

Chapter 17 Quality Assurance

17.0 Introduction

This section of the referenced DCD is incorporated by reference with the following departures and/or supplements.

Add the following after the last paragraph.

EF3 SUP 17.0-1

The QAPD applicable to the COL licensee is described in [Section 17.5](#). The licensee's QAPD describes the basis of the program, its scope of activities, and the control of work performed by suppliers.

17.1 Quality Assurance During Design

This section of the referenced DCD is incorporated by reference with the following departures and/or supplements.

Add the following after the first paragraph.

EF3 SUP 17.1-1

QA applied during COL application preparation and site specific design activities is addressed in [Section 17.5](#).

17.2 Quality Assurance During Construction and Operations

This section of the referenced DCD is incorporated by reference with the following departures and/or supplements.

Replace the first paragraph with the following.

EF3 COL 17.2-1-A EF3 COL 17.2-2-A

The licensee's Quality Assurance Program in place during the construction and operations phases, including adapting the design to specific plant implementation, is described in [Section 17.5](#).

COL Information

EF3 COL 17.2-1-A

17.2-1-A QA Program for the Construction and Operations Phases

This COL Item is addressed in [Section 17.2](#).

EF3 COL 17.2-2-A

17.2-2-A QA Program for Design Activities

This COL Item is addressed in [Section 17.2](#).

17.3 Quality Assurance Program Description

This section of the referenced DCD is incorporated by reference with the following departures and/or supplements.

Replace the first and second sentences with the following.

EF3 COL 17.3-1-A

The Quality Assurance Program Document applicable to the licensee is described in [Section 17.5](#).

COL Information

17.3-1-A Quality Assurance Program Document

EF3 COL 17.3-1-A

This COL Item is addressed in [Section 17.3](#).

17.4 Reliability Assurance Program During Design Phase

This section of the referenced DCD is incorporated by reference with the following departures and/or supplements.

17.4.1 Introduction

Replace the third paragraph with the following.

STD COL 17.4-1-A

There are no site specific SSCs within the scope of the Reliability Assurance Program (RAP). The quality elements for all SSCs within the scope of the Design Reliability Assurance Program (D-RAP) are in accordance with the Quality Assurance Program Description (QAPD).

Replace the fourth paragraph and subsequent bulleted list with the following.

STD COL 17.4-2-A

The objectives of reliability assurance during the operations phase are integrated into the Quality Assurance Program ([Section 17.5](#)), the Maintenance Rule (MR) Program ([Section 17.6](#)), and other operational programs. Specific reliability assurance activities are addressed within operational programs (e.g., maintenance rule, surveillance testing, inservice testing, inservice inspection, and quality assurance) and the maintenance programs.

The MR Program incorporates the following aspects of operational reliability assurance (refer to [Section 17.6](#)):

- Use of PRA importance measures, the expert panel process, and deterministic methods to determine the list of risk-significant SSCs
- Evaluation and maintenance of the reliability of SSCs in the scope of the D-RAP
- Monitoring the effectiveness of maintenance activities needed for operational reliability assurance
- Classifying, initially, as high-safety-significant, all SSCs that are in the scope of the D-RAP, or applying expert panel review for any exceptions
- Use of historical data and industry operating experience on equipment performance as available
- Use of specific criteria to establish the level of performance or condition being maintained for SSCs within the scope of the MR Program; and use of monitoring to identify declining trends between surveillances and to minimize the likelihood of undetected performance or condition degradation to unacceptable levels, to the extent possible
- Use of maintenance programs to determine the nature and frequency of maintenance activities to be performed on plant equipment, including SSCs within the scope of the MR Program

17.4.6 **SSC Identification/Prioritization**

Add the following new paragraph at the end of this section.

STD COL 17.4-1-A

The list of risk-significant SSCs will be confirmed via ITAAC (see DCD Tier 1 Table 3.6-1).

17.4.9 **Operational Reliability Assurance Activities**

Replace the second paragraph with the following.

STD COL 17.4-2-A

Refer to [Section 17.4.1](#) for the implementation of reliability assurance during the operations phase.

17.4.10 **Owner/Operator's Reliability Assurance Program**

Replace the fifth bullet with the following.

STD COL 17.4-2-A

- **MR Program:** The MR Program is described in [Section 17.6](#).

Replace the last sentence in this section with the following:

Refer to [Section 17.4.1](#) for the implementation of reliability assurance activities.

COL Information

17.4-1-A **Identification of Site-Specific SSCs Within the Scope of the RAP**

STD COL 17.4-1-A

This COL Item is addressed in [Section 17.4.1](#) and [Section 17.4.6](#).

17.4-2-A **Operation Reliability Assurance Activities**

STD COL 17.4-2-A

This COL Item is addressed in [Section 17.4.1](#), [Section 17.4.6](#), [Section 17.4.9](#), [Section 17.4.10](#), and [Section 17.6](#).

EF3 COL 17.3-1-A

17.5 Quality Assurance Program Description – Design Certification, Early Site Permits, and New License Applicants

QA applied to the DC activities is described in DCD Section 17.1. ESP QA is not applicable to Fermi 3.

EF3 SUP 17.5-2

In early 2007, Detroit Edison initiated a project to prepare a Combined License Application (COLA) for a potential new unit to be located at the site of the company's existing Fermi 2 nuclear power plant. The project was a corporate initiative and was conducted independent of Fermi 2 so as not to be a distraction and to minimize the burden on the plant organization and infrastructure. As such, the project was initiated independent of the Fermi 2 Quality Assurance (QA) program. Initially, the COLA project was to be conducted as essentially a turnkey project, using a primary COLA contractor with minimal Detroit Edison staff. The objective for the project was to prepare and submit a COLA prior to December 31, 2008, corresponding to the initial tax credit qualifying

milestone from the Energy Policy Act of 2005. The COLA would be categorized as referencing a Certified Design without an Early Site Permit, for the purpose of defining the applicable guidance from Regulatory Guide 1.206 (DG-1145).

