

October 5, 2009

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

SUBJECT: NRC INSPECTION REPORT 05200033/2009-201 AND NOTICE OF VIOLATION
TO DETROIT EDISON COMPANY

Dear Mr. Davis:

On August 18-21, 2009, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Detroit Edison Company (DECo) in Detroit, MI. The enclosed report presents the results of this inspection.

This was a limited scope inspection that focused on assessing your compliance with the provisions of selected portions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," (Appendix B) to Part 50, "Domestic Licensing of Production and Utilization Facilities," of Title 10 of the *Code of Federal Regulations* (10 CFR)." Specifically, the NRC inspection team reviewed certain portions of your quality assurance (QA) program implementation to ensure that they were effectively implemented with respect to the Fermi Unit 3 combined license (COL) application. While the NRC did review the implementation of portions of your QA program, this NRC inspection report does not constitute NRC the approval of your QA program.

Based on the results of this inspection, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. The NRC evaluated these violations in accordance with the agency's Enforcement Policy, available on the NRC's Web site at http://adamswebsearch2.nrc.gov/idmws/doccontent.dll?library=PU_ADAMS^PBNTAD01&ID=092450167.

The enclosed Notice of Violation (NOV) cites the violations, and the subject inspection report describes in detail the circumstances surrounding them. The NOV cites these violations based on a review of your QA program and implementation found that certain QA policies and procedures were not in compliance with the applicable requirements of Appendix B to 10 CFR Part 50. Specifically, the NRC identified that you failed to establish and implement a Fermi 3 QA program between March 2007, when the initial contract was placed with B&V for the conduct of COL activities, until February 2008, and retain overall control of contracted COL activities as required by Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. The NRC concluded that the failure to establish a Fermi 3 QA program resulted in inadequate control of procurement documents and ineffective control of contract services performed by Black and Veatch (B&V) for COL application activities. Additionally, you failed to perform internal audits of QA programmatic areas implemented for Fermi 3 COL application activities and to document trending of your corrective action reports (CARs). These violations

are cited in the enclosed NOV and the circumstances surrounding them are described in detail in the enclosed inspection report.

You are required to provide a written explanation within 30 days of this letter in accordance with the instructions specified in the enclosed NOV. 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/

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

Docket No. 052-00033

Enclosure: 1. Notice of Violation
2. Inspection Report 05200033/2009-201

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Richard Rasmussen, Chief
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DATE	10/02/2009	10/01/2009	10/01/2009	10/02/2009
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DATE	10/02/2009	10/01/2009	10/05/2009	

NOTICE OF VIOLATION

Detroit Edison Company
One Energy Plaza
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, MI on August 18 – 21, 2009, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are described below.

- A. 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.

ENCLOSURE 1

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.

These issues have been identified as Violation 05200033/2009-201-01.

This is a Severity Level IV violation (Supplement II of the Enforcement Manual).

- B. 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).

- 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).

Pursuant to the provisions of 10 CFR 2.201, DECo is hereby required to submit a written statement or explanation 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 05200033/2009-201-01" 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 5th day of October 2009.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION & OPERATIONAL PROGRAMS
VENDOR INSPECTION REPORT

Docket No.: 05200033

Report No.: 05200033/2009-201

Applicant: Detroit Edison Company
One Energy Plaza
Detroit, MI 48226-1279

Applicant Contact: Mr. Jack Davis
Chief Nuclear Officer

Nuclear Industry: In September 2008, Detroit Edison Company (DECo) submitted an application to the U.S. Nuclear Regulatory Commission (NRC) for a Combined License (COL) for a new reactor in Monroe County, MI. The reactor design selected is the Economic Simplified Boiling Water Reactor (ESBWR).

Inspection Dates: August 18-21, 2009

Inspectors: Aida Rivera-Varona, NRO/DCIP/CQVB Team Leader
Richard McIntyre, NRO/DCIP/CQVB
Sabrina Cleavenger, NRO/DCIP/CQVB
George Lipscomb, NRO/DCIP/CQVB

Approved by: _____ Date _____
Richard Rasmussen, Chief
Quality & Vendor Branch B
Division of Construction Inspection
& Operational Programs
Office of New Reactors

EXECUTIVE SUMMARY

Detroit Edison
05200033/2009-201

This inspection focused on quality assurance (QA) policies and procedures implemented to support the Fermi Unit 3 (Fermi 3) combined license (COL) application, as described in the Nuclear Regulatory Commission (NRC) Inspection Manual Chapter 2502, "Construction Inspection Program: Pre-Combined License (Pre-COL) Phase." The purpose of this inspection was to verify that DECo had implemented an adequate QA program that complies with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," (Appendix B) to Part 50, "Domestic Licensing of Production and Utilization Facilities," of Title 10 of the *Code of Federal Regulations* (10 CFR).

