

April 30, 2013

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of:

DTE ELECTRIC COMPANY

(Fermi Nuclear Power Plant, Unit 3)

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Docket No. 52-033-COL

INITIAL WRITTEN TESTIMONY OF DTE ELECTRIC
COMPANY WITNESSES PETER SMITH, STANLEY STASEK,
RONALD SACCO, AND STEVEN THOMAS ON CONTENTION 15

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EXPERT WITNESSES

A. Peter Smith

Q1. Please state your full name.

A1. Peter W. Smith (“PS”).

Q2. By whom are you employed and what is your position?

A2. (PS) I am employed by DTE Electric Company¹ as the Director, Nuclear Development – Licensing and Engineering. I have served in that position since 2007. I have overall responsibility for the Fermi Unit 3 (“Fermi 3”) project, including the combined license (“COL”) application and other State and Federal permits and approvals. I report to the Senior Vice President for Major Enterprise Projects and the Chief Nuclear Officer. I am specifically responsible for the implementation of Quality Assurance (“QA”) measures specified by the Fermi 3 Quality Assurance Program Description (“QAPD”), including management of the corrective action and non-conformance process.

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.

Q3. Please summarize your education and professional qualifications.

A3. (PS) A copy of my qualifications statement is attached to Exhibit DTE000017.

Q4. What is the purpose of your testimony?

A4. (PS) The purpose of my testimony is to address the issues raised in Intervenors' Contention 15. Put simply, 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 nuclear plant. I will describe the evolution of the QA program in the pre-application phase through the current application review phase. In particular, I will describe the QA programs implemented during the development of the COL Application. I will also describe the Fermi 3 Quality Assurance Program Description ("QAPD") that applied during the NRC Staff's review of the COL Application. I will describe how the Fermi 3 QAPD meets NRC and industry standards, and will address the specific issues identified by the NRC Staff during a QA program inspection conducted in August 2009 — two Severity Level IV Notices of Violation ("NOVs") issued in April 2010 — as well as the corrective actions that responded to the findings. In total, in both the pre-application phase and the COL Application review phase of the project, DTE has ensured, through systematic processes, that suppliers of safety-related equipment or services meet the applicable requirements of 10 C.F.R. Part 50, Appendix B. The oversight that has been conducted over specific safety-related activities assures the quality of information in the Fermi 3 COL Application. Finally, I will

address some specific concerns that have been identified by the Intervenors' witness, Mr. Gundersen, in this proceeding.

Q5. What documents have you reviewed to prepare your testimony?

A5. (PS) I am very familiar with the various QAPDs, the NRC's issues in 2009, as well as the audits and other reports that will be referenced in this testimony. Additionally, to prepare this testimony I have reviewed the filings made to date by the Intervenors, including the Declaration of Mr. Gundersen filed in support of Contention 15,² the second Declaration of Mr. Gundersen filed in support of Contention 15,³ and the Declaration of Mr. Gundersen filed in opposition to DTE's motion for summary disposition.⁴

B. Stanley Stasek

Q6. Please state your full name.

A6. Stanley Stasek ("SS").

Q7. By whom are you employed and what is your position?

A7. (SS) I am employed by DTE as Director, Quality Management, for the Fermi 3 project. In this position, I am responsible for developing and maintaining the

² "Declaration of Arnold Gunderson Supporting Petition of Intervenors Contention 15: DTE COLA Lacks Statutorily Required Cohesive QA Program" (December 8, 2009) ("Gundersen Dec. 1").

³ "Second Declaration of Arnold Gundersen Supporting Supplemental Contention 15: DTE COLA Lacks Statutorily Required Cohesive QA Program" (June 11, 2010) ("Gundersen Dec. 2").

⁴ "Second Declaration of Arnold Gundersen Supporting Supplemental Petition of Intervenors Contention 15: DTE Cola Lacks Statutorily Required Cohesive QA Program" (May 17, 2012) ("Gundersen Dec. 3").

Fermi 3 QAPD, evaluating compliance with the program, and managing the QA organization resources.

Q8. Please summarize your education and professional qualifications.

A8. (SS) A copy of my professional qualifications statement is attached to Exhibit DTE000018.

Q9. What is the purpose of your testimony?

A9. (SS) The purpose of my testimony is also to address issues raised in Contention 15. The Fermi 3 QAPD submitted with the COL Application, and implemented since that date, meets applicable regulatory requirements. The program is functioning in accordance with the NRC's regulations. I will explain that program, as well as various benchmarks and metrics for the program. I will also address the only "discrepant" conditions identified by the Intervenors — the two Severity Level IV NOV's issued in April 2010. These do not demonstrate either a pervasive breakdown of the Fermi 3 QA program or a lack of commitment to continue to implement the program as broadly alleged by the Intervenors. The NRC Staff also has not found any ongoing compliance issues, much less a programmatic breakdown, in the Fermi 3 QA program.

Q10. What documents have you reviewed to prepare your testimony?

A10. (SS) I am very familiar with the Fermi 3 QAPD, the implementing procedures, and the audits and other reports that will be referenced in this testimony. Additionally, to prepare this testimony I have reviewed the filings made to date by

the Intervenors, including the declarations of Mr. Gundersen filed in support of Contention 15 to date, and cited by Mr. Smith above.

C. Ronald Sacco

Q11. Please state your full name.

A11. Ronald Sacco (“RS”).

Q12. By whom are you employed and what is your position?

A12. (RS) I am employed by Black & Veatch (“B&V”) as the Director of Nuclear Quality Assurance for B&V Energy in Overland Park, Kansas.

Q13. Please summarize your education and professional qualifications.

A13. (RS) A copy of my professional qualifications statement is attached to Exhibit DTE000016.

Q14. What is the purpose of your testimony?

A14. (RS) The purpose of my testimony is to assist my company’s client, DTE, in responding to Intervenors’ Contention 15 by specifically addressing the QA program implemented by B&V and applied to safety-related work for the Fermi 3 COL Application project. I will describe the B&V QA Program that has been applied during the B&V scope of work and our basis for assurance that the work — in particular, the work prior to September 2008 — met NRC QA requirements.

Q15. What documents have you reviewed to prepare your testimony?

A15. (RS) I am very familiar with the B&V QA program and implementing procedures, as well as audits and surveillances conducted under the B&V program for the Fermi 3 project. To prepare this testimony I have also reviewed the

declarations of Mr. Gundersen filed in support of Contention 15 to date, and cited by Mr. Smith above.

D. Steven Thomas

Q16. Please state your full name.

A16. Steven Thomas (“ST”).

Q17. By whom are you employed and what is your position?

A17. (ST) I am employed by B&V as an Engineering Manager in Overland Park, Kansas. I have 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, I have been responsible for responding to requests for information and resolving technical issues arising during the regulatory review. I also supported DTE during their meetings on the application with the Advisory Committee on Reactor Safeguards (“ACRS”).

Q18. Please summarize your education and professional qualifications.

A18. (ST) A copy of my professional qualifications statement is attached to Exhibit DTE000019.

Q19. What is the purpose of your testimony?

A19. (ST) The purpose of my testimony is to assist my company’s client, DTE, in responding to Intervenors’ Contention 15 by specifically addressing the work controls implemented under the B&V QA program and applied to safety-related work for the Fermi 3 project. I will describe the specific scope of safety-related

work performed by B&V and its contractors and my basis for assurance that the work was of high quality and consistent with NRC expectations.

Q20. What documents have you reviewed to prepare your testimony?

A20. (ST) I am very familiar with the work control procedures employed for Fermi 3 COL Application development activities. To prepare this testimony I have also reviewed the declarations of Mr. Gundersen filed in support of Contention 15 to date, and cited by Mr. Smith above.

QUALITY ASSURANCE REQUIREMENTS AND STANDARDS

Q21. What NRC QA requirements apply to pre-application activities?

A21. (PS, SS) There are no QA requirements that apply prior to submittal of a COL application — that is, before a company is an “applicant.” Rather, implicitly, the prospective applicant must conduct activities that are important to safety (particularly safety-related site investigation activities) in a manner such that the quality can be demonstrated to support the eventual application.

Q22. What QA requirements apply to COL applicants and licensees?

A22. (PS, SS) Once a COL application is submitted, the applicant is explicitly subject to 10 C.F.R. Part 50, Appendix B, and therefore must establish and implement a compliant program. In particular, every applicant for a COL is required to include in its Final Safety Analysis Report (“FSAR”) a description of the managerial and administrative controls applied to the design, fabrication, construction, and testing of the safety-related structures, systems, and components

of the facility and to be used to assure safe operation.⁵ The application includes a QAPD that the NRC must find to be acceptable in order to issue the COL. Thereafter, an approved QAPD is subject to regulatory control in accordance with 10 C.F.R. § 50.54(a).

(PS, SS) Further standards are detailed in industry and NRC guidance documents, including American Society of Mechanical Engineers (“ASME”) Standard NQA-1, “Quality Assurance Requirements for Nuclear Facility Applications.” NQA-1-1994 is an NRC-approved standard for a Quality Assurance program. NQA-1 provides additional detailed guidance on how to implement the requirements of Part 50, Appendix B. NRC guidance on QA is set forth in Regulatory Guide 1.28, “Quality Assurance Program Requirements (Design and Construction),” Revision 3. In Reg. Guide 1.28, Rev. 3, the NRC endorsed NQA-1. The Fermi 3 QAPD is based on NQA-1.

Q23. What are the key attributes of a nuclear QA program for a COL applicant?

A23. (PS, SS) QA programs typically have four basic attributes in common:

- Establishes *administrative and programmatic controls* for safety-related activities that reflect compliance with regulatory requirements, industry standards of performance, and management expectations. For the Fermi 3 project, these controls primarily consist of the QAPD and implementing procedures.
- Requires consistent and thorough *execution* of all work in accordance with the aforementioned procedural requirements. DTE personnel are trained and qualified to perform their assigned tasks to support this attribute.
- Includes *verification activities* that provide reasonable assurance that the execution of work is in conformance with the established procedural

⁵ 10 C.F.R. § 50.34(b)(6)(ii).

requirements, regulatory requirements, and industry standards. These verification activities may take the form of management reviews, peer checks, self-assessments, and performance trending, which typically are functions of the line organization, and audits, surveillances, vendor reviews, and third party audits, which are typically independent activities led by or involving the QA organization.

- Includes a *corrective action program* so that if any performance gaps or areas for improvement are identified — whether from verification activities or otherwise — management is made aware, the cause is determined, and actions then taken to address the gap and improve performance levels.

QUALITY ASSURANCE FOR THE FERMI 3 COL APPLICATION

A. Quality Affecting Activities in COL Application

Q24. When did DTE begin to develop the COL Application for Fermi 3?

A24. (PS) 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. The COL Application was ultimately submitted to the NRC on September 18, 2008.

Q25. Describe in broad terms the scope of activities involved to prepare a COL Application?

A25. (PS, ST) Primarily the COL Application involves preparation of an FSAR to support the NRC Staff’s technical review and an Environmental Report (“ER”) to support the environmental review. The major activities to develop the Fermi 3 COL Application therefore involved site characterization, information gathering, and preparation of the FSAR and ER. The ER is not a safety-related document subject to a QA program. 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.

These are the work activities that had at least the potential to influence the design of safety-related structures, systems, and components. Information incorporated into the COL Application addressing the safety-related topics would be developed under controlled processes defined under a QA program.

Q26. How does the scope of work for the Fermi 3 COL Application relate to the Design Certification activities for the ESBWR?

A26. (PS, ST) The Fermi 3 COL Application references the General Electric Economic Simplified Boiling Water Reactor (“ESBWR”) Design Certification being pursued in parallel by the reactor vendor. Design work within the scope of the proposed design certification is subject to the reactor vendor’s 10 C.F.R. Part 50, Appendix B, QA Program, and is beyond the scope of the COL Application. In this regard, it is important to point out that for Fermi 3 there is relatively little site-specific safety-related design engineering. The safety-related aspects of the ESBWR design are encompassed within the ESBWR Design Certification Document (“DCD”). Unlike other reactor designs, there are no site-specific safety-related design features for the ESBWR. The Fermi 3 COL Application simply demonstrates that the Fermi 3 site characteristics are bounded in the ESBWR design. And, DTE did not propose any departures from the ESBWR design certification for Fermi 3 that involve new, site-specific safety-related work. As a result, 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.

Q27. Explain what is in those chapters of the FSAR.

A27. (PS, ST) Chapter 2 of the FSAR addresses site characteristics, including geography and demography, nearby industrial and military activities, meteorology and air quality, hydrology (flooding hazards), geology, seismology and geotechnical engineering. Only discrete portions of this information are safety-related. The principal safety-related site activities involved (1) gathering of meteorological data from the Fermi 2 meteorological tower and (2) core borings and test wells to determine whether hydrogeological characteristics and site seismic hazards fall within the bounds of the ESBWR design certification.

