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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))

**DTE ELECTRIC COMPANY’S INITIAL
STATEMENT OF POSITION ON CONTENTION 15**

I. INTRODUCTION

Pursuant to 10 C.F.R. § 2.1207(a)(1) and the Licensing Board’s Order (Modifying the Schedule), dated December 12, 2012, DTE Electric Company (“DTE” or “Applicant”) hereby submits this Initial Statement of Position on Contention 15.¹ This Initial Statement of Position is supported by direct testimony from Peter Smith, Stanley Stasek, Ronald Sacco, and Steven Thomas (“DTE Testimony”) and by the exhibits submitted concurrently. For the reasons set forth below, there is reasonable assurance of the quality of the safety-related information in the combined license (“COL”) application for Fermi Nuclear Power Plant, Unit 3 (“Fermi 3”) that is based on tests, investigations, or other safety-related activities conducted by DTE’s contractor, Black & Veatch (“B&V”). DTE has also demonstrated its commitment to implementation of a Quality Assurance (“QA”) program that complies with applicable NRC QA regulations and guidance. Contention 15 should be resolved in favor of DTE.

¹ DTE Electric formerly operated under the name Detroit Edison Company. The name change was effective on January 1, 2013. For simplicity, the name “DTE” will be used throughout this testimony.

II. SUMMARY OF ARGUMENT

Although the Intervenors suggest “serial” violations of QA requirements and a lack of commitment to a QA program, the assertion in the contention is wholly inconsistent with the clear record. DTE has demonstrated its commitment to QA from the start of the Fermi 3 project by selecting a contractor with an existing Appendix B QA program and by requiring by contract that safety-related work be performed under that program. DTE has also assured quality throughout the COL project by exercising direct oversight of relevant work and by establishing its own Appendix B QA program prior to accepting any information for use in the COL Application. There was one NRC enforcement action cited in the contention, but there were no safety consequences and the issue was resolved based on corrective actions. There has been no pattern of violations of QA requirements on the Fermi 3 project.

As described in the COL Application, DTE has implemented a Quality Assurance Program Description (“QAPD”) for the Fermi 3 project. Work on the Fermi 3 project has been and is being performed under procedures and other work control processes. DTE has performed numerous audits, surveillances, assessments, and other actions to ensure effective implementation of the DTE QA program. The NRC Staff has completed its review of the QAPD and determined that it is consistent with NRC regulations. Ongoing implementation of the program is also subject to ongoing NRC oversight. In sum, there is reasonable assurance that the Fermi 3 QA program has been, can be, and will be implemented in accordance with NRC regulations and the applicable QAPD.

III. PROCEDURAL HISTORY

Contention 15 was originally submitted on November 6, 2009, along with a declaration from Arnold Gundersen.² In Contention 15, Intervenors stated that, in or about March 2007, DTE entered into a contract with B&V under which B&V performed activities in support of the Fermi 3 COL Application, including site-related testing and investigation. According to the Intervenors, DTE was at that time required to establish a QA program and to apply that program to the safety-related activities of B&V. The original contention was extrapolated largely from an NRC Staff inspection in August 2009 which found, in certain clearly-defined (and limited) respects, that DTE had failed to comply with the QA requirements of Appendix B. The contention incorrectly inflated the inspection finding to “willing and deliberate” failures to comply with 10 C.F.R. Part 50.

On October 5, 2009, the NRC Staff issued an Inspection Report and Notice of Violation (“NOV”) in which it described the results of its August 18-21, 2009 inspection. In the NOV, the NRC Staff cited DTE for three violations of NRC requirements:

- A. Failing to establish and implement a Fermi Unit 3 QA program between March 2007 (when Detroit Edison initially contracted with B&V for the conduct of COLA activities for Fermi Unit 3) and February 2008, and failing to retain overall control of contracted COLA activities as required under Criterion II, “Quality Assurance Program” of Appendix B, resulting in inadequate control of procurement documents and ineffective control of contract services performed by B&V for COLA activities;
- B. Failing to perform internal audits of QA programmatic areas implemented for Fermi Unit 3 COLA activities; and
- C. Failing to document trending of Detroit Edison’s corrective action reports (“CARs”).

² “Supplemental Petition of [Intervenors] for Admission of a Newly-Discovered Contention, and for Partial Suspension of COLA Adjudication,” dated Nov. 6, 2009 (“Supplemental Petition”).

These were all characterized by the NRC Staff as Severity Level IV violations under the NRC's Enforcement Policy — the lowest significance level for cited violations.

After Contention 15 was proposed, DTE replied to the NOV, on November 9, 2009, denying that a violation occurred.³ Among other reasons given, DTE was not a COL applicant before September 18, 2008, and thus was not subject to Appendix B requirements. DTE's response to the NOV clearly established that there was no "willing" or "deliberate" choice by DTE to ignore Appendix B QA requirements.

On April 27, 2010, the NRC Staff responded to DTE's reply to the NOV.⁴ The NRC Staff accepted that, prior to September 18, 2008, DTE was not yet an applicant and that the NRC's requirements were not applicable to DTE at that time. As a result, Violation A of the NOV was withdrawn. There was therefore no longer any basis for a contention that DTE ignored QA requirements prior to September 2008.

The NRC Staff response of April 27, 2010, articulated a new Violation A and consolidated the former Violations B and C into one other violation as follows:

- A. 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 after September 18, 2008; and
- B. Failure to follow procedures in two cases: (1) failing to perform internal audits of QA programmatic areas implemented for Fermi Unit 3 COLA activities; and (2) failing to document trending of CARs.

³ NRC3-09-0041, "Detroit Edison Reply to Notice of Violation 05200033/2009-201-01, 02, and 03," dated Nov. 9, 2009 (ADAMS Accession No. ML093160318) ("Reply to NOV") (Exh. DTE000035).

⁴ EA-09-286, "NRC Response to Detroit Edison Reply to Notice of Violation 05200033/2009-201-01, 02, and 03 and Revised Notice of Violation to Detroit Edison Company," dated April 27, 2010 (ADAMS Accession No. ML100330687) ("Revised NOV") (Exh. DTE000086).

Far from reflecting a programmatic breakdown in QA, both violations were very specific and were again characterized as Severity Level IV violations.

DTE had responded to the revised Violation B (incorporating originally proposed Violations B and C) in its correspondence of November 9, 2009, explaining the reasons and the corrective actions for the violation. No further response to Violation B was therefore required. On May 26, 2010, DTE responded to the new issue identified in revised Violation A, documenting the corrective steps taken to address that issue and prevent recurrence.⁵

DTE also provided additional information on QA issues to the NRC Staff in a May 10, 2010 response to an NRC Staff Request for Additional Information (“RAI”) addressing Standard Review Plan (“SRP”) Section 17.5 (QA).⁶ The RAI Response included information responsive to the following NRC Staff requests:

- A detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were conducted in a manner consistent with the requirements of Appendix B.
- A table of information identifying: (1) a list of safety-related activities and safety-related COL application sections; (2) dates of the activity or section creation; (3) contracting entity conducting the activity/section creation and governing QAPD; (4) QA organization responsible for oversight of the activity/section creation; (5) dates and type of any specific contractor QA oversight activities (*i.e.*, surveillance, document review, etc.); (6) contractor approval date; (7) dates of DTE review and approval; and (8) dates and type of any specific DTE QA oversight activities (*i.e.*, surveillance document review, etc.).

⁵ NRC3-10-0023, “Detroit Edison Company Reply to Notice of Violation 05200033/2009-201-04, Enforcement Action EA-09-286,” dated May 26, 2010 (ADAMS Accession No. ML101480046) (“Reply to Revised NOV”) (Exh. DTE000057).

⁶ NRC3-10-0019, “Detroit Edison Company Response to NRC Request for Additional Information Letter No. 26, Related to SRP Section 17.5,” dated May 10, 2010 (ADAMS Accession No. ML101320254) (“RAI Response”) (Exh. DTE000054).