Development of COLA Work Product (January 2007 to November 2007)

The first objective of the project was to select a COLA contractor who would establish and execute 10 CFR 50 Appendix B requirements and prepare the COLA. Detroit Edison fully recognized that information developed in the preparation of a COLA, most significantly the site investigation activities, would subsequently be used to support the design of safety related structures, systems, and components, and needed to be conducted in a quality manner. Accordingly, a request for proposal to perform all activities necessary to prepare a COLA and establish and execute a QA program for the COLA project was prepared. The request for proposal required all bidders to establish that they had the prerequisite 10 CFR 50 Appendix B QA program and to describe how their Appendix B QA program was to be applied to the Fermi 3 COLA development project. Requests for proposal were solicited only from potential contractors who were established in the nuclear services business, and who were currently executing comparable projects for other potential applicants.

In February 2007, Detroit Edison received several proposals in response to the request for solicitation. Black & Veatch, headquartered in Overland Park, Kansas and hereafter simply identified as B&V, provided a detailed proposal in response. Detroit Edison based its selection on a review of the submitted proposal including, but not limited to, the following attributes:

1. Knowledge that B&V's 10 CFR 50 Appendix B/NQA-1 QA program was being properly implemented based on reporting of independent reviews by other NRC approved 10 CFR 50 Appendix B programs such as Entergy, American Electric Power and Nebraska Public Power District in the proposal; and
2. B&V was leading the development of Entergy's River Bend COLA.

In April 2007, Detroit Edison established a contract with B&V for the development of the COLA. The procurement controls documented within the COLA contract included:

1. Scope of work to be performed by B&V,
2. Technical requirements for the prepared COLA in accordance with 10 CFR 52, 10 CFR 51, 10 CFR 50, 10 CFR 20, NUREG-0800, NUREG-1555, Reg. Guide 1.206 (DG-1145), etc.,
3. Acceptance requirements and control measures for Detroit Edison's evaluation of COLA and intermediary work product developed by B&V,
4. Organizational responsibilities (including reporting and communication methods), 10 CFR 50 Appendix B/NQA-1 requirements, and 10 CFR 50 Appendix B/NQA-1 applicability 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,
5. Access to B&V's facilities and records for inspection or audit by Detroit Edison,
6. Identification of the documentation requirements and dates of submission required by Detroit Edison, and
7. Requirements for reporting and disposition of non-conformances in accordance with 10 CFR 21.

The requirements necessary to assure adequate quality were incorporated by reference in the documents for procurement, i.e. the "Contract" and the "Proposal" for COLA preparation activities and a QA program satisfying the requirements of 10 CFR 50 Appendix B for the COLA development was established. Detroit Edison through contract, delegated the work of establishing and executing the QA program to B&V for COLA development related activities.

In March 2007, B&V, in establishing and executing a QA program, issued a Project Management Memorandum for "Detroit Edison (Fermi Site) COL Application Preparation" (PMM Phase I), Rev. 0. PMM Phase I identified to Detroit Edison and all team members (including subcontractors) the scope of the project, means of correspondence, document control requirements, project specific quality assurance

requirements, training requirements, applicable procedures, and applicable codes and standards.

PMM Phase I, Rev. 0, identified those quality attributes required of the geotechnical subcontractor execution practices and quality assurance programs that required oversight and acceptance by B&V prior to and during execution of work scope to support COLA development. Attachment C-2, "Geotechnical Subcontractor Quality Oversight" identified two key elements:

1. All field and laboratory activities would be performed under the auspices of the B&V 10 CFR 50 Appendix B/NQA-1 QA program. B&V Nuclear Quality Assurance, part of Black & Veatch Overland Park, Kansas, would perform a series of pre-work surveillance and/or audit activities as well as periodic in-process surveillance and/or audit activities to verify the geotechnical activities performed by these subcontractors were of sufficient quality to support the analysis for a COL application.
2. Oversight activities would be performed by B&V Nuclear Quality Assurance, geotechnical, engineering and/or field oversight personnel. The initial vendor oversight activities would be performed at the contractor's primary laboratory/staging office for the Fermi COL Project scope of work by both B&V Nuclear Quality Assurance and geotechnical representatives prior to commencement of related work activities. Project execution oversight activities would be performed at the jobsite and in the laboratory by B&V Nuclear Quality Assurance, geotechnical, engineering, or field oversight personnel. B&V Nuclear Quality Assurance planned on performing a surveillance of the geotechnical field activities shortly after initiation of the geotechnical field investigation. Likewise, B&V Nuclear Quality Assurance planned for performing a surveillance/audit of the laboratory activities shortly after initiation of the laboratory scope of work. Subsequent B&V QA activities would be scheduled based on the results of the initial activities. Field activities would be performed under continuous observation by the B&V oversight representative and B&V geotechnical personnel with surveillance activities periodically documented to ensure compliance.

PMM Phase I, Rev. 0, specified in Attachment C, "Detroit Edison Fermi COL Project Quality Assurance Plan," restated the applicability of the

B&V 10 CFR 50 Appendix B/NQA-1 QA program to COLA activities consistent with the requirements of the COLA contract:

Activity	Nuclear Quality Assurance Program Applicability
FSAR Chapters 1, 10, 11, 12, 13, 17, and 19 development	Commercial quality program applies
FSAR Chapters 2, 3, 4, 5, 6, 7, 8, 9, 14, 15, 16, 18 and 20	Nuclear quality assurance program applies
Environmental Report	Commercial quality program applies
Hydrogeology Site Boring Program	Commercial quality program applies
Geotechnical Site Boring Program – on site and laboratory investigation and testing	Nuclear quality assurance program applies
Site Specific System Design (non-safety)	Commercial quality program applies
Radiological Analysis and Associated Meteorological Analysis (sub-contracted)	Nuclear quality assurance program applies
Technical Advisory Board	Commercial quality program applies
Emergency Plan	Commercial quality program applies
Security Plan	Commercial quality program applies
DCD Departures if any	Commercial quality program applies unless safety-related
Site Redress Plan	Commercial quality program applies

Detailed information identifying COLA sections to which the requirements of 10 CFR 50 Appendix B were applied and activities that supported those sections to which the requirements of 10 CFR 50 Appendix B were applied is provided in Table 17.5-201.

