QUALITY ASSURANCE SYSTEMS DOCUMENT

Franklin Research Center A Division of The Franklin Institute 20th and Race Streets, Phila., Pa. 19103 (215) 448-1000 **QUALITY ASSURANCE SYSTEMS**	**QASD No.** 17-1	**Page** 1 **of** 6
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	☒ **Prepared** R.J. Saggiomo ☒ **Approved** R.J. Saggiomo **QA Manager**	
TITLE SYSTEM FOR CONTROL OF NONCONFORMANCES	**Concurred By** T.S. Hermann **Dr. T.S. Hermann, President**	

1.0 PURPOSE

1.1 This second level document establishes the system necessary for implementing the requirements of Criteria XV and XVI in 10CFR50, Appendix B, the equivalent ANSI sections, and 10CFR21. The purpose of this document is twofold:

1.1.1 To establish a control system that provides for the documentation, segregation, and disposition of non-conformances, and the notification to affected organizations.

1.1.2 To establish a Corrective Action system which assures that conditions adverse to quality will be properly defined, controlled and actively corrected in a timely way.

2.0 RESPONSIBILITIES

2.1 Any individual who discovers a nonconformance is responsible for initiating a Nonconformance Report (NCR), and having it reviewed and approved by the Manager of Quality Assurance.

2.2. The Project Manager is responsible for initiation and implementation of Corrective Action Requests (CAR) that are appropriate to his area of responsibility. Furthermore, he is responsible for ensuring the implementation of the appropriate instructions in this QASD and for filing all completed Nonconformance Reports (NCR) and Corrective Action Requests with the Quality Assurance Manager.

2.3 The Manager of Quality Assurance is responsible as Chairman of the Material Review Board for the processing (dispositioning) and control of all Nonconformance Reports, and for assuring the timely notification to affected organizations.

2.4 The Manager of Quality Assurance is responsible for the approval and control of Corrective Action Requests, and for ensuring that corrective action is accomplished in a timely way.

2.5 The Manager of Quality Assurance is responsible for designating a segregated quality-controlled hold area for nonconforming items awaiting final disposition. Furthermore, he shall provide nonconformance material tags or other suitable designation for items found to be discrepant.

3.0 DEFINITIONS

3.1 Nonconformance is a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate. Examples of nonconformances include: physical defects; test failures; incorrect or inadequate documentation; deviation from prescribed processing, inspection, or test procedures.

3.2 Deviation is a departure from specified requirements.

3.3 Nonconformance Report (NCR) is a written report which documents the information required for ultimate disposition of a nonconforming item (material, part, component) or activity. (See Exhibit I).

3.4 Corrective Action Request (CAR) is a written report which documents the information required to minimize or prevent recurrence of a nonconformance. (See Exhibit II)

3.5 Nonconformance Material Tag (Exhibit III)

4.0 INSTRUCTIONS

4.1 When an item is determined to be nonconforming, the inspector shall carry out the instructions below. If the nonconformance reasonably indicates a substantial safety hazard, implement QAP No. 17-1, Rev. 1, "Implementation of 10CFR21."

4.1.1 Prepare a Nonconformance Report (NCR) after obtaining from the Manager of Quality Assurance an assigned NCR number. The latter will consist of the four digit Franklin project number, a hyphen, the letters NCR, a hypen, and for each NCR generated on that project a sequential number commencing with 01. For example, 5653-NCR-02 will represent the second Nonconformance Report on Project 5653. (Corrective Action Requests will correspondingly be designated using the notation CAR in place of NCR).

4.1.2 Prepare a Nonconformance Material Tag, as required, and affix it to the item. Identification of nonconforming items may be made by marking the item, provided it does not adversely affect the end use of the item, and is legible and easily recognizable. If identification of each nonconforming item is not practical the container, package, or segregated storage area will be identified.

4.1.3 Affix a copy of the Nonconformance Report to the item by use of a plastic holder.

4.1.4 Move the item to the designated quality-controlled hold area. When segregation is impractical or impossible due to physical conditions (such as size, weight or access limitations), other precautions shall be employed to preclude inadvertent use of the nonconforming item.

4.1.5 The original Nonconformance Report shall be given to the Manager of Quality Assurance, and a copy provided the responsible Project Manager and Purchasing Manager.

4.2 As Chairman of the Material Review Board, the Manager of Quality Assurance shall do the following in a timely way.

4.2.1 Determine proper disposition by a review with the Project Manager and Sponsor.

4.2.2 Document the agreed upon disposition and obtain written approvals from Sponsor and Project Manager. Technical justification for the acceptability of a nonconforming item (dispositioned repair or use-as-is) shall be documented. The as-built records, if such records are required, shall reflect the accepted deviation. Deviations from approved Test Procedures shall be documented using Exhibit I, QAP No. 9-2, Rev. 0, "Request for Deviation from Test Specification."

4.2.3 Review and approve all rework or repair planning which shall include necessary reinspection and acceptance criteria.

4.2.4 Initiate "Corrective Action Request" if required, and take necessary action to ensure corrective action is conducted in a timely way.

5.0 CROSS REFERENCES

5.1 Quality Assurance Manual - Sections 17 and 18

5.2 Quality Assuance Procedure No. 9-2, Rev. 0 - "Revisions to Test Procedures"

5.3 Quality Assurance Procedure No. 17-1, Rev. 1 - "Implementation of 10CFR21 - Reporting of Defects and Noncompliance"

6.0 COUNSEL AND REVIEW CONTACT

6.1 Manager of Quality Assurance

7.0 DISTRIBUTION

7.1 Manager of Quality Assurance

7.2 Department Heads

7.3 Manager of Purchasing

QUALITY ASSURANCE

NONCONFORMANCE REPORT

NCR No. _____ Project No. _____

Date _____ Contract No. _____

Preparer _____ P.O. No. _____

DESCRIPTION OF ITEM:

LOCATION OF ITEM:

DESCRIPTION OF NONCONFORMANCE:

DISPOSITION OF NONCONFORMANCE:

(Technical justification for the acceptability of a nonconformance, dispositioned repair or use-as-is, shall be documented.)

CORRECTIVE ACTION REQUEST:

Issued to:

Date:

_____
Project Manager

Approved _____ _____
Project Manager Date

Approved _____ _____
Client Representative Date

Approved _____ _____

QUALITY ASSURANCE

CORRECTIVE ACTION REQUEST

CAR No. _____ Project No. _____

Date _____ Contract No. _____

Preparer _____ P.O. No. _____

ISSUED TO:

DESCRIPTION OF ITEM:

DESCRIPTION OF NONCONFORMANCE:

REQUEST REPLY WITHIN ____ DAYS OF ABOVE DATE:

Cause of Nonconformance --

Corrective Action To Be Taken --

Measures To Prevent Recurrence --

Date for Completed Action --

_____ _____
Addressee Signature Date

Approved _____ _____
Project Manager Date

Action Verified _____ _____
Quality Assurance Manager Date

NON CONFORMING MATERIAL

NCR #_____