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Date: 5/10/01 11:34AM
Subject: FENOC draft response to RAI

See attached draft response to RAI
(See attached file: Response to RAI.doc)

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1. NRC RAI Question 1.

Question

The Direct Final Rule, effective on April 26, 1999 (64 FR 9030), revises the regulation of Title 10 of the Code of Federal Regulations (10 CFR) Section 50.54(a)(3) to provide additional flexibility for licenses making changes to their QAP without obtaining Nuclear Regulatory Commission (NRC) approval of these changes in advance. Forty-nine changes to the QAP have been identified in Attachment 4 of the submittal. Please identify those changes considered to be reductions in commitments.

Response

BVPS identified the following items as reductions in commitments: 14, 24, 30, 32, 44 and 46.

Perry identified the following items as RIC's: 1, 11, 12, 14, 15, 17, 19, 20, 21, 23, 24, 27, 28, 29, 30, 32, 33, 34, 37, 39, 42, 43, 44, 45, 46, 47, and 49.

Davis-Besse identified the following as RIC's: 11, 12, 14, 15, 17, 19, 20, 21, 23, 24, 27, 28, 29, 30, 32, 33, 34, 37, 39, 42, 43, 44, 45, 46, 48 and 49.

2. NRC RAI Question 2.
Question:

The QAPM revision creates a corporate QA oversight function (Attachment 3, Section A.2.a). Please clarify whether this function implements the guidance of ANSI N18.7 – 1976, Section 4.3, for an independent review. Clarify how the provisions of Section 4.3 are implemented. Describe any reporting relationships between the sites and the corporate function. (Side Bar 3)

Response:

Revision 0 of the FENOC Quality Assurance Program Manual (QAPM), as currently implemented by Davis-Besse and Perry, established the corporate function for establishing the policies, goals, and objectives for the FirstEnergy Nuclear Operating Company (FENOC), and implementing and controlling the FENOC QAPM (paragraph A.2.a.1). The Director of this organization also functions as the off-site review committee chairman, which includes responsibility for the administration of the committee's activities. This function reports to the chief executive officer (President and Chief Nuclear Officer of FENOC) as described in paragraph A.2.a. During the development of Revision 1 of the FENOC QAPM this function was evolving, and it was decided to include the quality assurance oversight function.

Revision 1 therefore moved the discussion for quality assurance oversight from its current reporting relationship at the site level (paragraph A.2.c.1) under paragraph A.2.a.1 (as described above). With this move, it was intended that the quality assurance oversight function (i.e., audits) would be a corporate function with dedicated QA organizations

physically located at each site. In addition to the site level traditional QA oversight function, this organizational alignment would facilitate a collective assessment function to improve performance at all sites consistently.

This organization and the associated functions fulfill the requirements of ANSI N18.7 – 1976 for the independent review and audit programs. As the QA oversight function, the organization satisfies the requirements of Section 4.4. As the off-site review committee function, the Director satisfies the requirements of Section 4.3. This includes ownership of the committee's charter (Section 4.2.1) and administration of the committee's activities (Sections 4.2.2, 4.2.3, 4.2.4, and 4.2.5). Individuals assigned to the committee satisfy the qualification requirements of Section 4.2 and ANSI N18.1. Subjects reviewed by the committee satisfy the requirements of Section 4.3.

The Director of this organization reports to the President and Chief Nuclear Officer. The QA Managers located at the sites report to the Director, but have access to site management for purposes of conducting audits and assessments. Individuals associated with paragraphs A.2.a.1 and A.2.a.1.a) are independent from cost and schedule when opposed to safety considerations. The independent review committee is comprised of both on-site and off-site individuals, and serves all sites.