Subsequent to the RAI Response, on June 11, 2010, the Intervenors filed a motion to amend their supplemental petition, once more supported by a declaration from Arnold Gundersen.⁷ The Intervenors again complained, in hyperbolic language, that the RAI Response “reinforces the perception that the Applicant is knowingly flaunting NRC regulations and explicit QA guidance from the nuclear industry.” Intervenors asserted, based on the opinions of its declarant, that there were four “major” QA concerns based on the RAI Response. The concerns related to organizational roles created for the Fermi 3 QA program during the organizational transitions discussed in the responses to the NOV and the NRC’s RAI.⁸

The Board issued its ruling on the admissibility of Contention 15 on June 15, 2010.⁹ Contention 15, as admitted for hearing, states 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

⁷ “Intervenors’ Motion to Amend Supplemental Petition for Admission of Proffered Quality Assurance Contention No. 15,” dated June 11, 2010 (“Supplemental Petition”).

⁸ *Id.* at 4-5.

⁹ LBP-10-09, “Ruling on Proposed New Contentions 15 and 16,” dated June 15, 2010 (“LBP-10-09”).

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.

In admitting Contention 15 the Board identified two specific issues for consideration.¹⁰ The first issue concerns the reliability of safety-related information in the FSAR. The contention, according to the Board, asserts that DTE's purported failure to comply with Appendix B requirements infects the safety-related information in the FSAR that is based on B&V's tests, investigations, or other safety-related activities, thereby precluding the NRC from relying on such information in its COL licensing decision.¹¹ The second issue relates to the Intervenors' assertion that there is a history of QA violations associated with the Fermi 3 project, and therefore a lack of commitment to compliance with Appendix B requirements.¹² The Intervenors demanded that DTE "provide[] satisfactory proof positive of a fully-implemented quality assurance program which integrates all previous and contemplated QA revisions."¹³

¹⁰ *Id.* at 15-16.

¹¹ *Id.* at 15.

¹² *Id.*

¹³ Supplemental Petition at 17.

On June 23, 2010, the Board issued an Order addressing the Motion to Amend Contention 15.¹⁴ The Board denied the motion as moot. The Board stated that its ruling was without prejudice to the Intervenors filing a motion to amend Contention 15 as admitted by the Board “to include the new allegations described in the Motion to Amend.”¹⁵ The Intervenors, to date, have not filed any such motion. The specific issues raised in the Motion to Amend therefore remain outside the scope of Contention 15 now before the Board.

On April 17, 2012, DTE moved for summary disposition of Contention 15. In LBP-12-23, the Board declined to grant summary disposition. According to the Board, summary disposition was not appropriate because issues of material fact remain in dispute. Specifically, the Board found that the adequacy of the QA program both before and after submission of the COL Application is a disputed issue of material fact that must be resolved through the evidentiary hearing process.

IV. APPLICABLE LEGAL STANDARDS

A. Regulatory Standards for Quality Assurance Programs

Every “application” for a COL must include in the Final Safety Analysis Report (“FSAR”) a description of the managerial and administrative controls applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility.¹⁶ In particular, the “Quality Assurance Criteria for Nuclear Plants and Fuel Reprocessing Plants,” set forth in Appendix B to 10 C.F.R. Part 50, must be implemented for activities affecting safety-related plant equipment. QA programs ensure systematic monitoring and evaluation of the

¹⁴ Licensing Board Order (Denying Motion to Amend Supplemental Petition for Admission of Proffered Quality Assurance Contention No. 15), June 23, 2010 (unpublished).

¹⁵ *Id.* at 1.

¹⁶ 10 C.F.R. § 50.34(b)(6)(ii).

design, construction, procurement of equipment, and operation of nuclear facilities to provide adequate confidence that structures, systems, and components required for safety will perform satisfactorily in service.

DTE's QA Program is addressed in Chapter 17 of the Fermi 3 COL Application FSAR. In accordance with NRC regulations, the Fermi 3 FSAR provides a detailed description of planned and systematic actions to assure safety and reliability during design (FSAR Chapters 17.1 and 17.4),¹⁷ and during construction and operation of the plant (FSAR Chapter 17.2). The FSAR also includes a detailed discussion of the Fermi 3 Quality Assurance Program Description ("QAPD") (FSAR Chapters 17.3 and 17.5). The QAPD itself was submitted to the NRC as Appendix 17AA to the FSAR.

The NRC's Standard Review Plan ("SRP")¹⁸ for QA programs is based on several standards and guidance documents, including American Society of Mechanical Engineers ("ASME") Standards NQA-1; Regulatory Guide 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," Revision 3; Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3; and NRC Review Standard (RS)-002, "Processing Applications for Early Site Permits." The NRC acceptance criteria for QA programs include a commitment by the applicant to comply with the regulations and applicable guidance

¹⁷ Substantial portions of the "design" work are the subject of the QA program of the nuclear technology vendor in accordance with the design certification application for the ESBWR and NRC's Part 52 regulations.

¹⁸ See NUREG-0800, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants" (March 2007).

outlined above. The Fermi 3 QAPD is based on the standards in NQA-1-1994.¹⁹ DTE's specific commitments with respect to NRC Regulatory Guides are included in QAPD Part IV.

The Nuclear Energy Institute ("NEI") also has developed a generic template, NEI-06-14A, "Quality Assurance Program Description," for use by COL applicants to implement the applicable requirements and industry standards for QA programs. The template includes the methods and administrative control requirements that meet 10 C.F.R. Part 50, Appendix B, and 10 C.F.R. Part 52. The NEI template is also based on the standards of NQA-1-1994. The NRC endorsed the current version of the generic template in July 2010,²⁰ and NEI issued the endorsed version as NEI-06-14A, Revision 7, in August 2010.²¹ The Fermi 3 QAPD was specifically developed based on the NEI-06-14A template.²²

B. Legal Standards for Quality Assurance Contentions

In evaluating alleged deficiencies in an applicant's quality assurance program, a licensing board "need[s] to bear in mind the enormous size and complexity of [a] nuclear power

¹⁹ NQA-1-1994 is an NRC-approved standard for a Quality Assurance program as referenced in the SRP.

²⁰ Final Safety Evaluation Report for Technical Report NEI-06-14, "Quality Assurance Program Description, Revision 9" (July 13, 2010) (ADAMS Accession No. ML101800497) (Exh. DTE000088).

²¹ NEI-06-14A, Rev. 7, dated August 2010 (ADAMS Accession No. ML102370305) (Exh. DTE000091).

²² DTE implemented Revision 7 of NEI-06-14A in Revision 3 of the Fermi 3 FSAR. FSAR Section 17.5 refers to NEI-06-14A, Revision 7, as does the revision summary of the QAPD (FSAR Appendix 17AA). Incremental NEI template revision updates to the Fermi 3 QAPD were provided to the NRC through markups of the COL Application within RAI responses. Revision 3 of the FSAR formally incorporated those updates into the FSAR.

plant.”²³ Perfection is not a precondition for a license.²⁴ Rather, the standard in any reactor licensing proceeding must be whether there exists “reasonable assurance” that the plant “will be constructed and will be operated” in conformity with Commission regulations and without endangering the public health and safety.²⁵

In *Georgia Power*, the Commission affirmed dismissal of a quality assurance contention where the affidavits submitted in the licensee’s motion for summary disposition “revealed that the quality assurance program met applicable regulatory requirements and functioned in accordance with the intent of the Commission’s regulations.”²⁶ The *Georgia Power* licensing board had “evaluated the discrepant situations identified by the intervenors and observed that none . . . has been shown to carry any material safety significance with respect to plant operation nor does the totality of them indicate a pervasive breakdown of the Applicants’ [quality assurance program].”²⁷

²³ *Pacific Gas and Electric Co.* (Diablo Canyon Nuclear Power Plant, Units 1 & 2), ALAB-756, 18 NRC 1340, 1344 (1983).

