

Mr. R. F. Saunders  
President  
FirstEnergy Nuclear Operating Company  
76 South Main Street  
Akron, OH 44308

December 19, 2001

SUBJECT: CLARIFICATION OF REVISION 1 TO THE FIRSTENERGY NUCLEAR  
OPERATING COMPANY QUALITY ASSURANCE PROGRAM MANUAL -  
BEAVER VALLEY POWER STATION, UNIT NOS. 1 AND 2, DAVIS-BESSE  
NUCLEAR POWER STATION, UNIT 1, PERRY NUCLEAR POWER PLANT,  
UNIT 1 (TAC NOS. MB3009 AND MB3010)

Dear Mr. Saunders:

By letter dated August 17, 2001, we issued "Revision 1 to the FirstEnergy Nuclear Operating Company (FENOC) Quality Assurance Program Manual (QAPM) - Beaver Valley Power Station, Unit Nos. 1 and 2, Davis-Besse Nuclear Power Station, Unit 1, Perry Nuclear Power Plant, Unit 1 (TAC Nos. MB0914 and MB0915)." By letter dated September 27, 2001, FENOC requested clarification of two of the items in our safety evaluation regarding this revision to your QAPM.

The staff has reviewed your request and has found the clarifications appropriate based on the information provided by FENOC. The staff's conclusion regarding Revision 1 to the FENOC QAPM remains that it satisfies the requirements of Appendix B to Title 10 of the *Code of Federal Regulations*, Part 50, and follows the guidance contained in Standard Review Plan 17.3, and is acceptable for use at Beaver Valley Power Station, Unit Nos. 1 and 2, Davis Besse Nuclear Power Station, Unit 1, and Perry Nuclear Power Plant, Unit 1. Consequently, the staff has re-issued the safety evaluation in its entirety as enclosed with the clarifications requested in your letter dated September 27, 2001. The clarifications are identified by revision marks in the right margin.

Sincerely,  
*/RA/*

Lawrence J. Burkhart, Project Manager, Section 1  
Project Directorate I  
Division of Licensing Project Management  
Office of Nuclear Reactor Regulation

Docket Nos. 50-334, 50-412, 50-346, and 50-440

Enclosure: Safety Evaluation

cc w/encl: See next page

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December 19, 2001

SUBJECT: CLARIFICATION OF REVISION 1 TO THE FIRSTENERGY NUCLEAR OPERATING COMPANY QUALITY ASSURANCE PROGRAM MANUAL - BEAVER VALLEY POWER STATION, UNIT NOS. 1 AND 2, DAVIS-BESSE NUCLEAR POWER STATION, UNIT 1, PERRY NUCLEAR POWER PLANT, UNIT 1 (TAC NOS. MB3009 AND MB3010)

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The staff has reviewed your request and has found the clarifications appropriate based on the information provided by FENOC. The staff's conclusion regarding Revision 1 to the FENOC QAPM remains that it satisfies the requirements of Appendix B to Title 10 of the *Code of Federal Regulations*, Part 50, and follows the guidance contained in Standard Review Plan 17.3, and is acceptable for use at Beaver Valley Power Station, Unit Nos. 1 and 2, Davis Besse Nuclear Power Station, Unit 1, and Perry Nuclear Power Plant, Unit 1. Consequently, the staff has re-issued the safety evaluation in its entirety as enclosed with the clarifications requested in your letter dated September 27, 2001. The clarifications are identified by revision marks in the right margin.

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Beaver Valley Power Station, Units 1 and 2

Mary O'Reilly, Attorney  
FirstEnergy Nuclear Operating Company  
FirstEnergy Corporation  
76 South Main Street  
Akron, OH 44308

FirstEnergy Nuclear Operating Company  
Regulatory Affairs Section  
Thomas S. Cosgrove, Manager (2 Copies)  
Beaver Valley Power Station  
Post Office Box 4, BV-A  
Shippingport, PA 15077

Commissioner James R. Lewis  
West Virginia Division of Labor  
749-B, Building No. 6  
Capitol Complex  
Charleston, WV 25305

Director, Utilities Department  
Public Utilities Commission  
180 East Broad Street  
Columbus, OH 43266-0573

