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71-0135

Nuclear Materials Division

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Telephone: (412) 842-0111

May 16, 1980



Mr. C. MacDonald, Chief
 Transportation Branch
 U.S. Nuclear Regulatory Commission
 Office of Nuclear Material Safety & Safeguards
 Washington, D.C. 20555

Dear Mr. MacDonald:

This refers to your March 14, 1980 letter and its enclosed request for additional information to satisfy the applicable requirements of Appendix E to 10 CFR Part 71.

In response to this request, seven copies of Revision No. 9 of the Pennsylvania Operations' Quality Assurance Policy and Procedures Manual are provided as enclosures to this letter.

To facilitate your review of this manual, a table referencing each of your comments to the applicable paragraphs of the manual is provided as an attachment to this letter.

If you have any questions regarding this submittal, please contact either myself or Mr. Robert M. Jackman, Manager of Quality Assurance.

Sincerely,

MA Austin

Michael A. Austin
 Manager, Technical Control

MAA/mhb

Attachments

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ATTACHMENT

Information Requested	Applicable Para. QA-72-1
1. Describe the QA responsibilities of each organizational element which falls under the QA department (Figure 1-3).	1.3.1
2. Identify the management level responsible for establishing B&W's QA policies, goals, and objectives.	1.1, 1.2, 1.3.1
3. Describe the qualification requirements for the position of Manager, Quality Assurance.	1.3.1.1(d)
4. Provide a statement that management (i.e., above or outside the QA organization) regularly assesses the scope, status, implementation, and effectiveness of the QA program to assure that the program is adequate and complies with 10 CFR Part 71, Appendix E criteria.	2.10
5. Describe the mechanism for communicating to all responsible organizations and individuals that quality policies, QA manuals, and procedures are mandatory requirements.	Introduction, QA Policies, Item 11
6. Provide a matrix of the QA procedures cross-referenced to each criterion of Appendix E to 10 CFR Part 71.	2.9.1, Appendix I
7. Identify the safety-related structures, systems, and components controlled by the QA program.	2.9.2, Appendix II
8. Provide a statement that B&W reviews and documents agreement with the QA program provisions of his contractors to the extent that he can be assured that Appendix E will be implemented.	4.2.5.3, 7.1
9. Describe how disputes involving quality, arising from a difference of opinion between QA/QC personnel and other department (engineering, procurement, manufacturing, etc.) personnel are resolved.	2.2
10. Clarify that the indoctrination and training program is established such that:	
a. Personnel responsible for performing quality-affecting activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.	2.6.2
b. Personnel performing quality-affecting activities are trained and qualified in the principles and techniques of the activity being performed.	2.6.1

ATTACHMENT (Cont'd)

Information Requested	Applicable Para. QA-72-1
c. The scope, the objective, and the method of implementing the indoctrination and training program are documented.	2.6.3
d. Proficiency of personnel performing quality-affecting activities is maintained by retraining, reexamining, and/or recertifying.	2.6.4
11. Provide a statement that procurement documents identify the applicable 10 CFR Part 71, Appendix E requirements which must be complied with and described in the supplier's QA program. This QA program or portions thereof shall be reviewed and concurred with by qualified personnel in QA prior to initiation of activities affected by the program.	4.2.5.3, 4.2.5.9
12. Provide a statement that procurement documents identify the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, and chemical and physical test results of material) to be prepared, maintained, and submitted to B&W for review and approval.	4.2.5.7, 4.2.5.9, 10.2.2.1
13. Provide a statement that procurement documents identify those records to be retained, controlled, and maintained by the supplier, and those delivered to B&W prior to use or installation of the hardware.	4.2.5.7
14. Provide a statement that procurement documents contain the B&W right of access to supplier's facilities and records for source inspection and audit.	4.2.5.10
15. Provide a statement that methods for complying with each of the 18 criteria of 10 CFR Part 71, Appendix E are specified in instructions, procedures, and drawings.	5.2.6
16. Provide a statement that instructions, procedures, and drawings include quantitative (such as dimensions, tolerances, and operating limits) and qualitative (such as workmanship samples) acceptance criteria to verify that important activities have been satisfactorily accomplished.	5.2.2, 5.2.6
17. Provide a statement that documents are available at the location where the activity will be performed prior to commencing the work.	5.3
18. Provide a statement that the results of supplier evaluations are documented and filed.	7.1, 7.5.8
19. Provide a statement that the supplier furnishes the following records as a minimum to B&W:	

