UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

AUG 26 1980

FCTC:RHO
71-0370

Amersham Corporation
ATTN: Mr. D. P. Belgrair
2636 S. Clearbrook Drive
Arlington Heights, IL 60005

Gentlemen:

We have evaluated your quality assurance program submitted with your July 14, 1980 letter to satisfy the requirements of 10 CFR §71.51.

Our review indicates that additional information is required to satisfy the applicable requirements of Appendix E to 10 CFR Part 71. Please address the enclosed request for additional information and submit seven copies of the revised program within 60 days following receipt of this letter.

If you have any questions regarding this request, please feel free to contact Mr. Jim Conway at (301) 492-7741.

Sincerely,

Charles E. MacDonald, Chief
Transportation Certification Branch
Division of Fuel Cycle and Material
Safety, NMSS

Enclosure:
Request for Additional
Information

AMERSHAM CORPORATION (71-0370)

Request for Additional Information

1. Describe the QA/QC functions performed by Amersham's QA organization or delegated to other organizations providing controls to assure appropriate elements of Appendix E will be implemented.

2. Provide a statement that procedures are established that clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of procurement documents.

3. 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.

4. Provide a statement that procurement documents contain or reference the design basis technical requirements including the applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and industrial standards, test and inspection requirements, and special process instructions.

5. Provide a statement that procurement documents identify the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedures qualifications, and chemical and physical test results of material) to be prepared, maintained, and submitted to the purchaser for review and approval.

6. Provide a statement that the review, approval, and issue of documents and changes thereto, prior to release, are procedurally controlled to assure they are adequate and the quality requirements are stated.

7. Provide a statement that changes to documents are reviewed and approved by the same organizations that performed the original review and approval or by other qualified responsible organizations delegated by Amersham.

8. Provide a statement that approved changes are included in instructions, procedures, drawings, and other documents prior to implementation of the change.

9. Provide a statement that documents are available at the location where the activity will be performed prior to commencing the work.

10. Provide a statement that a master list, or equivalent, is established to identify the current revision number of instructions, procedures, specifications, drawings, and procurement documents.

11. Provide a statement that procedures are established to identify and control materials, parts, and components including partially fabricated subassemblies.

12. Provide a statement that identification of materials and parts important to the function of safety-related 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.

13. Provide a statement that correct identification of materials, parts, and components is verified and documented prior to release for fabrication, assembling and installation.

14. Clarify that inspection personnel are independent from the individuals performing the activity being inspected.

15. Provide a statement that measuring and test instruments are calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.

16. Provide a statement that reference and transfer standards are traceable to nationally recognized standards; or, where national standards do not exist, provisions are established to document the basis for calibration.

17. 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.

18. Provide a statement that departure, arrival time, and destination of a package will be established and monitored to a degree consistent with the safe transportation of the package.

19. Provide a statement that bypassing of required inspections, tests, and other critical operations is procedurally controlled.

20. Provide a statement that records are identifiable and retrievable.

21. Provide a statement that a list of the required records and their storage locations will be maintained.

22. Provide a statement that design related records (e.g., drawings, calculations, etc.) are maintained for the life of the shipping package and all other records are maintained for a minimum of two years.

23. Provide a statement that inspection and test records contain the following where applicable:

    (1) A description of the type of observation.

    (2) Evidence of completing and verifying a manufacturing, inspection, or test operation.

    (3) The date and results of the inspection or test.

(4) Information related to conditions adverse to quality.

(5) Inspector or data recorder identification.

(6) Evidence as to the acceptability of the results.

24. Provide a statement that audits are performed in accordance with preestablished written procedures or check lists and conducted by personnel not having direct responsibilities in the areas being audited.

25. Provide a statement that audit results are documented and then reviewed with management having responsibility in the area audited.

26. Provide a statement that deficient areas are reaudited on a timely basis to verify implementation of corrective actions which minimize recurrence of deficiencies.