In the original COL Application submitted in September 2008 there was no site-specific safety-related information in Chapter 3. Information was incorporated from the ESBWR DCD. Subsequently, in 2010, a site-specific soil structure interaction analysis was initiated to demonstrate conformance with the ESBWR DCD. This was not part of the information developed prior to the submittal of the COL Application in 2008.

The site-specific safety-related information in Chapter 6 is related to demonstrating that the ESBWR Control Room habitability analysis is bounding for the Fermi 3 site. This analysis draws upon the site-specific meteorology data described in Chapter 2.

B. QA Program During Application Development

Q28. Was there a QA program for COL Application development and supporting work?

A28. (PS, SS, RS, ST) Yes. From the outset of the Fermi 3 COL Application development project in March 2007, DTE contracted with B&V for the COL Application development work.⁶ Under the contract DTE delegated to B&V the responsibility for establishing and executing a QA program for the B&V scope of work on the project. Fermi 3 was, and remains, a corporate initiative conducted independent of the operating Fermi unit (Fermi 2) to minimize the burden on the operating plant organization and reduce distractions. As such, the Fermi 3 COL project was initiated independent of the Fermi 2 QA program.

Q29. Was this delegation to B&V allowed by regulation?

A29. (PS, SS, RS) Yes. 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.

Further, as the NRC Staff noted in a Part 52 rulemaking, services (*e.g.*, geologic or seismic analyses) that are safety-related and could be relied upon in the siting, design, and construction of a nuclear power plant, are to be treated as basic

⁶ DTE required all potential COL Application contractors to have an Appendix B QA program.

components as defined in Part 21.⁷ According to the NRC, these site-specific safety-related services must be purchased as basic components, requiring the service provider to have an Appendix B to Part 50 QA program, as well as its own Part 21 program, or the applicant could dedicate the service in accordance with Part 21, which requires the dedication process itself to be controlled under an Appendix B QA program. DTE followed the former approach, purchasing the services from B&V, which had its own Appendix B program.

Q30. How did DTE “retain responsibility” for the QA program during this time?

A30. (PS) First, DTE retained responsibility as a commercial or contract matter. DTE began the process by preparing a formal Request for Proposals (“RFP”) from contractors to perform the activities necessary to prepare a COL application. Proposals were solicited only from contractors who were established in the nuclear services business, and who were currently executing comparable projects for other potential applicants. The RFP required bidders to demonstrate as a prerequisite that they had an established Appendix B QA program. Bidders were also required to explain how their Appendix B QA program would be applied to the Fermi 3 COL Application development project. DTE made the contractor selection and negotiated specific contract terms with respect to QA.

Second, after contract award, DTE retained responsibility for the QA program as a practical and organizational matter. B&V reported to the Fermi 3 Nuclear Development organization, which had responsibility for the COL Application.

⁷ “Licenses, Certifications, and Approvals for Nuclear Power Plants; Final Rule,” 72 Fed. Reg. 49352, 49424 (August 28, 2007).

The Nuclear Development organization, under the Director & Project Manager Nuclear Development, reported to the DTE Senior Vice President, Major Enterprise Projects. The Nuclear Development organization exercised management oversight and supervision over B&V and their work activities. We will discuss this oversight in more detail later in this testimony.

Third, 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 beginning in February 2008. We will discuss this later in the testimony as well.

After the COL Application was submitted in September 2008, DTE has through the Nuclear Development organization continued to manage the project activities, including B&V's work, to update the application, respond to NRC Staff Requests for Additional Information ("RAIs") on the application, and otherwise support the NRC Staff and ACRS reviews of the application.

Q31. Why was B&V selected to develop the Fermi 3 COL Application and implement the Appendix B QA program?

A31. (PS) In February 2007 DTE received several proposals in response to the RFP. DTE eventually selected B&V, based on several factors, including the fact that B&V maintains an Appendix B QA program based on the standards of NQA-1. As noted earlier, NQA-1 is the NRC-approved standard for QA programs and is the standard being applied for current COL applicants.

In making the selection there was documentation available to DTE of oversight and reviews of the B&V QA program conducted by other established Appendix B QA programs, including reviews by Entergy, American Electric Power Company, and Nebraska Public Power District. These reviews by established nuclear organizations provided strong evidence that the B&V program was being properly implemented for nuclear work, including COL application work. In particular, at that time B&V was successfully leading the development of the Entergy River Bend COL application, which had a similar scope of work as the Fermi 3 COL Application.

Q32. What were the QA requirements for B&V established in the contract?

A32. (PS, ST, RS) In April 2007, DTE established the contract with B&V to develop the Fermi 3 application. The contract specified:

- The scope of work to be performed by B&V;
- Technical requirements for the application in accordance with 10 C.F.R. Parts 20, 50, 51, and 52, NUREG-0800, NUREG-1555, Reg. Guide 1.206, and others;
- Acceptance requirements and control measures for DTE's evaluation of the application and intermediary work product developed by B&V;
- Organizational responsibilities (including reporting and communication methods);
- 10 C.F.R. Part 50 Appendix B/NQA-1 requirements, to be applied to FSAR Chapters 2 through 9, 14, 15, 16, 18 and 20, the geotechnical site boring program, radiological analyses, and meteorological analyses associated with the radiological analyses;
- Access to B&V's facilities and records for inspection or audit by DTE;

- Documentation requirements and the required dates for submission to DTE; and
- Requirements for reporting and disposition of non-conformances in accordance with 10 C.F.R. §50.55(e) and Part 21.

Q33. Why did the contract specify that Appendix B QA applied to FSAR chapters beyond those you discussed earlier?

A33. (PS, ST) The scope of FSAR chapters specified as being subject to Appendix B QA requirements was conservatively broad. At that time DTE had not made a reactor technology selection. As noted above, once the ESBWR was selected, the potential scope of site-specific safety-related design work was reduced. Accordingly, ultimately only Chapters 2, 3, and 6 incorporated safety-related work. However, as a practical matter, development of the originally specified chapters was subject to the B&V QA program.

Q34. Was there any other oversight of the B&V program by DTE in the pre-application period?

A34. (PS) As discussed above, the DTE Nuclear Development group, under the DTE Major Enterprises organization, had the functional responsibility for oversight of the project contractors. To assist in this, DTE also secured the services of an Owner's Engineer ("OE") to support owner-related activities. The scope of this support was envisioned to include reactor technology selection, development of project cost estimates, development of a DTE QA program for the Fermi 3 project, engineering support services, and COL Application contractor oversight.

Q35. When did DTE implement its own QA program and QA organization for the Fermi 3 project?

A35. (PS, SS) DTE first established its own QA program for the project under the Nuclear Development Quality Assurance Program Description (“ND QAPD”), which was approved for use on February 4, 2008 — seven months prior to submitting the COL Application to the NRC.⁸ In order to develop and implement the ND QAPD, in November 2007 DTE began to develop the necessary staffing, including experienced QA personnel. 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 developed by B&V.

Q36. When did DTE establish the current QAPD for Fermi 3?

A36. (PS, SS) The Fermi 3 QAPD, Rev. 0, was submitted to the NRC on September 18, 2008 — the date of the COL Application for Fermi 3. The Fermi 3 QAPD was submitted as part of the COL Application in FSAR Chapter 17 and Appendix 17A. It became effective on October 8, 2008 and replaced the ND QAPD. On that date, the ND QAPD — which had the specific focus of review and acceptance of COL Application work — was superseded by the Fermi 3 QAPD.⁹ Under the Fermi 3 QAPD there is a Nuclear Quality Management Organization responsible for the QA/oversight function. The Nuclear Quality Management

⁸ The ND QAPD is Exh. DTE000070.

⁹ During this time, there was a transition from COLA development, which was led by B&V and supported by DTE, to COLA maintenance, which was led by DTE and supported by B&V.

Organization is responsible for independently planning and performing activities to verify effective implementation of the Fermi 3 QAPD.¹⁰ The verification activities address engineering, licensing, document control, the corrective action program, and procurement for Fermi 3, among others. The QA organization's function includes:

- Coordinating the development of audit schedules,
- Auditing, performing surveillances, and evaluating suppliers of quality services,
- Supporting general QA indoctrination and training for DTE personnel performing activities covered by the QAPD, and
- Quality Control.

C. COL Application Quality Prior to February 2008

Q37. What specific quality-affecting activities that were conducted in the pre-application period would be of concern?

A37. (PS, ST) As previously noted, the pre-application safety-related activities specific to Fermi 3, and within the scope of the COL (as opposed to the Design Certification), involved certain site investigation activities. Specifically, meteorological data was obtained from DTE. That data was obtained from the Fermi 2 meteorological tower, which operates under the longstanding Fermi 2 QA program. The geological, hydrogeological, and seismic information was developed from borings and test wells at the Fermi site completed by B&V and its subcontractors during the time frame April 2007 - September 2007.

¹⁰ As discussed later in the testimony, similar functions also existed under the ND QAPD.

Q38. Do you have confidence in the quality affecting activities completed during the pre-application period? If so, what is your basis?

A38. (PS, SS, RS, ST) Yes. We can point to multiple programmatic controls that existed to assure the quality of safety-related work documented in the COL Application (FSAR):

- The B&V Appendix B QA Program, including (1) specific work controls implemented under the B&V QA Program; (2) training for personnel and subcontractors; and (3) B&V QA oversight.
- Oversight by the DTE Fermi 3 Project, as augmented by DTE's Owner's Engineer.
- NRC inspections.

Quality is assured by the performance of activities under the controls required and established in accordance with a QAPD and implemented by the organization doing the work. Oversight involves an assessment — on a sample basis and based on record reviews and personal observations — of implementation of quality controls by the line organization.

1. *B&V QA Program*

Q39. Describe the B&V QA program? What standards does it meet?

A39. (RS, ST) As discussed previously, the B&V QA Program complies with 10 C.F.R. Part 50, Appendix B, and NQA-1. Appendix B consists of 18 criteria, and NQA-1 establishes 18 requirements to address the Appendix B criteria. These include:

- Organization;
- QA Program;
- Design Control
- Instructions, Procedures, and Drawings;

- Test Control;
- Control of Measuring and Test Equipment;
- Inspection;
- Corrective Action;
- QA Records; and
- Audits

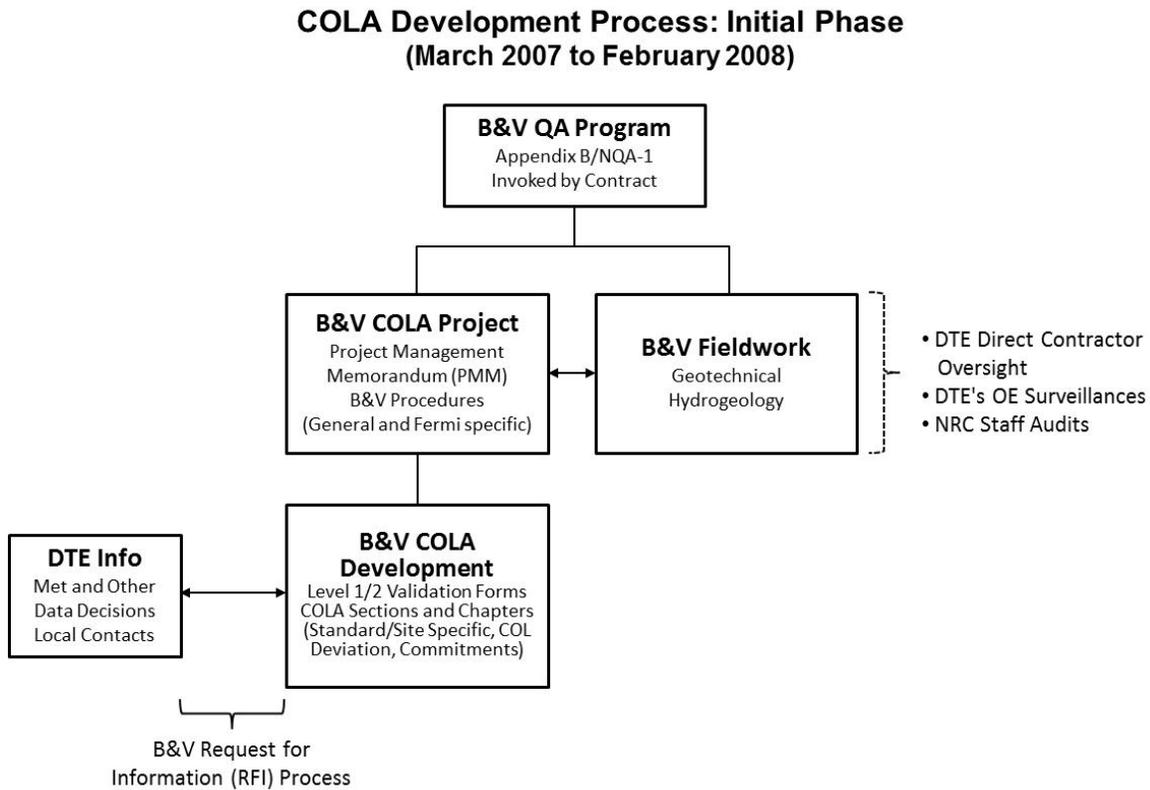
All of these elements existed within the B&V program that applied to the Fermi 3 information gathering and safety-related site activities. The B&V QA program is implemented through a set of procedures written to comply with the NQA-1 requirements.

