Nutherm
International, Inc.
www.nutherm.com

QUALITY ASSURANCE MANUAL

QA-N-10179-5
Revision 6
Effective Date: November 4, 2019

Approval:

Wade Bowlin — 11/4/19 — Date
Chairman of the Board

Adrienne B. Smith — 11/4/2019 — Date
Quality Assurance Manager

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NEW REVISION NOTICE

Nutherm International, Inc. (NI) Quality Assurance Manual (QAM) QA-N-10179-5, Rev. 6 supersedes Rev. 5, dated 3/8/93, in its entirety. NI's Quality Assurance (QA) Program described in Rev. 6 of NI's QAM meets or exceeds the requirements of 10 CFR 50, Appendix B; 10 CFR Part 21; ANSI/ASME N45.2; ASME NQA-1-1994 Edition; and ASME NQA-1-2008 including ASME NQA-1a-2009 (addenda to ASME NQA-1-2008) for supply of safety related items and services.

The following are additional enhancements associated with Rev. 6 of NI's QA Program:

Adds a section for Commercial Grade Dedication

Revision 6 does not impose or cause any retrofitting measures on past work performed by or for NI, as this revision meets or exceeds the prior QA requirements. The changes reflect NI's commitment to maintain QA excellence through continuous evaluation and updating of our quality program.

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STATEMENT OF POLICY

Nutherm International, Inc. (NI) policy is to manufacture all its products and perform all its work to quality standards that meet or exceed the requirements of 10CFR50 Appendix B, 10CFR Part 21, ANSI/ASME N45.2, ASME NQA-1-1994 Edition; and ASME NQA-1-2008 including ASME NQA-1a-2009 (addenda to ASME NQA-1-2008).

This Quality Assurance Manual (QAM) and its implementing procedures document the methods used to execute this policy. Since only by each employee's involvement and commitment to this program can true quality be achieved, each employee is informed by management that the employees primary work responsibility is to quality. All NI work is performed under this program in order that management can maintain this message and the employee can maintain a consistent goal. The goal of Nutherm upper management is the establishment and maintenance of an effective Quality Program.

Nutherm upper management is committed to support and provide the necessary resources and environment for the implementation of the NI Quality Assurance Program and foster the values of a nuclear safety culture. A nuclear safety culture is defined by the Institute of Nuclear Power Operations as "The core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment."

11/4/19
Thomas A. Sterbis Date
President

11/4/19
Wade Bowlin Date
Chairman of the Board

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INTRODUCTION

Nutherm International, Inc. (NI) exclusively serves the commercial nuclear power industry and government nuclear facilities. Nutherm manufactures and supplies a wide variety of seismically qualified, environmentally qualified, safety related, and/or Class 1E electrical equipment, qualifies and supplies replacement parts, and performs a variety of testing, commercial grade dedication, and qualification services on electrical and mechanical parts and systems. The Nutherm Quality Assurance (QA) Program shall apply to these activities.

Nutherm is a service oriented company. Our goal is to provide the best possible service to our customers. Each order has a project manager assigned to handle customer interface and to coordinate all aspects of the project. The project manager shall assure that all technical and quality requirements of the customer's purchase order/contract have been translated into the appropriate work documents.

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1.0 Organization

1.1 Scope

This section establishes requirements for the organizational structure, management, direction and execution of NI's QA Program.

1.2 Responsibility

Quality Assurance is the primary responsibility of each NI employee performing activities affecting quality and should not be regarded as solely the responsibility of the QA department.

The ultimate responsibility and authority for the quality of the work performed by NI rests with the Chairman of the Board (COB). The COB is responsible for establishing the expectations for effective implementation of the NI QA Program and for obtaining the desired end result.

The Manager of Quality Assurance (MQA) is responsible for defining and measuring the overall effectiveness of the QA Program. The MQA reports directly to the President and has access to the Chairman of the Board through dotted line reporting organizational structure.

The performance of quality assurance functions may be delegated. All delegated quality assurance functions must include a documented and defined interface control. In all cases, the person/organization delegating the work retains responsibility for the work performed.

1.3 Program Requirements

NI's organizational structure shall be depicted by organization charts. Functional responsibilities and levels of authority, to assure effective execution and implementation of the QA Program, shall be defined in NI QA Procedures (QAP's). The organization charts and QAP's shall document lines of communication.

Interfaces between organizations, groups, and/or individuals performing activities affecting quality, both internal and external, shall be documented and shall clearly define and document the responsibility and levels of authority.

The organizational structure and the responsibility assignments shall be such that:

A. Quality is achieved and maintained by those who have been assigned responsibility for the work; and
B. Quality achievement is verified by persons or organizations not directly responsible for performing the work.

The MQA shall be sufficiently independent from the pressures of production and have direct access to responsible management at a level where appropriate action can be effected.

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Personnel and organizations performing QA functions shall have sufficient well-defined responsibility, access to work areas, and organizational authority, independence, and freedom to:

A. Identify quality problems
B. Initiate, recommend or provide solutions through designated channels
C. Verify implementation of solutions
D. Control further processing, delivery or installation of a nonconforming item, deficiency or unsatisfactory condition until proper dispositioning has occurred.

