

| United States Nuclear Regulatory Commission Official Hearing Exhibit | |
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| In the Matter of: | DETROIT EDISON COMPANY (Fermi Nuclear Power Plant, Unit 3) |
|  | ASLBP #: 09-880-05-COL-BD01 |
| | Docket #: 05200033 |
| | Exhibit #: NRCS007-00-BD01 |
| | Admitted: 10/30/2013 |
| | Rejected: |
| Other: | Identified: 10/30/2013 Withdrawn: Stricken: |

EXHIBIT NRC S7

Detroit Edison Company Response to NRC Request for
Additional Information Letter No. 26, Related to
SRP Section 17.5 (May 10, 2010)



10 CFR 52.79

May 10, 2010
NRC3-10-0019

U. S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, DC 20555-0001

- References:
- 1) Fermi 3
Docket No. 52-033
 - 2) Letter from Jerry Hale (USNRC) to Jack M. Davis (Detroit Edison), "Request for Additional Information Letter No. 26 Related to the SRP Sections 12.2.2, 13.6.1, 14.3.2, 14.3.12 and 17.5 for the Fermi 3 Combined License Application," dated March 18, 2010
 - 3) Letter from Peter W. Smith (Detroit Edison) to US RC, "Detroit Edison Response to NRC Requests for Additional Information Related to Letter No. 26, SRP Sections 12.2.2, 13.6.1, 14.3.2, and 14.3.12," dated May 3, 2010
 - 4) Letter from Richard Rasmussen (USNRC) to Jack M. Davis (Detroit Edison), "NRC Response to Detroit Edison reply to Notice of Violation 05200033/2009-01, 02, and 03 and Revised Notice of Violation to Detroit Edison Company," dated April 27, 2010

Subject: Detroit Edison Company Response to NRC Request for Additional Information Letter No. 26, Related to SRP Section 17.5

In Reference 2, the NRC requested additional information to support the review of certain portions of the Fermi 3 Combined License Application (COLA). The responses to those Requests for Additional Information (RAIs) in Reference 2 associated with SRP Sections 12.2.2, 13.6.1, 14.3.2, and 14.3.12 were provided in Reference 3. Reference 3 also notified the NRC that Detroit Edison was reviewing the RAI responses associated with SRP Section 17.5 in light of the information provided in Reference 4 and that the response to the RAIs associated with SRP Section 17.5 would be provided by May 10, 2010. The responses to those RAIs associated with SRP Section 17.5 from Reference 2 are provided as Attachments 1 through 4 of this letter. Information contained in the responses to the RAIs associated with SRP Sections 17.5 will be incorporated into a future COLA submission as described in each RAI response and presented in Attachment 5.

DO 95
NRC

If you have any questions, or need additional information, please contact me at (313) 235-3341.

I state under penalty of perjury that the foregoing is true and correct. Executed on the 10th day of May 2010.

Sincerely,



Peter W. Smith, Director
Nuclear Development – Licensing and Engineering
Detroit Edison Company

Attachments: 1) Response to RAI Letter No. 26 (Question No. 17.5-16)
2) Response to RAI Letter No. 26 (Question No. 17.5-17)
3) Response to RAI Letter No. 26 (Question No. 17.5-18)
4) Response to RAI Letter No. 26 (Question No. 17.5-19)
5) Markup of Detroit Edison COLA.

cc: Jerry Hale, NRC Fermi 3 Project Manager
Bruce Olson, NRC Fermi 3 Environmental Project Manager (w/o attachments)
Fermi 2 Resident Inspector (w/o attachments)
NRC Region III Regional Administrator (w/o attachments)
NRC Region II Regional Administrator (w/o attachments)
Supervisor, Electric Operators, Michigan Public Service Commission (w/o attachments)
Michigan Department of Environmental Quality
Radiological Protection and Medical Waste Section (w/o attachments)

Attachment 1
NRC3-10-0019

Response to RAI Letter No. 26

RAI Question No. 17.5-16
(eRAI Tracking No. 4408)

NRC RAI 17.5-16

10 CFR 52.79(a) requires the applicant FSAR to contain sufficient depth of information to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a combined license. 10 CFR 52.79(a)(25) requires the applicant to provide a QA program consistent with Appendix B to 10 CFR Part 50 for design, fabrication and construction activities.

Appendix B establishes quality assurance requirements for the design, manufacture, construction, and operation of the structures, systems, and components of the facility. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of the structures, systems, and components to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

Regulatory Guide 1.206 section C.I.17.5.3 states that the FSAR should 1) describe how the applicant will retain responsibility for, and maintain control over, those portions of the QA program delegated to other organizations, 2) should identify the responsible organization and the process for verifying that delegated QA functions are effectively implemented, 3) identify major work interfaces for activities affecting quality, and 4) describe 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.

Attachment 3 to NRC3-09-0027, "Detroit Edison Company Response to NRC RAI Letter No. 10," dated September 30, 2009, states during the Project Initiation Phase (January 2007 to November 2007) Black & Veatch (B&V) was selected as the COLA contractor and COLA development commenced under the B&V 10 CFR 50 Appendix B/NQA-1 QA program. Additionally, Detroit Edison secured the services of an OE (B&V, Ann Arbor) to support owner related activities, including COLA contractor oversight.

Later, during the Development, Receipt, Review and Acceptance of COLA Work Product Phase (November 2007 to September 2008), Detroit Edison began to develop the necessary staffing to support the receipt, acceptance review, submittal, NRC review, and concurrent maintenance of the COLA. Detroit Edison then 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). The ND QAPD was approved for use in February 2008 and remained in effect until the Fermi 3 COLA was filed in September 2008, and the Fermi 3 QAPD superseded it.

In Attachment 1 to NRC3-09-0041, "Detroit Edison Reply to a Notice of Violation 05200033/2009-201, 02, and 03," dated November 9, 2009, Detroit Edison asserts that the requirements of Appendix B to 10 CFR Part 50 were not applicable to Detroit Edison prior to September 18, 2008, because Detroit Edison was not yet an applicant. Detroit Edison also contends that, prior to becoming an applicant, a QA program was established by contractually

delegating the work of establishing and executing the QA program to the COLA contractor. In summary, Detroit Edison has stated that prior to the Fermi 3 COLA filing:

- 1) the FSAR required Appendix B compliant QA program was contractually established with B&V for safety-related activities,*
- 2) Appendix B requirements were not applicable to Detroit Edison, and*
- 3) multiple QAPDs were utilized for pre-COLA activities (both Detroit Edison and B&V)*

Sufficient detail has not been provided in the Fermi 3 FSAR to enable the NRC staff to reach a final conclusion on whether all Fermi 3 project safety-related activities completed prior to the COL application date were consistent with the requirements of Appendix B to 10 CFR Part 50.

Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B. The summary must include more detailed information than was presented in the RAI 17.5-3 response.

Included as part of the summary, please provide the following information presented in the form of a table: 1) list of safety-related activities and safety-related COL application sections, 2) dates of the activity or section creation, 3) contracting entity conducting the activity / section creation and governing QAPD, 4) QA organization responsible for oversight of the activity / section creation, 5) dates and type of any specific contractor QA oversight activities (i.e., surveillance, document review, etc), 6) contractor approval date, 7) dates of Detroit Edison review and approval, and 8) dates and type of any specific Detroit Edison QA oversight activities (i.e., surveillance, document review, etc). If documented evidence of information presented in the table or the summary is not available for future inspection, please note within the table or summary.

Note: This RAI is supplemental to RAI 17.5-3 and 17.5-4 included in NRC RAI Letter No. 10, dated August 12, 2009.

Response

Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B. The summary must include more detailed information than was presented in the RAI 17.5-3 response.

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 is a corporate initiative and is currently being 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 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. Thus a QA program satisfying the requirements of 10 CFR 50 Appendix B for the COLA development was established by Detroit Edison through contractually delegating 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 subcontractors 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 of 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 Enclosure 1.

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

| Entity | Nuclear Quality Assurance Program Applicability |
|---|--|
| B&V | Holder of an approved nuclear quality assurance program |
| Excel Services Corporation (licensing support & emergency plan development) | Working directly under the B&V 10 CFR 50 Appendix B/NQA-1 QA program |

**Nuclear Quality Assurance Program
 Applicability**

| Entity | Nuclear Quality Assurance Program Applicability |
|---|--|
| Geomatrix Consultants (seismic analyses & FSAR geotechnical development) | Working directly under the B&V 10 CFR 50 Appendix B/NQA-1 QA program |
| Numerical Applications, Inc (radiological & meteorological analyses) | NAI Nuclear Quality Assurance Program audited and approved by B&V. B&V Audit No. 06NS06 |
| Boart Longyear / Prosonic (geotechnical boring & drilling service) | Working directly under the B&V 10 CFR 50 Appendix B/NQA-1 QA program. B&V personnel recorded data, identified and marked samples for traceability, etc. |
| Professional Service Industries (PSI) (geotechnical laboratory services) | Working under the B&V 10 CFR 50 Appendix B/NQA-1 QA program, using a hybrid of B&V procedures and PSI procedures. Laboratory related geotechnical investigation activities will provide information important to safety. B&V to perform pre-work surveillance (specifically of laboratory activities) and in-process oversight. |
| ENSR (environmental/aquatic investigations) | Commercial quality, activities contain no quality information to support safety-related structures, systems and components |
| Commonwealth Cultural Resource Group (cultural resource investigations) | Commercial quality, activities contain no quality information to support safety-related structures, systems and components. |
| Automated Engineering Services (seismic & geotechnical reviews, technical advisory board) | Commercial quality – peer review of seismic/geotechnical work, not directly responsible for quality of products |

B&V reviewed PMM Phase I, Rev. 0 with Detroit Edison at a meeting on March 28, 2007. The review presented to Detroit Edison how quality assurance would be implemented for the project under the B&V 10 CFR 50 Appendix B/NQA-1 QA program.