3. NRC RAI Question 3.

Question

Changes in commitment to Regulatory Guide (RG) 1.8, "Personnel Selection and Training," should continue to be subject to the review requirements of 10 CFR 50.54(a). RG 1.8 is explicitly referenced by Standard Review Plan 17.3 as applicable to the QA regulations of Appendix B. (Side Bar 6)

Response

The wording deletion was not meant to reflect any change in the application of RG 1.8, "Personnel Selection and Training." The Regulatory Guide or its equivalent is contained as a requirement in each plants technical specifications. The following information will be added to Table 1 of the FENOC QAPM:`

A. Regulatory Guide 1.8 (Revision 1) [September 1975], *Personnel Selection and Training*

1. FENOC commits to the regulatory position of this Guide with the following clarifications:

    a. Regulatory Guide 1.8 states "The RPM should have a bachelor's degree or the equivalent in a science or engineering subject including some formal training in radiation protection and at least 5 years of professional experience in applied radiation protection." It is FENOC's position that equivalent as used in this Regulatory Guide for

the bachelor's degree means (a) four years of post secondary schooling in science or engineering, or (b) four years of applied experience at a nuclear facility in the area for which qualification is sought, or (c) four years of operational or technical experience or training in nuclear power, or (d) any combination of the above totaling four years. The years of experience used to meet the education requirements as allowed by this exception shall not be used to also meet the experience requirements.

b. FENOC commits to the requirements of ANSI N18.1-1971 as modified by plant specific Technical Specifications.

2. NRC RAI Question 4

Question

The original wording "the guidance will be applied to activities comparable in nature and extent to construction phase activities," is clearer than the proposed clarification (Attachment 3, Section A.7.a.5) and should be retained. (Side Bar 9)

Response

The wording change was intended to provide clarity and was not intended to reflect any change in the application of regulatory guidance to plant operations. To ensure clarity, the wording in Section A.7.a.5 will be revised to read as follows: "Regulatory guidance originally intended to apply to design or construction phase activities, will be applied to activities during the operations phase that are comparable in nature and extent to construction phase activities."

3. NRC RAI Question 5

Question

The revised QAPM differentiates between audits that satisfy appendix B requirements and those that do not. Identify which of the audits in Section C.2.a satisfies appendix B requirements. Clarify any differences in QAP implementation for the two audit types. Particularly with respect to RG 1.144 and 1.146. (Side Bar 16)

Response

Side Bar 16 indicates that not all of the subsequently listed audits are Appendix B audits. This statement was added because the list contained only those audits that had been located in technical specifications. Technical specifications identified these as audits performed under the cognizance of the independent review committee. In practice, many of these audits were performed by the QA organization at the request of the independent review committee because these auditing resources were readily available. However, the audits were not necessarily being performed for the purpose of satisfying Appendix B, particularly when they examined activities that were not subject to Appendix B. Since the QAPM describes an Appendix B QA program, it is expected that readers would naturally

infer that the listed audits are all related to Appendix B unless a clarifying statement is provided. The statement was also added to prevent possible misconception that all of the audited topic areas and activities are subject to Appendix B controls.

Regulatory Guides 1.144 and 1.146 describe acceptable methods for auditing of Appendix B QA programs. These must be applied to audits of the Appendix B program and when a commitment has been made to apply the Appendix B QA program to satisfy non-Appendix B QA requirements, such as for dry fuel storage. Although not required by the license, FENOC commitments to these guides would usually be applied also to other audits (i.e. non-Appendix B audits) because there is normally no practical advantage to deviating from prevailing practices of the auditing organization. Therefore, no differences in audit implementation are anticipated.

Items “e through j” are the activities which are not directly subject to Appendix B requirements.

