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AN AMERICAN NATIONAL STANDARD

ANSI/ASME NQA-1c-1988

ADDENDA

to

ANSI/ASME NQA-1-1986 EDITION
QUALITY ASSURANCE PROGRAM
REQUIREMENTS FOR NUCLEAR FACILITIES

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THE AMERICAN SOCIETY OF MECHANICAL ENGINEERS

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ANSI/ASME NQA-1c-1988

Following approval by the Main Committee of the Committee on Nuclear Quality Assurance, and after public review, ANSI/ASME NQA-1c-1988 was approved by the American National Standards Institute on December 28, 1988.

Addenda to the 1986 Edition of ANSI/ASME NQA-1 are issued in the form of replacement pages. Revisions, additions, and deletions are incorporated directly into the affected pages. It is advisable, however, that this page, the Addenda title and copyright pages, and all replaced pages be retained for reference.

SUMMARY OF CHANGES

This is the third and last Addenda to be published to ANSI/ASME NQA-1-1986 Edition. Previous Addenda were approved in 1986 and 1987.

Changes given below are identified on the indicated pages by a margin note, 1c-88, placed next to the affected area. Previous Addenda changes are indicated by 1a-86 and 1b-87. The pages not listed are the reverse sides of the listed pages and contain no changes.

<i>Page</i>	<i>Location</i>	<i>Change</i>
v, vi	Preparation of Technical Inquiries to the Nuclear Quality Assurance Committee	Revised
x	Contents	Updated to reflect 1c-88 Addenda
3	II, 11	First paragraph revised
5, 5.1	S-1, 2	(1) Definition of <i>Computer Program</i> added (2) Definition of <i>Design Output</i> revised
	Footnote 2	Added
	Footnote 3	Added
16	3S-1, 4 3S-1, 4.1	Revised First paragraph revised
30.1, 30.2	11S-2	Added
36, 37	17S-1, 4.4.2 17S-1, 4.4.3	(1) Subparagraphs (a) and (b) revised (2) First paragraph of subparagraph (c) revised Redesignated as para. 4.4.4 and new para. 4.4.3 added

(c)

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<i>Page</i>	<i>Location</i>	<i>Change</i>
36, 37	Footnote 1	Revised
62	17A-1, 3.1	Revised

SPECIAL NOTE

The Interpretations to ANSI/ASME NQA-1-1986 Edition are included in this Addenda as a separate section for the user's convenience. This section, however, is not part of the Addenda or of the Standard itself.

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PREPARATION OF TECHNICAL INQUIRIES
TO THE NUCLEAR QUALITY
ASSURANCE COMMITTEE

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INTRODUCTION

The ASME Nuclear Quality Assurance Committee will consider written requests for interpretations and revisions to NQA Standards and develop new requirements or guidance if dictated by technological development. The Committee's activities in this regard are limited strictly to interpretations of the requirements and guidance, or to the consideration of revisions to the present Standard on the basis of new data or technology. As a matter of published policy, ASME does not approve, certify, rate, or endorse any item, construction, proprietary device, or activity and, accordingly, inquiries requiring such consideration will be returned. Moreover, ASME does not act as a consultant on specific engineering problems or on the general application or understanding of the Standard requirements. If, based on the inquiry information submitted, it is the opinion of the Committee that the inquirer should seek assistance, the inquiry will be returned with the recommendation that such assistance be obtained.

All inquiries that do not provide the information needed for the Committee's full understanding will be returned.

INQUIRY FORMAT

Inquiries shall be limited strictly to interpretations of the requirements and guidance, or to the consideration of revisions to the present Standard on the basis of new data or technology.

Inquiries shall be submitted in the following format.

(a) *Scope.* The inquiry shall involve a single requirement/guidance or closely related requirements/guidance. An inquiry letter concerning unrelated subjects will be returned.

(b) *Background.* State the purpose of the inquiry, which would be either to obtain an interpretation of the Standard, or to propose consideration of a revision to the present Standard. Provide concisely the information needed for the Committee's understanding of the inquiry, being sure to include reference to the applicable Standard, Edition, Addenda, Basic Requirements, Supplements, Parts, Appendices, paragraphs, figures, and tables. If sketches are provided, they shall be limited to the scope of the inquiry.

(c) *Inquiry Structure*

(1) *Proposed Question(s).* The inquiry shall be stated in a condensed and precise question format, omitting superfluous background information, and, where appropriate, composed in such a way that "yes" or "no" (perhaps with provisos) would be an acceptable reply. The inquiry statement should be technically and editorially correct.