In April 2007, as part of B&V's 2006 annual internal audit, B&V arranged 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 programs 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 Enclosure 1 for dates of specific activities associated with B&V's development of FSAR Chapter 2).

Subsequently and 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 surveillance, B&V Nuclear Quality Assurance 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 the Owner's Engineer (OE), Black & Veatch Ann Arbor (referred to as OE Black & Veatch throughout), observed B&V (Black & Veatch Overland Park referred to as B&V throughout) obtaining core samples 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.

Also 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:

| Nuclear Quality Assurance Program | |
|---|---|
| Entity | Applicability |
| GEOVision (seismic testing & data collection) | Working under the B&V 10 CFR 50 Appendix B/NQA-1 QA program |
| ARM Geophysics (geotechnical testing & data collection for soil & bedrock) | Working under the B&V 10 CFR 50 Appendix B/NQA-1 QA program |

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) subcontractors, 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. Specifically:

Boart Longyear / Prosonic - The results of the surveillance at Boart Longyear / Prosonic demonstrated that Boart Longyear / Prosonic maintains a program to adequately address the drilling operations (i.e., safety, training, calibration, proper licenses, and chemical control)

GEOVision - The results of the surveillance of GEOVision demonstrated that GEOVision had a quality assurance program written to the requirements in 10 CFR 50 Appendix B and ASME NQA-1-1994.

Professional Service Industries (PSI) - The results of the surveillance at PSI laboratory in Plymouth, Michigan demonstrated that PSI has an adequate quality commercial quality assurance program written to the guidance in International Standard ISO 25, "Requirements for the Competence of Testing and Calibration Laboratories."

ARM Geophysics - The results of the surveillance of ARM Geophysics indicate adequate capability to perform and meet the requirements of the PMM and the B&V service contract for qualification as a Commercial Grade supplier of geotechnical field services and that ARM Geophysics would be working under the B&V 10 CFR 50 Appendix B/NQA-1 QA program.

Further, PMM Phase I, Rev 1 outlined how each of the 18 Criteria from 10 CFR 50 Appendix B were to be addressed:

Criterion 1, Organization - B&V NP-1 series procedures address the B&V organization. PSI Quality Assurance Manual (Manual) QA-M-5 addresses the PSI organization. GEOVision Quality Assurance Manual addresses the GEOVision organization. The PMM addresses the Fermi project organization.

Criterion 2, Quality Assurance Program - Addressed by B&V NP-2 series procedures, PSI Manual QA-M-5 and GEOVision's Quality Assurance Manual.

- Criterion 3, Design Control - Addressed by B&V NP-3 series of procedures, PSI Manual QA-M-5 and GEOVision Quality Assurance Manual.
- Criterion 4, Procurement Documents Control - Addressed by B&V NP-4 series procedures, PSI Manual QA-M-5 and GEOVision Quality Assurance Manual.
- Criterion 5, Instructions, Procedures and Drawings - Addressed by B&V NP-5 series procedures, PSI Manual QA-M-5 and GEOVision Quality Assurance Manual.
- Criterion 6, Document Control - Addressed by B&V NP-6 series procedures, and subcontractor QA programs.
- Criterion 7, Control of Purchased Materials, Equipment and Services – Addressed by B&V NP-7 series procedures, PSI Manual QA-M-5 and GEOVision Quality Assurance Manual.
- Criterion 8, Identification and Control of Materials, Parts and Components – Addressed by B&V NP-8 series procedures, PSI Manual QA-M-5 and GEOVision Quality Assurance Manual.
- Criterion 9, Control of Special Processes - Components – Addressed by B&V NP-9 series procedures, PSI Manual QA-M-5 and GEOVision Quality Assurance Manual.
- Criterion 10, Inspection - Components – Addressed by B&V NP-10 series procedures and B&V oversight of work.
- Criterion 11, Test Control – Addressed by PSI Manual QA-M-5, GEOVision Quality Assurance Manual with B&V oversight.
- Criterion 12, Control of Measuring and Test Equipment - Addressed by PSI Manual QA-M-5, GEOVision Quality Assurance Manual with B&V oversight.
- Criterion 13, Handling, Storage and Shipping - Addressed by PSI Manual QA-M-5, GEOVision Quality Assurance Manual with B&V oversight.
- Criterion 14, Inspection, Test and Operating Status - Addressed by PSI Manual QA-M-5, GEOVision Quality Assurance Manual with B&V oversight.
- Criterion 15, Nonconforming Materials, Parts and Components - Addressed by B&V NP-15 series procedures, PSI Manual QA-M-5 and GEOVision Quality Assurance Manual with B&V Oversight
- Criterion 16, Corrective Action - Addressed by B&V NP-16 series procedures ensure that non conforming conditions are adequately addressed, including 10 CFR Part 21.
- Criterion 17, Quality Assurance Records - Addressed by B&V NP-17 series procedures, PSI Manual QA-M-5, and GEOVision Quality Assurance Manual.
- Criterion 18, Audits - Addressed by B&V NP-18 series procedures and GEOVision performance of internal audits as required by the GEOVision Quality Assurance Manual.

Also in July 2007 the OE, Black & Veatch Ann Arbor, observed B&V boring on 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 on 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, 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.

Also in August 2007, the OE, Black & Veatch Ann Arbor, observed B&V boring, split spoon sampling, and performing vacuum excavation on 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 controlled copy was available for reference. It was 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 the 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.

Also in September 2007, B&V Nuclear Quality Assurance 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 1) communicate to Detroit Edison and all team members that the COLA was to be based upon the ESBWR Certified Design and to 2) update the project organization chart. PMM Phase I, Rev. 2 also communicated the addition of one B&V subcontractor:

| Nuclear Quality Assurance Program | |
|---|--|
| Entity | Applicability |
| Northwest Cone Exploration (in situ engineering) | Working under the B&V 10 CFR 50 Appendix B/NQA-1 QA program |

The revised PMM Phase I also identified that B&V Nuclear Quality Assurance had performed 1) a surveillance on the subsurface field activities 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 (a copy is provided as an enclosure to the response to RAI 17.5-3 in Detroit Edison letter NRC3-09-0027 dated September 30, 2009 [ML092790561]), 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" (see RAI 17.5-18 in Attachment 3 for additional details). Subsequently, the implementing procedures were approved (see response to RAI 17.5-17 in Attachment 2) and the Nuclear Development staff

was trained on the procedures necessary to review and accept the B&V developed COLA work product. 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 (see Enclosure 1 for the date of review for each COLA section to which the requirements of 10 CFR 50 Appendix B were applied).

In February 2008, Detroit Edison began its review of individual FSAR Chapters or FSAR Sections in response to an NF-6.4-1, "Request for Review" submitted by B&V. The individual FSAR chapters or sections were reviewed by the Nuclear Development staff as prescribed by Standard Work Instruction (SWI) – 03-001-001-0529, "COLA Section and Chapter Review and Acceptance Process" (see RAI 17.5-18 in Attachment 3 for additional details). The review prescribed by SWI-03-001-001-0529 was to confirm that COLA work product prepared by B&V would be acceptable to the NRC. SWI-03-001-001-0529 noted that COLA preparation remained the responsibility of B&V. These reviews, and follow-up reviews, continued through September 2008. Upon completion of each review, Detroit Edison's comments were returned to B&V with the RFR for resolution or incorporation. Items from these RFRs that could not be readily resolved or incorporated were collected in an FSAR "punchlist" RFR for tracking and subsequent resolution or incorporation. This collection of open items was repeated until the submittal version of the Fermi 3 FSAR was delivered by B&V to Detroit Edison in September 2008 (see Enclosure 1 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:

| Entity | Nuclear Quality Assurance Program Applicability |
|--|--|
| KLD (evacuation time estimate) | Commercial quality, activities contain no quality information to support safety relate structures, systems and components. |
| Tetra Tech NUS (ER Chapter 7 support) | Commercial quality, activities contain no quality information to support safety relate structures, systems and components. |

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 the Fermi 3 COLA 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.

Included as part of the summary, please provide the following information presented in the form of a table: 1) list of safety-related activities and safety-related COL application sections, 2) dates of the activity or section creation, 3) contracting entity conducting the activity / section creation and governing QAPD, 4) QA organization responsible for oversight of the activity / section creation, 5) dates and type of any specific contractor QA oversight activities (i.e., surveillance, document review, etc), 6) contractor approval date, 7) dates of Detroit Edison review and approval, and 8) dates and type of any specific Detroit Edison QA oversight activities (i.e., surveillance, document review, etc). If documented evidence of information presented in the table or the summary is not available for future inspection, please note within the table or summary.