Q40. How was the B&V QA program implemented for the Fermi 3 project?

A40. (PS, RS, ST) Major work interfaces for activities affecting COL Application development, including clear and effective lines of communication, were established through the implementation of a B&V Project Management Memorandum (“PMM”) (Exh. DTE000056). The PMM is a controlled project document and serves as the B&V mechanism for addressing how project activities will be conducted, including organization, responsibilities, QA, interfaces, and communication mechanisms with DTE. Consistent with the requirements of the contract, the PMM identified the quality attributes required for the B&V work activities. The PMM and its revisions specifically identified the applicability of Appendix B requirements to B&V subcontractors. Lastly, any information to be obtained from DTE for the COL Application was requested through a formal Request for Information (“RFI”) process.

Q41. Can you illustrate how this process worked?

A41. (PS, RS, ST) Yes. Exhibit DTE000020 (excerpted below) is an illustration of the process: “COL Application Development: Initial Phase (March 2007 through February 2008).” The B&V QA program applied to safety-related activities. Field work (geotechnical, hydrogeology) was subject to specific implementing procedures. As also mentioned previously, other data (most particularly including meteorological data) was obtained from DTE via the RFI process.



Q42. How did this process apply to the hydrogeology investigations?

A42. (PS, ST, RS) All work was controlled as described in the PMM. B&V professionals on the project were trained in accordance with B&V nuclear and

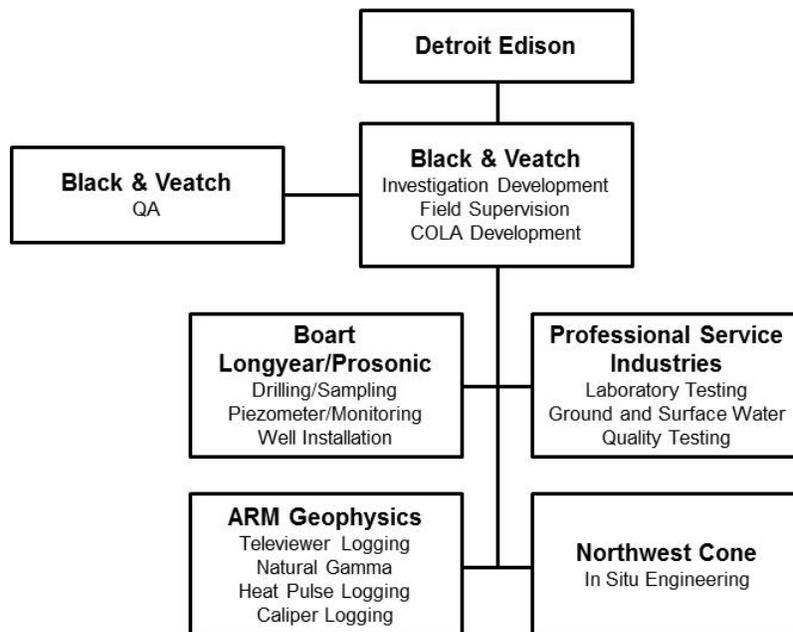
project-specific procedures. The training requirements were also applied to subcontractors working under the B&V QA program.

Specific project documents were issued for the hydrogeology investigations. The documents were reviewed in accordance with a B&V document review and approval procedure and a B&V design verification procedure. Vendor test reports (down hole and laboratory) were also provided to B&V for review and acceptance in accordance with a B&V review and approval procedure.

Consistent with the PMM, during the on-site investigation B&V assigned a geotechnical/geology expert to each of the drill rigs to record data and provide oversight of the site activities. Data collected was recorded in a boring log in accordance with a project instruction.

Data collected during the investigation was used as an input for various analyses. The analyses were prepared in accordance with a B&V procedure for calculations and verified in accordance with B&V verification procedures. Laboratory testing was performed by PSI. The following chart demonstrates the relationships for the hydrogeology investigations:

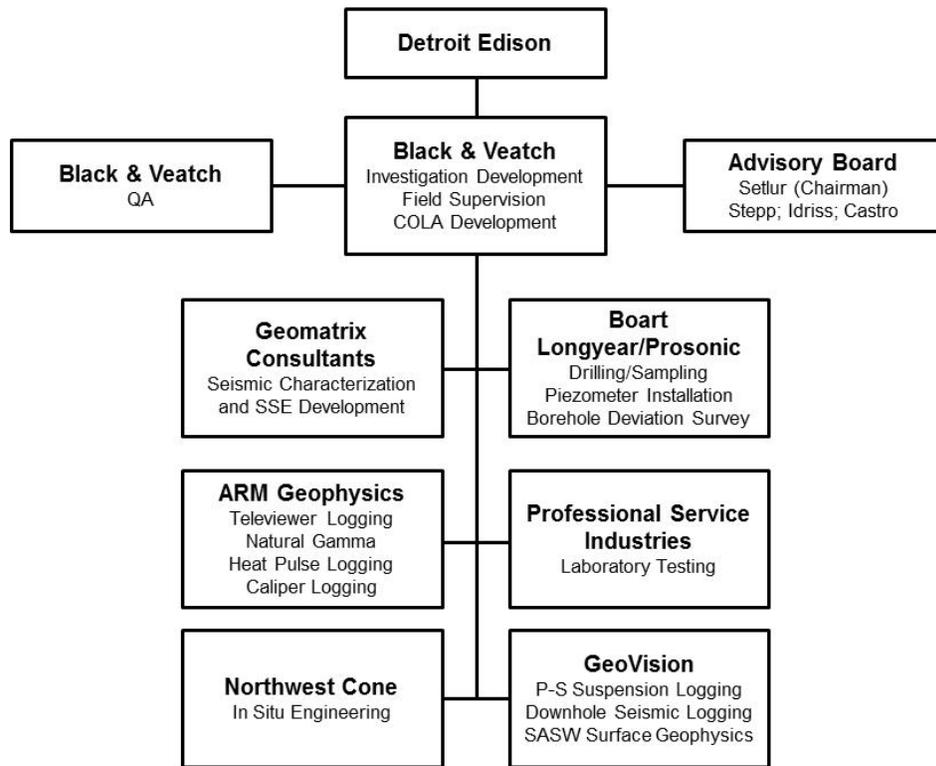
Hydrogeology Investigation



Q43. Were there similar process controls for the geotechnical investigations?

A43. (PS, ST, RS) Yes. Again, work was conducted under the PMM with training of professionals in accordance with procedures. Specific project documents were developed and issued to control the work plan, data collection, and investigation. Laboratory testing, vendor test reports, and seismic analyses were performed under the B&V program and established nuclear procedures. Boart Longyear/Prosonic, ARM Geophysics, GEOvision, Northwest Cone Exploration were the contractors. All four worked under the B&V QA program. PSI performed laboratory testing. The following chart demonstrates the relationship for the geotechnical investigations:

Geotechnical Investigation



Q44. Was meteorological data developed differently?

A44. (PS, ST, RS) As noted above, meteorological data was provided to B&V by DTE under an RFI. Information obtained by B&V from DTE to support development of the COL application was reviewed and accepted by B&V consistent with B&V's QA program and procedures. B&V examined the meteorological data to validate its integrity. This review was documented in a calculation prepared in accordance with a B&V nuclear procedure, and verified in accordance with a B&V design verification procedure. The subsequent meteorological analyses were prepared using the QA calculation and design verification procedures.

Analyses to determine site specific atmospheric release parameters were performed by Numerical Applications, Inc. (“NAI”) under the NAI NQA-1 QA program, which was audited and approved by B&V.

Q45. Were there additional procedures for preparation of the FSAR sections?

A45. (PS, ST, RS) Yes. Each FSAR section that used the hydrogeology, 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.

Q46. Were there specific B&V QA reviews completed of the work for the Fermi 3 COL Application?

A46. (RS, ST) Yes, there were a number of QA reviews of Fermi 3 COL Application work. As early as April 2007, as part of B&V’s annual internal audit, B&V arranged an audit of the B&V QA program led by a lead-auditor-qualified individual from outside the B&V office developing the Fermi 3 application. The purpose of this audit was to evaluate compliance with the B&V QA program and procedures, which met Appendix B QA and NQA-1-1994 requirements. The audit team consisted of an audit team leader, auditors, and technical specialists. The audit report concluded that the B&V Nuclear Organization was “in compliance with the Nuclear Organization Quality Assurance Program and other project specific requirements and effectively implemented.”¹¹

¹¹ B&V Audit Report 07NP01, dated May 14, 2007 (Exh. DTE000021). The audit report found that the B&V Nuclear Organization had a clear understanding and commitment to quality objectives.

Also, in April 2007, B&V Nuclear QA conducted a survey of the PSI Quality Program to evaluate the quality of activities controlled under that program.¹² PSI's test laboratory was approved to provide geotechnical laboratory services as a qualified supplier. B&V Nuclear QA also conducted a surveillance of Boart Longyear/Prosonic to evaluate geotechnical drilling and boring activities controlled under their quality control program documents.¹³ B&V accepted Boart Longyear/Prosonic's quality control program upon satisfactory resolution of certain open items.

In May 2007, B&V Nuclear QA conducted a surveillance of the hydrogeology activities on the Fermi site (Exh. DTE000024).¹⁴ The surveillance reviewed drilling operations, sample control, procedural control of activities, record quality, and measuring and test equipment calibration. During this surveillance, B&V Nuclear QA followed-up and accepted those corrective actions associated with the open items identified during their initial review of the Boart Longyear/Prosonic's quality control program.

In June 2007, B&V Nuclear QA conducted a surveillance to evaluate GEOVision work activities associated with seismic testing and data collection.¹⁵ The surveillance found that the quality and procedural processes for seismic testing

¹² B&V Audit 07NS07, dated April 25, 2007 (Exh. DTE000022).

¹³ B&V Surveillance SR-00007, dated May 1, 2007 (Exh. DTE000023).

¹⁴ B&V Surveillance SR-00008, dated May 31, 2007 (Exh. DTE000024).

¹⁵ B&V Surveillance SR-00010, dated June 27, 2007 (Exh. DTE000025).

and data collection at GEOVision were acceptable. B&V Nuclear QA also conducted a pre-work surveillance to evaluate ARM Geophysics work activities associated with geotechnical testing of soil and bedrock.¹⁶ The surveillance found that the quality and procedural processes for geotechnical testing of soil and bedrock at ARM Geophysics were acceptable.

In July 2007, B&V Nuclear QA conducted a surveillance to evaluate Geomatrix work activities associated with geological, seismological, geophysical, and geotechnical characteristics of the Fermi site.¹⁷ The surveillance found that the contractor's procedural requirements and technical capabilities were adequate to satisfy the requirements of the PMM while working under the B&V Appendix B/NQA-1 QA program.

In September 2007, and during the conduct of geotechnical measurement activities on the Fermi site, B&V Nuclear QA conducted a surveillance of testing activities, sample control, procedural control of activities, record quality, and measuring and test equipment calibration.¹⁸ This surveillance also included follow-up on the corrective actions associated with the issues identified during the B&V Nuclear QA surveillance of hydrogeology activities on the Fermi site in May 2007.

¹⁶ B&V Surveillance SR-00011, dated June 29, 2007 (Exh. DTE000026).

¹⁷ B&V Surveillance SR-00012, dated July 3, 2007 (Exh. DTE000027).

¹⁸ B&V Surveillance SR-00014, dated September 19, 2007 (Exh. DTE000028).

In September 2007, B&V Nuclear QA also conducted a surveillance of PSI to verify implementation of the PSI Quality Program, focusing on controls and testing activities.¹⁹ During the surveillance, B&V Nuclear QA observed work activities and reviewed documents and records. The surveillance found that technical and contractual requirements for geotechnical testing and data collection activities were effectively implemented. PSI management personnel were interviewed and found to be cognizant of geotechnical and quality program expectations. The geotechnical work activities and responsibilities for custody of samples were evaluated as having been satisfactorily implemented in accordance with the governing specifications at the laboratory facility.

