July 23, 2004

10 CFR 50.54(a)(3)
10 CFR 50.54(a)(4)
L-HU-04-030

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

Duane Arnold Energy Center
Docket 50-331
License No. DPR-49

Palisades Nuclear Plant
Docket 50-255
License No. DPR-20

Kewaunee Nuclear Power Plant
Docket 50-305
License No. DPR-43

Point Beach Nuclear Plant
Units 1 and 2
Dockets 50-266 and 50-301
License Nos. DPR-24 and DPR-27

Monticello Nuclear Generating Plant
Docket 50-263
License No. DPR-22

Prairie Island Nuclear Generating
Plant Units 1 and 2
Dockets 50-282 and 50-306
License Nos. DPR-40 and DPR-60

Response to NRC Staff Request for Additional Information Re: Request for Approval of Nuclear Management Company Quality Assurance Topical Report, Dated June 20, 2004

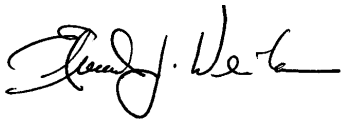
Nuclear Management Company, LLC (NMC) provides herewith its response to NRC Staff's request for additional information concerning the reduction in commitment involved in its October 31, 2003 submittal of a common Quality Assurance Topical Report (QATR) for NMC nuclear power plants. Enclosure 1 provides the specific responses to the NRC questions. In developing this response, certain changes were identified to the submitted version of the NMC QATR that were necessary to more clearly establish review requirements consistent with NMC philosophies and the content of this response. Enclosure 2 provides the relevant revised text (underlined italic). In addition, changes were identified for Enclosure 6 of the October 31, 2003 letter. Therefore, this response also provides a revised Enclosure 6, which replaces entirely the October 31 version.

The following are enclosed with this letter:

(1) Responses to the specific questions in the NRC's June 20, 2004 letter
(2) Revised text for the NMC QATR
(3) Revised Enclosure 6 from the NMC October 31, 2003 letter

SUMMARY OF COMMITMENTS

This letter contains no new commitments or changes to any existing commitments.



Edward J. Weinkam
Director of Regulatory Services
Nuclear Management Company, LLC

Enclosures (3)

cc: Regional Administrator, USNRC, Region III
Project Managers, Office of Nuclear Reactor Regulation (Duane Arnold Energy Center, Kewaunee Nuclear Power Plant, Monticello Nuclear Generating Plant, Palisades Nuclear Plant, Point Beach Nuclear Plant, Prairie Island Nuclear Generating Plant)
NRC Resident Inspectors (Duane Arnold Energy Center, Kewaunee Nuclear Power Plant, Monticello Nuclear Generating Plant, Palisades Nuclear Plant, Point Beach Nuclear Plant, Prairie Island Nuclear Generating Plant)

ENCLOSURE 1

RESPONSES TO NRC RAI QUESTIONS

1. Scope of Review

For each subject identified in Section 4.3.4 of ANS-3.2, (a) identify the organizational element(s) that would be responsible for the independent review of the subject and the specific procedural or other administrative processes that will be used in implementing these reviews, or (b) provide justification why review of the subject is unnecessary.

Response:

Section 4.3.4 of ANS-3.2 states: "The following subjects shall be reviewed by the independent review body:"

"4.3.4(1) Written safety evaluations of changes in the facility …, changes in procedures …, and tests or experiments not described … which are completed without prior NRC approval under the provisions of 10CFR50.59(a)(1). This review is to verify that such changes did not involve a change in the technical specifications or an unreviewed safety question as defined in 10CFR50.59(a)(2)." [Note that the term "unreviewed safety question" is no longer used, based on changes to 10CFR50.59 that have occurred since 1976.]

Appropriate reviews of the items listed are specified in the NMC QATR as follows:

> For changes in the facility as described in the SAR completed without prior NRC approval, the QATR, Appendix A, section 4.0, requires that the Plant Operating Review Committee (PORC) review "(3) Proposed changes or modifications to plant systems or equipment that affect nuclear safety," and "(4) Written 10CFR50.59/72.48 Evaluations to verify that changes to the facility or procedures, tests or experiments do not involve a change in the Technical Specifications or require prior NRC review." The PORC review of item (3) focuses on the change's effect on nuclear safety, while the review of item (4) determines whether prior NRC review is necessary. In addition, QATR sections B.2 and B.3 provide for design verification that items and activities are suitable for their intended application, consistent with their effect on safety (for this to occur, the effect on safety is established as part of the design change process, and thus becomes available for review during design verification). QATR section B.3 commits to NQA-1, 1994. NQA-1, 3S-1, states "Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization." Collectively, these reviews provide adequate assurance that changes in the facility maintain design safety margins and were not incorrectly completed without prior NRC approval, when required.