Upper management shall regularly review the effectiveness of the QA Program.

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2.0 Quality Assurance Program

2.1 Scope

This section sets forth requirements for the establishment, execution, and maintenance of NI's QA Program to ensure that the Nutherm QA Program is planned, implemented and maintained.

2.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for establishing, documenting and maintaining an effective QA Program and monitoring and verifying implementation when not directly responsible for implementation. Responsible for reviewing Quality Assurance Procedures (QAP). Responsible for designating activities that require qualified inspection and test personnel. Responsible for assuring that personnel performing test and inspections are qualified and/or certified, as applicable.

Management, defined in this section of the QAM as Upper Management and Departmental Managers and Supervisors, - Responsible for active participation and support of the QA Program.

2.3 Program Requirements

NI's QA Program is designed to meet or exceed the requirements of 10 CFR 50 - Appendix B, 10 CFR Part 21, ANSI/ASME N45.2 and applicable daughter standards, ANSI/ASME NQA-1 1993 including the 1994 addenda; and NQA-1, 2008 including the 2009 addenda, other recognized and appropriate engineering codes, standards and practices. Description of methods to implement the requirements and provide controls, consistent with their importance, over activities affecting quality are defined in NI QA Procedures (QAP's). All activities affecting quality shall be planned and performed in controlled conditions; these activities shall be monitored against acceptance criteria to assure they are performed correctly and satisfactorily.

The QA Program ensures that activities affecting quality are recorded within a documented control system and are accomplished in accordance with written instructions, procedures or drawings. Activities affecting quality shall be planned and performed under controlled conditions including, as required, the following: appropriate equipment, suitable environmental conditions, completion of all prerequisites, implementation of any required special controls, processes, test equipment, tools, and/or skills. The requirement for qualified test and inspection personnel to perform activities affecting quality shall be designated by the responsible organization.

The QA Program provides for qualification, indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. Training requirements for activities affecting quality shall be delineated in QAP; requirements for achieving and maintaining proficiency shall be included within the procedures. Only trained/qualified personnel are permitted to

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perform activities affecting quality. Personnel qualification, indoctrination, and training records shall be maintained. Training and qualification requirements shall include guidance for qualification of personnel permitted to define inspection and test requirements and acceptance criteria.

The QA Program shall assure that personnel performing activities affecting quality, Non-Destructive Examinations, and audit functions are qualified and/or certified in accordance with appropriate codes, standards, and/or specified requirements. Provisions shall be made to provide for removal of personnel if it is determined that the individual's capabilities are not in accordance with specified requirements.

Only qualified audit personnel shall be used. Lead auditors shall be certified. The basis of certification of lead auditors shall include, as a minimum, the following: communication skills, training, audit participation, and examination. The basis continued certification and maintenance of certification shall be included in the implementing procedures along with requirements for requalification of lapsed certifications. Qualification and requirements for the use of Technical Specialists in audits shall be established.

Management of those organizations implementing the QA Program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation. Processes to detect and correct quality problems shall be established.

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3.0 Design Control

3.1 Scope

This section describes the requirements for establishing a design control program for nuclear safety-related structures, systems and components.

3.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for verifying the implementation of an effective design control program, when applicable.

Manager of Engineering - Responsible for ensuring that the appropriate technical aspects are performed and that designers, engineers, analysts and verifiers are in compliance with NI's design control program, when applicable. Responsible for assignment of design interface responsibilities.

Manager of Equipment Qualification - Responsible for ensuring that appropriate qualification test aspects are properly performed in accordance with NI's Design Control Program, when applicable.

Engineering – Department responsible for performing design activities.

3.3 Program Requirements

The design control program shall establish controlled processes for design activities. Procedural controls shall be established for providing guidance and control over design inputs, analysis, verification, changes, and interfaces. As applicable, procedural controls shall be established for providing guidance and control over computer software engineering, including, but not limited to software acquisition, development, operation, maintenance, lifecycle, and support software (software used to develop, operate, and/or maintain software) controls.

Controlled processes shall be established for design interfaces, for both internal (within Nutherm) and external entities, to document information transmitted across these interfaces. These processes shall control the review, approval, release, distribution, and revision of design documents.

Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented, and their selection reviewed and approved by the responsible design organization. The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner (correctly translated into specifications and/or work documents), to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. Changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled.

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Design methods, materials, parts, equipment and processes that are essential to the function of the structure, system or component, shall be selected and reviewed for suitability of application.

Procedures and processes shall include measures to assure that design analyses and calculations are documented and performed in a planned and controlled manner. Documents shall be legible as well as suitable for reproduction, filing and retrieval. Documents shall be in sufficient detail that a technically qualified person can review, understand and verify results without recourse to originator. Design documents shall provide the objective, method, assumptions (including identifying those that must be verified as the design proceeds), design inputs (and their sources), computer calculations/programming, references, and units.