²⁴ *Union Electric Co.* (Callaway Plant, Unit 1), ALAB-740, 18 NRC 343, 345 (1983); *see Duke Power Co.* (Catawba Nuclear Station, Units 1 and 2), LBP-84-24, 19 NRC 1418, 1433 (1984).

²⁵ *See* 10 C.F.R. § 52.97; *Union Electric Co.*, 18 NRC at 345 (citing 42 U.S.C. §§ 2133(d), 2232(a); *Power Reactor Development Co. v. International Union*, 367 U.S. 396, 407 (1961); *Maine Yankee Atomic Power Co.* (Maine Yankee Atomic Power Station), ALAB-161, 6 AEC 1003, 1004 (1973), *aff’d sub nom. Citizens for Safe Power v. NRC*, 524 F.2d 1291 (D.C. Cir. 1975)).

²⁶ *Georgia Power Co.* (Vogtle Electric Generating Plant, Units 1 and 2), ALAB-872, 26 NRC 127, 139-140 (1987).

²⁷ *Id.* at 140 (internal citations omitted).

In *Cleveland Electric*, the Commission upheld dismissal of a QA contention where the NRC Staff had discovered deficiencies in the applicant's oversight of its contractor.²⁸ The Commission found it persuasive that the NRC Staff subsequently decided that a significant breakdown in the contractor's quality assurance program had not occurred, the applicant's quality assurance program was providing active oversight of the contractor's program prior to commencement of the NRC investigation, and the applicant took corrective steps to upgrade the quality assurance program.²⁹ The Commission reiterated that there will "undoubtedly be a substantial number of construction deficiencies" that require correction, but acknowledged that the steps taken to address those deficiencies were subject to a reasonableness test that considered their nature and significance, the stage of plant construction, and the potential for the deficiency to be constructed over prior to resolution.³⁰

At bottom, resolution of a quality assurance contention is warranted where (1) a quality assurance program has been established that meets applicable regulatory requirements and the applicable standards and guidance; (2) the Intervenors have not identified any QA problems that carry material safety significance with respect to plant design, equipment procurement, construction, or operation; and (3) where the totality of any QA issues do not indicate a pervasive breakdown of the QA program.

²⁸ *Cleveland Electric Illuminating Co. (Perry Nuclear Power Plant)*, ALAB-802, 21 NRC 490, 504 (1985).

²⁹ *Id.*

³⁰ *Id.* at 503.

C. Burden of Proof

An applicant generally has the burden of proof in a licensing proceeding.³¹ The NRC in its administrative proceedings has generally relied upon the “preponderance of the evidence”³² standard in reaching the ultimate conclusions after a hearing to resolve a contention.³³ Thus, the Board must consider the evidence and testimony and determine whether DTE has shown by the preponderance of the evidence that the QA program meets applicable regulatory requirements, that there are no QA issues that carry material safety significance, and that there is no pervasive breakdown of the QA program.

V. APPLICANT WITNESSES

DTE’s Initial Written Testimony on Contention 15 is presented by Mr. Peter Smith, Mr. Stanley Stasek, Mr. Ronald Sacco, and Mr. Steven Thomas. Through the testimony and supporting exhibits, DTE’s expert witnesses demonstrate that that appropriate quality measures were applied to the development of safety-significant information in the COL Application, that there has been no breakdown in the QA program, and that the QAPD provided in the COL Application meets NRC’s regulatory requirements.

³¹ 10 C.F.R. § 2.325.

³² The definition of “preponderance of the evidence” in Black’s Law Dictionary, 6th ed. (p. 1182), is “[e]vidence which is of greater weight or more convincing than the evidence offered in opposition to it; that is, evidence which as a whole shows that the fact sought to be proved is more probable than not.”

³³ *Advanced Medical Systems, Inc.* (One Factory Row, Geneva, Ohio 44041), CLI-94-6, 39 NRC 285 (1994), *aff’d*, *Advanced Medical Systems, Inc. v. NRC*, 61 F.3d 903 (6th Cir. 1995); *see also Commonwealth Edison Co.* (Zion Station, Units 1 & 2), ALAB-616, 12 NRC 419, 421 (1980) (stating that applicants are not held to an absolute standard or required to prove a matter conclusively but rather, consistent with the Administrative Procedure Act, are held to a preponderance standard).

A. Peter Smith

Mr. Smith is the Director, Nuclear Development – Licensing and Engineering, for Fermi 3 and has served in that position since 2007. He has had overall responsibility for the COL Application for Fermi 3. He presently reports to the Senior Vice President for Major Enterprise Projects and the Chief Nuclear Officer. Mr. Smith testifies that, since the beginning of the Fermi 3 project, and prior to submittal of the COL Application, DTE has been committed to implementing quality assurance procedures for all aspects of work that are important to the safety of the Fermi 3. He describes the evolution of the QA program in the pre-application phase through the current application review phase and discusses how the Fermi 3 QAPD meets NRC and industry standards. He also addresses the specific deficiencies identified by the NRC Staff during a QA program inspection conducted in August 2009, as well as the corrective actions that responded to the findings.

Mr. Smith concludes that, in both the pre-application phase and the application review phase of the project, DTE has ensured, through systematic processes, that suppliers of safety-related equipment or services have met the applicable requirements of 10 C.F.R. Part 50, Appendix B. The oversight that has been conducted over specific safety-related activities further assures the quality of information in the Fermi 3 COL Application.

B. Stanley Stasek

Mr. Stasek has been employed by DTE as Director, Quality Management, for the Fermi 3 project since 2009. In that position, he is responsible for developing and maintaining the Fermi 3 QAPD, evaluating compliance with the program, and managing the QA organization resources. He testifies that the Fermi 3 QAPD submitted with the COL Application meets applicable regulatory requirements. He states that the program is currently functioning in

accordance with the NRC's regulations. He also addresses the only "discrepant" conditions identified by the Joint Intervenors — the two Severity Level IV NOVs issued in April 2010. He concludes that these do not demonstrate either a pervasive breakdown of the Fermi 3 QA program or a lack of commitment to implementing the program, as broadly alleged by the Intervenors. And, he notes that the NRC Staff has not found any ongoing compliance issues, much less a pervasive or programmatic breakdown, in the Fermi 3 QA program.

C. Ronald Sacco

Mr. Sacco is employed by B&V as the Director of Nuclear Quality Assurance for B&V Energy in Overland Park, Kansas. In his testimony, he explains the Part 50, Appendix B, QA program implemented by B&V during COL Application development and applied to safety-related work for the Fermi 3 COL Application project. He also describes the scope of work for B&V in connection with the Fermi 3 COL Application and his basis for assurance that the work — particularly work prior to September 2008 — meets NRC expectations and requirements.

D. Steven Thomas

Mr. Thomas is employed by B&V as an Engineering Manager in Overland Park, Kansas. He has been in that position since 2007 and was responsible for all engineering and technical activities necessary to develop the Fermi 3 COL Application. Since the application was submitted to the NRC, he has been responsible for assisting DTE in responding to requests for information and resolving technical issues arising during the regulatory review. He also supported DTE during their meetings with the Advisory Committee on Reactor Safeguards ("ACRS"), including on quality assurance issues. In his testimony, he addresses the work controls implemented under the B&V QA program and applied to safety-related work for the Fermi 3 project performed by B&V and its contractors, as well as his basis for assurance that the work was of high quality and consistent with NRC expectations.

