

EXIDE INDUSTRIAL BATTERY DIVISION
ESB INCORPORATED



101 Gibraltar Road
Horsham, PA 19044

June 19, 1979

Mr. Uldis Potapovs, Chief
Vendor Inspection Branch
United States Nuclear
Regulatory Commission, Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Re: NRC Audit of Horsham, Pa.
May 1-4, 1979
Inspection Report No. 99900358/79-01

Gentlemen:

In regard to Mr. W. E. Foster's audit, our responses are as follows on the subject findings:

Deviation: Criterion V of Appendix B to 10 CFR 50 states, "Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

Contrary to the above, instructions or procedures have not been established which identify personnel authorized to review and approve documents which prescribe activities affecting quality. These documents include drawings, temporary manufacturing requirements, and material testing procedures.

Corrective Action: The responsible individuals in Design and Documentation were contacted to respond. Written procedures have been formulated to satisfy the above. Completion date will be on or before 8/1/79.

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Preventative Measures: Written procedures were available at the time of the audit. However, they were outdated and did not reflect the current operation. We appreciate your cooperation in pointing this out to us. The deviation has been communicated to the top level in the Engineering Dept. Commitments have been received that this area will be a dynamic one and written documented procedures will be updated on a periodic basis. Furthermore, the Q.A. activity will ascertain that this is being carried out.

Exide

Unresolved Item: Re page 5 of Report No. 99900358/79-01, paragraph 3.b.(1). An inconsistency exists between paragraph 6.4.2. of Revision 8 of the Quality Assurance Manual, dated January 27, 1979, and paragraph 5.1 of Quality Control Procedure No. 55.0 dated January 28, 1976. The latter indicates that quality documents shall be prepared by any responsible Q.A. personnel, while the former indicates that quality documents shall be prepared by any responsible person.

Corrective Action: Yes, the inconsistency exists. The Q.C.P. is correct in stating that quality documents shall be prepared by any responsible Q.A. person.

Furthermore, it can be stated in reality that inputs for quality documents can come from individuals outside the Q.A. activity. However, these inputs are cleared through the Q.C. Manager before any documents are issued.

The corrective action will be to change the wording of the Quality Assurance Manual to reflect the Q.C.P. This change is to be performed at the next review of the Q.A.M. on or before January 28, 1980.

Preventative Measures: The next review of the Q.A.M. and Q.C.P. will be more comprehensive to ascertain that a direct correlation exists between the two documents.

Unresolved Item: Re page 5 of Report No. 99900358/79-01, paragraph 3.b.(2). Paragraph 5.4 of Quality Control Procedure No. 55.0, dated January 28, 1976, indicates Q.A. approval shall appear on documents identified as: Manufacturing Requirements, Temporary Manufacturing Requirements, Engineering Specifications, and Purchase Requirements. However, Q.A. approval signature appears on the Design Notices for Manufacturing Requirements rather than on the Manufacturing Requirements.

Corrective Action: The Q.A. approval will appear on the first page of all future Manufacturing Requirements effective June 5, 1979.

Preventative Measures: See Corrective Action.

Unresolved Item: Re page 5 of Report No. 99900358/79-01, paragraph 3.b.(3). Routine Orders, Design Notices, Bills of Material, Assembly and Tray Drawings are distributed in accordance with a distribution list other than the one identified in Design Engineering Procedure No. S-25.11.1, dated May 2, 1975.

Corrective Action: The corrective action for the deviation, contained within this report, encompasses the distribution requirements as currently in effect. This written and documented procedure has been formulated and will be in effect on or before August 1, 1979.

Preventative Measures: The distribution list will be reviewed on a semi-annual basis.

Comments: Re page 6 of Report No. 99900358/79-01, paragraph 3.c.(1) and (2).
(1) The Cleveland Electric Illuminating Company letter to ESB Incorporated, dated September 15, 1977, confirms award of contract P-1480-B and requires implementation of Exide's Quality Assurance Manual, Revision 7, dated May 5, 1977. The Quality Assurance Manual is currently at Revision 8 and Revision 7 had not been maintained on distribution for implementation on contract P-1480-B.

(2) The identified customer order invoked the requirements for control of changes to software and hardware.

Corrective Action: Revision 8 is now specified as the Quality Assurance Manual for the Cleveland Illuminating Company contract P-1480-B. This action was pursued based on NRC's audit and Gilbert Associates, who is the contracting firm for C.E.I.

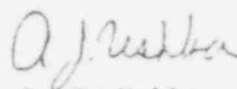
All other open contracts have been evaluated for the same condition. Submittals have been transmitted and acknowledgements have been received to reflect that Exide's Revision 8 manual is now in effect per contract.

Preventative Measures: Acknowledgements will be requested in all future changes to software where open contracts exist.

Summary: As can be noted, we took the prerogative to respond to all the findings, even though we were only required to indicate compliance to the deviations.

Should you have any questions concerning the responses, we will be pleased to discuss them with you.

Sincerely,



A. J. Ushka
Quality Assurance Director

cc: A. G. Koch
L. J. Thomas
J. Vinkler
G. R. Wallis