Design analysis using computer software programs and reference or provide evidence of verification and validation of the software for the specific use. Software not procured as safety related shall either be verified for each application with the design analysis, or dedicated for use for the application.

Design analyses and calculations shall be reviewed and approved. Calculations shall be retrievable, and have, as a minimum, a subject, originator, reviewer, and dates.

Design control shall include measures to verify or check the adequacy of the design such as by one or more of the following: design reviews, the use of alternate calculations, or the performance of qualification tests. The design verification method used shall be identified and documented. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. The results of the verification shall be documented, any unverified portion of the design shall be identified with controls established to require completion of all verification activities prior to releasing the design for use in safety related applications. The verifier shall be identified in the design verification documentation.

Design verification activities shall be in sufficient detail to assure that the final design meets all requirements. The final design shall permit design verification activities by including sufficient documentation to relate the final design to the design inputs. All required tests and inspections shall be included in the final design together with the associated acceptance criteria. The final design shall identify the assemblies, components, and subcomponents that make up the design, including the identification of commercial grade items requiring dedication plans.

Changes to design documents shall be governed by design control measures commensurate with those applied to the original design. Design changes shall be justified. Design changes shall be reviewed and approved by the same group or organizations that performed the original design, review and approval.

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Procedures and processes for control of software applications shall be established. Software controls shall include, as applicable, design, configuration management, acquisition, development, operation, maintenance, and retirement. Development of software shall include planning, requirements, specifications, design, implementation, acquisition, verification and validation testing. Maintenance of software shall include configuration control, error reporting, and life cycle activities. The activities for control of software shall be documented and the records maintained in accordance with the Nutherm procedures established for records.

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4.0 Procurement Document Control

4.1 Scope

This section establishes requirements for the preparation, review and approval of procurement documents for nuclear safety-related items and services.

4.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for verifying the implementation of an effective procurement document control program. Responsible for assuring that suppliers have an acceptable quality assurance program consistent with the supplier's scope of supply for safety related items and services. Responsible for assuring that procurement documents contain requirements for the supplier to have a quality assurance program consistent with the requirements of the NI QA Manual.

Manager of Engineering – Responsible for ensuring that technical requirements are correctly specified in procurement documents for safety related items and Engineering services.

Manager of Laboratory – Responsible for ensuring that technical requirements are correctly specified in procurement documents for safety related calibration services.

4.3 Program Requirements

The program shall assure that applicable regulatory requirements, design bases and other requirements which are necessary to assure adequate quality are included or referenced in the documents for the procurement of nuclear safety-related items or services.

Procurement documents issued at all tiers for the procurement of nuclear safety-related items or services shall include provisions for the following, as applicable:

A. Scope of Work - A statement of the scope of the work to be performed by the supplier shall be in the procurement documents.
B. Technical Requirements - Technical requirements shall be specified in the procurement documents by reference to specific drawings, specifications, codes, standards, regulations, procedures or instructions, including revisions thereto that describe the items or services to be furnished. As applicable, test, inspections, acceptance requirements and any special instructions shall be identified.
C. Quality Assurance Program Requirements - Supplier QA program requirements shall be specified in the procurement documents and shall require the supplier to incorporate appropriate QA program requirements in subtier procurement documents. As applicable, the procurement document shall require suppliers to provide a Quality Assurance program consistent with the pertinent requirements of 10 CFR 50, Appendix B.

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D. Right of Access - The procurement documents shall provide for access to the Supplier's plant facilities, subtier facilities, and records for inspection or audit by NI or other parties authorized by NI.

E. Documentation Requirements - The procurement documents shall identify the documentation required to be submitted for information, review or approval and establish the time of submittal. Retention periods and disposition requirements for QA records shall be prescribed. This shall apply to required supplier generated documents, including changes and revision.

F. Nonconformances - The procurement documents shall include requirements for reporting and approving dispositions of nonconformances.

G. 10 CFR Part 21 - Reporting of Defects - The procurement documents shall invoke the requirements of Title 10 of the Code of Federal Regulations, Part 21.

H. Spare/Replacement Part Identification – The procurement documents shall require the supplier to provide information identifying spare and replacement parts or assemblies and the related data required for ordering them.

Prior to award, a review of the procurement documents and changes thereto shall be made to assure that documents transmitted to the prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements. The review shall be documented and performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents. Prior to issuance, changes made as a result of bid evaluations or negotiations to the technical or quality assurance program shall be incorporated into procurement documents.

Procurement document changes affecting the technical or quality assurance program requirements shall be subject to the same degree of control as utilized in the preparation of the original documents.

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5.0 Instructions, Procedures and Drawings

5.1 Scope

This section establishes requirements for the development of instructions, procedures and drawings to control activities affecting quality.

5.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for verifying that activities affecting quality are implemented in accordance with approved and documented instructions, procedures and drawings.

Department Managers - Responsible for generating instructions, procedures and drawings for activities affecting quality.

5.3 Program Requirements

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished with a level of detail commensurate with the complexity of the activity. These documents shall be readily available for use by the appropriate personnel.