For changes in procedures [as described in the SAR] completed without prior NRC approval, B.14 establishes provisions to control the development, review, approval, issue, use and revision, of documents that specify quality requirements or prescribe activities affecting quality or safe operation to assure the correct documents are being employed. One of these provisions is that procedures used at generating sites are reviewed by qualified persons, independent of the preparer, as designated by the Plant Manager. This review includes determination whether additional cross-discipline reviews are required. In addition, to meet 10CFR50.59 requirements, which are separate from 10CFR50, Appendix B and thus not directly addressed in the QATR, the procedure review process also includes determination whether the procedure or procedure change affects Technical Specifications or requires prior NRC approval per 50.59. In this manner, changes to procedures completed without prior NRC approval are reviewed, as they are developed, to assure that NRC approval is not required. If NRC approval under 50.59 is required, or a Technical Specification change is necessary, appropriate actions are taken to secure NRC review and approval prior to the change becoming effective. As specified in C.3, independent assessments include examination of selected procedures to verify that the procedure review and revision controls of section B.14 are effectively implemented. Thus, the procedure review and independent assessment processes provide adequate assurance that procedure changes did not involve a change in the Technical Specifications or require prior NRC approval.

For tests and experiments [not described in the SAR] completed without prior NRC review, B.8 states that tests are performed according to procedures. Such procedures would be subject to the reviews discussed above. In addition, QATR Appendix 4.0 requires the PORC to review "(2) Proposed test or experiments that affect nuclear safety," and to review "(4) Written 10CFR50.59/72.48 Evaluations to verify that changes to the facility or procedures, tests or experiments do not involve a change in the Technical Specifications or require prior NRC review." These provisions ensure that no testing requiring NRC approval under 50.59 is done without first obtaining such approval.

Section 4.3.4 of ANS-3.2 states: "The following subjects shall be reviewed by the independent review body:"

"4.3.4(2) Proposed changes in procedures, proposed changes in the facility, or proposed tests or experiments, any of which involves a change in the technical specifications or an unreviewed safety question as defined in 10CFR50.59(c). Matters of this kind shall be referred to the independent review body by the onsite operating organization following its review, or by other functional organizational units within the owner organization, prior to implementation."

As described above, all of the reviews specified for 4.3.4(1) are before the fact reviews, and the items to be reviewed are the same as in 4.3.4(2). These reviews are intended to assure that changes in procedures or the facility, or test or experiment, that involve a change in the Technical Specifications or requires NRC approval are appropriately undertaken. At NMC, because they occur before requesting approval, the reviews also occur before implementation of the change and serve to maintain design safety margins and assure that NRC review and approval are obtained when required. In addition to PORC reviews, NMC management having authority to submit the request for NRC approval are charged in the Regulatory Affairs process with the responsibility to assure the accuracy, completeness and correctness of the material, as required by 10CFR50.9.

Section 4.3.4 of ANS-3.2 states: "The following subjects shall be reviewed by the independent review body:"

"4.3.4(3) Changes in the technical specifications or license amendments relating to nuclear safety prior to implementation, except in those cases where the change is identical to a previously reviewed proposed change."

QATR, Appendix A, 4.0 requires that PORC review "(5) Proposed changes to Operating License and Technical Specifications." Since the review is of <u>proposed</u> changes, it must necessarily occur prior to implementation. In cases where a prior Technical Specification change or NRC approval was required, Regulatory Affairs procedures require that the approved change be confirmed to match what was requested, or that substantive differences be re-reviewed prior to implementation. These reviews provide for the "prior to implementation" reviews per the N18.7 item.

Section 4.3.4 of ANS-3.2 states: "The following subjects shall be reviewed by the independent review body:"

"4.3.4(4) Violations, deviations and reportable events, which require reporting to the NRC in writing within 24 hours, such as (a) violations of applicable codes, regulations, orders, technical specifications, license requirements or internal procedures or instructions having nuclear safety significance, (b) significant operating abnormalities or deviations from normal or expected performance of plant safety-related structures, systems or components, (c) reportable events, which require reporting to the NRC in writing within 24 hours, as defined in the plant technical specifications. Review of events covered under this subsection shall include the results of any investigations made and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event."

QATR, Appendix A, 4.0 requires that PORC review "(6) Reports covering violations of applicable statutes, codes, regulations, orders, Technical Specifications, license requirements, or of internal documents having nuclear safety significance," "(8) Events reportable in writing to the NRC according to applicable regulations," and "(9) Any other matter related to nuclear safety requested by the Site Vice President, Site Director or Plant Manager, selected by PORC members, or referred to PORC by other NMC organizations, such as: plant operations to detect potential nuclear safety hazards, reports covering any indication of an unanticipated deficiency in some aspect of design or operation of safety-related structures, systems or components, and significant Nuclear Industry operating experience." In addition, section 4.0 establishes the extent of these reviews as "Reviews of items (6) through (9) include the results of any investigations made and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event." In this manner, review for these items is accomplished by an appropriate review body.