During this inspection, the NRC inspectors utilized Inspection Procedure 35017, "Quality Assurance Implementation Inspection," dated July 29, 2008.

On July 9 – 11, 2007, NRC Region II, with NRO participation, conducted an audit at the Fermi 3 site. The purpose of the audit was to observe COL pre-application subsurface investigation activities being conducted to obtain geotechnical/seismic data to support the Fermi 3 COL application. The team observed in-progress COL pre-application subsurface investigation activities being performed by DECo's COL contractor, Black and Veatch (B&V). The team reviewed B&V's quality assurance measures being applied to the work. No findings were identified during the Fermi 3 site audit.

This was the first inspection of the implementation of the Fermi 3 QA program. The NRC concluded that certain DECo QA policies and procedures were not in compliance with the applicable requirements of Appendix B, as described below. Based on the results of this inspection, the NRC inspectors determined that three Severity Level IV violations of NRC requirements occurred.

QA Program

The NRC inspectors issued Violation 05200033/2009-201-01 as a result of DECo's failure to establish and implement a Fermi 3 QA program between March 2007, when the initial contract was placed with B&V for the conduct of safety-related COL activities, until February 2008, and retain overall control of these activities as required by Criterion II, "Quality Assurance Program," of Appendix B.

Control of Procurement Documents

As part of Violation 05200033/2009-201-01, the NRC inspectors concluded that DECo's failure to establish a Fermi 3 QA program resulted in the issuance of an inadequate purchase order and ineffective procurement control of contract services to B&V for COL application activities. The NRC inspectors identified the following examples: (1) the inadequate safety classification of the safety-related B&V COL application and owner's engineering (OE) contracts, and (2) the failure to impose adequate QA requirements and specify a sufficient statement of work in the OE Contract for QA oversight activities performed by B&V.

Control of Purchased Material, Equipment, and Services

As part of Violation 05200033/2009-201-01, the NRC inspectors concluded that DECo's failure to establish a Fermi 3 QA program resulted in lack of documented evidence to support the qualification of B&V for COL application and OE contract activities, and the failure of DECo to perform an annual supplier evaluation to assess B&V performance.

Audits

The NRC inspectors issued Violation 05200033/2009-201-02 as a result of DECo's failure to complete any internal audits of QA programmatic areas implemented for the Fermi 3 project.

Corrective Actions

The NRC inspectors issued Violation 05200033/2009-201-03 as a result of DECo's failure to document the trending of corrective actions to identify recurring conditions adverse to quality in the time period since the Fermi 3 project began.

Training

The NRC inspectors concluded that DECo's training and qualification program requirements and implementation for the Fermi 3 project were consistent with the regulatory requirements of Criterion II, "Quality Assurance Program," of Appendix B. The NRC inspectors did not identify any findings in this area.

REPORT DETAILS

1. Quality Assurance Program Review

a. Scope

The NRC inspectors reviewed the Detroit Edison Company (DECo) Fermi 3 QA Policy and implementing procedures that govern the quality assurance (QA) program to verify compliance with the requirements of Criterion II, "Quality Assurance Program" of Appendix B.

Specifically, the NRC inspectors reviewed the following policies and procedures established by DECo for the Fermi 3 project:

- Detroit Edison Nuclear Development (ND) Quality Assurance Program Description (QAPD), Revision 0, dated February 4, 2008.
- DECo Fermi 3 Policy: COL Quality Assurance Program Description (QAPD) During Construction and Operation, Revision 1, dated March 25, 2009.
- Fermi 3 COL FSAR, Chapter 17.5, Revision 1, dated March 2009.
- B&V Project Management Memorandum (PMM), File Number 21.1, Revision 3, dated April 28, 2008.

The NRC inspectors also reviewed previous QA program descriptions implemented prior to Revision 1 of the DECo Fermi 3 QA Policy to verify that appropriate QA program provisions were applied in support of the Fermi 3 COL application and the evolving performance of quality activities.

b. Observations and Findings

Chapter 17.5 of the Fermi 3 COL application described the QA program applied to activities performed in support of the Fermi 3 COL application, including preparation of the application by a subcontractor: B&V, Kansas City, MO. The DECo Fermi 3 COL application project, including site characterization and COL preparation, was performed under the B&V QA program, which complies with Appendix B. Chapter 17.5-2 further stated that DECo provided oversight of the contracted activities by way of procurement control, control of purchased services, and oversight/surveillances of those activities and services. DECo oversight and control of contracted activities is discussed in sections 2 and 3 of this report.

