B to 10 CFR Part 50.

Detroit Edison fully recognized that information developed in the preparation of a COLA, most significantly the site investigation activities, would subsequently be used to support the design of safety related structures, systems, and components and therefore needed to be conducted in a quality manner. Accordingly, Detroit Edison systematically took appropriate quality actions.

D095
IE01
NRO

Furthermore, Detroit Edison recognizes the importance to the success of future new construction of considering lessons learned from construction experience when planning for and constructing new nuclear plants, such as those documented in the 1984 study NUREG-1055, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants." Detroit Edison remains committed to the robust implementation of our QA program described in the Fermi 3 COLA, Part 2, Chapter 17, Appendix 17AA, "Quality Assurance Program Description".

Consistent with our understanding and commitments regarding quality assurance, Detroit Edison's response to the cited violations is summarized below:

Violation 05200033/2009-201-01 - Detroit Edison disagrees that a violation occurred.
Violation 05200033/2009-201-02 - Detroit Edison disagrees that a violation occurred.
Violation 05200033/2009-201-03 - Detroit Edison disagrees that a violation occurred.

While Detroit Edison disagrees that the violations occurred, Detroit Edison does acknowledge the constructive insights resulting from the cited review of the Fermi 3 QA program by the NRC and corrective steps have been taken or will be taken to address the concerns noted in the Notice of Violation and to assure that all COLA activities continue to be conducted at a level of quality necessary to support future safety related activities.

There are no commitments being made in this letter.

A request for the extension of the 30-day requirement for Detroit Edison's written response specified in Reference 2 from November 4, 2009 to November 9, 2009 was granted via teleconference by Richard Rasmussen, signatory of Reference 2, on October 28, 2009.

Should you have any questions or require additional information, please contact me at (313) 235-3341.

Sincerely,

Peter W. Smith, Director
Nuclear Development – Licensing & Engineering
Detroit Edison Company

Attachments: 1) Response to Violation 05200033/2009-201-01
2) Response to Violation 05200033/2009-201-02
3) Response to Violation 05200033/2009-201-03
4) Clarifications to Vendor Inspection Report 05200033/2009-201
5) Copy of Response to RAI 17.5-3 (without Enclosure 1)

cc: Richard Rasmussen, Chief, Quality and Vendor Branch B, Division of Construction Inspection and Operational Programs, Office of New Reactors
Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington
Jerry Hale, NRC Fermi 3 Project Manager
Ilka T. Berrios, NRC Fermi 3 Project Manager
Bruce Olsen, NRC Fermi 3 Environmental Project Manager
Fermi 2 Resident Inspector
NRC Region III Regional Administrator
NRC Region II Regional Administrator
Supervisor, Electric Operators, Michigan Public Service Commission
Michigan Department of Environmental Quality Radiological Protection and Medical Waste Section

Attachment 1
NRC3-09-0041

Response to Violation 05200033/2009-201-01

Statement of Violation 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:

Failure to classify safety-related B&V COL application and OE contracts as safety-related.

Failure to impose adequate QA requirements and a sufficient statement of work in the OE Contract for QA oversight activities performed by B&V.

Failure to adequately document the qualification of B&V to perform safety- related COL application activities.

Failure to adequately document an annual supplier evaluation of B&V.

These issues have been identified as Violation 05200033/2009-201-01. This is a Severity Level IV violation (Supplement II of the Enforcement Manual).

The Reason for the Violation, or If Contested, the Basis for Disputing the Violation or Severity Level:

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.

Both of these bases for disputing the violation are amplified below.

Detroit Edison, in its letter to the NRC (NRC3-09-0027) dated September 30, 2009 (ML092790561), provided a response to Request for Additional Information (RAI) 17.5-3 (eRAI Tracking No. 3341) which provides a description of the QA programs and controls that were applied to the development of the Fermi 3 COLA through the period of the alleged violation. A copy of the response to RAI 17.5-3 without Enclosure 1 is provided in Attachment 5 for ease in reference.

Detroit Edison fully recognizes that information developed in the preparation of a COLA, most significantly the site investigation activities, would subsequently be used to support the design of safety related structures, systems, and components and therefore needs to be conducted in a quality manner. Detroit Edison systematically took appropriate quality actions and contends that the approach to implementation of quality requirements was deliberate and timely, and provided the required level of quality. We observe that the level of quality applied to the COLA to support future safety related design activities has not been questioned by the NRC.

At issue with the violation is whether 10 CFR 52.83, which states, in part that "all provisions of 10 CFR part 50 and its appendices [*sic*] applicable to holders of construction permits for nuclear power reactors also apply to holders of combined licenses issued under this subpart" required Detroit Edison to establish a QA program satisfying the requirements of Appendix B to 10 CFR Part 50 prior to becoming an applicant, or even to delegate the "establishment and execution" of a quality assurance program that was to be applied to the COLA development activities. Detroit Edison contends that it was not required.

Again, 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.

A clear statement of the NRC's recognition that the establishment of a QA program satisfying the requirements of Appendix B to 10 CFR Part 50 is not required is found in the pertinent inspection guidance used for pre-application audits. As noted in the Vendor Inspection Report for the August 18 – 21, 2009 inspection, a pre-application audit of COL subsurface investigation activities for the Fermi project was conducted July 9-11, 2007 (ML072190660). The purpose of the July 9 – 11, 2007 audit was to observe COL, pre-application subsurface investigation activities being conducted to obtain geotechnical and seismic data necessary to support a COLA for the purpose of providing background information for the NRC's future review of the expected COLA. The inspection, therefore, supported the NRCs licensing function rather than potential enforcement actions.

