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



10 CFR 2.201

May 26, 2010 NRC3-10-0023

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

References: 1) Fermi 3

Docket No. 52-033

- 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
- Letter from Peter W. Smith (Detroit Edison) to U.S. Nuclear Regulatory Commission, "Detroit Edison Reply to a Notice of Violation 05200033/2009-201-01,02, and 03," NRC3-09-0041, dated November 9, 2009
- 4) Letter from Richard Rasmussen (NRC) to Jack M. Davis (Detroit Edison),
  "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," dated April 27, 2010

Subject: Detroit Edison Company Reply to Notice of Violation 05200033/2009-201-04, Enforcement Action EA-09-286

In Reference 2, the U.S. Nuclear Regulatory Commission (NRC) cited three Severity Level IV violations in a Notice of Violation (NOV) that related to a limited scope inspection conducted by the 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. The three violations were designated as Violation A - 05200033/2009-201-01, B - 05200033/2009-201-02, and C - 05200033/2009-201-03.

In Reference 3, Detroit Edison contested the three violations, while at the same time acknowledging the constructive insights into the Fermi 3 QA program being made by the NRC. Detroit Edison took corrective steps to address the concerns noted in the inspection report to assure that all COLA activities continue to be conducted at a level of quality necessary to support safety related activities.

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In Reference 4, the NRC revised the NOV by withdrawing Violation A (05200033/2009-201-01), revising and combining Violations B and C (05200033/2009-201-02 and 03), and issuing one new violation (05200033/2009-201-04). The NRC acknowledged in Reference 4, that Detroit Edison's corrective actions presented in Reference 3 were responsive to the previous NOV and stated that no further response is required for the revised Violation B/C.

Pursuant to the provisions of 10 CFR 2.201, Detroit Edison is replying to the new violation identified in Reference 4 (05200033/2009-201-04). The reply is enclosed in Attachment 1. Detroit Edison acknowledges the violation and has taken corrective steps to address the concerns noted in the NOV to assure that all COLA activities continue to be conducted at a level of quality necessary to support safety related activities.

There are no commitments being made in this letter.

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

Sincerely,

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

Attachments: 1) Reply to Notice of Violation 05200033/2009-201-04

cc: Richard Rasmussen, Chief, Quality and Vendor Branch B, Division of Construction Inspection and Operational Programs, Office of New Reactors Jerry Hale, NRC Fermi 3 Project Manager

Bruce Olson, 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

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Attachment 1 NRC3-10-0023

Reply to Notice of Violation 05200033/2009-201-04

### Statement of Violation 05200033/2009-201-04

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.

### **Reason for the Violation:**

Detroit Edison acknowledges violation 05200033/2009-201-04 as stated. Detroit Edison failed to sufficiently document a review of the Black & Veatch, Overland Park, Kansas (B&V) 10 CFR 50 Appendix B QA program, which would typically include the basis for qualifying the B&V QA program, thereby assuring that B&V was qualified to perform safety-related Fermi 3 COL activities. During the relevant period, Detroit Edison had instead based the qualification of B&V's QA program to perform safety-related Fermi 3 COL activities on contract records and Detroit Edison Nuclear Development procedures, reviewed and approved by Detroit Edison. The reason for the violation is that at the time Detroit Edison became a COL applicant, Detroit Edison believed the documentation in place fulfilled the vendor qualification requirements of Criterion VII of 10 CFR 50 Appendix B, specifically to assure that B&V was qualified to supply the safety-related services detailed contractually.

