

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of)
)
DTE ELECTRIC COMPANY) Docket No. 52-033-COL
)
(Fermi Nuclear Power Plant, Unit 3))

WRITTEN DIRECT TESTIMONY OF GEORGE A. LIPSCOMB
CONCERNING THE STAFF'S REVIEW OF THE FERMI 3
QUALITY ASSURANCE PROGRAM
AS IT RELATES TO CONTENTION 15

Q1. Please state your name, occupation, and by whom you are employed.

A1. My name is George A. Lipscomb. I am an electrical engineer with the Office of New Reactors (NRO) at the US Nuclear Regulatory Commission (NRC). In my current position, I am primarily a Quality Assurance (QA) inspector, but also have technical reviewer responsibilities, both supporting the activities of the Construction Electrical Vendor Branch (CEVB) in the Division of Construction Inspection and Operational Programs (DCIP). The CEVB organization and its predecessor organizations, Quality and Vendor Branch A (CQVA) and Quality and Vendor Branch B (CQVB), support NRC Combined License Application (COLA) QA reviews and inspections to verify applicant compliance with regulatory requirements. A statement of my professional qualifications is attached hereto as Exhibit NRC S17.

Q2. Please describe your responsibilities in relation to this review.

A2. I have served in several capacities related to the QA review of the Fermi 3 application. I was the lead technical reviewer for Chapter 17.5 of the Fermi 3 COLA Final Safety Analysis

Report (FSAR). I was an inspection team member of the August 2009 QA implementation inspection of DTE Electric Company (DTE of Applicant) in Detroit, Michigan. Finally, I was also an inspection team member of the September 2010 vendor inspection of Black & Veatch (B&V) in Overland Park, Kansas.

Q3. Please describe your professional qualifications as they relate to this review.

A3. I have participated in QA review activities on two COL applications in the past four years—one full COL application as the lead reviewer and one acceptance review. I have also reviewed multiple industry or NRC regulatory guidance technical documents in my capacity as a technical reviewer during the same period. Currently, I am the lead technical reviewer on a first-of-a-kind industry software commercial-grade dedication (CGD) guide that is being considered for NRC endorsement.

Prior to my employment at the NRC, I managed multiple U.S. Navy aviation QA programs as an operational squadron QA officer and as a training squadron safety department head. Both positions required inspection and maintenance of QA standards and programs.

Q4. What is the purpose of this testimony?

A4. The purpose of this testimony is to provide a summary of the Staff's activities related to resolution of the issues presented in Contention 15. These include (1) review of the Fermi 3 combined license application (COLA); (2) resolution of QA violations cited following a Staff inspection of DTE in August 2009; (3) resolution of Requests for Additional Information regarding the QA programs in place during COLA development; and (4) inspection of DTE's contractor B&V.

Q5. Are you familiar with Contention 15?

A5. Yes.

Q6. Are you familiar with the materials filed by the Intervenor in connection with Contention 15?

A6. Yes.

Q7. Are you familiar with the Applicant's QA programs as related to Contention 15?

A7. As the technical reviewer for Section 17.5 in Chapter 17 of the Staff SER, I am familiar with the Applicant's Quality Assurance Program Description (QAPD) in the Fermi 3 COLA and with the Nuclear Development Quality Assurance Program Description (ND QAPD) that was in place prior to submittal of the Fermi 3 COLA. In that capacity and in my capacity as a QA inspector, I am also familiar with the Applicant's responses to Staff Notices of Violation (NOVs) and Requests for Additional Information (RAIs), as described in the exhibits listed below.

Q8. What documents did you rely on in preparing this testimony?

A8. I relied on the following documents in preparing this testimony:

- Exhibit NRC S1 – Chapter 17 of the Advanced Safety Evaluation Report (SER) With No Open Items (Oct. 17, 2011), ADAMS Accession No. ML112630120.
- Exhibit NRC S2 – NRC Inspection Report 05200033/2009-201 and Notice of Violation (Oct. 5, 2009) (October 2009 NOV), ADAMS Accession No. ML092740064.
- Exhibit NRC S3 – Detroit Edison Reply to a Notice of Violation 05200033/2009-201-01, 02, and 03 (Nov. 9, 2009) (Reply to October 2009 NOV), ADAMS Accession No. ML093160318.
- Exhibit NRC S4 – 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 (Apr. 27, 2010) (April 2010 NOV), ADAMS Accession No. ML100330687.
- Exhibit NRC S5 – Detroit Edison Company Reply to Notice of Violation 05200033/2009-201-04 (May 26, 2010) (Reply to April 2010 NOV), ADAMS Accession No. ML101480046.
- Exhibit NRC S6 – Nuclear Regulatory Commission Inspection Report 05200033/2009-201 and Revised Notice of Violation to Detroit Edison Company (June 4, 2010) (DTE NOV Closure Letter), ADAMS Accession No. ML101530596.

