



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

January 3, 1996

50-416

Mr. C. R. Hutchinson  
Vice President-Operations, GGNS  
Entergy Operations, Incorporated  
P.O. Box 756  
Port Gibson, MS 39150

SUBJECT: GRAND GULF NUCLEAR STATION OPERATIONAL QUALITY ASSURANCE MANUAL  
CHANGES REGARDING AUDIT SCHEDULING PROCESS (REFERENCE ENTERGY  
OPERATIONS, INC. LETTER, GNRO-95/00119, DATED NOVEMBER 6, 1995)

Dear Mr. Hutchinson:

We have completed a review of the changes that Entergy Operations, Incorporated (Entergy) has made to its Grand Gulf Nuclear Station (GGNS) Operational Quality Assurance Manual (OQAM) and Technical Requirements Manual (TRM) regarding the elimination of required audit frequencies and audit topics as described in your letter of November 6, 1995. We have also reviewed additional information that was provided to the staff by GGNS personnel on December 1, 1995. Further details regarding the change had also been discussed during a public meeting at Region IV offices on November 16, 1995.

As indicated in your November 6, 1995, letter, these changes to the OQAM and the TRM were made in accordance with 10 CFR 50.54 based on your determination that the changes enhanced the quality assurance commitments and increased the effectiveness of the audit program. Although you have already made the changes in your OQAM and TRM, you planned to phase the changes in over the next 6 to 12 months. You took the additional action to highlight these changes and initiate a dialog with the NRC staff to ensure a common understanding of the basis for these changes. We appreciate the proactive method in which you have engaged the staff in this issue and the multiple opportunities to discuss the merits of this change. Nevertheless, based on our review of the information you provided regarding these changes, we have concluded that the elimination of the required audit frequencies and audit topics is a reduction of your quality assurance program commitments. Our conclusion is based on the fact that your change has eliminated quality assurance program content that describes how the quality assurance requirements of 10 CFR Part 50, Appendix B, will be fulfilled. The specific staff concerns and questions regarding the OQAM and TRM changes are provided as an attachment.

In general, the staff's minimum expectation is that the licensee will perform internal audits of mature operational activities approximately every 2 years, or more frequently where poor performance dictates. Although we recognize that a detailed analysis of the status and importance of these operational activities could conclude that an audit is not warranted within this 2-year time frame, the quality assurance program would need to include a description of this process. Accordingly, we request that you cease implementation of the proposed audit program changes until your QA program has been supplemented and the staff has approved the changes.

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If you have any comments or questions regarding this letter or its attachment, please contact Ms. Suzanne C. Black (301) 415-1017.

Sincerely,

Original signed by: William D. Beckner  
William D. Beckner, Project Director  
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Office of Nuclear Reactor Regulation

Docket No. 50-416

Enclosure: As stated

cc: See next page

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NRC STAFF COMMENTS AND CONCERNS ON GRAND GULF NUCLEAR STATION (GGNS)  
OPERATIONAL QUALITY ASSURANCE MANUAL (OQAM)  
AND TECHNICAL REQUIREMENTS MANUAL (TRM) CHANGE

