ASME NQA-1 Interpretations

Replies to Technical Inquiries

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 ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications.

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 Subsequent revisions to the rules may have superseded the reply.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. vi of 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, which are the compilation of former NQA-1 and NQA-2 interpretations indexes, will be updated with each Edition and Addenda.

File: QA 79-8

Subject: Use of ANSI/ASME NQA-1-1979 With Unincorporated Daughter Standards

Date Issued: August 13, 1979

Question: It is intended to use ANSI/ASME NQA-1 and one or more of the daughter Standards which have not been incorporated in NQA-1. However, these daughter Standards reference N45.2 and other Standards which have been incorporated. May NQA-1 be used in lieu of N45.2 and the referenced incorporated Standards?

Reply: Yes. The user, however, should be aware that there are differences between NQA-1 and N45.2 plus the incorporated Standards, and a blanket reference to NQA-1 may not be appropriate. The user should clearly specify those corresponding portions of NQA-1 which are to used in place of the requirements contained in N45.2 and referenced incorporated Standards.

File: QA 80-2

Subject: ANSI/ASME N45.2-1977 Quality Program Qualification

Date Issued: March 13, 1981

Question: Is it required to qualify the quality program of material manufacturers and material suppliers through survey or audit in accordance with ANSI/ASME N45.2-1977 if the manufacturer's (material user's) quality program provides assurance that the material or item is supplied in accordance with the material specification (as applicable), and the quality of the item can be verified through review of test reports and inspection upon receipt or source inspection?

Of particular interest, is the method of selection of procurement sources at new manufacturers or manufacturers at new locations where little vendor historical quality performance data exists?

Reply: Source inspection or receipt inspection and review of test reports are not methods of evaluation prescribed in ANSI N45.2.2.13-1976 or ANSI/ASME NQA-1-1979 as adequate for qualification of a supplier's program. The requirements for such evaluation are listed under ANSI N45.2.13-1976, 4.2(a), (b), and (c) and ANS/ASME NQA-1-1979, 7S-1 3.1 requires evaluation to be performed prior to award of contract.

When historical data and/or current quality records cannot provide sufficient data for evaluation, a survey or audit is prescribed by ANSI N45.2.13-1976, 4.2© and ANSI/ASME NQA-1-1979, 7S-1 3.1(c). Additional guidance on evaluation methods is provided in ANSI/ASME NQA-1-1979, 7A-1 2.0, 2.1, 2.2, and 2.3.

File: QA 80-12

Subject: ANSI/ASME NQA-1-1979, 3@l, Supplementary Requirements for Design Control, and 3A-1, Nonmandatory Guidance on Design Control

Date Issued: March 13, 1981

Question (1): Clarify the meaning and requirements of review as presented in 3S-1 3.1 (f). Is there a difference between reviewing and checking as presented in 3A-1 2.0? If different, what are the definition and requirements for checking?

Reply (1): In 3S-1 3.1 (f), the term review pertains to the review of the design analysis as outlined in the first paragraph of 3.1. The term checking, as used in 3A-1 2.0, refers to the checking method associated with producing drawings [see 3A-1 4.1 (e)].

Question (2): In 3A-1 4.1 (e) and (f), the terms checking methods and review ... requirements are presented. What results are the checking methods intended to produce? Is the review intended to be by an individual following the checking methods? Are there any requirements limiting the designer from performing the review checking, i.e., can the designer follow the checking methods and qualify as the reviewer?

Reply (2): In 3A-1 4.1(e), the checking methods are intended to assure that the drawings have been produced in conformance with approved drafting room operating procedures and practices. No, the review is not intended to be performed by an individual following the checking methods. In 3A-1 4.1 (f), the term review refers to the type of design review outlined in 3S-1 4.2.1, but not necessarily in the full context of design verification as outlined in 4.0. Yes, there are requirements limiting the designer. If the review is performed for the purpose of design verification, the person performing the review must be independent and, therefore, cannot be the designer.

Question (3): If the individual who serves as the reviewer/checker and who performs the review/check for the design process complies with the design verification requirements of 3S-1 4.0, can he also qualify as the verifier when the method of verification is by design review or alternate calculations?

Reply (3): Yes, if a person complies with the design verification requirements of 3S-1 4.0, including independence, he qualifies as the verifier when the method of verification is by design review or alternate calculations.

File: QA 80-13

Subject: ANSI N45.2.10-1973

Date Issued: July 10, 1981

Question: Is it required by the definitions in ANSI N45.2.10-1973 that Certificates of Compliance, Certificates of Conformance, and Certified Test Reports be signed in longhand, or may the initials or stamp attributable to particular individuals be used for signing these certificates?

Reply: The term signed as used in all definitions means that a signature is required. However, it is recognized that the method by which a person responsible for the quality assurance function attests to the quality of an item is not specified in ANSI/ASME NQA-1-1979 7S-1. The definition of Certification in ANSI/ASME NQA-11979 S-1 specifies that certification shall be in writing, and the definition of Certificate of Conformance requires that it be signed. The Committee will consider in the future a revision to the definition of Certificate of Conformance in order to remove any ambiguities, It should be noted that the terms Certificate of Compliance and Certified Test Report have been deleted from the definitions in ANSI/ASME NQA-1-1979.

File: QA 81-4

Subject: ANSI/ASME NQA-1-1979,18S-1 3.2, Personnel

Date Issued: March 13, 1981

Question: ANSI/ASME NQA-1-1979, 18S-1 3.2, Personnel, requires auditors to be "independent of any direct responsibility for performance of the activities which they will audit" and "personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team." Under what conditions can an organization use an internal group to audit the quality assurance organization?

Reply: An organization can use an internal group to audit the quality assurance organization provided one or more of the following measures, as applicable, is exercised:

(a) use of personnel in one section or function of the quality assurance organization to audit other sections or functions;

(b) use of appropriately qualified personnel from nonquality assurance organizations to audit the quality assurance organization;

(c) use of personnel from sister divisions in the company to audit the quality assurance organization;

(d) use of personnel from corporate headquarters quality functions to audit the quality assurance organization.

File: QA 81-7

Subject: ANSI/ASME NQA-1-1979, Basic Requirement 6 Document Control

Date Issued: July 10, 1981

Question: What controls are required on the use of vendor technical manuals?

Reply: Vendor technical manuals fall under Basic Requirement 6 of ANSI/ASME NQA-1-1979, depending on the records classification that you establish.

File: QA 81-9

Subject: ANSI/ASME N45.2.13-1976, 3.3, Procurement Document Review

Date Issued: July 14, 1982

Question: Does a review of procurement requisitions, for inclusion of all applicable requirements of ANSI N45.2.13, 3.2 prior to issuance for bid, satisfy the intent of 3.3a of the above referenced document or must another review be conducted prior to award after the bid is put into contract format?

Reply: A second review of the procurement requisition is not required, provided a review of the requisition was performed and no subsequent changes in the procurement requirements were made. This clarification is included in ANSI/ASME NQA-1-1979, 4S-1, 3.0.

File: QA 81-10

Subject: ANSI/ASME NQA-1-1979 3S-1: 4.0, Design Verification and 4.2.3, Qualification Tests 3A-1: 6.0, Design Verification Basic Requirement 3 - Design Control

Date Issued: July 13, 1982

Question: In cases where the designer performs some of the qualification testing activities, is verification of these activities required?