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6.0 Document Control

6.1 Scope

This section establishes requirements for the control of documents including changes thereto that specify quality requirements or prescribe activities affecting quality.

6.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for verifying the implementation of an effective document control system.

6.3 Program Requirements

Documents shall be controlled to ensure that correct and applicable documents are available at the location where they are used. Document control measures shall provide for the following:

A. Identification of documents to be controlled and their specified distribution.
B. Identification of personnel, positions or organizations responsible for preparing, reviewing, approving and issuing documents.
C. Review of documents for adequacy, completeness and correctness prior to approval and issuance.

Procedures for the control of documents and changes shall have provisions to preclude the possibility of use of outdated or inappropriate documents. These controls shall include requirements for issuance, distribution, use, and disposition of documents.

Changes to documents shall be reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated. The reviewing organizations shall have access to pertinent background data or information upon which to base their approval.

Minor changes, which do not require that the revised documents receive the same review and approval as the original documents, are defined as any change to a document that does not change, alter, add, or remove any technical or quality requirement or acceptance criteria. Procedures for the control of documents and changes shall document the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision.

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7.0 Control of Purchased Items and Services

7.1 Scope

This section establishes requirements for purchased items and services to be utilized in a safety-related application.

7.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for verifying the implementation of an effective program for the control of purchased items and services.

7.3 Program Requirements

A program shall be established and documented to ensure that all purchased items and services intended to be utilized in a safety-related application conform to all specified procurement document requirements. Procurement activities shall be planned prior to initiating the purchase document. Documented procurement activities shall include procurement methods and organizational responsibilities.

The procurement program shall provide for the integration of:

A. Procurement document preparation, review and change control.
B. Evaluation and selection of procurement sources.
C. Bid evaluation and award.
D. Control of supplier performance, including, but not limited to, an evaluation of quality furnished by the supplier.
E. Verification (surveillance, inspection, CGI survey, or audit) activities including notification of hold and witness points.
F. Control of nonconformances.
G. Corrective action.
H. Acceptance of item or service shall use source verification, receiving inspection, supplier's Certificate of Conformance/Compliance or a combination of these.
    a. Receipt inspection shall provide documented evidence that items conform to the procurement documents.
    b. Receipt inspection shall, as a minimum, ensure that the items were not damaged during shipment, the items/services satisfy the acceptance criteria for all identified and/or specified critical characteristics, and all specified documentation was received and has been determined to be acceptable.
I. Quality records.

The selection of suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents prior to award of contract.

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Procurement source evaluation and selection measures shall provide for identification of NI organizational responsibilities for determining supplier capability.

Measures for evaluation and selection of procurement sources, and the results therefrom, shall be documented and shall include one or more or the following:

A. Evaluation of the supplier's history of satisfactorily providing an identical or similar product or service.
B. Supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated.
C. Supplier's technical and quality capability as determined by a direct evaluation of supplier's facilities and personnel and implementation of the supplier's Quality Assurance Program.

Individuals or organizations performing bid evaluations shall be designated. Bid evaluations shall include a determination of the supplier's ability to meet the technical and quality requirements. Prior to contract award, unacceptable quality assurance conditions shall be resolved and reviewed for acceptability during the bid evaluation.

NI shall establish measures to interface with the supplier and to verify supplier's performance at intervals consistent with the importance, complexity, and quality of the item or service.

Measures to control changes in procurement documents shall be established, implemented, documented in accordance with this section.

Services may be accepted by any or all of the following:

A Technical review, verification, and acceptance of data produced by the supplier,
B verification (surveillance, CGI survey, and/or audit) of the activity, or
C review of objective evidence for conformance to the procurement document.

Records received or generated in the performance of the control of purchased items or services shall be maintained in accordance with the NI records retention program.

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8.0 Identification and Control of Items

8.1 Scope

This section establishes requirements for the identification and control of items.

8.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for developing and implementing an effective program for the identification and control of items.

8.3 Program Requirements

The program shall provide measures to assure that items are identified and controlled. Controls shall be established to assure that only correct and accepted items are used and installed at any stage, from initial receipt through fabrication, installation, repair or modification to an applicable drawing, specification or other pertinent or technical document. These controls shall provide measures to assure that each item and/or service is traceable to documented dedication plans, procedures, procurement documents, technical evaluations, identified critical characteristics, acceptance criteria, and any other essential element of the dedication process, as applicable.

To the maximum extent possible, physical identification by marking or tagging shall be used. Where physical identification is either impractical or insufficient, physical separation, procedural control, documentation or other appropriate means shall be employed. Identification may be either on the item or on records traceable to the item. When identification marking is used, the marking shall be clear, unambiguous and shall be applied in such a manner as not to affect or be detrimental to the function or quality of the item.

Provisions shall be made for maintaining and replacing markings and identification records when damaged or illegible. Provisions shall be made to protect identification markings and labels for items stored in areas where there is potential environmental exposure that could cause damage or deterioration to identification markings.