Director, Pennsylvania Emergency  
Management Agency  
2605 Interstate Dr.  
Harrisburg, PA 17110-9364

Ohio EPA-DERR  
ATTN: Zack A. Clayton  
Post Office Box 1049  
Columbus, OH 43266-0149

Dr. Judith Johnsrud  
National Energy Committee  
Sierra Club  
433 Orlando Avenue  
State College, PA 16803

L. W. Pearce, Plant Manager (BV-IPAB)  
FirstEnergy Nuclear Operating Company  
Beaver Valley Power Station  
Post Office Box 4  
Shippingport, PA 15077

Bureau of Radiation Protection  
ATTN: Larry Ryan  
P O Box 2063  
Harrisburg, PA 17120

Mayor of the Borough of  
Shippingport  
P O Box 3  
Shippingport, PA 15077

Regional Administrator, Region I  
U.S. Nuclear Regulatory Commission  
475 Allendale Road  
King of Prussia, PA 19406

Resident Inspector  
U.S. Nuclear Regulatory Commission  
Post Office Box 298  
Shippingport, PA 15077

FirstEnergy Nuclear Operating Company  
Beaver Valley Power Station  
ATTN: R. E. Donnellon, Director  
Projects and Scheduling (BV-IPAB)  
Post Office Box 4  
Shippingport, PA 15077

Mr. J. A. Hultz, Manager  
Projects & Support Services  
FirstEnergy Corporation  
76 South Main Street  
Akron, OH 44308

FirstEnergy Nuclear Operating Company  
Beaver Valley Power Station  
Mr. B. F. Sepelak  
Post Office Box 4, BV-A  
Shippingport, PA 15077

Mr. L. W. Myers  
Senior Vice President  
FirstEnergy Nuclear Operating Company  
Beaver Valley Power Station  
Post Office Box 4, BV-A  
Shippingport, PA 15077

Perry Nuclear Power Plant, Units 1 and 2  
FirstEnergy Nuclear Operating Company

cc:

Mary E. O'Reilly  
FirstEnergy Corporation  
76 South Main St.  
Akron, OH 44308

Resident Inspector's Office  
U.S. Nuclear Regulatory Commission  
P.O. Box 331  
Perry, OH 44081-0331

Regional Administrator, Region III  
U.S. Nuclear Regulatory Commission  
801 Warrenville Road  
Lisle, IL 60532-4531

Sue Hiatt  
OCRE Interim Representative  
8275 Munson  
Mentor, OH 44060

Gregory A. Dunn  
Manager - Regulatory Affairs  
FirstEnergy Nuclear Operating Company  
Perry Nuclear Power Plant  
P.O. Box 97, A210  
Perry, OH 44081

Robert W. Schrauder, Plant Manager  
FirstEnergy Nuclear Operating Company  
Perry Nuclear Power Plant  
P.O. Box 97, SB306  
Perry, OH 44081

Mayor, Village of North Perry  
North Perry Village Hall  
4778 Lockwood Road  
North Perry Village, OH 44081

Donna Owens, Director  
Ohio Department of Commerce  
Division of Industrial Compliance  
Bureau of Operations & Maintenance  
6606 Tussing Road  
P. O. Box 4009  
Reynoldsburg, OH 43068-9009

Carol O'Claire, Chief, Radiological Branch  
Ohio Emergency Management Agency  
2855 West Dublin Granville Road  
Columbus, OH 43235-7150

Mayor, Village of Perry  
P.O. Box 100  
Perry, OH 44081-0100

Dennis Clum, Supervisor  
Radiological Assistance Section  
Bureau of Radiation Protection  
Ohio Department of Health  
P.O. Box 118  
Columbus, OH 43266-0118

Ohio Environmental Protection  
Agency  
DERR--Compliance Unit  
ATTN: Mr. Zack A. Clayton  
P.O. Box 1049  
Columbus, OH 43266-0149

Chairman  
Perry Township Board of Trustees  
3750 Center Road, Box 65  
Perry, OH 44081

State of Ohio  
Public Utilities Commission  
East Broad Street  
Columbus, OH 43266-0573

Davis-Besse Nuclear Power Station, Unit 1  
FirstEnergy Nuclear Operating Company

cc:

Mary E. O'Reilly  
FirstEnergy  
76 South Main Street  
Akron, OH 44308

Manager - Regulatory Affairs  
FirstEnergy Nuclear Operating Company  
Davis-Besse Nuclear Power Station  
5501 North State - Route 2  
Oak Harbor, OH 43449-9760

Jay E. Silberg, Esq.  
Shaw, Pittman, Potts  
and Trowbridge  
2300 N Street, NW.  
Washington, DC 20037

Regional Administrator  
U.S. Nuclear Regulatory Commission  
801 Warrenville Road  
Lisle, IL 60523-4351

Michael A. Schoppman  
Framatome ANP  
1700 Rockville Pike, Suite 525  
Rockville, MD 20852

Resident Inspector  
U.S. Nuclear Regulatory Commission  
5503 North State Route 2  
Oak Harbor, OH 43449-9760

Plant Manager  
FirstEnergy Nuclear Operating Company  
Davis-Besse Nuclear Power Station  
5501 North State - Route 2  
Oak Harbor, OH 43449-9760

Harvey B. Brugger, Supervisor  
Radiological Assistance Section  
Bureau of Radiation Protection  
Ohio Department of Health  
P.O. Box 118  
Columbus, OH 43266-0118

Carol O'Claire, Chief, Radiological Branch  
Ohio Emergency Management Agency  
2855 West Dublin Granville Road  
Columbus, OH 43235-2206

Director  
Ohio Department of Commerce  
Division of Industrial Compliance  
Bureau of Operations & Maintenance  
6606 Tussing Road  
P.O. Box 4009  
Reynoldsburg, OH 43068-9009

Ohio Environmental Protection Agency  
DERR--Compliance Unit  
ATTN: Zack A. Clayton  
P.O. Box 1049  
Columbus, OH 43266-0149

State of Ohio  
Public Utilities Commission  
180 East Broad Street  
Columbus, OH 43266-0573

Attorney General  
Department of Attorney  
30 East Broad Street  
Columbus, OH 43216

President, Board of County  
Commissioners of Ottawa County  
Port Clinton, OH 43252

SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION (NRC)

REVISION 1 TO THE FIRSTENERGY NUCLEAR OPERATING COMPANY (FENOC)

QUALITY ASSURANCE PROGRAM MANUAL

FIRSTENERGY NUCLEAR OPERATING COMPANY, ET AL.,

BEAVER VALLEY POWER STATION, UNIT NOS. 1 AND 2 (BVPS-1 AND 2)

DOCKET NOS. 50-334 AND 50-412

DAVIS-BESSE NUCLEAR POWER STATION, UNIT 1 (DBNPS)

DOCKET NO. 50-346

PERRY NUCLEAR POWER PLANT, UNIT 1 (PNPP)

DOCKET NO. 50-440

## 1.0 INTRODUCTION

By letter dated December 27, 2000, (Agencywide Documents Access and Management System [ADAMS] Accession No. ML010120365), First Energy Nuclear Operating Company, et al., (FENOC, the licensee) submitted Revision 1 to the consolidated FENOC Quality Assurance Program Manual (QAPM) for use at BVPS-1 and 2, DBNPS, and PNPP. Revision 0 to the FENOC QAPM was previously approved for DBNPS and PNPP on December 8, 1999 (ADAMS Accession No. ML993550385). The licensee's submittals related to Revision 1 to the FENOC QAPM proposes changes to the QAPM to include the quality program controls for BVPS-1 and 2.

The licensee states that it is highly desirable to maintain a common quality program basis for all of its plants. A consolidated QA program promotes consistent understanding, implementation, administration and oversight of all FENOC QA programs while efficiently using both FENOC and the Nuclear Regulatory Commission (NRC) staff resources by permitting a single evaluation of changes to the QAPM. With this objective in mind, the licensee has requested that the NRC staff review the proposed QAPM for general FENOC application, including future acquisitions.

## 2.0 BACKGROUND

In developing its consolidated QAPM, the licensee has followed the guidance of NUREG-0800, "Standard Review Plan [SRP] for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.3, "Quality Assurance Program Description," and the NRC staff review of a consolidated QA program description previously approved for Entergy Operations, Inc. (EOI), dated November 6, 1998 (Nuclear Documents System [NUDOCS] Accession No. 9811120023).