Reply: Paragraph 4.0 of 3S-1 requires that qualification testing activities (e.g., the specification of the test Requirements and acceptance criteria, the establishment of the test procedures, the conduct of the tests, the documentation of the test results, and/or the evaluation of the test results) be performed by competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. To fulfill this requirement, those qualification testing activities performed by the designer shall be verified by personnel meeting the above requirement for independence.

File: QA 82-2

Subject: ANSI/ASME NQA-1-1979, 3S-1: 2.0, Design Input and 3.0, Design Process is ANSI N45.2.11-1974, 3.1 and 4. 1, General

Date Issued: November 17, 1982

Question: May changes be made to the final design that conflict, without making a revision to the design inputs to resolve the conflict?

Reply: No. In 3S-1, the last sentence of 3.0 states, "The final design (approved design output documents and approved changes thereto) shall be relatable to the design input by documentation in sufficient detail to permit verification." The last sentence of 2.0 also states, "Changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled." This response is also valid for ANSI N45.2.11, 4.1, which states, "Methods shall provide for relating the final design back to the source of design input." and 3.1, which states, "Changes from specified design inputs including the reason for changes shall be identified, approved, documented, and controlled."

File: QA 82-3

Subject: ANSI N45.2-1977, Section 8

Date Issued: November 17, 1982

Question: When ANSI N45.2 is imposed on a Supplier, is the Supplier required to perform audits and surveys on his subtier suppliers where the items supplied are materials to ASTM specifications?

Reply: ANSI N45.2, Section 8, states that it is the Purchaser's responsibility to assure that what. is supplied meets specified requirements. In discharging this responsibility, it may be necessary for the Purchaser to perform audits and surveys to assure that what is supplied meets the requirements. Factors to be considered when determining the need for audits, surveys, or other means for procurement control are addressed in N45.2, Section 5, (5); ANSI N45.2.13; ANSI/ASME NQA-1-1979, 4S-1, 7S-1, 4A-1, 7A-1, and Interpretation QA 80-2 contained in the lb-1981 Addenda to ANSI/ASME NQA-1 -1979.

Note: This interpretation should have been included with the lc-1982 Addenda to ANSI/ASME NQA-1 -1 979, covering the period from September 1, 1981, to December 31, 1982.

File: QA 82-4

Subject: ANSI N45.2-1977, Section 8

Date Issued: November 17, 1982

Question: Does ANSI N45.2-1977 require that Suppliers of calibration services be audited if the Supplier certifies that the calibration is traceable to the National Bureau or Standards?

Reply: A certificate of calibration purported to be traceable to the National Bureau of Standards by itself is not sufficient unless means are provided to verify the validity of the Supplier's certificate and effectiveness of the certification system, such as during the performance of surveys and/or audits of the Supplier or independent inspection or test of the items. For more complete guidance on the control of purchased items and services, see ANSI/ASME NQA-1-1979, 7S-1 and 7A-1, and N45.2.13-1976.

Note: This interpretation should have been included with the lc-1982 Addenda to ANSI/ASME NQA-1 -1 979, covering the period from September 1, 1981, to December 31, 1982.

File: QA 82-8

Subject: ANSI/ASME NQA-1, Introduction and Requirements

Date Issued: March 2, 1983

Question (1): Is ANSI/ASME NQA-1 intended to apply to all departments, such as manufacturing and engineering, or is it only to be used by Quality Assurance for the purpose of establishing a Quality Assurance Program?

Reply (I): ANSI/ASME NQA-1 applies to all departments performing activities that affect quality and are within the scope of ANSI/ASME NQA-1.

Question (2): Is Basic Requirement 3, Design Control, directed to engineering, or is it intended to serve to establish the quality requirements by which Quality Assurance will control the design process?

Reply (2): Design Control requirements in ANSI/ASME NQA-1 apply to engineering, Quality Assurance, and other organizations involved in the design process.

Question (3): Are Quality Assurance auditors supposed to observe welders welding, machinists machining, and operators operating to determine whether or not they are or are not following procedures or, are auditors to review Quality Assurance documentation to assure that the quality procedures are causing the welders machinists, and operators to be watched and that the records of this are adequate?

Reply (3): Quality Assurance auditors should observe quality affecting work being performed as well as review the documentation generated to provide evidence that the work was performed correctly.

File: QA 82-11

Subject: ANSI/ASME N45.2.9-1979,1.4

Date Issued: March 2, 1983

Question: ANSI/ASME N45.2.9-1979, 1.4, states in part: "A document is considered a Quality Assurance record when the document has been completed." At what point is a document considered complete:
(a) after sign-off by the field personnel and QA Inspectors, after the task is completed?
(b) after review for correctness by the QA review groups, or the supervisors, or both?
(c) after it has been through all approval cycles and then has been sent to final file in QA records, and after being cataloged or indexed, filed, and ready for turnover to the client or Owner?

Reply: In ANSI/ASME N45.2.9-1979, 1.4, this same sentence refers to 3.2.1, which states in part:
"Documents shall be considered valid records only if stamped, or initialed, or signed and dated by authorized personnel or otherwise authenticated."

It is the responsibility of the licensee or its designee to appoint individual (s) or an organization as the authorized personnel to stamp, initial or sign, date, and otherwise authenticate documents. It is at this time that the document officially becomes a record. Therefore, (a), or (b), or (c), or a combination, could all be areas in which the document becomes a record, depending on how the implementing procedure is written. The Records Management Procedure prepared by the licensee or its designee must clearly designate or define the authorized personnel.

Should you use ANSI/ASME NQA-1-1979 and its Addenda, please refer to 17S-1, 2.2, Generation of Records, and 2.3, Record Validation.

File: QA 83-1

Subject: ANSI/ASME N45.2.9-1974, 3.2.2 and 4.3.1

Date Issued: March 3, 1983

Question (1): Is ANSI N45.2.9-1974, 3.2.2, intended to apply to traditional "A/E-to-Client" turnover at the completion of a project?

Reply (1): Yes. ANSI N45.2.9-1974, 3.2.2, is intended to apply to any type of record turnover, for example, A/E to client, manufacturer to client, service organization to client, and manufacturer to A/E.

Question (2): How does ANSI N45.2.9-1 974, 3.2.2, apply to an ongoing turnover of project records?

Reply (2): On an ongoing turnover of project records, the recipient who stores and maintains the records is responsible for complying with the requirements of ANSI N45.2.9-1974, 3.2.2.

Question (3): What, if any, are the specific format requirements of the index described in ANSI N45.2.9-1 974, 3.2.2, i.e., is a computer-generated listing of project records acceptable as an index?

Reply (3): The format is to be defined in the Records Management Procedure, and no specific format is required by the Standard. A computcr-generated listing of project records is one of the acceptable forms. Should you use ANSI/ASME NQA-1-1979 and its Addenda, please refer to 17S-1, 2.4, Index, and 3.2, Receipt Control.

File: QA 83-3

Subject: ANSI/ASME N45.2.9

Date Issued: June 14, 1983

Question: To aid in the collection, storage, and maintenance of records, our company has developed a computer-assisted records retrieval system. It seems probable that during the life of the records management program revisions may be made in the computer software program. Is it the intent of ANSI/ASME N4S.2.9 that compliance will require that we maintain all revisions of the software program used for the records management system? The computer software program is not safety related.