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(2) *Proposed Reply(ies)*. State what it is believed that the Standard requires. If, in the inquirer's opinion, a revision to the Standard is needed, recommended wording shall be provided.

(d) *Submittal*. The inquiry shall be submitted in typewritten form; however, legible, handwritten inquiries will be considered. It shall include the name and mailing address of the inquirer and be mailed to the following address:

Secretary
ASME Nuclear Quality Assurance Committee
Nuclear Department
345 East 47th Street
New York, N.Y. 10017

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5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

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.

6 DOCUMENT CONTROL

The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

7 CONTROL OF PURCHASED ITEMS AND SERVICES

The procurement of items and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.

8 IDENTIFICATION AND CONTROL OF ITEMS

Controls shall be established to assure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner which assures that identification is established and maintained.

9 CONTROL OF PROCESSES

Processes affecting quality of items or services shall be controlled. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using

qualified procedures in accordance with specified requirements.

10 INSPECTION

Inspections required to verify conformance of an item or activity to specified requirements shall be planned and executed. Characteristics to be inspected and inspection methods to be employed shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected.

11 TEST CONTROL

Tests required to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with acceptance criteria shall be evaluated.

Tests required to collect data, such as for siting or design input, shall be planned, executed, documented, and evaluated.

12 CONTROL OF MEASURING AND TEST EQUIPMENT

Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.

13 HANDLING, STORAGE, AND SHIPPING

Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.

14 INSPECTION, TEST, AND OPERATING STATUS

The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to as-

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sure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified. Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.

15 CONTROL OF NONCONFORMING ITEMS

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

16 CORRECTIVE ACTION

Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality,

the cause of the condition shall be determined and corrective action taken to preclude 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 implementation of this corrective action.

17 QUALITY ASSURANCE RECORDS

Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

18 AUDITS

Planned and scheduled audits shall be performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.

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III SUPPLEMENTS

SUPPLEMENT S-1 TERMS AND DEFINITIONS

1 GENERAL

This Supplement contains definitions of certain quality-related terms used in this Standard or in ANSI/ASME NQA-2.

2 TERMS AND DEFINITIONS

Acceptance Criteria. Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

Audit. A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Certificate of Conformance. A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

Certification. The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

Characteristic. Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

1b-87 *Commercial Grade Item.* An item satisfying (a), (b), and (c) below:

(a) not subject to design or specification requirements that are unique to nuclear facilities;¹

1b-87 ¹Nuclear facilities can be either nuclear power facilities or any other facilities subject to the requirements of 10 CFR Part 21. Additionally, any unique requirements which one nuclear facility may elect to apply, including the requirements of 10 CFR Part 21, does not necessarily impact the "commercial grade" status of the item for all nuclear facilities.

(b) used in applications other than nuclear facilities;

(c) is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, catalog).

Computer Program.^{2,3} A sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution as well as to execute it. 1c-88

Condition Adverse to Quality. An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability.

Corrective Action. Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Design Change. Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

Design Input. Those criteria, parameters, bases, or other design requirements upon which detailed final design is based.

Design Output. Drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs. 1c-88

Design Process. Technical and management processes that commence with identification of de-

²Computer programs covered by this Standard are those used for: 1c-88

(a) design analysis;

(b) operations or process control; or

(c) data base or document control registers when used as the controlled source of quality information for (a) or (b) above.

³This definition has been copied from ANSI/IEEE 729-1983, Glossary of Software Engineering Terminology, with the permission of IEEE. 1c-88

sign input and that lead to and include the issuance of design output documents.

Deviation. A departure from specified requirements.

Document. Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined in this Supplement.

External Audit. An audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.

Final Design. Approved design output documents and approved changes thereto.

Guideline. A suggested practice that is not mandatory in programs intended to comply with a standard. The word *should* denotes a guideline; the word *shall* denotes a requirement.

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SUPPLEMENT 3S-1 SUPPLEMENTARY REQUIREMENTS FOR DESIGN CONTROL

1 GENERAL

This Supplement provides amplified requirements for design control. It supplements the requirements of Basic Requirement 3 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 DESIGN INPUT

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 and 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.

3 DESIGN PROCESS

The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall be adequate to support facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.

Changes from specified quality standards, including the reasons for the changes, shall be identified, approved, documented, and controlled.