4. NRC RAI Question 6

Question

Commitments to the following regulatory guides (and associated standards) are proposed to be removed from the QAPM: RG 1.26, RG 1.29, RG 1.54, RG 1.55, RG 4.15, and RG 1.78. If these commitments are duplicated elsewhere in the Final Safety Analysis Reports (FSAR’s), please provide the reference to applicable FSAR sections for each plant. If these commitments are to be relocated in conjunction with the QAPM revision, identify the FSAR sections where they will be relocated, provide marked-up pages indicating any revisions that will be made to the relocated QAPM revision. Cite instances where an NRC safety evaluation has approved removal of any of these commitments to RGs from a licensee’s QAP. (Side Bar 19, 21, 33, 34, 48, 49)

Response

For those regulatory guides which are being relocated, both their proposed location and schedule for the relocation are provided. In those instances where a regulatory guide already exists in the USAR (Beaver Valley), the locations where they reside is being provided to you, along with any clarifying information. It should be noted, that Davis-Besse is the only FENOC plant committed to R.G. 4.15 and that Beaver Valley Unit 1 is not committed to R.G. 1.55. The version of the subject regulatory guides committed to at the various plants may vary, due to the different licensing dates.

In regard to the request to cite instances where an NRC safety evaluation has approved removal of any of these commitments to RGs from a licensee’s QAP (side Bars 19-RG 1.26, 21-RG 1.29, 33 RG 1.54, 34-RG 1.55, 48-RG 4.15 and 49-RG-1.78), see the BVPS-1 and 2 SERs (enclosure1 In the Section 4.9 of the SER for ENTERGY, the NRC staff noted the increased importance of regulatory guide positions due to the elimination of text in the QAPM. Specifically, NRC staff reviewed the proposed regulatory guide positions in Table 1 against existing commitments to

regulatory guides and standards for each of the ENTERGY plants (in the QA Program descriptions). Several existing regulatory guide positions which were in the QA Program descriptions were removed from the QAPM. The NRC noted changes to regulatory guide positions that they considered significant reductions in commitments and the regulatory guide positions being deleted were not included in their discussion.

BVPS-2

In Table 17.1 , the original SER for BVPS-2 (NUREG 1057) the NRC listed the regulatory guidance applicable to the quality assurance program. Regulatory Guides 1.26, 1.29, 1.54, 1.55, 4.15 and 1.78 are not listed in this Table. Therefore, although BVPS-2 committed to all but R.G. 4.15, these commitments were not considered to be part of the quality assurance program description for Unit 2 .

BVPS-2 UFSAR Table 1.8-1 contains the positions for Regulatory Guides 1.26, 1.29, 1.54, 1.55, and 1.78. BVPS-2 has not committed to R. G. 4.15 and therefore it would not be included in Table 1.8-1.

BVPS-1

The applicable sections of the BVPS-1 UFSAR that contain the positions for the Regulatory Guides Unit 1 is committed to follow: Safety Guide 26, Section 1.3.3.26, Safety Guide 29, Section 1.3.3.29, R.G. 1.54, Section 1.3.4.1 and R.G. 1.78, Sections 2.1.5 and 9.13.4. It should be noted that BVPS-1 has not committed to R. G.s 1.55 and 4.15. When the NRC reviewed the BVPS-1 quality assurance program description for compliance with the requirements of 10 CFR 50, Appendix B, the results of their review were documented in Section 17.1 of the SER.

Davis-Besse

Regulatory Guides 1.26 and 1.29 are currently discussed in USAR Section 3D. Regulatory Guide 1.78 is discussed in USAR Sections 2.2, 2.7, 6.4 and 15.5. Regulatory Guides 1.54, 1.55 and 4.15 are not currently discussed in the USAR. For those Regulatory Guides not discussed in the USAR, USAR changes will be made to include them in the USAR, within 60 days of NRC approval of the QAPM and prior to adoption of the FENOC QAPM at Davis-Besse. Marked up copies of the USAR pages where these Regulatory Guides will be included are contained in enclosure 2.