As noted in the report for the July 9 – 11, 2007 audit, the audit was conducted using NRC Inspection Manual Chapter (IMC) 2502, "Construction Inspection Program: Pre Combined License Phase." The version of IMC 2502 available at the time of the July 9 – 11, 2007 audit was dated June 22, 2005. Since the Fermi 3 project was classified as a COL application not referencing an Early Site Permit (ESP), IMC 2502 invokes Inspection Procedure (IP) 35004, "Pre-Docketing Early Site Permit Quality Assurance Controls Inspection," dated May 29, 2003, includes additional inspection items relating to the sufficiency of QA measures for site investigations applicable for ESPs as also applicable for COLAs not referencing an ESP. IP 35004 Section: "Inspection Guidance" states:

> *The current regulations in 10 CFR Part 52 do not require that a Part 50 Appendix B quality assurance program be implemented in support of ESP applications. However, ESP activities associated with site safety should be controlled by QA measures sufficient to provide reasonable assurance that information used as input for design or construction of future systems, structures, and components (SSCs) important to safety, would not adversely impact their ability to perform satisfactorily in service. The regulations in 10 CFR 52.39, with certain exceptions, require the Commission to treat matters resolved in an ESP proceeding as resolved in making findings for issuance of a construction permit, operating license, or combined license (COL). Because of this finality, conclusions made during the ESP phase will be relied upon for use in the subsequent design, construction, fabrication, and operation of a reactor that might be constructed on the site for which an ESP is issued.*
>
> *For these reasons, applicants must apply quality controls to each ESP activity associated with the generation of design information for future SSCs important to safety that are equivalent to the controls specified in Appendix B for similar activities. The staff plans to evaluate quality controls for such activities using the criterion that these controls shall be equivalent in substance to controls specified in Appendix B.*

It follows that deficiencies in quality would affect the licensing review, but there is no suggestion that there are requirements enforceable by the issuance of a Notice of Violation (NOV).

In July 2007, it was clearly acknowledged by NRC inspection guidance that there were no current regulatory requirements that would require Detroit Edison to establish a QA program satisfying the requirements of Appendix B to 10 CFR Part 50. Detroit Edison notes that on September 27, 2007, after the completion of on-site investigations, clarifying revisions to 10 CFR Parts 50 and 52 became effective which were intended to clarify the regulatory requirements (see 72 FR 40505). Detroit Edison observes that IMC 2502 was revised on October 3, 2007 and no longer references IP 35004. However, these changes occurred after the principle activities being questioned by the alleged violation had occurred. Detroit Edison also notes that IP 35004, dated May 29, 2003, was still the effective version as of November 4, 2009.

Even if one concludes that there was an operative requirement to establish a QA program satisfying the requirements of Appendix B to 10 CFR Part 50 for initial COLA development, Detroit Edison did in fact establish a QA program satisfying the requirements of Appendix B to 10 CFR Part 50 for the COLA development by contractually delegating the work of establishing and executing the QA program to the COLA contractor for COLA development related activities.

As noted in the response to RAI 17.5-3, Detroit Edison fully delegated the establishment and execution of the QA program related to the COLA project to the COLA contractor. Assuming that the requirements of Appendix B to 10 CFR Part 50 applied, This full delegation is explicitly permitted by 10 CFR 50 Appendix B, Criterion I which states:

> *...The applicant[1] shall be responsible for the establishment and execution of the quality assurance program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program...*
>
> *[1] While the term "applicant" is used in these criteria, the requirements are, of course, applicable after such a person ... has received an early site permit (or) design approval.... These criteria will also be used for guidance in evaluating the adequacy of quality assurance programs in use by holders of ... early site permits ... (and) combined licenses.....*

Detroit Edison notes that "retaining responsibility for the quality assurance program" as required by Criterion I has a different meaning than "retain overall control of safety-related activities performed by B&V," as stated in the Inspection Report. Criterion I holds Detroit Edison responsible for the establishment and execution of the QA program and, as such, Detroit Edison is accountable for the quality of the COLA in the COL licensing matters as the applicant and eventual licensee. This responsibility does not negate the allowance provided for by Criterion I to fully delegate the work of establishing and executing the QA program to the COLA contractor. The COLA contractor had "control of safety related activities" under their QA program satisfying the requirements of Appendix B to 10 CFR Part 50.

Detroit Edison's position is further supported by Statements of Consideration associated with the clarifying revisions to 10 CFR Parts 50 and 52 (see 71 FR 12782). Specifically, the Statements of Consideration associated with conforming changes to 10 CFR Part 21 (see 71 FR 12818) define the concept of "regulatory life" which begins with docketing of the COLA. This implies that regulatory requirements set forth in the regulations do not apply until docketing of the application, as discussed above. Furthermore in the context applying the requirements of 10 CFR Part 21 to contractors, the Statements of Consideration (see 71 FR 12821) states that:

> *...services that are required to support an early site permit application (e.g. geologic or seismic analyses, etc.) that are safety-related and could be relied upon in the siting, design, and construction of a nuclear power plant, are to be treated as basic components as defined in part 21. Therefore, these services must be either purchased as basic components, requiring the service provider to have an appendix B to part 50 QA program, as well as its own part 21 program, or the early site permit applicant could dedicate the service in accordance with part 21 and the standard review plan, which requires the dedication process itself to be controlled under an appendix B to part 50 QA program.*
>
> Note: This is equally applicable to a COLA not relying on an ESP since the ESP siting scope of work is accomplished as part of the COLA development.

Two approaches are endorsed by the Statement of Consideration for the conforming changes to 10 CFR Part 21:

1. Services must either be purchased requiring the provider to have a QA program satisfying the requirements of Appendix B to 10 CFR Part 50 as well as a program satisfying the requirements of 10 CFR Part 21, or
2. The applicant could dedicate the service which requires the dedication process to be controlled under a QA program satisfying the requirements of Appendix B to 10 CFR Part 50.

In the case of Fermi 3, Approach 1 was used.

Notwithstanding the rule changes, the full delegation of the establishment and execution of the QA program for initial COLA development, as was done by Detroit Edison for the Fermi 3 COLA in January 2007, remains acceptable for initial COLA development today.

Further, the violation also raises the question of what constitutes "the earliest practicable time, consistent with the schedule for accomplishing the activities," under Appendix B Criterion II. Detroit Edison contends that it had established a QA program as permitted by Criterion I by contractually delegating the work of establishing and executing the QA program to the COLA contractor. Regardless, Detroit Edison considers that the February 2008 establishment of the Nuclear Development QA Program Description (ND QAPD), provided as an enclosure to RAI 17.5-3 in Detroit Edison's letter to the NRC dated September 2009 (MP092790561), satisfied

the "earliest practical time consistent with the schedule for accomplishing the activities." As described in the response to RAI 17.5-3, the ND QAPD was in place prior to Detroit Edison conducting its acceptance review of the COLA work product from the COLA contractor.

Based on the foregoing discussion, Detroit Edison contends there were no operative regulatory requirements imposing the provisions of a QA program satisfying the requirements of Appendix B to 10 CFR Part 50 for the period between March 2007 and February 2008. Accordingly, no violations of Criterion II, IV, or VII occurred.