VI. BACKGROUND

A. Overview of Quality Affecting Activities in COL Application

The Fermi 3 COL project was initiated in December 2006. In late April 2007, DTE formally established the Fermi 3 Nuclear Development (“ND”) project group to oversee the COL Application project. Development of the COL Application included preparation of an FSAR to support the NRC Staff’s technical review. The major activities to develop the FSAR involved site characterization, information gathering, and preparation of the FSAR. With respect to the site characterization and information gathering for the FSAR, the principal safety-related activities were:

- Site geotechnical and hydrogeological investigations,
- Seismic analysis, and
- Meteorological analysis.³⁴

These are the work activities that had at least the potential to influence the design of safety-related structures, systems, and components. Because there are no site-specific safety-related design features for the Economic Simplified Boiling Water Reactor (“ESBWR”), the safety-related information in the Fermi 3 COL Application was ultimately limited to Chapter 2 and portions of Chapters 3 and 6 of the FSAR. As DTE’s experts testify, all safety-related work for the Fermi 3 application was subject to 10 C.F.R. Part 50, Appendix B, QA programs.³⁵

B. Overview of QA Program During Application Development

At the outset of the Fermi 3 project in January 2007, DTE contracted with B&V for the COL Application development work. Under the contract DTE delegated to B&V the

³⁴ DTE Testimony at ¶25.

³⁵ *Id.* at ¶¶4, 32, 39-40, 54-55, 61, 95-96.

responsibility for establishment and execution of a QA program for the project scope of work.

Delegation is explicitly permitted in 10 C.F.R. Part 50, Appendix B, Criterion I, which states:

The applicant shall be responsible for the establishment and execution of the quality assurance program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program.

As Mr. Smith and Mr. Thomas testify, DTE retained responsibility for quality assurance as a commercial and contract matter.³⁶ DTE solicited proposals only from contractors who were established in the nuclear services business and who were currently executing comparable projects for other potential applicants. DTE required bidders to demonstrate as a prerequisite that they had an established Appendix B QA program and explain how their Appendix B QA program would be applied to the Fermi 3 COL Application. The contract also included specific terms with respect to QA.

DTE's approach was consistent with the approach to QA outlined by the NRC in a Part 52 rulemaking. There, the NRC Staff explained that services (*e.g.*, geologic or seismic analyses) that are safety-related and that could be relied upon in the siting, design, and construction of a nuclear power plant are to be treated as "basic components" as defined in Part 21.³⁷ According to the NRC, these site-specific safety-related services must be either purchased as basic components, requiring the service provider to have an Appendix B QA program and a Part 21 program, or the applicant could dedicate the service in accordance with Part 21, which requires the applicant's dedication process to be controlled under an Appendix B QA program.

³⁶ *Id.* at ¶¶28, 30, 32, 95-96.

³⁷ "Licenses, Certifications, and Approvals for Nuclear Power Plants; Final Rule," 72 Fed. Reg. 49352, 49424 (August 28, 2007).

As discussed in the testimony, DTE followed the former approach, purchasing the services from B&V, which had its own Appendix B program.

After contract award, B&V reported to the Fermi 3 Nuclear Development organization, which had responsibility for the COL Application. As Mr. Smith testifies, the Nuclear Development organization exercised management oversight and supervision over B&V and their work activities.³⁸ And, beginning in November 2007, DTE began a formal process for the receipt, review, and acceptance of COL Application work product from B&V for submittal to the NRC. No work product was accepted until the Fermi 3 project had its own QA program in place beginning in February 2008 to apply to the acceptance process.

VII. DISCUSSION OF CONTENTION 15A

As the testimony and exhibits summarized below demonstrate, COL Application work was performed by B&V at DTE's direction under B&V's established Appendix B/NQA-1 QA program. This program included procedures, training, and work controls applied to site investigations, tests, and other safety-related activities to support the development of a COL Application. DTE also established an Appendix B program for the review and acceptance of COL Application work product prior to accepting any COL Application work product and prior to submitting the COL Application for NRC review. Based on the comprehensive set of work controls and oversight applied to safety-related information in the COL Application, the information developed prior to COL submittal is of high-quality. There has been no pattern of QA violations. No issues of material significance have been identified.

³⁸ DTE Testimony at ¶¶30, 48-51.

A. COL Application Quality Prior to February 2008

The DTE witnesses discuss the pre-application safety-related activities specific to Fermi 3 that fall within the scope of the COL (*i.e.*, site investigation activities). In particular, geological, hydrogeological, and seismic information was developed from borings and test wells at the Fermi site conducted by B&V and its subcontractors between April and September 2007. Several layers of programmatic controls existed to assure the quality of safety-related work documented in the COL Application during the site investigation:

- The B&V Appendix B QA Program, including training and specific work controls implemented under the B&V QA Program and B&V QA oversight.³⁹
- Oversight by the DTE Fermi 3 Project, augmented by DTE's Owner's Engineer.⁴⁰
- NRC inspections.⁴¹

1. *B&V QA Program*

Mr. Sacco describes how the B&V QA Program, which existed prior to the Fermi 3 project, is a 10 C.F.R. Part 50, Appendix B, program that meets the standards of NQA-1.⁴² The B&V QA program is implemented through a set of procedures consistent with NQA-1. The witnesses explain that major work interfaces for activities affecting COL Application development, including clear and effective lines of communication, were established through

³⁹ *Id.* at ¶¶39-47.

⁴⁰ *Id.* at ¶¶48-51.

⁴¹ *Id.* at ¶52.

⁴² *Id.* at ¶39.

implementation of a B&V Project Management Memorandum (“PMM”).⁴³ The PMM also identified the quality attributes required for the B&V work activities consistent with the contract.

The B&V QA program applied to safety-related field work (e.g., geotechnical and hydrogeological work) was implemented through specific procedures.⁴⁴ B&V professionals on the project and subcontractors working under the B&V QA program were all trained in accordance with B&V nuclear procedures. The specific project documents that were issued for site investigations were reviewed in accordance with a B&V document review and approval procedure and a B&V design verification procedure. Vendor test reports were also provided to B&V for review and acceptance in accordance with a B&V review and approval procedure.⁴⁵

During the on-site investigations, B&V assigned a subject matter expert to each of the drill rigs to record data and provide oversight of site activities. Data collected was recorded in accordance with a project instruction. The data was used as input for various analyses, which were prepared in accordance with a B&V procedure for calculations and verified in accordance with B&V verification procedures.⁴⁶

Meteorological data was obtained from the Fermi 2 meteorological tower, which operates under the Fermi 2 QA program. The data was also subjected to a B&V verification process prior to being used in a safety-related calculation.⁴⁷

⁴³ *Id.* at ¶40.

⁴⁴ *Id.* at ¶41.

⁴⁵ *Id.* at ¶42.

⁴⁶ *Id.*

⁴⁷ *Id.* at ¶44.

Ultimately, each FSAR section that relied on hydrogeological, geotechnical, or meteorological data was prepared in accordance with specific project instructions. Each FSAR section was also reviewed in accordance with the B&V nuclear procedure for review and approval.⁴⁸

B&V also conducted QA reviews during COL Application development.⁴⁹ In April 2007, as part of B&V's annual internal audit, a lead-auditor-qualified individual from outside the B&V office developing the Fermi 3 application audited the B&V QA program to evaluate compliance with Appendix B requirements. The audit report concluded that the B&V Nuclear Organization was in compliance with the B&V QA program and other project-specific requirements, and the program was being effectively implemented. Similar annual audits have been conducted since then, consistent with B&V QA procedures. During the site investigation phase, B&V also conducted surveillances of its subcontractors, including PSI, Boart Longyear/Prosonic, GEOVision, ARM Geophysics, and Geomatrix.⁵⁰

2. DTE Oversight

DTE also exercised substantial oversight of the B&V work throughout the COL Application development phase.⁵¹ In particular, during the site investigation work, the Fermi 3 Nuclear Development organization maintained a presence to oversee those activities and ensure that workers were subject to the applicable programs for the operating Fermi 2 (*e.g.*, access, work control, and contractor oversight).

⁴⁸ *Id.* at ¶45.

⁴⁹ *Id.* at ¶46-47.

⁵⁰ *Id.*

⁵¹ *Id.* at ¶48.