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. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel. The final design (approved design output documents and approved changes thereto) shall:

(a) be relatable to the design input by documentation in sufficient detail to permit design verification; and

(b) identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

3.1 Design Analyses

Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date; or by other data such that the calculations are retrievable.

(a) Computer programs may be utilized for design analysis without individual verification of the program for each application provided:

(7) the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and

(2) the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on (1) and (2) above.

(b) Documentation of design analyses shall include (1) through (6) below:

(1) definition of the objective of the analyses;

(2) definition of design inputs and their sources;

(3) results of literature searches or other applicable background data;

(4) identification of assumptions and indication of those that must be verified as the design proceeds;

(5) identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem;

(6) review and approval.

4 DESIGN VERIFICATION

Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests. Verification of computer programs shall include appropriate testing. The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be clearly documented with the identification of the verifier clearly indicated. 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. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular

design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification. cursory supervisory reviews do not satisfy the intent of this Standard.

Verification shall be performed in a timely manner. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.

4.1 Extent of Design Verification

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The extent of the design verification required is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with this Standard, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proven designs and their effects on other features shall be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to previously verified design.

4.2 Methods

Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.

**SUPPLEMENT 11S-2
SUPPLEMENTARY REQUIREMENTS FOR COMPUTER PROGRAM TESTING**

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1 GENERAL

This Supplement provides amplified requirements for testing of computer programs and associated computer systems. It supplements the requirements of Basic Requirement 11 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 TEST REQUIREMENTS

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design or use of the program to be tested unless otherwise designated. Required tests including (as appropriate) verification tests, hardware integration tests, and in-use tests shall be controlled. Test requirements and acceptance criteria shall be based upon applicable design or other pertinent technical documents.

2.1 Verification Tests

Verification tests shall demonstrate the capability of the computer program to produce valid results for test problems encompassing the range of permitted usage defined by the program documentation. Acceptable test problem solutions are as follows:

- (a) hand calculations;
- (b) calculations using comparable proven programs; or
- (c) empirical data and information from technical literature.

For programs used for operational control, testing shall demonstrate required performance over the range of operation of the controlled function or process.

Depending on the complexity of the computer program being tested, testing may range from a

single test of the completed computer program to a series of tests performed at various stages of computer program development to verify correct translation between stages and proper working of individual modules, followed by an overall computer program test. Regardless of the number of stages of testing performed, verification testing shall be sufficient to establish that test requirements are satisfied and that the computer program produces a valid result for its intended function.

2.2 In-Use Tests

Test problems shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. Test problems shall be run whenever the computer program is installed on a different computer, or when significant hardware or operating system configuration changes are made. Periodic in-use manual or automatic self-check routines shall be prescribed and performed for those applications where computer failures or drift can affect required performance.

3 TEST PROCEDURES

Test procedures or plans shall specify the following, as applicable:

- (a) required tests and test sequence
- (b) required ranges of input parameters
- (c) identification of the stages at which testing is required
- (d) criteria for establishing test cases
- (e) requirements for testing logic branches
- (f) requirements for hardware integration
- (g) anticipated output values
- (h) acceptance criteria
- (i) reports, records, standard formatting, and conventions

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4 TEST RESULTS

Test results shall be documented. Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied.

5 TEST RECORDS

(a) Verification test records shall identify (1) through (10) below.

- (1) computer program tested
- (2) computer hardware used
- (3) test equipment and calibrations, where applicable
- (4) date of test

- (5) tester or data recorder
- (6) simulation models used, where applicable

- (7) test problems
- (8) results and acceptability
- (9) action taken in connection with any deviations noted
- (10) person evaluating test results

(b) In-use test results shall identify (1) through (6) below.

- (1) computer program tested
- (2) computer hardware used
- (3) test equipment and calibrations, where applicable
- (4) date of test
- (5) tester or data recorder
- (6) acceptability

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maintaining, reworking, repairing, replacing, or modifying an item;

(c) those which would be of significant value in determining the cause of an accident or malfunction of an item;

(d) those which provide required baseline data for in-service inspections.

Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use.

2.7.2 Nonpermanent Records. Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.

2.8 Retention of Records

Records shall be retained in accordance with the above classifications. The retention period for non-permanent records shall be established in writing.

2.9 Corrected Information in Records

Records may be corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction shall include the date and the identification of the person authorized to issue such correction.

3 RECEIPT

3.1 Responsibility

The individual or organization responsible for receiving records shall provide protection from damage or loss during the time that the records are in their possession.