Q47. Were there more audits and surveillances under the B&V QA program after that?

A47. (PS, ST, RS) Yes. Annual audits of the adequacy and implementation of the B&V QA program for all B&V nuclear activities and projects were conducted to comply with RG 1.28, including January 2008,²⁰ March/April 2009,²¹ April 2010,²² April 2011,²³ and March 2012.²⁴ Each audit found that the B&V QA program met the quality requirements of Appendix B and NQA-1-1994 for the

¹⁹ B&V Surveillance SR-00015, dated September 21, 2007 (Exh. DTE000029).

²⁰ Audit Report 08NP01, dated March 5, 2008 (Exh. DTE000030).

²¹ Audit Report 09NP01, dated May 6, 2009 (Exh. DTE000031).

²² Audit Report 10NP01, dated May 18, 2010 (Exh. DTE000032).

²³ Audit Report 11NP01, dated May 6, 2011 (Exh. DTE000033).

²⁴ Audit Report 12NP01, dated April 20, 2012 (Exh. DTE000034).

areas evaluated. Additionally, a satisfactory DTE Fermi 3 project-only audit was performed in March 2010.²⁵

2. DTE Oversight

Q48. Did DTE exercise oversight of B&V to ensure that B&V followed its QA program and procedures?

A48. (PS, ST) Yes. DTE ensured that there was substantial oversight of the B&V QA program throughout the COL Application development. During the Initial Phase, prior to the implementation of the ND or Fermi 3 QA programs, there were no formal audits or surveillances by DTE personnel. However, as already discussed, the most important pre-application quality activities involved site investigation work (monitoring wells for hydrology investigation and core boring activities for geotechnical data collection). The Fermi 3 ND organization maintained a presence on site to oversee those activities. In addition, the applicable programs for the operating Fermi Unit 2 (“Fermi 2”) — for access, work control, and contractor oversight — were utilized for that site work.²⁶ As discussed below, DTE also used an Owner’s Engineer to augment efforts by DTE personnel.

²⁵ Audit Report 10NP02, dated April 15, 2010 (Exh. DTE000051).

²⁶ NRC3-09-0041, Attachment 5, at 4-5 (Exh. DTE000035). Experienced DTE personnel provided direct oversight for all site work to ensure compliance with existing Fermi 2 programs and to provide the necessary interface between the COL project and Fermi 2 plant.

3. DTE's Owner's Engineer

Q49. Earlier you mentioned DTE's Owner's Engineer. What was the role of the OE?

A49. (PS) 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. As discussed previously, the OE had several significant tasks including reactor technology selection, site utilization planning, cooling tower location and technology selection, construction schedule development, and initial QAPD development. In addition, experienced OE personnel were used to enhance DTE's oversight and observation of site work activities.

Q50. Did the OE conduct specific observations during the Initial Phase?

A50. (PS) Yes. The Owner's Engineer staff performed and documented surveillances of the site investigation activities. In June 2007, DTE's 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.

In July 2007 and in August 2007, the OE 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/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 also 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.

The OE documented its observations of onsite work in the following reports:

- Surveillance 07SR001, dated July 3, 2007 (Exh. DTE000041);
- Surveillance 07SR002, dated August 1, 2007 (Exh. DTE000042);
- Surveillance 07SR003, dated August 23, 2007 (Exh. DTE000043); and
- Surveillance 07SR004, dated September 6, 2007 (Exh. DTE000044).

The OE Staff also performed and documented surveillances of offsite activities, including the following:

- Surveillance 07SR005, dated October 19, 2007 (PSI Laboratory) (Exh. DTE000045); and

- Surveillance 07SR006, dated September 26, 2007 (B&V – Overland Park) (Exh. DTE000046).

Q51. How was the independence of the Owner’s Engineer maintained relative to the B&V COL Application work?

A51. (PS) 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 B&V COL Application project and relied on different personnel. The OE reported directly to the DTE Nuclear Development organization.

4. NRC Oversight

Q52. Was there NRC oversight of the pre-application activities?

A52. (PS, ST) Yes. In May 2007, during the conduct of site investigation activities, 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/NQA-1 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.²⁷ Additionally, in May 2007, the Company notified the NRC of the schedule for on-site geotechnical investigation activities and stated that “[t]he Black & Veatch Quality Assurance Program, which meets the requirements

²⁷ 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).

of 10 CFR 50, Appendix B and ASME NQA-1, is being applied to the geotechnical investigation work scope.”²⁸

Subsequently, on July 9-11, 2007, NRC inspectors conducted an audit at the Fermi site in accordance with Inspection Manual Chapter (“IMC”) 2502, *Construction Inspection Program: Pre-Combined License (Pre-COL) Phase*, dated June 22, 2005.²⁹ The purpose of the audit was to observe pre-application subsurface investigation activities being conducted to obtain geotechnical and seismic data necessary to support the COL Application. The audit report concluded that “the work was being done in an appropriately controlled manner.”³⁰

D. COL Application Development: Acceptance Phase

Q53. Can you explain the next phase in development of the COL Application?

A53. (PS, ST) Yes. The period from February 2008 to September 2008 was the Acceptance Phase. The responsibilities and oversight are depicted in Exhibit DTE000020, “COLA Development Process: Acceptance Phase (February 2008 to September 2008)” (excerpted below). During this phase DTE had established the

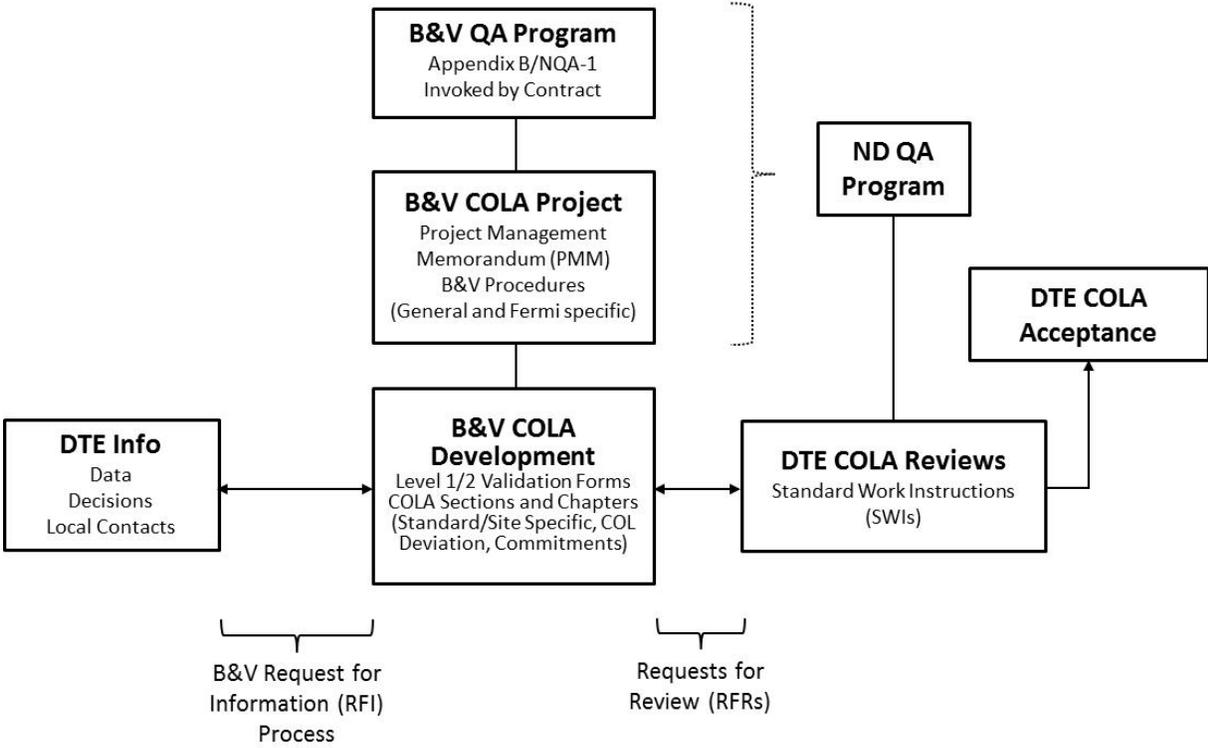
²⁸ NRC3-07-0002, “Notification of Combined License Application Geotechnical Investigation Schedule for the DTE Energy Fermi Site,” dated May 31, 2007 (ADAMS Accession No. ML071580350) (Exh. DTE000048).

²⁹ IMC 2502 invokes, for COL applications that do not reference an Early Site Permit (such as the Fermi 3 application), Inspection Procedure 35004, *Pre-Docketing Early Site Permit Quality Assurance Controls Inspection*, dated May 29, 2003.

³⁰ Audit of Combined License Pre-Application Subsurface Investigation Activities at Fermi (Project No. 757), Enclosure 1 at 3 (ADAMS Accession No. ML072190660) (Exh. DTE000084).

ND QA Program and began the acceptance review of application inserts. The acceptance review was in accordance with Standard Work Instructions (“SWIs”) and subject to the ND QA program.

**COLA Development Process: Acceptance Phase
(February 2008 to October 2008)**



Q54. What was the significance of the acceptance process for COL Application inputs?

A54. (PS, ST) DTE staff were trained on the approved SWIs for review and acceptance of the COL Application products developed by B&V. The 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” (Exh. DTE000050). 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. By early September 2008, DTE completed the review of application work product. Comments were documented and provided to B&V for formal resolution. All comments were resolved in accordance with procedures.

Q55. Did DTE utilize any data in the COL Application that it obtained from B&V before DTE had its own Fermi 3 QA Program?

A55. (PS, ST) No. As mentioned above, all data from B&V was accepted after the ND QAPD was in place to apply to the application product acceptance process.

Q56. What was the role of the Nuclear Development QA Manager?

A56. (PS, SS) The Nuclear Development QA Manager (“QAM”) position was established in March 2008 under the ND QAPD. This individual was responsible for independently planning and performing activities to verify the development and effective implementation of the DTE 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. The Nuclear Development QA Manager position was initially filled by an engineer (J. Werner) with over twenty years of nuclear experience, including four years’ experience as lead auditor.

Q57. Did the Nuclear Development QA Manager lead any audits or surveillances?

A57. (PS, SS) Yes. After forming the DTE QA organization, DTE conducted a surveillance of B&V for the COL Chapter Review Process from April 29, 2008 to May 6, 2008, using Nuclear Development Procedure (NDP)-NP-18.1.³¹ The purpose of the surveillance was to ensure the adequacy of the B&V activities involved in preparing quality site-specific information to be placed in the FSAR. Specific process areas reviewed were: procedure use and adherence, QA oversight effectiveness, corrective actions, and staff training. 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.

In June 2008, 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.³² This included a review of a complete core boring document package obtained from B&V Overland Park. 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.

In July 2009, an audit team from DTE performed an audit of B&V's Appendix B/NQA-1 QA processes, in accordance with the Fermi 3 QAPD implementing

³¹ Surveillance Report 08SR001, dated May 16, 2008 (Exh. DTE000036).

³² Surveillance Report 08SR002, dated June 13, 2008 (Exh. DTE000037).

procedures.³³ 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 safety-related COLA activities. The audit team concluded that the B&V QA Program was 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 November 2011³⁴ and an audit to maintain B&V on the Fermi 3 Approved Supplier List in late-January/early-February 2012.³⁵

Q58. Did B&V conduct audits or surveillances during this phase?

A58. (PS, ST, RS) Yes. In September 2008, B&V specifically conducted a surveillance of activities associated with the preparation of the Fermi 3 COLA.³⁶ The surveillance reviewed records generated during the review of input for the COL application. The surveillance also examined B&V's training records and implementation of the corrective action program for the Fermi 3 project. These processes and surveillance activities give us high confidence in the quality of the work. The COL Application was subsequently submitted by DTE on September 18, 2008.

³³ Audit Report 09NS01, dated August 7, 2009 (Exh. DTE000038).

³⁴ Audit Report 11NS02, dated November 17, 2011 (Exh. DTE000039).

³⁵ 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.

³⁶ B&V Surveillance Report S08SR05-DTE, dated September 12, 2008 (Exh. DTE000083).

Q59. Later in your testimony you will discuss audits in connection with the NRC Staff inspection findings cited by the Intervenors. How do those audits fit in?

A59. (PS, SS) Those audits provide another means of assurance that the program was working. For example, as noted above, an audit team from DTE performed an audit of B&V's Appendix B/NQA-1 QA processes, in accordance with the Fermi 3 QAPD implementing procedures. 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.³⁷

Q60. DTE previously submitted to the NRC a chart showing oversight for sections of the COL Application and FSAR. Can you explain?