Once the ND QAPD was in place in February 2008, DTE conducted a surveillance of B&V for the COL Chapter Review Process to ensure the adequacy of the B&V processes used to prepare site-specific information for the FSAR.⁵² The assessment concluded that the B&V Nuclear Organization had a good understanding of procedural requirements and a commitment to providing a quality product to DTE as part of the COL development project for Fermi 3. DTE also performed a surveillance of storage and chain of custody controls of geotechnical core drilling and subsurface samples for Fermi 3 COL project work. Since then, DTE has continued to regularly audit B&V's QA program according to the DTE QA program, in accordance with the QAPD implementing procedures.⁵³

3. *DTE's Owner's Engineer*

Beginning early in the project, DTE also retained an Owner's Engineer ("OE") to support owner-related activities, such as reactor technology selection, project cost estimates, engineering support services, and COL Application contractor oversight.⁵⁴ The OE was retained under a contract with the Ann Arbor, Michigan, office of B&V. This contract was separate and independent of the contract between DTE and the Overland Park, Kansas, office of B&V responsible for the COL Application work. As a matter of practice, the OE maintained separation from the COL Application project and relied on different personnel.⁵⁵ The OE reported directly to the DTE Nuclear Development organization.

⁵² *Id.* at ¶57.

⁵³ *Id.* at ¶59.

⁵⁴ *Id.* at ¶¶34, 49-51.

⁵⁵ *Id.* at ¶51.

DTE used the OE to enhance its oversight and observation of site work activities, such as by conducting surveillances of site investigation activities.⁵⁶ For example, in June 2007, the OE observed B&V obtaining core samples and reported to DTE's Nuclear Development project the status of procedural compliance, including the availability of ASTM standards, compliance with the Hydrogeology Data Collection Plan and the Geotechnical Data Collection Plan, chain of custody processes, control of measurement and test equipment, and handling of corrective actions as a result of B&V Nuclear QA surveillances. The OE also observed B&V borings on the Fermi site and reported to the Nuclear Development project that on-site work was being performed under the B&V Appendix B QA program in July and August 2007. And, the OE performed surveillances of offsite activities, including work performed by a testing laboratory and B&V Nuclear.

4. NRC Oversight

There was also NRC oversight during the site investigation phase.⁵⁷ DTE submitted a voluntary response to NRC Regulatory Issue Summary ("RIS") 2007-08, "Updated Licensing Review Approach," notifying the NRC that B&V's Appendix B QA program was being applied to appropriate aspects of the work scope and that B&V's principal subcontractors would be governed by the B&V QA program.⁵⁸ DTE also notified the NRC of the schedule for on-site geotechnical investigation activities and confirmed that the B&V Appendix B QA

⁵⁶ *Id.* at ¶¶49-51.

⁵⁷ *Id.* at ¶52.

⁵⁸ NRC3-07-0001, "Voluntary Response to RIS 2007-08: Plans for the Submittal of a Combined License Application for the DTE Energy Fermi Site," dated May 31, 2007 (ADAMS Accession No ML071580347) (Exh. DTE000047).

program was being applied to the geotechnical investigation work scope.⁵⁹ NRC inspectors subsequently conducted an audit at the Fermi site focused on pre-application subsurface investigation activities being conducted to obtain geotechnical and seismic data. The NRC concluded that “the work was being done in an appropriately controlled manner.”⁶⁰

B. COL Application Development: Acceptance Phase

DTE established its own QA program for the Fermi 3 project under the Nuclear Development Quality Assurance Program Description (“ND QAPD”) (Exh. DTE000070) on February 4, 2008 — seven months prior to submitting the COL Application to the NRC.⁶¹ DTE drafted the ND QAPD and implementing procedures specifically for the scope of activities to be performed by DTE in reviewing and accepting the COL Application being prepared by B&V.

The period from February 2008 to September 2008 was the COL Application Acceptance Phase. During this phase, DTE was working under its ND QA Program as it began the DTE acceptance review of application material.⁶² The acceptance review was conducted in accordance with Standard Work Instructions (“SWIs”) and itself was subject to the ND QA program. DTE staff were trained on the approved SWIs for review and acceptance of the B&V-developed COL Application products. DTE reviewed the application work product against relevant regulatory guidance, information provided by DTE to B&V, and the Reference COL

⁵⁹ NRC3-07-0002, “Notification of Combined License Application Geotechnical Investigation Schedule for the DTE Energy Fermi Site,” dated May 31, 2007 (ADAMS Accession No. ML071580350) (Exh. DTE000048).

⁶⁰ Audit of Combined License Pre-Application Subsurface Investigation Activities at Fermi (Project No. 757), Enclosure 1 at 3 (ADAMS Accession No. ML072190660) (Exh. DTE000084).

⁶¹ DTE Testimony at ¶¶35, 53.

⁶² *Id.* at ¶53.

Application (R-COLA), as applicable. Comments were documented and provided to B&V for formal resolution. All comments were resolved in accordance with procedures.

By early September 2008, DTE completed the review of application work product. All data from B&V was accepted after the ND QAPD was in place to apply to the acceptance process. Accordingly, DTE did not rely on any data in the COL Application that it obtained from B&V before DTE had its own Fermi 3 QA Program.⁶³

During the COL Application Acceptance Phase, the Nuclear Development QA Manager was responsible for independently planning and performing activities to verify the development and effective implementation of the ND QAPD with respect to those activities that supported the COL Application. The Nuclear Development QA Manager was also responsible for evaluating compliance with regulatory requirements and procedures through audits and technical reviews, monitoring organization processes to ensure conformance to licensing document requirements, and ensuring that vendors providing quality services to DTE in support of the COL Application were meeting the requirements of Appendix B.⁶⁴ For example, in May 2008, the Nuclear Development QA Manager led a surveillance of B&V application development activities. In June 2008, the Nuclear Development QA Manager conducted a surveillance of the storage and handling of the core drilling and subsurface samples in DTE's possession, including record reviews and interviews. DTE has subsequently conducted additional audits of B&V's Appendix B QA processes, in accordance with the Fermi 3 QAPD implementing procedures.⁶⁵

⁶³ *Id.* at ¶54-55.

⁶⁴ *Id.* at ¶56.

⁶⁵ *Id.* at ¶57.

C. Conclusions on Contention 15A

Contention 15A concerns the reliability of the safety-related information in the COL Application and supporting FSAR. The Intervenor's specific concern relates to information collected at the beginning of the COL project — that is, prior to approval and use of the ND QAPD in February 2008. Relying on the original NRC Staff NOV (that was superseded by a narrowed and revised NOV), the Intervenor questioned the reliability of safety-related design information in the FSAR that was based in whole or in part on B&V tests, investigations, or other activities conducted during the period of time before the Fermi 3 project implemented its own QA program.

As the record and testimony demonstrate, during the period of time that B&V was performing site investigations, tests, and other safety-related activities to support the development of a COL Application, the work was performed by B&V, at DTE's direction, under B&V's established Appendix B QA program — as allowed by NRC regulations. Because B&V had an established Appendix B program, internal process controls and oversight of safety-related activities were inherent in the B&V program. During the site investigation phase, the Fermi 3 Nuclear Development organization maintained a presence to oversee those activities and workers were subject to the applicable programs for the operating Fermi 2. DTE retained an OE to enhance its oversight and observation of site work activities, including by conducting surveillances of the site investigation activities. The NRC Staff also exercised oversight of the pre-application subsurface investigation activities.

Even though DTE is permitted to delegate the QA function prior to application submittal, DTE established an Appendix B program prior to filing the COL Application. DTE developed the ND QAPD to apply during the process of reviewing and accepting COL Application work product. The ND QAPD and implementing procedures included surveillances

and audits of the B&V QA program and provided an additional means of assuring the quality of the COL Application.