3.2 Receipt Control

Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage.

As a minimum, a receipt control system shall include the following:

(a) a method for designating the required records;

(b) a method for identifying records received;

(c) procedures for receipt and inspection of incoming records;

(d) a method for submittal of completed records to the storage facility without unnecessary delay.

3.3 Status

Each receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process.

4 STORAGE, PRESERVATION, AND SAFEKEEPING

4.1 Storage

The records shall be stored in predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies.

Prior to storage of records, a written storage procedure shall be prepared and responsibility assigned for enforcing the requirements of that procedure. This procedure shall include, as a minimum, (a) through (g) below:

(a) a description of the storage facility;

(b) the filing system to be used;

(c) a method for verifying that the records received are in agreement with the transmittal document and that the records are legible;

(d) a method of verifying that the records are those designated (see para. 3.2 above);

(e) the rules governing access to and control of the files;

(f) a method for maintaining control of and accountability for records removed from the storage facility;

(g) a method for filing supplemental information (see para. 2.9 above) and disposing of superseded records.

4.2 Preservation

Records shall be stored in a manner approved by the organization or organizations responsible for storage. In order to preclude deterioration of the records, the requirements of (a) through (c) below shall apply.

(a) Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature, and pressure.

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(b) Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers.

(c) Provisions shall be made for special processed records (such as radiographs, photographs, negatives, microform, and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

4.3 Safekeeping

Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism.

Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.

4.4 Facility

Records shall be stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:

- (a) natural disasters such as winds, floods, or fires;
- (b) environmental conditions such as high and low temperatures and humidity;
- (c) infestation of insects, mold, or rodents.

There are two satisfactory methods of providing storage facilities, single or dual.

4.4.1 Single Facility. Design and construction of a single record storage facility shall meet the criteria of (a) through (i) below:

- (a) reinforced concrete, concrete block, masonry, or equal construction;
- (b) floor and roof with drainage control. If a floor drain is provided, a check valve (or equal) shall be included.
- (c) doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2 hr fire rating;
- (d) sealant applied over walls as a moisture or condensation barrier;
- (e) surface sealant on floor providing a hard wear surface to minimize concrete dusting;
- (f) foundation sealant and provisions for drainage;
- (g) forced air circulation with filter system;
- (h) fire protection system;
- (i) only those penetrations used exclusively for fire protection, communication, lighting, or temperature/humidity control are allowed; all such

penetrations shall be sealed or dampered to comply with the minimum 2 hr fire protection rating.

The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing.

If the facility is located within a building or structure, the environment and construction of that building can provide a portion or all of these criteria.

4.4.2 Alternate Single Facilities. The following are acceptable alternatives to the criteria of para. 4.4.1 above for a single facility:

- (a) 2 hr fire rated vault meeting NFPA 232-1986 or NFPA 232AM-1986 or both;¹
- (b) 2 hr fire rated Class B file containers meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both;¹ or
- (c) 2 hr fire rated file room meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both¹ with the following additional provisions:

- (1) early warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station;
- (2) records storage in fully enclosed metal cabinets;
- (3) adequate access and aisle ways;
- (4) prohibition in the room of work not directly associated with record storage or retrieval;
- (5) prohibition in the room of smoking, eating, or drinking;
- (6) 2 hr fire rated dampers or doors in all boundary penetrations.

4.4.3 Temporary Storage. When temporary storage of records (such as for processing, review, or use) is required by an organization's procedures, the records shall be stored in a 1 hr fire rated container. The procedures shall specify the maximum allowable time limit for temporary storage. The container shall bear a UL label (or equivalent) certifying 1 hr fire protection or be certified by a person competent in the technical field of fire protection.

4.4.4 Dual Facilities. If storage at dual facilities for each record is provided, the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each facility is not required to satisfy the requirements of either para. 4.4.1 or para. 4.4.2

¹NFPA 232-1986 and NFPA-232AM-1986 are published by the National Fire Protection Association, Batterymarch Park, Quincy, MA 02269.

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above, but shall meet the other requirements of this Standard.

5 RETRIEVAL

Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type.

A list shall be maintained designating those personnel who shall have access to the files.

Records maintained by a Supplier at his facility or other location shall be accessible to the Purchaser or his designated alternate, e.g., the Owner.

6 DISPOSITION

Records accumulated at various locations, prior to transfer, shall be made accessible to the Owner

directly or through the procuring organization. The custodian shall inventory the submittals, acknowledge receipt, and process these records in accordance with this Standard.