Additionally, PMM Phase I, Rev. 0 identified the applicability of 10 CFR 50 Appendix B requirements to the various B&V subcontractors.

In April 2007, B&V arranged, as part of the 2006 annual internal audit, an independent audit of the B&V 10 CFR 50 Appendix B/NQA-1 QA program by a lead-auditor-qualified individual outside the B&V Overland Park office. The purpose of this independent audit was to evaluate the program's compliance with the 10 CFR 50 Appendix B quality requirements specified in Reg. Guide 1.28, Rev. 3. The audit team

consisted of an audit team leader and three auditors supported by four technical specialists (mechanical engineering).

Also in April 2007, B&V Nuclear Quality Assurance conducted a commercial grade survey of PSI's Quality Program to evaluate commercial grade quality of activities controlled under the PSI Quality Program prior to beginning activities. Professional Services Industries (PSI's) test laboratory was approved to provide geotechnical laboratory services as a qualified commercial grade supplier. B&V Nuclear Quality Assurance also conducted a surveillance of Boart Longyear / Prosonic to evaluate activities controlled under Boart Longyear / Prosonic's quality control program document. B&V accepted Boart Longyear / Prosonic's quality control program upon satisfactory resolution of certain open items.

In May 2007, B&V began site hydrogeology investigation monitoring well construction. Core boring activities for geotechnical data collection, under the B&V 10 CFR 50 Appendix B/NQA-1 QA program, commenced upon completion of the monitoring well construction. These activities, as well as site geotechnical and other related activities by B&V and their various subcontractors, would continue through September 2007 (see Table 17.5-201 for dates of specific activities associated with B&V's development of FSAR Chapter 2). Also in May 2007, B&V Nuclear Quality Assurance conducted a surveillance of hydrogeology activities on the Fermi site. The surveillance reviewed drilling operations, sample control, procedural control of activities, record quality, and measuring and test equipment calibration. During this subsequent surveillance, B&V Nuclear Quality Assurance reviewed the corrective actions associated with certain open items identified during B&V Nuclear Quality Assurance's initial review of the Boart Longyear / Prosonic's quality control program.

In June 2007 the Owner's Engineer (OE), Black & Veatch Ann Arbor (referred to as "OE, Black & Veatch Ann Arbor," throughout), observed B&V (Black & Veatch Overland Part referred to as "B&V" throughout) obtaining core samples at the Fermi site and reported to Nuclear Development the status of procedural compliance, ASTM standards availability, status of compliance with the Hydrogeology Data Collection Plan and the Geotechnical Data Collection Plan, that chain of custody processes were being followed, status of control of measurement and test equipment, and how corrective actions as a result of B&V Nuclear Quality Assurance surveillances were being handled.

Also in June 2007, B&V Nuclear Quality Assurance conducted a pre-work surveillance to evaluate GEOVision work activities associated with seismic testing and data collection. The surveillance found that the commercial grade quality and procedural processes for seismic testing and data collection at GEOVision were acceptable. B&V Nuclear Quality Assurance also conducted a pre-work surveillance to evaluate ARM Geophysics work activities associated with geotechnical testing of soil & bedrock. The surveillance found that the commercial grade quality and procedural processes for geotechnical testing of soil & bedrock at ARM Geophysics were acceptable.

In July 2007, B&V Nuclear Quality Assurance conducted a surveillance to evaluate Geomatrix work activities associated with geological, seismological, geophysical, and geotechnical characteristics of the Fermi site. The surveillance found that Geomatrix procedural requirements and technical capabilities were adequate to satisfy the requirements of PMM Phase I while working under the B&V 10 CFR 50 Appendix B/NQA-1 QA program.

In July 2007, B&V revised PMM Phase I to address the applicability of 10 CFR 50 Appendix B requirements to the geotechnical subcontractor and added two additional B&V subcontractors. The revised PMM Phase I reported that B&V Nuclear Quality Assurance had performed a pre-work surveillance inspection for each of the sub-surface investigation (geotechnical) sub-contractors, where necessary to support the implementation of 10 CFR 50 Appendix B. The pre-work surveillance would establish a baseline set of procedures from the B&V NP's and the sub-contractor procedures to meet the requirements of the B&V 10 CFR 50 Appendix B/NQA-1 QA program.

Also in July 2007 the OE, Black & Veatch Ann Arbor, observed B&V boring at the Fermi site and reported to Nuclear Development that on-site work was being performed under the B&V 10 CFR 50 Appendix B/NQA-1 QA program and that a copy was available for reference. It was also reported that work was being performed in accordance with the Hydrogeology Data Collection Plan and the Geotechnical Data Collection Plan and that copies of these documents were available, chain of custody processes were being followed, and the status of compliance with ASTM standards, specifically ASTM D 5079-02(2006).

In August 2007, the OE, Black & Veatch Ann Arbor, observed B&V boring at the Fermi site and reported to Nuclear Development that on-site work

was being performed under the B&V 10 CFR 50 Appendix B/NQA-1 QA program and that a copy was available for reference. It was also observed that work was being performed in accordance with the Hydrogeology Data Collection Plan and Geotechnical Data Collection Plan and that copies of these documents were available, that chain of custody processes were being followed, and how corrective actions as a result of B&V Nuclear Quality Assurance surveillances were being handled. Later in August, the OE, Black & Veatch Ann Arbor, observed B&V boring, split spoon sampling, and performing vacuum excavation at the Fermi site. The OE, Black & Veatch Ann Arbor, reported to Nuclear Development that on-site work was being performed under the B&V 10 CFR 50 Appendix B/NQA-1 QA program and that a controlled copy was available for reference. They also 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 B&V corrective action program continued to be effective.