Section 4.3.4 of ANS-3.2 states: "The following subjects shall be reviewed by the independent review body:"

"4.3.4(5) Any other matter involving safe operation of the nuclear power plant which an independent reviewer deems appropriate for consideration, or which is referred to the independent reviewers by the onsite operating organization or by other functional organizational units within the owner organization."

QATR, Appendix A, 4.0 requires that PORC review "(9) Any other matter related to nuclear safety requested by the Site Vice President, Site Director or Plant Manager, selected by PORC members, or referred to PORC by other NMC organizations, such as: plant operations to detect potential nuclear safety hazards, reports covering any indication of an unanticipated deficiency in some aspect of design or operation of safety-related structures, systems or components, and significant Nuclear Industry operating experience."

2. <u>Authority/Independence/Organizational Freedom</u>

For the organizational element(s) identified above, (a) describe the organizational structure that ensures that personnel conducting independent reviews have sufficient authority, independence, and organizational freedom to identify safety problems, to initiate, recommend or provide solutions and to verify implementation of solutions, or (b) provide justification why this is unnecessary.

Response:

N18.7-1976 defined **independent review** as "Review completed by personnel not having direct responsibility for the work function under review …," and further defined **review** as "A deliberately critical examination, including observation of plant operation, evaluation of audit results, procedures, certain contemplated actions, and after-the-fact investigations of abnormal conditions." As discussed above and below, the NMC QATR provides for review of the subjects enumerated in section 4.3.4 of N18.7/ANS 3.2, as well as other reviews. In particular, the reviews conducted by PORC meet the cited definition for independence in that a majority of the members reviewing any item will not have had "direct responsibility for the work function (or product) under review," and can provide the degree of independence and challenge inherent in the intent of the definitions. The response to question #9 provides additional information regarding the independence of PORC.

3. <u>Oversight of Audit Program</u>

With respect to the periodic review of the audit program described in Section 4.5 of ANS 3.2, (a) describe how this periodic, independent review would be performed, or (b) provide justification why this is unnecessary.

Response:

Independent review of the audit program (Nuclear Oversight function) is provided for in QATR section C.1 and C.3, as follows:

> C.1: "NMC establishes programs for reviews and assessments to verify that activities covered by this QATR are performed in accordance with the requirements established, review significant proposed plant changes or tests, verify that reportable events are promptly investigated and corrected, and detect trends which may not be apparent to the day to day observer. These programs are, themselves, reviewed for effectiveness as part of the overall assessment process, as described herein."
>
> C.3: "Independent assessment results are documented and reviewed by Nuclear Oversight management and by management having responsibility for the area assessed. In addition, Nuclear Oversight activities are periodically assessed for effectiveness. Results are documented and reported to responsible management."

In addition, section A.3 provides assurance that senior company management is aware of, and can respond to, any program implementation problems by requiring:

> A.3: "Senior management is regularly apprised of assessment results evaluating the adequacy of implementation of the QAP through the

assessment functions described in section C." [Note that, in addition to the above, section C also specifies requirements for self-assessments.]

At the present time, NMC is a member of the Nuclear Industry Evaluation Program (NIEP), which is a cooperative effort among nearly all nuclear plant operators in the USA. This program provides for periodic (one to two years), comprehensive evaluations of the compliance and effectiveness of quality assurance/oversight activities at both the plant and corporate levels. Performance is evaluated against several objectives to determine if oversight activities are effective at identifying problems and precursors to problems, and that identified problems are appropriately addressed. The NIEP process differs from previous cooperative audit programs in the level of persons performing the evaluations; NIEP Evaluations are expected to use management and senior management level personnel with the experience and judgment capabilities to critically assess effectiveness of the oversight function, as well as recommend improvements. Whether NMC remains a member of the NIEP or not, the QATR establishes requirements such that the level of review is sufficient to identify whether the oversight (audit) process meets requirements established in the QATR and is effective.

4. <u>Oversight of Corrective Action Process</u>

Section 5.2.11 of ANS-3.2 states that, "In the case of significant conditions adverse to safety, the measures shall assure that the cause of the condition is determined and corrective actions taken shall be documented and reported to appropriate levels of management and for independent review." (a) Describe how independent review of the adequacy of corrective actions is accomplished if the independent review function described in Section 5.2.11 of ANS-3.2 were eliminated, or (b) provide justification why this is unnecessary.

Response:

Review of the cause and corrective actions taken to address significant conditions adverse to quality are provided for in the QATR in sections A.6, C.3 and Appendix A, and in Basic Requirement 16 of NQA-1, 1994, as follows:

> A.6: "NMC implements a corrective action program to promptly identify, control, document, classify, and correct conditions adverse to quality. In addition, for significant conditions adverse to quality, the program provides for cause evaluation and corrective actions to prevent recurrence. Provisions are also made to ensure that corrective actions for significant conditions adverse to quality are completed as intended and are not inadvertently nullified by subsequent actions. Results of evaluations of conditions adverse to quality are analyzed to identify trends. Significant

conditions adverse to quality and significant adverse trends are documented and reported to responsible management."