Various regulatory agencies have requirements concerning records that are within the scope of this Standard. The most stringent requirements shall be used in determining the final disposition.

The Supplier's nonpermanent records shall not be disposed of until the applicable conditions listed in (a) through (e) below are satisfied:

(a) items are released for shipment, a Code Data Report is signed, or a Code Symbol Stamp is affixed;

(b) regulatory requirements are satisfied;

(c) operational status permits;

(d) warranty consideration is satisfied;

(e) Purchaser's requirements are satisfied.

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SUPPLEMENT 18S-1 SUPPLEMENTARY REQUIREMENTS FOR AUDITS

1 GENERAL

This Supplement provides amplified requirements for quality assurance audits. It supplements the audit requirements of Basic Requirement 18 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 SCHEDULING

Internal or external quality assurance audits, or both, shall be scheduled in a manner to provide coverage and coordination with ongoing quality assurance program activities. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity. The audit schedule shall be reviewed periodically and revised as necessary to assure that coverage is maintained current. Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

3 PREPARATION

3.1 Audit Plan

The auditing organization shall develop and document an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

3.2 Personnel

The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit. In the case of internal audits, per-

sonnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

3.3 Selection of Audit Team

An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more auditors and shall have an individual appointed to lead the team who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses. The audit team leader shall ensure that the audit team is prepared prior to initiation of the audit.

4 PERFORMANCE

Audits shall be performed in accordance with written procedures or checklists. Auditing shall begin as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity. Elements that have been selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Audit results shall be documented by auditing personnel and shall be reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

5 REPORTING

The audit report shall be signed by the audit team leader and issued, and it shall include the following information, as appropriate:

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commercial grade given in Supplement S-1. The manufacturer's published product description should specify what documents, if any, are supplied with the item. When documentation is required beyond that indicated in the manufacturer's published product description, and when such information is not available for all items with the same part number obtained from the same manufacturer, the item does not meet the definition of commercial grade.

5.2 Reordering

The requirements applicable to the initial procurement of an item should be documented to facilitate reordering. Appropriate catalog pages may be retained or catalog descriptions copied.

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APPENDIX 17A-1 NONMANDATORY GUIDANCE ON QUALITY ASSURANCE RECORDS

1 GENERAL

This Appendix provides nonmandatory guidance on records as specified in Basic Requirements 17 and Supplement 17S-1.

1.1 Records System

A procedure describing the records system(s) should include control of records withdrawn from storage which may be required during the completion of work activity.

1.2 Generation of Records

Documents which may later become records should be maintained and processed in a prudent manner to avoid unnecessary delay and/or expense when the record is needed.

1.3 Records Stored on Magnetic or Optical Media

Provisions should be made for the capability to retrieve information stored on magnetic or optical media. Compatible processing systems should be available, or information should be transferred to other readable media.

2 LOST OR DAMAGED RECORDS

If replacement or restoration of lost or damaged records is not practical, action should be taken to assure the quality of items or activities affecting quality, e.g., reexamination or investigation by alternate means.

3 LIST OF TYPICAL LIFETIME RECORDS

The following is a list of typical lifetime records. The nomenclature of these may vary. Records not identified on this list are nonpermanent.

3.1 Design Records

Applicable codes and standards used in design
Computer programs or corresponding mathematical model
Design drawings
Design calculations and record of checks
Approved design change requests
Design deviations
Design reports
Design verification data
Design specifications and amendments
Safety analysis report
Stress reports for code items
Systems descriptions
Systems process and instrumentation diagrams
Technical analysis, evaluations, and reports

3.2 Procurement Records

Procurement specification
Purchaser order (unpriced) including amendments

3.3 Manufacturing Records

Applicable code data reports
As-built drawings and records
Certificate of compliance
Eddy current examination final results
Electrical control verification test results
Ferrite test results
Heat treatment records
Liquid penetrant examination final results
Location of weld filler material
Magnetic particle examination final results
Major defect repair records
Material properties records
Nonconformance reports
Performance test procedure and results records
Pipe and fitting location report
Pressure test results (hydrostatic or pneumatic)

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ANSI/ASME NQA-1-1986 EDITION
QUALITY ASSURANCE PROGRAM
REQUIREMENTS FOR NUCLEAR FACILITIES

INTERPRETATIONS

Replies to Technical Inquiries
October 1, 1987, through October 30, 1988

FOREWORD

General Information

This publication includes all of the written replies issued between the indicated dates by the Secretarial Staff, speaking for the ASME Committee on Nuclear Quality Assurance, to inquiries concerning interpretations of technical aspects of ANSI/ASME NQA-1 Quality Assurance Program Requirements for Nuclear Facilities.

