

April 30, 2013

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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

NRC STAFF INITIAL STATEMENT OF POSITION
FOR CONTENTION 15

BACKGROUND

Pursuant to 10 C.F.R. §§ 2.337(g)(2) and 2.1207(a)(1) and the Licensing Board's order of March 29, 2013,¹ the NRC Staff (Staff) hereby presents its Initial Statement of Position, together with its pre-filed initial testimony and exhibits regarding the Intervenor's Contention 15. For the reasons discussed below and in the attached testimony, Contention 15 as admitted by the Board is without merit, and the Board should rule in favor of the Applicant, the DTE Electric Company (DTE or Applicant).²

By letter dated September 18, 2008, the Applicant submitted a combined license (COL) application (Application or COLA) for one ESBWR advanced boiling water reactor to be located

¹ Licensing Board Order (Granting Motion for Extension of Time for Submission of Testimony for Adjudication of Contention 15, and Modifying the Schedule) (Mar. 29, 2013) (unpublished).

² The DTE Electric Company was named the Detroit Edison Company prior to a formal name change on January 1, 2013, and is referred to as such in documents dated before that time. However, the legal entity has remained the same throughout this proceeding.

at the site of the operating Fermi Nuclear Power Plant, Unit 2 in Monroe County, Michigan.³

The ESBWR design is the subject of an NRC rulemaking under Docket No. 52-010.

On March 9, 2009, the Intervenors⁴ filed a Petition for Leave to Intervene in the Fermi 3 COLA proceeding, along with a separate document containing 14 contentions. Following oral argument, the Licensing Board found that the Intervenors had standing in this proceeding and had filed four contentions that were admissible in part. *Detroit Edison Co. (Fermi Nuclear Power Plant, Unit 3)*, LBP-09-16, 70 NRC 227 (2009). On November 6, 2009, the Intervenors filed a Supplemental Petition for Admission of a Newly Discovered Contention, which included a quality assurance (QA) contention numbered as Contention 15.⁵ As originally submitted, Contention 15 stated that

[DTE] has failed to comply with Appendix B to 10 C.F.R. Part 50 to establish and maintain a quality assurance program since March 2007 when it entered into a contract with [B&V] for the conduct of safety-related [COL] application activities and to retain overall control of safety-related activities performed by B&V. DTE further has failed to complete any internal audits of QA programmatic areas implemented for Fermi 3 COLA activities performed to date. And DTE has also failed to demonstrate trending of corrective actions to identify recurring conditions adverse to quality since the beginning of the Fermi 3 project in March 2007.

Supplemental Petition at 2-3. The Applicant and Staff filed answers to this contention on December 1, 2009,⁶ and the Intervenors filed their reply on December 8, 2009.⁷ The Staff moved to file a surreply on December 18, 2009.⁸

³ Letter from Jack M. Davis, DTE, to NRC, Detroit Edison Company Submittal of a Combined License Application for Fermi 3 (NRC Project No. 757) (Sept. 18, 2008), ADAMS Accession No. ML082730763.

⁴ Beyond Nuclear, Citizens for Alternatives to Chemical Contamination, Citizens Environmental Alliance of Southwestern Ontario, Don't Waste Michigan, Sierra Club, Keith Gunter, Edward McArdle, Henry Newman, Derek Coronado, Sandra Bihn, Harold L. Stokes, Michael J. Keegan, Richard Coronado, George Steinman, Marilyn R. Timmer, Leonard Mandeville, Frank Mantei, Marcee Meyers, and Shirley Steinman (collectively, Intervenors).

⁵ Supplemental Petition for Admission of a Newly Discovered Contention, and for Partial Suspension of COLA Adjudication (Nov. 6, 2009) (Supplemental Petition).

⁶ Applicant's Response to Proposed Supplemental Contention (Dec. 1, 2009); Staff Answer to Supplemental Petition (Dec. 1, 2009).

Following all briefing, the Board admitted a reformulated version of Contention 15 that reads as follows:

Detroit Edison (DTE) failed to comply with Appendix B to 10 C.F.R. Part 50 to establish and implement its own quality assurance (QA) program when it entered into a contract with Black and Veatch (B&V) for the conduct of safety-related combined license (COL) application activities and to retain overall control of safety-related activities performed by B&V. This violation began in March 2007 and continued through at least February 2008. Further, DTE failed to complete internal audits of QA programmatic areas implemented for the Fermi 3 COL Application, and DTE also has failed to document trending of corrective actions to identify recurring conditions adverse to quality since the beginning of the Fermi Unit 3 project in March 2007.

Contention 15A: These deficiencies adversely impact the quality of the safety-related design information in the FSAR that is based on B&V's tests, investigations, or other safety-related activities. Because the NRC may base its licensing decision on safety-related design information in the FSAR only if it has reasonable assurance of the quality of that information, it may not lawfully issue the COL until the deficiencies have been adequately corrected by the Applicant, or until the Applicant demonstrates that the deficiencies do not affect the quality of safety-related design information in the FSAR.

Contention 15B: Although DTE claims that in February 2008 it adopted a QA program that conforms to Appendix B, DTE has failed to implement that program in the manner required to properly oversee the safety-related design activities of B&V. This demonstrates an ongoing lack of commitment on the part of DTE's management to compliance with NRC QA regulations. The NRC cannot support a finding of reasonable assurance that the plant, as built, can and will be operated without endangering the public health and safety until DTE 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.