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, the dates of section development or supporting activity, the organization responsible for section development or performing the supporting activity, the QA organization responsible for oversight of section development or supporting activity, dates and type of any contractor QA oversight activities (i.e., surveillance, document review, etc), contractor approval date, dates of Detroit Edison review and approval, and dates and type of any specific Detroit Edison QA oversight activities is provided in Enclosure 1.

Proposed COLA Revision

Sufficient detail has not been provided in the Fermi 3 FSAR to enable the NRC staff to reach a final conclusion on whether all Fermi 3 project safety-related activities completed prior to the COL application date were consistent with the requirements of Appendix B to 10 CFR Part 50.

The proposed markup to FSAR Section 17.5 summarizing the responses to RAI 17.5-16, RAI 17.5-17, RAI 17.5-18, and RAI 17.5-19 is provided in Attachment 5.

**NRC3-10-0019
RAI 17.5-16**

Enclosure 1

Table of Safety-related Activities and Safety-related COLA Sections

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|---|---|--|-----------------------------|--|--|
| 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. (RFR-296) Section validated per B&V Project Instructions. | June 17, 2008 (RAR-0144) | Initial Review/Acceptance June 18, 2008 – July 9, 2008 (RFR-0304) Final Review/Acceptance July 3, 2008 – September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |
| 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. (RFR-275 and-276) Section validated per B&V Project Instructions. | June 6, 2008 (RAR-0126) | Initial Review/Acceptance June 6, 2008 – July 11, 2008 (RFR-295) Final Review/Acceptance July 3, 2008 – September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |
| 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 (RFR-271 and -272). Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | June 5, 2008 (RAR-0133) | Initial Review/Acceptance June 5, 2008 – July 8, 2008 (RFR-288) Final Review/Acceptance July 3, 2008 – September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |
| 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 (B&V Audit Report 06NS06). NAI deliverable reviewed per B&V Nuclear Procedures (RFR-265). | July 31, 2008 | Note 4 | Note 3 |

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|---|---|---|-----------------------------|--|--|
| 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. (RFR-238) Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | May 24, 2008 (RAR-0124) | Initial Review/Acceptance June 6, 2008 – July 11, 2008(RFR-271) Final Review/Acceptance August 15, 2008 – September 16, 2008 (RFR-0344) | Note 3 |
| 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 Instructions (RFR-290). Section validated per B&V Project Instructions. | June 10, 2008 (RAR-0137) | Initial Review/Acceptance June 10, 2008 – July 29, 2008 (RFR-298) Final Review/Acceptance August 15, 2008 – September 16, 2008 (RFR-0344) | Note 3 |
| 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 (B&V Audit Report 06NS06). NAI deliverable reviewed per B&V Nuclear Procedures (RFR-342). | August 8, 2008 | Note 4 | Note 3 |
| 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 (B&V Audit Report 06NS06). NAI deliverable reviewed per B&V Nuclear Procedures (RFR-342). | August 8, 2008 | Note 4 | Note 3 |
| 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 (B&V Audit Report 06NS06). NAI deliverable reviewed per B&V Nuclear Procedures (RFR-342). | August 8, 2008 | Note 4 | Note 3 |

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|--|---|--|-----------------------------|--|--|
| 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. (RFR-0200) Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | June 3, 2008 (RAR-0131) | Initial Review/Acceptance June 3, 2008 – July 9, 2008 (RFR-0283) Final Review/Acceptance July 3, 2008 - September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |
| 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. (RFR-0200) Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | June 3, 2008 (RAR-0131) | Initial Review/Acceptance June 3, 2008 – July 9, 2008 (RFR-0283) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0273) Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | June 3, 2008 (RAR-0131) | Initial Review/Acceptance June 3, 2008 – July 9, 2008 (RFR-0283) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0132) Section validated per B&V Project Instructions. | April 11, 2008 (RAR-0098) | Initial Review/Acceptance April 11, 2008 – June 27, 2008 (RFR-0170) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|--|---|--|-----------------------------|---|--|
| 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. (RFR-0200) Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | June 3, 2008 (RAR-0131) | Initial Review/Acceptance June 3, 2008 – July 9, 2008 (RFR-0283) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0132) Section validated per B&V Project Instructions. | April 11, 2008 (RAR-0098) | Initial Review/Acceptance April 11, 2008 – June 27, 2008 (RFR-0170) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0144) Section validated per B&V Project Instructions. | April 11, 2008 (RAR-0098) | Initial Review/Acceptance April 11, 2008 – June 27, 2008 (RFR-0170) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0132) Section validated per B&V Project Instructions. | April 11, 2008 (RAR-0098) | Initial Review/Acceptance April 11, 2008 – June 27, 2008 (RFR-0170) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|--|---|--|-----------------------------|--|--|
| 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. (RFR-0132) Section validated per B&V Project Instructions. | April 11, 2008 (RAR-0098) | Initial Review/Acceptance April 11, 2008 – June 27, 2008 (RFR-0170) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0250) Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | June 3, 2008 (RAR-0131) | Initial Review/Acceptance June 3, 2008 – July 9, 2008 (RFR-0283) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0250) Section validated per B&V Project Instructions. | June 3, 2008 (RAR-0131) | Initial Review/Acceptance June 3, 2008 – July 9, 2008 (RFR-0283) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0201) Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | June 5, 2008 (RAR-0134) | Initial Review/Acceptance June 5, 2008 – July 28, 2008 (RFR-0292) Final Review/Acceptance July 3, 2008 - September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|--|---|--|---|---|--|
| 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. (SR-00007) 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 (SR-00008). | April 23, 2007 (RAR-0011, 0012) (DCP and WP approval) | Note 4 | Note 3 |
| 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. (SR-00007) 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 (RAR-0011, 0012) (DCP and WP approval) | Note 4 | Note 3 |
| 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. (B&V Audit Number 07NS07) Surveillance of laboratory activities performed, September 21, 2007 (SR-00015). Water analytical testing performed per PSI procedures. Laboratory report reviewed by B&V (RFR-0075) | March 12, 2008 | Note 4 | Note 3 |

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|--|---|--|-----------------------------|---|--|
| 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. (RFR-0251) Section validated per B&V Project Instructions. | May 23, 2008 (RAR-0121) | Initial Review/Acceptance May 23, 2008 – June 30, 2008 (RFR-0263) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0189) Section validated per B&V Project Instructions. | April 28, 2008 (RAR-0104) | Initial Review/Acceptance April 29, 2008 – June 10, 2008 (RFR-0198) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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 SR-00012) B&V review performed per Nuclear Procedures and Project Process Instructions. (RFR-0121 and 0160). Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | April 4, 2008 (RAR-0095) | Initial Review/Acceptance April 4, 2008 – June 26, 2008 (RFR-0161) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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 SR-00012) B&V review performed per Nuclear Procedures and Project Process Instructions. (RFR-0285). Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | June 12, 2008 (RAR-0142) | Initial Review/Acceptance June 12, 2008 – July 31, 2008 (RFR-0299) Final Review/Acceptance July 3, 2008 - September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

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|---|--|--|---|--|-----------------------------|--|--|
| 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 SR-00012) B&V review performed per Nuclear Procedures and Project Process Instructions. (RFR-0188). Section validated per B&V Project Instructions. | May 6, 2008 (RAR-0107) | Initial Review/Acceptance May 6, 2008 – July 3, 2008 (RFR-0213) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0184). Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | May 6, 2008 (RAR-0108) | Initial Review/Acceptance May 6, 2008 – July 8, 2008 (RFR-0215) Final Review/Acceptance July 3, 2008 - September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |
| 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. (RFR-0196) Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | May 6, 2008 (RAR-0109) | Initial Review/Acceptance May 6, 2008 – July 8, 2008 (RFR-0214) Final Review/Acceptance July 3, 2008 - September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |

RAI-17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|--|---|--|--|---|---|
| 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 (SR-00007) 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 (SR-00008), September 19, 2007 (SR-00014), and December 5, 2007 (SR-00017). | Various dates tied to revisions to DCP and WP. | Note 4 | Surveillance of storage and handling of subsurface samples at Detroit Edison for long term storage, May 30 through June 6, 2008 |
| 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. (B&V Audit Number 07NS07) Surveillance of laboratory activities performed, September 21, 2007 (SR-00015). Geotechnical laboratory testing performed per PSI procedures. Laboratory report reviewed by B&V (RFR-0093) | July 2, 2008 | Note 4 | Note 3 |
| 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&V (RFR-0185). Laboratory report reviewed by B&V (RFR-0326) | July 25, 2008 | Note 4 | Note 3 |

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|--|---|--|------------------------------|--|--|
| 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 (B&V SR-00011) Field testing performed in accordance with ARM procedures. Geophysical well logging report reviewed by B&V (RFR-0116). | June 16, 2008 | Note 4 | Note 3 |
| 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 (B&V SR-00010) Field testing performed in accordance with GEOVision procedures, reviewed by B&V (RFR-0066). Geophysical testing report reviewed by B&V (RFR-0092). | March 14, 2008 | Note 4 | Note 3 |
| 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 (RFR-0063). Geophysical testing report reviewed by B&V (RFR-0068). | January 25, 2008 | Note 4 | Note 3 |
| 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. (RFR-0090) Section validated per B&V Project Instructions. | January 25, 2008 (RAR-0073) | Initial Review/Acceptance February 6, 2008 - June 30, 2008 (RFR-0099) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0071) Section validated per B&V Project Instructions. | December 14, 2007 (RAR-0065) | February 6, 2008 - April 21, 2008 (RFR-0082) | Note 3 |