These replies are taken verbatim from the original letters except for a few typographical corrections and some minor editorial corrections made for the purpose of improved clarity. In some instances, a review of the interpretation revealed a need for corrections of a technical nature; in these cases a corrected interpretation follows immediately after the original reply.

These interpretations were prepared in accordance with the accredited ASME procedures. ASME procedures provide for reconsideration of these interpretations when or if additional information is available which the inquirer believes might affect the interpretation. Further, persons aggrieved by this interpretation may appeal to the cognizant ASME committee or subcommittee. ASME does not "approve," "certify," "rate," or "endorse" any item, construction, proprietary device, or activity.

An interpretation applies to the Edition and Addenda stated in the interpretation itself or, if none is stated, to the latest published Edition and Addenda at the time it is issued. Subsequent revisions to the rules may have superseded the reply.

For detailed instructions on the preparation of technical inquiries, refer to the Preparation of Technical Inquiries to the Nuclear Quality Assurance Committee (p. v of ANSI/ASME NQA-1).

Subject and Numerical Indexes

Subject and numerical indexes have been prepared to assist the user in locating interpretations by subject matter or location in this Standard. These indexes cover interpretations issued as a supplement to the 1a-81 Addenda through the 1c-88 Addenda, and will be updated with each separate supplement included with the Addenda to ANSI/ASME NQA-1.

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File: QA87-005

Subject: ANSI N45.2.9-1974, Para. 5.6; ANSI/ASME NQA-1-1986 Edition With the 1a-1987 Addenda, Supplement 17S-1, Para. 5.6: Quality Assurance Records — Documents in a Package

Date Issued: November 30, 1987

Question (1): Some document types listed on our records checklist are document packages consisting of many individual documents. The individual documents in the package are not all completed at the same time, and all documents in the package are not safety related (for example, pipe welding package, audit report package, purchase order document package, etc.). In accordance with ANSI N45.2.9, is it correct to say that the aggregate document package becomes a Quality Assurance Record only when the last document in the package is completed?

Reply (1): No.

Question (2): In accordance with ANSI N45.2.9, does each individual document in the package become a Quality Assurance Record at the time it is completed?

Reply (2): Yes. A completed quality assurance document is defined as a Quality Assurance Record in ANSI N45.2.9, para. 1.4, and the second paragraph of para. 3.2.1.

Question (3): Can the document package be assembled without providing for storage in accordance with ANSI N45.2.9, para. 5.6, until completion of the last document in the package?

Reply (3): Yes. As long as the documents in the document package do not meet the definition of records, the provisions of ANSI N45.2.9 do not apply. However, if the work package contains records, then the package can be assembled under the requirements of ANSI N45.2.9, paras. 4.2 and 4.3, and the records may be stored as a package rather than as individual records provided proper consideration is given to ANSI N45.2.9, Section 6.

Question (4): Must each individual document in the package be stored in accordance with ANSI N45.2.9, para. 5.6, as soon as it is completed?

Reply (4): ANSI N45.2.9 does not apply to documents, only to Quality Assurance Records. Should the contents of the work package include Quality Assurance Records, as defined in ANSI N45.2.9, paras. 1.4 and 3.2.1, then they must be handled in accordance with para. 5.6.

If you should be using ANSI/ASME NQA-1, please refer to Supplement S-1 for the definition of Quality Assurance Record and Supplement 17S-1, para. 2.5 and Section 3.

File: QA87-006
Subject: ANSI/ASME NQA-1-1986 Edition, Appendix 2A-3, Para. 2.3: Other Credentials of Professional Competence
Date Issued: October 26, 1988

Question: ANSI/ASME NQA-1, Appendix 2A-3, para. 2.3 allows two credits to be scored for "certification of competency in engineering, science, or quality assurance specialities issued and approved by a State Agency or National Professional or Technical Society." Do American Welding Society (AWS) Certified Weld Inspector Certificate holders or American Society for Nondestructive Testing (ASNT) NDT Level III Certificate holders qualify for credits under this paragraph?

Reply: No, they do not. It is the intent of this paragraph to recognize certification of engineering or similar competency, as contrasted to competency in the performance of an inspection function and/or technique.

