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SUBJECT: USNRC Inspection

Docket No. 99900503/82-02 Notice of Nonconformance

September 8, 1982

SEP 1 3 1982

U. S. Nuclear Regulatory Commission Region IV 611 Ryan Plaza Drive Suite 1000 Arlington, Texas 76011

Attention: Uldis Potapous, Chief Vendor Programs Branch

Gentlemen:

Attached are the responses to the Notice of Nonconformance transmitted by your letter for the inspections conducted on June 7-11, 1982, at our New York/New Jersey offices.

Each of our responses contain, in the requested format, a description of the steps that have been or will be taken regarding the nonconformances. The responses are not proprietary.

Should you have any questions regarding the subject responses, please feel free to contact either me at (201) 265-2000, extension 2456 or Mr. William P. Rausch, Director of Project Support and Quality Assurance Divisions, at extension 2655.

Wery truly yours, William P. Raugh

Tom A. Hendrickson Vice President

TAH:map

Attachments (1) Nonconformance "A"

(2) Nonconformance "B"

(3) Nonconformance "C"

(4) Nonconformance "D"

NONCONFORMANCE A

Paragraph 2.1 of Chapter VI, "Document Control" of the Burns and Roe (B&R) topical report (B&ROE-COM4-1-NP) states in part that, "The Burns and Roe, Inc. document control program is governed by a series of policy statements, standards, and procedures contained in the CORPORATE OPERATIONS MANUAL..."

The Corporate Operations Manual, states in part that the "Division and Department CORPORATE OPERATIONS MANUAL coordinators...personally removes and destroys any superseded or deleted material."

Contrary to the above, the B&R document control program was not effectively governed by a procedure contained in the Corporate Operations Manual as evidenced by the fact that superseded revision 0 of the procedure "Program (Computer) Approval and Certification" was not removed by the designated coordinator from the controlled copy of the Corporate Operations Manual assigned to the B&R Woodbury facility library. This is the second consecutive inspection in which controlled manuals were determined to contain superseded procedures.

Company's Response

The "nonconformance" is acknowledged. However, it should be noted that the finding of one superseded procedure in one 7 volume manual which contains over 295 controlled policies, procedures, and chapters does not constitute a significant audit finding. The NRC inspector did note that the revised procedure was contained in the book along with the outdated document.

Corrective Action

A special audit will be performed to verify that each Corporate Operations Manual in the New York/New Jersey/Richland, Washington area is up-to-date. The audit will assure each of the seven volumes of the copies distributed have the correct revision for each policy, procedure, and chapter (100% inspection). This audit will be completed by 10/8/82.

A procedure, Administration of and Changes to the CORPORATE OPERATIONS MANUAL, PARTS I through V, will be developed and issued by 10/15/82.

Preventive Action

As part of the audit, the entire seven volumes of the Corporate Operations Manual will be removed from the assigned holder if the results warrant that action. The holder of the removed Manuals must then request that the Manuals be returned. The request to the Director of Project Support and Quality Assurance will require the assigned holder to describe the actions taken to assure that the Corporate Operations Manual will be maintained up-to-date.

DESIGNATED ORIGINAL
Certified By La Calle

NONCONFORMANCE B

Paragraph 2.1 of Chapter V (Instructions, Procedures, and Drawings) of the B&R Topical Report states in part that, "Burns and Roe, Inc. working documents, such as instructions, procedures, drawings, and specifications, and changes thereto, are prepared, reviewed, and approved in accordance with this manual, project procedures, and company standards which outline the sequence of actions in detail."

Computer Users Manual procedure, "Abstracts of Available Programs," states in part that, "All programs available to Burns and Roe computer users are contained in the computer program index...(the) computer program index...(is a listing which) consists of one line of information about each computer program. It contains: program number, name, description, machine requirements, program status and advisor's name..."

Contrary to the above, the latest issue of the Computer Program Index (dated December 31, 1981) was not prepared in accordance with procedural requirements in that:

- The index did not list all engineering and design programs available to B&R computer users.
- 2. The index did not contact the advisor's name for approximately one fourth of the 270 engineer of design programs that were listed in the index.

Company's Response

The nonconformance is acknowledged.

Corrective and Preventive Action

Currently, abstracts of available engineering programs which are technically approved are contained in the Burns and Roe Engineering Standards. It has been determined that the index produced by Technical Services is a duplication of that information and will be deleted. The Computer Users Manual will be revised to indicate that the Computer Program Index is a Technical Services internal division document which will be for their information and use only. The Computer Users Manual will be updated by 10/29/82. The reference to the Computer Program Index in the Burns and Roe Engineering Standards will be deleted by 10/29/82.