Perry

At the time of implementation of the proposed revision to the QAPM, the degree of conformance to the affected Regulatory Guides being deleted from the QAPM which Perry is committed to, will be placed in Table 1.8-1 of the Perry USAR. A draft copy of the proposed USAR change is included as enclosure 3. In Table 17.1 , of the original SER for PNPP (NUREG ____) the NRC listed the regulatory guidance applicable to the quality assurance program. Regulatory Guides 1.54, 1.55, 4.15 and 1.78 are not listed in this Table. Therefore, these commitments were not considered to be part of the quality assurance program description for PNPP.

7. NRC RAI Question 7

Question

With respect to RG 1.30, the QAPM commitment is revised to meet the intent instead of the positions of the RG. Clarify the term “intent” by specifying the proposed exceptions or alternatives to RG 1.30. (Side Bar 22)

Response:

Although BVPS 2 was licensed to the position in the proposed Revision 1 of the FENOC QAPM, it was decided to maintain the existing FENOC position and apply it to all plants by including the following position in Table 1 of the FENOC QAPM:

Regulatory Guide 1.30 (Revision 0) [August 1972], *Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment*

1. FENOC commits to the regulatory position of this Guide.

2. FENOC commits to the requirements of ANSI N45.2.4-1972 with the following clarifications:

a. Section 1.1 specifies equipment to which this Standard applies. In lieu of this, requirements of this Standard shall apply to those systems and components that are within the scope of the QAPM. Each plant maintains a list of equipment subject to QAPM requirements. This Standard is also applied to other systems and components when required by approved procedures, engineering specifications, or other work controlling documents.

b. Section 2.2 requires that evidence of compliance by the manufacturer with purchase requirements, including quality assurance requirements, be available at the site prior to applying the requirements of ANSI N45.2.4. In lieu of this requirement, installation, inspection, and testing activities of equipment lacking its quality documentation may proceed provided that this equipment has been identified and released in accordance with non-conforming material procedures and that all required quality documentation has been received and accepted prior to the item being placed in service.

c. Section 3 requires that records of protective measures maintained during storage for conformance to storage requirements be checked to verify that items are in satisfactory condition for installation. This check shall be made only if equipment requires special storage or handling as specified in procurement documents.

d. Sections 5.2 and 6.2 list the tests which are to be conducted during construction and post-construction activities. In lieu of these tests, FENOC shall conduct only those tests necessary to verify that work activities specified by work controlling documents have been satisfactorily accomplished during maintenance or modification activities. The requirements of Sections 5.2 and 6.2 of ANSI N45.2.4 shall be used as guidelines in determining these testing requirements.

e. Section 6.2.1 states in part that “Items requiring calibration shall be tagged or labeled on completion indicating date of calibration and identity of person that performed the calibration.” In lieu of this requirement, FENOC may alternatively implement programs that require the equipment to be suitably marked to indicate the date of the next calibration and the identity of the person that performed the calibration.

8. NRC RAI Question 8

Question

The QAPM revision proposes an exception to the guidance of ANSI N18.7, Section 4.3 in that the license amendments will not be independently reviewed. The basis provided (Attachment 4) is that amendments are reviewed by an onsite review body (ANSI N 18.7, Section 4.4). Since the onsite review body already reviews license amendment changes as part of its responsibilities, the exception effectively eliminates independent review. Provide additional justification for this exception. (Side Bar 24)

Response:

The proposed changes to the FENOC Quality Assurance Plan include the elimination of the requirement for the Company Nuclear Review Board (CNRB) to independently review all license amendment requests (LARs). The three FENOC plants each generate 10 to 20 LARs, on average, per year. Each LAR typically contains detailed system or analysis related information. The presentation and explanation of this information to the CNRB consumes a significant amount of the CNRB's time. In FENOC's experience, the detailed information contained within the LAR documentation now receives a comparable independent review by plant organizations, as required by the plant administrative procedures governing LAR preparation, review, and approval prior to submittal to the NRC. Recognition of these independent reviews and the elimination of the CNRB independent review of LARs would allow the CNRB to focus on other more pertinent contemporary issues that warrant oversight.

