

Brand-Rex Company  
Electronic and Industrial Control Division  
Docket No. 99900325/80-01

NOTICE OF DEVIATION

Based on the results of an NRC inspection conducted on May 20-22, 1980, it appears that certain of your activities were not conducted in accordance with NRC requirements as indicated below:

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." Deviations from these requirements are as follows:

A. Section V, Revision 1, dated August 1976, of the Quality Assurance Manual, contains the following requirements:

1. Paragraph 5.0 states, "The quality program assures that all work affecting quality, such as purchasing, manufacturing, inspection, test and any operation affecting our product is prescribed in clear and complete documented instructions of a type appropriate to the circumstances. These instructions provide the criterion for inspection and work performance, acceptance and workmanship directed towards the product."

Contrary to the above, the Production Control Department is responsible for initiating Shop Orders, but had not generated clear and complete documented instructions for such initiation.

2. Paragraph 5.1 states in part, "The responsibility for generating these procedures lies with the department performing the operation." Additionally, Manufacturing Procedure No. 030, Revision 0, dated April 1978, states in part, "At each extruder there are Extruding Guideline Books by tab number. Each tab number product should have a guideline. If Extruding Guideline is not available, inform your foreman who will have one made out. The Extruding Guidelines are used as guidelines for setting up the extruder and for running speeds." Note: The inspector was informed that Extruding Guidelines were formerly identified as Manufacturing Specifications; many of which are still in use.

Contrary to the above, the Manufacturing Department had not generated Manufacturing Specifications (Extruding Guidelines) for the following tasks which were observed to be in progress:

- a. Primary extrusion on Part No. T-7222(1/08) for Order No. A-81670-64 on Machine No. 38.
- b. Primary extrusion on Part No. T-7499 (3/4/0) for Order No. B-89368-4 on Machine No. 75.
- c. Primary extrusion on Part No. T-549 (1/12) for Order No. A-89069-42 on Machine No. 34.
- d. Primary extrusion on Part No. T-458 (1/16) for Order No. G-81120-8 on Machine No. 49.

Note: There was no Extruding Guidelines Book at Machine No. 49.

During the exit interview, the NRC inspector was informed that Machine No. 49 was a new machine undergoing set-up procedures; however, the wire being processed represented an active order.

- B. Operating Memo No. 317-00-1 (also numbered 313-00-2), Issue 1, dated September 9, 1975, states in part, "Note: Photographs of actual joints will be taken and added to this operating memo."

Contrary to the above, photographs of actual joints had not been taken and added to the operating memo.

- C. Engineering Procedure No. XII-0, dated August 17, 1979 (page 4), contains the following requirements:

1. Paragraph 5.3.2 states, "All ECN's pertaining to products which specification references 10 CFR-50 and/or ANSI 45.2 must be submitted to Quality Assurance for approval and returned to Product Engineering within one working day."
2. Paragraph 5.3.5 states, "All ECN's will be approved by a Product Engineer and the Engineering Manager."

Note: ECN's are entitled Engineering Revisions.

Contrary to the above, the following Engineering Revisions (ECN's), on products requiring 10 CFR 50, Appendix B and/or ANSI N45.2, had not been approved by QA: Part No. T-7243-3PR/19, dated April 29, 1980; Part No. T-458-1/16, dated February 18, 1980, nor had this document been approved by Engineering.

Also, an Inter-Office Correspondence (IOC) dated December 28, 1979, was used "in lieu of the regular change notice normally issued with each change" to effect changes on numerous part numbers, T-7301 4P/16 being among them. This document had not been approved by Q.A. nor were there documented instructions or procedures that permitted the use of an IOC for effecting changes.

- D. An unnumbered procedure entitled, Procedure for Repairs, dated October 1979, requires that a foreman complete a Repair Request set of forms on questionable product in his area. The shift superintendent authorizes processing or holding that material in the department pending final disposition. The pink copy of the set of tags is placed on the material awaiting final disposition and there is a prohibition of moving material with a pink tag attached.

Contrary to the above, the following material identified with the pink copies of the Repair Request tag attached, had been moved from one department to another: Part No. T-7540 3/4/0, Order No. D89124-21 on Tag No. 00946 dated May 13, 1980, and Part No. T-8715 37/16, Order No. HB6422-1 on Tag No. 01029 dated May 21, 1980.