C.3: "NMC has established a program of planned and periodic performance-based independent assessments to monitor overall performance and confirm that activities affecting quality comply with the QAP and that the QAP is effectively implemented. … Results of independent assessments are reported in an understandable form and in a timely fashion to a level of management having the authority to effect corrective action. Nuclear Oversight conducts timely follow-up action, including re-assessment of deficient areas, as necessary to establish adequacy of corrective actions."

Appendix A, 4.0: "The PORC reviews at least the following: (6) Reports covering violations of applicable statutes, codes, regulations, orders, Technical Specifications, license requirements, or of internal documents having nuclear safety significance. (8) Events reportable in writing to the NRC according to applicable regulations. (9) Any other matter related to nuclear safety … such as: … reports covering any indication of an unanticipated deficiency in some aspect of design or operation. Reviews of items (6) through (9) include results of any investigations made and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event."

NQA-1, BR16: "The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation of this corrective action."

Collectively, these review, follow-up and verification activities achieve a level of review and control equivalent to the referenced section of N18.7 to assure that the causes for significant conditions adverse to quality are properly determined and that corrective actions taken are effective. In addition, Section C.3 requires that Nuclear Oversight conduct assessments of program implementation, including the corrective action process, and the NMC corrective action process includes provisions for management level review (independent of the responsible management) of the causal analysis and corrective actions for significant conditions adverse to quality, as well as effectiveness review following completion of corrective actions.

5. Results of Independent Reviews

(a) Describe how deficiencies, adverse trends, and recommendations resulting from independent reviews are reported, corrected, and verified, or (b) provide justification why this is unnecessary.

Response:

QATR section A.6 requires the "identification of conditions adverse to quality. This includes failures, malfunctions, deficiencies, deviations, defective material and equipment, abnormal occurrences, nonconformances, and out-of-control processes, including the failure to follow procedures." In addition, it requires that "Results of evaluations of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management." Any of the review processes described in the QATR (and in this response) may identify the types of conditions cited, or may provide recommendations for the correction of conditions or trends noted. The general approach at NMC is to use the corrective action process that implements section A.6 to capture, report, correct and verify the correction or implementation of necessary actions. In addition, section C.3 requires that Nuclear Oversight conduct assessments of program implementation, including the corrective action process, as well as conduct timely follow-up action, including re-assessment of deficient areas, as necessary to establish adequacy of corrective actions. In this manner, adequate provisions are made for the reporting, correction and verification of issues identified in the various review processes applied.

6. Qualifications for Independent Review Personnel

For personnel performing independent reviews, (a) define the qualifications requirement for personnel performing independent reviews, including competence to review the areas identified in ANS-3.2, Section 4.3.1. The requirements should be equivalent to those currently required for independent review personnel, or (b) provide justification why this is unnecessary.

Response:

QATR section A.3 establishes that "Individual managers ensure that personnel working under their management cognizance are provided the necessary training and resources to accomplish their assigned tasks." Section A.5 states that "To this end NMC establishes and maintains formal indoctrination and training programs for personnel performing, verifying or managing activities within the scope of the QAP to assure that suitable proficiency is achieved and maintained." Item one of section A.7.3 establishes that "staff qualification requirements are as delineated in each site's Technical Specifications." Thus, the qualification

requirements for persons performing the reviews specified in the QATR are established in relation to competency for performing, verifying or managing the work under review. For most reviews, in particular for those conducted as part of a defined process such as design review, NMC considers this level of qualification adequate to address the "review" expectations as defined in N18.7.

For the reviews conducted by PORC, member qualifications must again meet site Technical Specification requirements, and membership includes representation from at least the disciplines of Operations, Maintenance, Engineering, Radiation Protection and Chemistry. QATR, Appendix A, section 2.0 indicates that "PORC collectively has, or has access to, the experience and competence necessary to review the areas of (1) nuclear power plant operations, (2) nuclear engineering, (3) chemistry and radiochemistry, (4) metallurgy, (5) nondestructive testing, (6) instrumentation and control, (7) radiological safety, (8) mechanical and electrical engineering, (9) administrative controls and quality assurance practices, and (10) any other fields associated with the unique characteristics of the plant. Consultants may be utilized to provide expert advice." This set of expectations is consistent with the cited N18.7/ANS 3.2 paragraph.

Thus, persons conducting reviews are appropriately qualified or provision is made for obtaining additional expertise when necessary.

7. Records

(a) Define the provisions for preparation and retention of records of reviews, including identification of document reviews, recommendations and proposed actions resulting from these reviews, and the method for promptly disseminating this information to management having responsibility for the areas reviewed, or (b) provide justification why this is unnecessary.