Further, all shortcomings asserted in the NOV do not affect the quality of the COLA preparation. The examples of "DECo's failure to establish and implement a Fermi 3 QA program," described in the violations are discussed below:

1. Failure to classify safety-related B&V COL application and Owner Engineer (OE) contracts as safety-related.

   As clarified in the response to RAI 17.5-3 contained in Detroit Edison's letter to the NRC (NRC3-09-0027) dated September 30, 2009 (ML092790561), the Fermi 3 project is a corporate initiative and is currently being conducted independent of Fermi 2 so as not to be a distraction and to minimize the burden on the plant organization and infrastructure. As such, the project was initiated independent of the Fermi 2 QA program and the associated safety related purchasing processes (i.e. "NQ" vice "Q").

   Detroit Edison disagrees that it was necessary to designate the COLA or OE contracts as safety-related. The designation of safety related, "Q," or non-safety related, "NQ," has relevance only in the context of the Fermi 2 program which was not used for the Fermi 3 project.

   Appropriate QA requirements were invoked for the COLA contractor via the contract documents. Criterion IV of Appendix B to Part 50, "Procurement Document Control," states, in part that "Measures shall be established to assure that applicable regulatory requirements, ...and other requirements which are necessary to assure adequate quality are suitably included or *referenced* (emphasis added) in the documents for procurement of ...services...," thus providing for the inclusion of requirements by reference. Detroit Edison's contract with B&V Kansas City for the COL application states: "Contractor shall implement the Quality Assurance Program as described in Section 1.1.3 (Pre-COL Activities) of the Proposal." Section 1.1.3 of the "Proposal," defined in the contract as the "Black & Veatch Proposal ... for Combined Construction and Operating Licensing Services dated February 2, 2007," states in part:

   1) *...the Detroit Edison COL Application Project, including the site characterization and COL preparation be* [*sic*] performed *under Black & Veatch's Quality Assurance Program, which complies with 10 CFR 50, Appendix B and ASME NQA-1.*

   2) *The Black & Veatch Quality Assurance Program is implemented by the way of the Black & Veatch set of Nuclear Procedures (NPs) that fulfill the*

requirements of ASME NQA-1 and the associated ANSI N45 nuclear standards, and

3) *The Black & Veatch Quality Assurance Program contains the necessary reporting attributes to ensure implementation of 10 CFR Part 50.55(e) and 10 CFR Part 21. The D/CQAP* (Design/Construction Quality Assurance program) *discussed above will have the requisite Part 50.55(e) and Part 21 attributes in the program document.*

Thus, the requirements which are necessary to assure adequate quality are suitably referenced in the documents for procurement, i.e. the "Contract" and the "Proposal" for COLA preparation activities. These contractual requirements are legally enforceable and incorporation of the proposal by reference avoids the potential for discrepancies between contract documents. The OE contract is described below.

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.

As described in the response to RAI 17.5-3, an OE concept was utilized for the COLA project. The OE was an extension of Detroit Edison to support COLA activities in lieu of initially dedicating a permanent staff to the project. As an extension of Detroit Edison, there was no requirement to implement the requirements of Appendix B to 10 CFR Part 50 given that the requirements of Appendix B had been fully delegated to the COLA contractor.

This initial contract for the OE included a list of potential activities that would be subsequently authorized by Detroit Edison. Two of the tasks related to QA activities. The first was to assist in the development of a Detroit Edison QA program for the Fermi 3 project that would apply to activities conducted by both Detroit Edison and the OE. The development of a QA program satisfying the requirements of Appendix B to 10 CFR Part 50 is not a safety related activity. Hence, there were no QA requirements specified in the OE contract. Also, there is no requirement to have a QA program in place in order to contract a vendor to assist in the development of a QA program, as the violation implies. This task ultimately resulted in the development and implementation of the ND QAPD in February 2008. The second QA related task was that of QA oversight. This would have been applicable once a Detroit Edison QA program had been developed and implemented. Detroit Edison acknowledges that the OE personnel with QA background assisted Detroit Edison in oversight of the field investigation activities in 2007 prior to the implementation of the ND QAPD and that these activities were documented as surveillances. These surveillances were not required because no Detroit Edison QA program was required to be in place at that time. Nonetheless, the surveillances constituted valuable practice during the conduct of site investigation activities. As noted above, the work to establish and execute the QA program for COLA development activities had been fully delegated to the COLA contractor. As such the COLA

contractor, under his 10 CFR 50 Appendix B QA program, performed and documented the required field audit and surveillance activities.

3. Failure to adequately document the qualification of B&V to perform safety- related COL application activities.

   As stated in the response to RAI 17.5-3, B&V was selected from a field of potential vendors. The field was limited to vendors who had established nuclear services businesses, who were performing similar scopes of COLA work for other potential applicants, and who had a QA program satisfying the requirements of Appendix B to 10 CFR Part 50. In each of the proposals, the vendors were required to provide evidence of a QA program satisfying the requirements of Appendix B to 10 CFR Part 50 and to describe the QA controls that would be applied to the project. As discussed above, there was no regulatory requirement in effect for a Detroit Edison QA program to be in place in order to contract the COLA vendor, and therefore no regulatory requirement to document the qualification of the selected contractor. The contract in itself is sufficient documentation that the selected contractor had the QA program required by Detroit Edison.

4. Failure to adequately document an annual supplier evaluation of B&V.

   As discussed above, there was no operative requirement for Detroit Edison to have a QA program satisfying the requirements of Appendix B to 10 CFR Part 50 as late as the docketing of the application. While Detroit Edison did implement the ND QAPD in February, 2008, neither the ND QAPD, its implementing procedures, nor 10 CFR 50 Appendix B establish an annual supplier evaluation requirement. A Detroit Edison audit of B&V as COLA contractor was completed in July 2009.

Corrective Steps that Have Been Taken and the Results Achieved:

To address the concerns noted in the violation and to assure that all COLA activities continue to be conducted at a level of quality necessary to support future safety related activities the following measures are now in place:

1) As stated in the NRC's "Vendor Inspection Report," Detroit Edison put in place the Nuclear Development Quality Assurance Program Description, Revision 0 on February 4, 2008.

2) Subsequently, Detroit Edison put in place the Fermi 3 Quality Assurance Program Description (Fermi 3 QAPD), Revision 0 on September 25, 2008 which implements in full the requirements from Criterion II, "Quality Assurance Program," Criterion IV, "Procurement Control," and Criterion VII, "Control of Purchased Materials, Equipment, and Services," of Appendix B to 10 CFR Part 50.