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|--|---|--|------------------------------|--|--|
| 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. (RFR-0095) Section validated per B&V Project Instructions. | January 25, 2008 (RAR-0074) | Initial Review/Acceptance February 6, 2008 – April 4, 2008 (RFR-0100) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0096) Section validated per B&V Project Instructions. | February 6, 2008 (RAR-0078) | Initial Review/Acceptance February 6, 2008 – April 8, 2008 (RFR-0105) Final Review/Acceptance July 3, 2008 – August 15, 2008 (RFR-0318) | Note 3 |
| 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 (RAR-0129) | Initial Review/Acceptance May 30, 2008 – July 22, 2008 (RFR-0280) Final Review/Acceptance July 3, 2008 – August 15, 2008 (RFR-0318) | Note 3 |
| 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. (RFR-0072) Section validated per B&V Project Instructions. | December 14, 2007 (RAR-0062) | February 6, 2008 – February 27, 2008 (RFR-0083) | Note 3 |
| 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. (RFR-0133) Section validated per B&V Project Instructions. | May 23, 2008 (RAR-0122) | Initial Review/Acceptance May 23, 2008 – July 21, 2008 (RFR-0264) Final Review/Acceptance July 3, 2008 – August 15, 2008 (RFR-0318) | Note 3 |

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|--|---|--|-----------------------------|---|--|
| 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. (RFR-0138) Section validated per B&V Project Instructions. | April 10, 2008 (RAR-0097) | Initial Review/Acceptance April 11, 2008 – July 1, 2008 (RFR-0168) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0113) Calculations verified per Nuclear Procedures. Section validated per B&V Project Instructions. | April 10, 2008 (RAR-0097) | Initial Review/Acceptance April 11, 2008 – July 1, 2008 (RFR-0168) Final Review/Acceptance June 3, 2008 - September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |
| 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. (RFR-0147) Section validated per B&V Project Instructions. | April 10, 2008 (RAR-0097) | Initial Review/Acceptance April 11, 2008 – July 1, 2008 (RFR-0168) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |
| 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. (RFR-0147) Section validated per B&V Project Instructions. | April 10, 2008 (RAR-0097) | Initial Review/Acceptance April 11, 2008 – July 1, 2008 (RFR-0168) Final Review/Acceptance August 15, 2008 - September 16, 2008 (RFR-0344) | Note 3 |

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|--|---|---|------------------------------|--|--|
| 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. (RFR-0138) Section validated per B&V Project Instructions. | April 10, 2008 (RAR-0097) | Initial Review/Acceptance April 11, 2008 – July 1, 2008 (RFR-0168) Final Review/Acceptance June 3, 2008 - September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |
| 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. (RFR-0136) Section validated per B&V Project Instructions. | April 10, 2008 (RAR-0097) | Initial Review/Acceptance April 11, 2008 – July 1, 2008 (RFR-0168) Final Review/Acceptance June 3, 2008 - September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |
| 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. (RFR-0097) Section validated per B&V Project Instructions. | February 8, 2008 (RAR-0079) | Initial Review/Acceptance February 8, 2008 – June 30, 2008 (RFR-0108) Final Review/Acceptance July 3, 2008 – September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |
| 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. (RFR-0074) Section validated per B&V Project Instructions. | December 14, 2007 (RAR-0066) | February 6, 2008 – July 22, 2008 (RFR-0084) | Note 3 |
| 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. (RFR-0236) Section validated per B&V Project Instructions. | May 21, 2008 (RAR-0120) | Initial Review/Acceptance May 21, 2008 – July 8, 2008 (RFR-0258) Final Review/Acceptance July 3, 2008 – September 16, 2008 (RFR-0318 and RFR-0344) | Note 3 |

RAI 17.5-16 -- Please provide a detailed summary describing how all Fermi 3 safety-related activities completed or in process prior to September 18, 2008, were consistent with the requirements of Appendix B.

| 1) list of safety-related activities and safety-related COL application sections, | 2) dates of the activity or section creation | 3) contracting entity conducting the activity / section creation and governing QAPD | 4) QA organization responsible for oversight of the activity / section creation | 5) dates and type of any specific contractor QA oversight activities (i.e. Surveillance, document review, etc) Note 1 | 6) contractor approval date | 7) dates of Detroit Edison review and acceptance Note 2 | 8) dates and type of any specific Detroit Edison QA oversight activities (i.e. Surveillance, document review, etc) |
|---|--|--|---|--|------------------------------|---|--|
| 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. (RFR-0073) Section validated per B&V Project Instructions. | December 14, 2007 (RAR-0064) | February 6, 2008 – February 27, 2008 (RFR-0085) | Note 3 |

- Notes**
- 1) Details of audits and surveillances are presented in the text of the response to RAI 17.5-16 in this Attachment.
 - 2) 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.
 - 3) Detroit Edison performed 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. Surveillance performed April 29 through May 6, 2008. Also, see column 7 for Detroit Edison document review and acceptance activities
 - 4) 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).

**Attachment 2
NRC3-10-0019**

**Response to RAI Letter No. 26
(eRAI Tracking No. 4410)**

RAI Question No. 17.5-17

NRC RAI 17.5-17

10 CFR 52.79(a)(25) requires the applicant to provide a QA program consistent with Appendix B to 10 CFR Part 50 for design, fabrication and construction activities. Regulatory Guide 1.206 section C.I.17.5.3 states that the FSAR should 1) describe how the applicant will retain responsibility for, and maintain control over, those portions of the QA program delegated to other organizations, 2) should identify the responsible organization and the process for verifying that delegated QA functions are effectively implemented, 3) identify major work interfaces for activities affecting quality, and 4) describe 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.

Attachment 3 to NRC3-09-0027, "Detroit Edison Company Response to NRC RAI Letter No. 10," dated September 30, 2009, states in late April 2007, Detroit Edison formally established a small Nuclear Development group to oversee the COLA project and secured the services of an OE (B&V, Ann Arbor) to support owner-related activities. 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.

In Attachment 1 to NRC3-09-0041, "Detroit Edison Reply to a Notice of Violation 05200033/2009-201, 02, and 03," dated November 9, 2009, Detroit Edison asserts that the requirements of Appendix B to 10 CFR Part 50 were not applicable to Detroit Edison prior to September 18, 2008, because Detroit Edison was not yet an applicant. Detroit Edison also contends that, prior to becoming an applicant, a QA program was established by contractually delegating the work of establishing and executing the QA program to the COLA contractor.

Sufficient detail has not been provided in the Fermi 3 FSAR to enable the NRC staff to reach a final conclusion on whether all Fermi 3 project safety-related activities completed prior to the COL application date were consistent with the requirements of Appendix B to 10 CFR Part 50.

Please provide a table summarizing QA support of Fermi 3 safety-related activities completed or in process prior to September 18, 2008. Specifically, please include the following information limited to Fermi 3 safety-related activities conducted prior to September 18, 2008: 1) list of Detroit Edison QA personnel providing project support including hire dates, QA qualification types & dates, type of QA support provided, and percentage dedicated to project if less than full time, 2) summary by job classification of Black & Veatch (B&V)-Ann Arbor QA personnel providing project support including, QA qualification types, type of QA support provided, and number of hours dedicated to project, and 3) summary by job classification of B&V (Overland Park, Kansas) QA personnel providing project support including, QA qualification types, type of QA support provided, and number of hours dedicated to project. Please include position titles for Detroit Edison personnel, while B&V data should be summarized by job classification. Please do not include names of personnel.

Note: This RAI is supplemental to RAI 17.5-3 included in NRC RAI Letter No. 10, dated August 12, 2009.

Response

- 1) *List of Detroit Edison QA personnel providing project support including hire dates, QA qualification types & dates, type of QA support provided, and percentage dedicated to project if less than full time,*

Project Engineer, September 2007 – March 2008. An engineer with twenty plus years of engineering, licensing and quality assurance experience (previous QA manager at Fermi 2) working with the OE, Black & Veatch Ann Arbor, developed 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). [Full time]

Nuclear Development QA Manager, March 2008 – April 2009. An engineer with twenty plus years of nuclear experience including four years experience as lead auditor was responsible to maintain the Nuclear Development QAPD and to independently plan and perform activities to verify the development and effective implementation of the QAPD for 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, to monitor organizational 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. [Full time]

In June 2009, the QA function was transitioned from reporting to the Director, Nuclear Development to the Sr. Vice President, Major Enterprise Projects.

- 2) *summary by job classification of Black & Veatch (B&V) - Ann Arbor QA personnel providing project support including, QA qualification types, type of QA support provided, and number of hours dedicated to project, and*

Quality Manager, May 2007 – September 2007. A quality assurance professional with 33 years of nuclear experience in engineering and quality assurance and Lead Auditor qualified since 2000. The Quality Manager for the OE, B&V Ann Arbor, conducted observations of hydrogeological and geotechnical activities at the Fermi site and reported to Nuclear Development.

Quality Manager, September 2007 – May 2008. A quality assurance professional with 33 years of nuclear experience in engineering and quality assurance and Lead Auditor qualified since 2000. The Quality Manager for the OE, B&V Ann Arbor, working with a Detroit Edison Project engineer developed 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). The Quality Manager for the OE, B&V Ann Arbor, fulfilled role of Nuclear Development QA Manager as a staff augmentation until the Detroit Edison position was filled.