Detroit Edison Co. (Fermi Nuclear Power Plant, Unit 3), LBP-10-9, 71 NRC 493, 510-11 (2010).

On April 17, 2012, the Applicant filed a motion for summary disposition of Contention 15.⁹ The

⁷ Intervenor's Combined Reply in Support of Supplemental Petition for Admission of a Newly-Discovered Contention (Dec. 8, 2009).

⁸ NRC Staff Motion for Leave to Reply to Intervenor's Combined Reply in Support of Supplemental Petition (Dec. 18, 2009).

⁹ Applicant's Motion for Summary Disposition of Contention 15 (Apr. 17, 2012) (Summary Disposition Motion).

Staff filed its answer to the Summary Disposition Motion on May 7, 2012.¹⁰ The Intervenors initially requested additional time to file, and the Board granted their request.¹¹ At the end of the extension period, the Intervenors requested a further extension, which the Board denied.¹² The Intervenors never filed a full substantive answer to the Applicant's Summary Disposition Motion. The Board nevertheless denied summary disposition, citing affidavits the Intervenors filed during an earlier phase of the proceeding. *Detroit Edison Co.* (Fermi Nuclear Power Plant, Unit 3), LBP-12-23, 76 NRC __ (slip op. at 37-38) (Nov. 9, 2012).

The Staff has completed its review of quality assurance (QA) issues related to the Fermi 3 combined license (COL) Application, and that review is documented in Chapter 17 of the Advanced Safety Evaluation Report (SER) With No Open Items, ADAMS Accession No. ML112630120, attached hereto as Exhibit NRC S1. This SER chapter was presented to the Advisory Committee on Reactor Safeguards (ACRS) on September 22, 2011, and released to the public on October 17, 2011. See Prefiled Direct Testimony of Adrian Muñiz at A2. No changes to Chapter 17 are anticipated prior to publication of the Final SER for the Fermi 3 COL Application. *Id.* at A4.

This Statement is accompanied by written direct testimony prepared by individual NRC Staff members Adrian Muñiz, Aida Rivera-Varona, and George Lipscomb. Mr. Muñiz is an electrical engineer with ten years of NRC experience. He has been a Project Manager in the New Reactor Licensing Division of the Office of New Reactors since 2008, and has been the

¹⁰ NRC Staff Answer to Applicant's Motion for Summary Disposition of Contention 15 (May 7, 2012) (Staff Answer to Summary Disposition Motion).

¹¹ Intervenors' Motion for Enlargement of Time to Respond to Pending Motions for Summary Disposition (May 4, 2012); Licensing Board Order (Granting Intervenors' Motion for Extension of Time) (May 9, 2012) (unpublished).

¹² Intervenors' Motion to Supplement Response in Opposition to Applicant's Motion for Summary Disposition of Contention 15 (May 17, 2012); Licensing Board Order (Denying Intervenors' Motion to Supplement) (June 21, 2012) (unpublished).

Lead Project Manager for the safety review of the Fermi 3 COLA since June 2010. In that capacity, he is responsible for overseeing preparation of the Staff SER for the Fermi 3 COLA.

Mrs. Rivera-Varona is a chemical engineer with eleven years of NRC experience. From February 2007 to January 2010, she was a Vendor Inspection Team Leader in Quality and Vendor Branch 2 in the Division of Construction Inspection and Operational Programs, Office of New Reactors. In that capacity, she led a Staff inspection at the Applicant's headquarters in August 2009 that resulted in three cited violations that form the basis for Contention 15. See NRC Inspection Report 05200033/2009-201 and Notice of Violation (Oct. 5, 2009) (October 2009 NOV), ADAMS Accession No. ML092740064, attached hereto as Exhibit NRC S2. In January 2010, Mrs. Rivera-Varona was promoted to Technical Assistant in the Division of Construction Inspection and Operational Programs in the Office of New Reactors, and she was not involved in the Fermi 3 COLA review after that date. In September 2012 she was promoted to Branch Chief in the Division of Program Management, Policy Development, and Analysis in the Office of New Reactors.

Mr. Lipscomb is an electrical engineer with over twenty-five years of experience in the U.S. Navy, in the nuclear industry, and at NRC. Since July 2008, he has worked as a QA Inspector and technical reviewer in the Division of Construction Inspection and Operational Programs in the Office of New Reactors. He was the lead technical reviewer for QA for Chapter 17 of the SER (Exhibit NRC S1), and he was a member of the inspection team for the August 2009 inspection of DTE that resulted in the cited QA violations that underlie Contention 15 (October 2009 NOV, Exhibit NRC S2). Prior to joining NRC, Mr. Lipscomb worked for the General Electric Company on the ESBWR project and for the U.S. Navy in several positions with substantial responsibilities related to QA.