File: QA87-007
Subject: ANSI/ASME NQA-1-1986 Edition, Supplement 2S-3, Paras. 2.1 and 5.2, and Supplement 7S-1: Responsible Auditing Organization and Lead Auditor Examination
Date Issued: November 30, 1987

Question (1): ANSI/ASME NQA-1, Supplement 2S-3, para. 2.1 states, "The responsible auditing organization shall establish the audit personnel qualifications." When an outside auditing organization is contracted to perform an auditing service per ANSI/ASME NQA-1, does the phrase "responsible auditing organization," as used in the above sentence, refer to the outside auditing organization or to the organization purchasing the auditing service?

Reply (1): The phrase "responsible auditing organization" refers to the outside auditing organization. The firm contracting for the service has the responsibility per ANSI/ASME NQA-1, Supplement 7S-1 of determining if the contractor is qualified to perform the service.

Question (2): ANSI/ASME NQA-1, Supplement 2S-3, para. 5.2 states, "The development and administration of the examination for a Lead Auditor required by para. 3.4 above is the responsibility of the employer." When an outside auditing organization is contracted, does the word "employer," as used in the above sentence, refer to the outside auditing organization or the organization purchasing the auditing service?

Reply (2): The word "employer" refers to the outside auditing organization.

Question (3): In accordance with ANSI/ASME NQA-1, Supplement 2S-3, para. 5.2, are there any qualifications required for the person who devises the examination for a Lead Auditor?

Reply (3): There are no specific qualifications required for the person who devises the examination for Lead Auditor.

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File: QA87-008
Subject: ANSI/ASME NQA-1-1986 Edition, Supplement 7S-1, Para. 3.1: Supplier Selection
— Sharing of Information
Date Issued: November 30, 1987

Question (1): In accordance with ANSI/ASME NQA-1, a purchaser must evaluate a potential supplier's capability to provide items or services in accordance with the requirements stipulated in the procurement documents. May this purchaser utilize data from direct evaluations from another company as input in determining whether to approve a supplier for a particular procurement?

Reply (1): Yes, if the other company's data allow the purchaser to comply with the requirements of ANSI/ASME NQA-1, Supplement 7S-1, para 3.1. However, evaluation of the data and selection of the supplier remain the responsibilities of the purchaser.

Question (2): In accordance with ANSI/ASME NQA-1, for a purchaser to utilize data from another company as input in determining whether to select a supplier for a particular procurement, must both companies be members of or affiliated with an industry, utility, or government group which has established a controlled program for sharing such information?

Reply (2): No, both companies need not be members of or affiliated with an industry, utility, or government group. However, evaluation of the data and selection of the supplier remain the responsibilities of the purchaser.

File: QA87-009
Subject: ANSI/ASME NQA-1-1986 Edition With the 1a-1986 Addenda, Supplement 2S-3,
Para. 4.1: Lead Auditors — Maintenance of Proficiency
Date Issued: November 30, 1987

Question: ANSI/ASME NQA-1, Supplement 2S-3, para. 4.1 requires that "regular and active participation in the audit process" be accomplished. Must the active participation in a quality assurance audit be in a nuclear program?

Reply: In accordance with ANSI/ASME NQA-1, Supplement 2S-3, there is no requirement that active participation in the quality assurance audit process be in a nuclear program.

File: QA87-011
Subject: ANSI/ASME N45.2.6-1978, Para. 2.2; ANSI/ASME NQA-1-1986 Edition With the 1a-1986 Addenda, Supplement 2S-1, Para. 2.5: Qualification of Inspection and Test Personnel — Initial Capability

Date Issued: October 26, 1988

Question: Is it acceptable for a candidate for certification under ANSI/ASME N45.2.6, para. 2.2 to be evaluated on the basis of test results and/or capability demonstration without a documented evaluation of education, training, or experience?

Reply: It is not acceptable to evaluate a candidate for certification solely on the basis of test results and/or capability demonstration. ANSI/ASME N45.2.6, para. 2.2 states, "The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate's education, experience, training, test results or capability demonstration." This is further clarified in ANSI/ASME NQA-1, Supplement 2S-1, para. 2.5 which states, in part, "a suitable evaluation of the candidate's education, experience, training and either test results or capability demonstration."

File: QA88-001
Subject: ANSI/ASME NQA-1-1979 and Later Editions and Addenda Through 1a-1986, Supplement 7S-1, Para. 3.1: Source Evaluation — Performed by

Date Issued: October 26, 1988

Question: Is it the intent of ANSI/ASME NQA-1, Supplement 7S-1, para. 3.1 that the process of source evaluation and selection requires an audit per Supplement 18S-1, conducted by auditor(s) qualified to Supplement 2S-3?