NONCONFORMANCE C

Paragraph 4.9 of Chapter III (Design Control) of the B&R Topical Report states in part that "The use of computer codes is procedurally controlled...by the Computer Users Manual..."

Computer Users Manual procedure, "Program Approval and Certification," states in part that, "Vendor supplied programs will be designated as 'Certified-V'..."

Computer Users Manual procedure, "Abstracts of Available Programs," states in part that the Computer Program Index "...is a listing of all currently available programs and the approval status or documentation status... The Program status is defined as follows...'Certified-V'..." for vendor supplied programs approved for use.

Contrary to the above, the use of computer codes was not controlled by the Computer Users Manual procedure in that none of the currently available vendor supplied programs listed in the Computer Program Index had an approval or documentation status designated as "Certified-V" even though they were available for use by B&R computer users.

Company's Response

The nonconformance is acknowledged.

Corrective Action

Vendor supplied programs that are used at Burns and Roe will be reviewed for conformance to the requirements for 'Certified-V' as stated in the 'Computer Users Manual'. If they satisfy the requirements, their status will be changed to 'Certified-V' on the Technical Services Divisional listing of Computer Programs (see Nonconformance B regarding the elimination of the Computer Program or obtained from a vendor, are listed in the Burns and Roe Engineering Standards.

Preventive Measures

Each vendor supplied program submitted for approval in the future will be reviewed for conformance to the requirements for 'Certified-V' and put into that the requirements, it is listed in the Engineering Standards under the section of Computer Programs.

This preventive measure is presently in effect.

NONCONFORMANCE D

Paragraph 2.0 of Chapter III "Design Control" of the B&R Topical Report states in part that, "The Burns and Roe, Inc. design control program complies with USNRC Regulatory Guide 1.64 (June 1976). The design control program has been established to assure that all design related activities are carried out in a planned, controlled, and orderly manner. These design activities include... analyses...(and) use of computer codes..."

Section 2.2 of ANSI N45.2.11-1974 "Quality Assurance Requirements for the Design of Nuclear Power Plants," endorsed by revision 2 of Regulatory Guide 1.64, dated June 1976, states in part that "Procedures shall be employed to assure that design activities are carried out in a planned, controlled, orderly, and correct manner. Program procedures shall cover the following...2.2.4. Document control including review, approval, release, distribution, and revision...2.2.5. Maintenance and retention of design documents...2.2.11. Performance of design verifications...2.2.13. Taking corrective action...2.2.14. Making experience reports available to cognizant design personnel...2.2.15. Controlling design changes."

Nonconformances with these commitments are as follows:

- Contrary to section 2.2.4 of ANSI N45.2.11, computer program users manuals, design manuals, and operations manuals for certified computer programs were not distributed in a controlled fashion by the Technical Services Librarian to all appropriate users.
- 2. Contrary to section 2.2.5 of ANSI N45.2.11-1974, design documents such as computer code user, design and operation manuals, review and approval records, and validation records, needed to provide traceability and to support "certified" computer programs, were not identified as quality assurance records and, therefore, were not maintained and retained with the status of a quality assurance record.
- 3. Contrary to section 2.2.11 of ANSI N45.2.11-1974, procedures did not exist, and thus were not implemented, to require design verification of computer programs, and revisions thereto, by individuals or groups other than those who defined or generated the analytical representation of the physical problem, the necessary assumptions to employ the analytical model selected, the solution methodology, and the implementing algorithms of the computer code. Further, approximately one half of the computer programs available for production use by B&R computer users are classified as "approval" (in accordance with procedure "Program Approval and Certification") for which design verification/validation of the program is not procedurally required.
- 4. Contrary to section 2.2.13 of ANSI N45.2.11-1974, as supplemented by section 9.0 of the subject standard, procedures did not exist, and, thus, were not implemented for: (1) determining the cause and instituting appropriate changes in the computer code development/validation process to prevent recurrence of a significant deficiency when detected in a computer code; (2) providing for reporting the deficiency and corrective action to appropriate levels of supervision and management; and (3) assuring follow-up action.

NONCONFORMANCE D (continued)

- 5. Contrary to section 2.2.14 of ANSI N45.2.11-1974, procedures did not exist, and, thus, were not implemented to make experience reports available to cognizant design personnel.
- 6. Contrary to section 2.2.15 of ANSI N45-2.11-1974, as supplemented by section 8.0 of the subject standard, procedures did not exist, and, thus, were not implemented for: (1) assuring that the impact of changes to computer codes is carefully considered and required actions documented; (2) justifying the change and subjecting the change to design control measures commensurate with those that were, or should have been, applied to the original code, including revalidation/reverification.