This Statement is also accompanied by seventeen Staff exhibits (Exhibits NRC S1-S17) related to Contention 15. Exhibits related to Contention 15 are prefixed with the letter "S" (S1, S2, S3 etc.) because the contention relates to safety issues documented in the Staff's Safety

Evaluation Report (SER). Exhibits related to environmental issues documented in the Staff's Final Environmental Impact Statement (FEIS) have been labeled with the letter "E" (E1, E2, E3 etc.) to distinguish them. The first eleven exhibits related to Contention 15 (Exhibits NRC S1-S11) were previously submitted with the Staff Answer to Summary Disposition Motion, filed in May 2012. They are resubmitted here with the same numbering as formerly, except for the addition of the "S" prefix. Exhibits NRC S1-S10 are all documents specific to the Fermi 3 COLA review or to inspections and audits of the Applicant and its contractor B&V. Exhibits NRC S11-S14 are general guidance and policy documents that are relevant to multiple NRC reviews. Exhibits NRC S15-S17 are Statements of Professional Qualifications for the three Staff witnesses.

Taken together, the Staff's testimony and supporting exhibits demonstrate that the challenges to the Applicant's QA program raised in Contention 15 lack merit.

DISCUSSION

I. LEGAL STANDARDS

NRC regulations state that, unless otherwise ordered, an applicant for a license has the burden of proof in NRC hearings. 10 C.F.R. § 2.325. For an applicant to prevail on a factual matter, its position must be established by a preponderance of the evidence. *See, e.g., Pacific Gas and Electric Co.* (Diablo Canyon Power Plant Independent Spent Fuel Storage Installation), CLI-08-26, 68 NRC 509, 521 n.64 (2008), citing *Pacific Gas and Electric Co.* (Diablo Canyon Nuclear Power Plant, Units 1 and 2), ALAB-763, 19 NRC 571, 577 (1984); *Tennessee Valley Authority* (Hartsville Nuclear Plant, Units 1A, 2A, 1B, and 2B), ALAB-463, 7 NRC 341, 360 (1978) ("Absent some special statutory standard of proof, factual issues . . . are determined by a preponderance of the evidence"). Accordingly, for the Applicant to prevail in this hearing, it must show by a preponderance of the evidence that the claims made by the Intervenors in Contention 15 are without merit.

NRC's regulations related to QA are found in Appendix B of 10 C.F.R. Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" (Appendix B), which states that

[e]very applicant for a combined license under part 52 of this chapter is required by the provisions of 10 C.F.R. § 52.79 of this chapter to include in its [FSAR] a description of the quality assurance applied to the design, and to be applied to the fabrication, construction, and testing of the structures, systems, and components of the facility and to the managerial and administrative controls to be used to assure safe operation.

Appendix B, 10 C.F.R. Part 50, "Introduction." Appendix B requires an applicant to "establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of [Appendix B]." *Id.*, Section II, "Quality Assurance Program." While Appendix B mentions "quality assurance applied to the design," and establishes QA requirements for design control, it does not require an applicant for a COL to do all of its design-related work in-house under its own QA program. *Id.*, "Introduction" & Section III, "Design Control."

NRC regulations permit applicants to "delegate to others, including contractors, agents, or consultants, the work of establishing and executing the [QA] program, or any part thereof, but [the applicant] shall retain responsibility for the [QA] program." *Id.*, Section I, "Organization." Appendix B imposes specific requirements related to procurement documents and control of purchased material, equipment, and services. *See id.*, Section IV, "Procurement Document Control," and Section VII, "Control of Purchased Material, Equipment, and Services." Appendix B also contemplates the situation in which an applicant uses procurement documents to "require contractors or subcontractors to provide a [QA] program consistent with the pertinent provisions of this appendix." *Id.*, Section IV, "Procurement Document Control."

NRC guidance related to the review of QA programs in COL applications is described in the discussion of the Staff's review of the QA Program Description (QAPD) in the Fermi 3 FSAR, which appears in Section II.A below and in the Staff testimony cited therein. While Staff

guidance documents are not themselves regulatory requirements, it has long been established that compliance with relevant guidance documents is accorded special weight when determining whether an applicant has complied with NRC regulations. See, e.g., *Consumers Power Co.* (Big Rock Point Nuclear Plant), ALAB-725, 17 NRC 562, 568 (1983); *Long Island Lighting Co.* (Shoreham Nuclear Power Station, Unit 1), ALAB-900, 28 NRC 275, 290 (1988). See also *Private Fuel Storage, L.L.C.* (Independent Spent Fuel Storage Installation), CLI-01-22, 54 NRC 255, 264 (2001) (reaffirming that compliance with guidance documents is entitled to “special weight” when the guidance was drafted for use in evaluating applications of the type under consideration); *Yankee Atomic Electric Co.* (Yankee Nuclear Power Station), CLI-05-15, 61 NRC 365, 375 n.26 (2005) (discussing the “special weight” to be given to Standard Review Plans).

II. THE APPLICANT HAS IMPLEMENTED A QA PLAN THAT COMPLIES WITH APPENDIX B OF 10 C.F.R. PART 50 AND DEMONSTRATED THAT THE DATA IN THE APPLICATION WAS DEVELOPED WITH APPROPRIATE QA CONTROLS, THEREBY RESOLVING ALL ISSUES RELATED TO CONTENTION 15.