In September 2007 and during the conduct of geotechnical measurement activities on the Fermi site, B&V Nuclear Quality Assurance conducted a surveillance of testing activities, sample control, procedural control of activities, record quality, and measuring and test equipment calibration. This surveillance also included follow-up on the corrective actions associated with the issues identified during B&V Nuclear Quality Assurance's surveillance of hydrogeology activities on the Fermi site in May 2007. B&V Nuclear Quality Assurance also conducted a surveillance of PSI to verify implementation of the PSI Quality Program focusing on controls and testing activities. During the surveillance B&V Nuclear Quality Assurance 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.

Beginning in March 2007 and through completion of the site investigations presented above, B&V commenced assembling the research, data, references, etc., necessary to support development of the COLA. Initial informational needs identified to Detroit Edison by B&V to support COLA development were provided. Subsequent informational needs from B&V or decisions from Detroit Edison needed by B&V were communicated using B&V's Request for Information process. The B&V Request for Information was then reviewed and accepted by the B&V 10 CFR 50 Appendix B/NQA 1 QA program as necessary.

In November 2007, PMM Phase I was revised to a) communicate to Detroit Edison and all team members that the COLA was to be based upon the ESBWR Certified Design and b) to update the project organization chart. PMM Phase I, Rev. 2 also communicated the addition of one B&V subcontractor. The revised PMM Phase I also identified that B&V Nuclear Quality Assurance had performed 1) a surveillance on the subsurface field activities by the B&V Nuclear Quality Assurance shortly after the initiation of the subsurface field investigation and again, during performance of the sub-surface downhole testing and 2) a surveillance/audit of the laboratory activities shortly after the initiation of the laboratory scope of work.

Receipt, Review and Acceptance of COLA Work Product (November 2007 to September 2008)

In November 2007, anticipating the activities necessary to receive, review and accept the COLA work product from B&V, Detroit Edison began to develop the necessary staffing to support the receipt, acceptance review, submittal, NRC review, and concurrent maintenance of the COLA. The increase in staffing also included the addition of an experienced QA professional. Subsequently, Nuclear Development staff drafted the Nuclear Development Quality Assurance Program Document (ND QAPD) and implementing procedures for those elements of the ND QAPD associated with the activities planned to be performed by Detroit Edison at the time (e.g., review of B&V COLA work product).

In January 2008, B&V Nuclear Quality Assurance conducted an audit to evaluate the B&V 10 CFR 50 Appendix B/NQA-1 QA program against the 10 CFR 50 Appendix B and NQA-1- 1994 quality requirements. The Nuclear Procurement Issues Committee (NUPIC) Audit Checklist was used to conduct the audit. The audit team consisted of an audit team leader and three auditors. The audit found that the B&V 10 CFR 50

Appendix B/NQA-1 QA program met the quality requirements of 10 CFR 50 Appendix B and NQA-1-1994 for the areas evaluated.

In February 2008, the Sr. VP Major Enterprise Projects approved for use the ND QAPD, which continued to delegate quality and safety-related services for COLA development to B&V in contract documents and implementing procedure NDP-NP-4.1, "Procurement of Services." Subsequently, the implementing procedures were approved and the Nuclear Development staff was trained on the procedures necessary to review and accept the B&V developed COLA work products. Specifically, Nuclear Development implemented a procedure to complete the formal review of each chapter of the Fermi 3 COLA submitted by B&V's Request for Review (RFR) process as a means to assure coordination and control of the finalization of the COLA. Comments generated during Detroit Edison's review of the COLA work product against relevant regulatory guidance, information provided by Detroit Edison to B&V, and the Reference COLA (R-COLA), as applicable, were provided to B&V for resolution and incorporation. The Request for Review process required signoff by both the Detroit Edison reviewer and B&V for all comments.

From February 2008 through September 2008, Detroit Edison conducted COLA chapter reviews with final acceptance and submission of the COLA. Detroit Edison reviewed individual FSAR chapters or sections consistent with the interfaces established by PMM Phase I and the Nuclear Development procedure for review of COLA work products (see Table 17.5-201 for details on specific activities associated with Detroit Edison's review of FSAR chapters or sections).

In March 2008, a Nuclear Development QA Manager was established and was responsible to develop the Nuclear Development QAPD and to independently plan and perform activities to verify the development and effective implementation of the QAPD to those activities that support the COLA. The Nuclear Development QA Manager was also responsible to evaluate compliance with regulatory requirements and procedures through audits and technical reviews, monitor organization processes to ensure conformance to licensing document requirements, and to ensure that vendors providing quality services to Detroit Edison in support of the COLA are meeting the requirements of 10 CFR 50 Appendix B.

In April 2008, PMM Phase I was revised to communicate to Detroit Edison and all team members the addition of two B&V subcontractors.

In May 2008, the Nuclear Development QA Manager, as lead auditor, conducted a surveillance of B&V COLA development activities using Nuclear Development Procedure (NDP)-NP-18.1 for the purpose of assessing the adequacy of B&V Project Instruction 147483.21.2008 (Rev. 2), "Fermi 3 COLA Process Workflow for Preparing Site-Specific FSAR and ER Sections," for the preparation of quality site-specific information to be placed in the Fermi 3 COLA. Specific process areas reviewed were: procedure use and adherence, QA oversight effectiveness, corrective action, and staff training. The surveillance concluded that B&V had a good understanding of procedural requirements and was committed to providing a quality product to Detroit Edison.

In June 2008, the Nuclear Development QA Manager, as lead auditor, conducted a surveillance of the storage and handling of the core drilling and subsurface samples in Detroit Edison's possession, including record reviews and interviews.

In September 2008, B&V Nuclear Quality Assurance conducted a surveillance of activities associated with the preparation of the Fermi 3 COLA. The surveillance reviewed records generated during the review of COLA product. This review included examining the implementation of the RFR process for resolution of comments and consolidation in preparation for storage and retention, record storage and retention. The surveillance also examined B&V's training records and their implementation of the corrective action program to the Fermi 3 COLA project.