Company's Response for D.1

The nonconformance is acknowledged.

Corrective and Preventive Action

A procedure will be prepared defining the role of the Technical Services Librarian in the issuance and control of the initial distribution and revisions for computer program users manuals. This will include manuals for Burns and Roe as well as vendor developed programs.

Procedures will be revised to require the prospective user of a computer program to request a copy of the users program manual from the Technical Services Librarian and caution him to return the document when he has completed his task or when he leaves Burns and Roe.

Revisions to the procedures will be completed by 10/29/82.

Company's Response for D.2

The nonconformance is acknowledged.

Corrective and Preventive Action

Burns and Roe is currently evaluating whether or not to upgrade the vault where the records are stored to meet the requirements of Regulatory Guide 1.88, Rev. 2, 10/76. At the time of this response, a decision has not been made since the necessary cost information is being developed. Regardless, Burns and Roe shall correct this deficiency by 10/29/82 if the duplicate records method is used or by 12/31/82 if the single storage criteria is used.

A Technical Services Divisional procedure will be developed to control the activities associated with the quality records. This procedure will be implemented by 10/29/82.

NONCONFORMANCE D (continued)

Company's Response for D.3

The conconformance is acknowledged.

Although written procedures did not exist to require design verification of computer programs and revisions thereto, nor did procedures require retention of records relating to verification, our approach provided assurance that the computer programs used gave satisfactory results. The programs fall into two categories; those which were obtained from outside sources and those which were written within the Burns and Roe organization.

Corrective Action

A review of all certified or approved programs was conducted to verify whether adequate validation documentation was available to support the programs. For those programs without adequate validation used on a nuclear project, the necessary data is being gathered together to assure the programs provide accurate results. This activity affects 15 specific programs for which the documentation will be available by 9/30/82.

Preventive Action

Burns and Roe is now developing procedures to implement a more formal approach to computer program validation including records retention. This approach will include the development of an Engineering Standard for assurance of independent review of computer programs and their revisions and for documenting the validation process. This standard will be issued by 10/29/82.

Company's Response for D.4

The nonconformance is acknowledged except that:

- a) Project Procedure ED-003, "Reporting of Defects and Noncompliance," which is in effect for each nuclear project is available to the Technical Services Division. Specifically, Exhibit I, which is the posting of 10CFR21 is located at the bulletin board where the employees enter the building.
- b) The procedure for revising a computer code is on pages IV-B-5 and IV-B-6 of the 'Computer Users Manual'.

Corrective Action

Section C, Chapter IV of the 'Computer Users Manual', 'Revisions to Certified Approved Programs' will be reviewed and revised if considered necessary to improve its clarity with respect to this nonconformance. This will be accomplished by 10/29/82.

NONCONFORMANCE D (continued)

To reinforce Technical Services personnel cognizance of reporting deficiencies in computer codes, a one hour lecture on ED-003 "Reporting of Defects and Non-compliances" was presented to all Technical Services programmers and their management on 8/6&13/82. A copy of the attendance record is included in each person's personnel file; a copy was sent to Quality Assurance and the original was filed in Technical Services Division.

Preventive Action

Each new Technical Services programmer will receive indoctrination regarding ED-003 upon employment. The Technical Services internal procedure covering this will be published by 10/29/82.

Company's Response for D.5

The nonconformance is acknowledged.

Although formal procedures did not exist to make experience reports available to the cognizant design personnel, a program advisor was named for each code who was kept informed of the problems in running the program as well as technical problems with the program by the users. The program advisor plays a key role in factoring user experience into computer codes; especially during the period immediately after a code is developed since the experience factor is especially important at this time. Therefore, experience was factored into computer codes although not on a formal basis.

Corrective and Preventive Action

The computer center has started to distribute experience bulletins to users. A procedure will be developed to formalize this sharing of experience data in accordance with the requirements of Section 2.2.14 of ANSI N45.2.11-1974. This will be accomplished by 10/29/82.

Company's Response for D.6

The nonconformance is acknowledged. However, the procedure for modifying programs is Section C, Part IV-B of the 'Computer Users Manual' and is consistent with the original program development procedure.

Corrective and Preventive Action

An Engineering Standard covering the procedure for the validation of technical computer programs has been prepared and will be incorporated into Burns and Roe's Engineering Standards which are available to all Burns and Roe engineers. This procedure will be issued by 10/29/82.

As part of the current update of the 'Computer Users Manual', Section D, Part IV-B will be reviewed and expanded to specify the necessary requirement. This will be accomplished by 10/29/82.