A60. (PS) Yes. In conducting its review of the COL Application, the NRC Staff requested additional information in an RAI. The Company responded on May 10, 2010.³⁸ The RAI Response included a chart demonstrating how all Fermi 3 safety-related activities either completed or in process prior to September 18, 2008 (the date of the COL Application and approval for use of the Fermi 3 QAPD) were conducted consistent with the requirements of Appendix B.

Q61. What is your conclusion regarding the oversight of the QA function?

A61. (PS, ST, SS) NRC Regulatory Guide 1.206, C.I. 17.5.3, identifies attributes of an appropriate delegation of QA responsibilities to outside contractors to be

³⁷ See, e.g., Audit Report 09NS01, dated August 7, 2009 (Exh. DTE000038); see also Audit Report 11NS02, dated November 17, 2011 (Exh. DTE000039); Audit Report 12NS01, dated March 1, 2012 (Exh. DTE000040).

³⁸ "Detroit Edison Company Response to NRC Request for Additional Information Letter No. 26, Related to SRP Section 17.5," NRC3-10-0019, dated May 10, 2010 ("RAI Response") (ADAMS Accession No. ML101320254) (Exh. DTE000054).

considered by applicants: (1) description of how the applicant will retain responsibility for, and maintain control over, those portions of the QA program delegated to other organizations; (2) identification of the responsible organization and the process for verifying that delegated QA functions are effectively implemented; (3) identification of major work interfaces for activities affecting quality; and (4) description of how clear and effective lines of communication between the applicant and its principal contractors are maintained to assure coordination and control of the QA program. All of these attributes were satisfied by our systematic approach to the QA function prior to implementation of the ND QAPD and, subsequently, during implementation of the ND QAPD.

E. Issues Identified in 2009 NRC Inspection

Q62. What were the results of the NRC Staff's August 2009 inspection of QA for Fermi 3?

A62. (PS, SS) On October 5, 2009, the NRC Staff issued an Inspection Report and Notice of Violation ("NOV") in which it described the results of an August 18-21, 2009 inspection.³⁹ In the NOV, the NRC Staff cited three violations of NRC requirements:

- A. Failing 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 failing to retain overall control of contracted COL Application activities as required under Criterion II, "Quality Assurance Program" of Appendix B.

³⁹ 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).

- B. Failing to perform internal audits of QA programmatic areas implemented for Fermi Unit 3 COL Application activities.
- C. Failing to document trending of DTE's corrective action reports ("CARs").

Each of these findings 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.

Q63. Did the Company agree with those findings?

A63. (PS, SS) DTE replied to the NOV, on November 9, 2009,⁴⁰ denying that a violation occurred. Among other reasons, DTE was not a COL applicant prior to September 18, 2008, and thus 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. As discussed above, the ND QAPD was subsequently approved for use in February 2008, before COL Application chapters were accepted from B&V and before the COL Application was submitted.

⁴⁰ NRC3-09-0041, "Detroit Edison Reply to Notice of Violation 05200033/2009-201-01, 02, and 03," dated November 9, 2009 (ADAMS Accession No. ML093160318) ("Reply to NOV") (Exh. DTE000035).

Q64. How did the NRC Staff respond to the Company’s position?

A64. (PS, SS) On April 27, 2010, the NRC Staff responded to DTE’s reply to the NOV.⁴¹ 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 and consolidated the former Violations B and C into one other final violation:

- 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 between September 2008 and August 2009 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.

Both violations are very specific and were again characterized as Severity Level IV violations — certainly not broad or “serial” failures to implement any QA program for safety-related work associated with the Fermi 3 COL Application.

Q65. What were the corrective actions for the issue identified in Violation A?

A65. (PS, SS) The issues identified in the Revised NOV were addressed in the Company’s reply to that violation, dated May 26, 2010.⁴² The Company

⁴¹ 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).

⁴² 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).

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. This did not mean that B&V was not qualified to perform the scope of work or the QA function. DTE had based the qualification on the contract solicitation process. The contract documentation referenced the basis for B&V QA qualification, including:

- B&V QA program details; and
- Audits of the B&V program by other U.S. nuclear utilities, including Entergy, American Electric Power, and Nebraska Public Power District.

DTE's Nuclear Development procedures (NDP-NP-4.1, "Procurement of Services" (Exh. DTE000055)) also stated the basis for B&V's qualifications to provide QA services. At the time, the Company considered this to be sufficient documentation.

But, in any event, by April 2009, the company had initiated a plan to establish a more comprehensive vendor qualification review and acceptance program. This program included: QA staff augmentation, vendor audits, procedure improvements, and establishment of an Approved Supplier's List ("ASL"). DTE also conducted an audit of B&V in July 2009 (Exh. DTE000038) and concluded that the B&V Program was being effectively implemented for Fermi 3 COL Application activities. B&V was subsequently listed in the Fermi 3 ASL. These actions were completed by July 2009, and sufficiently responded to the violation.

We discussed earlier in this testimony in more detail our basis for concluding that B&V's safety-related activities prior to July 2009 were completed in accordance with Appendix B requirements.

Q66. Were there corrective actions for the two issues identified in Violation B?

A66. (PS, SS) Yes. As noted above, Violation B 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 CAP. The reasons for these violations, and the corrective actions, were discussed in the Company's November 9, 2009 Reply to NOV.

Q67. What were the corrective actions for the issue involving audits?

A67. (PS, SS) 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.

As discussed above, following the submission of the COL Application, the ND QAPD was superseded by the Fermi 3 QAPD. The Fermi 3 QAPD, Section 18, "Audits," Revision 1,⁴³ states that "[i]nternal audits of organization and facility

⁴³ Fermi 3 QAPD, Revision 1 went into effect on October 20, 2009, and was in effect at the time of the NRC inspection.

activities, conducted prior to placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed at least once each year or at least once during the life of the activity, whichever is shorter.” This language is restated in DTE Procedure NP 18.1, “Audits (Internal),” Revision 1, dated August 7, 2009 (Exh. DTE000053). Contrary to these newly-implemented procedures, as of August 21, 2009 (during the NRC Staff inspection), DTE QA personnel had not completed an internal audit of QA programmatic areas implemented for the Fermi 3 COL Application activities.

As discussed in the Reply to NOV,⁴⁴ the violation related to an inconsistency resulting from the transition in the QA program and implementing procedures at the time. As was described above, numerous reviews and surveillances had been completed, but no internal audits under the newly implemented Fermi 3 QAPD had been conducted. As a corrective action, an internal audit was therefore conducted during the week of October 26, 2009.⁴⁵ Consistent with the Fermi 3 QAPD, appropriately trained DTE personnel conducted the audit of applicable QA program elements for COL Application activities.

As of August 2009, DTE’s Procedure NP-18.1 has specifically required an annual audit. These audits are conducted to assess the effectiveness of the Nuclear

⁴⁴ Reply to NOV, Attachment 2.

⁴⁵ Nuclear Development Quality Assurance, Audit Report 09NI01, “Annual Audit of Implementation of the Fermi 3 Quality Assurance Program Description Requirements.” The audit took place from October 26-30, 2009 (Exh. DTE000058).

Quality Management organization's implementation of the Fermi 3 QAPD requirements, including verification of development and ongoing implementation of processes, procedures and organizational structures as required by the QAPD.

Elements of the audit are to include:

- Independence of Nuclear Quality Management for monitoring Nuclear Development activities;
- Training and personnel qualification;
- Adequacy of, and compliance to, Quality Management instructions and procedures;
- Adequacy of review and control of Quality Management instructions and procedures;
- Effectiveness of controls for qualification of suppliers furnishing safety related items;
- Effectiveness of internal audits and surveillances to meet QAPD requirements; and
- Previous findings

Since the NRC's inspection finding and corrective action audit in October 2009, the following annual QA audits have been performed, as required:

- Nuclear Development Quality Assurance, Audit Report 10NI01, "Annual Audit of Implementation of the Fermi 3 Quality Assurance Program Description Requirements." The audit took place from July 26 to August 5, 2010 (Exh. DTE000059).
- Nuclear Development Quality Assurance, Audit Report 11NI02, "Annual Audit of Implementation of the Fermi 3 Quality Assurance Program Description Requirements." The audit took place from July 13 to July 27, 2011 (Exh. DTE000060).
- Nuclear Development Quality Assurance, Audit Report 12NI02, "Annual Audit of Implementation of the Fermi 3 Quality Assurance Program Description Requirements." The audit took place from July 9 to July 18, 2012 (Exh. DTE000061).

Accordingly, DTE is presently complying with the audit requirements.

Q68. What were the corrective actions for the issue involving trend reports?

A68. (PS, SS) 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, Section 16, “Corrective Action,” Revision 1, sets forth the requirement that “[r]eports of conditions adverse to quality are analyzed to identify trends.” DTE Procedure NP 16.1, “Corrective Action Program” (Exh. DTE000052), states that the Director of Quality Management “is responsible for trending corrective actions to determine if there are adverse trends that require management attention.”

Contrary to the procedures, as of August 21, 2009 (during the NRC Staff audit), DTE had not documented trending of corrective actions to identify recurring conditions adverse to quality since the COL Application was submitted. The ND QAPD, which was in effect from February 2008 until October 2008, implemented Criterion XVI in Section 16, “Corrective Action,” and prescribed that procedures “assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with this QAPD, regulatory requirements and applicable quality standards.” A “trend” requirement had not been included in the ND QAPD.

As discussed in the Reply to NOV,⁴⁶ this issue again reflected an inconsistency resulting from the transition in the Fermi 3 QA program and implementing procedures at the time. DTE has acknowledged that trending of corrective actions is a valuable practice and, as such, has included trending as part of its quality procedures and practices under the Fermi 3 QAPD. DTE performed the corrective action trending required by DTE Procedure NP-16.1 on October 31, 2009.⁴⁷ The trend review considered all corrective actions from January 22, 2008 through October 31, 2009. No trends adverse to quality were identified.

To assure that all COL Application activities continue to be conducted at a level of quality necessary to support future safety related activities, DTE issued NP-16.1, Revision 2, dated October 14, 2009 (Exh. DTE000052), to prescribe for the Nuclear Development Review Committee an additional responsibility for “review of potential Corrective Action Report (CAR) trends.” Under the procedure, potential CAR Trends are discussed at the regular (*i.e.*, nominally weekly) Nuclear Development Review Committee meeting. The Director, Quality Management, also implemented procedural guidance for performing and reporting trend results as appropriate for the current phase of the COL Application development in accordance with the Fermi 3 QAPD Corrective Action Program.

⁴⁶ Reply to NOV, Attachment 3.

⁴⁷ 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.

DTE has subsequently performed additional corrective action trending at approximately six-month intervals. For example, DTE performed corrective action trend analyses in June 2010 (Exh. DTE000063), November 2010 (Exh. DTE000064), April 2011 (Exh. DTE000065), October 2011 (Exh. DTE000066), April 2012 (Exh. DTE000067), and October 2012 (Exh. DTE000068). Each trend analysis focused on the corrective actions for the preceding one-year period.

Q69. Has the NRC Staff accepted the corrective actions for the violations as sufficient?

A69. (PS, SS) Yes. With respect to Violation A (documentation of B&V's qualifications) the NRC Staff acknowledged the Company's Reply to Revised NOV in a letter dated June 4, 2010.⁴⁸ The NRC Staff found the Company's letter to be responsive. With respect to Violation B (audits and trend reports), the NRC Staff provided a detailed evaluation of the Company's position in its April 27, 2010 Revised NOV. The NRC Staff found the corrective actions for Violation B to be responsive as well.⁴⁹

FERMI 3 QA PROGRAM DESCRIPTION

A. Program Overview

Q70. Describe the development and implementation of the Fermi 3 QAPD.

A70. (PS, SS) 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

⁴⁸ 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).

⁴⁹ Revised NOV, Enclosure 1, at 7 and 11.

FSAR provides a detailed description of planned and systematic actions to assure safety and reliability during design (FSAR Chapters 17.1 and 17.4),⁵⁰ and during construction and operation of the plant (FSAR Chapter 17.2). The FSAR also contains a detailed discussion of the Fermi 3 QAPD (FSAR Chapters 17.3 and 17.5). The QAPD itself was submitted to the NRC as Appendix 17AA to the FSAR. The current version is Revision 5, which became effective on January 7, 2013 (Exh. DTE000074).

Q71. What standards does the Fermi 3 QAPD meet?