In conducting the EOI review, the NRC staff found that details specific to the QA program descriptions for individual plants could be reduced by incorporating applicable regulatory guides (RGs) and endorsed standards as a supplement to the QAPM. Further, the NRC staff found that the level of detail could be reduced by describing organizational titles and reporting configurations in more general terms and consolidating details, such as commitments for QA record keeping, into single statements rather than appearing throughout the QA program description. Alternatives and exceptions approved for individual plants were found to be acceptable for application to other plants within the scope of the consolidated QA program. Based on this approach, the NRC staff found that the QA programs for several plants could be consolidated into a single QA program description satisfying Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.34(b)(6)(ii), in describing how the applicable requirements of 10 CFR Part 50, Appendix B, will be satisfied.

### 3.0 EVALUATION

This evaluation adopts the approach used for previous NRC staff reviews of QA program consolidations (e.g., the reviews for the consolidated QAPM for FENOC and EOI that were previously mentioned). The evaluation follows the standardized format of SRP 17.3, which provides acceptance criteria for NRC staff evaluations of QA programs. Licensees may make changes to QA programs without prior NRC approval when those changes conform to the criteria specified in 10 CFR 50.54(a)(3). Such changes were reviewed pursuant to the request of the licensee, but may not be explicitly addressed by this safety evaluation (SE).

SRP 17.3 is organized into three discrete areas of activity: (1) Management, (2) Performance/Verification, and (3) Self-Assessment. Included within these three areas are acceptance criteria for the requirements of 10 CFR Part 50, Appendix B. Except when acceptable alternatives or exceptions are provided, SRP 17.3 identifies the attributes to be addressed for acceptable QA programs. FENOC alternatives and exceptions to applicable RGs and standards are addressed in Section 3.4 of this SE.

#### 3.1 Management

##### 3.1.1 Organization

The proposed revision makes the QA function a corporate position. The individual responsible for QA reports to the individual responsible for oversight and has overall authority and responsibility for verifying the implementation and adequacy of the QA program as described in the QAPM. The individual responsible for QA has the authority and responsibility to escalate matters directly to the president and chief nuclear officer. The revision includes provisions to reflect the continued independence of quality control functions that will remain on-site. The change remains consistent with the guidance of SRP 17.3.II.A.2 and is, therefore, acceptable.

##### 3.1.2 Regulatory Commitments

A general clarification is added to this section stating that regulatory guidance originally intended to apply to design or construction activities will be applied to operational activities that are comparable in nature and extent to construction phase activities. This is not a change in commitment, but is appropriately brought forward to the main body of the QAPM rather than duplicating the clarification for specific RGs. Because this change does not reduce any commitments, it is acceptable.

### 3.2 Performance/Verification

Changes to this section are consistent with the guidance provided in SRP 17.3. The changes can be characterized as changes that do not reduce commitments. In general, the level of detail is reduced to allow for differences in the way individual plants implement the QA program. Examples include a list of documents included in the document control program and a list of controlled processes. These details are adequately covered by the licensee's commitments to applicable RGs or at a level controlled by site administrative procedures. The revised QAPM commitments are consistent with the level of detail previously approved by the NRC staff. Therefore, these changes are acceptable.

### 3.3 Self-Assessment

#### 3.3.1 Audits

The licensee follows the guidance of RG-1.33, "Quality Assurance Program Requirements (Operations)," Revision 2, and RG-1.144, "Auditing of Quality Assurance Programs for Nuclear Power Plants," Revision 1, with regard to the conduct of audits. RG 1.33 endorses ANSI N18.7-1976/ANS-3.2, subject to certain regulatory positions. ANSI N18.7-1976/ANS-3.2 recommends that audits of selected aspects of operational phase activities be performed with a frequency commensurate with their safety significance and in such a manner as to ensure that an audit of all safety-related functions is completed within a period of 2 years. RG-1.33, Regulatory Position C.4, amplifies the guidance of ANSI N18.7 in establishing minimum audit frequencies of 6 months for review of corrective action programs (CAPs) and of 12 months for review of conformance to the technical specifications (TSs) and license conditions. The NRC staff has found acceptable a 24-month minimum frequency for audits of CAPs, TSs and license conditions. The licensee's program for conducting periodic audits (QAPM, C.2.a.2) is consistent with this guidance.