When items are subdivided, markings shall be transferred to each part of the item and shall not be obliterated or hidden by surface treatments or coatings unless other means are substituted.

When required by codes, standards or specifications, the program shall provide traceability of materials, parts or components to specific documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports and physical and chemical mill test reports.

Provisions shall be made to preclude use of expired items having limited calendar (shelf life) or operating life or cycles.

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9.0 Control of Special Processes

9.1 Scope

This section establishes requirements for the control of special processes. Special processes include, but are not limited to, welding, cleaning, and nondestructive examination performed by NI or subcontracted to others.

9.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for verifying the implementation of an effective special process control program.

9.3 Program Requirements

The program for the control of special processes shall assure that special processes are controlled and accomplished by qualified personnel using qualified procedures which comply with the applicable codes, standards, specifications, regulatory and any other imposed criteria.

Special processes shall be controlled through the use of instructions, drawings, travelers, or other appropriate means. These process control documents shall include (or reference) procedure, personnel, and equipment qualification requirements, conditions necessary to accomplish the process (e.g. equipment, controlled parameters for the process, environment, and/or calibration requirements), and acceptance criteria.

Qualification of personnel, processes, or equipment shall be accomplished and documented. The documentation shall comply with requirements of pertinent codes and standards. The appropriate records shall be maintained. Only qualified personnel using qualified procedures shall perform special processes.

When special processes are not covered by existing codes or standards, or where the item's quality requirements exceed the established codes or standards, the necessary qualifications of personnel, procedures, or equipment shall be identified, defined, and controlled.

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10.0 Inspection

10.1 Scope

This section establishes requirements for the planning and execution for inspection of activities affecting quality.

10.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for establishing and executing an effective inspection program.

10.3 Program Requirements

The program for the inspection of activities affecting quality shall be planned and executed to verify and document conformance to documented instructions, procedures and drawings for accomplishing the activity. Prepared work documents shall include document number and revision number with, or referencing, inspection requirements and acceptance criteria; sufficient space for recording the results/acceptability of the inspection; and space for identifying the inspector.

The inspection program shall include the following as applicable:

A. Inspection personnel shall not report directly to the immediate supervisors responsible for the work being inspected. Inspections may not be performed by those who either performed or directly supervised the work being inspected.
B. Each person who verifies conformance of work activities for purposes of accepting shall be qualified to perform the assigned inspection tasks.
C. If mandatory inspection hold points are required, the specific hold point shall be indicated in appropriate documents. Work shall not proceed without the specific consent of the assigner of the hold point or a designated representative. Consent to waive specific hold points shall be recorded prior to continuation of work beyond the designated hold point
D. Inspection activities shall be planned, accomplished and documented. The documentation shall identify characteristics, methods and acceptance criteria and shall provide for recording objective evidence of inspection results.
E. Where a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices.
F. Inspection of items in-process shall be performed for work activities, where necessary, to verify quality. In-process inspection procedures shall include or reference acceptance criteria. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment and personnel shall be provided.
G. Final inspection shall include a records review of the results and resolution of nonconformances identified by prior inspections. Final inspection procedures shall include or reference acceptance criteria. Final inspections shall include an

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inspection for completeness to verify the quality and conformance of the item to specified requirements. The final inspection shall be planned to arrive at a conclusion regarding conformance/compliance of the item to specified requirements. Documented acceptance shall be included in the quality records.

H. As a minimum, quality records shall be controlled and identify:
   a. item inspected
   b. date of inspection
   c. authorized inspector
   d. type of observation
   e. results or acceptability (acceptance of item by authorized inspector)
   f. reference to information on action taken in connection with nonconformances

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11.0 Test Control

11.1 Scope

This section establishes requirements for the control of all testing activities.

11.2 Responsibility

Manager of Test Lab (MTL) - Responsible for implementing an effective test control program.

Manager of Engineering (ME) – Responsible for assuring that the technical requirements are correctly incorporated into test procedures implementing the test control program.

Manager of Quality Assurance (MQA) - Responsible for verifying the implementation of an effective test control program.

11.3 Program Requirements

The program for control of all testing activities affecting quality shall assure that all testing activities are performed in accordance with specified written procedures or other appropriate documents to verify conformance to specified requirements and/or demonstrate satisfactory performance. These procedures and documents shall be approved by the ME/designee prior to performing the activity. These documents shall contain the requirements and acceptance limits of the design documents, instructions, procedures and drawings associated with the assigned projects.

Test procedures shall include, or reference, the following, as applicable:

A. Test objectives
B. Test requirements
C. Prerequisites
D. Environmental conditions
E. Instrumentation requirements
F. Test configuration
G. Acceptance criteria
H. Required inspection, witness and hold points

Recognized industry standard test methods, supplier manuals, maintenance instructions, or approved drawings or work travelers can be used in lieu of specially prepared test procedures if these documents include adequate instructions to assure the satisfactory performance of the test and are approved for use by Engineering Manager/designee.