Response:

QATR section B.15 states "NMC establishes and implements provisions to ensure that sufficient records of items and activities affecting quality are generated and maintained to reflect completed work. Such records may include, but are not limited to, design, engineering, procurement, manufacturing, construction, inspection, test, installation, modification, operations, maintenance, corrective action, assessment, and associated reviews. The provisions establish requirements for records administration, including generation, receipt, preservation, storage, safekeeping, retrieval and final disposition." In addition, QATR Appendix A, section 6.0 requires that "PORC maintains written minutes of each PORC meeting, to include identification of items reviewed, and decisions and recommendations of the Committee. Copies of the minutes are provided to the onsite management position(s) above the Plant Manager, and to other onsite and offsite management responsible for the areas reviewed as necessary." These

requirements, along with those already discussed, will provide for the preparation and retention of records of reviews, as well as dissemination of appropriate reports to responsible management.

8. Regulatory Basis

The independent review program is an administrative control, as defined under Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.36(c)(5). The source of the requirement is the regulation at 10 CFR 50.40(b), as it relates to the licensee being technically qualified to engage in license activities. The staff reviews changes to the independence [sic] review program in accordance with Chapter 13.4, "Operational Review," of the Standard Review Plan (NUREG 0800).

Enclosure 6 of the submittal contains a section titled "Basis for Concluding Continued Compliance with Appendix B." The independent review program is not an Appendix B requirement. The technical specification was relocated to the quality assurance program under a burden reduction initiative in accordance with the Commission's Final Policy Statement on Technical Specification Improvements for Nuclear Power Reactors (59 FR 39132). The 10 CFR 50.54(a) change control process requires regulatory review and approval of changes to the independent review program, but independent review is not an Appendix B requirement.

The submittal should be revised to delete the reference to Appendix B compliance and to address the regulations applicable to the independent review program.

Response:

In Enclosure 6 of the NMC October 31, 2003 letter, NMC correctly stated that the independent review function, as specified via Regulatory Guide 1.33 and ANS N18.7/3.2, is not required by 10CFR50, Appendix B as part of an acceptable quality assurance program. However, it was incorrectly concluded that, as provided in 10CFR50.54(a)(4)(ii), the "revised program incorporating the changes continues to satisfy the criteria of Appendix B of this part and the Safety Analysis Report quality assurance program description commitments previously accepted by the NRC." The "changes" of concern being the elimination of the independent review function. A revised Enclosure 6 is submitted with this response. The revision is based on the following considerations:

The requirements for independent review were originally imposed via plant Technical Specifications that addressed them in the manner discussed in NRC Standard Review Plan (SRP) Section 13.4, although the exact wording differed among plants. In 1995, the NRC provided the cited guidance that allowed

licensees to move certain “administrative” requirements from Technical Specifications to other documents subject to NRC review. Many licensees, including all the NMC plants, exercised this option and relocated independent review requirements to their Appendix B Quality Assurance Program Description. Thus, the requirements for independent review became “quality assurance program description commitments previously accepted by the NRC.”

While Appendix B does not require the independent review function, the NRC staff has established acceptance criteria in Standard Review Plan (SRP) (NUREG 0800), Section 13.1.1 (Rev 4, November 1999), and provided a connection to 10CFR50.40(b) in that the independent review provisions discussed in SRP Section 13.4 (Rev 2, July 1981) form part of the basis for the NRC’s conclusion that the licensee meets the relevant requirements of 10CFR50.40(b) as it relates to the licensee being technically qualified to engage in licensed activities. Further, SRP Section 13.1.1 states, “Meeting the requirements of 10CFR50.40(b) provides assurance that the applicant is technically qualified to engage in the proposed activities and has established the necessary management and technical-support organizations to safely operate the proposed facility.” 10CFR50.40(b) states, in part, “In determining that a license will be issued to an applicant, the Commission will be guided by the following considerations: (b) The applicant is technically and financially qualified to engage in the proposed activities in accordance with the regulations in this chapter.”

The independent review requirements were originally established at a time when the nuclear industry was experiencing rapid growth and a shortage of highly experienced and qualified operating and technical support staff. Since that time, nuclear plant staffs have increased both in number and in levels of experience, and in the ability to perform focused and independent reviews of operating activities (as defined in ANSI N18.7/3.2). Reviews are specified in the QATR for several key processes, including design activities, procedures, procurements, inspection, and testing. Reviews of operating, regulatory and safety performance, plant changes, and important industry experience are also specified to be conducted by plant operating review committees (PORC). The PORC membership includes persons competent in Operations, Maintenance, Engineering, Radiation Protection and Chemistry, and typically meets much more frequently than the minimum of twice per year required for off-site committees performing independent reviews. PORC provides for timely, before the fact, review and feedback on the safe operation of the plant. Although PORC’s primary role is advisory to the Plant Manager, results of its reviews are reported to higher management.