As of March 25, 2009, DECo has been implementing Revision 1 of the Fermi 3 QA Policy. Revision 0 of the Fermi 3 QA Policy was issued for use on September 18, 2008.

Prior to its submission of Revision 0 of the Fermi 3 QA Policy, DECo had implemented the DECo ND QAPD for Fermi 3 COL activities. This was a top-level policy document that established the manner in which quality was to be achieved for COL application

activities and presented DECo's overall philosophy regarding achievement and assurance of quality. During the review of Section 17.5 of the COL application, the NRC staff noted that Section 17.5 of the COL application did not include a copy of the ND QAPD that DECo implemented prior to Revision 0 of the Fermi 3 QA Policy. DECo's 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). Please Refer to RAI 17.5-1.

Upon review of the initial procedures developed by DECo to implement the ND QAPD, the NRC inspectors found that most procedural controls for Fermi 3 QA activities were not established and implemented until February 2008, to coincide with the initial issuance of the ND QAPD. The NRC inspectors noted that prior to February 2008, no DECo QA program and procedural controls were established for QA activities implemented by DECo for the Fermi 3 project to ensure that DECo maintained overall QA program responsibility for safety-related activities and performed the requisite QA oversight of contracted activities.

The NRC inspectors discussed the DECo QA program development with DECo senior management to gain a better understanding of how the QA program was developed and implemented during the early stages of Fermi COL application activities. 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.

Between March 2007, when the initial contract was placed with B&V for the conduct of COL activities, until the issuance of the ND QAPD in February 2008, DECo stated that it relied on the B&V QA program for COL application activities. As described in Chapter 17.5 of the Fermi 3 FSAR, the B&V QA Program invoked the applicable requirements of the Appendix B and 10 CFR Part 21. The B&V QA Program also allowed for project specific procedures, that were used to identify which activities in the project required the application of the B&V QA Program and which were able to be performed under the B&V commercial quality assurance program.

The NRC inspectors found that for the time period between March 2007, when the initial contract was placed with B&V for the conduct of pre-COL activities, until February 2008, all of the DECo QA program responsibilities were delegated to B&V, and DECo did not retain overall programmatic control of these contract services under any documented QA program. The failure for DECo to have a documented QA Program in place for Fermi 3 COL application activities performed prior to February 2008, and control and retain oversight of B&V contracted activities and has been identified as part of Violation 05200033/2009-201-01.

c. Conclusions

As identified in Violation 05200033/2009-201-01, the NRC inspectors concluded that DECo failed to implement a QA program for Fermi 3 COL application activities conducted between March 2007 and February 2008. DECo did not meet the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50 in that DECo failed to (1) have a documented Fermi QAPD in place prior to February 2008; and (2) retain overall control of QA activities, including the oversight of contracted COL application activities.

DECo's failure to submit the DECo ND QAPD, which was implemented in February of 2008, to the NRC for review and approval, has been captured in RAI 17.5-1.

2. Control of Procurement Document

a. Inspection Scope

The NRC inspectors reviewed DECo policies and procedures governing procurement document control to verify compliance with the QA requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors assessed how those guidelines have been applied to the DECo Fermi 3 COL application activities. The NRC inspectors focused on Fermi 3 supplier contracts issued in support of Fermi 3 COL application activities, including the Fermi 3 FSAR.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following contracts, procedures and records:

- DECo ND QAPD, Revision 0, dated February 4, 2008.
- DECo NP 4.1, "Procurement of Services," Revision 0, dated February 4, 2008.
- DECo NP 4.1, "Procurement of Services," Revision 1, dated August 7, 2009.
- DECo Request for Proposal (RFP) number DECO-06023 for Combined Construction & Operating License Services, dated January 12, 2007.
- DECo RFP number DECO-06024 for Owner's Engineer Services, dated January 24, 2007.
- B&V proposal number 902468.7010.005 for Combined Construction & Operating License Services, dated February 2, 2007 (B&V Proposal).
- DECo contract number 4400000082 with B&V for COL application development (COL application contract), dated March 5, 2007.
- DECo contract number 4400000137 with B&V for owners engineer activities (OE contract), dated April 5, 2007.
- B&V Project Management Memorandum (PMM) number 147483, "Detroit Edison (Fermi Site) COL application Preparation," Revision 3, dated April 28, 2008 (B&V COL application PMM).
- B&V PMM number 147885, "Detroit Edison Nuclear Development Program Owners Engineer Services," Revision 2, dated May 7, 2008 (B&V OE PMM).
- B&V Work Scope, Estimates and Schedules for Detroit Edison Owner's Engineer (OE) Services (Tasks #1-9), dated October 19, 2007.