Reply: The computer software described does not meet the criteria for a lifetime record as delineated in ANSI/ASME N45.2.9-1974 and -1979, 2.2.1, or ANSI/ASME NQA-1-1979, 17S-1, 2.7.1 Thus, superseded revisions need not be permanently maintained.

File: QA 83-004

Subject: ANSI N45.2.9-1974, Para. 5.3(3) and Section 7

Date Issued: November 28, 1983

Question (1)Does ANSI N45.2.9-1974, para. 5.3(3), which states, "A method for verifying that the records received are in agreement with the transmittal document . . ." apply to records such as Procedure

Data Sheets when transferred from within the Owner's operating organization to the permanent on-site storage facility?

Reply (1): ANSI N45.2.9-1974, para. 5.3(3), applies to any document that is defined as a record.

Question (2): Does ANSI N45-2.9-1974, Section 7, apply to records generated and transferred from within the Owner's operating organization?

Reply (2): No. Please refer also to ANSI/ASME NQA-1-1983 Edition, 17S-1, para. 6.

File: QA 83-006

Subject: ANSI/ASME NQA-1 -1 979, 2A-3, and ANSI/ASME N45.2.23-1978, para. 2.3.1.3

Date Issued: January 10, 1984

Question: ANSI/ASME NQA-1-1979, 2A-3, para. 2.0 (also ANSI/ASME N45.2.23-1978, para. 2.3.1.3), allows two credits to be scored for "certification of competency and engineering, science, or quality assurance specialties issued and approved by a state agency or national professional or technical society." Does any of the following qualify for credits under this paragraph?

(a) AWS-Certified Weld Inspector Certificate
(b) active senior reactor operator license
(c) inactive senior reactor operator license
(d) active reactor operator license
(e) inactive reactor operator license

No. It was not intended that ANSI/ASME NQA-1-1979, 2A-3, para. 2.0 (also ANSI/ASME N45.2.23-1978, para. 2.3.1.3) be interpreted to include organizations such as utilities, or architectural or engineering firms, even though they may hold a valid construction permit for a nuclear power plant, or have on the staff a licensed architectural engineer responsible for the design of a nuclear power plant. They are clearly not state agencies or national professional or technical societies.

File: QA 83-008

Subject: ANSI/ASME N45.2.9-1979

Date Issued: November 30, 1983

Question (1): Is it mandatory for the contractor to apply the requirements of ANSI/ASME N45.2.9 1979 to documents maintained in a temporary vault by the contractor that have not yet been turned over to the Owner during construction?

Reply (1): No, it is not mandatory to apply the requirements of ANSI/ASME N45.2.9-1979 to documents. However, when these documents become quality assurance records in accordance with ANSI/ASME N4S.2.9-1979, paras. 1,4 and 3.2.1, the requirements apply. Please refer also to ANSI/ASME NQA-1-1983 Edition, 17S-1.

Question (2): Is it the intent of ANSI/ASME N45.2.9-1979 to provide the requirements for the collection, storage, and maintenance of QA records for the Owner during construction and operation, or for the contractor during construction?

Reply (2): Yes, ANSI/ASME N45.2.9-1979 applies to both the contractor and Owner as stated by ANSI/ASME N45.2.9-1979, para. 1.2. Please refer also to ANSI/ASME NQA-1-1983 Edition, 17S-1, para. 2.1.

File: QA 83-009

Subject: ANSI/ASME NQA-1-1979, With la, I b, and Ic Addenda, 18S-1, Para. 3.2

Date Issued: November 1, 1983

Question: According to ANSI/ASME NQA-1-1979, including la, lb, and lc Addenda, 18S-1, para. 3.2, when using an internal group from a nonquality assurance department to audit the quality assurance department, do the auditing personnel have to be qualified to 2S-3 as auditors?

Reply: If an organization's Quality Assurance Program includes a commitment to 2S-3 for internal audits, then the audit personnel must be qualified per the requirements of 2S-3, even though external audits are performed by independent sources not under the organization's control.

File: QA 83-011

Subject: ANSI N45.2.9-1974 and ANSI/ASME N45.2.9-1979

Date Issued: November 30, 1983

Question (1): Do ANSI N45.2.9-1974 and ANSI/ASME N45.2.9-1979, para. 5.6, apply to the storage of in-process records that include NDE personnel certificates, lead auditor certificates, inspector certificates, nonconformance reports, calibration records, training records, audit reports that include corrective action requests, and technical reports?

Reply (1): Yes, if the records are completed as defined in ANSI N45.2.9-1974 and ANSI/ASME N45.2.9-1979, para. 1.4.

Question (2): Does the word hardware as used in ANSI N45.2.9-1974 and ANSI/ASME N45.2.9-1979, para. 5.6.1, include fire-rated file cabinets for the storage of in-process records?

Reply (2): No. Please refer also to ANSI/ASME NQA-1-1983 Edition, 17S-1, para. 4.4, which allows 2 hr fire-rated containers for storage of records.

File: QA 83-014

Subject: ANSI/ASME N45.2.12-1977, ANSI/ASME N45.2.23-1978, and ANSI/ASME NQA-1-1983 Edition

Date Issued: February 27, 1984

Question (1): In accordance with ANSI/ASME N45.2.12-1977, can an audit be performed by other than a Lead Auditor?

Reply (1): No. For each audit performed, there must be a qualified Lead Auditor. Members of the audit team functioning under the supervision of the Lead Auditor can be qualified auditors. If only one auditor is involved in the audit, he must be a qualified Lead Auditor.

Question (2): Does ANSI/ASME N45.2.12-1977 require every organization performing audits to have one person designated as Lead Auditor?

Reply (2): Yes. Planning, scheduling, performance, and evaluation of results must be under the supervision of a Lead Auditor, The Lead Auditor may be provided by outside organizations, as long as the Lead Auditor is certified in accordance with the auditing organization's programs.

Question (3): If an audit can be performed only by a Lead Auditor, who qualified him under ANSI/ ASME N45.2.23-1978, para. 2.3.4, when he performed his first audit?

Reply (3): ANSI/ASME N45.2.23-1978, para. 2.3.4, requires participating in five audits prior to qualification. This participation can be as an auditor-in-training under the supervision of a Lead Auditor provided by an outside organization.

Question (4): Has ANSI/ASME N45.2.23-1978 been reaffirmed, revised, or withdrawn? If not, is it still a valid standard?

Reply (4): ANSI/ASME N45.2.23-1978 has been withdrawn as an American National Standard as of September 30, 1983. ANSI/ASME N45.2.23-1978 provisions have been incorporated into and superseded by ANSI/ASME NQA-1.

ANSI/ASME N45.2.23 provisions are valid for those organizations and activities to which they have been committed and to which the provisions of ANSI/ASME NQA-1 have not been adopted in lieu of N45.2.23. The Nuclear Quality Assurance Committee will continue to provide interpretations of N45.2.23 provisions but will not entertain requests to amend or revise N45.2.23.

File: QA 84-001

Subject: ANSI N45.2.9-1974, Appendix A

Date Issued: February 17, 1984

Question (1): Does ANSI N45.2.9-1974 require the retention of a manufacturers quality assurance manuals at a nuclear power plant?

Reply (1): No. The manufacturer's quality assurance manual is a nonpermanent record as described in ANSI N45.2.9-1974, para. 2.2.2. The contractual arrangement between the manufacturer and the licensee or his agent will determine where and for what duration the manufacturer's quality assurance manual is to be maintained.