In addition, the industry has established the Institute of Nuclear Power Operations (INPO) to provide reviews of plant operations as well as identify and communicate industry experience and lessons learned so plants can take appropriate action to prevent similar events; the NRC has modified its regulatory philosophy to focus on the risk-significant aspects of plant operation; and the industry has recognized the

importance of maintaining a robust safety culture to safe and reliable plant operations. Important parts of a robust safety culture include effective self-assessment and corrective action programs. The NMC QATR establishes requirements for these programs that assure they are focused on identifying and correcting equipment and process issues that could affect safe operation of the plants.

As noted in its October 31, 2003 letter, NMC does not intend to use N18.7 as a base standard, but has addressed in its QATR those N18.7 requirements for administrative controls it considers necessary and sufficient to provide adequate control of nuclear plant operating activities. Because of the changes discussed above, and the provisions of the QATR, NMC considers that the N18.7 requirements for independent review are redundant and, in accordance with SECY-02-0081 guidance for reducing regulatory burden, has submitted the QATR without the requirements for each NMC plant to have an Offsite Safety Review Committee. Further, NMC believes the review provisions established in the submitted QATR [as amended] provide an acceptable alternative to the independent review provisions discussed in SRP Section 13.4 (ANS N18.7/3.2), and support the conclusion that NMC is "technically … qualified to engage in the proposed activities" as provided in applicable regulations.

9. Independent Review

Enclosure 6 of the submittal refers to the plant operations review committee as performing the "independent review" function. Please clarify whether the committee meets the definition of "independent review," as defined in Section 2.2 and further described in the third paragraph of Section 3.2 of ANSI N18.7-1976.

Response:

The response to question #2 has addressed the "independent review" definition from Section 2.2. With respect to the additional considerations provided in Section 3.2 of ANSI N18.7-1976, Appendix A of the NMC QATR [as amended] provides the following requirements in Section 1.0: "In discharging its independent review responsibilities, the PORC shall keep safety considerations paramount when opposed to cost or schedule considerations. Should a voting member at a particular meeting have direct responsibility for an item under review where a conflict of such considerations is likely, that member shall be replaced (to fill the quorum) by another voting member not having such potential conflict." NMC believes this provides adequate guidance to assure that PORCs focus on safety over production, and assures that members understand their role and responsibility for safety. Other aspects of Section 3.2 are addressed in the responses to the other eight questions of this RAI.

ENCLOSURE 2

REVISED TEXT (underlined italic)
FOR THE NMC QATR
(REPLACES SAME SECTIONS FROM OCTOBER 31, 2003 LETTER)

4 pages follow

REVISED TEXT (HIGHLIGHTED)
FOR THE NMC QATR

A.6 Corrective Action

NMC management, at all levels, fosters a non-punitive ("no-fault") attitude toward the identification of conditions adverse to quality. This includes failures, malfunctions, deficiencies, deviations, defective material and equipment, abnormal occurrences, nonconformances, and out-of-control processes, including the failure to follow procedures.

NMC implements a corrective action program to promptly identify, control, document, classify, and correct conditions adverse to quality. In addition, for significant conditions adverse to quality, the program provides for cause evaluation and corrective actions to prevent recurrence. Provisions are also made to ensure that corrective actions for significant conditions adverse to quality are completed as intended and are not inadvertently nullified by subsequent actions. Results of evaluations of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are *documented and* reported to responsible management.

Prior to installation, nonconforming items, services or activities are reviewed and accepted, rejected, repaired, or reworked, and are identified and controlled to prevent their inadvertent test, installation or use.

In establishing requirements for corrective action, NMC commits to compliance with NQA-1, 1994, Basic Requirements 15 and 16, and Supplement 15S-1.

B.15 Records

NMC establishes and implements provisions to ensure that sufficient records of items and activities affecting quality are generated and maintained to reflect completed work. Such records may include, but are not limited to, design, engineering, procurement, manufacturing, construction, inspection, test, installation, modification, operations, maintenance, corrective action, assessment, *and associated reviews*. The provisions establish requirements for records administration, including generation, receipt, preservation, storage, safekeeping, retrieval and final disposition.

Appendix A **Plant Operating Review Committee**

1.0 General

The Plant Operating Review Committee (PORC) is responsible to the Plant Manager for advice on all plant-related matters concerning nuclear safety. The requirements for personnel, committee composition, meeting frequency, quorum and meeting records are identified in implementing procedures. A general description of these areas is included below. (Note: Each plant may name this function differently. Regardless of the name, these requirements are met.)

In discharging its independent review responsibilities, PORC shall keep safety considerations paramount when opposed to cost or schedule considerations. Should a voting member at a particular meeting have direct responsibility for item under review where a conflict of such considerations is likely, that member shall be replaced (to fill the quorum) by another voting member not having such potential conflict.