[Total Effort, May 2007 – May 2008: 850 hours]

- 3) *summary by job classification of B&V (Overland Park, Kansas) QA personnel providing project support including, QA qualification types, type of QA support provided, and number of hours dedicated to project.*

Project Quality Manager, Project Start – Present. A quality assurance professional with 35 years of nuclear experience in engineering and quality assurance and Lead Auditor qualified since 1999. The B&V Project Quality Manager provides quality management support to COLA activities including oversight activities and surveillances of on-site activities. The B&V Project Quality Manager conducted or directed supplier qualification reviews, audits and surveillances for 10 CFR 50 Appendix B and commercial quality related supplies. The B&V Project Quality Manager was responsible for ensuring compliance with regulatory requirements and reviewing quality related documents such as the B&V 10 CFR 50 Appendix B/NQA-1 QA program and associated implementing procedures. [Assigned to the Fermi 3 COLA Project full time]

Surveillance Specialist(s), Project Start – Present. Qualified surveillance specialists, qualified in accordance with B&V Nuclear Procedure NP-18.2, “Surveillance.” The B&V Surveillance Specialist provides surveillance support to COLA activities including, performing and documenting surveillance activities, notifying management of surveillance findings, evaluating surveillance finding responses, and verification of corrective actions and the prevention of reoccurrence. [260 hours to date]

Proposed COLA Revision

Sufficient detail has not been provided in the Fermi 3 FSAR to enable the NRC staff to reach a final conclusion on whether all Fermi 3 project safety-related activities completed prior to the COL application date were consistent with the requirements of Appendix B to 10 CFR Part 50.

The proposed markup to FSAR Section 17.5 summarizing the responses to RAI 17.5-16, RAI 17.5-17, RAI 17.5-18, and RAI 17.5-19 is provided in Attachment 5.

**Attachment 3
NRC3-10-0019**

**Response to RAI Letter No. 26
(eRAI Tracking No. 4411)**

RAI Question No. 17.5-18

NRC RAI 17.5-18

10 CFR 52.79(a)(25) requires the applicant to provide a QA program consistent with Appendix B to 10 CFR Part 50 for design, fabrication and construction activities. Regulatory Guide 1.206 section C.I.17.5.3 states that the FSAR should 1) describe how the applicant will retain responsibility for, and maintain control over, those portions of the QA program delegated to other organizations, 2) should identify the responsible organization and the process for verifying that delegated QA functions are effectively implemented, 3) identify major work interfaces for activities affecting quality, and 4) describe 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.

Attachment 3 to NRC3-09-0027, "Detroit Edison Company Response to NRC RAI Letter No. 10," dated September 30, 2009, states Detroit Edison 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). The ND QAPD was approved for use in February 2008 and remained in effect until the Fermi 3 COLA was filed in September 2008 and the Fermi 3 QAPD superseded it.

In Attachment 1 to NRC3-09-0041, "Detroit Edison Reply to a Notice of Violation 05200033/2009-201, 02, and 03," dated November 9, 2009, Detroit Edison asserts that the requirements of Appendix B to 10 CFR Part 50 were not applicable to Detroit Edison prior to September 18, 2008, because Detroit Edison was not yet an applicant. Detroit Edison also contends that, prior to becoming an applicant, a QA program was established by contractually delegating the work of establishing and executing the QA program to the COLA contractor.

Sufficient detail has not been provided in the Fermi 3 FSAR to enable the NRC staff to reach a final conclusion on whether all Fermi 3 project safety-related activities completed prior to the COL application date were consistent with the requirements of Appendix B to 10 CFR Part 50.

Please provide a table summarizing the ND QAPD and Fermi 3 implementing procedures effective prior to September 18, 2008. Please include a brief description of the implementing procedure (or change to procedure, if revision) and the effective dates of all revisions. Also note when the ND QAPD or implementing procedures were contractually imposed on, or applied by, contracted personnel, if applicable.

Note: This RAI is supplemental to RAI 17.5-3 included in NRC RAI Letter No. 10, dated August 12, 2009.

Response

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

B&V headquartered in Overland Park, Kansas and hereafter simply identified as B&V, was fully responsible for establishing and executing the QA program, and verifying that the QA functions were effectively implemented in accordance with the B&V 10 CFR 50 Appendix B/NQA-1 QA program which satisfies the requirements of 10 CFR 50 Appendix B.

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

Nuclear Development Quality Assurance Program Description (Rev. 0, Feb 4, 2008) - covered Detroit Edison professionals and OE, Black & Veatch Ann Arbor, professionals, as staff augmentation, assigned to the Fermi 3 project.

NDP-NP-1.1, Nuclear Development Project Organization (Rev. 0, Feb 4, 2008) – established the organizational structure for the Fermi 3 project and the respective functional responsibilities necessary for the implementation of the Nuclear Development Quality Assurance Program Description (ND QAPD), including the establishment of the ND Quality Assurance Manager (see RAI 17.5-17). NDP-NP-1.1, Rev. 0 covered Detroit Edison professionals and OE, Black & Veatch Ann Arbor, professionals, as staff augmentation, assigned to the Fermi 3 project.

Notes: Nuclear Development Project (NDP), and Nuclear Procedure (NP)

NDP-NP-2.1, Training (Rev. 0, Feb 4, 2008) – identified training requirements for orientation/indoctrination and continuing training and assigned responsibilities and methods for determining, scheduling and monitoring completion of NDP training. NDP-NP-2.1, Rev. 0 covered Detroit Edison professionals and OE, Black & Veatch Ann Arbor, professionals, as staff augmentation, assigned to the Fermi 3 project.

Note: Training requirements for QA auditors and their certification is addressed in NDP-NP-2.2.

NDP-NP-2.2, Auditor/Lead Auditor Qualification (Rev. 0, Mar 24, 2008) – established the requirements for an auditor and lead auditor.

NDP-NP-4.1, Procurement of Services (Rev. 0, Feb 4, 2008) – defined the content requirements for procurement documents used in the purchase of safety-related services for NDP work by Detroit Edison. NDP-NP-4.1, Rev. 0 identified that Black & Veatch, Overland Park (hereafter identified as B&V) and their approved suppliers are the only approved suppliers for activities requiring application of a nuclear quality assurance program. NDP-NP-4.1, Rev. 0 prescribed that the Detroit Edison COL Application Project, including the site characterization and COL preparation was to be performed under B&V's Quality Assurance program, which complies with 10 CFR 50 Appendix B and ASME NQA-1 and invokes the requirements of 10 CFR 50.55(e) and 10 CFR 21. NDP-NP-4.1, Rev. 0 also provided the applicability of the B&V 10 CFR 50 Appendix B/NQA-1 QA as it related to COL scopes of work via the table below:

| Activity | Nuclear Quality Assurance Program Applicability¹ |
|---|---|
| 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 pertains to safety-related SSCs |
| Site Redress Plan | Commercial quality program applies |

Note: 1. Where the B&V 10 CFR 50 Appendix B/NQA-1 QA program applies, procurement documents shall include B&V's requirements for reporting and approving the disposition of non-conformances. The documents shall also include the requirements of 10 CFR 21.

NDP-NP-4.1, Rev. 0 covered Detroit Edison professionals and OE, Black & Veatch Ann Arbor, professionals, as staff augmentation, assigned to the Fermi 3 project.

NDP-NP-5.1, Nuclear Procedure and Project Management, Memorandum Preparation (Rev. 0, Feb 4, 2008) – established the requirements for preparation, review, approval, revisions, and cancellation of Nuclear Procedures (NPs). NDP-NP-5.1 also prescribed the basic requirements for the format, approval and document control for OE, Black & Veatch Ann Arbor, Project Management Memorandums (OE PMMs). NDP-NP-4.1, Rev. 0 applied to procedures and OE PMMs prepared by Detroit Edison professionals and OE, Black & Veatch Ann Arbor, professionals, as staff augmentation, assigned to the Fermi 3 project.

NDP-NP-6.1, Document Control (Rev. 0, Feb 4, 2008) – provided the requirements for preparation of correspondence and other text type documents including the process for filing, distribution, preservation, and reference. The requirements of NDP-NP-6.1, Rev 0 apply to correspondence, procedures, and design documents and supplement the requirements of NDP-NP-6.3, Rev. 0, "Project File Numbering." NDP-NP-6.1, Rev. 0

covered Detroit Edison professionals and OE, Black & Veatch Ann Arbor, professionals, as staff augmentation, assigned to the Fermi 3 project.

NDP-NP-6.2, Document Review and Approval (Rev. 0, Feb 4, 2008) – established the methods and responsibilities for conducting and documenting the review and approval of NDP documents, including administrative or technical documents that may be project organization related (e.g. procedures, Requests for Information, COLA sections and chapters). NDP-NP-6.2, Rev. 0 covered Detroit Edison professionals and OE, Black & Veatch Ann Arbor, professionals, as staff augmentation, assigned to the Fermi 3 project.

NDP-NP-16.1, Nuclear Development Project Corrective Action Program (Rev. 0, Feb 4, 2008) – provided the instructions for the administration of the NDP Corrective Action Program, including identification, evaluation, reporting, correction and trending of undesirable conditions as well as opportunities for improvement (e.g. conditions adverse to quality, potential concerns that could be precursors to more significant events, and areas of improvement identified during assessments and other activities). NDP-NP-16.1, Rev. 0 also provided administrative Stop Work Action controls for conditions adverse to quality. NDP-NP-16.1, Rev. 0 covered Detroit Edison professionals and OE, Black & Veatch Ann Arbor, professionals, as staff augmentation, assigned to the Fermi 3 project.