Corrective Steps that Will Be Taken to Avoid Further Violations:

No additional corrective actions are necessary to address the concerns noted in the violation and to assure that all COLA activities continue to be conducted at a level of quality necessary to support future safety related activities.

Date when full compliance will be achieved:

Detroit Edison remains in compliance with the requirements from Criterion II, "Quality Assurance Program," Criterion IV, "Procurement Control," and Criterion VII, "Control of Purchased Materials, Equipment, and Services," of Appendix B to 10 CFR Part 50.

Attachment 2
NRC3-09-0041

Response to Violation 05200033/2009-201-02

Statement of Violation 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.

This issue has been identified as Violation 05200033/2009-201-02. This is a Severity Level IV violation (Supplement II of the Enforcement Manual).

The Reason for the Violation, or If Contested, the Basis for Disputing the Violation or Severity Level:

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).

Corrective Steps that Have Been Taken and the Results Achieved:

To address the concerns noted in the violation and to assure that all COLA activities continue to be conducted at a level of quality necessary to support future safety related activities the following measures are now in place:

1) 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) did possess the suggested practice, i.e. stated as "should" in the procedure, that internal audits be conducted "at least once every calendar year or at least once during the project if the duration is less than once per year." and initiated the required Corrective Action Report (CAR 1544905) to evaluate compliance.

2) As scheduled in the cited Audit Schedule dated August 6, 2009, the October 2009 internal audit was conducted in accordance with Detroit Edison Procedure Number NP-18.1, "Audits (Internal)", Revision 1, dated August 7, 2009.

Corrective Steps that Will Be Taken to Avoid Further Violations:

No additional corrective actions are necessary to address the concerns noted in the violation and to assure that all COLA activities continue to be conducted at a level of quality necessary to support future safety related activities. Detroit Edison Procedure Number NP-18.1, "Audits (Internal)", Revision 1 (applicable from August 2009 through present) requires an internal audit of all elements of the ND QAPD be "conducted at least once every calendar year or at least once during the project if the duration is less than one year".

Date when full compliance will be achieved:

An internal audit conducted during the week of October 26, 2009 addresses the concerns noted in the violation.

Attachment 3
NRC3-09-0041

Response to Violation 05200033/2009-201-03

Statement of Violation C

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.

This issue has been identified as Violation 05200033/2009-201-03. This is a Severity Level IV violation (Supplement II of the Enforcement Manual).

The Reason for the Violation, or If Contested, the Basis for Disputing the Violation or Severity Level:

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.

Corrective Steps that Have Been Taken and the Results Achieved:

To address the concerns noted in the violation and to assure that all COLA activities continue to be conducted at a level of quality necessary to support future safety related activities the following measures are now in place:

1) Detroit Edison Procedure Number NP-16.1, "Corrective Action," Revision 2, dated October 14, 2009 was issued to prescribe for the Nuclear Development Review Committee an additional responsibility for "review of potential Corrective Action Report (CAR) trends."

2) Director, Quality Management addressed the concern noted in the violation by a completed and documented a trend review of all Nuclear Development CARs initiated to date, i.e. January 22, 2008 through October 31, 2009 (reference CAR 1902170).

Corrective Steps that Will Be Taken to Avoid Further Violations:

To address the concerns noted in the violation and to assure that all COLA activities continue to be conducted at a level of quality necessary to support future safety related activities, the following measures will be taken:

1) Utilizing process information learned during the completion of the trend review of all Nuclear Development CARs initiated to date described above, the Director, Quality Management, as part of the corrective actions to CAR 1902170, will implement the procedural guidance for performing and reporting trend results deemed appropriate for the current phase of the COLA development in accordance with the Fermi 3 QAPD corrective action program.

Date when full compliance will be achieved:

Detroit Edison remains in full compliance with the requirement from Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50.

Attachment 4
NRC3-09-0041

Clarification of Vendor Inspection Report 05200033/2009-201

Clarification of Vendor Inspection Report Details

1.a, "Quality Assurance Program Review"

For completeness, the history of the QA program descriptions implemented by Detroit Edison for the Fermi 3 project is:

Detroit Edison Nuclear Development Quality Assurance Program Description (ND QAPD), Revision 0, effective February 4, 2008, (provided as an enclosure to the response to RAI 17.5-3 in letter to the NRC (NRC3-09-0027) dated September 30, 2009 - ML092790561)

Detroit Edison Fermi 3 Quality Assurance Program Description (Fermi 3 QAPD), Revision 0, effective September 25, 2008, (provided in FSAR, Revision 0 as Appendix 17AA to Chapter 17), and

Detroit Edison Fermi 3 Policy: COL Quality Assurance Program Description During Construction and Operation, (Fermi 3 QAPD), Revision 1, effective March 25, 2009, (provided in FSAR, Revision 1 as Appendix 17AA to Chapter 17).

1.b, "Quality Assurance Program Review," end of 1st para:

"Chapter 17.5-2 further stated that DECo provided oversight of the contracted activities by way of procurement control, control of purchased service, and oversight/surveillances of those activities and services."

Subsequent to the inspection, Detroit Edison, in letter to the NRC (NRC3-09-0027) dated September 30, 2009 (ML092790561), provided a COLA Markup for Chapter 17.5-2 with the response to RAI 17.5-3 which states, in part that "Detroit Edison formally established a Nuclear Development group to oversee the COLA project and secured the services of an OE to support owner-related activities such as, but not limited to: reactor technology selection, project cost estimates, development of owner's QA program, engineering support services, and COLA contractor oversight."

1.b, "Quality Assurance Program Review," end of 3rd para:

"DECo failure to submit the ND QAPD to the NRC for review and approval has been captured in a request for additional information (RAI) to the Final Safety Analysis Report (FSAR)."

The identified ND Quality Assurance Program Description (ND QAPD), Revision 0, effective February 4, 2008 was provided in Detroit Edison's letter to the the NRC (NRC3-09-0027) dated September 30, 2009 (ML092790561).

1.b, "Quality Assurance Program Review," 5th para

"DECo stated that in 2006, a decision not to utilize the Fermi Unit 2 operating QAPD and to develop a totally new QA program and implementing procedures for all activities was made."