The requirement for the CNRB to review all changes proposed to the Technical Specifications and Operating License is based on the standards contained in ANSI N18.7-1976, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants" (the standard) which is endorsed by Regulatory Guide 1.33, " Quality Assurance Program Requirements." The specific review requirement is contained in Section 4.3.4 of the standard, " Subjects Requiring Independent Review." Section 4.3.4 of the standard lists the items that require independent review. Item (3) of Section 4.3.4 specifies "Changes in the technical specifications or license amendments relating to nuclear safety…." The standard defines an independent review as follows:

> “Review completed by personnel not having direct responsibility for the work function under review regardless of

> whether they operate as part of an organizational unit or as individual staff members…"

Each FENOC plant performs an extensive independent onsite review of LARs. The preparation of LAR documentation is typically the direct responsibility of the Regulatory Affairs section at each FENOC site. As a minimum, each LAR typically receives an independent review by engineering personnel with specific system or analysis background pertinent to the subject of the LAR, an Operations independent review, and an independent committee review by the onsite safety review committee. Additional reviews of the LAR are performed by Regulatory Affairs personnel and upper management prior to submitting the LAR to the NRC. As part of the proposed elimination of the CNRB required review of LARs, FENOC would commit to a more formal requirement that each LAR receive an independent review by engineering personnel and, Operations personnel in addition to the currently required independent review by the onsite safety review committee.

The series of onsite reviews used to process an LAR ensures that each LAR receives a multidisciplinary independent review by qualified plant personnel. As such, the onsite review process fulfills the requirement for an independent review as defined in the standard. In addition, once submitted to the NRC, the LAR undergoes additional detailed review by the NRC staff. It is significant to note that unlike many other items reviewed by the CNRB, LARs are ultimately subject to NRC review and approval.

In Section 4.1 of the standard, where general review and audit information is discussed, the standard explains that,

> "This standard does not specify an organizational structure for meeting the review and audit functions, but in lieu thereof delineates essential elements of satisfactory comprehensive programs for review and for audit in the manner best suited to the owner organization involved."

Section 4.1 recognizes that "The programs provided for reviews and for audits may take different forms." The standard goes on to describe that,

> "Historically a committee approach was used to provide both review and audit capability for early commercial nuclear power plants. This approach was employed to make the most efficient use of people with pertinent experience and qualifications. In the ensuing period, the availability of competent personnel has significantly increased as the nuclear power industry has expanded and the sources of trained manpower have responded to the resulting demand. This growing pool of talent in the aggregate, is sufficient to encourage alternative approaches to the review and audit committees commonly used in the past."

The standard further recognized that expanding nuclear power owner organizations "should regard the use of committees to meet the independent review functions as an interim approach for effective utilization of available technical expertise." Accordingly, even as early as 1972 the standard recognized that the necessity of a standing committee to effectively share experienced manpower may no longer be necessary. Over the years

the FENOC plants have developed a large extensive body of onsite technical expertise that is now routinely utilized for the review functions addressed in the standard.

In the early 1970's, during which time the standard was being developed, onsite staffing levels at plants being built were projected to typically be less than a hundred in total number. Today, however, the typical onsite technical and operating staff levels alone are several hundred. This much larger onsite staff provides a significant increase in the technical expertise available to review LARs. Factoring this growth of expertise available for use at each FENOC plant to independently review LARs provides a viable alternative to the CNRB's review of LARs.

In summary, the proposed change to the FENOC Quality Assurance Plan eliminates the requirement for the CNRB to review LARs. However, for LARs, the FENOC plants have developed the "alternative" approach to a standing "offsite" review committee as suggested by the standard. The utilization of onsite expertise, including an independent review by the onsite review committee, effectively meets the requirements of the standard and has eliminated the need for an additional CNRB review of LARs. Due to the level of review now provided by experienced onsite personnel, which is comparable to the level of review provided by the CNRB, the elimination of the CNRB review of LARs does not reduce the effectiveness of the FENOC Quality Assurance Plan nor does it affect how the plan complies with 10CFR50 Appendix B.