b. Observations and Findings

The NRC inspectors reviewed DECo's implementing procedures that govern the control of procurement documents that were utilized to issue and control the COL application contract and OE contract.

As noted in Section 1 of this inspection report, the NRC inspectors noted that no DECo Fermi 3 QA program had been implemented since March 2007, including procurement implementing procedures. DECo personnel informed the NRC inspectors that a management decision was made to fully separate the existing Fermi Unit 2 program from the Fermi 3 project. As a result, existing Fermi Unit 2 procedures were not utilized for Fermi 3 procurement activities.

The NRC inspectors reviewed the COL application and OE contracts signed in March and April 2007, respectively, with B&V in support of COL application activities. One contract was issued to B&V of Kansas City (B&V-KC) for COL application activities and another to B&V of Michigan (B&V-MI) for OE services, which included oversight of COL application activities performed by B&V-KC.

The NRC inspectors found that both contracts 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. The failure of DECo to adequately classify and process the contracts with B&V under an Appendix B QA program is an example identified as part of Violation 05200033/2009-201-01. DECo opened Corrective Action Report (CAR) 1544889 to document this issue.

b.1 Procurement Documents Quality and Technical Requirements

The NRC inspectors reviewed the COL application and OE contracts to verify that DECo had adequately imposed Appendix B and 10 CFR Part 21 requirements on B&V for safety-related work. The NRC inspectors found that neither contract directly specified or imposed these requirements on B&V.

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. However, the contract did not specify any regulation in particular. The NRC inspectors noted that the B&V Contract Proposal, and the subsequently developed B&V COL application PMM, specified which Fermi 3 COL application activities had to be performed under the B&V Nuclear QA Program (Appendix B QA program) and which had to be performed under the B&V Commercial QA Program. Both QA programs were maintained by B&V and were not reviewed by the NRC inspectors during this inspection.

The NRC inspectors noted that during July 9 - 11, 2007, NRC Region II staff, with NRO participation, conducted an audit at the Fermi site. The purpose of the audit was to

observe COL pre-application subsurface investigation activities being conducted by B&V to obtain geotechnical/seismic data to support the Fermi COL application. During this audit, the NRC team reviewed B&V's quality assurance measures being applied to site characterization activities being conducted. The NRC team concluded that the work was being done in an appropriately controlled manner, and no findings were identified during the audit.

The NRC inspectors found that the OE contract did not impose any specific QA requirements on B&V-MI. Additionally, the NRC inspectors noted that the B&V OE PMM did not specify which B&V QA program would govern the B&V OE contract activities. DECo's failure to adequately impose QA requirements on B&V in the OE contract for oversight activities has been identified as part of Violation 05200033/2009-201-01.

The NRC inspectors reviewed the COL application and OE contracts with B&V to verify the statement of work and technical requirements for each of the contracts. The NRC inspectors noted that the COL application contract provided a broad statement of work for B&V-KC by stating that the contractor shall provide all services necessary to develop a COL application to be submitted to the NRC. The COL application contract further directed B&V to provide support and services as outlined in the B&V Proposal. The NRC inspectors reviewed portions of the B&V Proposal and noted that it included a detailed scope, technical requirements, and adequately classified safety-related work for which the B&V Nuclear QA Program was required to be implemented. Although DECo only indirectly imposed the requirements on B&V by referencing the B&V Proposal in the COL application contract, the NRC inspectors did not identify any issues with the COL application contract scope of work and technical requirements.

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. Additionally, the NRC inspectors noted that the OE contract stated that any services would be requested by a separate purchase order (PO) containing a statement of work.

DECo personnel indicated that B&V OE activities were typically discussed during meetings, and formal documentation was not available for inspector review. DECo's failure to adequately document and issue a separate PO that included the statement of work to B&V for the oversight activities has been identified as part of Violation 05200033/2009-201-01.

b.2 Policies and Procedures for Control of Procurement Activities

DECo procedure NP 4.1, Revision 0, was applicable to COL application preparation activities that required application of the DECo ND QAPD which also became effective in February 2008. The NRC inspectors noted that NP 4.1, Revision 0, was limited to changes to the COL application contract or the OE contract since those were the only activities that DECo expected to take place at that time.