Question (2): In ANSI N45.2.9-1974, is Appendix A a mandatory list of records to be retained at a nuclear power plant?

Reply (2): Appendix A is a non-mandatory list of records. The Committee does suggest that you research your contractual requirements for imposition of Regulatory Guide 1.88, which does impose additional regulatory guidance.
Please refer also to ANSI/ASME NQA-1-1 983 Edition, 17S-1, para. 2.7.2.

File: QA 84-002

Subject: ANSI N45.2.10-1973 and ANSI/ASME NQA-1-1983 Edition

Date Issued: August 20, 1 984

Question: Can a Certificate of Compliance be composed of a Certificate of Conformance and a Certified Test Report?

Reply: Yes. When defined under ANSI N45.2.10-1973, a Certificate of Compliance can be composed of a Certificate of Conformance, and a Certified Test Report could be a part of the required information to substantiate the statement. Documentation required with the Certificate of Compliance should be

determined by the inquirer and his customer. It is further noted that during the preparation of ANSI/ASME NQA-1 (which supersedes and incorporates ANSI N45.2.10-1973), Certificate of Conformance is the only term defined, i.e., the term Certificate of Compliance is no longer used in ANSI/ASME NQA-1 and ANS[I ASME NQA-2.

File: QA 84-005

Subject: ANSI/ASME N45.2.6-1978, Para. 2.5, and ANSI/ASME NQA-1-1983 Edition, 2S-1, Para. 2.8

Date Issued: July 12, 1984

Question (1): Does ANSI/ASME N45.2.6-1978, para. 2.5, require passing eye examinations, such as a Jaeger-I Test Chart and Bausch and Lomb Vision test (including color and far- and near-distance test) for certification?

Reply (I): It is the responsibility of each organization, individually, to determine the physical requirements for those personnel who perform inspection, examination, and testing to verify conformance to specified requirements of nuclear plant items.

Question (2): Does ANSI/ASME NQA-1-1983 Edition, with the Addenda la-1983, 2S-1, para. 2.8, require passing eye examinations, such as a Jaeger-I Test Chart and Bausch and Lomb Vision test (including color and far- and near-distance test) for certification?

Reply (2): ANSI/ASME NQA-1 -1 983 Edition states, "The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination."

File: QA 84-006

Subject: ANSI N45.2.9-1974, Paras. 4.3 and 5.3.4

Date Issued: August 1, 1984

Question: In accordance with ANSI N45.2.9-1974:
(a) what constitutes a records checklist per para. 4.3(l)? lb) how is it intended that this records checklist be applied to the storage of records for an operating power plant, as required in para. 5.3(4)?

Reply: In accordance with ANSI N45.2.9-1974:

(a) Paragraph 4.3 (1) refers to a records checklist. A records checklist is a listing of the records expected to be received at the records storage facility. The records checklist should be structured in a manner that best suits the circumstances.
(b) The "Records Checklist" specified in para. 5.3(4) is intended to be used as the pre-established checklist for verifying that the correct records are being received at the records storage area. Verification could be by personnel in your records management section, by a QA audit, or other methods.
Please refer also to ANSI/ASME NQA-1 -1983 Edition, 17S-1, paras. 3.2 and 4.1.

File: QA 84-007

Subject: ANSI/ASME NQA-1 -1979, 3S-1, Para. 4.2.1

Date Issued: July 12, 1984

Question: Does a written report need to be prepared to address the six questions posed in NQA-1 -1 979, 3S-1, para. 4.2.1, to substantiate the design review method of design verification?

Reply: No. The degree of documentation of the design verification by design review can vary from the signature of the verifier to a format report depending on the user's design verification procedures and the extent of design verification required by para. 4.1. Procedures for design verification are required (Basic Requirements 5). It is the intent of the Standard that these procedures address the six questions of para. 4.2.1 and be considered by the user, as applicable, as well as other considerations.

File: QA 84-008

Subject: ANSI/ASME NQA-1-1983 Edition, 2A-3, Para. 2.3, and ANSI/ASME N45.2.23-1978, Para. 2.3.1.3

Date Issued: July 12, 1 984

Question: ANSI/ASME NQA-1 -1 983 Edition, with the Addenda I a-1 983, 2A-3, para. 2.3 (also ANSI/ ASME N45.2.23-1978 para. 2.3.1.3), allows two credits to be scored for certification of competency in engineering, science, or quality assurance specialties issued and approved by a state agency or national professional or technical society. Does a certificate of competency in statistical methods qualify for credits under this paragraph?

Reply: No. Both ANSI/ASME NQA-1-1983 Edition, 2A-3, para. 2.3, and ANSI/ASME N45.2.231978, para. 2.3.1.3, are directed towards established measures of professional competence granted by a state agency or national professional or technical society. In the context used therein, state agency is meant to indicate an established department or division of a state government empowered to control professional registration. Typically, the state agency would grant professional engineering licenses under controlled conditions. In the context used therein, national professional or technical society is meant to indicate a professional organization such, as the American Society for Quality Control, that has established a program of certified competency in engineering, science, or quality assurance specialties. In the case of the American Society for Quality Control, these credentials include the Certified Quality Engineer and Certified Reliability Engineer. It should be understood that the intent of the above paragraphs is to recognize professional competence as a broad field or knowledge in a profession rather than a narrow slice of technical specialty.

File: QA 84-012*

Subject: ANSI N45.2.9-1974, Paras. 4.3 and 5.3, and ANSI/ASME NQA-1-1983 Edition, 17S-1, Paras. 3.2 and 4.1, and 1 7A-1

Date Issued: September 4, 1984

Question (1): In accordance with ANSI N45.2.9-1974, paras. 4.3 and 5.3, is a list of documents required such that only the documents on the list must be processed?

Reply (1): A records checklist is required by ANSI N45.2.9-1974, para. 4.3. This checklist may be prepared and structured in any manner that best suits the circumstances. A checklist and/or index of records is a document which requires frequent revisions. Experience, plus the contents of specifications, procedures, instructions, and other work controlling documents, must be considered. Guidance for the contents of the checklist is provided in ANSI N45.2.9-1974, Appendix A.

Question (2): In accordance with ANSI N45.2.9-1974, paras. 4.3 and 5.3, is a records forwarding schedule required which can be used by the records facility to determine which records are required to be received and to establish a schedule for receiving them?

Reply (2): ANSI N45.2.9-1974 requires timely submittal of a record. A records forwarding schedule, the intent of which is to insure timely transfer of documents to the records facility, is one way of meeting the Standard.

Please refer also to ANSI/ASME NQA-1 -1 983 Edition, 17S-1, paras. 3.2 and 4.1. The guidance for the checklist can be found in Nonmandatory Appendix 17A-1.

File: QA 84-012

Subject: ANSI/ASME NQA-1 -1 979, 2S-3, Paras. 3.4 and 5.2

Date Issued: October 30,1984

Question: Does an examination as administered by the National Board of Boiler and Pressure Vessel Inspectors for an Authorized Nuclear Inspector or an Authorized In-service Inspector satisfy ANSI/ASME NQA-1, 2S-3, para. 3.4?