- Exhibit NRC S7 – Detroit Edison Company Response to NRC Request for Additional Information Letter No. 26, Related to SRP Section 17.5 (May 10, 2010) (May 2010 RAI Responses), ADAMS Accession No. ML101320254.
- Exhibit NRC S8 – Letter from Mark S. Lesser, Division of Construction Inspection, NRC, to Douglas R. Gipson, DTE, Audit of Combined License Pre-Application Subsurface Investigation Activities at Fermi (Project No. 757) (Aug. 8, 2007) (2007 B&V Audit Report), ADAMS Accession No. ML072210911.
- Exhibit NRC S9 – NRC Inspection Report No. 99901391/2010-201 and Notice of Violation (Oct. 14, 2010) (2010 B&V Inspection Report), ADAMS Accession No. ML102790137.
- Exhibit NRC S10 – NRC Inspection Report No. 99901391/2010-201 and Notice of Violation (Dec. 17, 2010) 2010 B&V (2010 B&V Inspection Letter), ADAMS Accession No. ML103500064.
- Exhibit NRC S11 – Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition (NUREG-0800) (March 2007), Section 17.5, ADAMS Accession No. ML063190019.
- Exhibit NRC S12 – Final Safety Evaluation for Technical Report NEI 06-14, “Quality Assurance Program Description,” Revision 9 (July 13, 2010) (SER for NEI 06-14), ADAMS Accession No. ML101800497.
- Exhibit NRC S13 – NEI 06-14A [Revision 7], “Quality Assurance Program Description” (August 2010), ADAMS Accession No. ML102370305.
- Exhibit NRC S14 – NRC Enforcement Policy (Jan. 28, 2013), pp. 8-11, ADAMS Accession No. ML12340A295.

The first three of these exhibits were introduced into the record of this proceeding by other witnesses. I hereby introduce the remaining documents, Exhibits NRC S4 through S14, into the record of this proceeding.

Q9. What regulations govern QA in a COL application?

A9. The NRC’s regulations governing QA are found in Appendix B of 10 C.F.R. Part 50. 10 C.F.R. § 52.79(a)(25) requires a COL applicant to include a description of its QA program, including how the program complies with Appendix B, in its COLA.

Q10. Is there applicable QA guidance available for applicants preparing their applications and for Staff in conducting its review?

A10. Regulatory Guide 1.206, Combined License Applications for Nuclear Power Plants (LWR Edition),” section C.I.17.5, “Quality Assurance Program Guidance,” provides applicants with information on how to prepare the portions of their application related to QA. The primary guidance for Staff reviewers evaluating an applicant’s QAPD is found in the Section 17.5 of the Standard Review Plan (SRP), which is attached hereto as Exhibit NRC S11. In addition, the Staff has approved Technical Report NEI 06-14A, Revision 7, as an acceptable template for a COL applicant’s QA program. The Staff’s safety evaluation of NEI 06-14 and the current approved version designated NEI 06-14A, Revision 7, are attached hereto as Exhibits NRC S12 and S13.

Q11. Please say more about the relevance of NEI 06-14 to the Staff QA review of COL applications.

A11. The Nuclear Energy Institute (NEI) is a nuclear energy industry organization. One of its activities is to develop proposed guidance that it considers adequate for nuclear power plant licensees and license applicants to meet NRC regulations. On some topics, this guidance includes specific “template” language that can be included in a license application. The Staff evaluates NEI templates to determine if applications based on those templates would meet applicable NRC regulations. Staff safety evaluations of NEI templates are found in their own SERs, separate from the SERs prepared in specific licensing cases. Once accepted by the NRC Staff, NEI templates have the status of guidance and represent an NRC-endorsed method an applicant may use to demonstrate compliance with applicable NRC regulations. As discussed below, NEI 06-14 has been accepted by the NRC Staff for use by COL applicants.

Q12. Are there other steps in the Staff review?

A12. Once the Staff has received a COL application and accepted it for docketing, the Staff formulates questions about the application's content and submits them to the applicant in the form of Requests for Additional Information (RAIs). The applicant responds to RAIs in writing, on the docket of the proceeding, and if necessary includes proposals for changing the COLA to address Staff concerns. The Staff may also conduct inspections and audits of an applicant or its contractors if it wishes to inspect items not on the docket of the proceeding in addition to items formally submitted to the NRC.

Q13. Where is the Staff's QA review for the Fermi 3 COL application documented?

A13. The NRC Staff review of Chapter 17.5 of the Fermi 3 COLA FSAR provides an assessment of the Fermi 3 QA program, including the QA program that is applicable during the design, construction, and operations phases of a nuclear power plant, and is documented in Chapter 17 of the Staff's Safety Evaluation Report (SER) dated October 17, 2011 (Exhibit NRC S1).

Q14. What was the Staff's conclusion about the Fermi 3 QA program?

A14. Section 17.5.4.22 of the Staff's SER draws the following conclusions. First, for activities prior to September 18, 2008 (the date the Fermi 3 COLA was submitted to the NRC), "the applicant has provided adequate assurance that the requirements of Appendix B have been met for safety-related activities supporting the Fermi 3 COL application." Second, for activities after September 18, 2008, "the applicant has provided adequate assurance that the Fermi 3 project has met the requirements of Appendix B." Finally, the Applicant has adequately resolved all NRC Staff Chapter 17.5 RAIs.