Evaluation and selection of a qualified 10 CFR 50 Appendix B COLA contractor was established during the Detroit Edison Fermi 3 COLA services bidding process as detailed in the response to Request for Additional Information (RAI) 17.5-3 (ML092790561). The contract established between Detroit Edison and B&V referenced the basis for B&V's QA qualification including; B&V QA program specified details, and the fact that the B&V QA program had been "audited and found acceptable by other U.S. nuclear utilities, including Entergy, AEP and NPPD." The acceptance and qualification of B&V was further documented in Detroit Edison procedure NDP-NP-4.1 "Procurement of Services" Rev. 0, which stated in part, that B&V is an approved supplier of Fermi 3 COLA services, and presented a basis for B&V's qualification to provide

QA COLA services, i.e. acceptable U.S. nuclear utility audits. NDP-NP-4.1 Rev. 0 was in effect when Detroit Edison became a COL applicant. At that time, Detroit Edison believed the documentation in place appropriately assured Detroit Edison that B&V was qualified to supply the safety-related services detailed contractually.

## Corrective Steps that Have Been Taken and the Results Achieved:

In April 2009, Detroit Edison initiated a plan to establish a more comprehensive vendor qualification review and acceptance program, which included: QA staff augmentation, vendor audits, procedural improvements, and initiation of an Approved Suppliers List (ASL), among others. A Detroit Edison audit of B&V in July 2009 assessed that the B&V QA Program was effectively implemented for Fermi 3 COLA activities. B&V was subsequently listed on the Fermi 3 ASL.

As of July 2009, Detroit Edison has taken the necessary steps to assure that B&V is qualified to supply the safety-related services to Detroit Edison, as required by Criterion VII, "Control of Purchased Material, Equipment, and Services" of 10 CFR 50 Appendix B. Detroit Edison expanded the guidance within implementing procedures NP-7.1, "Supplier Audits, Surveillances, and Commercial Grade Surveys", and NP-7.2, "Supplier Evaluations." Audit and surveillance schedules initiated by Detroit Edison further specify supplier evaluation activities. With these changes in place, Detroit Edison has established a program to comply with the requirements of Criterion VII, "Control of Purchased Materials, Equipment, and Services," of Appendix B to 10 CFR Part 50.

Detroit Edison has confirmed that the safety-related activities performed by B&V prior to July 2009 were completed in accordance with 10 CFR 50 Appendix B requirements. Assurance that B&V was qualified to supply the safety-related services procured by Detroit Edison prior to July 2009 is based upon: knowledge of the B&V QA program including QA program description detailed in contract documents; audits and acceptance of COLA services under the B&V QA program by other U.S. nuclear utilities; over three years of Detroit Edison experience with B&V including direct interface with B&V's QA program implementation throughout COLA preparation and COLA maintenance activities; Detroit Edison review of B&V work product throughout COLA development and revision; and, Detroit Edison audit which contains a documented review of B&V records and project implementation documentation for multiple phases of the Detroit Edison Fermi 3 COLA project as well as documented historical review of audits performed by Entergy in 2006 (prior to Detroit Edison's establishment of the Fermi 3 COLA contract with B&V) and 2007 (concurrent with B&V performance of Detroit Edison contract activities). A review of the B&V QA program as applied to Fermi 3 COLA activities. which contains details for the qualifications summarized above, is documented in Detroit Edison letter NRC3-10-0019 dated May 10, 2010 (ML101320254) in response to NRC RAI Letter 26.

# **Corrective Steps that Will Be Taken to Avoid Further Violations:**

Detroit Edison has established processes to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to Detroit Edison's procurement documents. Assurance that Fermi 3 COLA contractors are qualified to supply the services procured by Detroit Edison will be maintained as defined procedurally. Source evaluations and selection activities shall be performed per the requirements of NP-7.2, "Supplier Evaluations". Audits of safety-related COLA contractors will be maintained per the requirements of NP-7.1, "Supplier Audits, Surveillances, and Commercial Grade Surveys." These processes provide Detroit Edison with objective evidence of the quality furnished by safety-related Fermi 3 COLA contractors.

## Date when full compliance will be achieved:

Detroit Edison is currently in compliance with the requirements from Criterion VII, "Control of Purchased Materials, Equipment, and Services," of Appendix B to 10 CFR Part 50, as stated above.