Based on the comprehensive set of QA measures applied to safety-related information, there is reasonable assurance that the safety-related information developed prior to COL Application submittal is of high-quality. To date, the Intervenors have shown no evidence to the contrary. DTE has retained responsibility for the quality of information in the COL application throughout the Fermi 3 project, and no issues of material significance have been identified in either the NRC Staff review or this proceeding. Contention 15A should be resolved in DTE's favor.

VIII. DISCUSSION OF CONTENTION 15B

A. Current QA Program for Fermi 3

DTE's QA Program for Fermi 3 is addressed in Chapter 17 of the Fermi 3 COL Application FSAR. In accordance with NRC regulations, the Fermi 3 FSAR provides a detailed description of planned and systematic actions to assure safety and reliability during design, construction, and operation. The FSAR also contains a detailed discussion of the Fermi 3 QAPD. The QAPD itself was submitted to the NRC as Appendix 17AA to the FSAR.

The Fermi 3 QAPD is based on a generic template, NEI-06-14A, "Quality Assurance Program Description," that has been established for use by COL applicants as a means to implement the applicable requirements and industry standards for QA programs. The NEI template, like the Fermi 3 QAPD, is based on the standards of NQA-1-1994. The NRC Staff has endorsed the NEI template.⁶⁶

⁶⁶ The NRC-endorsed QAPD template was initially released in May 2008 as NEI-06-14A, Revision 5 (ADAMS Accession No. ML081350560) (Exh. DTE000089). The NRC-approved version of NEI-06-14A, Revision 7, was issued by NEI in August 2010 (ADAMS Accession No. ML102370305) (Exh. DTE000091).

Applicants using the template must address conformance with the NRC's regulatory guidance by including a commitment to the applicable regulatory guides or by providing an alternative (or exception) to be reviewed by the NRC Staff. As the DTE witnesses testify, the Fermi 3 QAPD is based on DTE's commitment to NQA-1-1994, and includes the required elements from the NEI template.⁶⁷ The policy statement in the Fermi 3 QAPD evidences a clear corporate commitment to implement the QAPD such that Fermi 3 is and will be designed, procured, constructed, and operated in a manner that ensures the safety of the public and workers.

B. Program Implementation

The DTE QA program is implemented through a set of procedures written to comply with the NQA-1 requirements. The procedures are organized to address the topical areas associated with the criteria of Appendix B that are applicable to the current phase of COL Application work. For example, there are Nuclear Procedures ("NPs") for organization, training, development of procedures, and the QAPD change process. Other NPs address document control, the Corrective Action Program, and supplier evaluations.

Under the Fermi 3 QA program, there also are regular audits and surveillances, including internal audits and surveillances, audits of DTE programs by external auditors, and audits of DTE vendors and suppliers. Any findings are entered into a Corrective Action Program for resolution. For example, DTE Quality Management performs annual audits to ensure that the Fermi 3 project team is performing its activities in compliance with the Fermi 3 QAPD.⁶⁸ External organizations also audit the DTE Quality Management organization. Requirements

⁶⁷ DTE Testimony at ¶¶71, 74-75.

⁶⁸ *Id.* at ¶80.

assessed during an audit may include those associated with organization, training, design control, procurement document control, procedures, document control, control of purchases, Part 21 reporting for nonconforming items, corrective actions, records, and previous audit and surveillance findings. As the testimony demonstrates, DTE frequently performs additional audits and surveillances in accordance with the Fermi 3 QAPD.⁶⁹

Nuclear Development management also performs a semi-annual management assessment of QAPD implementation and effectiveness. This includes a review of the status of the Corrective Action Program, a review of internal and external assessments (*e.g.*, NRC audits, QA audits/surveillances, RAI responses, and other related activities), and other benchmarking activities. Nuclear Development management uses this assessment to identify areas, if any, that warrant heightened focus or attention or deployment of additional resources.⁷⁰

C. **NRC Staff Reviews of QA Program and FSAR**

The NRC Staff has completed its review of Chapter 17 of the FSAR and the QAPD, and there are no outstanding RAIs or unresolved issues with respect to the program.⁷¹ The NRC Staff found the Fermi 3 QAPD acceptable based on reviews of twenty-two different subject areas. The NRC Staff specifically addressed the items raised in the enforcement action (discussed further below). The NRC Staff concluded that (a) DTE's answers were responsive to the violations, (b) the implemented corrective actions are appropriate, and (c) the activities cited in the enforcement action were addressed and are consistent with the requirements of Appendix

⁶⁹ *Id.*

⁷⁰ *Id.* at ¶83.

⁷¹ *See* Chapter 17 SER (ADAMS Accession No. ML112630120) (Exh. DTE000092).

B.⁷² Overall, the NRC Staff concluded that the Fermi 3 QA program meets the relevant standards and therefore can be employed during the design, construction, and operation of Fermi 3.

D. Conclusions on Contention 15B

Contention 15B alleges that there is an ongoing lack of commitment to implementation of a QA program for Fermi 3. However, the testimony and exhibits demonstrate that DTE has developed and implemented, and will continue to implement, an effective QA program — that is, one that meets all relevant requirements and guidance.⁷³ While there was one enforcement action with two Severity Level IV violations, those issues were resolved based on corrective actions. There has not been any subsequent “pattern” of QA violations. To the contrary, DTE has demonstrated its commitment to QA from the start of the project by selecting a COL application contractor with an existing Appendix B QA program, requiring that contract work be performed under the contractor’s QA program, establishing its own Appendix B QA program prior to accepting any information for use in the COL Application, and implementing the Fermi 3 QAPD program for ongoing and future COL-related work.⁷⁴

As the record demonstrates, DTE has effectively implemented the Fermi 3 QAPD since its adoption.⁷⁵ DTE has performed numerous audits, surveillances, assessments, and other actions in accordance with the program. The NRC Staff verified implementation of the Fermi 3

⁷² *Id.* at 17-34.

⁷³ DTE Testimony at ¶96.

⁷⁴ *Id.*

⁷⁵ *Id.*

QAPD by inspection and also concluded that DTE has provided satisfactory oversight of the contracted activities.

At bottom, there has been no pervasive (or ongoing) breakdown in the Fermi 3 QA program.⁷⁶ And, no issues of material safety significance have been identified. As a result, there is reasonable assurance that the Fermi 3 QA program has been, can be, and will be implemented in accordance with NRC regulations and the applicable QAPD.

IX. NRC INSPECTION FINDINGS

As noted above, on October 5, 2009, the NRC Staff issued an Inspection Report in which it described the results of an August 2009 inspection and cited three violations. These violations, as well as DTE's response and corrective actions, are discussed below.

A. Resolution of Violation A

One of the violations alleged that DTE failed “to establish and implement a Fermi Unit 3 QA program between March 2007 (when DTE initially contracted with B&V for the conduct of COL Application activities for Fermi Unit 3) and February 2008 (the date of implementation of the ND QAPD), and fail[ed] to retain overall control of contracted COL Application activities as required under Criterion II, ‘Quality Assurance Program’ of Appendix B.”⁷⁷ This finding was characterized by the NRC Staff as a Severity Level IV violation under the NRC's Enforcement Policy — the lowest significance level for cited violations.

⁷⁶ *Id.* at ¶84.

⁷⁷ NRC Inspection Report 05200033/2009-201 and Notice of Violation to Detroit Edison Company, dated October 5, 2009 (ADAMS Accession No. ML092740064) (“NRC Inspection Report”) (Exh. DTE000085).

DTE replied to the NOV, denying the violation.⁷⁸ Among other reasons, DTE explained that it was not a COL applicant before September 18, 2008, and therefore was not subject to Appendix B requirements until that date. DTE's response to the NOV clearly established that there was no "willing" or "deliberate" choice by DTE to ignore Appendix B QA requirements. As discussed above, DTE had contracted with B&V to perform specific services under the B&V Appendix B QA Program. DTE took responsibility for the program, delegated the function to a qualified vendor, and exercised organizational oversight of that work.⁷⁹ As discussed above, the ND QAPD was subsequently approved in February 2008, before COL Application information was accepted from B&V and before the COL Application was submitted.