NDP-NP-17.1, Handling and Storage of Nuclear Records (Rev. 0, Feb 4, 2008) – established the requirements for the classification, collection, retention, maintenance, and disposition of quality records associated with NDP activities, including the filing of quality project and organization records in local files and transfer to permanent storage. NDP-NP-17.1, Rev. 0 applied to those records generated by Detroit Edison's NDP organization, those records generated by or for NDP, and those quality records retained by departments or other organizational units of the OE, Black & Veatch Ann Arbor.

NDP-NP-18.1, Audit Performance (Rev. 0, Mar 24, 2008) – established the requirements for planning, performing, and reporting internal and external audits. NDP-NP-18.1, Rev. 0 applied to audits of Fermi 3 activities, audits performed at Fermi 3 jobsites, and audits of supplier activities.

NDP-NP-18.2, Surveillance (Rev. 0, Mar 24, 2008) – established requirements for performing surveillance activities conducted by NDP, provided the qualification requirements of personnel conducting surveillances, and provided the requirements for planning, conducting, reporting and tracking of surveillance activities. NDP-NP-18.2, Rev. 0 applied to the surveillance of project and field activities conducted by Detroit Edison or the OE, Black & Veatch Ann Arbor, as staff augmentation, assigned to the Fermi 3 project.

SWI 03-001-001-0529, COLA Section and Chapter Review and Acceptance Process (Ver. 1 – initial issue, Dec 17, 07) – described the prerequisite experience and qualification requirements and the necessary process steps to assure that the Fermi 3 COLA submittal will: 1) pass the NRC acceptance test for completeness and 2) support the “complete and accurate” information requirement of 10 CFR 52.6. SWI 03-001-001-0529, Rev. 0 applied to Detroit Edison professionals and OE, Black & Veatch Ann Arbor,

professionals, as staff augmentation, participating in review of the Fermi 3 COLA submittal.

SWI 03-001-001-0529 was revised in May 2008 to reflect process refinements and lessons learned.

Note: Standard Work Instruction (SWI)

Proposed COLA Revision

Sufficient detail has not been provided in the Fermi 3 FSAR to enable the NRC staff to reach a final conclusion on whether all Fermi 3 project safety-related activities completed prior to the COL application date were consistent with the requirements of Appendix B to 10 CFR Part 50.

The proposed markup to FSAR Section 17.5 summarizing the responses to RAI 17.5-16, RAI 17.5-17, RAI 17.5-18, and RAI 17.5-19 is provided in Attachment 5.

**Attachment 4
NRC3-10-0019**

**Response to RAI Letter No. 26
(eRAI Tracking No. 4412)**

RAI Question No. 17.5-19

NRC RAI 17.5-19

10 CFR 52.79(a) requires the applicant FSAR to contain sufficient depth of information to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a combined license. 10 CFR 52.79(a)(25) requires the applicant to provide a QA program consistent with Appendix B to 10 CFR Part 50 for design, fabrication and construction activities.

Appendix B establishes quality assurance requirements for the design, manufacture, construction, and operation of the structures, systems, and components of the facility. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of the structures, systems, and components to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

Regulatory Guide 1.206 section C.I.17.5.3 states that the FSAR should 1) describe how the applicant will retain responsibility for, and maintain control over, those portions of the QA program delegated to other organizations, 2) should identify the responsible organization and the process for verifying that delegated QA functions are effectively implemented, 3) identify major work interfaces for activities affecting quality, and 4) describe 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.

Attachment 3 to NRC3-09-0027, "Detroit Edison Company Response to NRC RAI Letter No. 10," dated September 30, 2009, states the following attributes from Reg. Guide 1.206, C.I.17.5.3 are discussed for each of the three distinct project periods:

- 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.*

The NRC staff has reviewed Attachment 3 to NRC3-09-0027, which includes proposed changes to FSAR part 2, chapter 17.5, and found it included descriptive project information that leads to a better understanding of the history of the Fermi 3 project. Furthermore, the NRC staff determined that the information presented did not fully address the four attributes contained in Regulatory Guide 1.206 section C.I.17.5.3, as stated in Attachment 3, nor did it provide justification for any exceptions to the Regulatory Guide 1.206 guidance.

Please clarify how FSAR part 2, chapter 17.5, meets the requirements of 10 CFR 52.79(a)(25) through the guidance provided in Regulatory Guide 1.206, or alternatively, provide justification

for any exceptions to the guidance. Specifically, describe how the four attributes from Regulatory Guide 1.206 section C.I.17.5.3 are met for the Fermi 3 project for each of the three project periods presented in Attachment 3 to NRC3-09-0027.

Note: This RAI is supplemental to RAI 17.5-3 included in NRC RAI Letter No. 10, dated August 12, 2009.

Response

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

A description of the quality activities of Detroit Edison and its COLA contractor, Black & Veatch, headquartered in Overland Park, Kansas, hereafter identified as B&V, associated with the conduct of safety-related activities and development of the safety-related COLA sections is provided with the response to RAI 17.5-16 in Attachment 1. The proposed change to FSAR Section 17.5 associated with the response to RAI 17.5-16 is provided in Attachment 5. The information presented in the proposed changes to FSAR Section 17.5 addresses the requirements of 10 CFR 52.79(a)(25) through the regulatory guidance provided in Reg. Guide 1.206, Section C.I.17.5.3 during the development of the COLA work product (January 2007 to November 2007) as summarized here:

1. *Description of how the applicant will retain responsibility for, and maintain control over, those portions of the QA program delegated to other organizations;*

10 CFR 50 Appendix B, Criterion I permitted Detroit Edison to delegate to B&V, Overland Park, the work of establishing and executing the QA program. Through contract, Detroit Edison delegated to B&V the work of establishing and executing a QA program satisfying the requirements of 10 CFR 50 Appendix B for COLA development. Detroit Edison retained responsibility for the QA program by being identified as the applicant and eventual licensee (see FSAR Subsection 1.4.1) in the application.

All COLA work product and associated activities from project initiation through COLA submission were conducted under B&V's 10 CFR 50 Appendix B/NQA-1 program. Utilizing a COLA contractor with a QA program satisfying the requirements of 10 CFR 50 Appendix B is consistent with the first approach to satisfying 10 CFR 50 Appendix B endorsed by the Statement of Consideration for the conforming changes to 10 CFR Part 21 (see 71 FR 12821).

2. *Identification of the responsible organization and the process for verifying that delegated QA functions are effectively implemented;*

In establishing and executing the QA program, B&V was responsible to Detroit Edison for verifying that the QA functions to support safety-related activities and safety-related COLA sections were effectively implemented in accordance with the B&V 10 CFR 50 Appendix B/NQA-1 QA program.

3. *Identification of major work interfaces for activities affecting quality, and*

B&V used Project Instruction 147483.21.2007, "Fermi 3 COL Request for Information to an Outside Organization" to request information necessary for the development of the COLA from Detroit Edison or other organizations outside B&V. The instruction clearly provided for B&V identification that the information was to support safety-related structures, systems or components to the requesting organization.

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.*

The Project Management Memorandum for "Detroit Edison (Fermi Site) COL Application Preparation" (PMM Phase I) identified to Detroit Edison and all COLA 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 was revised by B&V as subcontractors were added or as needed due to other changes, including quality assurance changes.

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

A description of the quality activities of Detroit Edison and B&V, associated with the conduct of safety-related activities and development of the safety-related COLA sections is provided with the response to RAI 17.5-16 in Attachment 1. The proposed change to FSAR Section 17.5 associated with the response to RAI 17.5-16 is provided in Attachment 5. How the information presented in the proposed changes to FSAR Section 17.5 addresses the requirements of 10 CFR 52.79(a)(25) through the regulatory guidance provided in Reg. Guide 1.206, Section C.I.17.5.3 during Detroit Edison's receipt, review and acceptance of the COLA work product (November 2007 to September 2008) is summarized here:

1. *Description of how the applicant will retain responsibility for, and maintain control over, those portions of the QA program delegated to other organizations;*

As presented previously, Detroit Edison retained responsibility for the QA program by being identified as the applicant and eventual licensee (see FSAR Subsection 1.4.1).

Responsibility for, and control of, the quality of safety-related activities and safety-related COLA sections was accomplished by continuing to delegate the work of establishing and executing the necessary elements of the QA program to B&V. B&V had control of safety-related activities under their 10 CFR 50 Appendix B/NQA-1 QA program.

Responsibility for and control of the quality associated with Detroit Edison's review and acceptance of the COLA work product from B&V and submission to the NRC was accomplished by establishing the Nuclear Development Quality Assurance Program (ND QAPD) and the implementing procedures for those elements of the ND QAPD associated with the activities planned in support of the review and acceptance of the B&V COLA work product.

2. *Identification of the responsible organization and the process for verifying that delegated QA functions are effectively implemented;*

B&V continued to be responsible to Detroit Edison for executing the QA program and verifying that the QA functions to support safety-related activities and safety-related COLA sections were effectively implemented in accordance with the B&V 10 CFR 50 Appendix B/ NQA-1 QA program.