A71. (PS, SS) The NRC's Standard Review Plan ("SRP")⁵¹ for QA programs is based upon several standards and guidance documents, including NQA-1; Regulatory Guide 1.8, Revision 3; Regulatory Guide 1.28, Revision 3; Regulatory Guide 1.33, Revision 2; and NRC RS-002. The NRC acceptance criteria for QA programs include a commitment to comply with the regulations and applicable guidance outlined above. The Fermi 3 QAPD is based on the standards in NQA-1-1994. The specific commitments with respect to NRC Regulatory Guides are included in QAPD Part IV. Specific exceptions or clarifications with respect to NQA-1-1994 are addressed in each section of the QAPD. The exceptions and clarifications are part of the NRC-approved Nuclear Energy Institute ("NEI")

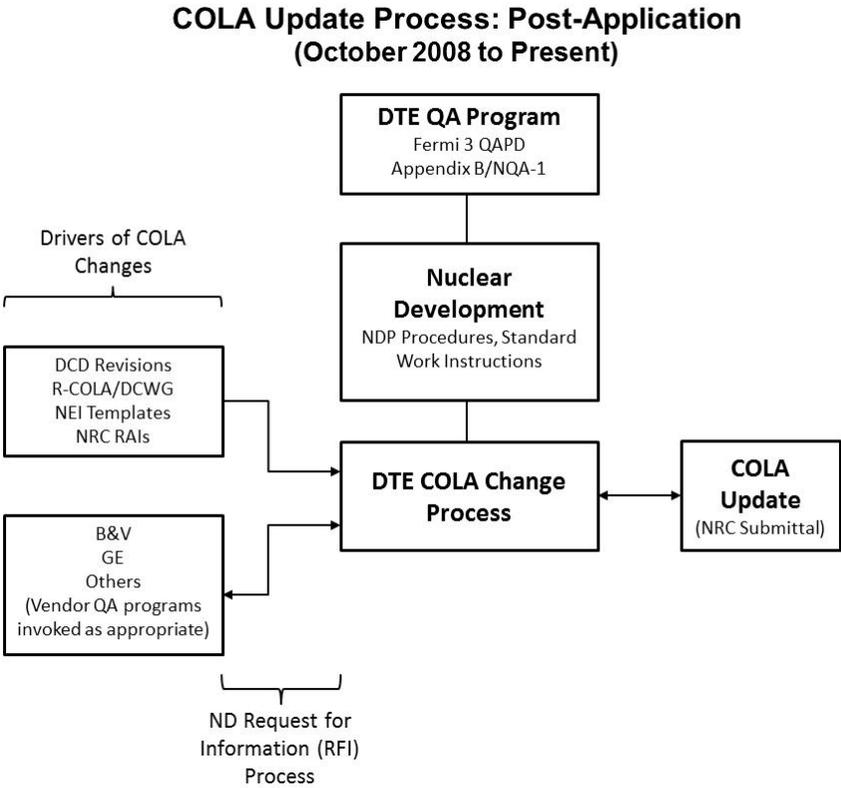
⁵⁰ Substantial portions of the "design" work will also be the subject of the QA program of the nuclear technology vendor in accordance with the design certification application for the ESBWR and NRC's Part 52 regulations.

⁵¹ See NUREG-0800, Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants" (March 2007) (Exh. DTE000093).

QAPD template (*i.e.*, they are not unique to Fermi 3), which is discussed in more detail below.

Q72. Does the Fermi 3 QAPD comply with NRC requirements that applied to DTE after the application was filed?

A72. (PS, SS) Yes. As discussed above, once the COL Application was filed, DTE became an applicant subject to 10 C.F.R. Part 50, Appendix B. The Fermi 3 QAPD, which was submitted with the COL Application, meets Appendix B requirements. The Fermi 3 QA Program now applies to all COL Application work. This is illustrated in Exh. DTE000020, “COLA Update Process: Post-Application (September 2008 to Present)” (excerpted below). This process principally applies to COL Application changes due to RAIs, DCD revisions, or other new information.



Q73. Does this program meet NRC requirements for the construction and operation phases of the Fermi 3 project?

A73. (PS, SS) Yes. QA programs must satisfy the eighteen criteria of 10 C.F.R. Part 50, Appendix B. These are incorporated into NQA-1 and are addressed by the Fermi 3 QAPD.⁵² Additionally, as laid out in SRP Section 17.5, COL applicants must address the following: (1) training and qualification criteria – quality assurance; (2) training and qualification – inspection and test; (3) quality assurance program commitments; (4) non-safety related structures, systems and components quality controls; (5) independent review; and (6) operational program description and implementation.

Q74. How does the Fermi 3 QAPD compare to industry guidance for QA programs for new plants?

A74. (PS, SS) As noted above, NEI 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

⁵²

The Appendix B criteria are: (1) organization; (2) quality assurance program; (3) design control and verification; (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) inspection test and operating status; (15) nonconforming materials, parts, or components; (16) corrective action; (17) quality assurance records; and (18) audits.

version of the generic template in July 2010,⁵³ and NEI issued the endorsed version as NEI-06-14A, Revision 7, in August 2010.⁵⁴ The Fermi 3 QAPD was specifically developed based on the NEI-06-14A template.⁵⁵ The significance of NRC acceptance is that the NRC does not repeat its review of material already accepted in NEI-06-14A when reviewing individual COL applications.

Applicants using the NEI-06-14A template must address conformance with the NRC's regulatory guidance either 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 NRC has accepted the generic QAPD in NEI-06-14A, the NRC Staff review of applicant-specific QAPDs focuses on any applicant-specific information provided, as opposed to the generic template. License applications that deviate from the generic template are subject to a plant-specific review in accordance with the applicable regulatory standards.

⁵³ See 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).

⁵⁴ The NRC-endorsed QAPD template was initially released in May 2008 as NEI-06-14A, Rev. 5 (ADAMS Accession No. ML081350560) (Exh. DTE000089). See also "Final Safety Evaluation for Technical Report NEI 06-14," dated April 25, 2007 (ADAMS Accession No. ML070510300) (Exh. DTE000090). The "A" denotes NRC Staff approval. The NRC subsequently approved a later revision of NEI-06-14. As many utilities had developed QAPD programs based on previous revisions to the document, and the highest revision being used at the time by industry was Revision 6, NEI issued the final document as Revision 7 to minimize confusion.

⁵⁵ 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.

The Fermi 3 QAPD itself is based on DTE's commitment to NQA-1-1994, and includes the required elements from the NEI template. The specific commitments with respect to NRC Regulatory Guides are included in QAPD Part IV.

Q75. What is DTE's policy for QA program implementation?

A75. (PS, SS) In accordance with the NEI template and the NRC guidance, the Fermi 3 FSAR includes the Fermi 3 policy for "Quality Assurance During Construction and Operation." The policy states:

DTE Electric Company shall design, procure, construct and operate the Enrico Fermi Nuclear Station, Unit 3 (Fermi 3) nuclear plant in a manner that will ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations (CFR), the applicable Nuclear Regulatory Commission (NRC) Facility Operating Licenses, and applicable laws and regulations of the state and local governments.

The Fermi 3 ESBWR Quality Assurance Program (QAP) is the Quality Assurance Program Description (QAPD) provided in this document and the associated implementing documents. Together they provide for control of Fermi 3 activities that affect the quality of safety-related nuclear plant structures, systems, and components and include all planned and systematic activities necessary to provide adequate confidence that such structures, systems, and components will perform satisfactorily in service. The QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes program requirements.

The QAPD is the top-level policy document that establishes the manner in which the quality is to be achieved and presents Fermi 3's overall philosophy regarding achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP. Compliance with the QAPD and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the Fermi 3 QAP.

The policy evidences a clear 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. NRC Staff Review

Q76. Has the NRC Staff completed its review of the QAPD?

A76. (PS, SS) Yes. 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.⁵⁶ The NRC Staff found the Fermi 3 QAPD acceptable based on reviews of twenty-two different subject areas.

Q77. Was the NRC Staff's conclusion affected by the August 2009 inspection findings discussed above?

A77. (PS, SS) No. The NRC Staff specifically addressed the items raised in the NOV, concluding that (a) DTE's answers were responsive to the Revised NOV, (b) the implemented corrective actions are appropriate, and (c) the activities cited in the Revised NOV were addressed and are consistent with the requirements of Appendix B.⁵⁷ 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.

Q78. Are there any outstanding NRC compliance issues related to the program?

A78. (PS, SS) No.

⁵⁶ See Chapter 17 SER (ADAMS Accession No. ML112630120) (Exh. DTE000092).

⁵⁷ *Id.* at 17-34.

C. Program Implementation

Q79. Have QA procedures been developed and implemented?

A79. (PS, SS) Yes. QA implementing procedures were developed and have been continuously in effect since implementation of the ND QAPD. The procedures are organized to address the topical areas associated with the 18 criteria of Appendix B that are applicable to the current phase of COL Application work. For example, Organization is addressed in procedure NP-1.1, Revision 7, “Nuclear Development Fermi 3 Organization” (Exh. DTE000075); NP-2.1, Revision 8, “Learning Management,” addresses training (Exh. DTE000076); NP-5.1, Revision 5, “Nuclear Procedure Preparation,” addresses development, review, approval, and implementation of procedures (Exh. DTE000077); and, NP-6.7, Revision 1, “QAPD Change Process,” address the change process for the QAPD (Exh. DTE000078). Other nuclear procedures address document control, the CAP, supplier evaluations, and audits and surveillances, for example.

Q80. Have there been any audits or surveillances of the Fermi 3 QA program?

A80. (PS, SS) Yes. As part of its QA program, DTE regularly performs audits and surveillances — including internal audits and surveillances, audits of DTE programs by external auditors, and audits of DTE vendors and suppliers. For example, DTE Quality Management performs audits to ensure that the Fermi 3 project team is performing its activities in compliance with the Fermi 3 QAPD.

These annual audits include:

- Nuclear Development Quality Assurance, Audit Report 09NI01, “Annual Audit of Implementation of the Fermi 3 Quality Assurance Program Description Requirements,” conducted October 26-30, 2009 (Exh. DTE000058);

- Nuclear Development Quality Assurance, Audit Report 10NI01, “Annual Audit of Implementation of the Fermi 3 Quality Assurance Program Description Requirements,” conducted July 26 - August 5, 2010 (Exh. DTE000059);
- Nuclear Development Quality Assurance, Audit Report 11NI02, “Annual Audit of Implementation of the Fermi 3 Quality Assurance Program Description Requirements,” conducted July 13-27, 2011 (Exh. DTE000060); and
- Nuclear Development Quality Assurance, Audit Report 12NI02, “Annual Audit of Implementation of the Fermi 3 Quality Assurance Program Description Requirements,” conducted July 9-18, 2012 (Exh. DTE000061).

External organizations also audit the DTE Quality Management organization, such as the audits documented in the following reports:

- Nuclear Development Quality Assurance, Audit Report 09NI02, “Annual Audit of the Fermi 3 Nuclear Quality Management Organization” (Exh. DTE000079). The audit took place from November 30 to December 3, 2009.
- Nuclear Development Quality Assurance, Audit Report 11NI01, “Annual Audit of the Fermi 3 Nuclear Quality Management Organization” (Exh. DTE000080). The audit took place from February 22-28, 2011.
- Nuclear Development Quality Assurance, Audit Report 12NI01, “Annual Audit of the Fermi 3 Nuclear Quality Management Organization” (Exh. DTE000081). The audit took place from February 27-29, 2012.
- Nuclear Development Quality Assurance, Audit Report 13NI01, “Annual Audit of the Fermi 3 Nuclear Quality Management Organization” (Exh. DTE000082). The audit took place from January 23-25, 2013.

The requirements that are assessed during an audit are identified in the audit plan and audit checklists and may include those associated with organization, training, design control, procurement document control, control of purchases,

nonconforming items/Part 21 reporting, corrective action, records, and previous audit and surveillance findings.