Q15. Does the Staff agree with the Intervenors that the Fermi 3 QA program is insufficient to “govern the design, construction, and operation of Fermi Unit 3 in conformity with all relevant NRC regulations”?

A15. No. As described below, the Staff has found the Applicant’s QA program to be in compliance with Appendix B of 10 C.F.R. Part 50 and has determined that all QA implementation issues are resolved.

Q16. Please describe how this testimony is organized.

A16. The following testimony is organized in four categories. My responses to Questions 17-18 address the Staff’s review of the QA program in the Fermi 3 COLA. My responses to Questions 19-24 address the Staff’s August 2009 inspection of the Applicant, the violations for which the Applicant was cited, and related follow-up. My response to Question 25 addresses QA issues prior to September 18, 2008, that were resolved through the RAI process. Finally, my responses to Questions 26-27 address audits and inspections of the Applicant’s contractor B&V.

Q17. How was the Staff’s review of the QA program in the Fermi 3 application conducted?

A17. The Staff’s review of the QA program was conducted as outlined in Section 17.5.4 of the SER (Exhibit NRC S1), which describes the NRC guidance used for reviewing the Fermi 3 COLA FSAR, Chapter 17.5. The Staff followed the guidance of NUREG-0800 Section 17.5 (Exhibit NRC S11), the Standard Review Plan (SRP) for QA Program Descriptions (QAPDs) submitted by applicants. As described in the SER, the Staff developed the guidance in Section 17.5 of the SRP using American Society of Mechanical Engineers (ASME) NQA-1–1994, “Quality Assurance Requirements for Nuclear Facility Applications,” supplemented by additional regulatory and industry guidance for nuclear operating facilities. ASME NQA-1 is a well

established consensus industry QA standard that provides detailed instructions to applicants on how to meet higher-level regulatory requirements.

Chapter 17.5 of the Fermi FSAR states that the Fermi 3 QAPD is based on NEI 06-14, commonly referred to as the “NEI QA Template.” The Staff specifically compared the Fermi 3 QAPD against NRC Staff-endorsed versions of NEI 06-14, which are indicated by the use of an ‘-A’ designation in the template title (e.g., NEI 06-14A). During the period of the Fermi 3 FSAR review and related inspections, NEI 06-14 was also being updated by NEI and reviewed by the Staff. The Staff’s safety review of the revised version of NEI 06-14 and the most recent NRC-endorsed version of the template itself, designated NEI 06-14A, Revision 7, are attached hereto as Exhibits NRC S12 and S13. Both were issued in 2010.

The initial version of the Fermi 3 COLA, submitted in 2008, was based on an earlier version of NEI 06-14, designated NEI 06-14A, Revision 5. The final reviews of the Fermi 3 QAPD used NEI 06-14A, Revision 7, issued in August 2010 (Exhibit NRC S13). Between 2008 and 2010, the Applicant made a number of changes to FSAR Chapter 17.5 in response to Staff RAIs issued to reflect changes to NEI 06-14, and I was responsible for reviewing these changes and ensuring that they were reflected in the Staff evaluation in SER Chapter 17. NEI 06-14A, Revision 7, is the version that the Applicant referenced in its February 2011 updates to the Fermi 3 FSAR and QAPD.

I note that NEI designates the draft version of NEI 06-14A, Revision 7, as NEI 06-14, Revision 9, and the Staff’s SER approving the latest version of NEI 06-14 (Exhibit NRC S12) makes reference to Revision 9. This may seem confusing because the revision numbering of the draft does not correspond to the revision numbering of the final, accepted version, i.e., NEI 06-14, Revision 9, corresponds to NEI 06-14A, Revision 7 (Exhibit NRC S13). However, only the final, Staff-endorsed version was used in the Staff evaluation of the Fermi 3 QAPD that is documented in the SER (Exhibit NRC S1).

The NRC Staff reviewed NEI 06-14, Revision 9, following the guidance in SRP Section 17.5 (Exhibit NRC S11). The Staff concluded that the QAPD template in NEI 06-14, Revision 9, provides an acceptable format and adequate guidance for establishing a QA program that complies with Appendix B to 10 C.F.R. Part 50. The QAPD template in NEI 06-14, Revision 9, is based on ASME NQA-1-1994, as supplemented by additional regulatory guidance and industry guidance applicable to administrative and quality controls during nuclear power plant operation. Accordingly, the Staff concluded that the QAPD template in NEI 06-14, Revision 9, can be used by applicants for 10 C.F.R. Part 52 permits or licenses, as applicable, for establishing a QA program description required by relevant sections of that part— 10 C.F.R. § 52.79(a)(25) for a COL application. See SER for NEI 06-14, Exhibit NRC S12 at 1. The current accepted version, NEI 06-14A, Revision 7 (Exhibit NRC S13) was released by NEI soon after the Staff's review of the draft was complete.