Additionally, the NRC inspectors reviewed NP 4.1, Revision 1 that was also applicable to changes to the contract with B&V for safety-related COL application preparation activities. DECo personnel informed the NRC inspectors that the procedure would be modified to accommodate any future changes in Fermi 3 project activities (e.g., procurement of long lead components). The NRC inspectors found that procedure

NP 4.1, Revision 1, was a high-level document which provided general information such as general responsibilities and general guidance for the scope of activities that have been conducted to date in support of the Fermi 3 project. The NRC inspectors did not identify any issues in this area.

c. Conclusions

Since February 2008, the Fermi 3 policies and procedures governing procurement of services were limited to changes to current contracts with B&V and general policy guidance. However, the NRC inspectors concluded that DECo had established program requirements consistent with the regulatory requirements of Criterion IV, "Control of Procurement Documents," of Appendix B to 10 CFR Part 50 for the scope of activities that have been conducted in support of the Fermi 3 project with the following exception.

As described in Sections 1 and 2 of this inspection report, prior to February 2008, DECo failed to establish and implement a Fermi 3 QA program, which resulted in inadequate PO issuance and ineffective procurement control of contract services to B&V for COL application activities. Examples include: (1) the inadequate safety classification applied to the safety-related B&V COL application and OE contracts; and (2) the failure of the PO to impose required QA requirements and provide sufficient statement of work to clearly define supplier requirements within the OE contract. These examples have been identified as part of Violation 05200033/2009-201-01.

3. Control of Purchased Material, Equipment, and Services

a. Inspection Scope

The NRC inspectors reviewed DECo policies and implementing procedures governing control of purchased material, equipment, and services to verify compliance with the QA requirements of Criterion VII of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors assessed how those guidelines have been applied to the Fermi 3 COL application supplier qualification and oversight activities. The NRC inspectors focused on the initial DECo's qualification of B&V, and DECo's oversight activities of B&V COL application and OE activities.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following contracts, procedures and records:

- DECo ND QAPD, Revision 0, dated February 4, 2008.
- DECo NP 7.1, "Supplier Audits, Surveillances, and Commercial Grade Surveys," Revision 0, effective August 7, 2008.
- DECo's and B&V's Surveillance Reports:
 - 07SR001 dated July 3, 2007;
 - 07SR002 dated August 1, 2007;
 - 07SR003 dated August 23, 2007;
 - 07SR004 dated September 6, 2007;
 - 07SR005 dated October 19, 2007;

- 07SR006 dated September 26, 2007;
 - 08SR001 dated May 16, 2008; and
 - 08SR002 dated June 13, 2008.
- DECo Audit Plan for B&V Audit, dated July 14, 2009.
 - DECo Audit Report Number 09NS01 for B&V, dated August 7, 2009.

b. Observations and Findings

b.1 Policies and Procedures for Qualification and Control of Suppliers

The NRC inspectors reviewed the DECo policies and procedures that govern the qualification and control of suppliers to verify the adequacy of the implementing procedures utilized to qualify and control B&V for the activities associated with the COL application contract and OE contract.

The NRC inspectors reviewed NP 7.1 and found that the procedure provided both high-level guidance and specific controls for performance of external audits and surveillances. The procedure also contained high-level guidance for the evaluation and use of third party audits to include their use for supplier qualification. The DECo QA manager also indicated to the NRC inspectors that the procedure would be modified to accommodate any future changes in Fermi 3 project activities.

b.2 B&V Qualification

When, the NRC inspectors requested DECo to provide the initial supplier qualification records that led to the qualification of B&V for the COL application and the OE contracts for their review, DECo personnel informed the NRC inspectors that audits from other utilities were utilized to qualify B&V for the initial contracts issued in early 2007. Additionally, DECo personnel provided the B&V Proposal in which B&V stated that they had recently been audited and found acceptable by other US nuclear utilities.

The NRC inspectors requested documentation of the DECo review of these audits as part of the supplier qualification process. DECo personnel indicated that formal QA qualification documentation was not performed, and no other evaluation documentation was provided by the end of the inspection.