Computer programs used for testing shall be verified and validated prior to use. Test procedures shall be written for the use of these computer programs. The procedures shall provide a method to demonstrate adherence to documented requirements and comparison of test results with alternative methods. The test procedures shall confirm correct performance of the computer program in the operating system. This confirmation

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shall be prescribed and performed periodically, as part of the software maintenance program.

All test results shall be documented and evaluated by the MTL/designee to assure that the test requirements have been satisfied. The test results shall be independently reviewed, evaluated, assessed, and approved/accepted by a qualified individual. Test results shall be maintained as quality records in accordance with the requirements of the Nutherm Quality Assurance Program.

Test documentation shall, as a minimum, identify:

A. The item tested
B. Date of the test
C. Individual performing the test and/or recording the test data
D. Test results
E. Acceptability of test
F. Identified test deviations and actions taken in connection with the identified deviation
G. Signature of the manager(s)/designee evaluating and approving/accepting the test results.

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12.0 Control of Measuring and Test Equipment

12.1 Scope

This section establishes requirements for the control of inspection and measuring and test equipment (M&TE).

12.2 Responsibility

Manager of Engineering - Responsible for specifying the type of M&TE to be used, and the required accuracy of each device for production testing.

Manager of Test Lab (MTL) - Responsible for establishing and maintaining a system for recording the use of calibrated M&TE and the identification of the activity for which the device was used. The MTL is responsible for ensuring the use of specified M&TE and for calibrating M&TE not calibrated by an outside calibration laboratory.

Manager of Quality Assurance (MQA) - Responsible for verifying the implementation of an effective program for the control of M&TE

12.3 Program Requirements

The program shall ensure that tools, gauges, instruments and other inspection, monitoring, measuring, test equipment and devices used in activities affecting quality are of the proper range, type and accuracy to verify conformance to established requirements. Controls shall be established to assure that M&TE is correctly selected taking considerations of the environmental use of the asset. Controls shall establish a method for maintaining traceability to the application and use of each asset.

To ensure accuracy, inspection and M&TE shall be controlled, calibrated, adjusted and maintained at prescribed intervals or prior to use against certified equipment having known relationships to nationally recognized standards. International standards may be used providing they are known to be equivalent to and verified against corresponding nationally recognized standards.

If no national standards exist, the basis for calibration shall be documented. Standards used to calibrate M&TE should have an accuracy of at least four times the required accuracy of the M&TE being calibrated. Where this is not possible, standards shall have an accuracy that assures that the equipment being calibrated will be within the required tolerance and the basis of acceptance shall be documented and authorized by responsible management.

This requirement is not intended to imply a need for special calibration and control measures on rulers, tape measures, levels and such other devices, if normal commercial practices provide adequate accuracy.

Calibration methods and intervals for each item shall be defined and based on the type of equipment, equipment use, manufacturers recommendations, stability characteristics,

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required accuracy and other conditions affecting measuring control. Calibrations shall be performed in a controlled environment. Calibration procedures shall identify or reference required accuracy; procedural controls shall include/define methods and frequency of checking accuracy.

When inaccuracy of the equipment is suspected, a special calibration shall be performed.

When inspection and M&TE are found to be out-of-calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. Out-of-calibration M&TE shall be tagged, segregated, or removed from service pending resolution of the condition. Inspection and M&TE consistently found out-of-calibration shall be repaired or replaced.

The documented results of the evaluation of the validity of previous inspection and/or test results shall be evaluated and approved by the Manager of Engineering or designee.

M&TE shall be stored in environmental conditions which are maintained within a range which maintains rated accuracy of the device. The MTL shall also identify special precautions to be taken to ensure the required accuracy of the M&TE.

Records shall be maintained and equipment suitably marked to indicate calibration status and to permit traceability to calibration records. Records include calibration reports. Calibration reports (and/or certificates reporting the results of calibrations) shall contain information and data permitting understanding and analysis of the calibration results and verification of conformance to applicable requirements.

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13.0 Handling, Storage and Shipping

13.1 Scope

This section establishes requirements for handling, storage and shipping of items in accordance with the applicable provision of ANSI Standard N45.2.2, NQA-1 1994, and NQA-1 2008(09a).

13.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for verifying implementation of an effective handling, storage and shipping program.

13.3 Program Requirements

The program shall include cleaning, packaging and preservation of material and equipment in accordance with established instructions, procedures or drawings to prevent damage, deterioration and/or loss. When necessary for particular items, special equipment and special protective environments such as inert gas atmosphere, specific moisture content levels and temperature levels shall be specified, provided and their existence verified.

Specific written procedures for handling, storage, packaging, shipping and preservation of critical, sensitive, perishable or high value articles shall be used. Special handling tools and equipment shall be provided and controlled as necessary to ensure safe and adequate handling, when applicable. The procedural controls for special handling tools and/or equipment shall include requirements for the inspection and tests at specified intervals (or prior to use) and training/experience requirements for operators.

Marking shall be adequate to identify, maintain and preserve the shipment, including identification of the presence of special environments or the need for special control, when applicable.