The NRC Staff reviewed the Fermi 3 QAPD against the acceptance criteria in SRP Section 17.5 and against NEI 06-14A, Revision 7, in the following areas: (1) Organization; (2) Quality Assurance Program; (3) Design Control; (4) Procurement Document Control; (5) Instructions, Procedures, and Drawings; (6) Document Control; (7) Control of Purchased Material, Equipment, and Services; (8) Identification and Control of Materials, Parts, and Components; (9) Control of Special Processes; (10) Inspection; (11) Test Control; (12) Control of Measuring and Test Equipment; (13) Handling, Storage, and Shipping; (14) Inspections, Tests, and Operating Status; (15) Nonconforming Materials, Parts, or Components; (16) Corrective Action; (17) Quality Assurance Records; (18) Quality Assurance Audits; and (19) Non-safety-Related SSC Quality Assurance Control. These areas are specified in the SRP (Exhibit NRC S11) and in NEI 06-14A, Revision 7 (Exhibit NRC S13), and together constitute the elements of a complete QAPD that meets the requirements of Appendix B. As summarized in the SER (Exhibit NRC S1), the Staff concluded that, for each of these areas, the QAPD in the

Fermi 3 Application met all applicable acceptance criteria and therefore complies with NRC regulations.

As discussed in my answer to the questions below, the Staff review of the Applicant's QA program also included resolution of RAIs and of violations identified during a Staff inspection in August 2009. The Staff's resolution of these issues is documented in the Staff SER (Exhibit NRC S1) and in other exhibits I cite below, all of which support the Staff's conclusion that the Fermi 3 QAPD complies with the applicable NRC QA requirements.

Q18. Is the Staff aware of any other relevant QA programs, in addition to the QAPD in the Fermi 3 Application?

A18. Yes. Prior to submittal of the Fermi 3 application in September 2008, other QA programs controlled the Applicant's activities for developing the COL application, including with respect to safety-related Fermi 3 site characteristics (i.e. radiological analysis and geotechnical boring). Initially, the Applicant relied on the B&V Appendix B/NQA-1 program, which was used as DTE hired staff and developed the Nuclear Development (ND) QAPD.

As stated in the FSAR, the Applicant created the ND QAPD, issued in February 2008, to provide control of COLA work product receipt and review prior to submittal to the NRC. The Applicant further stated the ND QAPD was developed specifically to control the Applicant's activities at the time (e.g., review of B&V COLA work product), but the Applicant also contractually delegated quality and safety-related services for COL application development to B&V. The Staff determined this arrangement provided for QA control of COLA development activities under the B&V Appendix B/NQA-1 program, and for QA control of work product receipt under the ND QAPD.

The Staff reviewed the ND QAPD during the August 2009 QA implementation inspection and found that it included those elements of an Appendix B QA program that were relevant to

reviewing B&V COLA work product. The ND QAPD is further discussed in my response to Question 25 below.

Q19. Please describe events leading up to NRC Staff's August 2009 inspection of the Applicant's QA Program.

A19. In April 2009, I was assigned to the Fermi 3 application review team as a technical reviewer. In the summer of 2009, the NRC Staff realized that it did not have sufficient information to determine what kind of QA program the Applicant had used to control COLA development activities. The Staff review team clarified DTE's use of various QA programs presented in the Fermi 3 FSAR with the Applicant by teleconference, but still wanted more information from the Applicant to determine whether appropriate QA controls had been in place when the COLA was developed.

At the beginning of the Fermi 3 FSAR review, the NRC Staff was familiar with other COL applications which used QA programs for those applicants' existing reactors to control both pre-application activities and activities in the application review phase. In contrast to the approach used by such applicants, the Fermi Applicant informed the Staff that, for the Fermi 3 project, it intended to develop a new QA program for Fermi 3 that was separate from the program in place for Fermi 2. The Staff determined that further clarification of this approach was necessary. The approach proposed by the Applicant was similar to the process an applicant might take who did not have the benefit of an existing QA program (e.g., a "green field" application). However, since the Fermi 3 application was submitted, other applicants have taken this approach and created QA program separation between the proposed new plant and existing fleets. This approach helps ensure that new applications are informed by current regulatory standards and guidance.

After the initial discussions with DTE, the Staff concluded that in addition to issuing RAIs to collect the information needed for a full evaluation of the Fermi 3 QA programs, it would be of

additional licensing benefit to conduct an inspection to assess the effectiveness of DTE control over current and COLA development activity. With approval of NRC Staff management, the licensing and inspection divisions in the NRC Office of New Reactors coordinated to schedule the August 2009 QA inspection at the Applicant's offices in Michigan.

Q20. What did the inspection team find, and how did your work contribute to the findings?

A20. I was assigned to the Fermi 3 QA implementation inspection as an inspector and assigned the areas of Procurement Document Control and External Audits. The inspection team included a mix of senior QA inspectors and inspectors specifically assigned to the Fermi 3 application. I submitted my input to the team leader, who incorporated it into the inspection report. The NRC Staff issued the Inspection Report and Notice of Violation (NOV) on October 5, 2009. October 2009 NOV, Exhibit NRC S2.