Contention 15, as admitted by the Board, consists of three parts. An unnumbered introductory paragraph makes reference to an Inspection Report and Notice of Violation (NOV) concerning QA issues that the NRC Staff issued to DTE on October 5, 2009, and lists the three violations contained therein. LBP-10-9, 71 NRC at 510; see also October 2009 NOV, Exhibit NRC S2. A second paragraph labeled “Contention 15A” focuses on alleged QA deficiencies at the time the Fermi 3 COLA was prepared, and states that the NRC “may not lawfully issue the COL until the deficiencies have been adequately corrected by the Applicant, or until the Applicant demonstrates that the deficiencies do not affect the quality of safety-related design information in the FSAR.” LBP-10-9, 71 NRC at 510. A third paragraph, labeled “Contention 15B,” focuses on future rather than past activities and states that

[t]he NRC cannot support a finding of reasonable assurance that the plant, as built, can and will be operated without endangering the public health and safety

until DTE 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.

Id. at 511.

The following sections of this Statement address the three portions of the contention, but in a different order. The first section describes the Staff's evaluation of the Fermi 3 QAPD in the Fermi 3 COLA and the Staff's conclusion that the program meets all applicable Appendix B requirements. This discussion relates to the portion of the contention labeled "Contention 15B." The second section explains how the Staff resolved the issues cited in the October 5, 2009, Inspection Report and NOV, cited by the Intervenors in support of their contention and attached hereto as Exhibit NRC S2, by requiring corrective actions to address the problems identified in the NOV. This discussion is related both to the unnumbered introductory paragraph of the contention and to the portion labeled "Contention 15B." The third section describes the resolution of issues prior to the COLA submittal date and demonstrates that proper QA controls were applied to information collected prior to that date and included in the Application. This discussion is related to the portion of the contention labeled "Contention 15A." Finally, the Staff has included a separate section addressing the first of the questions identified by the Licensing Board in its February 28, 2013, order concerning pre-filed testimony.¹³ This discussion is related to all portions of the contention, but is of particular significance in relation to the portion labeled "Contention 15A." Taken together, these sections demonstrate that all issues related to Contention 15 have been resolved, and that claims to the contrary are without merit.

¹³ See Licensing Board Order (Identifying Questions for the Parties to Address in their Pre-Filed Written Testimony on Contention 15) (Feb. 28, 2013) (unpublished) (Board Questions). Staff testimony also discusses the sixth of the Board's questions, identification of any data the Applicant used in its COL that it obtained from its contractor before establishing its own QA program for Fermi 3. See Section II.C below and Staff testimony cited therein. The Staff interprets the remaining Board Questions as directed primarily at the other parties.

A. The Staff's review of the QA program description in the Fermi 3 COLA confirms that the program meets the requirements of Appendix B of 10 C.F.R. Part 50 and is consistent with applicable guidance.

The portion of Contention 15 labeled "Contention 15B" states that

[t]he NRC cannot support a finding of reasonable assurance that the plant, as built, can and will be operated without endangering the public health and safety until DTE 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.

LBP-10-9, 71 NRC at 511. However, the Staff has completed its technical review and confirmed that the Applicant's QAPD follows detailed, NRC-approved guidance for all aspects of its QA program, and that the Applicant has thereby demonstrated that it meets the applicable NRC requirements.

The wording of this portion of the contention reflects the core "reasonable assurance" finding that the Staff must make as part of its safety review prior to issuance of any license under 10 C.F.R. Part 50 or 52. See, e.g., 10 C.F.R. § 50.40. The Applicant's description of its QA program for Fermi 3 is in Section 17.5 of the Fermi Final Safety Analysis Report (FSAR), which is found in Part 2 of the Fermi 3 COLA. The Staff's review of the Fermi 3 QAPD, which is documented in Chapter 17 of the SER, assesses the information the Applicant provided related to its QA program and compliance with applicable NRC regulations. See Written Direct Testimony of George Lipscomb (Lipscomb Testimony) at A13-A14; Exhibit NRC S1 at 17-14 to 17-36. The SER describes the regulatory basis against which the Applicant's documents were evaluated, including Appendix B of 10 C.F.R. Part 50 and those Part 52 regulations that incorporate Appendix B into the regulations governing combined licenses. Lipscomb Testimony at A9; SER, Exhibit NRC S1 at 17-14.

The SER also describes the NRC's Standard Review Plan (SRP), which the Staff developed using the 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, and which the Staff used in

evaluating DTE's QA program. Lipscomb Testimony at A17; SER, Exhibit NRC S1 at 17-14 to 17-15, citing Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition (NUREG-0800) (March 2007), ADAMS Accession No. ML063190019, attached hereto as Exhibit NRC S11. The SRP provides an outline of an acceptable QA program and acceptance criteria used by the NRC Staff in its review. See Lipscomb Testimony at A17.

The SER also refers to the Nuclear Energy Institute's (NEI) Technical Report NEI 06-14A, Revision 7, "Quality Assurance Program Description." Lipscomb Testimony at A17; Exhibit NRC S1 at 17-15. As described in the attached testimony, the Staff separately reviewed the QA program description template in NEI 06-14 and prepared a separate SER accepting it for use by COL applicants. See Lipscomb Testimony at A11. The SER endorsing the use of NEI 06-14 and the most current accepted revision of NEI 06-14, designated "NEI 06-14A, Revision 7," are attached hereto as Exhibits NRC S12 and S13, respectively.¹⁴ Once an NEI template has been accepted by NRC, as NEI 06-14A, Revision 7, has been, it has the status of guidance that applicants can use in their demonstration of regulatory compliance. Lipscomb Testimony at A11; Exhibit NRC S12 at 2. In the case of NEI 06-14A, Revision 7, the Staff has determined that "that the QAPD template can be used by applicants of [sic] 10 C.F.R. Part 52 permits or licenses, as applicable, for establishing a quality assurance program that complies with Appendix B . . . 10 C.F.R. Part 50 requirements." Exhibit NRC S12 at 1; see *also* Lipscomb Testimony at A17.

