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March 3, 1980
E&L-2160

Mr. Harold R. Denton
Director of Nuclear Reactor
Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Denton:

SUBJECT: RESPONSES TO INFORMAL NRC QUESTIONS
CONCERNING THE QUALITY ASSURANCE PROGRAM

Enclosed are responses to the fifty-two subject questions. These responses will be factored into the TMI-1 Restart Report after formal NRC questions have been received.

Very truly yours,

GPU SERVICE

J. R. Thorpe
Director - Environment,
Health and Safety

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RESPONSE TO NRC QUESTIONS

ON TMI-1 OPERATIONAL QUALITY ASSURANCE PLAN

1. The "Nuclear Safety Evaluation Department" (NSED) described in 2.2.4.3 has been changed to the "Nuclear Safety Assessment Department" and is now shown on the revised organization chart. Section 1 has been revised to reflect the latest organization structure.

2. The information requested was provided during the meeting held at GPU on February 5 & 6, 1980.

3. The qualification requirements for the Manager of Quality Assurance have been revised to specify the minimum nuclear QA experience and knowledge of QA regulations, policies, and standards.

4. The terms QA Plan and QA Program are not intended to be interchangeable. The QA Plan is the document submitted, while the QA Program includes the QA Plan plus the implementing procedures. Section 2.1.1 has been revised to clarify this.

5. Section 2.1.2 "Scope" and Appendix C have been expanded to include Regulatory Guide 1.29. The position on Reg. Guide 1.26 is already included in Appendix C. Also item (f) will be revised to delete Reg. Guide 1.120 and add Branch Technical Position ASB 9.5-1 "Guidelines for Fire Protection for Nuclear Power Plants".

6. A representative QCL will be included as a change to Section 5 of the TMI Restart Report. The QCL will be a controlled document subject to periodic update and controlled distribution; however, the sample list to be included in the Restart Report will not be controlled or updated.

7. Section 2.2.2 has been revised to comply with your comment.

8. Section 2.1.3 has been expanded to comply with your comment by describing responsibilities and guidelines for determining appropriate QA requirements and defining the QA Organizations involvement.

9. The method to be used for determining how and to what extent the three level approach is to be applied will be contained in implementing procedures. Section 6.2.1.2 has been added to amplify how "Plant Monitoring" is used for activities important to safety.

10. Section 2.2.1 has been revised to comply with your comment.

11. The Operational QA Plan has been edited to purge the text of ambiguous words; however, where words like "applicable" or "appropriate" add clarity they have been left in the text.

12. Section 2.2.2 has been expanded to identify who is responsible for identifying the quality classification of spare and replacement parts and the extent of the QA organization involvement with the classification process.

13. Section 2.2.2 has been expanded to describe the classification of spare or replacement parts.

14. Section 2.2.3 has been expanded to comply with your comment.

15. The position with regard to Reg. Guide 1.26 is stated in Appendix C.

16. The qualification program for on-site and off-site personnel performing activities important to safety is to be covered in implementing procedures. Section 2.2.5(b) has been revised to clarify which personnel require qualification.

17. Section 2.2.5(b) has been revised to include requirements for establishment of acceptance criteria.

18. Section 2.2.6 has been added to comply with the comment.

19. Section 3.3.1 has been revised to comply with this comment.

20. The requested statement has been added to Section 3.1.2 after (h).

21. Appendix B to the Operational QA Plan describes the QA involvement in review, and documented concurrence with procedures which are important to safety. Clarification has been added to better describe the terms "reviewed by" and "concurred by".

22. As built drawings will be controlled and limited to revised drawings or elements which control changes. Changes to functional drawings, i.e. electrical one line, will be maintained current for users.

23. Paragraph h of page III-5 has been revised to describe approval responsibilities for maintenance, modification and inspection procedures prior to implementation.

24. Compliance with the comment has been accomplished by adding 3.2.2.h.3.

25. Section 3.3.2.a has been expanded to comply with the comment.

26. Section 3.1.2 has been revised to require procedures, instructions and/or drawings to be in compliance with the Plan.

27. The words "major participating organizations" in Section 3.3.3.1(a) have been deleted.

28. The purpose and use of ECM's is described in Appendix B to the Plan. ECM's are one form of document covered under the broad heading of design control.

29. Design verification will be completed prior to making the tie-in to the plant system. This requirement has been added to Section 4.2.1(i).

30. Appendix B identifies the engineering documents that are reviewed, approved or concurred with by QA.

31. A requirement to implement the QA Plan in the procurement of spare or replacement parts has been added to Section 5.1.2.1(a).

32. Section 5.1.2.3(c) has been revised to add QA concurrence of nonconformances dispositioned "use-as-is" or "repair" and to provide follow up of corrective action implementation.

33. The requirements for control of identification of materials, parts and components during the maintenance and operations phase have been included in Section 6.2.1.6(e) and 6.2.1.11.

34. The comment has been incorporated. Section 5.2.2.c.2 has been supplemented to include "as built" drawings.

35. The extent necessary is as determined by responsible management personnel and reviewed by the Quality Assurance Department. The response to comment #8 above also addresses this concern.

36. To assure that individuals performing inspections are sufficiently independent from individuals responsible for costs and schedules, the provisions of 6.2.1.1 will be amplified in the implementing procedures. These procedures will clarify that inspections will be performed by QA personnel or by individuals under the control of the QA Department.

37. The requirement for QA concurrence of work authorization documents, relating to work important to safety, has been added to Section 6.2.1.1, page VI-4.

38. The second sentence, fourth paragraph, page VI-4 has been revised to read:

> "Where verification of inspection is being performed on previously accepted lots, sampling inspection shall be representative and only to the extent necessary to assure adequacy of control".

39. The test program to cover tests associated with technical specifications and inservice inspection is covered in Sections 6.2.1.4(1 thru 4) and 6.2.1.7.

40. A statement has been added that programs for control of measuring and test equipment are subject to QAD surveillance and auditing (see 3rd paragraph, page VI-9) and Section 6.2.1.2 has been added describing Plant QA Monitoring.

41. This subject is addressed in the description of Level I activities in Section 2.1.3 and in Section 6.2.1.2 which describes Plant QA Monitoring.

42&43. The QA organization involvement in these areas is described in Section 6.2.1.

44. The QA organization involvement in these areas is described in Sections 6.2.1 6.2.1.2.

45. Appendix B identifies documents which are reviewed, approved or concurred with by the QAD, and also indicates whether such review, approval or concurrence is performed prior to implementation.

46.47. Sections 6.2.1 and 6.2.1.2 describe the involvement of the QAD in these areas.

48. Section 7.1 has been revised to comply with this comment.

49. Sections 8.2.b and 8.2.e(2) have been modified to require QAD concurrence in the disposition of nonconformances. The requirement for reinspection and close out is contained in 8.2.e(4).

50. Malfunctions resulting from material or manufacturing deficiencies will be reported via the nonconformance reporting system. Technical Specifications include provisions for reporting designated malfunctions to the Nuclear Regulatory Commission via Licensing Event Reports. These will not normally be duplicated on a nonconformance report.

51. Section 9.2.e includes the requested coverage.

52. The TMI QA organization is and will be sufficiently staffed and managed to assure proper and effective implementation of the QA Program for TMI Unit 1 through the attention of the Vice President - Nuclear Assurance and the Manager of Q.A. in day-to-day activities at TMI-1. This effort will assure that the QA staff and its activities associated with TMI-1 will not be diluted or compromised to support other activities and responsibilities outside of TMI-1.