Reply: As stated in ANSI/ASME NQA-1, 2S-3, para. 5.2, "The employer may delegate this activity to an independent certifying agency, but shall retain responsibility for conformance of the examination and its administration to this Standard." Therefore, it is the employer's responsibility to assure that the examination adequately assesses the body of knowledge identified in para. 3.2.

File: QA 84-014

Subject: ANSI N45.2.11-1974 and ANSI/ASME NQA-1-1983 Edition With NQA-la-1983 and NQA-lb-1984 Addenda

Date Issued: June 28, 1985

Question (1): What is the intent of ANSI N45.2.11 and of ANSI/ASME NQA-1 with regard to documenting the planning of design verification?

Reply (1): The intent of the standards is that design verification be controlled by a procedure(s) which is in place prior to the verification activity. The procedure(s) is required to identify acceptable verification methods but need not require a verification plan for each design.

Question (2): Does a generic procedure applicable to all design verifications satisfy the requirements of documented procedures, or are documented procedures required for individual designs or design packages?

Reply (2): ANSI N45.2.11 and ANSI/ASME NQA-1 permit the use of either generic or individual design verification procedures. A generic procedure is acceptable provided it satisfies the standard and is adequate for the design being verified.

Question (3): Is it the intent of ANSI N45.2.11 and ANSI/ASME NOA-1 that design verification procedures be prepared by individuals or groups other than those who prepared the original design?__

Reply (3): No, neither ANSI N45.2.11 nor ANSI/ASME NQA-1 requires such independence.

File: QA 84-015

Subject: ANSI/ASME N45.2.6-1978, Para. 2.2, and ANSI/ASME NQA-1 -1 983 Edition With NQA-la-1 983 Addenda, 2S-1, Para. 2.5

Date Issued: October 30, 1984

Question (1): Does ANSI/ASME N45.2.6, para. 2.2, which 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," require either test results or capability demonstration; or, is it acceptable to initially evaluate a candidate based on education, training, and past experience alone without either test results or a capability demonstration?

Reply (1): No. In addition to evaluating a candidate based on education, training, and past experience, you must also evaluate a candidate's test results or capability demonstration.

Question (2): Does ANSI/ASME NQA-1, 2S-1, para. 2.5, require initial evaluation of a candidate based on education, training, and past experience alone without either test results or a capability demonstration?

Reply (2): No. In addition to evaluating a candidate based on education, training, and past experience, you must also evaluate a candidate's test results or capability demonstration.

File: QA 84-016

Subject: ANSI/ASME N45.2.6-1978, Para. 3.5.3, and ANSI/ASME NQA-1-1983 Edition With NQA-la-1983 Addenda, Appendix 2A-1, Para. 3.3.3

Date Issued: October 30, 1984

Question (I): Must an individual possess an Associate's Degree in order to satisfy the requirements of ANSI/ASME N45.2.6, para. 3.5.3(3), or will satisfactory completion of all of the course work leading to the degree, without actual possession of the degree itself, meet the requirement?

Reply (1): An individual must have either obtained the Associate's Degree or have verifiable proof of the satisfactory completion of the college level courses that are at least those required for an Associate's Degree from an accredited institution granting such a degree.

Question (2): Must an individual possess an Associate's Degree in order to satisfy ANSI/ASME NQA-1, Appendix 2A-1, para. 3.3.3, or will satisfactory completion of all of the course work leading to the degree, without actual possession of the degree itself, meet the Appendix requirement?

Reply (2): An individual must have either obtained the Associate's Degree or have verifiable proof of the satisfactory completion of the college level courses that are at least those required for an Associate's Degree from an accredited institution granting such a degree.

File: QA 84-017

Subject: ANSI/ASME NQA-1-1983 Edition, Basic Requirement 13 and 13S-1

Date Issued: March 25, 1985

Question: Is it the intent of ANSI/ASME NQA-1, Basic Requirement 1 3 and Supplement I 3S-1, to encompass the handling, storage, and shipping of all materials, including radioactive materials, at facilities specifically stating that their quality program meets the requirements of this Standard?

Reply: The Nuclear Quality Assurance Subcommittee on General Requirements agrees that Basic Requirement 1 3 and Supplement 1 3S-1 are intended to cover the handling, storage, and shipping of any

programmatically significant materials, including, for example, spent nuclear fuel, high level waste, analytical samples, and other radioactive materials at nuclear facilities. The extent to which these requirements are applied should be specified by the organization imposing this Standard and be defined in the quality program of the using organization.

File: QA 8S-003

Subject: ANSI/ASME N45.2.9-1979, Para. 5.6.1, and ANSI/ASME NQA-1 -1 983 Edition With NQA-1 a-] 983 Addenda, 17S-1, Para. 4.4

Date Issued: March 18, 1985

Question: Do file cabinets with a National Fire Protection Association (NFPA) fire rating of 1 hr, housed in an office with a fire protection system, provide adequate protection to satisfy the ten criteria of ANSI/ASME N45.2.9, para. 5.6.1?

Reply: Yes, as stated in ANSI/ASME N45.2.9, para. 5.6.1, "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." However, we refer you to para. 5.6.1, criterion IO, which states, in essence, that a person specializing in the field of fire protection should review the adequacy of protection to determine that the record storage facility, including the characteristics of the building construction, meets the minimum fire rating of para. 5.6.1. Should you be using ANSI /ASME NQA-1 , please refer to I 7S-1 , para. 4.4.

File: QA 85-005

Subject: ANSI/ASME NQA-1 -1 983 Edition, I 7S-1, Para. 4.4.3

Date Issued: July 1, 1985

Question: What is meant by the words "sufficiently remote" as used in ANSI/ASME NQA-1, para. 4.4.3?

Reply: Two locations are considered "sufficiently remote" if their separation precludes exposure to a simultaneous hazard, such as fire, flood, nuclear incident, hurricane, etc. Either of the two examples cited by the inquirer may or may not fulfill the requirement. The inquirer should make this decision based on his investigation of the siting conditions.

File: QA 85-004

Subject: ANSI/ASME NQA-1-1979 and Subsequent Editions and Addenda Through ANSI/ ASME NQA-lc-1985: Basic Requirement 6 and Supplement 6S-1, Document Control

Date Issued: February 27, 1986

Question: Does ANSI/ASME NQA-1, Basic Requirement 6 and Supplement 6S-l, control documents other than those which prescribe activities affecting quality, such as instructions, procedures, and drawings?

Reply: No. There is a basic problem regarding the application of the term document. There is a tendency among many to view Basic Requirement 6 as requiring the application of the same types of controls to pieces of paper or other media on which results are recorded (such as test reports and weld histories) as are applied to documents which provide instructions for performing work (such as instructions, procedures, and drawings). The only documents requiring controls in Basic Requirement 6

and Supplement 6S-1 are those that specify quality requirements or prescribe activities affecting quality, such as:

Safety Analysis Reports (SAR)
Licensing Requirements (Technical Specifications)
Instructions, e.g., manufacturing, QA/QC Manuals, and others
Procedures
Drawings
Specifications

The second component of this problem is a tendency to confuse the requirements for document control with the more rigorous requirements specified for Quality Assurance Records in Supplement 17S-1.