The NRC Staff reviewed the Fermi 3 QAPD against the acceptance criteria in SRP

¹⁴ 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; NEI 06-14A [Revision 7], "Quality Assurance Program Description" (August 2010), ADAMS Accession No. ML102370305.

NEI 06-14 was revised while the Fermi 3 COL review was in progress, and the Staff issued RAIs to ensure that the Fermi 3 COLA was updated to reflect the changes to the template. The issue of revision numbers for NEI 06-14 is discussed in the testimony of George Lipscomb. Lipscomb Testimony at A17.

Section 17.5 and against NEI 06-14A, Revision 7, in nineteen 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. Lipscomb Testimony at A17, citing Exhibit NRC S1 at 17-15 to 17-30.

Based on its review in these nineteen areas, as summarized in the SER, the Staff concluded that the Fermi 3 QAPD meets the requirements of Appendix B to 10 C.F.R. Part 50. Lipscomb Testimony at A17; Exhibit NRC S1 at 17-36. Thus, contrary to the contention as admitted by the Board, the Applicant has demonstrated that the Fermi 3 QA program described in the QAPD meets all relevant NRC regulatory requirements with respect to the design, construction, and operation of the facility.

B. All enforcement issues related to the October 2009 NOV have been resolved, and the Applicant is in compliance with Appendix B of 10 C.F.R. Part 50.

This section describes the process by which the Staff resolved QA implementation issues described in the October 5, 2009, Inspection Report and NOV. See Exhibit NRC S2. The Staff's safety evaluation, summarized in the SER, confirms that the Applicant's QAPD meets applicable NRC requirements. Lipscomb Testimony at A17. However, because Contention 15 was initially admitted based on the QA implementation NOV issued to DTE on October 5, 2009, the Staff's testimony also addresses how the NOV was fully resolved and why no issues related to QA implementation remain. In the October 2009 NOV, the Staff stated that the Applicant:

- A. 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;
- B. had not completed any internal audits of QA programmatic areas implemented for Fermi 3 COL application activities performed to date; and
- C. had not documented trending of corrective actions to identify recurring conditions adverse to quality since the beginning of Fermi 3 project in March 2007.

Exhibit NRC S2 at 1-3. All three violations were assigned Severity Level IV, the level assigned to the least significant violation used in traditional enforcement as described in the NRC's Enforcement Policy. *Id.*; Written Direct Testimony of Aida Rivera-Varona (Rivera-Varona Testimony) at A7; Lipscomb Testimony at A21, citing NRC Enforcement Policy (Jan. 28, 2013), pp. 8-11, ADAMS Accession No. ML12340A295, attached hereto as Exhibit NRC S14. The introductory paragraph of Contention 15 restates these three violations. See LBP-10-9, 71 NRC at 510. Because the violations cited in the NOV form the basis for the specific issues raised in Contentions 15A and 15B, the Staff's testimony describes the resolution of the three violations and demonstrates that no QA implementation issues identified in the October 2009 NOV remain.

In the summer of 2009, the NRC Staff identified various discrepancies associated with the Applicant's documentation of its QA program. See Rivera-Varona Testimony at A5; Lipscomb Testimony at A19. The Staff subsequently conducted an inspection at the Applicant's headquarters in August 2009 in order to resolve its concerns related to DTE's QA documentation. Rivera-Varona Testimony at A6-A7; Lipscomb Testimony at A19-A20. Following the August 2009 inspection, the NRC Staff issued the October 2009 Inspection Report and NOV described above. Rivera-Varona Testimony at A7; Lipscomb Testimony at A19. The sequence of events leading to the resolution of this NOV is described in SER Chapter

17 and summarized in Staff Testimony and below. See Lipscomb Testimony at A22-A23; Exhibit NRC S1 at 17-32 to 17-36.

The Applicant responded to the NOV and denied the violations, arguing in part that DTE was not an applicant prior to submitting the Fermi 3 COLA on September 18, 2008, and that it could therefore not be cited for violations related to events that occurred prior to that date. Lipscomb Testimony at A22; Exhibit NRC S1 at 17-33. See *also* Detroit Edison Reply to a Notice of Violation 05200033/2009-201-01, 02, and 03 (Nov. 9, 2009) (Reply to October 2009 NOV), Attach. 1 at 3, ADAMS Accession No. ML093160318, attached hereto as Exhibit NRC S3.

The Staff agreed that, in keeping with NRC practice in other proceedings and the plain reading of NRC regulations and policies, no violations can be issued to organizations for actions or omissions occurring before they become applicants for NRC licenses. In this case the COLA was submitted to the NRC on September 18, 2008, and DTE is deemed to have become an applicant for an NRC license on that date. The Staff therefore issued a revised NOV that included a new Violation A limited to activities after the COLA submission date. Lipscomb Testimony at A22; Exhibit NRC S1 at 17-33. See *also* 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, attached hereto as Exhibit NRC S4. The April 2010 NOV also combined Violations B and C into a single item, and therefore included a total of two violations, both designated as Severity Level IV:

- A. from September 18, 2008 to August 21, 2009, DECo¹⁵ failed to establish measures to assure that safety-related services purchased through its contractor, Black & Veatch (B&V) for Fermi 3, conformed to procurement documents. Specifically, DECo failed to assure that B&V was qualified to supply the services procured in the contract between DECo and B&V.