ATTACHMENT (Cont'd)

Information Requested	Applicable Para. QA-72-1
a. Documentation that identifies the purchased material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications) met by the items.	4.2.5.7, 7.6.1
b. Documentation that identifies any procurement requirements which have not been met together with a description of those nonconformances dispositioned "accept as is" or "repair."	7.6.2
The review and acceptance of these documents shall be described in BMW's QA program and as a minimum shall be undertaken by a responsible QA individual.	7.6.3
20. Provide a statement that supplier's certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid.	7.5.3.5, 10.2.2
21. Provide a statement that identification requirements are determined during generation of specifications and design drawings.	8.2.1.1
22. Provide a statement that the identification and control procedures assure that identification is maintained either on the item or on records traceable to the item to preclude use of incorrect or defective items.	8.2.1.2
23. Provide a statement that identification of materials and parts important to the function of safety-related structures, systems and components can be traced to the appropriate documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports.	8.2.1.3
24. Provide a statement that the location and the method of identification do not affect the fit, function, or quality of the item being identified.	8.2.1.2
25. Provide a statement that special processes such as welding and heat treating are procedurally controlled.	9.2.1, 9.2.2
26. Provide a statement that procedures, equipment, and personnel connected with special processes are qualified in accordance with applicable codes, standards, and specifications.	9.1
27. Provide a statement that special processes are performed by qualified personnel and accomplished in accordance with written process sheets or equipment with recorded evidence of verification.	9.2.4
28. Provide a statement that inspection procedures or instructions are used with necessary drawings and specifications when performing inspection operations.	10.2.1.4

ATTACHMENT (Cont'd)

Information Requested	Applicable Para. QA-72-1
29. Provide a statement that inspectors are qualified in accordance with applicable codes, standards, and company training programs; and their qualifications and certifications are kept current.	2.6, 10.2.1.5
30. Provide a statement that modifications, repairs, and replacements are inspected in accordance with the original design and inspection requirements or acceptable alternatives.	10.2.1.6
31. Provide a statement that indirect control by monitoring processing methods, equipment, and personnel is undertaken when direct inspection is not possible.	7.5.1, 10.2.6
32. Provide a statement that special handling, preservation, storage, cleaning, packaging, and shipping requirements are established and accomplished by qualified individuals in accordance with predetermined work and inspection instructions.	13.1
33. Provide a statement that procedures are prepared which control the cleaning, handling, storage, packaging, shipping, and preservation of materials, components, and systems in accordance with design and specification requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.	13.1
34. Provide a statement that bypassing of required inspections, tests, and other critical operations is procedurally controlled under the cognizance of the QA organization.	14.2.1.2
35. Provide a statement that acceptability of rework or repair of materials, parts, components, systems, and structures is verified by reinspecting and retesting the item as originally inspected and tested or by a method which is at least equal to the original inspection and testing method. Inspection, testing, rework, and repair procedures are documented.	8.2.4.7, 15.2.1.3
36. Provide a statement that nonconformance reports dispositioned "accept as is" or "repair" are made part of the inspection records and forwarded with the hardware to B&W for review and assessment.	8.2.4.9, 15.2.2
37. Provide a statement that record storage facilities are constructed, located, and secured to prevent destruction of the records by fire, flooding, theft, and deterioration by environmental conditions such as temperature or humidity.	17.2.4
38. Provide a statement that deficient areas are reaudited on a timely basis to verify implementation of corrective actions which minimize recurrence of deficiencies.	18.3 - 16(a)
39. Provide a statement that audits include an objective evaluation of quality-related practices, procedures, and instructions and the effectiveness of implementation.	18.3 - 7