The NRC Staff responded to DTE's reply to the NOV.⁸⁰ The NRC Staff accepted that, prior to September 18, 2008, DTE was not yet an applicant and the NRC's requirements were not applicable to DTE at that time. As a result, Violation A of the original NOV was withdrawn. The NRC Staff response of April 27, 2010, articulated a new Violation A for a "[f]ailure 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 after September 18, 2008." The violations were again characterized as Severity Level IV violations. The revised violations did not involve, as alleged by the Intervenors, a failure to implement any QA program for safety-related work associated with the Fermi 3 COL Application.

⁷⁸ Reply to NOV (Exh. DTE000035).

⁷⁹ DTE Testimony at ¶¶30, 32, 63.

⁸⁰ Revised NOV (Exh. DTE000086).

In its response to the revised NOV, DTE acknowledged Violation A, and accepted that it had failed to sufficiently *document* the basis for qualifying the B&V QA program for safety-related Fermi 3 COL activities.⁸¹ This did not mean that B&V was not qualified to perform the scope of work or the QA function. DTE subsequently documented the basis for qualifying the B&V QA program under a newly-implemented vendor qualification review and acceptance program.⁸² The NRC Staff acknowledged DTE's reply to the revised NOV and found it responsive.⁸³

B. Resolution of Violation B

As noted above, Violation B in the revised NOV cited by the Intervenors included two issues that existed as of August 21, 2009: a failure (as of that date) to perform internal audits of the QA program and a failure (as of that date) to document trending of conditions adverse to quality entered into the Corrective Action Program. Neither of these issues undermines the sufficiency of the QA program or DTE's commitment to the program.

With respect to audits, Appendix B, Criterion XVIII, "Audits," states, in part, that "[a] comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program." Criterion XVIII does not state a frequency of internal audits. Under DTE's ND QAPD, there was also no specification for the frequency of internal audits. However, the Fermi 3 QAPD calls for an audit at least once each year or at least once during the life of the activity,

⁸¹ Reply to Revised NOV (Exh. DTE000057).

⁸² DTE Testimony at ¶65.

⁸³ NRC Letter, EA-09-286, "Nuclear Regulatory Commission Inspection Report 05200033/2009-201 and Revised Notice of Violation to Detroit Edison Company," June 4, 2010 (ADAMS Accession No. ML101530596) (Exh. DTE000087).

whichever is shorter. At the time of the NRC Staff inspection, DTE QA personnel had not yet completed an internal audit of QA programmatic areas implemented for the Fermi 3 COL Application activities. As a corrective action, an internal audit was conducted during the week of October 26, 2009.⁸⁴ Since the NRC's inspection finding and DTE's subsequent audit in October 2009, DTE has completed the annual QA audits, as required.⁸⁵

With respect to trend reports, Appendix B, Criterion XVI, "Corrective Action," states, in part, that "[m]easures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected." Criterion XVI does not specifically require the trending of corrective actions. Nonetheless, the Fermi 3 QAPD and implementing procedures include a requirement to analyze condition reports to identify trends. At the time of the NRC Staff inspection, DTE had not yet documented trending of corrective actions due, in part, to the fact that a "trend report" requirement had not been included in the ND QAPD. DTE performed the trending on October 31, 2009.⁸⁶ DTE has subsequently performed additional corrective action trending at approximately six-month intervals.⁸⁷

⁸⁴ Nuclear Development Quality Assurance, Audit Report 09NI01, "Annual Audit of Implementation of the Fermi 3 Quality Assurance Program Description Requirements" (Exh. DTE000058).

⁸⁵ DTE Testimony at ¶67.

⁸⁶ DTE-09-0042, "Trend Analysis of Corrective Action Reports," dated November 2, 2009 (Exh. DTE000062). This action was acknowledged in the NRC inspection report accompanying the original NOV.

⁸⁷ DTE Testimony at ¶68.

C. Conclusions

Overall, the issues identified by the NRC Staff in the NOV and cited by the Intervenors in Contention 15 were specific and of limited scope and duration. DTE performed the necessary corrective actions and has conducted subsequent activities in accordance with DTE's QAPD and implementing procedures. The violations did not have material safety significance and do not indicate a pervasive breakdown in the Fermi 3 QA program.

X. RESPONSES TO BOARD QUESTIONS

On February, 28, 2013, the Board issued an Order (Identifying Questions for the Parties to Address in their Pre-filed Written Testimony on Contention 15). The Board's questions are addressed throughout the testimony of DTE's expert witnesses. That testimony is summarized below.

1. ***Describe the Black and Veatch (B&V) quality assurance (QA) program used in connection with its safety-related COLA activities for the Fermi 3 project. State whether that QA program was audited by DTE or others.***

The B&V QA program applied to Fermi 3 COL development activities is described in the DTE Testimony at ¶¶39-40. In short, B&V maintains an Appendix B QA program based on the standards of NQA-1. The B&V QA program has been subject to internal and external audits and surveillances by DTE and others before, during, and after COL Application development activities for Fermi 3. These assessments are described in DTE Testimony at ¶¶34, 46, 47, 50, 57-59, 80.

2. ***If DTE audited B&V's QA program, explain what DTE did in its audits to ensure that B&V followed its own QA program, and that B&V's QA program met Appendix B requirements.***

DTE has performed numerous audits and surveillances of the B&V QA program. Prior to the ND QAPD, DTE retained an Owner's Engineer to enhance its oversight and observation of site work activities. The OE staff performed and documented surveillances of the

onsite activities on behalf of DTE.⁸⁸ For example, in June 2007, the OE observed B&V obtaining core samples and reported to DTE's Nuclear Development project the status of procedural compliance, including the availability of ASTM standards, compliance with the Hydrogeology Data Collection Plan and the Geotechnical Data Collection Plan, chain of custody processes, control of measurement and test equipment, and handling of corrective actions as a result of B&V surveillances.

Also in July 2007 and in August 2007, the OE observed B&V borings on the Fermi site and reported to the DTE Nuclear Development project that on-site work was being performed under the B&V Appendix B/NQA-1 QA program. The OE reported that work was being performed in accordance with the Hydrogeology Data Collection Plan and the Geotechnical Data Collection Plan, that chain of custody processes were being followed, and that corrective actions as a result of B&V Nuclear QA surveillances had been implemented and continued to be effective.

In August 2007, the OE observed B&V boring, split spoon sampling, and vacuum excavation on the Fermi site. The OE reported to the Nuclear Development project that on-site work was being performed under the B&V Appendix B/NQA- 1 QA program and that controlled documentation was available for reference. The OE reported that work was being performed in accordance with the Hydrogeology Data Collection Plan, Hydrogeology Work Plan, and Geotechnical Data Collection Plan, and that copies of these documents were available, that chain of custody processes were being followed, and that corrective actions associated with the B&V corrective action program continued to be effective.

⁸⁸ *Id.* at ¶¶49-50.

After the ND QAPD was in place, DTE QA personnel conducted audits and surveillances in accordance with QA implementing procedures. DTE conducted a surveillance of B&V for the COL Chapter Review Process from April 29, 2008 to May 6, 2008.⁸⁹ The purpose of the surveillance was to ensure the adequacy of the B&V activities involved in preparing site-specific safety-related information for the FSAR. The assessment concluded that the B&V Nuclear Organization had a good understanding of procedural requirements and a commitment to providing a quality product to DTE as part of the COL development project for Fermi 3.⁹⁰

DTE also performed a surveillance of storage and chain of custody controls of geotechnical core drilling and subsurface samples for Fermi 3 COL project work.⁹¹ This included a review of a complete core boring document package obtained from B&V. Overall storage, handling, and custody controls for handling of core drilling and subsurface samples, including records and personnel practices, were found to be adequate with no issues noted.