¹⁵ DECo is an abbreviation for Detroit Edison Company, the former name of the DTE Electric Company. See n.2 *supra*.

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

April 2010 NOV, Exhibit NRC S4, Enclosure 2 at 1-2. The April 2010 NOV also stated that the Applicant's reply to the October 2009 NOV included corrective actions that resolved Violations B and C (now combined as Violation B), specifically that the Applicant conducted the internal audit and performed the trending evaluations that were required by the Applicant's procedures and that the October 2009 NOV had stated were necessary. See Lipscomb Testimony at A22; April 2010 NOV, Exhibit NRC S4 at 2; SER, Exhibit NRC S1 at 17-34. The Staff determined that no further actions were required to resolve Violation B in the April 2010 NOV. Lipscomb Testimony at A22, citing Exhibit NRC S4, Enclosure 1.

The Applicant responded to Violation A of the April 2010 NOV in a letter admitting the violation and outlining the corrective steps taken to address it. Lipscomb Testimony at A23; SER, Exhibit NRC S1 at 17-33; Detroit Edison Company Reply to Notice of Violation 05200033/2009-201-04 (May 26, 2010) (Reply to April 2010 NOV), ADAMS Accession No. ML101480046, attached hereto as Exhibit NRC S5. Specifically, the Applicant noted that it expanded its vendor qualification and review program, and listed the series of steps taken to ensure that B&V's work related to the Fermi 3 COLA was completed in accordance with 10 C.F.R. Part 50, Appendix B requirements. Lipscomb Testimony at A23; Reply to April 2010 NOV, Exhibit NRC S5, Attach. 1 at 3.

The Staff reviewed the Reply to April 2010 NOV, together with the Applicant's responses to a series of Requests for Additional Information (RAIs) that addressed DTE's qualification of and supervision of its contractor both before and after the COLA was submitted, and concluded

that the information provided by the Applicant was sufficient to resolve the cited violation by demonstrating that the Applicant was in compliance with Appendix B for the period after September 18, 2008. Lipscomb Testimony at A23. The Staff documented its acceptance of this response in a letter dated June 4, 2010. Lipscomb Testimony at A23, citing Nuclear Regulatory Commission Inspection Report 05200033/2009-201 and Revised Notice of Violation to Detroit Edison Company (June 4, 2010), ADAMS Accession No. ML101530596, attached hereto as Exhibit NRC S6.

Consequently, there are no aspects of the October 2009 NOV, which the Intervenors relied upon as support for Contention 15, that remain unaddressed. All issues related to internal audits and trending evaluations (Violations B and C in the October 2009 NOV; Violation B in the April 2010 NOV) were resolved in the November 2009 NOV response. Lipscomb Testimony at A22; April 2010 NOV, Exhibit NRC S4 at 2; SER, Exhibit NRC S1 at 17-34. The issues related to vendor qualification and oversight in Violation A of the April 2010 NOV were resolved in the May 2010 NOV response and related RAIs. Lipscomb Testimony at A23; Exhibit NRC S6 at 1. There are no additional violations related to Contention 15 pending against DTE. Lipscomb Testimony at A24. For this reason, any claim based on the original October 2009 NOV that the Applicant is not currently in compliance with Appendix B is without merit. Lipscomb Testimony at A24.

In summary, the Staff has determined that the QAPD described in the Fermi 3 FSAR meets all requirements of Appendix B and that the Applicant has resolved all QA implementation issues identified during the Staff inspection of August 2009. *Id.* 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.” *Id.*; *see also* LBP-10-9, 71 NRC at 511. Accordingly, all issues related to the portion of the contention labeled “Contention 15B” have been resolved, as have issues in the unnumbered introductory paragraph of the contention as they relate to activities after September 18, 2008.

C. All pre-application issues related to Contention 15A have been resolved.

The portion of the contention labeled “Contention 15A” focuses on alleged QA deficiencies at the time the Fermi 3 COLA was prepared, and states that the NRC “may not lawfully issue the COL until the deficiencies have been adequately corrected by the Applicant, or until the Applicant demonstrates that the deficiencies do not affect the quality of safety-related design information in the FSAR.” LBP-10-9, 71 NRC at 510. As explained in Section IIB above and in testimony cited therein, the closure of the October 2009 NOV did not address potential QA deficiencies associated with pre-application activities (those carried out before submission of the COLA on September 18, 2008) because an applicant cannot be cited for actions or omissions occurring before it became an applicant for an NRC license.

However, once an application is submitted to the NRC and accepted for docketing, the Staff does examine the nature, quality, sources, and reliability of the information it contains. Lipscomb Testimony at A25. The Staff therefore used the RAI process, a standard part of NRC licensing reviews, to examine the impact of potential QA deficiencies on safety-related design information in the COL Application. This process is documented in Chapter 17 of the SER. Exhibit NRC S1 at 17-34 to 17-35. As explained in Staff testimony and below, the Applicant’s RAI responses and corresponding updates to the COLA resolve all Staff concerns related to DTE’s oversight of B&V during the period when the COLA was developed, see Lipscomb Testimony at A25, which is the specific issue raised in Contention 15A. Those responses and revisions demonstrate that deficiencies originally cited in the October 2009 NOV “do not affect the quality of safety-related design information in the FSAR.” See LBP-10-9, 71 NRC at 510.