Reply: No. ANSI/ASME NQA-1, Supplement 7S-1, para. 3.1 requires one or more of three measures for source evaluation and selection. None of these measures requires the performance of an audit per Supplement 18S-1 conducted by auditor(s) qualified to Supplement 2S-3.

File: QA88-002
Subject: ANSI/ASME N45.2.6-1978, Para. 3; ANSI/ASME NQA-1-1986 Edition With the 1a-1986 Addenda, Appendix 2A-1, Para. 2: Qualification of Inspection and Test Personnel of Other Disciplines

Date Issued: July 22, 1988

Question: In accordance with ANSI/ASME N45.2.6, para. 3, can a Level III certify a Level I, Level II, or Level III of a different discipline?

Reply: Yes. A Level III of one discipline may certify Level III, Level II, or Level I individuals in other disciplines, provided the Level III meets the qualification requirements contained in paras. 3.2, 3.3, and 3.4 of ANSI/ASME N45.2.6 for those other disciplines.

If you are using ANSI/ASME NQA-1, see Appendix 2A-1.

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File: QA88-003

Subject: ANSI/ASME NQA-1-1986 Edition With the 1a-1986 Addenda, Supplement 17S-1, Para. 2.3: Record Validation

Date Issued: July 22, 1988

Question: Do the options stated in ANSI/ASME NQA-1, Supplement 17S-1, para. 2.3 for record validation eliminate the need to stamp, initial, or sign records such as inspection reports, assuming the reports are identified by the reporting individual or organization?

Reply: Yes, if the record can be clearly identified as a statement by the reporting individual or organization. Techniques such as controlled forms, security codes, etc., may be required so that the record can be traced to the authenticating individual or organization.

File: QA88-004

Subject: ANSI N45.2.11-1974, Sections 2 and 7; ANSI/ASME NQA-1-1986 Edition With the 1a-1986 and 1b-1987 Addenda, Basic Requirement 5; Supplement 3S-1, Para. 5; and Supplement 6S-1: Design Control — Review of Changes

Date Issued: October 26, 1988

Question: In accordance with ANSI N45.2.11, if, during the review cycle for a proposed plant modification, one reviewer requires a change to the proposed modification, must the modification, with the changes incorporated, be recycled to all reviewers who did not see the change, even if some of the reviewers are not affected by the change?

Reply: No. It is the intent of ANSI N45.2.11 that only the changes affecting a given group or organization are required to be reviewed and approved by that affected group or organization. ANSI N45.2.11 allows the implementing organization to decide how changes to proposed plant modifications identified during the review cycle will be controlled. However, the requirements of Sections 2 and 7 must be satisfied. These sections address the requirements for proceduralizing the review process (para. 2.2 and the first paragraph of Section 7), and decide how significant and minor changes will be reviewed and approved (para. 7.2).

The intent of ANSI N45.2.11, relative to the control of a design change review and approval, is addressed in ANSI/ASME NQA-1, Basic Requirement 5, Supplement 3S-1, para. 5, and Supplement 6S-1.

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File: QA88-007
Subject: ANSI/ASME NQA-1-1986 Edition, Basic Requirement 1; Supplement 1S-1, Para. 2.1; Supplement 2S-2; and Supplement 10S-1, Para. 2.1: Inspection Personnel — Independence
Date Issued: October 26, 1988

Question (1): In accordance with ANSI/ASME NQA-1, is it acceptable for a welder to preclean a weld and apply liquid penetrant and developer for subsequent interpretation by a certified nondestructive examination (NDE) Level II liquid penetrant examiner?

Reply (1): No. Precleaning and application of the penetrant materials are an integral part of the examination process and must be performed by a certified examiner in accordance with the requirements of ANSI/ASME NQA-1, Supplement 2S-2.

Question (2): Provided the welder meets the requirements of ANSI/ASME NQA-1, Supplement 2S-2, and works for the same or different shift supervisor, may the welder perform the function described in Question (1)?

Reply (2): No. Basic Requirement 1, Supplement 1S-1, para. 2.1, and Supplement 10S-1, para. 2.1 require that the certified NDE examiner, who will accept the work, shall not have direct responsibility for the work and not report directly to immediate supervisors who are responsible for performing the work.

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