As an alternative to the frequency-based method for scheduling audits, the licensee proposes to adopt a performance-based alternative. The alternative performance-based method (QAPM, C.2.a.1) is implemented through an expert panel and uses performance indicators. The currently approved scheduling method (QAPM, C.2.a.2) will be used except when the expert panel determines on the basis of performance results that an audit frequency requirement can be waived. The assessment process and expert panel determinations are documented as QA records and are available for NRC review.

The NRC staff has previously found this alternative to be acceptable for the EOI QAPM. The licensee states that the performance-based alternative provides adequate assurance that degradation in performance is detected in a timely manner and that additional audits must be performed (QAPM, C.2.a.2.6) when the effectiveness of quality program controls is in doubt. The CAP (QAPM, A.6) provides a mechanism for performance issues to be identified and subsequently audited (QAPM, C.2.a.2.c). The NRC staff finds the previously-approved alternative to be acceptable for application to the FENOC QA program.

### 3.4 Supplemental RGs (Table 1)

SRP 17.3, Section A.II.7, "Regulatory Commitments," effectively states that, except where acceptable alternatives are provided, the licensee shall comply with the regulatory positions in the appropriate revisions of the applicable guidance documents specified in SRP 17.3, Section VI, "References." RG 1.33, Revision 2, supplements this guidance by incorporating by

reference additional RGs and standards applicable to the operations phase. The licensee proposes to relocate the following commitments to RGs from the QAPM to other sections of the updated final safety analysis reports (UFSARs) for the individual plants.

#### 3.4.1 Relocation of Certain QAPM Commitments

The licensee proposes to relocate commitments to RG 1.28, "Quality Assurance Program Requirements (Design and Construction)," and RG 1.54, "Quality Assurance Requirements for Protective Coatings Applied to Water-Cooled Nuclear Power Plants," from the QAPM to the UFSARs for the individual plants. Applicable portions of RG-1.28 and RG-1.54 and their associated standards are incorporated by reference in ANSI N18.7/ANS 3.2-1976 and by Regulatory Position C.2 of RG-1.33, Revision 2. Since the licensee has retained its commitments to RG-1.33, Revision 2, and ANSI N18.7/ANS 3.2-1976 in the QAPM, the proposed relocation of these commitments is acceptable.

The licensee proposes to relocate commitments to RG 1.78 "Assumptions for Evaluating the Habitability of a Nuclear Power Plant Control Room During a Postulated Hazardous Chemical Release," from the QAPM to the UFSARs for the individual plants. This RG provides guidance in specific technical areas covered by 10 CFR Part 50, Appendix A. Davis Besse also proposes to relocate its commitment to RG 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operation) Effluent Streams and the Environment." This RG provides guidance on technical areas covered by 10 CFR Part 20. Subsequent to relocation, changes to these commitments would be controlled by the change control process established by 10 CFR 50.59. Therefore, the proposed relocation of these commitments is acceptable.

The licensee proposes to relocate commitments to RG 1.26, "Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," and RG 1.29, "Seismic Design Classification," from the QAPM to the UFSARs for the individual plants. These RGs and complementary standards provide the technical bases for determining the set of structures, systems, and components subject to the QA requirements of Appendix B to 10 CFR Part 50. Subsequent to relocation, changes to these commitments would be controlled through the regulatory change control process established by 10 CFR 50.59. Since these guides provide a technical basis for equipment classification, the NRC staff finds that 10 CFR 50.59 provides an appropriate change control process for these guides. Therefore, the proposed relocation of these commitments is acceptable.