2.0 Composition

PORC is comprised of a minimum number of members as designated by the Plant Manager and detailed in implementing procedures. All members are qualified in accordance with implementing procedure requirements that meet site Technical Specifications. Membership includes representation from at least the following disciplines: Operations, Maintenance, Engineering, Radiation Protection and Chemistry. *PORC collectively has, or has access to, the experience and competence necessary to review the areas of (1) nuclear power plant operations, (2) nuclear engineering, (3) chemistry and radiochemistry, (4) metallurgy, (5) nondestructive testing, (6) instrumentation and control, (7) radiological safety, (8) mechanical and electrical engineering, (9) administrative controls and quality assurance practices, and (10) other fields associated with the unique characteristics of the plant. Consultants may be utilized to provide expert advice as needed.*

Alternate chairmen and members may be appointed by the Plant Manager to serve on a permanent or temporary basis.

3.0 Meetings

The PORC meets commensurate with the scope of activities, but minimal frequency requirements are specified in procedures.

Rules for a quorum are established and adhered to. However, no more than a minority of alternates may participate as voting members at any one time.

4.0 Review

The PORC reviews at least the following:

- (1)Changes to the Offsite Dose Calculation Manual (ODCM) and the Process Control Program (PCP).
- (2)Proposed tests or experiments that affect nuclear safety.
- (3)Proposed changes or modifications to plant systems or equipment that affect nuclear safety.

- (4)Written 10CFR50.59/72.48 Evaluations to verify that changes to the facility or procedures, tests or experiments *do* not involve a change in the Technical Specifications or require prior NRC review.
- (5)Proposed changes to Operating License and Technical Specifications.
- (6)Reports covering violations of applicable statutes, codes, regulations, orders, Technical Specifications, license requirements, or of internal documents having nuclear safety significance.
- (7)Reports of special reviews and investigations as requested by the Site Vice President, Site Director, or Plant Manager.
- (8)Events reportable in writing to the NRC according to applicable regulations.
- (9)Any other matter related to nuclear safety requested by the Site Vice President, Site Director or Plant Manager, *selected by PORC members, or referred to PORC by other organizations*, such as: plant operations to detect potential nuclear safety hazards, reports covering any indication of an unanticipated deficiency in some aspect of design or operation of safety-related structures, systems or components, and significant Nuclear Industry operating experience.

Reviews of items (6) through (9) include results of any investigations made and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.

5.0 Authority

The PORC:

- Recommends in writing to the Plant Manager approval or disapproval of items reviewed.
- Renders determinations in writing with regards to whether items (1) through (5), or changes thereto, require prior NRC approval in accordance with 10CFR50.59/72.48.
- Provides written notification to the onsite management level(s) above the Plant Manager of any disagreements between the PORC and the Plant Manager.

The PORC *shall* advise the Plant Manager on matters related to safe operation and overall performance. The PORC has authority to obtain access to records and personnel as needed to conduct reviews.

In carrying out its review responsibilities, the PORC may establish subcommittees or use designated organizational units to carry out the review. The subcommittees or organizational units regularly report results of reviews for full committee consideration and may recommend items for full committee review as warranted.

6.0 Records

The PORC maintains written minutes of each PORC meeting, to include identification of items reviewed, and decisions and recommendations of the Committee. Copies of the minutes are provided to the onsite management position(s) above the Plant Manager, *and to other onsite and offsite management responsible for the areas reviewed as necessary*. PORC records are retained according to section B.15.

ENCLOSURE 3

REPLACEMENT ENCLOSURE 6 FOR THE OCTOBER 31, 2003
NMC LETTER REQUESTING APPROVAL OF THE NMC QA TOPICAL REPORT

3 pages follow

REPLACEMENT ENCLOSURE 6 FOR THE OCTOBER 31, 2003
NMC LETTER REQUESTING APPROVAL OF THE NMC QA TOPICAL REPORT

Reduction in Commitment Regarding Offsite Review Committees

Introduction

NMC plants currently have in their Quality Assurance Program Descriptions requirements for an Offsite Review Committee (OSRC) to function as an independent review body. The QATR submitted herewith does not include requirements for any type of independent review body. NMC considers the elimination of this function (OSRC) to be a reduction in commitment requiring NRC approval in accordance with 10 CFR 50.54(a)(4).