As clarified in the response to RAI 17.5-3 contained in Detroit Edison's letter to the NRC (NRC3-09-0027) dated September 30, 2009 (ML092790561), the Fermi 3 project is a corporate initiative and is currently being conducted independent of Fermi 2 so as not to be a distraction and minimize the burden on the plant organization and infrastructure. As such, the project was initiated independent of the Fermi 2 QA program.

2.b, "Control of Procurement Document," 4th & 5th para

"The NRC inspectors found that both contracts (B&V of Kansas City for COL application and B&V of Michigan for OE services) were coded as "NQ" indicating they were non-safety procurements. However, the NRC inspectors noted both contracts contained safety-related activities, such as geotechnical site boring in the COL application contract and QA oversight of safety-related activities in the OE contract."

"The NRC inspections discussed the safety classification of the contracts with DECo QA and procurement personnel. DECo explained that the contracts with B&V were performed by a Fermi Unit 2 procurement specialist using the DECo commercial procurement process/program with direct oversight provided by senior management."

Additionally, as clarified in the response to RAI 17.5-3 contained in Detroit Edison's letter to the NRC (NRC3-09-0027) dated September 30, 2009 (ML092790561), the Fermi 3 project is a corporate initiative and is currently being conducted independent of Fermi 2 so as not to be a distraction and minimize the burden on the plant organization and infrastructure. As such, the project was initiated independent of the Fermi 2 QA program.

2.b1, "Control of Procurement Document," 1st para

"The NRC inspectors noted that the COL application contract indirectly imposed QA requirements on B&V-KC by requiring the Fermi 3 COL application contractor to fully conform to all applicable NRC and industry guidance, as well as the B&V Proposal."

Criterion IV of Appendix B to Part 50, "Procurement Document Control," states, in part that "Measures shall be established to assure that applicable regulatory requirements, ...and other requirements which are necessary to assure adequate quality are suitably included or *referenced* (emphasis added) in the documents for procurement of ...services..." provides for the inclusion of requirements by reference.

Specifically, the referenced Detroit Edison contract with B&V Kansas City for the COL application states: "Contractor shall implement the Quality Assurance Program as described in Section 1.1.3 (Pre-COL Activities) of the Proposal" and Section 1.1.3 of the "Proposal," defined in the contract as the "Black & Veatch Proposal ... for Combined Construction and Operating Licensing Services dated February 2, 2007," states in part:

> "...the Detroit Edison COL Application Project, including the site characterization and COL preparation be performed under Black & Veatch's Quality Assurance Program, which complies with 10 CFR50, Appendix B and ASME NQA-1."

"The Black & Veatch Quality Assurance Program is implemented by the way of the Black & Veatch set of Nuclear Procedures (NPs) that fulfill the requirements of ASME NQA-1 and the associated ANSI N45 nuclear standards." and

"The Black & Veatch Quality Assurance Program contains the necessary reporting attributes to ensure implementation of 10 CFR Part 50.55(e) and 10 CFR Part 21. The D/CQAP discussed above will have the requisite Part 50.55(e) and Part 21 attributes in the program document."

2.b1, "Control of Procurement Document," 6th para

"The NRC inspectors reviewed the OE contract and noted that the scope of work section outlined 19 broad areas of potential activities including DECo QA program development and oversight/audit of all contractor activities."

In addition to the information presented in the response to Violation 05200033/2009-201-01 (see Attachment 1, pg 8), since September 2008, after Phase I of the COLA contract was completed (COLA development), the activities of the OE contractor have been limited to completing environmental monitoring necessary to support the Environmental Report. This was done for Detroit Edison's convenience in that COLA Phase II work (Review Support) had not yet been authorized under the COLA contract. The OE contractor has not performed safety related activities, specifically the identified "QA oversight and audit functions."

4.b, "Corrective Action,"

"Procedure NP 16.1 provided instructions for the administration of the Fermi 3 Nuclear Development Corrective Action Program, including ... trending of undesirable conditions ...." and "stated that the Director of Quality Management 'is responsible for trending corrective actions to determine if there are adverse trends that require management attention.'"

Detroit Edison Fermi 3 Policy: COL Quality Assurance Program Description During Construction and Operation, (Fermi 3 QAPD), Revision 0 through present, Section 16, "Corrective Action" state in part, that "Reports of conditions adverse to quality are analyzed to identify trends." and further states "...significant adverse trends are documented...."

As noted by the inspectors to Detroit Edison's Director of Quality Management during the inspection, no adverse trends existed. Thus no significant adverse trends existed and as such none were required by the Fermi 3 QAPD to be documented.

Additionally, the Fermi 3 QAPD, Revision 1, 16.2, "NQA-1-1994" states "In establishing provisions for corrective action, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 16."

NQA-1-1994, Basic Requirement 16, "Corrective Action" states " Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause and corrective action for significant conditions adverse to quality shall be documented and reported to appropriated

levels of management; follow-up action shall be taken to verify implementation of this corrective action." Basic Requirement 16 does not require trending.

It is noteworthy that the Fermi 3 QAPD, All Revisions, do not commit to NQA-1-1994, Appendix 16A-1, "Nonmandatory Guidance on Corrective Action" which does require the documentation of trending when used as part of an "analysis to determine the action(s) to be taken to prevent recurrence of significant conditions adverse to quality...."

Attachment 5
NRC3-09-0041

Copy of Response to RAI Letter No. 10
(eRAI Tracking No. 3341)

RAI Question No. 17.5-3

(*without Enclosure 1*)

NRC RAI 17.5-3

10 CFR 52.79(a)(25) requires the applicant to provide a QA program consistent with Appendix B to 10 CFR Part 50 for design, fabrication and construction activities. Regulatory Guide 1.206 section C.I.17.5.3 states that the FSAR should 1) describe how the applicant will retain responsibility for, and maintain control over, those portions of the QA program delegated to other organizations, 2) should identify the responsible organization and the process for verifying that delegated QA functions are effectively implemented, 3) identify major work interfaces for activities affecting quality, and 4) describe how clear and effective lines of communication between the applicant and its principal contractors are maintained to assure coordination and control of the QA program.

FSAR part 2, chapter 17.5, states that 1) the Black & Veatch's Quality Assurance Program is used for the Detroit Edison Company COL Application Project, including the site characterization and COL preparation, 2) Detroit Edison provided oversight of the contracted activities by way of procurement control, control of purchased services, and oversight / surveillances of those activities and services, and 3) subsequent to contracting with Black & Veatch, Detroit Edison developed and implemented a Nuclear Development Quality Assurance Program which invokes the COLA contractor QA program for COLA activities.