Other types of documents are required to be controlled only as specified in other sections of NQA-1; the controls of Basic Requirement 6 and Supplement 6S-1 do not apply. Documents in this category are those that report, certify, or provide results of activities affecting quality, such as-

Weld Histories
Inspection Reports
Process Control Data (required by codes and standards)
Test and Examination Results
Data Sheets
Personnel Qualifications and Certifications (required by codes and standards)

File: QA 85-007

Subject: ANSI/ASME NQA-1-1983 Edition: Supplement 17S-1, Quality Assurance Records

Date Issued: October 16, 1985

Question(l)Is there a recommended frequency such as monthly, quarterly, etc., that copies of completed records are to be forwarded to the dual storage facility?

Reply(l)It is the intent of ANSI/ASME NQA-1, Supplement l7S-l, to require timely submittal of a record. No specific frequency is required by the Standard. However, internal procedures shall designate the time period for records to be submitted to the storage facility.

Question (2): Do records forwarded to the dual storage facility have to be maintained to the same level of control as in the primary storage facility? That is, do they have to be indexed, access controlled, and equally retrievable?

Reply (2): Yes.

File: QA 85-009

Subject: ANSI N45.2-1971, ANSI N45.2.11-1974, and ANSI/ASME NQA-1-1979 and later Editions and Addenda Through the 1986 Edition: Supplement 3S-1, Para. 4, Verification, Checking, and Design Review

Date Issued: September 30, 1986

Question (1): Is checking recognized as one of the acceptable methods for verifying the adequacy of design output documents in ANSI N45.2.11 or ANSI/ASME NQA-1?

Reply (1): The purpose served by checking varies widely depending on how the process is defined in procedures by the design organization. If the checking process complies with all the design verification

requirements of ANSI/ASME NQA-1, Supplement 3S-1, para. 4 or ANSI N45.2.11, para. 6, the process qualifies as design verification.

Question (2): Would you define the differences between verification, checking, and design review as used in ANSI N45.2, para. 4.3 or ANSI N45.2.11?

Reply (2): As used in ANSI N45.2, para. 4.3, "verification" and "checking" are intended to be synonymous terms which represent the same requirement. As indicated, this requirement may be met by the performance of such activities as design reviews, alternate or simplified calculations, and/or performance of a suitable testing program. As used in ANSI N45.2.11, "design review" is a design verification effort performed by a competent individual or individuals, other than those who performed the original design, to provide assurance that the final design is correct and satisfactory. The following are addressed, as applicable.

(a) Were the design inputs correctly selected?

(b) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?

(c) Was an appropriate design method used?

(d) Were the design inputs correctly incorporated into the design?

(e) Is the output reasonable compared to the inputs?

(f) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents?

Question (3): Does the normal "design checking" processes used in the architech/engineer (A/E) world serve as a self-sufficient means of design verification?

Reply (3): If the activity termed the "normal checking process" accomplished the above [the second paragraph of Reply (2)], it qualifies as a design review; and, therefore, it is an adequate means for design verification. To the extent that the process does not accomplish the above [the second paragraph of Reply (2)], it must either be supplemented by appropriate actions so that the aggregate process does accomplish the above, or the design verification must be accomplished by other appropriate means, such as alternate or simplified calculations and/or performance of a suitable testing program.

File: QA 85-010

Subject: ANSI/ASME NQA-1-1979: Supplement 3S-1, Para. 3.1, Design Analyses

Date Issued: October 16, 1985

Question (1): Is it a requirement of ANSI/ASME NQA-1, Supplement 3S-1, that design analyses be documented in the exact sequence as outlined in paras. 3.1(a) through (f)?

Reply (1): No.

Question (2): Must each of the referenced articles in Supplement 3S-1, paras. 3.1(a) through (f), be precisely identified by using headings such as (1) "Objectives," (2) "Design Inputs," (3) "Assumptions," etc., in the design analyses documentation?

Reply (2): No.

Question (3): Can the engineer who prepares the design document describe the assumptions he used throughout the different portions of the design document without using the heading "Assumptions," provided anyone who is qualified to review the document can easily identify what assumptions have been utilized?

Reply (3): Yes.

Question (4): In accordance with Supplement 3S-1, para. 3.1, when documenting a design analysis where no assumptions have been made, does this have to be stated in the design document?

Reply (4): No.

File: QA 85-012

Subject: ANSI/ASME NQA-1-1983 Edition, Basic Requirement 2

Date Issued: November 21,1985

Question (1): What is the intent of ANSI/ASME NQA-1, Basic Requirement 2, which states, "Management of those Organizations implementing the Quality Assurance 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?"

Reply(l):The intent of this requirement is to regularly assess the adequacy and effectiveness of the Quality Assurance Program.

Question (2): To what level of line organization management does it extend?

Reply (2): It extends to the level of management consistent with the scope of the assessment and should be specified in your procedures.

Question (3): What is required of management to attest that this assessment has been accomplished?

Reply (3): Management is required to provide documentary evidence that the assessment took place and that resulting action items were documented.

File: QA 85-013

Subject: ANSI N45.2.9-1974 and ANSI/ASME N45.2.9-1979, Para. 2.2; ANSI/ASME NQA-1 1979 and Subsequent Editions and Addenda Through ANSI/ASME NQA-lb-1984, Supplement 17S-1, Para. 2.3: Quality Assurance Records - Microfilmed Copies

Date Issued: October 16, 1985

Question (l)-. Does ANSI (ANSI/ASME) N45.2.9 allow the retention of microfilmed copies of records or are the originals of the records required to be maintained?

Reply (1): Records may be originals or reproduced copies, e.g., microfilm.

Question (2)- Does ANSI/ASME NQA-1, Supplement 17S-1, allow the retention of microfilmed copies of records or are the originals of the records required to be maintained?

Reply (2): Records may be originals or reproduced copies, e.g., microfilm.

File: QA 85-014

Subject: ANSI/ASME N45.2-1977, Section 15, and ANSI/ASME NQA-1-1983 Edition With the la-1983 and lb-1984 Addenda: Basic Requirement 14, Inspection, Test, and Operating Status

Date Issued: November 21, 1985

Question: Is a supplier who is committed to meet ANSI/ASME N45.2, Section 15, required to control quality assurance stamps which identify the approver by signature and title?

Reply: Yes. ANSI/ASME N45.2, Section 15, states, measures shall include procedures for control of status indicators, including the authority for application and removal of tags, markings, labels, and stamps."

If you are using ANSI/ASME NQA-1, Basic Requirement 14 states, "The authority for application and removal of tags, markings, labels, and stamps shall be specified."

File: QA 85-015

Subject: ANSI/ASME NQA-1-1983 Edition: Supplement 4S-1, Para. 2.7, Spare and Replacement Parts

Date Issued: March 10, 1986

Question: When spare or replacement parts are ordered, does ANSI/ASME NQA-1 require that spare or replacement parts be subject to specifications and codes equivalent to those specified for the original equipment or those specified by a properly reviewed and approved revision? In those cases when the requirements of the original item cannot be determined, does ANSI/ ASME NQA-1 require that an engineering evaluation be conducted by qualified individuals to establish the requirements and controls?

Reply: It is the intent of ANSI/ASME NQA-1 that spare or replacement parts be subject either to specifications and codes equivalent to those specified for the original equipment or to those specified by properly reviewed and approved revisions to the original specifications and codes. In those cases where the requirements for the original item cannot be determined, it is the intent of ANSI/ASME NQA-1 that appropriate requirements be established by the responsible design organization. ANSI/ASME NQA-1 specifies this process as follows.