The Staff issued four RAIs to the Applicant to determine whether the deficiencies cited in the October 2009 NOV affected the quality of safety-related design information in the Fermi 3 COLA. Lipscomb Testimony at A25; Exhibit NRC S1 at 17-34. See *also* LBP-10-9, 71 NRC at 510. The first requested information on all safety-related activities carried out prior to September 18, 2008, and the QA programs that applied to them. Lipscomb Testimony at A25.

The second dealt with QA personnel employed by both the Applicant and B&V. *Id.* The third dealt with a QA program, the Nuclear Development Quality Assurance Program Description (ND QAPD) that was implemented specifically to control the Applicant's receipt of B&V work product prior to submittal of the Application. *Id.* Finally, the fourth requested detailed information concerning the interactions between the Applicant and its contractor both before and after submittal of the Application. *Id.* See also 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, attached hereto as Exhibit NRC S7.

The Applicant's response to these RAIs explains details of the QA programs applicable to work on safety-related COL Application sections for the Fermi 3 project during development of COLA work product by B&V (January 2007 to November 2007), during receipt and acceptance of B&V work product by DTE (November 2007 to September 2008), and following submittal of the COLA to NRC (after September 2008). See Lipscomb Testimony at A25, citing May 2010 RAI Responses, Exhibit NRC S7. In its response, the Applicant provided the following information: (1) a list of safety-related activities and safety-related COLA sections; (2) dates of the activity or section creation; (3) the contracting entity conducting the activity/section creation and governing QA; (4) the QA organization responsible for oversight of the activity/section creation; (5) information related to the contractors conducting QA oversight activities (e.g., surveillance, document review); (6) contractor approval dates; (7) dates of the Applicant's review and approval; (8) dates and type of Applicant QA oversight activities; (9) personnel information for both Applicant and contractor organizations; and (10) a summary of the various versions of the Fermi 3 QAPD and related implementation procedures. See Lipscomb Testimony at A25, citing May 2010 RAI Responses, Exhibit NRC S7.

The Staff reviewed the information in the May 2010 RAI Responses and determined that, for activities occurring before submission of the COLA on September 18, 2008, the Applicant had contractually delegated to B&V the work of developing and implementing a QA

program for COLA development that satisfied the requirements of 10 C.F.R. Part 50, Appendix B, and that B&V had established such a program. Lipscomb Testimony at A25; Exhibit NRC S1 at 17-35. See also Appendix B, Section IV, "Procurement Document Control." The Staff also determined that while the Applicant was not required to establish a full QA program meeting all requirements of Appendix B prior to submitting the COLA to the NRC, the Applicant did establish the ND QAPD that included those elements of an Appendix B QA program necessary to support the review and acceptance of B&V work product. Lipscomb Testimony at A25; Exhibit NRC S1 at 17-35. The Staff also reviewed the dates of B&V work product acceptance and concluded that the Applicant used the ND QAPD for review and acceptance of B&V work product prior to submittal of the COLA.¹⁶ Lipscomb Testimony at A25, citing May 2010 RAI Responses, Exhibit NRC S7, Attach. 1 at RAI 17-5.16 Table.

As documented in the SER, these RAIs are now closed, see Exhibit NRC S1 at 17-36, and the NRC Staff has concluded that pre-application deficiencies in DTE's QA documentation "do not affect the quality of safety-related design information in the FSAR." Lipscomb Testimony at A25; LBP-10-9, 71 NRC at 510. Claims to the contrary in the part of the contention labeled "Contention 15A" are therefore without merit.

D. Audits/Inspections of B&V also show that its QA program complies with Appendix B.

In its February 28, 2013, Order identifying questions for the parties to address in their pre-filed written testimony, the Board inquired about audits of B&V performed by the Applicant or others. See Board Questions at 1. The Staff has conducted two separate audits/inspections that are relevant to this question, one in 2007 limited to B&V's work on the Fermi 3 project and a broader vendor inspection in 2010. See Lipscomb Testimony at A26. The Staff is also aware of two other audits of B&V's QA program, one by Nuclear Procurement Issues Committee (NUPIC) in 2007 and another by the Applicant in 2009. *Id.* at A27.

¹⁶ The Board inquired about this topic in the sixth of the questions it submitted to the parties in its order of February 28, 2013. Board Questions at 2.

In July 2007, the Staff conducted a field audit of pre-application subsurface investigations carried out to support the site characterization discussion in the Fermi 3 COLA. Lipscomb Testimony at A26, citing 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, attached hereto as Exhibit NRC S8. The Staff reviewed B&V's QA program at the time of the audit and determined that "[d]rilling and field testing activities were controlled by adequate procedures and standards with an appropriate level of supervisory and quality assurance oversight." 2007 B&V Audit Report, Exhibit NRC S8 at 3-4.