The NRC inspectors found that, although the use of a third party audit as a method of initial placement on the ASL was acceptable, DECo lacked the required documentary objective evidence to justify B&V's initial qualification in early 2007. The failure of DECo to adequately document the qualification of B&V to perform COL application activities has been identified as part of Violation 05200033/2009-201-01.

b.3 Oversight Activities and Supplier Annual Evaluations

The NRC inspectors requested all Fermi 3 audits, surveillances, and annual evaluations of B&V. The NRC inspectors were provided eight surveillances of Fermi 3 site characterization and COL application activities between July 2007 and June 2008, and one audit conducted by DECo personnel in July 2009.

Five of the eight surveillances were conducted by B&V-MI personnel between July 2007 and June 2008 to observe site activities conducted by sub-contractors to B&V-KC.

The NRC inspectors noted that B&V-MI personnel conducted two programmatic surveillances in September and October 2007. One surveillance verified QA program implementation by a sub-supplier during site characterization activities, while the other surveillance verified the COL application development by B&V-KC. The NRC inspectors also reviewed a surveillance of COL application development at B&V-KC performed in May 2008 by DECo personnel.

The NRC inspectors reviewed the August 2009 audit that was conducted by qualified DECo QA personnel at BV-KC using Revision 14 of the NUPIC Audit Checklist. The audit was limited to COL application development. The NRC inspectors noted that the audit included objective evidence to support the conclusions.

With regards to annual supplier evaluations, DECo personnel informed the NRC inspectors that the surveillances were utilized to assess supplier performance, but no documentation of an annual evaluation was available for review. The failure of DECo to adequately perform and document an annual supplier evaluation has been identified as part of Violation 05200033/2009-201-01.

c. Conclusion

Since February 2008, the Fermi 3 policies and procedures governing procurement of services have been limited to performance of external audits and surveillances. However, the NRC inspectors concluded that DECo had established program requirements consistent with the regulatory requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 for the scope of activities that have been conducted in support of the Fermi 3 project with the following exception.

DECo failed to establish and implement a Fermi 3 QA program between March 2007, when the initial contract was placed with B&V for the conduct of safety-related COL activities, and February 2008, which resulted in DECo's ineffective control of contract services provided by B&V for COL application activities. Examples include: (1) failure to adequately document the qualification of B&V to perform COL application activities; and (2) failure to adequately perform and document an annual supplier evaluation. The NRC inspectors concluded that, during this period, the Fermi 3 policies and procedures for the qualification and control of suppliers did not meet the QA requirements of Criterion VII of Appendix B to 10 CFR Part 50. These findings have been identified as part of Violation 05200033/2009-201-01.

4. Audits

a. Scope

The NRC inspectors reviewed the DECo Fermi 3 QA Policy and implementing procedures that govern the process for internal audits to verify compliance with the requirements of Criterion XVIII, "Audits" of Appendix B to 10 CFR Part 50.

Specifically, the NRC inspectors reviewed the following policies and procedures established by DECo for the Fermi 3 project:

- DECo Fermi 3 Policy: COL Quality Assurance Program Description During Construction and Operation, Section 18, Audits, Revision 1, dated March 25, 2009.
- DECo NP 18.1, "Audits (Internal)," Revision 1, dated August 7, 2009.

No internal audits had been performed to date for review of internal audit implementation.

b. Observations and Findings

Section 18 of the Fermi 3 QA Policy established requirements for the performance of internal audits to verify that all activities covered under the DECo QA Policy were performed in accordance with applicable requirements. The policy stated, "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 was also stated in NP 18.1. However, the NRC inspectors found that DECo failed to complete any internal audits of QA programmatic areas implemented to date for the Fermi 3 project. This failure to perform annual audits of QA program implementation has been identified as Violation 05200033/2009-201-02.

Procedure NP 18.1 provided responsibilities for personnel involved in audits and for the maintenance of the audit procedure. The procedure also described DECo processes for audit scheduling, conduct, checklist development and use, reporting, and follow-up.

Procedure NP 18.1 also required that an audit schedule be prepared and maintained by the Director of Quality Management (DQM). DECo furnished an Audit Schedule dated August 6, 2009, which identified planned audits of QA program implementation for the Nuclear Development Organization and the Nuclear Quality Management Organization for October 2009 and November 2009, respectively. Prior to the August 6, 2009, Schedule, no prior audit schedule had been prepared for DECo QA activities.

During the inspection, DECo opened CAR 1544905 to evaluate the timeliness of internal audits.

c. Conclusions

With the exception of the issues identified in Violation 05200033/2009-201-02, the NRC inspectors concluded that DECo's audit program requirements and implementation for the Fermi 3 project were consistent with the regulatory requirements of Criterion XVIII "Audits," of Appendix B to 10 CFR Part 50.