Supplement 4S-1 addresses procurement of spare and replacement parts in para. 2.7, technical requirements in para. 2.2, and quality assurance program requirements in para. 2.3. Supplement 3S-1 augments Supplement 4S-1 by addressing the design process in Section 3, design verification in para. 4.1, and change control in Section 5. Requirements for commercial grade items are included in Section 3 of Supplement 3S-1 and Section 10 of Supplement 7S-1.

File: QA 85-016

Subject: ANSI/ASME NQA-1-1983 Edition: Basic Requirement 2, Quality Assurance Program

Date Issued: February 27, 1986

Question: In ANSI/ASME NQA-1, Basic Requirement 2, does the phrase "Management of those organizations implementing the quality assurance program . . ." mean outside the "original" company (i.e., contractors, subcontractors) or does it pertain to internal functions?

Reply: The phrase applies to both "internal" and "outside" functions. As stated elsewhere in Basic Requirement 2, "The program shall provide control over activities consistent with their importance."

File: QA 85-017

Subject: ANSI/ASME NQA-1-1983 Edition With All Addenda (la-1983, lb-1984, lc-1985): Supplement 17S-1, Para. 2.3 and Para. 4.1, Quality Assurance Records

Date Issued: February 27,1986

Question: In accordance with ANSI/ASME NQA-1, Supplement 17S-1, what are the requirements for a quality assurance record for the interval that exists from the time a quality assurance record is considered valid (para. 2.3) until the quality assurance record reaches storage (para. 4.1)?

Reply: ANSI/ASME NQA-1, Supplement 17S-1, para. 3.2(d) states, in essence, that the system of receipt control shall include a method for submittal of completed records to the storage facility without unnecessary delay. Procedures should specify a time frame for unnecessary delay and include what delays are appropriate, exercising reasonable prudence, for submitting records to the storage facility, or removing records for further processing at the particular locations.

File: QA 8@18
Subject: ANSI/ASME NQA-1-1983 Edition: Supplement 2S-3, Para. 2.1, Qualification of Auditors
Date Issued: February 27, 1986

Question (1): ANSI/ASME NQA-1-1983 Edition, Supplement 2S-3, para. 2.1, states, "Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits." Does this excerpt mean that audit personnel must have actual experience or training commensurate with (i.e., equal in measure to) the scope, complexity, or special nature of the activity to be audited?

Reply (1): Yes. This provision applies to any audit team member depending on the special nature of the specific audit as defined in the Audit Plan. The Lead Auditor (Supplement 2S-3, para. 5.1) is responsible for assuring the collective competence of the audit team to perform the audit, which includes his competence as well as the competence of those selected as team members. An example of this nature would be reexamination of selected design calculations which have been accepted. The individual performing the technical audit of the design calculation must have actual experience or training in that technical function. An individual auditing adherence to the programmatic requirements related to design control would not need training or experience in making design calculations.

Question (2): Must documentation exist describing said experience or training?

Reply (2): Yes.

File: QA 86-002

Subject: ANSI/ASME NQA-1-1983 Edition: Basic Requirement 2, Implementation of the Quality Assurance Program

Date Issued: July 15, 1986

Question: ANSI/ASME NQA-1 states, "Management of those organizations implementing the quality assurance 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." Does this require formal internal self-audits, with objective evidence of accomplishment, or are variations which meet the assessment objective adequate?

Reply: Formal internal self-audits or multiple department self-assessments are not the only methods of satisfying this requirement. Assessment may be performed by management using any resources and information at its disposal including, for example, results from meetings and verification activities.

The methods used to meet the requirement for management of those organizations implementing the quality assurance program, or portions thereof, to regularly assess the adequacy of that part of the program for which they are responsible and to assure its effective implementation must be formalized, i.e., documented, and objective evidence of accomplishing the requirements is necessary.

File: QA 86-003

Subject: ANSI/ASME N45.2.6-1979, Para. 3.5. and ANSI/ASME NQA-1-1983 Edition With All Addenda (la-1983, lb-1984, lc-1985): Appendix 2A-1, Section 3, Qualifications of Inspection and Test Personnel - Experience

Date Issued: February 27, 1986

Question (1): ANSI/ASME N45.2.6, paras. 3.5.1, 3.5.2, and 3.5.3, state recommended education and experience for each level of qualification. How exact should the recommended time interval for the experience be interpreted? Should we take into account the number of hours worked per week for 26 weeks, if they took a vacation day, or if they worked on activities other than inspection, examination, and testing?

Reply (1): The type of precision delineated in this question was not the intent of the framers of this guidance. The user of the Standard must establish, as an element of his qualification program, the specific or generic experience to quality.

Question (2): ANSI/ASME NQA-1, Appendix 2A-1, paras. 3.1, 3.2, and 3.3, provide guidance on the education and experience for each level of qualification. How exact should the recommended time interval for the experience be interpreted? Should we take into account the number of hours worked per week for 26 weeks, if they took a vacation day, or if they worked on activities other than inspection, examination, and testing?

Reply (2): The type of precision delineated in this question was not the intent of the framers of this guidance. The user of the Standard must establish, as an element of his qualification program, the specific or generic experience to quality.

File: QA 86-004

Subject: ANSI/ASME NQA-1-1983 Edition With the la-1983 and lb-1984 Addenda: Supplement 2S-2, Para, 2.1, Qualification of Nondestructive Examination Personnel

Date Issued: February 26, 1986

Question: Do the requirements of ANSI/ASME NQA-1-1983 Edition with the la-1983 and lb 1984 Addenda, Supplement 2S-2, para. 2.1, that SNT-TC-lA, June l980 Edition, and its applicable supplements, apply as requirements to NDE personnel covered by Supplement 2S-2, make the provisions of SNT-TC-1A (1980 Edition) mandatory rather than guidance; i.e., "shall" is inserted in place of the permissive "should" throughout SNT-TC-lA-1980?

Reply: Yes.

File: QA 86-006

Subject: ANSI/ASME N45.2.12-1977, Para. 5.2, ANSI N45.2.9-1974, Appendix A, ANSI/ASME NQA-1-1983 Edition With All Addenda (la-1983, lb-1984, lc-1985): Audit Records

Date Issued: July 15, 1986

Question: Is it the intent of ANSI/ASME N45.2.12, para. 5.2, to require that all the items listed as audit records be controlled as quality assurance records under ANSI N45.2.9, even though only the audit report is listed in ANSI N45.2.9, Appendix A?

Reply: Yes. The intent of ANSI/ASME N45.2.12 is to require that those records listed in para. 5.2 be controlled as quality assurance records under ANSI N45.2.9. Appendix A of ANSI N45.2.9 is meant to be a typical listing of records only and is not necessarily all inclusive of quality assurance records required to be maintained. It should be noted that this is commensurate with ANSI/ASME NQA-1, Supplement 18S-1, Section 8 and Supplement l7S-1, para. 2.7.2, which require that audit plans, audit reports, written replies, and the record of completion of corrective action be maintained as nonpermanent quality assurance records.

File: QA 86-007

Subject: ANSI N45.2.9-1974, Para. 5.5 and ANSI/ASME NQA-1-1983 Edition With All Addenda (la-1983, lb-1984, lc-1985), and Supplement 17S-1, Section 4: Location and Safekeeping of Quality Assurance Records

Date Issued: July 15,1986

Question (1): Does ANSI N45.2.9, para. 5.5, require that an "alarmed detection system" be present in record storage facilities?