Background

The requirements for an independent review function were based on ANSI N18.7-1976, as endorsed by Regulatory Guide 1.33, Revision 2, 1978. ANSI N18.7 provides two options for independent review: (1) a standing committee functioning as an independent review body, or (2) an organizational unit functioning as an independent review body. The requirements for independent review were originally imposed via plant Technical Specifications that addressed them in the manner discussed in NRC Standard Review Plan (SRP) Section 13.4, although the exact wording differed among plants. In 1995, the NRC provided guidance (59 FR 39132) that allowed licensees to move certain "administrative" requirements from Technical Specifications to other documents subject to NRC review. Many licensees, including all the NMC plants, exercised this option and relocated independent review requirements to their Appendix B Quality Assurance Program Description. Thus, the requirements for independent review became "quality assurance program description commitments previously accepted by the NRC." These requirements were established at a time when the nuclear industry was experiencing rapid growth and a shortage of highly experienced and qualified operating and technical support staff. Since that time, nuclear plant staffs have increased both in number and in levels of experience, and in the ability to perform focused and "independent" reviews of operating activities (as the term is defined in ANSI N18.7-1976). Reviews will be specified in the QATR for several key processes, including design activities, procedures, procurements, inspection, and testing. Appropriately independent reviews of operating, regulatory and safety performance, plant changes, and important industry experience will also be specified to be conducted by plant operating review committees (PORC). These are essentially the same reviews currently done by the OSRCs. The PORC membership will include persons competent in Operations, Maintenance, Engineering, Radiation Protection and Chemistry. PORCs typically have and will continue to meet much more frequently than the minimum of twice per year required for OSRCs. PORC thus will provide for timely, before the fact, review and feedback on the safe operation of the plant. Although PORC's primary role is advisory to the Plant Manager, results of its reviews will be reported to higher management.

In addition, the industry has established the Institute of Nuclear Power Operations (INPO) to provide independent reviews of plant operations as well as identify and communicate industry experience and lessons learned so plants can take appropriate action to prevent similar events; the NRC has modified its regulatory philosophy to focus

on the risk-significant aspects of plant operation; and the industry has recognized the importance of maintaining a robust safety culture to safe and reliable plant operations. Important parts of a robust safety culture include effective self-assessment and corrective action programs. The NMC QATR establishes requirements for these programs that assure they are focused on identifying and correcting equipment and process issues that could affect safe operation of the plants. For self-assessments, NMC sites make extensive use of each other's staff, as well as expertise from non-NMC sources, to provide an outside perspective. For corrective action, NMC fosters a non-punitive attitude toward the identification of adverse conditions, and implements a program that includes trending, cause evaluation, corrective actions and reporting to management.

Proposed Change

As noted elsewhere in this letter, NMC does not intend to use N18.7 as a base standard, but has addressed in its QATR those N18.7 requirements for administrative controls it considers necessary and sufficient to provide adequate control of nuclear plant operating activities. Because of the changes discussed above, and the provisions of the enclosed QATR, NMC considers that the N18.7 requirements for independent review, as defined therein, are redundant and, in accordance with SECY-02-0081 guidance for reducing regulatory burden, is submitting the QATR without the requirements for each plant to have an independent review function as specified by N18.7.

Reason for Proposed Change

As noted above, conditions have changed since the requirements for an independent review function were first promulgated and endorsed by the NRC. In NMC's opinion, these changes, not the existence of an independent review function, have contributed to continued improvements in NMC plants' and industry performance, as shown in key performance indicator trends for availability, reliability, industrial safety, radiation safety, and plant events. (See INPO and NRC performance indicators.) NMC considers the imposition of an independent review function an unnecessary burden deserving of relief. In addition, NMC's effort to update the basis for its Quality Program includes elimination of the link to N18.7, which provides an opportunity to establish requirements appropriate to the conditions of today, rather than 1978.

Basis for Concluding Continued Compliance with 10 CFR 50, Appendix B and Other Regulations

While Appendix B does not require the independent review function, the NRC staff has established acceptance criteria in Standard Review Plan (SRP) (NUREG 0800), Section 13.1.1 (Rev 4, November 1999), and provided a connection to 10CFR50.40(b) in that the independent review provisions discussed in SRP Section 13.4 (Rev 2, July 1981) form part of the basis for the NRC's conclusion that the licensee meets the relevant requirements of 10CFR50.40(b) as it relates to the licensee being technically qualified to engage in licensed activities. Further, SRP Section 13.1.1 states, "Meeting the requirements of 10CFR50.40(b) provides assurance that the applicant is technically qualified to engage in the proposed activities and has established the necessary management and technical-support organizations to safely operate the proposed facility." 10CFR50.40(b) states, in part, "In determining that a license will be issued to an applicant, the Commission will be guided by the following considerations: (b) The applicant is technically and financially qualified to engage in the proposed activities in accordance with the regulations in this chapter."

NMC believes the review provisions established in the submitted QATR [as amended] provide an adequate alternative to the independent review provisions discussed in SRP Section 13.4 (ANSI N18.7/ANS-3.2), and support the conclusion that NMC is "technically … qualified to engage in the proposed activities" as provided in applicable regulations.

In conclusion, the QATR will establish requirements that comply with 10 CFR 50, Appendix B, and other regulations related to the technical qualifications to engage in licensed activities, without the need for the independent review function (OSRC) as contained in each plant's current Quality Assurance Program Description.