NDP-NP-4.1, Procurement of Services (Rev. 0, Feb 4, 2008) – identified that Black & Veatch, Overland Park (hereafter identified as B&V) and their approved suppliers are the only approved suppliers for activities requiring application of a nuclear quality assurance program. NDP-NP-4.1, Rev. 0 prescribed that the Detroit Edison COL Application Project, including the site characterization and COL preparation was to be performed under B&V's Quality Assurance program, which complies with 10 CFR 50 Appendix B and ASME NQA-1 and invokes the requirements of 10 CFR 50.55(e) and 10 CFR 21.

The Nuclear Development QA Manager was responsible for performing activities to verify the development and effective implementation of the ND QAPD to Detroit Edison's review and acceptance of the COLA work product from B&V including a) assuring compliance with regulatory requirements and b) compliance with the applicable implementing procedures. The Nuclear Development QA Manager surveyed B&V COLA development activities to assess the adequacy, compliance, and the effectiveness of B&V QA oversight through audits and technical reviews; monitoring organization processes to ensure conformance to procurement document requirements; and ensuring that vendors providing quality services to Detroit Edison are meeting the requirements of 10 CFR 50 Appendix B.

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.

3. *Identification of major work interfaces for activities affecting quality, and*

B&V used Project Instruction 147483.21.2007, "Fermi 3 COL Request for Information to an Outside Organization" to request information necessary for the development of the COLA from Detroit Edison or other organizations outside B&V. The instruction clearly provided for B&V identification that the information was to support safety-related structures, systems or components to the requesting organization.

B&V used Nuclear Procedure (NP) 6.4, "Document Review and Approval" to submit individual FSAR chapters or sections to Detroit Edison for review by the Nuclear Development staff.

The Nuclear Development staff conducted their review 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.

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.*

The Project Management Memorandum for "Detroit Edison (Fermi Site) COL Application Preparation" (PMM Phase I) continued to identify to Detroit Edison and all COLA 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 was revised by B&V as subcontractors were added or as needed due to other changes, including quality assurance changes.

Additionally, SWI – 03-001-001-0529, "COLA Section and Chapter Review and Acceptance Process" stated that COLA preparation remained the responsibility of B&V.

Application for the Combined Operating License (September 2008 to Present)

This section continues the description of the quality activities of Detroit Edison and B&V associated with the conduct of safety-related activities and development of the safety-related COLA sections provided with the response to RAI 17.5-16 in Attachment 1. The proposed change to FSAR Section 17.5 associated with this description is provided in Attachment 5.

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 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 (RAI) 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 is led 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 is 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 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 process.

In October 2009, the quality assurance organization, led by the group's lead-auditor-qualified individual and 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.

1. *Description of how the applicant will retain responsibility for, and maintain control over, those portions of the QA program delegated to other organizations;*

After submittal of the COLA, Detroit Edison took direct ownership of the application.

In the transition of ownership of the COLA from B&V to Detroit Edison, Nuclear Development adopted the Fermi 3 Quality Assurance Program Description (QAPD), formerly know as the ND QAPD, provided in Appendix 17AA of the FSAR. Use of those procedures implemented under the ND QAPD continued, and additional procedures to address maintenance of the COLA were developed.

Subsequently, Detroit Edison now directly controlled the COLA content and requested the execution of safety-related COLA work product from B&V through the Request for Information (RFI) quality process.

Primary responsibility for, and control of, the quality of safety-related activities and safety-related COLA sections was accomplished by continuing to delegate the work of establishing and executing the necessary elements of the QA program to B&V. B&V had control of safety-related activities under its 10 CFR 50 Appendix B/NQA-1 QA program.

2. *Identification of the responsible organization and the process for verifying that delegated QA functions are effectively implemented;*

NDP-NP-4.1, Procurement of Services (Rev. 0, Feb 4, 2008) – identified that Black & Veatch, Overland Park (hereafter identified as B&V) and their approved suppliers are the only approved suppliers for activities requiring application of a nuclear quality assurance program. NDP-NP-4.1, Rev. 0 prescribed that the Detroit Edison COL Application Project, including the site characterization and COL preparation was to be performed under B&V's Quality Assurance program, which complies with 10 CFR 50 Appendix B and ASME NQA-1 and invokes the requirements of 10 CFR 50.55(e) and 10 CFR 21.

B&V continued to be responsible to Detroit Edison for executing the QA program and verifying that delegated QA functions to support safety-related activities and safety-related COLA sections were effectively implemented in accordance with the B&V 10 CFR 50 Appendix B/NQA-1 QA program.

The Nuclear Development QA Manager was responsible for performing activities to verify the development and effective implementation of the Fermi 3 QAPD for Detroit Edison's review and acceptance of the COLA work product from B&V including assuring compliance with regulatory requirements and compliance with the applicable implementing procedures through June 2009. 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 is led 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 is 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 organization, with technical support from Nuclear Development, completed an audit of B&V in July 2009. The quality assurance group schedules and conducts surveillances and audits of quality activities in accordance with the Fermi 3 QAPD and 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.

3. *Identification of major work interfaces for activities affecting quality, and*

After transition of COLA ownership from B&V to Detroit Edison, Detroit Edison now directly controlled the COLA content and requested the execution of safety-related COLA work product from B&V through the Request for Information (RFI) quality process.

Nuclear Procedure NDP-NP-6.4, "COLA Change Process" provides four integrated processes necessary to maintain the COLA: request for information, license change request, request for review, and change incorporation. The request for information process has been removed and issued as NP-6.6, "Nuclear Development Request for Information."

B&V's Request for Information project instruction provides a means for B&V to request information necessary for the development of the COLA from Detroit Edison or other organizations outside B&V. The instruction clearly provided for B&V identification that the information was to support safety-related structures, systems or components to the requesting organization.

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.*

The Project Management Memorandum for "Detroit Edison (Fermi Site) COL Application Phase II" (PMM Phase II) continues to identify to Detroit Edison and all COLA 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 II was revised by B&V as subcontractors were added or as needed due to other changes, including quality assurance changes.

Proposed COLA Revision

The proposed markup providing the description of the quality activities of Detroit Edison and B&V associated with the conduct of safety-related activities and development of the safety-related COLA sections for the period "Application for the Combined Operating License" (September 2008 to Present) is provided in Attachment 5.

Attachment 5
NRC3-10-0019

Markup of Detroit Edison COLA
(following 28 page(s))

The following markup represents how Detroit Edison intends to reflect this RAI response in the next submittal of the Fermi 3 COLA. However, the same COLA content may be impacted by revisions to the ESBWR DCD, responses to other COLA RAIs, other COLA changes, plant design changes, editorial or typographical corrections, etc. As a result, the final COLA content that appears in a future submittal may be different than presented here.

1.3 Comparison Tables

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

Add the following at the end of this section.

EF3 COL 1.3-1-A

There are no updates to DCD Table 1.3-1 based on unit specific information.

1.3.1 COL Information

1.3-1-A Update Table 1.3-1

This COL item is addressed in Section 1.3.

1.4 Identification of Agents and Contractors

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

EF3 SUP 1.4-1

1.4.1 Detroit Edison Company

Detroit Edison is the applicant for the COL, and Detroit Edison will be the licensee authorized to construct and operate Fermi 3. Detroit Edison is therefore responsible for making each of the key project decisions, including the ultimate decision on whether to build a new nuclear power plant, and would be the plant operator.

Detroit Edison has selected GE-Hitachi Nuclear Energy Americas, LLC (GEH) as its primary contractor for the design of the unit. **[START COM 1.4-001]** The primary contractor for site engineering has not been selected at the time of COLA submittal; this information will be supplied in an FSAR update following selection. **[END COM 1.4-001]** Detroit Edison has responsibility for the operation of the unit. The following sections provide information on the experience and qualifications of the aforementioned agents and contractors as well as the division of responsibility between Detroit Edison and its agents and contractors.

1.4.2 GE-Hitachi Nuclear Energy Americas, LLC (GEH)

GEH is responsible for developing the complete standard plant for the ESBWR necessary to obtain a DC from the NRC, supporting preparation of the COL application, and activities to support deployment of the

ESBWR on the Fermi site. GEH, established in June 2007, is a business alliance of GE and Hitachi's respective nuclear businesses, established to serve the global nuclear industry.

DCD Table 1.4-1 lists the commercial nuclear reactors that were completed by GE or are under construction by GEH. For 50 years, GE provided advanced technology for nuclear energy. GE developed breakthrough light water technology in the mid-1950s: the Boiling Water Reactor (BWR). Since then, GE developed nine evolutions of BWR technology, including the first operational advanced light water design in the world, the ABWR, and culminating in its latest generation of design, the ESBWR. All of GE's nuclear technology has been transferred to GEH. There are 67 plants operating worldwide utilizing GEH designs with an operating capacity of over 59 GW, including 36 BWR plants in North America. Various subcontractors are supporting GEH.

1.4.2.1 **Construction of the Turbine Island and Nuclear Island**

The contractors for the construction of the turbine island and the nuclear island have not yet been selected. The turbine island and the nuclear island together represent the power block. The contractor for the construction of the turbine island will be responsible for the erection and delivery of the turbine building, the electric building, and the contents of each building. The contractor for the construction of the nuclear island will be responsible for the erection and delivery of the reactor and fuel building, the control building, the hot machine shop, the radwaste building, and the contents of each building. Each contractor will be selected based on their historical work in the nuclear industry, ongoing nuclear business, ability to deliver integrated engineering and construction services, and available resources.