On September 18, 2008, Detroit Edison submitted an "Application for a Combined License for Fermi 3" under NRC Project No. 757 (ML082730763). By letter dated November 25, 2008 (ML082381145), the NRC notified Detroit Edison that the NRC staff had completed its acceptance review and had determined that the COLA was acceptable for docketing and that docket number 52-033 had been established for the Fermi 3 COLA.

Application for the Combined Operating License (September 2008 to December 2009)

After submittal of the COLA, Nuclear Development prepared, approved, and trained on the procedures necessary to adopt the Fermi 3 Quality Assurance Program Description (QAPD) provided in Appendix 17AA of the FSAR, and to support the post-application scope of work. In this

transition, Detroit Edison took ownership of the application; however, contractually, Detroit Edison continued to delegate the execution of quality and safety-related services associated with COLA revision and review support to the B&V 10 CFR 50 Appendix B/NQA-1 QA program under the Fermi 3 QAPD.

In November 2008, Nuclear Development Procedure (NDP) NP-6.4, "COLA Change Process," was issued and provided four integrated processes necessary to maintain the COLA: request for information, license change request, request for review, and change incorporation.

The Nuclear Development Request for Information (NDRFI) provides a process to request safety-related services from B&V pertaining to COLA sections that were originally developed under the B&V 10 CFR 50 Appendix B/NQA-1 QA program as specified in the COLA contract. In response to an NDRFI, B&V executes the necessary safety-related activities to provide the requested information such as 1) responses to NRC requests for additional information including the associated FSAR markup, 2) markup of the FSAR necessary to implement a change to the certified design, 3) markup of the FSAR necessary to implement a change to the site layout, 4) markup of the FSAR as a result of implementation following approval of an industry template, etc. Subsequently B&V's response to the NDRFI was reviewed and accepted for incorporation into a COLA revision or a response to an NRC Request for Additional Information (RAI).

The Nuclear Development License Change Request (NDLCR) provides a controlled process to document approval of individual changes to the Fermi 3 COLA for incorporation. The NDLCR documents the references (e.g. NDRFI, Detroit Edison RAI response, etc.) supporting the change to the COLA and provides for coordination with the Reference COLA (R-COLA) as necessary.

The Nuclear Development Request for Review (NDRFR) provides a process to document comments resulting from an individual or organization's review of a proposed change to the COLA and the resolution of those comments.

The change incorporation process provides for the incorporation of an approved NDLCR into the COLA for approval and subsequent submission.

In February 2009, B&V established a new Project Management Memorandum for “Detroit Edison (Fermi Site) COL Application Phase II” (PMM Phase II), Rev. 0 for the engineering site characterization, field investigation and licensing activities necessary to support Detroit Edison interaction with the NRC subsequent to the submittal of the COLA. PMM Phase II identified to Detroit Edison and all team members (including subcontractors) the scope of the project, means of correspondence, document control requirements, project specific quality assurance requirements, training requirements, applicable B&V procedures, and applicable codes and standards. Subsequently, those B&V project instructions necessary to support Phase II were issued, including Project Instruction 163696.21.2001, “Fermi 3 COL Request for Information to an Outside Organization.”

In March 2009, Detroit Edison submitted an updated COLA reflecting the updated R-COLA and ESBWR DCD, Revision 5 under cover of Detroit Edison letter NRC3-09-0006 dated March 25, 2009 (ML091760903). Concurrently, the Fermi 3 QAPD was revised to reflect the QAPD presented in FSAR, Appendix 17AA of the March 2009 COLA submission.

In June 2009, the quality assurance organization began reporting to the Sr. Vice President, Major Enterprise Projects as described in FSAR Appendix 17AA. The quality assurance organization was lead by the Director, Quality Management and consists of two full time equivalent staff, including as a minimum the Director and one lead-auditor-qualified individual. The quality assurance organization was responsible for verifying that B&V effectively implements those QA functions necessary to support safety-related activities and safety-related COLA work product. The quality assurance group schedules and conducts surveillances and audits of quality activities in accordance with the Fermi 3 QAPD and the established schedule.

In July 2009, the quality assurance organization, with technical support from Nuclear Development, performed a limited scope audit of implementation of the B&V 10 CFR 50 Appendix B/NQA-1 QA program to Detroit Edison contracts for COLA activities. The audit concluded that the B&V 10 CFR 50 Appendix B/NQA-1 QA program was well documented in the Nuclear Organization Quality Assurance Manual, Nuclear Procedures, and Fermi 3 Project instructions.

In September 2009, the NDRFI process was established as a stand alone procedure to allow for use outside of the COLA change processes.

In October 2009, the quality assurance organization, lead by the group's lead-auditor qualified individual supported by a lead auditor-in-training and an auditor-in-training, performed an audit to assess the effectiveness of the Nuclear Development organization's implementation of the Fermi 3 QAPD requirements. Assessment activities included verification of development and implementation of, and adherence to processes, procedures, and organizational structure for COLA activities set forth in the QAPD.

In November 2009, an external audit to assess the effectiveness of the Nuclear Quality Management organization's implementation of the Fermi 3 QAPD requirements was conducted. The audit concluded that the Fermi 3 Quality Assurance Program was effectively implemented and in compliance with the Fermi 3 QAPD.

EF3 COL 17.2-1-A
EF3 COL 17.2-2-A

QA applied to activities to adapt the design to specific plant implementation, construction, and operations is addressed in the Detroit Edison Fermi 3 QAPD ([Appendix 17AA](#)). The QAPD is based on NEI 06-014A ([Reference 17.5-201](#)).

The implementation milestones for the Operational Quality Assurance Program are provided in [Section 13.4](#)

References

17.5-201 Nuclear Energy Institute, "Quality Assurance Program Description." NEI 06-14A, Revision 7, August, 2010.