The NRC Staff also conducted a routine vendor inspection of B&V in 2010. Lipscomb Testimony at A26. This inspection was not limited to B&V's activities in support of the Fermi 3 COL Application, but also included B&V activities related to other applications pending before the NRC. The NRC Staff issued a B&V Inspection Report and NOV on October 14, 2010. *Id.*, citing NRC Inspection Report No. 99901391/2010-201 and Notice of Violation, ADAMS Accession No. ML102790137, attached hereto as Exhibit NRC S9. The inspection team found no violations of the QA requirements in Appendix B of 10 C.F.R. Part 50. Lipscomb Testimony at A26. The sole violation identified in the NOV concerned requirements under 10 C.F.R. Part 21 rather than Appendix B and was for activities unrelated to Fermi 3; the NRC Staff documented closure of the NOV in a letter dated December 17, 2010. Lipscomb Testimony at A26, citing NRC Inspection Report No. 99901391/2010-201 and Notice of Violation ML103500064, attached hereto as Exhibit NRC S10. Because this inspection found no violations of Appendix B requirements by B&V, it lends additional support to the Staff's conclusion that B&V's work on the Fermi 3 Application was carried out under appropriate QA controls.

The Staff inspection team for the August 2009 inspection at the Applicant's Michigan

headquarters, see October 2009 NOV, Exhibit NRC S2, obtained information about two other audits of B&V's QA program. The first, NUPIC's audit of B&V's QA program, was conducted prior to the Applicant's selection of B&V for COLA development in April 2007, and the Staff inspection team was informed that the selection and qualification of B&V was largely based on the NUPIC audit. Lipscomb Testimony at A27. The second, the Applicant's own audit of B&V in July 2009, is discussed in the Staff's October 2009 NOV. Lipscomb Testimony at A27, citing October 2009 NOV, Exhibit NRC S2, Enclosure 2 at 10-11. Both of these audits provide additional support for the conclusion that B&V's activities related to the Fermi 3 Application were carried out under appropriate QA controls.

CONCLUSION

The NRC Staff has conducted a thorough review of QA issues related to the Fermi 3 COL Application. The licensing review documented in the SER (Exhibit NRC S1) was carried out according to the guidance in SRP Section 17.5 (Exhibit NRC S11) and NEI 06-14A, Revision 7 (Exhibit NRC S13) and involved the review of RAI responses (Exhibit NRC S7) related to Chapter 17 of the FSAR. In addition, the Staff carried out an inspection of the Applicant (Exhibits NRC S2-S6), and an audit and an inspection of the Applicant's contractor B&V (Exhibits NRC S8-S10). The extensive record that has been developed since 2009, when Contention 15 was first submitted in this proceeding, demonstrates that all issues related to the contention have been resolved. Accordingly, the contention is without merit and the Board should rule in favor of the Applicant.

Respectfully Submitted,

/Signed (electronically) by/
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Dated at Rockville, Maryland
this 30th day of April, 2013

ATTACHMENT 1

**DTE Electric Company
(Fermi Nuclear Power Plant Unit 3)
Docket No. 52-033-COL
October 2013 Evidentiary Hearing
NRC Staff Exhibit List for Contention 15**

NRC Exhibit #	Witness/Panel	Description, ADAMS Accession Number, and Short Reference Name
NRC S1	all	Chapter 17 of the Advanced Safety Evaluation Report (SER) With No Open Items for Fermi 3 (Oct. 17, 2011), ADAMS Accession No. ML112630120.
NRC S2	Rivera-Varona, Lipscomb	NRC Inspection Report 05200033/2009-201 and Notice of Violation (Oct. 5, 2009) (October 2009 NOV), ADAMS Accession No. ML092740064.
NRC S3	Rivera-Varona, Lipscomb	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.
NRC S4	Lipscomb	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.
NRC S5	Lipscomb	Detroit Edison Company Reply to Notice of Violation 05200033/2009-201-04 (May 26, 2010) (Reply to April 2010 NOV), ADAMS Accession No. ML101480046.
NRC S6	Lipscomb	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.
NRC S7	Lipscomb	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.

NRC S8	Lipscomb	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.
NRC S9	Lipscomb	NRC Inspection Report No. 99901391/2010-201 and Notice of Violation (Oct. 14, 2010) (2010 B&V Inspection Report), ADAMS Accession No. ML 102790137.
NRC S10	Lipscomb	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. ML 103500064.
NRC S11	Lipscomb	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.
NRC S12	Lipscomb	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.
NRC S13	Lipscomb	NEI 06-14A [Revision 7], "Quality Assurance Program Description" (August 2010), ADAMS Accession No. ML 102370305.
NRC S14	Lipscomb	NRC Enforcement Policy (Jan. 28, 2013), pp. 8-11, ADAMS Accession No. ML12340A295.
NRC S15	Muñiz	Statement of Professional Qualifications for Adrian Muñiz
NRC S16	Rivera-Varona	Statement of Professional Qualifications for Aida Rivera-Varona
NRC S17	Lipscomb	Statement of Professional Qualifications for George A. Lipscomb

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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

CERTIFICATE OF SERVICE

I hereby certify that "CONTENTION 15 – NRC STAFF INITIAL STATEMENT OF POSITION," along with the Staff's pre-filed written direct testimony for Contention 15 and associated exhibits, has been filed through the E-Filing system this 30th day of April, 2013

Respectfully Submitted,

/Signed (electronically) by/
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Dated at Rockville, Maryland
This 30th day of April, 2013