Please clarify how FSAR part 2, chapter 17.5, meets the requirements of 10 CFR 52.79(a)(25) and provide justification for any exceptions to the guidance provided in Regulatory Guide 1.206. Specifically, explain how DTE retains responsibility and maintains control over those portions of the QA program that have been delegated to Black & Veatch, and how DTE verifies that delegated QA functions have been effectively implemented.

Response

In early 2007, Detroit Edison initiated a project to prepare a Combined License Application (COLA) for a potential new unit to be located at the site of the company's existing Fermi 2 nuclear power plant. The project is a corporate initiative and is currently being conducted independent of Fermi 2 so as not to be a distraction and minimize the burden on the plant organization and infrastructure. As such, the project was initiated independent of the Fermi 2 Quality Assurance (QA) program. Initially, the COLA project was to be conducted as essentially a turnkey project, using a primary COLA contractor with a minimal Detroit Edison staff. An Owner's Engineer (OE) concept was envisioned as an extension of the Detroit Edison staff to support the project. The initial mandate for the project was to prepare a COLA to be ready for submittal prior to December 31, 2008, corresponding to the initial tax credit qualifying milestone from the *Energy Policy Act of 2005*. The COLA would be categorized as referencing a Certified Design without an Early Site Permit (ESP), for the purpose of defining the applicable guidance from Regulatory Guide 1.206 (DG-1145).

With this background, the response will discuss the four attributes from Reg. Guide 1.206, C.I.17.5.3 related to this question and how they were satisfied for three distinct periods from

project initiation to present. The first period covers from project initiation in January 2007 until November 2007. Major activities in this period included: selection of COLA contractor and OE, conduct of site characterization, information gathering, and initial COLA development. The second period began in November 2007 and ended with submittal of the COLA on September 18, 2008. The major activity in this period was the receipt, review, and acceptance of COLA work product from the COLA contractor for submittal to the NRC. The third period began with submittal of the COLA on September 18, 2008 and continues to the present. Major activities to date in this period include: updating the COLA, responding to RAIs and other activities to support NRC review.

The following attributes from Reg. Guide 1.206, C.I.17.5.3 are discussed for each of these project periods:

1. Description of how the applicant will retain responsibility for, and maintain control over, those portions of the QA program delegated to other organizations;
2. Identification of the responsible organization and the process for verifying that delegated QA functions are effectively implemented;
3. Identification of major work interfaces for activities affecting quality, and
4. Description of how clear and effective lines of communication between the applicant and its principal contractors are maintained to assure coordination and control of the QA program;

Project Initiation (January 2007 to November 2007)

The initial phase of the project was to select a COLA contractor. No QA program was used for the procurement of a COLA contractor as this corporate project was being executed independent of Fermi 2. The intention was to fully delegate to the COLA contractor the establishment and execution of the QA program related to the COLA project, as permitted by 10 CFR 50 Appendix B Criterion 1 and associated footnote. Accordingly, requests for proposal were solicited only from potential contractors who were established in the nuclear services business, and who were currently executing comparable projects for other potential applicants.

Specifically, Detroit Edison prepared a request for proposal to perform all activities necessary to prepare a COLA. In part the request for proposal required bidders to establish that they had the prerequisite 10 CFR 50 Appendix B QA program and how it was to be applied to the COLA development project.

In February 2007, Detroit Edison received several proposals in response to the request for proposal solicitation. Black & Veatch (B&V), headquartered in Overland Park, Kansas, and who was ultimately selected as the COLA contractor, provided a detailed proposal in response. Detroit Edison based its selection on a review of the submitted proposal including, but not limited to the following attributes:

1. Knowledge that the B&V's 10 CFR 50 Appendix B/NQA-1 QA program was being properly implemented based on reporting of independent reviews by other NRC approved

10 CFR 50 Appendix B programs such as Entergy, American Electric Power and Nebraska Public Power District in the proposal; and

2. B&V was leading the development of the Entergy River Bend COLA

In April 2007, Detroit Edison established a contract with B&V for the development of the COLA. The procurement controls documented within the COLA contract included:

1. Scope of work to be performed by B&V,
2. Technical requirements for the prepared COLA in accordance with 10 CFR 52, 10 CFR 51, 10 CFR 50, 10 CFR 20, NUREG-0800, NUREG-1555, Reg. Guide 1.206 (DG-1145), etc.,
3. Acceptance requirements and control measures for Detroit Edison's evaluation of COLA and intermediary work product developed by B&V,
4. Organizational responsibilities (including reporting and communication methods), 10 CFR 50 Appendix B/NQA-1 requirements, and 10 CFR 50 Appendix B/NQA-1 applicability to FSAR Chapters 2 through 9, 14, 15, 16, 18 and 20, geotechinical site boring program, radiological analyses, and meteorological analyses associated with the radiological analyses,
5. Access to B&V's facilities and records for inspection or audit by Detroit Edison,
6. Identification of the documentation requirements and dates of submission required by Detroit Edison, and
7. Requirements for reporting and disposition of nonconformances in accordance with 10 CFR 21.

In late April 2007, Detroit Edison formally established a small Nuclear Development group to oversee the COLA project and secured the services of an OE (B&V, Ann Arbor) to support owner-related activities such as, but not limited to: reactor technology selection, project cost estimates, development of owner's QA program, engineering support services, and COLA contractor oversight.

With these organizational and contractual elements in place, COLA development commenced under the B&V 10 CFR 50 Appendix B/NQA-1 QA program. Major work interfaces for activities affecting COLA development including clear and effective lines of communication were established through the implementation of the B&V Project Management Memorandum (PMM) for the Detroit Edison COLA project. The PMM is the B&V mechanism for addressing project organization, responsibilities, interfaces, communication mechanisms, and invoking applicable B&V 10 CFR 50 Appendix B/NQA-1 QA program implementing procedures. For example, the B&V Request for Review process was used to obtain owner's review of changes to the data collection plan. Similarly, the B&V Request for Information process was used to provide owner information and decisions (e.g. site layout, meteorological data) necessary for COLA development.

In late April, 2007, construction of the monitoring wells for hydrology investigation and core boring activities for geotechnical data collection commenced at the Fermi 2 site. The applicable Fermi 2 programs for access, work control, and contractor oversight were followed for site work.