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14.0 Inspection and Test Status

14.1 Scope

This section establishes requirements for identifying the status of inspection and test activities.

14.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for implementing an effective inspection and test status program.

14.3 Program Requirements

Indication/identification of the inspection and test status of items shall be maintained through the use of status indicators traceable to the item, such as physical location and tags, markings, shop travelers, stamps or inspection records.

The program shall provide measures for assuring that required inspections and tests are performed and that the acceptability of items with regard to inspections and tests performed are known throughout manufacturing, reworking, repairing, inspection and testing operations. The program shall provide measures for assuring that items that have not passed required inspections and tests are not inadvertently installed, used or operated. Nonconforming items shall be clearly identified and differentiated from those items that conform.

Measures shall include procedures for the control of status indicators including the authority for application and removal of tags, markings, labels and stamps.

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15.0 Nonconforming Items, Services and Activities

15.1 Scope

This section establishes requirements for the control of nonconforming items, services and activities to prevent further processing, delivery, installation, or their inadvertent use.

15.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for implementing and monitoring an effective nonconformance program. Responsible for the approval of proposed dispositions of nonconforming items, services, and activities.

Manager of Engineering – Responsible for evaluation and disposition of nonconforming items, services, and activities.

15.3 Program Requirements

The program shall control items, services or activities, which do not conform to specific requirements. The program shall include, as applicable, written procedures for identification, documentation, evaluation, segregation, disposition and notification to affected organizations.

The program shall control further processing, testing, delivery or installation of a nonconforming item pending an evaluation of the nonconforming characteristics and approval of its disposition. Personnel performing evaluations shall have demonstrated competence in the area under evaluation, adequate understanding of the requirements, and access to background information necessary to perform the evaluation.

Disposition of nonconforming items such as use as is, reject, repair or rework shall be identified, documented and approved. Nonconforming items dispositioned as rework or repair shall be reexamined in accordance with applicable procedures with documented acceptance criteria. This acceptance criteria may be either the original acceptance criteria or alternative acceptance criteria established during the disposition of repaired items.

Nonconformances corrected by a supplier shall be evaluated, reexamined, and accepted in accordance with applicable procedures with documented acceptance criteria.

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16.0 Corrective Action

16.1 Scope

This section addresses those aspects of the QA program concerned with the identification, reporting and correction of conditions adverse to quality.

16.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for the development and implementation of an effective corrective action program.

16.3 Program Requirements

The corrective action program shall provide procedural guidance to ensure that conditions adverse to quality such as failures, malfunctions, deficiencies, deviations, defective material/equipment, nonconformances, and computer software problems are promptly identified, documented, evaluated, and corrected.

In the case of significant conditions adverse to quality, the corrective action program procedures shall assure that the cause of the condition is determined/identified, documented, and corrective actions taken to preclude repetition/recurrence.

The identification, cause and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify completion and implementation of corrective action taken.

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17.0 Quality Assurance Records

17.1 Scope

This section establishes requirements for the collection, storage and maintenance of QA records. Records which document evidence that items/activities meet specified requirements shall be legible and maintained in accordance with the requirements of this section.

17.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for verifying the implementation of a QA records system.

17.3 Program Requirements

The term "record(s)" used throughout this section is to be interpreted as Quality Assurance Records.

Sufficient records shall be prepared as work is performed to furnish documentary evidence of the quality of items and of activities affecting quality. Records shall be consistent with applicable codes, standards, specifications, and contracts and shall be adequate for use in management of the program.

The procedural controls established for records shall include guidance for the identification, generation, authentication, maintenance, and final disposition of the quality record. Written procedures shall establish a record system which includes the guidance for the following:

A. identification of records to be maintained;
B. validation of records;
C. an indexing method which includes retention times and location within the record system;
D. controls for distribution and handling;
E. maintaining traceability between record and item/activity to which it applies;
F. approval from originating organization for authorized persons to correct records.

The records shall include the results of reviews, inspections, tests, audits, monitoring of work performance, materials analyses, and operating logs. The records shall also include, as appropriate, closely related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the date of inspection or test, the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Required records shall be legible, identifiable, and retrievable.

Requirements and responsibilities for record transmittal, retention periods, and maintenance subsequent to completion of work shall be established and documented consistent with applicable codes, standards, and procurement documents. A receipt

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control system shall be established to designate the person/organization to receive and process records. The procedure shall provide this designee a method to perform the following activities:

A. Identify the record(s);
B. Receive and inspect the record(s);
C. Determine retention period and retain the record for the appropriate period;
D. Submit records for storage;
E. Protect records from damage or loss;
F. Retrieve records after hardware, software or technology changes;
G. Limit access of processing, storage areas, and retrieval or records to authorized personnel.

The records shall be classified as "Lifetime" or "Nonpermanent" and shall be retained in accordance with their classification.

The record retention system shall provide procedural guidance for storage facilities for records. This guidance shall include provisions for permanent and temporary storage facilities. Requirements for appropriate fire ratings of vault or containers shall be established.