This October 2009 NOV identified three violations for activities both before and after the date the Fermi 3 COLA was submitted to the NRC. My inspection activities identified deficiencies that, when combined with other inspector-identified deficiencies, resulted in the first of those three violations, NOV 05200033/2009-201-01. This violation cited the Applicant for failure to establish and implement a QA program, and was supported by several examples of programmatic and documentation failures that had occurred prior to the date of application. The Staff also issued two other violations relating to a failure to conduct internal audits and trending of corrective actions.

Q21. How severe were these violations, and how was the severity level determined?

A21. All three were designated as Severity Level IV, the level assigned to the least significant violation used in traditional enforcement. The severity level of the three violations was determined by reference to the NRC Enforcement Policy (Exhibit NRC S14), which defines

Severity Level IV as “less serious, but ... of more than minor concern, that resulted in no or relatively inappreciable potential safety or security consequences (e.g., violations that created the potential of more than minor safety or security consequences).” It is similar to a “Green Finding” for licensees falling under the Reactor Oversight Process (ROP) used with operating reactors. A ROP ‘Green Finding’ is a finding of very low safety significance.

The factors the Staff considers when assessing violations are described in the NRC Enforcement Policy (Exhibit NRC S14). They are (a) whether the violation resulted in actual safety or security consequences, (b) whether the violation had potential safety or security consequences, (c) whether the violation impacted the ability of the NRC to perform its regulatory oversight function, and (d) whether the violation involved willfulness.

Q22. How did the Applicant correct the violations identified by the Staff in the October 2009 NOV?

A22. The Applicant responded to the Initial NOV by letter dated November 9, 2009 and contested all three violations. Reply to October 2009 NOV, Exhibit NRC S3. DTE contested the violations, in part, because it claimed that (a) some deficiencies were for activities that occurred prior to DTE becoming an applicant, (b) the requirements of Appendix B were not specific enough to show that DTE’s activities were in violation, and (c) the Fermi 3 QAPD was not yet incorporated as a condition of a license.

The review team considered the Applicant’s assertions in consultation with the NRC Office of Enforcement and the Office of the General Counsel late in 2009. The Staff concluded that DTE was correct that an applicant’s actions before it became an applicant were not a proper basis for an NOV. However, the Staff concluded that the Applicant’s objections related to the other two violations were largely unsupported.

The NRC Staff issued a revised NOV by letter to DTE on April 27, 2010. April 2010 NOV, Exhibit NRC S4. The letter stated that, “While Detroit Edison must demonstrate

compliance with Appendix B in order to receive a COL from the Nuclear Regulatory Commission (NRC), the NRC cannot issue a Notice of Violation for actions or omissions occurring before it submitted the Fermi 3 COL application to the NRC.” The revised NOV identified two violations of NRC requirements for activities performed after September 18, 2008, the date on which DTE submitted the Fermi 3 COL application. The first of these replaced the first of the three violations in the October 2009 NOV (see Exhibit NRC S2, Enclosure 1 at 1-2), and cited the Applicant for failure to perform an evaluation of the B&V quality assurance program and adequately document the basis for the qualification of B&V to perform safety-related Fermi 3 COL activities as of September 18, 2008. See April 2010 NOV, Exhibit NRC S4, Enclosure 1 at 1-3. The second combined two previous violations (NOV 05200033/2009-201-02 and -03) into a single violation. Both of these violations were still designated as Severity Level IV. However, the Staff noted that the Applicant had responded to the second violation (which combined the second and third violations in the October 2009 NOV) by conducting an internal audit of its QA program and by performing a trending analysis of its corrective action reports, both of which were required by the Applicant’s QA implementation procedures and cited as missing in the second violation. The Staff stated that no further action regarding the second violation was required. April 2010 NOV, Exhibit NRC S4, Enclosure 1 at 7, 11.

Q23. How did the Applicant correct the violation in the revised NOV?

A23. The Applicant responded to the revised NOV by letter dated May 26, 2010. Reply to April 2010 NOV, Exhibit NRC S5. The sole remaining violation at that time related to the Applicant’s failure to perform an evaluation of the B&V QA program and adequately document the basis for qualifying B&V to perform safety-related Fermi 3 activities after September 2008.

The Applicant response included (a) the reason for the violation, (b) the corrective steps taken, and (c) the preventive steps taken to prevent reoccurrence. The Applicant stated in Attachment 1 to this letter that B&V was a qualified Appendix B COLA contractor, as established

through the contracting process. According to the Applicant, B&V's qualifications were further assessed during the Applicant's July 2009 audit of B&V, which confirmed that the safety-related activities performed by B&V prior to July 2009 were completed in accordance with 10 C.F.R. 50 Appendix B requirements.