Senior, nuclear experienced, Detroit Edison personnel provided direct oversight for all site work to ensure compliance with the Fermi 2 programs and provided the necessary interface between the COLA project and the operating Fermi 2 plant. To maintain oversight, and consistent with Detroit Edison's overall responsibility, staff of the OE performed and documented surveillances of onsite activities.

In May 2007 and during the conduct of site investigation activities, Detroit Edison submitted a voluntary response to Regulatory Issue Summary 2007-08, *Updated Licensing Review Approach*, notifying the NRC that (Ref. ML071580347):

1. Activities to prepare the COLA referencing a Certified Design without an Early Site Permit, were underway,
2. B&V had been secured to support the preparation of the COLA and was performing similar work for the Entergy River Bend COLA,
3. B&V's 10 CFR 50 Appendix B/NQA-1 QA program was being applied to appropriate aspects of the work scope,
4. B&V's principal subcontractors would be governed by the B&V QA requirements, and
5. An OE had been secured to support the project.

Additionally, in May 2007, Detroit Edison notified the NRC of the schedule for on-site geotechnical investigation activities and stated that "The Black & Veatch Quality Assurance Program, which meets the requirements of 10 CFR 50, Appendix B and ASME NQA-1, is being applied to the geotechnical investigation work scope." (ML071580350).

Subsequently on July 9 – 11, 2007, Region II inspectors accompanied by members of the Office of New Reactors (NRO) conducted an audit at the Fermi site in accordance with Inspection Manual Chapter 2502, *Construction Inspection Program: Pre-Combined License (Pre-COL) Phase,* dated June 22, 2005. Inspection Manual Chapter 2502 invokes, for COLAs not referencing an ESP, Inspection Procedure 35004, *Pre-Docketing Early Site Permit Quality Assurance Controls Inspection* dated, May 29, 2003. As stated in the inspection procedure, the purpose of the audit was to observe COL, pre-application subsurface investigation activities being conducted to obtain geotechnical and seismic data necessary to support a COLA for the purpose of providing background information for the NRC's future review of the expected COL. The audit report concluded that "the work was being done in an appropriately controlled manner" (ML072190660).

Concurrent with site investigation, B&V commenced assembling the research, data, references, etc. necessary to support development of the COLA. When B&V required information or decisions from Detroit Edison, a formal request was communicated using B&V's Request for Information process. The B&V Request for Information was then reviewed and accepted consistent with B&V's 10 CFR 50 Appendix B/NQA-1 QA program as applicable.

Development, Receipt, Review and Acceptance of COLA Work Product (November 2007 to September 2008)

In November 2007, anticipating the activities necessary to receive, review and accept the COLA work product from B&V, Detroit Edison began to develop the necessary staffing to support the receipt, acceptance review, submittal, NRC review, and concurrent maintenance of the COLA. The increase in staffing also included the addition of an experienced QA professional. Subsequently, staff of Nuclear Development drafted the *Nuclear Development Quality Assurance Program Document* (ND QAPD) and implementing procedures for those elements of the ND QAPD associated with the activities planned to be performed by Detroit Edison at the time (e.g., review of B&V COLA work product).

In February 2008, the Sr. VP Major Enterprise Projects approved for use the ND QAPD (a copy is provided as an enclosure to this response), which continued to delegate quality and safety related services for COLA development to B&V (e.g., site characterization, development of conceptual designs). Subsequently, the implementing procedures were approved and the Nuclear Development staff was trained on the procedures necessary to review and accept the B&V developed COLA products. Specifically, Nuclear Development implemented a procedure to complete the formal review of each chapter of the Fermi 3 COLA submitted by B&V's Request for Review process as a means to assure coordination and control of the finalization of the COLA. Comments generated during Detroit Edison's review of the COLA work product against relevant regulatory guidance, information provided by Detroit Edison to B&V, and the Reference COLA (R-COLA), as applicable, were provided to B&V for resolution and incorporation. The Request for Review process required signoff by both the Detroit Edison reviewer and B&V for all comments.

In May 2008, a Nuclear Development lead auditor conducted a surveillance of B&V COLA development activities and verified selected portions of B&V's 10 CFR 50 Appendix B/NQA-1 QA program were being satisfactorily implemented.

Application for the Combined Operating License (September 2008 to Present)

By early September 2008, the review was completed and all comments were documented, incorporated and accepted by Detroit Edison in accordance with applicable procedures. On September 18, 2008, Detroit Edison submitted the COLA for Fermi 3. Additionally, with the submittal of the Fermi 3 COLA, the ND QAPD was superseded by the Fermi 3 QAPD submitted as part of the COLA. The in-use Fermi 3 QAPD is revised with the submission of each COLA revision containing a revision to FSAR, Appendix 17 AA, *QAPD*.

After submittal of the COLA, Nuclear Development prepared, approved, and trained on the procedures necessary to make the transition post-application, adopting the Fermi 3 QAPD, and to support the post-application scope of work. In this transition, Detroit Edison took ownership of the application; however, contractually, continues to delegate the execution of quality and safety related services associated with COLA revision and review support to the B&V 10 CFR 50 Appendix B/NQA-1 QA program in accordance with the Fermi 3 QAPD. To assure clear and effective lines of communication, Nuclear Development utilizes its own Request for Information

process to request quality related services from B&V pertaining to COLA sections that were originally developed under the B&V 10 CFR 50 Appendix B/NQA-1 QA program as specified in the COLA contract. B&V then executes the necessary activities to provide the requested information contained in FSAR Chapters 2 through 9, 14, 15, 16, 18 and 20, geotechinical site boring information, radiological analyses, and meteorological analyses associated with the radiological analyses. Subsequently, B&V's response to Detroit Edison's Request for Information is reviewed and accepted for incorporation into a COLA revision or a response to an NRC Request for Additional Information. This and other B&V COLA project interfaces are described in a new Project Management Memorandum developed for this phase.

In March 2009, the Sr. VP Major Enterprise Projects established the functional quality assurance manager (current title Director, Quality Management) who reports to the Sr. VP/CNO and to the Sr. VP Major Enterprise Projects to implement the Fermi 3 QAPD, evaluate compliance to the program, and manage QA organization resources.