1. The staff does not agree with the GGNS determination that the change does not constitute a reduction in commitment. The proposed 10 CFR 50.54(a) rule published on July 2, 1981, spoke to the ability of licensees to change their quality assurance programs as long as the change did not decrease the effectiveness of the program. However, the final 10 CFR 50.54(a) rule revised the language to preclude confusion or misinterpretation. As such, the final rule allowed licensees to make quality assurance program changes so long as they did not reduce the commitments of the quality assurance program. Commitments in this context include those quality assurance program provisions that licensees implement to fulfill the quality assurance requirements of 10 CFR Part 50, Appendix B. Thus, the deletion of specific information that describes how the requirements of Appendix B will be met is considered a reduction in commitment. The OQAM and TRM changes described in the GGNS letter of November 6, 1995, are a reduction in commitment because provisions related to 10 CFR Part 50, Appendix B, Criterion XVIII, were deleted from the quality assurance program.
2. To meet the intent of Regulatory Guide 1.33, the NRC staff would expect to see licensees perform internal audits of their mature operational activities approximately every 2 years, or more frequently if poor performance indicates. Any deviations from the regulatory guide audit schedule provisions should be based on a licensee analysis of the status and importance of the activity that concludes that an extension of the audit frequency is warranted. The analysis should be documented and available for NRC review. This process would need to be documented within the quality assurance program.
3. Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50 requires, in part, that periodic audits be planned to verify compliance with all aspects of the quality assurance program and to verify acceptance of the program. Licensees and vendors have previously questioned the intent of the term "periodic." The NRC has provided guidance on the meaning of this term through Regulatory Guides that have endorsed the various ANSI quality assurance standards. For example, Regulatory Guide 1.144, Revision 1, conditionally endorses ANSI 45.2.12-1978, "Auditing of Quality Assurance Programs for Nuclear Power Plants," and states the following:
  - a) Internal audits of design and construction activities during the Construction Phase shall be conducted at least annually. [Reference Regulatory Guide 1.144, Position C.3.a(2)]

ENCLOSURE

- b) Internal audits during Operational Phase Activities shall be in accordance with Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)." Regulatory Guide 1.33, Revision 2, conditionally endorses ANSI N18.7, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants." Regulatory Position C.4 of Regulatory Guide 1.33 specifies that an audit of all safety-related activities be completed within a period of 2 years with the exception of activities identified in Regulatory Position C.4.(a-c) which are specified to be completed between 6 and 12 months (depending on the activity).

This regulatory guidance was satisfied when GGNS relocated the list of specific audit areas and frequencies from the Technical Specifications to the TRM. That is no longer the case after those specifics were eliminated. The staff position is that the OQAM or TRM must explicitly describe a sub-set of plant activities that will be typically audited every 2 years. As described in Comment 2, there is flexibility for the OQAM or the TRM to describe provisions under which the time between audits can be lengthened.

4. Sections 18.5.6.1, 18.5.6.2, and 18.5.6.3 of Revision 13 of the GGNS OQAM, have been deleted. However, it appears that Sections 18.5.6.1 and 18.5.6.2 were written to address aspects from ANSI N45.2.12, Section 3.5, "Scheduling." The deletion of these sections is a reduction of commitment. The GGNS submittal does not clarify why these sections were deleted nor provide a justification for deleting these requirements. Deletion of these requirements removes the commitments to audit new safety-related activities or modified operational programs as soon as practical after they have been implemented. Such activities could include the upcoming implementation of ASME Section XI, Appendix 8 regarding the qualification of equipment, procedures, and individuals for detection of defects in piping or the new initiative to apply a risk ranking process in support of graded-quality assurance activities. For activities that are not operationally mature, the performance-based approach does not provide the equivalent level of confidence in quality assurance program integrity as the previous commitments. Further justification and staff evaluation is required.
5. The quality assurance program change deletes the audits previously described by the TRM Section 7.4.2.8. In particular, the change deleted Item d of Section 7.4.2.8, which describes the commitment to audit activities required by the operational quality assurance program at least once every two years, which was consistent with ANSI N18.7 as endorsed by Regulatory Guide 1.33. The deletion of the explicit functional areas that are to be audited is not acceptable without further justification. As discussed in Comment 2, the staff expectation is that the intent of Regulatory Guide 1.33 will be met.

6. The staff sees merit in the use of a performance-based audit process espoused by GGNS. For example, the performance-based approach could be used as a basis for extending the audit frequencies beyond 2 years as outlined in Comment 2. In this manner, performance-based evaluations could be used to make adjustments in audit scheduling based on objective data when warranted. However, these decisions would need to be appropriately documented in those cases where the time between audits is lengthened.