

NOTICE OF DEVIATION

Based on the results of an NRC inspection conducted on July 18-21, 1978, it appeared that certain of your activities were not conducted in full compliance with NRC requirements as indicated below:

- A. Section 5 of the General Electric Topical Report, NEDO-11209-03A, states in part, "Activities affecting quality, including methods of complying with 10 CFR 50, Appendix B, are delineated, accomplished, and controlled by such documents as policies, procedures, operating instructions, design specifications, shop drawings, planning sheets, test and inspection procedures, and standing instructions."

Wilmington Manufacturing Department Quality Assurance Program, dated March 1978, Section 6.13.5, states in part, "Establish measures to control . . . packaging . . . of items in accordance with established instructions, procedures, or drawings to prevent damage, deterioration, and loss Control of packaging, marking, and preservation is in accordance with manufacturing Packaging Data Sheets and/or Product and Process Quality Plans developed for each area of need."

Contrary to the above, it was observed that the measures established to control the packaging of items for shipment were not being followed. (See Details Section, Paragraph C.3.).

- B. Section 6 of the General Electric Topical Report, NEDO-11209-03A, states in part, "Procedures and practices are established, documented and implemented to control the issuance and use of documents These measures provide assurance that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are promptly distributed for use at the location where the prescribed activity is performed."

Wilmington Manufacturing Department Quality Assurance Program, dated March 1978, Section 6.6.3 states in part, "Documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed"

Contrary to the above, the humidity test requirements of Quality Control Instruction (QCII) for Packaging Data Sheet #001 had been revised (relaxed) and released to the work station without evidence that this change had been reviewed for adequacy by authorized personnel.

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- C. Section 7 of the General Electric Topical Report, NED0-11209-03A, states in part, "Procedures and practices are established and documented to provide assurance that purchased items and services, whether purchased directly or through subcontractors, conform to the procurement document requirements. These measures include provisions, as appropriate, for the following; source evaluation and selection,"

Practices and Procedure, Vendor Survey, 60-11, paragraph 3.2, states in part, "Purchase Material Quality Control is responsible for . . . completing survey forms and supplements, issuing the Survey Approval Vendor List quarterly, and filing and maintaining vendor survey forms."

Contrary to the above, some vendors were found that were not on the Survey Approved Vendor List nor were survey forms on file (See Details Section, Paragraph D.3.).

inspection instructions were not properly reviewed prior to release in accordance with the Topical Report, Section 6, and the Quality Assurance Programs, Section 6.13.5, (See Enclosure, Item B). Procurement Procedures - some vendors were not found on the Survey Approved Vendor List nor were surveys on file in compliance with the Topical Report, Section 7, and Practices and Procedure, 60-11, (See Enclosure, Item C).

Unresolved Items: Handling, Storage, and Shipping - some confusion exists on how ANSI 45.2.2 requirements on deleterious or halogen content of tapes, desiccants, wraps etc., are to be identified in specifications and how these specifications are to be implemented (See Details Section, Paragraph C.3.b(1)). Handling, Storage, and Shipping - Time did not allow for recovery of records which would demonstrate conformance of shipping containers to the Certificate of Compliance (See Details Section, Paragraph C.3.b.(2)).