4. Corrective Action Program

a. Scope:

The NRC inspectors reviewed the DECo Fermi 3 QA Policy and implementing procedures that govern corrective actions to verify compliance with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. The NRC inspectors also reviewed a sample of CARs to assess DECo's implementation of the corrective action program.

Specifically, the NRC inspectors reviewed the following policies and procedures established by DECo for the Fermi 3 project:

- DECo Fermi 3 Policy: COL Quality Assurance Program Description During Construction and Operation, Section 16, "Corrective Action," Revision 1, dated March 25, 2009.
- DECo NP 16.1, "Corrective Action Program," Revision 0, dated February 4, 2008.
- DECo NP 16.1, "Corrective Action Program," Revision 1, dated August 4, 2009.

b. Observations and Findings:

Section 16 of the Fermi 3 QA Policy identified the requirement for Fermi 3 personnel to identify conditions adverse to quality and to document and report significant conditions adverse to quality. The Policy also identified the applicability of 10 CFR Part 21 to defects and noncompliances in safety-related activities and services performed by Fermi 3 and suppliers/sub-suppliers to Fermi 3.

Procedure NP 16.1 provided instructions for the administration of the Fermi 3 Nuclear Development Corrective Action Program, including the identification, documentation, classification, resolution, reporting, and trending of undesirable conditions and opportunities for improvement. The procedure described the Fermi 3 process for the initiation, assignment, review, and closure of CARs, including the review of potential defects and noncompliances for 10 CFR Part 21 applicability.

Procedure NP 16.1 set forth timelines for closure of CARs based on a numerical priority ranking from 1-5 that was assigned to each CAR based on its urgency. The time spans established for completion of corrective actions ranged from 30-180 days, and measures were established for requesting and documenting extensions to closure dates for CARs that exceeded their targeted closure date.

The NRC inspectors examined the log of CARs issued for Nuclear Development activities at DECo for the past two years and verified that CARs were generally closed within the applicable timelines specified in NP 16.1 (only one of the 29 CARs issued to date exceeded its target date). The NRC inspectors also verified that corrective actions identified in a sample of CARs were sufficient to address the conditions identified.

Procedure NP 16.1 stated that the Director of Quality Management “is responsible for trending corrective actions to determine if there are adverse trends that require management attention.” The NRC inspectors found that, as of the date of the inspection, no trending had been documented by DECo personnel to identify recurring conditions adverse to quality for the Fermi 3 project. The Director of Quality Management indicated, in a discussion with the NRC inspectors, that DECo had performed CAR trending during the weekly meeting of the Nuclear Development Review Committee (NDRC). Procedure NP 16.1 identified that the NDRC reviews resolved CARs weekly to verify that all actions are completed and implemented; however, the procedure did not specify that a discussion of historical CARs takes place during these meetings for trending purposes. The lack of documented evidence to confirm that the trending of CARs had taken place during the Fermi 3 COL application process has been identified an example of Violation 05200033/2009-201-03.

c. Conclusions:

With the exception of the issues identified in Violation 05200033/2009-201-03, the NRC inspectors concluded that DECo’s corrective action program requirements and implementation for the Fermi 3 project were consistent with the regulatory requirements of Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50.

6. Training

a. Scope:

The NRC inspectors reviewed the DECo Fermi 3 QA Policy and implementing procedures that govern personnel training to verify compliance with the requirements of Criterion II, “Quality Assurance Program,” of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors verified that DECo adequately implemented and maintained personnel training and qualification processes to assure that proficiency was achieved and maintained by DECo personnel supporting the Fermi 3 project.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following policies and procedures:

- DECo NP 2.1, “Training,” Revision 0, dated February 4, 2008.
- DECo NP 2.2, “Auditor/Lead Auditor Qualification,” Revision 0, dated March 24, 2008.
- DECo NP 18.2, “Surveillance,” Revision 0, dated March 24, 2008.

The NRC inspectors also reviewed a sample of personnel training records to verify that qualification and training were achieved and maintained.

b. Observations and Findings:

Procedure NP 2.1 identified the training requirements for orientation/indoctrination and continuing training of Nuclear Development Project (NDP) personnel. NP 2.1 stated that NDP personnel should be trained in regulatory requirements, codes, and standards as they relate to the employee’s particular function, QA program elements, procedures, and

job responsibilities and authority. The procedure specified that this training should be documented on an NDP Training Plan and should be completed prior to the employee performing nuclear work.