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 1 of 18)

[EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.0 Section Development	April 16, 2008 – June 17, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	June 17, 2008	Initial Review/Acceptance June 18, 2008 – July 9, 2008 Final Review/Acceptance July 3, 2008 – September 16, 2008
FSAR Section 2.1 Section Development	December 17, 2007 – June 6, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	June 6, 2008	Initial Review/Acceptance June 6, 2008 – July 11, 2008 Final Review/Acceptance July 3, 2008 – September 16, 2008
FSAR Section 2.2 Section Development	September 28, 2007 – June 5, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	June 5, 2008	Initial Review/Acceptance June 5, 2008 – July 8, 2008 Final Review/Acceptance July 3, 2008 – September 16, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 2 of 18)

[EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.2 Chemical Hazards Calculation	July 30, 2007 – July 31, 2008	By Numerical Applications Inc. (NAI) using HABIT computer code under the NAI QA Plan NAI-QA-1, Revision 14. Contract for work on Fermi project established between B&V and NAI on June 18, 2007.	NAI QA (as accepted by B&V)	B&V performed audit to establish NAI as a qualified supplier on November 29, 2006. NAI deliverable reviewed per B&V Nuclear Procedures.	July 31, 2008	Note 2
FSAR Sections 2.3.1 through 2.3.3 Section Development	August 27, 2007 – May 24, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	May 24, 2008	Initial Review/Acceptance June 6, 2008 – July 11, 2008 Final Review/Acceptance August 15, 2008 – September 16, 2008
FSAR Sections 2.3.4 and 2.3.5 Section Development	August 27 2007 – June 10, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instruction. Section validated per B&V Project Instructions.	June 10, 2008	Initial Review/Acceptance June 10, 2008 – July 29, 2008 Final Review/Acceptance August 15, 2008 – September 16, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 3 of 18)

[EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.3.4 Short Term X/Q Analysis	December 14, 2007 – August 8, 2008	By Numerical Applications Inc. (NAI) using PAVAN computer code under the NAI QA Plan NAI-QA-1, Revision 14. Contract for work on Fermi project established between B&V and NAI on June 18, 2007.	NAI QA (as accepted by B&V)	B&V performed audit to establish NAI as a qualified supplier on November 29, 2006. NAI deliverable reviewed per B&V Nuclear Procedures.	August 8, 2008	Note 2
FSAR Section 2.3.4 On-Site X/Q Analysis	December 14, 2007 – August 8, 2008	By Numerical Applications Inc. (NAI) using ARCON96 computer code under the NAI QA Plan NAI-QA-1, Revision 14. Contract for work on Fermi project established between B&V and NAI on June 18, 2007.	NAI QA (as accepted by B&V)	B&V performed audit to establish NAI as a qualified supplier on November 29, 2006. NAI deliverable reviewed per B&V Nuclear Procedures.	August 8, 2008	Note 2
FSAR Section 2.3.5 Long Term X/Q Analysis	December 14, 2007 – August 8, 2008	By Numerical Applications Inc. (NAI) using XOQDOQ computer code under the NAI QA Plan NAI-QA-1, Revision 14. Contract for work on Fermi project established between B&V and NAI on June 18, 2007.	NAI QA (as accepted by B&V)	B&V performed audit to establish NAI as a qualified supplier on November 29, 2006 NAI deliverable reviewed per B&V Nuclear Procedures.	August 8, 2008	Note 2

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 4 of 18)

[EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.4.1 Section Development	December 13, 2007 – June 3, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	June 3, 2008	Initial Review/Acceptance June 3, 2008 – July 9, 2008 Final Review/Acceptance July 3, 2008 - September 16, 2008
FSAR Section 2.4.2 Section Development	February 13, 2008 – June 3, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	June 3, 2008	Initial Review/Acceptance June 3, 2008 – July 9, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008
FSAR Section 2.4.3 Section Development	February 13, 2008 – June 3, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	June 3, 2008	Initial Review/Acceptance June 3, 2008 – July 9, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 5 of 18)

[EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.4.4 Section Development	February 18, 2008 – April 11, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions Section validated per B&V Project Instructions.	April 11, 2008	Initial Review/Acceptance April 11, 2008 – June 27, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008
FSAR Section 2.4.5 Section Development	March 13, 2008 – June 3, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	June 3, 2008	Initial Review/Acceptance June 3, 2008 – July 9, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008
FSAR Section 2.4.6 Section Development	February 18, 2008 – April 11, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	April 11, 2008	Initial Review/Acceptance April 11, 2008 – June 27, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 6 of 18)

[EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.4.7 Section Development	February 18, 2008 – April 11, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	April 11, 2008	Initial Review/Acceptance April 11, 2008 – June 27, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008
FSAR Section 2.4.8 Section Development	August 30, 2007 – April 11, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	April 11, 2008	Initial Review/Acceptance April 11, 2008 – June 27, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008
FSAR Section 2.4.9 Section Development	January 24, 2008 – April 11, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	April 11, 2008	Initial Review/Acceptance April 11, 2008 – June 27, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 7 of 18)

[EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.4.10 Section Development	April 24, 2008 – June 3, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	June 3, 2008	Initial Review/Acceptance June 3, 2008 – July 9, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008
FSAR Section 2.4.11 Section Development	January 30, 2008 – June 3, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	June 3, 2008	Initial Review/Acceptance June 3, 2008 – July 9, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008
FSAR Section 2.4.12 Section Development	February 29, 2008 – June 5, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	June 5, 2008	Initial Review/Acceptance June 5, 2008 – July 28, 2008 Final Review/Acceptance July 3, 2008 - September 16, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 8 of 18)

[EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.4.12 Developing Wells	May 3, 2007 – June 7, 2007	By Boart Longyear/Prosonic under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	Boart Longyear determined to be acceptable sub-contractor per B&V procedures on May 1, 2007. Data Collection Plan (DCP), Work Plan (WP) and Specification developed per B&V Procedures. B&V maintained field oversight during drilling operations. Surveillance of on-site hydrogeology activities performed, May 31, 2007.	April 23, 2007 (DCP and WP approval)	Note 2
FSAR Section 2.4.12 Field Permeability Tests	May 21, 2007 – June 28, 2007	By Boart Longyear/Prosonic under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	Boart Longyear determined to be acceptable sub-contractor per B&V procedures on May 1, 2007. Data Collection Plan (DCP), Work Plan (WP) and Specification developed per B&V Procedures. Testing performed per DCP and WP under B&V direction.	April 23, 2007 (DCP and WP approval)	Note 2

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 9 of 18)

[EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.4.12 Water Analytical Analysis	August 1, 2007 – March 12, 2008	By PSI under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	PSI qualified as a commercial grade supplier per B&V procedures, April 25, 2007. Surveillance of laboratory activities performed, September 21, 2007. Water analytical testing performed per PSI procedures. Laboratory report reviewed by B&V	March 12, 2008	Note 2
FSAR Section 2.4.13 Section Development	May 2, 2008 – May 23, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	May 23, 2008	Initial Review/Acceptance May 23, 2008 – June 30, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008
FSAR Section 2.4.14 Section Development	April 21, 2008 – April 28, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	April 28, 2008	Initial Review/Acceptance April 29, 2008 – June 10, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 10 of 18) [EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.5.1 Section Development	November 28, 2007 – April 4, 2008	By B&V and Geomatrix under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	Geomatrix qualified per B&V procedures, July 3, 2007. B&V review performed per Nuclear Procedures and Project Process Instructions. Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	April 4, 2008	Initial Review/Acceptance April 4, 2008 – June 26, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008
FSAR Section 2.5.2 Section Development	December 13, 2007 – June 12, 2008	By Geomatrix under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	Geomatrix qualified per B&V procedures, July 3, 2007. B&V review performed per Nuclear Procedures and Project Process Instructions. Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	June 12, 2008	Initial Review/Acceptance June 12, 2008 – July 31, 2008 Final Review/Acceptance July 3, 2008 - September 16, 2008
FSAR Section 2.5.3 Section Development	December 13, 2007 – May 6, 2008	By Geomatrix under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	Geomatrix qualified per B&V procedures, July 3, 2007. B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	May 6, 2008	Initial Review/Acceptance May 6, 2008 – July 3, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 11 of 18) [EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.5.4 Section Development	December 13, 2007 – May 6, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	May 6, 2008	Initial Review/Acceptance May 6, 2008 – July 8, 2008 Final Review/Acceptance July 3, 2008 - September 16, 2008
FSAR Section 2.5.5 Section Development	December 13, 2007 – May 6, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	May 6, 2008	Initial Review/Acceptance May 6, 2008 – July 8, 2008 Final Review/Acceptance July 3, 2008 - September 16, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 12 of 18) [EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.5 Boring Operations	June 12, 2007 – September 21, 2007	By Boart Longyear/Prosonic under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	Boart Longyear determined to be acceptable sub-contractor per B&V procedures on May 1, 2007 Data Collection Plan (DCP), Work Plan (WP) and Specification developed per B&V Procedures. B&V maintained field oversight during drilling operations. Surveillance of on-site hydrogeology and geotechnical activities performed, May 31, 2007, September 19, 2007, and December 5, 2007.	Various dates tied to revisions to DCP and WP.	Note 2
FSAR Section 2.5 Geotechnical Laboratory Analysis	June 4, 2007 – July 2, 2008	By PSI under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	PSI qualified as a commercial grade supplier per B&V procedures, April 25, 2007. Surveillance of laboratory activities performed, September 21, 2007. Geotechnical laboratory testing performed per PSI procedures. Laboratory report reviewed by B&V	July 2, 2008	Note 2

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 13 of 18) [EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 2.5 Geotechnical Laboratory Analysis	April 22, 2008 - July 25, 2008	By Kleinfelder under the PSI Quality Assurance Program under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	Kleinfelder qualified as a sub-contractor to PSI. Analytical testing performed per Kleinfelder test plan, reviewed by B&. Laboratory report reviewed by B&V	July 25, 2008	Note 2
FSAR Section 2.5 Field Geotechnical Testing	July 10, 2007 - June 16, 2008	By ARM Geophysics under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	ARM qualified per B&V procedures, June 29, 2007 Field testing performed in accordance with ARM procedures. Geophysical well logging report reviewed by B&V.	June 16, 2008	Note 2
FSAR Section 2.5 Field Geotechnical Testing	September 12, 2007 - March 14, 2008	By GEOVision under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	GEOVision qualified per B&V procedures, June 27, 2007 Field testing performed in accordance with GEOVision procedures, reviewed by B&V. Geophysical testing report reviewed by B&V.	March 14, 2008	Note 2
FSAR Section 2.5 Field Geotechnical Testing	September 14, 2007 – January 25, 2008	By In Situ Engineering under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	Field testing performed in accordance with In Situ Engineering Technical Specification, reviewed by B&V. Geophysical testing report reviewed by B&V.	January 25, 2008	Note 2