1.4.3 **Black & Veatch**

Black & Veatch served as primary contractor for development of the COL application, supplying engineering support, conceptual design, environmental impact assessments, and project management. Black & Veatch, based in Overland Park, KS, is an engineering, environmental, technical, construction services, and management services firm providing a broad range of professional services to private and government sector clients throughout the world since 1915. Black & Veatch's nuclear activities date back to the closing years of World War II with early work including extensive service to the Atomic Energy Commission in the

The markup to this page was also provide with the response to RAI 17.5-11 in Detroit Edison letter NRC3-10-0016 dated April 16, 2010. It is also provided here to aid in the review.

development of facilities at Los Alamos, New Mexico. More recent activities include the development activities for other COLAs, the Advanced Boiling Water Reactor (AWBR) Design Certification Program, and the Department of Energy's 2010 initiative for the deployment of new nuclear plants in the United States

Various subcontractors are supporting Black & Veatch, including:

may be

(after Geomatrix) Other subcontractors may be added as needed

Environmental Report

Move text up to here

1.4.4 Other Contractors

In addition to the major contractors listed above, contractual relationships were established with several specialized consultants to assist in developing the COLA. Other subcontractors may be added as the need arises.

1.4.3.1 Professional Service Industries, Inc. (PSI)

PSI performed laboratory testing in support of Fermi 3 site specific evaluations in Chapter 2 and the Emergency Plan. This effort included laboratory testing of rock and soil materials and water quality.

1.4.3.2 Boart Longyear

Boart Longyear performed geotechnical field investigations in support of Chapter 2. That effort included performing standard penetration tests; obtaining core samples and rock cores; performing cone penetrometer tests; supporting down-hole seismic tests and laboratory tests of soil and rock samples; installing ground water observation wells; and preparing a data report.

1.4.3.3 Geomatrix

Geomatrix Inc. performed probabilistic seismic hazard assessments and related sensitivity analyses in support of Chapter 2. These assignments included sensitivity analyses of seismic source parameters and updated ground motion attenuation relationships, development of updated Safe Shutdown Earthquake (SSE) ground motion values, and preparation of the related sections.

1.5 Requirements for Further Technical Information

This section of the referenced DCD is incorporated by reference with no departures or supplements.

Table 1.9-203 Conformance with the FSAR Content Guidance in RG 1.206
 (Sheet 35 of 39) [EF3 COL 1.9-3-A]

| Section | Section Title | Conformance Evaluation |
|----------------|---|---|
| C.III.1 17.2 | Quality Assurance During the Operations Phase | Conforms |
| C.III.1 17.3 | Quality Assurance Program Description | Conforms |
| C.III.1 17.4.1 | New Section 17.4 in the Standard Review Plan | Conforms |
| C.III.1 17.4.2 | Reliability Assurance Program Scope, Stages, and Goals | Not applicable |
| C.III.1 17.4.3 | Reliability Assurance Program Implementation | Conforms. Addressed in Section 17.4 and Section 17.6. |
| C.III.1 17.4.4 | Reliability Assurance Program Information Needed in a COL Application | Conforms. Addressed in DCD Section 17.4 and in Section 17.4, Section 17.5, and Section 17.6 |
| C.III.1 17.5 | Quality Assurance Program Guidance | See below |
| C.III.1 17.5.1 | COL Applicant QA Program Responsibilities | Conforms |
| C.III.1 17.5.2 | Updated SRP Section 17.5 and the QA Program Description | Conforms. QA applied to safety-related activities performed prior to the start of construction (e.g., site investigation, design and safety analysis, early procurements) and QA applied during activities to adapt the design to specific plant implementation, construction, and operations is addressed in Section 17.5. |
| C.III.1 17.5.3 | Evaluation of the QAPD Against the SRP and QAPD Submittal Guidance | Conforms |
| C.III.1 17.6 | Description of the Applicant's Program for Implementation of 10 CFR 50.65, the Maintenance Rule | Conforms |
| C.III.1 17.6.1 | Scoping per 10 CFR 50.65(b) | Conforms |
| C.III.1 17.6.2 | Monitoring per 10 CFR 50.65(a) | Conforms |
| C.III.1 17.6.3 | Periodic Evaluation per 10 CFR 50.65(a)(3) | Conforms |
| C.III.1 17.6.4 | Risk Assessment and Management per 10 CFR 50.65(a)(4) | Conforms |
| C.III.1 17.6.5 | Maintenance Rule Training and Qualification | Conforms |

10 CFR 50 Appendix B, Criterion I permits delegation of the work of establishing and executing the QA program. Detroit Edison retained responsibility for the quality assurance program as the applicant identified in Subsection 1.4.1. Through contract, Detroit Edison delegated to B&V the work of establishing and executing a QA program satisfying the requirements of 10 CFR 50 Appendix B for COLA development. Safety related COLA sections and associated activities from project initiation through COLA submission were conducted under B&V's 10 CFR 50 Appendix B/NQA-1 program.

STD COL 17.4-1-H Refer to Subsection 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 17.4-1-H • **MR Program:** The MR Program is described in Section 17.6.

Replace the last sentence in this section with the following:

Refer to Subsection 17.4.1 for the implementation of reliability assurance activities.

17.4.13 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 Subsection 17.4.1.

17.4-2-A Operation Reliability Assurance Activities

STD COL 17.4-2-A This COL Item is addressed in Subsection 17.4.1, Subsection 17.4.6, Subsection 17.4.9, Subsection 17.4.10, and Subsection 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

Insert following

~~The following section describes the quality assurance programs applied to Fermi 3 COLA development activities, and COLA support activities, through anticipated COL issuance, in three phases. The first period began with project initiation including, selection of COLA contractor and OE, conduct of site characterization, information gathering, and initial COLA development. The second period began with the approval of the Nuclear Development Quality Assurance Program Description and ends with submittal of the COLA including activities such as; receipt, review, and acceptance of COLA work product from the~~

~~COLA contractor for submittal to the NRC. The third period began with submittal of the COLA and continues through to anticipated COL issuance including updating of the COLA, responding to RAIs and other activities to support NRC review.~~

~~The initial phase of the project was to select a COLA contractor. Detroit Edison intended to fully delegate to the COLA contractor the establishment and execution of the QA program related to the COLA project. Accordingly, 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 under a 10 CFR 50 Appendix B QA program. Black & Veatch (B&V), headquartered in Overland Park, Kansas was ultimately selected as the COLA contractor. Detroit Edison formally established a Nuclear Development group to oversee the COLA project and secured the services of an OE to support owner-related activities such as, but not limited to: reactor technology selection, project cost estimates, development of owner's QA program, engineering support services, and COLA contractor oversight. With these organizational and contractual elements in place, COLA development commenced under the B&V 10 CFR 50 Appendix B/NQA-1 QA program. Major work interfaces for activities affecting COLA development including clear and effective lines of communication were established through the implementation of the B&V Project Management Memorandum (PMM) for the Detroit Edison COLA project.~~

~~The second phase began as Detroit Edison developed the necessary staffing to support the submittal, review, and subsequent maintenance of the COLA. The increase in staffing also included the addition of an experienced QA professional. At the same time, staff of Nuclear Development 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).~~

~~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 (e.g., site characterization, development of conceptual designs). 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 products.~~

~~The third phase commences with submittal of the Fermi 3 COLA. At this point, the ND QAPD is superseded by the Fermi 3 QAPD submitted as part of the COLA (FSAR Chapter 17, Appendix 17AA). B&V remains the COLA contractor for Detroit Edison and continues to perform delegated quality functions. Detroit Edison retains responsibility via processes and programs necessary to implement the Fermi 3 QAPD, including procurement control and verification of the effectiveness of B&V's 10 CFR 50 Appendix B/NQA-1 QA program. All COLA activities through anticipated COL issuance will be completed in accordance with the Fermi 3 QAPD, this includes delegating responsibilities as described in Part II, Section 2 of 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

17.5.1 References

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

STD COL 17.4-1-H

17.6 Maintenance Rule Program

NEI 07-02, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," (Reference 17.6-7) is incorporated by reference with the following supplemental information:

STD SUP 17.6-1

The text of the template provided in NEI 07-02 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)**

Insert 1

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 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 two experienced QA professionals. 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 NDRIF 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.

INSERT NEW TABLE, Table 17.5-201, Quality Assurance Activities for FSAR Section and Supporting Activities

| 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 |
| 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 |

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| 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 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 |
| 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 |
| 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 |

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| 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 2.4.3 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 |
| 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 |
| 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 |

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| 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 2.4.9 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 |
| 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 (RFR-0283) 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 |
| 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 |

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| 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 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 |
| 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 |
| 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 SR-00012) 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 |

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| 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 2.5.2 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 |
| 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 |

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|--|--|--|---|--|--|---|
| 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 |
| 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&V. 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 |

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|---|--|--|---|---|----------------------------|--|
| 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 |
| 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 |

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| 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 |
| 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. Calculations verified per Nuclear Procedures. 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 |

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| 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 9.2.3 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 |
| 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 |

INSERT NEW TABLE, Table 17.5-201, Quality Assurance Activities for FSAR Section and Supporting Activities

| 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 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 |
| 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).