The NRC inspectors identified that the NP 2.1 Training Plan template (which provided specific reading assignments based on DECo guidance documents) had not been kept up to date with the latest procedure revisions. However, in order to keep employees training updated on the current DECo policies, continuing training was performed for NDP staff.

The NRC inspectors verified, for a sample of employees, that NDP personnel (1) were trained in the requirements of NP 2.1, (2) had completed the applicable training in a timely fashion and prior to completing nuclear work per the procedural requirements, and (3) all training was documented on NDP Training Plans or, for continuing training, on Training Attendance Rosters.

Procedure NP 2.2 established the DECo requirements for auditor and lead auditor qualification and asserted that each auditor must be qualified before working independently. The procedure required that qualification be documented on a form titled "Record of Auditor/Lead Auditor Qualification" and, for auditors include familiarization with ASME NQA-1 and the DECo audit procedure, training in audit performance, and on-the-job training and guidance under a lead auditor. For lead auditors, NP 2.2 qualification requirements included participation in at least 5 QA audits in the 3 years prior to qualification, a qualification examination, documented certification, and maintenance of proficiency, which is documented through an annual assessment memo.

For the Fermi 3 project, DECo has had only two auditors on staff, both qualified as lead auditors. The NRC inspectors were able to verify that both individuals had been certified as lead auditors and had maintained proficiency, as documented on records of annual evaluations.

Procedure NP 18.2 described the qualification requirements for personnel performing NDP surveillance activities. Surveillance specialists were qualified based on recommendation from a project discipline engineer and surveillance training. NP 18.2 identified that a lead auditor is qualified to perform surveillances based on their qualifications as a lead auditor.

The NRC inspectors verified that DECo personnel who had performed surveillance activities had the proper, documented qualifications. Specifically, one DECo employee who was qualified as a lead auditor had performed two surveillances for the Fermi 3 project. No other personnel had been qualified as surveillance specialists as of the date of the inspection.

c. Conclusions:

The NRC inspectors concluded that DECo's training and qualification program requirements and implementation for the Fermi 3 project were consistent with the regulatory requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. The NRC inspectors did not identify any findings in this area.

7. Entrance and Exit Meetings

On August 18, 2009, the NRC inspectors presented the inspection scope during an entrance meeting with DECo Director of Quality Management, Stan Stasek, and other DECo personnel.

On August 21, 2009, the NRC inspectors presented the inspection results during an exit meeting with DECo Senior Vice President, Ron May, and other DECo personnel.

See Attachment 1 for a list of attendees for the entrance and exit meetings.

Fermi - Mailing List

(Revised 07/13/2009)

cc:

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ATTACHMENT 1

1. PERSONS CONTACTED

Name	Department/Organization	Entrance Meeting	Exit Meeting	Contacted
Aida Rivera-Varona	NRC	√	√	
Richard McIntyre	NRC	√	√	
Sabrina Cleavenger	NRC	√	√	
George Lipscomb	NRC	√	√	
Ron May	Senior Vice President – Enterprise Projects		√	
Dave Hardwood	Director – Nuclear Development		√	
Stanley Stasek	Director – Quality Management, DECo	√	√	√
Jerry Bragg	Quality Assurance Auditor	√	√	√
Peter Smith	Director – Nuclear Licensing and Engineering, DECo		√	√
LaShawn Green	Supervisor – Engineering and Licensing, DECo	√	√	
Joe La Prad	Licensing Engineer, DECo	√	√	√
William Miller	Nuclear Development	√		
Norm Peterson	Consultant, DECo	√		
Tannis Cummings	Principal Analyst - Customer Services Program Management, DECo			√
Michelle Underwood	Strategic Supply Category Manager, DECo			√
Rob Ziembiec	Procurement Operations Manager, DECo			√
Steve Thomas	Engineering Manager, B&V	√	√	
Art Layfield	Project Quality, B&V	√	√	

2. INSPECTION PROCEDURES USED

Inspection Procedure 35017, “Quality Assurance Implementation Inspection,” dated July 29, 2008

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
05200033/2009-201-01	Opened	NOV	Criterion II
05200033/2009-201-02	Opened	NOV	Criterion XVIII – Failure to complete any internal audits of QA programmatic areas implemented to date for the Fermi 3 project
05200033/2009-201-03	Opened	NOV	Criterion XVI – Failure to document trending of CARs.