Overall, DTE performs audits and surveillances regularly and at a frequency determined by the audit and surveillance program and commensurate with the level and nature of work activities. The following table highlights most of the audit and surveillance activities that have been performed under the Fermi 3 QAPD during the COL Application reviews and also lists the audits and surveillances performed or scheduled for 2013:

Fermi 3 Audits and Surveillances conducted by DTE	
Completed in 2009	July 2009, Supplier Audit – B&V QA Program October 2009, Audit – QA Program Implementation, ND Org. November 2009, Audit – External Review of Quality Management Org. November 2009, Surveillance – RAI Response Process December 2009, Surveillance – Commitment Management Process
Completed in 2010	January 2010, Surveillance – Geologic Core Sample Storage February 2010, Surveillance – RAI Response Process March 2010, Surveillance – Preparation of COLA Revision April 2010, Surveillance – Document Control / Records Management June 2010, Supplier Audit – Advent Engineering QA Program July 2010, Audit – QA Program Implementation, ND Org. August 2010, Surveillance – Training November 2010, Surveillance – Procurement
Completed in 2011	January 2011, Surveillance – Preparation of COLA Revision February 2011, Supplier Audit – GEH QA Program February 2011, Audit – External Review of Quality Management Org. April 2011, Surveillance – Procedure Use and Adherence May 2011, Surveillance – Corrective Action Program (CARs) July 2011, Audit – QA Program Implementation, ND Org. October 2011, Surveillance – Procedure Use and Adherence - Follow-up October 2011, Supplier Limited Scope Audit – Soil Structure Interaction November 2011, Surveillance – Procurement Control

Completed in 2012	January 2012, Surveillance – Preparation of COLA Revision January 2012, Supplier Audit – B&V QA Program Full Scope February 2012, Audit – External Review of Quality Management Org. February 2012, Surveillance – B&V File Transfer to DTE process April 2012, Surveillance – B&V File Transfer to DTE May 2012, Surveillance – Procurement July 2012, Audit – QA Program Implementation, ND Org. September 2012, Surveillance – Corrective Action Process October 2012, Surveillance – Document Control / Records Management
Performed or Scheduled for 2013*	January 2013, Audit – External Review of QA Function (complete) April 2013, Surveillance – Fermi 3 Roles and Responsibilities June 2013, Audit – Annual QA Program Review October 2013, Surveillance – Doc. Transfer to DTE (S&L, B&V, GEH) November 2013, Surveillance – Preparation of COLA Revision 6

* As of March 28, 2013. Actual dates subject to change.

Q81. Have these audits and surveillances identified findings or made recommendations?

A81. (PS, SS) Yes. As expected, the audits and surveillances performed during the Fermi 3 project have identified issues and made recommendations for improvement.

Q82. When issues or recommendations are identified, how are they addressed?

A82. (PS, SS) Issues and recommendations are entered into the Corrective Action Program (“CAP”) for resolution and tracking. The Fermi 3 CAP is implemented through procedures that address identification, control, documentation, classification, investigation, and resolution of potentially undesirable conditions and opportunities for improvement.⁵⁸ The procedures assure that corrective actions are documented and initiated in accordance with regulatory requirements and applicable quality standards. The Fermi 3 CAP procedure, NP-16.1 (Exh.

⁵⁸ As explained in the Fermi 3 QAPD Section 16, *Corrective Action* (Exh. DTE000074 at 55), the CAP will be applied throughout the construction and operation of Fermi 3.

DTE000052), is designed to assist the Nuclear Development team with initiating, assigning, reviewing, dispositioning, and closing corrective action requests (“CARs”).⁵⁹ The person assigned the CAR will investigate the condition, determine causes, evaluate and implement measures to correct the condition, and document the resolution. DTE’s Nuclear Development CAR Review Committee, which is comprised of representative directors and managers from Nuclear Development, manages and oversees the effectiveness of the CAR process.

Q83. Have there been any other assessments of the Fermi 3 QA program?

A83. (PS, SS) Yes. Consistent with Section 6.1.4 of NP 1.1, Nuclear Development management performs a semi-annual management assessment of QAPD implementation and effectiveness. These reviews were conducted in January 2010, July 2010, June 2011, December 2011, June 2012, and December 2012. The assessments include a review of the implementation and status of the CAP, a review of internal and external assessments (*e.g.*, NRC audits, QA audits/surveillances, RAI responses, and other related activities), and benchmarking activities. As a result of these reviews, Nuclear Development management identifies areas, if any, that warrant heightened focus or attention and deploys additional resources to those areas as needed.

⁵⁹ A CAR is an electronic record form used by individuals to document potential conditions and initiate the corrective action program.

Q84. Do the audit, surveillance, or assessment findings or recommendations suggest a failure to implement the QA program?

A84. (PS, SS) No. To the contrary, the fact that audits and surveillances find issues is evidence that the program is working effectively. We would, frankly, be concerned if the audits and surveillances were not finding any issues or areas for improvement. That said, none of the issues found during the course of the Fermi 3 project to date indicate a pervasive or programmatic breakdown in the QA program, such as multiple and recurring significant deficiencies associated with an activity.

SPECIFIC ISSUES RAISED BY MR. GUNDERSEN

A. Nuclear Development QA Manager Position in COLA

Q85. Mr. Gundersen has expressed a concern that the COL Application makes no mention of the position of Nuclear Development QA Manager. Is there an explanation for this alleged omission from the application?

A85. (PS, SS) Mr. Gundersen has filed several declarations based on his review of the COL Application and the Company's RAI Response of May 10, 2010. Mr. Gundersen states that he has a concern that the RAI Response introduced a new position, Nuclear Development QA Manager, not discussed in the COL Application. He is concerned that the RAI Response states that the Nuclear Development QA Manager held that position as of March 2008 (prior to the date of the COL Application), but the "COLA makes no reference to that role."⁶⁰

Mr. Gundersen's statement reflects a misunderstanding of the evolution of the QA program for Fermi 3. The Nuclear Development QA Manager was a position that

⁶⁰ Gundersen Dec. 3 at ¶15.

existed only while the ND QAPD was in effect. As discussed above, the ND QAPD was in effect prior to submission of the COL Application for Fermi 3 and was not submitted as part of the COL Application. The same position does not exist in the Fermi 3 QAPD, which is incorporated into the Fermi 3 FSAR. Instead, the duties of the Nuclear Development QA Manager were taken over by the New Plant Oversight Manager (Revision 0 of the Fermi 3 QAPD), which became the Director, Quality Management (in Revision 1 of the Fermi 3 QAPD in October 2009).⁶¹ The Nuclear Development QA Manager position under the ND QAPD was discussed in the RAI response, and is now discussed in the current revision of the COL Application, as part of a historical description of the QA program applied to the Fermi 3 project prior to the COL Application date.⁶²

Q86. Were there conflicting roles between the New Plant Oversight Manager and the Nuclear Development QA Manager?

A86. (PS, SS) No. The roles are serial in nature, under different QAPDs. This is illustrated below:

QAPD	Title	Description
ND QAPD	ND Quality Assurance Manager	ND Quality Assurance Manager is “responsible for developing and maintaining the DECo Nuclear Development QAPDs, evaluating compliance to the programs and managing the QA resources.”
Fermi 3 QAPD, Revision 0	New Plant Oversight Manager	The New Plant Oversight Manager “is responsible for developing and maintaining the Fermi 3 QAPD, evaluating compliance to the programs, and managing QA resources.”

⁶¹ Although they have different titles, all three positions have the same responsibilities, as discussed further below.

⁶² See FSAR, Revision 3, Section 17.5 (at page 17-13) (Exh. DTE000049).

Fermi 3 QAPD, Revision 1	Director, Quality Management	The Director, Quality Management, “is responsible for developing and maintaining the Fermi 3 QAPD, evaluating compliance with the program and managing the QA organization resources.”
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Q87. Are authorities and responsibilities clearly established in the Fermi 3 QAPD?

A87. (PS, SS) Yes. The role of the current Director, Quality Management, is specified in the Fermi 3 QAPD. The Director, Quality Management, reports to the Senior Vice President, Major Enterprise Projects, and separately to the Chief Nuclear Officer. Under Revision 5 of the QAPD, the Director, Nuclear Licensing and Engineering is responsible for line functions. The Director, Nuclear Licensing and Engineering, reports to the Senior Vice President, Major Enterprise Projects, and separately to the Chief Nuclear Officer.

B. QA Personnel

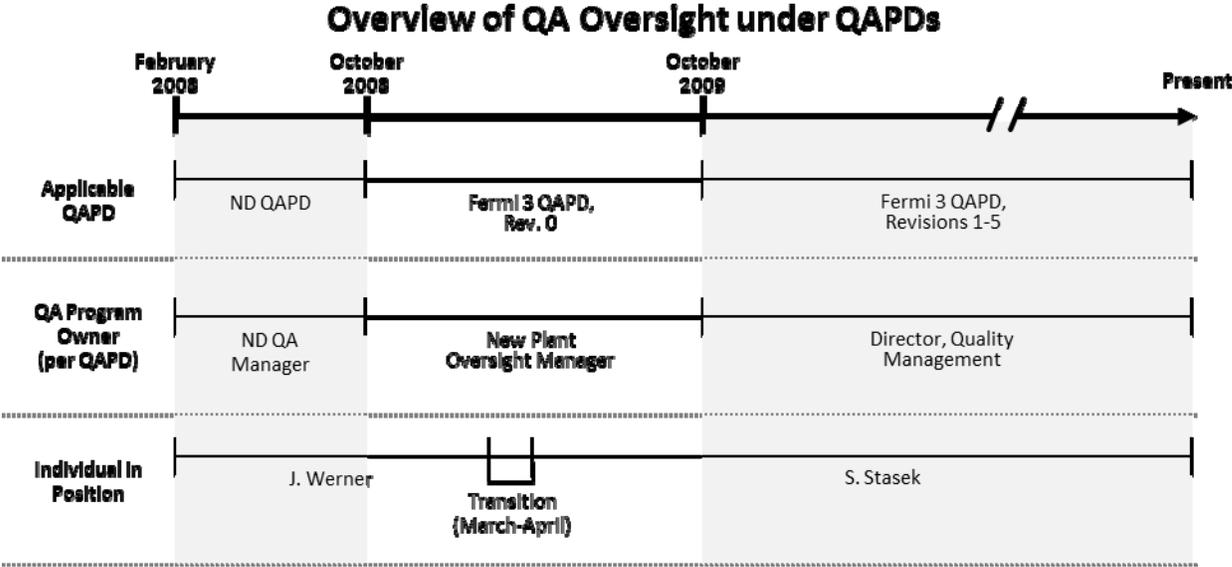
Q88. Mr. Gundersen expresses concern regarding a “3-month long gap” from April 2009 to June 2009 with no personnel in charge of QA. Is that an accurate assessment?

A88. (PS, SS) No. Mr. Gundersen reviewed the RAI Response and incorrectly concluded that there was a “three-month long gap” from April 2009 through June 2009” in which there was no person in charge of QA.⁶³ The RAI Response provided a list of DTE QA personnel providing project support, including their hire dates, QA qualification types and dates, the type of QA support provided, and percentage dedicated to the project if less than full time.⁶⁴ The response identified

⁶³ Gundersen Dec. 3, at ¶17.1.

⁶⁴ RAI Response, Attachment 2, at 1 (RAI 17.5-17) (Exh. DTE000054).

the Nuclear Development QA Manager (J. Werner) employment dates between March 2008 and April 2009.⁶⁵ The current Director, Quality Management (Mr. Stasek) arrived at the project in early March 2009, to fill the role of New Plant Oversight Manager. He has served uninterrupted in that role through the present under the current title of Director, Quality Management. Thus, there was continuous QA oversight during the relevant period. The figure below (Exh. DTE000094) illustrates the circumstances described above.



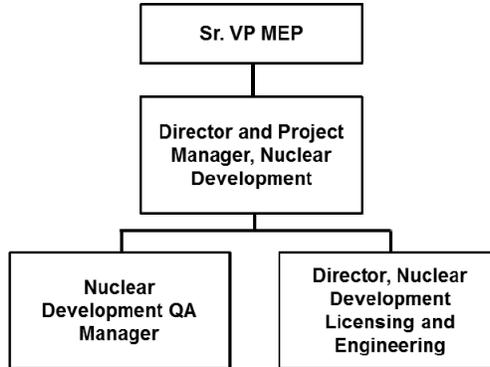
In the RAI Response, DTE also noted that “in June 2009, the QA function was transitioned from reporting to the Director, Nuclear Development, to the Sr. Vice President, Major Enterprise Projects.”⁶⁶ Contrary to Mr. Gundersen’s claims, this does not indicate a gap in QA oversight, but rather indicates a transition in QA reporting relationships. As the figures below demonstrate (Exh. DTE000095), the change in reporting relationship actually increased the independence of the

⁶⁵ *Id.* at 3.

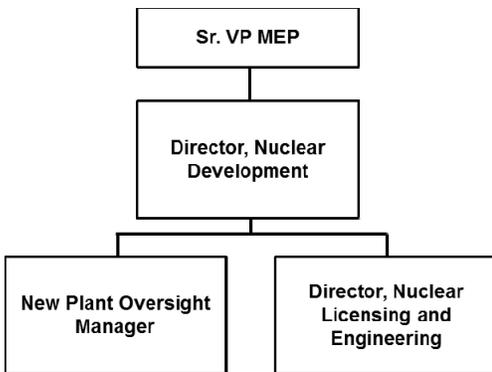
⁶⁶ *Id.* at 3.

QA functions from the line organization.