The Staff reviewed the Applicant's response to several Staff RAIs, in addition to the Applicant's May 2010 letter, to resolve this violation. In RAIs issued to DTE in 2009 and 2010, the Staff specifically sought clarification of issues related to DTE oversight of B&V in various periods, including after September 2008. These RAIs are discussed in more detail in my response to Question 25 below and in the Staff SER. See Exhibit NRC S1 at 17-34.

Two RAIs primarily related to pre-application activities, RAI 17.5-16 and RAI 17.5-19, were relevant to the resolution of the remaining violation in the April 2010 NOV because they provide details of B&V's qualification for safety-related work and the Applicant's control over that work. B&V's qualification and the Applicant's control over its contractor are relevant to both pre-application and post-application activities. The Applicant's response to RAI 17.5-16 includes information specifically related to how B&V was qualified for the Fermi 3 project and how contracting documents established QA controls governing B&V. May 2010 RAI Responses, Exhibit NRC S7, Attach. 1 at 5-7. The response to RAI 17.5-19 clarifies how the Applicant retained responsibility for, and maintained control over those portions of the QA program delegated to other organizations, and specifically identified the responsible organizations and processes used for verifying that the delegated QA functions were implemented effectively. May 2010 RAI Responses, Exhibit NRC S7, Attach. 4 at 6-10. The Staff examined the portions of these RAI responses that related to the remaining violation, together with the Applicant's response to the April 2010 NOV (Exhibit NRC S5), in order to determine whether the Applicant had provided sufficient information to resolve the violation.

The Staff's process for resolving violations cited in NOVs is coordinated by the inspection team leader. This process includes the inspection team members and involves

consultation with other expert NRC personnel as required. The determination of whether the violation is resolved is approved by NRC management. Prior to the release of the final NRC letter related to the inspection on June 4, 2010 (see DTE NOV Closure Letter, Exhibit NRC S6), the Staff conducted multiple meetings to discuss Fermi 3 QA both before and after September 18, 2008. To resolve the remaining violation in the NOV, the Staff examined the Applicant's information related to B&V's qualification for Fermi 3 post-application safety-related work. In the judgment of those involved in the process, the additional information contained in the above-mentioned RAI responses, the Fermi 3 process changes outlined in the response to the April 2010 NOV, and DTE's successful audit of B&V in July 2009 provided sufficient information to show that the Applicant had performed an appropriate evaluation of the B&V QA program and had adequately documented the basis for qualifying B&V to perform safety-related Fermi 3 activities after September 2008. Accordingly, the Staff concluded that (a) the DTE information submitted was responsive to the revised NOV, (b) the implemented corrective actions were appropriate, and (c) the activities cited in the April 2010 NOV are again consistent with the requirements of Appendix B to 10 CFR Part 50.

Q24. Has the Staff identified any more QA implementation issues related to activities after September 18, 2008, when the Fermi 3 COLA was submitted to the NRC?

A24. No. The NRC Staff documented the acceptance of the Applicant's responses to the revised NOV in a letter dated June 4, 2010 (Exhibit NRC S6). The NRC considered the Applicant's QA program returned to regulatory compliance upon the Staff's acceptance of the Applicant's response to the last remaining issue in the revised NOV. The NRC Staff has discretion to conduct inspections at any time to verify ongoing regulatory compliance.

As documented in the SER, the Staff has found that the QAPD in the COLA meets NRC regulatory requirements, and all known implementation issues related to that QAPD are resolved. This provides "satisfactory proof of a fully-implemented QA program that will govern

the design, construction, and operation of Fermi Unit 3 in conformity with all relevant NRC regulations,” and claims to the contrary in Contention 15 are without basis.

Q25. How did the Staff address QA questions related to activities before the COLA was submitted on September 18, 2008?

A25. As described above, the Staff determined that activities occurring before the Fermi 3 COL application was submitted to the NRC are not subject to enforcement actions such as NOVs. However, the Staff does consider whether there were appropriate QA controls at the time the COL application was developed and whether the information in the COLA as submitted is reliable.

In general, the Staff uses RAIs within the licensing process to obtain additional information regarding the nature, quality, sources, and reliability of information contained in the COLA. In this case, the Staff sent RAI 17.5-16 through 17.5-19, which were specifically related to QA for activities prior to September 18, 2008, to the Applicant on March 18, 2010. The Applicant responded to the RAIs in a letter dated May 10, 2010, which includes the full text of the Staff’s RAIs as well as the Applicant’s answers. May 2010 RAI Responses, Exhibit NRC S7.

The first of these RAIs, RAI 17.5-16, requested the Applicant to “provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.” The Applicant responded with thirteen pages of narrative description and a thirteen-page table setting out all safety-related pre-application activities and the associated QA programs that applied to them. May 2010 RAI Responses, Exhibit NRC S7, Attach. 1. As noted in my response to Question 23 above, a portion of the Applicant’s response to this RAI was related to the initial qualification of B&V to perform safety-related work on the Fermi 3 application.