Records shall be duplicated and stored in separate remote locations which provide for safe keeping, retrieval and a suitable environment to minimize deterioration, damage and loss.

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18.0 Audits

18.1 Scope

This section establishes requirements for a comprehensive system of planned and periodic audits to verify compliance with all aspects of the QA program and to determine the effectiveness of the program for both internal and external audits.

18.2 Responsibility

Manager of Quality Assurance (MQA) - Responsible for establishing and maintaining an effective audit program.

18.3 Program Requirements

Planned and scheduled audits shall be performed in accordance with written procedures or checklists by appropriately trained/qualified personnel who do not have direct responsibilities for performing the activities being audited. Each audit shall be conducted in accordance with a documented audit plan. Objective evidence evaluated against specified requirements shall be used to determine effective implementation of the selected audit elements.

The audit team shall be identified prior to the beginning of the audit. A Lead Auditor shall be appointed at that time. The audit team shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

Audit frequency shall be adequate to verify that performance criteria are met and the effectiveness of the Quality Assurance Program is determined. When necessary to cover all aspects of the Quality Assurance Program, regularly schedule audits shall be supplemented by additional audits of specified subjects. The audit schedule shall be periodically reviewed and revised to assure audits maintain adequate coverage of ongoing activities.

Audit results shall be documented and reported to and reviewed by responsible management. The audit results shall be transmitted by audit report that is signed by the Lead Auditor, issued to the audited organization, includes a description of the audit scope, a list of auditors and persons contacted, audit results summary, statement of effectiveness of audited elements, and a description of each audit finding.

Audit responses shall be evaluated for adequacy. In order to verify completion of documented corrective actions, audit follow up actions, including re-audit of deficient areas, shall be taken where indicated and the results documented. Audit records shall include the audit plan, report, written correspondence, and record of completion of corrective actions.

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19.0 Reporting Defects and Noncompliance Per 10 CFR Part 21

19.1 Scope

This section establishes requirements and assigns responsibilities for compliance to the requirements of the United States Nuclear Regulatory Commission Code of Federal Regulations 10 CFR Part 21, "Reporting of Defects and Noncompliance".

19.2 Responsibility

President and Chairman of the Board - Responsible for reporting to the Nuclear Regulatory Commission (NRC) safety-related defects and noncompliance as outlined in 10 CFR Part 21.

Manager of Quality Assurance (MQA) - Responsible for assuring all NI personnel have read and are informed of the requirements of 10 CFR Part 21 and Section 206 of The Atomic Energy Reorganizational Act of 1974.

19.3 Program Requirements

Procedures shall be established to provide guidance for the assessment of deviations, failures, potential defects and failures to comply to determine if they are reportable to the Nuclear Regulatory Commission (NRC) per the requirements of 10 CFR Part 21. These procedures shall also provide guidance for performing the required notifications under the requirements of 10 CFR Part 21.

A copy of the following shall be posted:

A. 10 CFR Part 21
B. Section 206 of the 1974 Energy Reorganization Act
C. Approved procedures that apply to the regulations

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20.0 Commercial Grade Dedication

20.1 Scope

This section establishes requirements and assigns responsibilities for performance of Commercial Grade Dedication Activities. Nutherm International, Inc. is the organization performing and responsible for the dedication process (dedicating entity).

20.2 Responsibility

Manager of Engineering (ME) – Responsible for assuring that the commercial grade dedication program is implemented in accordance with the Nutherm QA Program, customer requirements, and governing standards.

Manager of Test Lab (MTL) - Responsible for assuring commercial grade dedication testing is performed in accordance with the Nutherm test control program.

Manager of Quality Assurance (MQA) - Responsible for verifying the implementation of an effective commercial graded dedication program.

20.3 Program Requirements

Terms and definitions for commercial graded dedication shall be included in the governing Nutherm QA procedures (QAP).

All Commercial Grade Item Dedication shall be performed in accordance with a documented dedication plan. This plan shall be developed prior to commencement of procurement activities. The dedication plan shall use a documented Technical Evaluation (TE) to establish required dedication activities.

The TE shall document the technical and quality requirements for the item/service. The TE shall ensure that these requirements are correctly translated into procurement documents. The TE shall be used to determine the dedication method to verify each critical characteristic. More than one method may be used, if required, to provide reasonable assurance that the item received meets the requirements specified in the procurement document and the acceptance criteria.

The dedication methods used by Nutherm are defined as follows: 1) Method 1 - Special Test(s), Inspection(s) and/or Analyses, 2) Method 2 - Commercial Grade Survey of the Supplier, and 3) Method 3 - Source Verification. Nutherm does not use Method 4 - Acceptable Supplier Item or Service Performance Record to verify any critical characteristic for commercial grade dedication. Personnel performing activities for Method 2 and/or Method 3 commercial grade dedication shall be trained and qualified in accordance with the Nutherm QA training program for these activities.

Additionally, for commercial grade services when the service cannot be related to measurable critical characteristics, the critical controls are to be identified during the technical evaluation and incorporated into the dedication plan.

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