#### 3.4.2 Adoption of Generic Positions

The licensee proposes to revise its currently-approved QAPM such that clarifications, alternatives, and exceptions to RGs and standards are applicable to all of its nuclear facilities. To accomplish this, certain plant-specific clarifications and alternatives have been deleted while others have been adopted on a generic basis. Adoption of generic positions is facilitated by 10 CFR 50.54(a)(3)(ii), which permits a licensee to adopt QA alternatives or exceptions approved by an NRC SE, provided that the bases of the NRC approval are applicable to the licensee's facility. In the event that alternatives or exceptions have been approved without an SE (e.g., prior to 1997), the regulatory analysis supporting the regulation (35 FR 9032) makes clear that NRC review is required prior to adoption of such alternatives or exceptions. The following sections address NRC staff review of previously approved alternatives for generic application to the FENOC QAPM.

3.4.2.1 RG 1.33, "Quality Assurance Program Requirements (Operations)," Revision 2, dated February 1978

RG 1.33, Revision 2, endorses ANSI N18.7/ANS 3.2-1976. For Revision 0 of the QAPM, the NRC staff accepted the licensee's proposed commitment to a later version of the standard (ANS 3.2-1982). The licensee's proposal to return to the endorsed version of the standard (ANSI N18.7/ANS 3.2-1976) is acceptable.

3.4.2.2 RG 1.39, "Housekeeping Requirements for Water Cooled Nuclear Power Plants," Revision 2, dated September 1977

The licensee proposes an alternative to guidance of ANS N45.2.3-1973 in that the ANSI five-level zone designation system may not be utilized, but the intent of the standard will be met for the areas of housekeeping, plant and personnel safety, and fire protection. The NRC staff finds that the alternative, previously accepted by the NRC staff (consolidated EOI QAPM SE dated November 6, 1998), is acceptable for application to the FENOC QAPM.

3.4.2.3 RG 1.58, "Qualification of Nuclear Power Plant Inspection, Examination and Testing Personnel," Revision 1, dated September 1980

1. The licensee clarifies its position that qualification of nondestructive examination personnel will be in accordance with the applicable version of American Society of Mechanical Engineers (ASME), Section XI, as defined by 10 CFR 50.55a. The NRC staff finds the clarification, which references the controlling regulation, acceptable.

2. The licensee proposes the following alternative to ANSI N45.2, Section 2.5, "Physical":

"Examinations to verify that personnel have the required physical characteristics will be scheduled on an annual basis with a maximum allowable extension of 90 days."

The NRC staff finds the extension, previously approved for BVPS-1 and 2, to be acceptable for application to the FENOC QAPM.

3. The licensee proposes the following alternative to ANSI N45.2, Section 3.5, "Education and Experience - Recommendations":

"The initial qualifications of individuals to Level I, II, or III will generally be to the education and experience recommendations in the Standard. However, in certain instances as determined by appropriate management, qualifications may be alternatively determined through test results and/or demonstration of capabilities. For Level I, FENOC will also accept a four-year college degree plus one month of related experience or equivalent inspection, examination or testing activities. Individual requalification will meet or exceed the recommendation of this Standard."

The NRC staff finds the alternative, approved for BVPS-2 at the time of licensing, acceptable for application to the FENOC QAPM.

3.4.2.4 RG 1.88, "Collection, Storage and Maintenance of Nuclear Power Plant Quality Assurance Records," Revision 2, dated October 1976

The licensee proposes the following alternative to ANSI N45.2.9-1974, Section 5.6, "Facility":

“...[T]he design and construction of quality assurance record storage facilities will follow the guidance of ANSI/ASME NQA-1-1983, Supplement 17S-1, Section 4.4. When temporary storage of records is required, the guidance of ASME NQA-1-1989, Supplement 17S-1, Section 4.4.3 will be followed. For storage of special processed records (such as radiographs and microfilm), humidity and temperature controls shall be provided so as to maintain an environmental condition as prescribed in Paragraph 6.1.1 of ANSI PH 1.43-1979...”

The NRC staff finds the alternative, previously approved for BVPS-1 and 2, acceptable for application to the FENOC QAPM.

3.4.2.5 RG 1.94, “Quality Assurance Requirements for Installation, Inspection and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants,” Revision 1, dated April 1976

The licensee proposes the following alternative to ANSI N45.2.5-1974 with respect to the frequency of calibration of impact wrenches and bolt projection criteria:

“Impact and torque wrenches shall be checked at least once daily per shift, and at least one full thread of all bolts shall project beyond the nut of all tightened connections. These criteria comply with the recommendations of the Research Council on Riveted and Bolted Structural Joints.”