The second RAI, RAI 17.5-17, requested the Applicant to provide a table summarizing QA support of Fermi 3 safety-related activities completed or in process prior to September 18, 2008. Specifically, the Staff requested that the Applicant include the following information limited to Fermi 3 safety-related activities conducted prior to September 18, 2008: 1) list of Detroit Edison QA personnel providing project support including hire dates, QA qualification types & dates, type of QA support provided, and percentage dedicated to project if less than full time, 2) summary by job classification of Black & Veatch (B&V)-Ann Arbor QA personnel providing project support including, QA qualification types, type of QA support provided, and number of hours dedicated to project, and 3) summary by job classification of B&V (Overland Park, Kansas) QA personnel providing project support including, QA qualification types, type of QA support provided, and number of hours dedicated to project. The Applicant responded with the requested information for QA personnel at DTE, B&V-Ann Arbor, and B&V-Overland Park. May 2010 RAI Responses, Exhibit NRC S7, Attach. 2.

The third RAI, RAI 17.5-18, requested the Applicant to “provide a table summarizing the ND QAPD and Fermi 3 implementing procedures effective prior to September 18, 2008,” and to “note when the ND QAPD or implementing procedures were contractually imposed on, or applied by, contracted personnel, if applicable.” The Applicant responded with a list describing the relevant procedures and when those procedures were contractually imposed on, or applied by, contracted personnel. May 2010 RAI Responses, Exhibit NRC S7, Attach. 3.

The fourth RAI, RAI 17.5-19, requested the Applicant to provide (1) a “description of how the applicant will retain responsibility for, and maintain control over, those portions of the QA program delegated to other organizations”; (2) the “identification of the responsible organization and the process for verifying that delegated QA functions are effectively implemented”; (3) the identification of major work interfaces for activities affecting quality”; and (4) a “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.” The

Applicant provided the requested information for the periods January 2007 to November 2007 (development of COLA work product by B&V); November 2007 to September 2008 (receipt, review, and acceptance of COLA work product by DTE); and September 2008 to present (post-Application activities). May 2010 RAI Responses, Exhibit NRC S7, Attach. 4. As noted in my response to Question 23 above, portions of the Applicant's RAI response related to activities after September 2008 are related to resolution of the April 2010 NOV (Exhibit NRC S4). However, activities in the other two periods occurred prior to submittal of the application and are therefore relevant here.

The Staff reviewed the Applicant's responses to the four RAIs and concluded that the Applicant provided detailed information outlining QA support for Fermi 3 safety-related activities completed before the Fermi 3 COLA submittal date. Specifically, the Applicant provided (1) a list of safety-related activities and safety-related COL application sections; (2) dates of the activity or section creation; (3) the contracting entity conducting the activity/section creation and governing the QAPD; (4) the QA organization responsible for oversight of the activity/section creation; (5) dates and type of any specific contractor conducting the QA oversight activities (e.g., surveillance, document review, etc.); (6) contractor approval dates; (7) dates of Applicant's review and approval; (8) dates and type of any specific Applicant QA oversight activities (e.g., surveillance, document review, etc.); (9) background personnel information (including QA qualification types, type of QA support provided, and number of support hours) for both Applicant and contractor organizations; and (10) a summary of the various versions of the Fermi 3 QAPD and the implementation procedures. Additionally, in the response to the fourth RAI, RAI 17.5-19, the Applicant provided detailed information regarding the relationship between DTE and its contractor B&V for the three periods noted above. SER, Exhibit NRC S1 at 17-34 to 17-36.

After reviewing the Applicant's extensive submittals in answer to the RAIs, the Staff determined that at the outset of the Fermi 3 project (a) DTE contractually delegated to B&V the

work of establishing and executing a QA program satisfying the requirements of 10 CFR 50 Appendix B for COL application development, and B&V did have such a program in place when the information in the COL was developed; and (b) internal oversight of safety-related activities was inherent in the B&V program. The B&V QA program covered activities carried out by B&V prior to February 2008 as well as later.

After February 2008, the Staff determined that the Applicant did establish portions of an Appendix B program related to review and acceptance of the B&V COL application work product by creating the ND QAPD and related implementing procedures. The table of safety-related activities and COLA sections that the Applicant provided in its response to RAI 17.5-16 shows all dates for Applicant review and acceptance of B&V work product as February 2008 or later, with the exception of preliminary work product that was reviewed again upon incorporation into the corresponding COLA sections in mid-2008. The ND QAPD provided additional DTE oversight over B&V, beyond the contractual oversight mechanisms established initially, as well as controlling work by DTE personnel. SER, Exhibit NRC S1 at 17-35.

Finally, the Staff confirmed that DTE continued to delegate the execution of quality- and safety-related services associated with COLA revision and application review support to the B&V 10 CFR 50 Appendix B/NQA-1 QA Program after submission of the COLA in September 2008, but that the QAPD in the Fermi 3 Application was in place and governed work by DTE personnel. SER, Exhibit NRC S1 at 17-36.