9. NRC RAI Question 9

Question

The revised commitment to RG 1.33 reduces the scope of applicability of QA requirements to structures, systems, and components (SSCs) that are "safety related." Currently, the QAPM is applicable to SSCs that are "important to safety. The regulations do not always differentiate between the terms "important to safety" and "safety-related." For example, the General Design Criteria apply to SSCs important to safety, although the term "safety-related" is generally implied. IEEE Standard 279 which addressees protection systems, refers to important to safety functions: this standard is incorporated by reference into the regulations (10 CFR 50.55a(h)). Further, SSCs that are "important to safety", but not necessarily "safety-related" generally fall within the scope of most QAPs to an extent consistent with their importance to safety (appendix B, criterion 11). Examples of nonsafety-related SSCs that are important to safety include those associated with systems designed to prevent or mitigate anticipated transients without scram, station blackout, and fire protection. A more complete discussion should be provided, which defines the scope of the FENOC QAP in general and the specific examples cited above. (Side Bar 26)

Response

The change in wording in Table 1, Section B.2.a, Revision 1 of the FENOC QAPM, from "… functions important to the safety of nuclear power plant structures, systems

and components" to "… affecting the safety-related functions of nuclear power plant structures, systems and components" was made to reflect the wording in Section 1, Scope of ANSI N18.7-1976 which FENOC is committing to, and which is the ANSI standard endorsed by the NRC in R.G. 1.33, Revision 2. The wording in Revision 0 of the FENOC QAPM reflected the words in Section 1 of ANSI/ANS 3.2-1982, which FENOC had previously committed to, and which the NRC has not endorsed. Both Revision 0 and Revision 1 of this section of the QAPM are in quotation marks, since they reflect the actual wording of the ANSI Standards referenced. The proposed change was not made to reflect any change in the scope of applicability of R.G. 1.33 to structures, systems and components at the FENOC plants.

10. NRC RAI Question 10

Question

Procedural controls are generally included in plant technical specifications under administrative controls (10 CFR 50.36(a)(5)). The NRC has allowed licensees to relocate certain administrative controls, including those for procedure adherence, to the QAP. For each plant covered by the QAPM, identify the licensing basis document that includes the process for controlling temporary changes to procedures. For each plant, identify the regulatory process used for controlling these changes. Cite references to NRC safety evaluations that have approved control of these changes through the 10 CFR 50.59 change control process. (Side Bar 30)

Response

Table 1, item B.2.c will be changed to read as follows:

Section 5.2.2 requires that "temporary changes which clearly do not change the intent of the approved procedure shall, at a minimum, be approved by two members of the plant staff knowledgeable in the areas affected by the procedure. At least one of these shall be the supervisor in charge of the shift and hold a senior operating license on the unit affected. Such changes shall be documented and if appropriate, incorporated into the next revision of the affected procedure." In lieu of these requirements, FENOC commits to the following:

Temporary changes to procedures which do not change the intent of the approved procedure shall be approved for implementation by two members of the plant management staff, at least one of whom holds a Senior Reactor Operating License for the unit affected. The temporary procedures shall be approved by the original approval authority within 14 days. For changes to procedures which may involve a change in intent of the procedure, the original approval authority shall approve the change prior to implementation. OR

Temporary changes to procedures will be approved by two knowledgeable members of the plant staff prior to implementation. At least one of these persons will be a member of supervision. If the change affects operations procedures, at least one of these persons will hold a senior reactor operator license for the unit affected. Prior to implementation, the OSC (PORC) shall review and recommend approval of temporary changes to procedures which require a 10CFR50.59 safety evaluation. Within 14 days of implementation, temporary changes will be reviewed by an independent qualified reviewer and approved by the Responsible Discipline Manager or his designee.