After the Fermi 3 QAPD was in place, a team from DTE performed an audit of B&V's Appendix B/NQA-1 QA processes.⁹² The B&V QA program was assessed as effectively implementing the requirements of 10 C.F.R. Part 50, Appendix B/NQA-1, for Fermi 3 quality-related COL Application activities. The audit report concluded that the B&V QA Program is well documented in the Nuclear Quality Assurance Manual, Nuclear Procedures, and Fermi 3 Project Instructions. DTE also conducted an audit of B&V QA program implementation in

⁸⁹ Surveillance Report 08SR001, dated May 16, 2008 (Exh. DTE000036).

⁹⁰ DTE Testimony at ¶57.

⁹¹ Surveillance Report 08SR002, dated June 13, 2008 (Exh. DTE000037).

⁹² Audit Report 09NS01, dated August 7, 2009 (Exh. DTE000038).

November 2011⁹³ and an audit to maintain B&V on the Fermi 3 Approved Supplier List in late-January/early-February 2012.⁹⁴

3. Describe to what extent and in what manner DTE supervised B&V's QA program.

From the outset of the Fermi 3 COL Application project in March 2007, DTE contracted with B&V for the COL Application development work. DTE retained responsibility for quality assurance as a commercial or contract matter.⁹⁵ B&V reported to the Fermi 3 Nuclear Development organization, which had responsibility for the COL Application. As Mr. Smith and Mr. Thomas testify, the Nuclear Development organization exercised management oversight and supervision over B&V and their work activities at the Fermi site, including the B&V QA program.⁹⁶ DTE's OE also conducted surveillances of site investigation activities.

Beginning in November 2007, DTE began a formal process for the receipt, review, and acceptance of COL Application work product from B&V for submittal to the NRC. No work product was accepted until after the Fermi 3 project had its own QA program in place.⁹⁷

Since the COL Application was submitted in September 2008, DTE has continued to manage project activities, including B&V's work, under the applicable DTE QA program.⁹⁸ And, DTE has continued to conduct audits of B&V's QA processes.⁹⁹

⁹³ Audit Report 11NS02, dated November 17, 2011 (Exh. DTE000039).

⁹⁴ Audit Report 12NS01, dated March 1, 2012 (Exh. DTE000040). No conditions adverse to quality were identified and the QA Program was assessed as effectively implemented for providing nuclear safety related engineering and consulting services.

⁹⁵ DTE Testimony at ¶¶29-30.

⁹⁶ *Id.*

⁹⁷ *Id.* at ¶¶35, 54-55.

⁹⁸ *Id.* at ¶¶78-83.

4. Who was the QA manager for B&V's safety-related COLA activities for the Fermi 3 project?

Mr. Sacco is the Director of Nuclear Quality Assurance for B&V. In that position, he is responsible for developing and maintaining the B&V Nuclear Quality Assurance program, evaluating compliance with the program, and managing the Nuclear QA organization resources. The B&V Nuclear Quality Assurance organization is responsible for independently planning and performing activities to verify the development and effective implementation of the B&V Nuclear Quality Assurance program. As noted above, the B&V Nuclear Quality Assurance organization maintains an Appendix B QA program based on NQA-1.¹⁰⁰

5. What was the role of the Owner's Engineer in safety-related COLA activities for the Fermi 3 project? Was this individual an employee of B&V or DTE?

The DTE Nuclear Development group, under the DTE Major Enterprise Projects organization, had the functional responsibility for oversight of the project contractors. To assist in this, DTE secured the services of the OE to support its own activities. Like other COL applicants, DTE initially adopted an OE model in which the capabilities of a small internal company staff are augmented by an external OE resource. The OE was retained under a contract with the Ann Arbor, Michigan, office of B&V. This contract was separate and independent of the contract between DTE and the Overland Park, Kansas, office of B&V responsible for the COL Application work.¹⁰¹ As a matter of practice, the OE maintained separation from the COL

⁹⁹ *Id.* at ¶¶57, 80.

¹⁰⁰ *Id.* at ¶¶39-40, 46.

¹⁰¹ *Id.* at ¶51.

Application project and relied on different personnel.¹⁰² The OE reported directly to the DTE Nuclear Development organization.

6. *Identify any data DTE used in its COLA that it obtained from B&V before DTE had its own Fermi 3-specific QA program.*

No work product used in the COL Application was accepted by DTE until the Fermi 3 project had its own QA program in place beginning in February 2008 — that is, all data from B&V was accepted after the ND QAPD was in place to apply to the COL Application product acceptance process.

7. *Before DTE had its own Fermi 3-specific QA program, what measures did DTE have in place to ensure data integrity and control after it was received from B&V?*

As noted above and discussed in the DTE testimony, no work product used in the COL Application was accepted by DTE until the Fermi 3 project had its own QA program in place beginning in February 2008.¹⁰³ The acceptance review for B&V information was conducted in accordance with Standard Work Instructions (“SWIs”) and subject to the ND QA program. DTE staff was trained on the approved SWIs for review and acceptance of the B&V-developed COL Application products. Individual FSAR chapters or sections were reviewed by the Nuclear Development staff as prescribed by SWI 03-001-001-0529, “COLA Section and Chapter Review and Acceptance Process.” DTE reviewed the application work product against relevant regulatory guidance, information provided by DTE to B&V, and the Reference COL Application (R-COLA), as applicable. DTE comments were documented and provided to B&V for formal resolution. All comments were resolved in accordance with procedures.

¹⁰² The OE is not a single individual. Instead, the OE is a group of persons from the Ann Arbor office.

¹⁰³ *Id.* at ¶¶30, 55.

8. *What difference do Intervenor maintain existed between the B&V QA program and the DTE's Fermi 3-specific QA program?*

Although this is a question for the Intervenor, DTE notes that, as a matter of fact, both the B&V QA program and the Fermi QA program are based on Part 50, Appendix B, and the standards of NQA-1. And, both programs are implemented through a set of procedures written to comply with NQA-1 requirements.

XI. CONCLUSIONS

For the reasons set forth in this Initial Statement of Position, as supported by the accompanying testimony and evidence, DTE has demonstrated its commitment to QA throughout the Fermi 3 project. All safety-related information was developed under an Appendix B QA program that met NRC requirements. No safety-related information was accepted by DTE for use in the COL Application until DTE had a QA program in place. Therefore, there is reasonable assurance of the quality of safety-related information included in the Fermi 3 COL Application.

There is also reasonable assurance that the Fermi 3 QA program has been, can be, and will be implemented in accordance with NRC regulations and the applicable QAPD. DTE controls safety-related activities under the Fermi 3 QAPD and implementing procedures. The QAPD is fully compliant with NQA-1 and industry guidance. DTE has performed numerous audits, surveillances, assessments, and other actions that demonstrate effective implementation of the DTE QA program. Implementation of the program also is subject to ongoing NRC oversight.

Based on the above, there is reasonable assurance that the Fermi 3 plant can and will be designed, constructed, and operated without endangering the public health and safety. There has been no pervasive breakdown in quality assurance and no issues of material safety

significance have been identified. Accordingly, the Board should resolve Contention 15A and 15B in favor of DTE.

Respectfully submitted,

 /s/ signed electronically by

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Dated at Washington, District of Columbia
this 30th day of April 2013

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))

CERTIFICATE OF SERVICE

I hereby certify that copies of “DTE ELECTRIC’S INITIAL STATEMENT OF POSITION ON CONTENTION 15” and “INITIAL WRITTEN TESTIMONY OF DTE ELECTRIC COMPANY WITNESSES PETER SMITH, STANLEY STASEK, RONALD SACCO AND STEVEN THOMAS ON CONTENTION 15” in the above captioned proceeding have been served via the Electronic Information Exchange.

Respectfully submitted,

/s/ signed electronically by
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COUNSEL FOR DTE ELECTRIC
COMPANY

Dated at Washington, District of Columbia
this 30th day of April 2013