The NRC staff finds the alternative, incorporated in the BVPS-1 and 2 construction QA program, acceptable for application to the FENOC QAPM.

3.4.2.6 RG 1.144, “Auditing of Quality Assurance Program for Nuclear Power Plants,” Revision 1, dated September 1980

1. The licensee proposes the following clarification to ANSI N45.2.12-1997, Sections 4.3.1 and 4.3.3, which address pre-audit and post-audit conferences.

“Pre-audit and post-audit conferences may be fulfilled by a variety of communications, such as telephone conversation.”

The NRC staff finds this clarification, previously approved for BVPS-1 and 2, acceptable for application to the FENOC QAPM.

“Pre-audit and post-audit conferences are only held when deemed necessary by quality assurance or when requested by the audited organization.”

The NRC staff finds this alternative, previously accepted by the NRC staff (consolidated EOI QAPM SE dated November 6, 1998), acceptable for application to the FENOC QAPM.

2. The licensee proposes the following alternative to ANSI N45.2.12-1997, Section 4.4, which addresses audit reporting.

“Audit reports shall be issued within thirty working days after the last day of the audit. The last day of an audit shall be considered to be the day of the post-audit conference. If a post-audit conference is not held because it was deemed

unnecessary, the last day of the audit shall be considered to be the date the post-audit conference was deemed unnecessary as documented in the audit report.”

The NRC staff finds this alternative, previously accepted by the NRC staff (consolidated EOI QAPM SE dated November 6, 1998), acceptable for application to the FENOC QAPM.

3.4.2.7 RG 1.146, “Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants,” Revision 0, dated August 1980

1. The licensee proposes the following alternative to ANSI N45.2.23-1978, Section 2.3.1.3, which discusses credentials of professional competence.

“Holders of NRC issued Reactor Operator/Senior Reactor Operator Licenses comply with the requirements of this section and may be awarded two credits.”

The NRC staff finds this alternative, previously accepted by the NRC staff (consolidated EOI QAPM SE dated November 6, 1998), acceptable for application to the FENOC QAPM.

2. The licensee proposes the following alternative to ANSI N45.2.23-1978, Section 2.3.4, which addresses previous audit participation by lead auditors.

“Prospective lead auditors shall demonstrate their ability to effectively implement the audit process and lead an audit team. They shall have participated in at least one nuclear audit within the year preceding the individual's effective date of qualification. Upon successful demonstration of the ability to effectively lead audits, licensee management may designate a prospective lead auditor as a lead auditor.”

The NRC staff finds this alternative, previously accepted by the NRC staff (consolidated EOI QAPM SE dated November 6, 1998), acceptable for application to the FENOC QAPM.

#### 4.0 CONCLUSION

Revision 1 of the QAPM describes the quality program controls for the four FENOC operating nuclear plants. In revising the QAPM, plant-specific elements have been suppressed in favor of a more generic approach. Based on the NRC staff's review of the revised QAPM, the staff concludes that the consolidated FENOC QAPM satisfies the requirements of Appendix B to 10 CFR Part 50 and follows the guidance contained in SRP 17.3. Consequently, Revision 1 to the FENOC QAPM, as proposed by letter dated March 19, 2001, and as supplemented by letters dated June 4, and June 28, 2001, is acceptable for use at BVPS-1 and 2, DBNPS, and PNPP.

The licensee's generic approach has been developed, in part, in anticipation of future license acquisitions. The submittal requested that the NRC staff review the acceptability of the QAPM for generic applicability. The regulations, as specified in 10 CFR 50.54(a), provide considerable flexibility for licensees to make changes to QA program descriptions without prior NRC approval. However, the NRC staff finds that it cannot conclude that the QA program would be generically acceptable prior to identification of a specific license. The applicability of the QAPM would need to be evaluated by the licensee and by the NRC staff, as required by applicable regulations, at the time a license is acquired. Potential candidates would need to be evaluated,

for example, with respect to specific conditions of the license, administrative control technical specifications, and other regulatory commitments prior to inclusion in the licensee's QA program.

Principal Contributor: K. Heck

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