In July 2009, an audit team from Detroit Edison performed an audit of B&V's 10 CFR 50 Appendix B/NQA-1 QA processes according to Fermi 3 QAPD implementing procedures. The B&V QA program was assessed as effectively implementing the requirements of 10 CFR 50, Appendix B/NQA-1 for Fermi 3, quality related, COLA activities.

B&V remains the COLA contractor for Detroit Edison and continues to perform delegated quality functions. Detroit Edison retains responsibility via processes and programs necessary to implement the Fermi 3 QAPD contained in FSAR, Appendix 17AA, including procurement control and verification of the effectiveness of B&V's 10 CFR 50 Appendix B/NQA-1 QA program.

Proposed COLA Revision

As the Fermi 3 project is not utilizing the Fermi 2 NRC approved QAPD, Chapter 17 of the FSAR will be revised to improve the description of the extent to which Detroit Edison has and will delegate the work of establishing and executing the 10 CFR 50 Appendix B/NQA-1 QA program, or any part thereof, to contractors (Ref. Reg. Guide 1.206, C.I.17.5.3) based upon the response to this RAI as shown on the attached markup.

Markup of Detroit Edison COLA
(Following 2 pages)

The following markup represents how Detroit Edison intends to reflect this RAI response in the next submittal of the Fermi 3 COLA Revision 2. However, the same COLA content may be impacted by revisions to the ESBWR DCD, responses to other COLA RAIs, other COLA changes, plant design changes, editorial or typographical corrections, etc. As a result, the final COLA content that appears in a future submittal may be different than presented here.

Refer to Subsection 17.4.1 for the implementation of reliability assurance activities.

17.4.13 **COL Information**

17.4-1-H **Operation Reliability Assurance Activities**

STD COL 17.4-1-H This COL Item is addressed in Subsection 17.4.1, Subsection 17.4.6, Subsection 17.4.9, Subsection 17.4.10, and Subsection 17.6.

EF3 COL 17.3-1-A

17.5 Quality Assurance Program Description – Design Certification, Early Site Permits, and New License Applicants

QA applied to the DC activities is described in DCD Section 17.1. ESP QA is not applicable to Fermi 3.

EF3 SUP 17.5-2

~~Black & Veatch was contracted as the COLA contractor responsible for activities related to COLA preparation. The Detroit Edison Company COL Application Project, including the site characterization and COL preparation was performed under the Black & Veatch's Quality Assurance Program, which complies with 10 CFR50, Appendix B. The Black and Veatch Nuclear Quality Assurance Program invokes the applicable requirements of 10CFR50.55(e) and 10CFR21. The Black & Veatch QA Program allows for project specific procedures which are the vehicle to identify which activities in the project require the application of the Black & Veatch Nuclear Quality Assurance Program and those that can be performed under the Black & Veatch Energy Commercial Quality Assurance Program. Detroit Edison provided oversight of the contracted activities by way of procurement control, control of purchased services, and oversight / surveillances of those activities and services. The Black and Veatch Quality Assurance Program has been audited and found acceptable by other US nuclear utilities. Subsequent to contracting with Black & Veatch, Detroit Edison developed and implemented a Nuclear Development Quality Assurance Program which invokes the COLA contractor QA program for COLA activities to provide assurance of the integrity and reliability of the COL data or analysis that would affect the performance of safety related systems, structures, and components (SSCs). The requirements of this quality assurance program are consistent with the applicable requirements of Appendix B to 10CFR Part 50.~~

Replace EF3 SUP 17.5-2 with insert 1.

Insert 1

The following section describes the quality assurance programs applied to Fermi 3 COLA development activities, and COLA support activities, through anticipated COL issuance, in three phases. The first period began with project initiation including, selection of COLA contractor and OE, conduct of site characterization, information gathering, and initial COLA development. The second period began with the approval of the Nuclear Development Quality Assurance Program Description and ends with submittal of the COLA including activities such as; receipt, review, and acceptance of COLA work product from the COLA contractor for submittal to the NRC. The third period began with submittal of the COLA and continues through to anticipated COL issuance including updating of the COLA, responding to RAIs and other activities to support NRC review.

The initial phase of the project was to select a COLA contractor. Detroit Edison intended to fully delegate to the COLA contractor the establishment and execution of the QA program related to the COLA project. Accordingly, requests for proposal were solicited only form potential contractors who were established in the nuclear services business, and who were currently executing comparable projects for other potential applicants under a 10 CFR 50 Appendix B QA program. Black & Veatch (B&V), headquartered in Overland Park, Kansas was ultimately selected as the COLA contractor. Detroit Edison formally established a Nuclear Development group to oversee the COLA project and secured the services of an OE to support owner-related activities such as, but not limited to: reactor technology selection, project cost estimates, development of owner's QA program, engineering support services, and COLA contractor oversight. With these organizational and contractual elements in place, COLA development commenced under the B&V 10 CFR 50 Appendix B/NQA-1 QA program. Major work interfaces for activities affecting COLA development including clear and effective lines of communication were established through the implementation of the B&V Project Management Memorandum (PMM) for the Detroit Edison COLA project.

The second phase began as Detroit Edison developed the necessary staffing to support the submittal, review, and subsequent maintenance of the COLA. The increase in staffing also included the addition of an experienced QA professional. At the same time, staff of Nuclear Development drafted the *Nuclear Development Quality Assurance Program Document* (ND QAPD) and implementing procedures for those elements of the ND QAPD associated with the activities planned to be performed by Detroit Edison at the time (e.g., review of B&V COLA work product).

The Sr. VP Major Enterprise Projects approved for use the ND QAPD, which continued to delegate quality and safety related services for COLA development to B&V (e.g., site characterization, development of conceptual designs). Subsequently, the implementing procedures were approved and the Nuclear Development staff was trained on the procedures necessary to review and accept the B&V developed COLA products.

The third phase commences with submittal of the Fermi 3 COLA. At this point, the ND QAPD is superseded by the Fermi 3 QAPD submitted as part of the COLA (FSAR Chapter 17, Appendix 17AA). B&V remains the COLA contractor for Detroit Edison and continues to perform delegated quality functions. Detroit Edison retains responsibility via processes and programs necessary to implement the Fermi 3 QAPD, including procurement control and verification of the effectiveness of B&V's 10 CFR 50 Appendix B/NQA-1 QA program. All COLA activities through anticipated COL issuance will be completed in accordance with the Fermi 3 QAPD, this includes delegating responsibilities as described in Part II, Section 2 of the Fermi 3 QAPD.