From the comprehensive description in the RAI responses, the Staff determined that both B&V's development of the information in the COLA and DTE's receipt and acceptance of B&V work product occurred under appropriate QA controls. The Staff therefore concluded that the information in the COLA is reliable and that the QA implementation violations described above "do not affect the quality of safety-related design information in the FSAR." Claims to the contrary in Contention 15 are without basis.

Q26. Has the Staff conducted any audits/inspections of the Applicant's contractor, B&V?

A26. The Board has specifically requested information regarding audits of the B&V QA program used in connection with its safety-related COLA activities for the Fermi 3 project. The NRC Staff conducted two audits/inspections related to B&V activities related to Fermi 3, one in 2007 and one in 2010.

The NRC Staff conducted an audit of the Applicant in July 2007 to observe combined license (COL) pre-application subsurface investigation activities. This audit, which included observation of work performed by B&V and examination of B&V QA documents, was conducted at the Fermi site and led by inspectors from NRC's Region II, accompanied by members of the Office of New Reactors (NRO) staff. A report of this audit was issued in August 2007. 2007 B&V Audit Report, Exhibit NRC S8. The NRC audit team concluded that the "drilling and field testing activities were controlled by adequate procedures and standards with an appropriate level of supervisory and quality assurance oversight," and "the work was being done in an appropriately controlled manner." No adverse observations were identified during the audit.

As part of the normal selection of vendors for NRC inspection, B&V was selected for a routine inspection in 2010. This inspection was not limited to activities related to the Fermi 3 COLA, but also included B&V work in support of other NRC applicants and licensees. I was a member of the inspection team, and the other inspectors were informed of the August 2009 DTE inspection and the ongoing Fermi 3 licensing activities. The NRC B&V vendor inspection, completed in September 2010, was led by NRO inspectors at B&V's facility in Overland Park, Kansas (outside of Kansas City, Missouri). The NRC Staff issued the B&V vendor inspection report on October 14, 2010. 2010 B&V Inspection Report, Exhibit NRC S9. The inspectors found no violations of 10 CFR Part 50, Appendix B QA requirements. The report identified one violation of 10 CFR Part 21 requirements for activities not directly related to Fermi 3, which B&V

responded to by letter. The NRC Staff documented the acceptance of B&V's response in a letter dated December 17, 2010. 2010 B&V Inspection Letter, Exhibit NRC S10.

The lack of adverse observations from the 2007 audit and the lack of Fermi 3-related findings from the 2010 B&V inspection support the Staff's conclusion that the Applicant has provided adequate assurance that the requirements of Appendix B have been met for safety-related activities supporting the Fermi 3 COL application.

Q27. Is the Staff aware of any other audits of B&V?

A27. The Staff is aware of two such audits. One, a Nuclear Procurement Issues Committee (NUPIC) audit of B&V's Appendix B/NQA-1 program, was conducted prior to the Applicant's selection of B&V for COLA development in April 2007. NUPIC is an industry organization of NRC-licensed utilities that conducts routine audits of vendors that serve the nuclear industry. The Staff inspection team for the August 2009 QA implementation inspection of Detroit Edison was informed that the selection and qualification of B&V was largely based on this NUPIC audit that occurred prior to selection. A description of activities during this period are contained in the Fermi 3 FSAR, Chapter 17.5, under the section titled "Development of COLA Work Product (January 2007 to November 2007)."

Second, the Applicant audited B&V in July 2009, prior to the Staff's August 2009 inspection of the Applicant. The NRC inspectors reviewed the Applicant's audit report dated August 7, 2009, during the Fermi 3 QA implementation inspection, and the details are included in section 3.b.3 of the NRC inspection report dated October 5, 2009. See October 2009 NOV, Exhibit NRC S2, Enclosure 2 at 10-11. The Applicant states in their May 26, 2010, response to the revised NOV, that this audit assessed the B&V QA Program and found it to be effectively implemented for Fermi 3 COL application activities. Exhibit NRC S5, Attach. 1 at 3. The lack of adverse observations in the Applicant's audit supports the Staff's conclusion that the Applicant

has provided adequate assurance that the requirements of Appendix B have been met for safety-related activities supporting the Fermi 3 COL application.

Q28. Has the Staff completed its review of Fermi 3 QA issues? If so, what were its findings?

A28. The Staff completed its review in 2011 with issuance of Chapter 17 of the Fermi 3 SER. All RAIs and NOVs related to QA issues for the Fermi 3 application are resolved, and the Staff's technical review is complete. The Staff has found that all violations of NRC regulations have been resolved, and that the Applicant is now in compliance with Appendix B to 10 C.F.R. Part 50. Furthermore, the Staff has concluded that those violations have not affected safety-related design information in the FSAR. For these reasons, Contention 15 is without basis.

Q29. Does this complete your testimony?

A29. Yes, it does.

Q30. Do you hereby certify under penalty of perjury that the foregoing is true and complete to the best of your knowledge, information, and belief?

A30. Yes. I hereby certify under penalty of perjury that the foregoing is true and complete to the best of my knowledge, information, and belief.

Executed in Accord with 10 CFR § 2.304(d)

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