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 14 of 18) [EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Chapter 3 Section Development	December 10, 2007 – January 25, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	January 25, 2008	Initial Review/Acceptance February 6, 2008 – June 30, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008
FSAR Chapter 4 Section Development	November 5, 2007 – December 14, 2007	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	December 14, 2007	February 6, 2008 – April 21, 2008
FSAR Chapter 5 Section Development	January 14, 2008 – January 25, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	January 25, 2008	Initial Review/Acceptance February 6, 2008 – April 4, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008
FSAR Chapter 6 (Excluding Section 6.4) Section Development	January 10, 2008 – February 6, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	February 6, 2008	Initial Review/Acceptance February 6, 2008 – April 8, 2008 Final Review/Acceptance July 3, 2008 – August 15, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 15 of 18) [EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 6.4 Section Development	April 28, 2008 – May 30, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. (RFR-0262) Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions.	May 30, 2008	Initial Review/Acceptance May 30, 2008 – July 22, 2008 Final Review/Acceptance July 3, 2008 – August 15, 2008.
FSAR Chapter 7 Section Development	November 9, 2007 – December 14, 2007	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	December 14, 2007	February 6, 2008 – February 27, 2008
FSAR Chapter 8 Section Development	January 14, 2008 – May 23, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	May 23, 2008	Initial Review/Acceptance May 23, 2008 – July 21, 2008 Final Review/Acceptance July 3, 2008 – August 15, 2008
FSAR Section 9.1 Section Development	March 17, 2008 – April 10, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	April 10, 2008	Initial Review/Acceptance April 11, 2008 – July 1, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 16 of 18) [EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 9.2 (Excluding Section 9.2.3) Section Development	January 31, 2008 – April 10, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	April 10, 2008	Initial Review/Acceptance April 11, 2008 – July 1, 2008 Final Review/Acceptance June 3, 2008 - September 16, 2008
FSAR Section 9.2.3 Section Development	March 14, 2008 – April 10, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	April 10, 2008	Initial Review/Acceptance April 11, 2008 – July 1, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008
FSAR Section 9.3 Section Development	March 18, 2008 – April 10, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	April 10, 2008	Initial Review/Acceptance April 11, 2008 – July 1, 2008 Final Review/Acceptance August 15, 2008 - September 16, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 17 of 18) [EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Section 9.4 Section Development	March 18, 2008 – April 10, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	April 10, 2008	Initial Review/Acceptance April 11, 2008 – July 1, 2008 Final Review/Acceptance June 3, 2008 - September 16, 2008
FSAR Section 9.5 Section Development	January 14, 2008 – April 10, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	April 10, 2008	Initial Review/Acceptance April 11, 2008 – July 1, 2008 Final Review/Acceptance June 3, 2008 - September 16, 2008
FSAR Chapter 14 Section Development	January 16, 2008 – February 8, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	February 8, 2008	Initial Review/Acceptance February 8, 2008 – June 30, 2008 Final Review/Acceptance July 3, 2008 – September 16, 2008
FSAR Chapter 15 Section Development	November 11, 2007 – December 14, 2007	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	December 14, 2007	February 6, 2008 – July 22, 2008

Table 17.5-201 Quality Assurance Activities for FSAR Section and Supporting Activities (Sheet 18 of 18) [EF3 SUP 17.5-2]

COLA Section and Supporting Activity(ies)	Date of the Section Creation or Activity	Organization Creating and Governing QAPD	QA organization Responsible for Oversight	Dates and Type of any Specific Contractor QA Oversight Activities (i.e. Surveillance, document review, etc)	Contractor's Approval Date	Date of Detroit Edison Review and Acceptance (see Note 1)
FSAR Chapter 16 Section Development	May 9, 2008 – May 21, 2008	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	May 21, 2008	Initial Review/Acceptance May 21, 2008 – July 8, 2008 Final Review/Acceptance July 3, 2008 – September 16, 2008
FSAR Chapter 18 Section Development	October 16, 2007 – December 14, 2007	By B&V under the B&V Nuclear Organization Quality Assurance Manual, Revisions 2 and 3.	B&V QA	B&V review performed per Nuclear Procedures and Project Process Instructions. Section validated per B&V Project Instructions.	December 14, 2007	February 6, 2008 – February 27, 2008

Notes

- 1) Detroit Edison reviewed FSAR chapters and sections as prescribed by Standard Work Instruction (SWI) –03-001-001-0529, “COLA Section and Chapter Review and Acceptance Process.” SWI-03-001-001- 0529 prescribed that Nuclear Development staff were to confirm that COLA products prepared by B&V would be acceptable by the NRC. SWI-03-001-001-0529 noted that COLA preparation remained the responsibility of B&V.
- 2) COLA intermediary work product produced by activities to support COLA section development was not directly reviewed by Detroit Edison. Detroit Edison reviewed the presentation of the information or result from this activity by reviewing incorporation of the information or result from this activity in the COLA section identified above (see Column 7).

STD COL 17.4-2-A 17.6 Maintenance Rule Program

NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," ([Reference 17.6-1](#)) is incorporated by reference with the following supplemental information:

STD SUP 17.6-1 The text of the template provided in NEI 07-02A is generically numbered as "17.X." When the template is incorporated by reference into this section, numbering is changed from "17.X" to "17.6."

STD SUP 17.6-3 17.6.1.1. **Maintenance Rule Scoping per 10 CFR 50.65(b)**
In Paragraph 17.6.1.1.b, replace "(DRAP - see FSAR Section 17.Y)" with the following.

(See [Section 17.4](#))

17.6.3 **Maintenance Rule Program Relationship with Reliability Assurance Activities**

Replace with the following.

STD SUP 17.6-2 Reliability during the operations phase is assured through the implementation of operational programs, i.e., the MR program ([Section 17.6](#)), the Quality Assurance Program ([Section 17.5](#)), the Inservice Inspection Program ([Subsection 5.2.4](#), [Section 6.6](#), and DCD Section 3.8.1.7.3), and the Inservice Testing Program ([Subsection 3.9.6](#), and [Section 3.9.3.7.1\(3\)e](#)), as well as the Technical Specifications Surveillance Requirements ([Chapter 16](#)), and maintenance programs.

17.6.4 **Maintenance Rule Program Relationship with Industry Operating Experience Activities**

Add the following at the end of this section.

STD SUP 17.6-4 Condition monitoring of underground or inaccessible cables is incorporated into the maintenance rule program. The cable condition monitoring program incorporates lessons learned from industry operating experience (e.g., GL 2007-01, NUREG/CR-7000), addresses regulatory guidance, and utilizes information from detailed design and procurement documents to determine the appropriate inspections, tests and

monitoring criteria for underground and inaccessible cables within the scope of the maintenance rule (10 CFR 50.65).

References

- 17.6-1 Nuclear Energy Institute, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," NEI 07-02A.