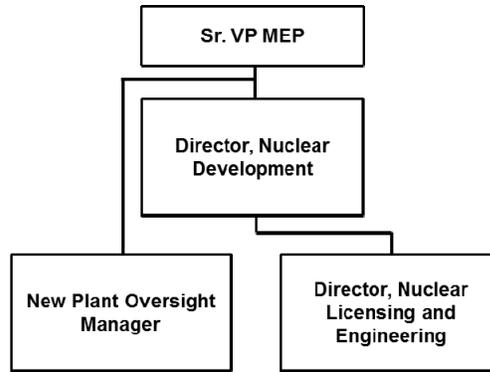
ND QAPD
(February 2008 to October 2008)



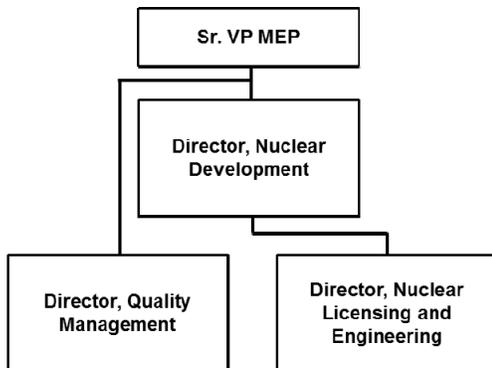
Fermi 3 QAPD, Rev. 0
(October 2008 to June 2009)



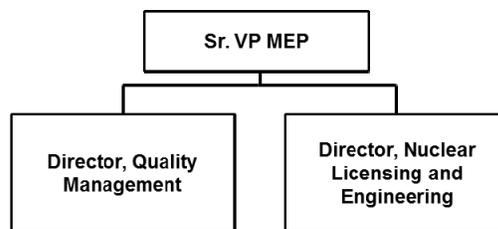
Fermi 3 QAPD, Rev. 0
(June 2009 to October 2008)



Fermi 3 QAPD, Revs. 1-4
(October 2009 to January 2013)



Fermi 3 QAPD, Rev. 5
(January 2013 to Present)



C. Separation and Independence of QA Organization

Q89. Mr. Gundersen next focuses on certain reporting relationships as addressed in the RAI Response. Can you clarify the issue and explain the reporting relationships as they have evolved?

A89. (PS, SS) Mr. Gundersen claims that for 13 months, between March 2008 and April 2009, the QA Department actually reported directly to the Director of Nuclear Development.⁶⁷ During that period, the QA Manager for the Nuclear Development project was filled by one individual, Mr. Werner.

From March 2008 until October 2008 the reporting relationship for that position was defined by the ND QAPD governing review and acceptance of B&V COL Application sections.⁶⁸ Specifically, independence was discussed in the description of the Nuclear Development QA Manager function and in Section 1.4, “Quality Assurance Organizational Independence.” In this pre-application phase the QA Manager reported directly to the Director/Project Manager Nuclear Development specifically to ensure that the personnel performing QA oversight functions were not subject to line organization influence.⁶⁹ This reporting relationship ensured that QA personnel were provided direct access to senior management that is independent of the line functions for reporting QA concerns. In addition, the position description for the Nuclear Development QA Manager included the following responsibility: “[i]f the [ND QA Manager] disagrees with

⁶⁷ Gundersen Dec. 3, at ¶17.2.

⁶⁸ Starting in October 2008, the position was defined by the Fermi 3 QAPD (first as New Plant Oversight Manager and, in later revisions, as Director, Quality Management).

⁶⁹ The line organization is led by the Director, Nuclear Development Licensing and Engineering (P. Smith).

any actions taken by the Nuclear Development organization and is unable to obtain resolution, the [QA Manager] shall bring the matter to the attention of the Senior Vice President DTE Energy who will determine the final disposition.”

According to Mr. Gundersen, having the QA Department report to the Director of Nuclear Development “does not provide the Quality Assurance function with adequate functional separation to assure the clear separation and independence between QA and other line functions within the Fermi 3 organization.”⁷⁰ However, the reporting relationship during this time was consistent with the approach in the NEI template, which was approved for use by the NRC. For the Fermi 3 project the ND QA Manager reported to the “Senior Nuclear Development Officer” — the Director and Project Manager, Nuclear Development (D. Harwood). While the most senior manager position for the project was at a Director level rather than a Vice President level, the reporting structure met the NEI template.

A similar relationship was in effect from October 2008 to June 2009, while the Fermi 3 QAPD, Revision 0, was in effect.⁷¹ Under Revision 0, the New Plant Oversight Manager reported to the Director, Nuclear Development (D. Harwood), under the Fermi 3 QAPD. The Director, Nuclear Development, was the most senior manager for the Fermi 3 project at that time. The reporting relationship

⁷⁰ *Id.* at ¶17.2.3.

⁷¹ *See e.g.*, Fermi 3 QAPD, Revision 0, at 9-10 (discussing the independence of the New Plant Oversight Manager and describing the position’s responsibility in the event of a disagreement with other Fermi 3 organizations) (Exh. DTE000071).

during this time was consistent with the approach in the NEI template.

As noted above, in June 2009, the reporting relationship for the QA function transitioned from the Director, Nuclear Development, to the Sr. Vice President, Major Enterprise Projects. As the charts above demonstrate, the change in reporting relationship actually increased the independence of the QA functions from the line organization.

Q90. Mr. Gundersen claims that from April 2009 to June 2009 the QA Department reported to no one in any chain of command.⁷² Is this accurate?

A90. (PS, SS) No. During this period, the New Plant Oversight Manager (Mr. Stasek) reported to the Director, Nuclear Development (D. Harwood), under the Fermi 3 QAPD. The Director, Nuclear Development, was the most senior manager for the project at that time. The reporting relationship during this time was consistent with the approach in the NEI template.

Mr. Stasek has since remained in the same functional position, the title of which was later changed to Director, Quality Management in subsequent revisions of the Fermi 3 QAPD. As illustrated above, under the subsequent revisions of the Fermi 3 QAPD, the reporting relationship of the Director, Quality Management changed from the Director, Nuclear Development, to the Senior Vice President, Major Enterprise Projects. The reporting relationship remained consistent with the NEI template.

⁷² Gundersen Dec. 3, at ¶17.2.2.

Q91. Does this organization plan meet the NEI-approved guidance?

A91. (PS, SS) Yes, as discussed above. More specifically, the current NRC-approved NEI template states that “[t]he Quality Assurance Manager reports to the Executive Vice President for the operations activities and to the Senior Nuclear Development Officer for the new reactor activities and is responsible for developing and maintaining the [company abbreviation (“CA”)] QAPDs, evaluating compliance to the programs and managing the QA organization resources.”⁷³ As noted above, for the ND QAPD the QAM reported to the Director, Nuclear Development, and had a responsibility to report any unresolved concerns to the Senior Vice President DTE Energy. This was consistent with the NEI template.

Q92. In the present Fermi 3 QAPD, is there functional separation between the QA function and other line functions?

A92. (PS, SS) Yes. The current Director, Quality Management (S. Stasek) reporting relationships, as described in the Fermi 3 QAPD, Revision 5, are to the Senior Vice President, Major Enterprise Projects, and the Chief Nuclear Officer.⁷⁴ The line organization, which is led by the Director, Nuclear Licensing and Engineering (P. Smith), also reports to the Senior Vice President, Major Enterprise Projects, and the Chief Nuclear Officer. This is consistent with the NEI template.

⁷³ NEI-06-14A, Rev. 7, at Section 1.5.2.1, *Quality Assurance Manager* (Exh. DTE000091).

⁷⁴ Fermi 3 QAPD, Rev. 5, at 9 (Exh. DTE000074).

D. Departures from QAPD Template

Q93. Mr. Gundersen suggests that the original COL Application “should have alerted the NRC that [DTE] had taken exception to the NEI approved reporting relationship for its QA function. Did the organization at that time represent “an exception”?”

A93. (PS, SS) No. Mr. Gundersen claims that DTE “should have alerted the NRC that it had taken exception to the NEI approved reporting relationship for its QA function.”⁷⁵ However, there was no exception taken and therefore no “alert” to be given. The Fermi 3 QAPD has been based on the guidance in the NEI template, including the organizational structure, both during the ND QAPD phase (prior to COL Application submittal) and after COL Application submittal. The NEI template contains guidance on organizational structure *components*. It recognizes that the QAPD organizational structure can be tailored to site specific organizational nomenclature.

Mr. Gundersen’s statements do not acknowledge revisions in the NEI template (or corresponding revisions to the ND QAPD and Fermi 3 QAPD). The NEI template in place at the time of the ND QAPD development has been revised several times since the development of the ND QAPD and the Fermi 3 QAPD. Changes to the template included changes to the organizational description guidance in the template. The Fermi 3 QAPD has also been revised to incorporate new revisions of the template and to reflect DTE’s responses to NRC RAIs, which typically followed releases of NEI template revisions.

⁷⁵ Gundersen Dec. 3, at ¶17.3.

E. OAPD Reference to Nuclear Development QA Manager

Q94. Lastly, Mr. Gundersen was frustrated in his review of the Fermi 3 QAPD, Rev. 0, because he was unable to find a reference to the ND QA Manager position. Can you explain?

A94. (PS, SS) Yes. Based on his review of the Fermi 3 QAPD, Mr. Gundersen asserts that there is no “reference to a Nuclear Development QA Manager anywhere” even though DTE claims that as of March 2008 the Nuclear Development QA Manager was assigned to the Fermi 3 project.⁷⁶ Mr. Gundersen’s statement reflects again his misunderstanding of the evolution of the QA program for Fermi 3. As noted above, the Nuclear Development QA Manager was a position that existed only while the ND QAPD was in effect. The position does not exist in the Fermi 3 QAPD. For this reason, there was no reference (nor should there have been any reference) to the Nuclear Development QA Manager in the Fermi 3 QAPD. The ND QAPD and Fermi 3 QAPD reference different titles in order to maintain a distinction between the two phases of COL development. While the titles have changed, the roles and responsibilities are identical.

CONCLUSIONS

Q95. What are your overall conclusions regarding Contention 15A?

A95. (PS, ST, RS) Contention 15A concerns the reliability of the safety-related information in the COL Application and supporting FSAR. The Intervenors’ 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.

⁷⁶ Gundersen Aff., at ¶17.4.

Relying on the original NRC Staff NOV (that was superseded by a narrowed and revised NOV), the Intervenors 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 to oversee those activities.

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 and under B&V's established Appendix B QA program. Because B&V had an established Appendix B Program, internal oversight of safety-related activities was inherent in the B&V program. During the site investigation phase, the Fermi 3 Nuclear Development organization also maintained a presence to oversee those activities and workers were subject to the applicable programs for the operating Fermi 2. And, DTE retained an OE to enhance its oversight and observation of site work activities, including surveillances of the site investigation activities. The NRC Staff also exercised oversight of the pre-application subsurface investigation activities being conducted to obtain geotechnical and seismic data.

(PS) Moreover, even though DTE was not required to implement a QA Program prior to application submittal, DTE did, in fact, establish an Appendix B program under the ND QAPD and developed procedures for review and acceptance of COL Application work product. The ND QAPD and implementing procedures provided additional measures of oversight beyond DTE's commercial contract

oversight, including surveillances and audits of the B&V Nuclear Organization QA program.

(PS, ST) 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 submittal is of high-quality. DTE 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.

Q96. What are your overall conclusions regarding Contention 15B?

A96. (PS, SS) 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 meets all relevant requirements and guidance. While there were two Severity Level IV violations that were resolved based on corrective actions, there has not been any “pattern” of QA violations. To the contrary, DTE has demonstrated its commitment to QA from the start of the project by selecting a contractor with an existing Appendix B QA program, requiring by contract that work be performed under that program, establishing its own Appendix B QA program prior to accepting any information for use in the COL Application, and implementing the applicable QAPD program throughout ongoing COL-related work.

(PS, SS) DTE has continued to implement the QAPD since its adoption through procedures based on the QAPD and NRC requirements. And, DTE has performed

numerous audits, surveillances, assessments and other actions to ensure effective implementation of the DTE QA program. The NRC Staff verified implementation of the Fermi 3 QAPD by inspection and also concluded that DTE has provided satisfactory oversight of the contracted activities by implementing the applicable oversight components of the DTE QA Program. Implementation of the program is also subject to ongoing NRC oversight.

(PS, SS) There has been no pervasive or ongoing breakdown in the Fermi 3 QA program and no “serial” violations of QA requirements. DTE has, since the beginning of the project, been providing active oversight of its contractor’s Appendix B program and has developed the Fermi 3 QAPD to carry oversight forward throughout the construction and operation of Fermi 3 — consistent with all NRC standards and expectations. 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.

Q97. Does this conclude your testimony?

A97. (PS, SS, RS, ST) Yes.