Reply (1): No. Procedures should specify what is necessary to preclude the entry of unauthorized personnel and guard against larceny and vandalism.

Question (2): Does ANSI N45.2.9, para. 5.2, require that the record storage facility be within the fenced-in and patrolled "protected area" of the nuclear power plant?

Reply (2): No. Procedures should specify what is necessary to preclude the entry of unauthorized personnel and guard against larceny and vandalism. Should you be using ANSI/ASME NQA-1, please refer to Supplement 17S-1, Section 4.

File: QA 86-008

Subject: ANSI N45.2.9-1974 and ANSI/ASME NQA-1-1983 Edition With All Addenda (la 1983, lb-1984, lc-1985): Supplements S-1 and 17S-1, Quality Assurance Records

Date Issued: July 15, 1986

Question: Are communications such as correspondence, interoffice memoranda, formalized telephone notes, telexes, or formalized conference/meeting minutes classified as quality assurance records under the requirements of ANSI N45.2.9?

Reply: Yes, if this form of documentation (communications) is the only record which furnishes documentary evidence of the quality of items and of activities affecting quality, then communications in the form of correspondence, interoffice memoranda, formalized telephone notes, telexes, or formalized conference notes/meeting minutes shall be classified as quality assurance records in accordance with

ANSI N45.2.9. Should you be using ANSI/ASME NQA-1, please refer to Supplement S-1, definition of Quality Assurance Record.

File: QA 86-009

Subject: ANSI/ASME N45.2.23-1978, Para. 2.3.5 and Para. 4.2, and ANSI/ASME NQA-1-1983 Edition With All Addenda (la-1983, lb-1984, lc-1985): Supplement 2S-3, Qualification Examination for a Lead Auditor

Date Issued: September 8, 1986

Question (1): When certifying a Lead Auditor in accordance with ANSI/ASME N45.2.23, is it permissible to obtain a letter (objective evidence) from the previous employer which states that the individual passed an examination in accordance with para. 2.3.5? The letter would state the type(s) and contents of the examination(s). This would be used in lieu of giving an additional examination or obtaining a copy of the actual examination given to the individual.

Reply (1): Yes, a letter from a previous employer or any other independent certifying agency is acceptable objective evidence that the individual passed an examination which evaluated his comprehension of and ability to apply the required knowledge. Note, however, that it is the employer's responsibility to assure that the examination adequately assesses the body of knowledge identified in para. 2.3.3.

Question (2): Is the practical test requirement of ANSI/ASME N4S.2.23, para. 2.3.5 satisfactorily met by having the individual perform during on-the-job training as the acting audit team leader? The actual audit team leader then evaluates the individual's performance and informs management whether or not the individual has adequate knowledge to perform as an audit team leader.

Reply (2): Yes, on-the-job training as the acting team leader that is evaluated by another team leader is an acceptable form of a practical test if the qualified team leader is an active participant in the audit.
If you are using ANSI/ASME NQA-1, see Supplement 2S-3, paras. 3.2, 3.4, and 5.2.

File: QA 86-012

Subject: ANSI/ASME N45.2-1977, ANSI N45.2.11-1974, and ANSI/ASME NQA-1-1979 and later Editions and Addenda Through the 1986 Edition: Supplement 3S-1, Para.
3.1 and Section 4, Design Verification

Date issued: July 15, 1986

Question (1): What is the intent of ANSI/ASME NQA-1, Supplement 3S-1, para. 3.1 and Section 4, regarding review, approval, and verification of design analyses and calculations?

Reply (1): ANSI/ASME NQA-1, Supplement 3S-1, para. 3.1, requires the documentation of design analyses and calculations, including their review and approval. Section 4 requires that the design be independently verified by design review, qualification testing, alternate calculations, or other methods to confirm the adequacy of the design. It is the responsibility of the design organization to define the requirements for review and approval of individual design analyses and calculation, and the relationship of these reviews in the design process to required design verifications. If the review and approval of individual design analyses and calculations satisfy the requirements of Section 4, an additional verification of those design analyses and calculations is not required. It is the intent of ANSI/ASME NQA-1 that the technical adequacy of design analyses and calculations be verified. This verification can be accomplished on an individual basis or as a part of a broader design verification activity.

Question (2): What is the intent of ANSI/ASME NQA-1, Supplement 3S-1, paras. 3.1 and 4.2.2, regarding the review and approval of alternate calculations performed for design verification purposes?

Reply (2):ANSI/ASME NQA-1 does not require an additional review and approval of alternate calculations performed for design verification purposes.

Question (3): Does ANSI/ASME NQA-1 or its predecessor standards require that each design analysis and calculation be reviewed for accuracy?

Reply (3): Neither ANSI/ASME NQA-1 nor its predecessors, ANSI/ ASME N45.2 or ANSI N45.2.11, explicitly requires (or required) that each design analysis and calculation be reviewed for accuracy. However, it is the intent of ANSI/ASME NQA-1 and its predecessors that the technical adequacy of design analyses and calculations be verified. This verification can be accomplished on an individual basis or as part of a broader design verification activity. As stated above, it is the responsibility of the design organization to define the requirements for review and approval of individual design analyses and calculations, and the relationship of these reviews to required design verifications.

File: QA87-004

Subject: ANSI/ASME NQA-1-1986 Edition, and later Addenda through 1c-1998, Supplement 2S-2; Nondestructive Examination Personnel – SNT-TC-1A

Date Issued: November 21, 1989

Question: If an individual has been certified as a Level III to SNT-TC-1A-1975 Edition and has maintained that certification, does the Level III individual have to be retested to SNT-TC-1A-1980 to comply with ANSI/ASME NQA-1-1986?

Reply: No, if evidence of continuing satisfactory performance is available. Re-examination or continued satisfactory performance are both stated as acceptable methods of recertification in SNT-TC-1A-1975 and 1980.

File: QA 88-002

Subject: ANSI/ASME N45.2.6-1978, Para. 3; ANSI/ASME NQA-1-1986 Edition With the la 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 1, Level 11, or Level III of a different discipline?

Reply: Yes. A Level III of one discipline may certify Level 111, Level 11, 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.

File: QA 88-003

Subject: ANSI/ASME NQA-1-1986 Edition With the la-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: QA 88-004

Subject: ANSI N45.2.11-1974, Sections 2 and 7; ANSI/ASME NQA-1-1986 Edition With the la-1986 and lb-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.

File: QA 88-007

Subject: ANSI/ASME NQA-1-1986 Edition, Basic Requirement 1; Supplement 1S-1, Para. 2.1; Supplement 2S-2; and Supplement 10 S-1, Para. 2.1: Inspection Personnel Independence

Date Issued: October 26, 1988

Question (1): In accordance with ANSI/ASME NQA-l, is it acceptable for a welder to pre-clean a weld and apply liquid penetrant and developer for subsequent interpretation by a certified nondestructive examination (NDE) Level 11 liquid penetrant examiner?

Reply (1) No. Pre-cleaning 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 l0 S-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.

File: QA88-009

Subject: ANSI/ASME NQA-1-1986 Edition, 17S-1, Para. 2.7; Classification of Records – Surveillance Report

Date Issued: May 19, 1989

Question: In accordance with ANSI/ASME NQA-1, 17S-1, para. 2.7 are Surveillance Reports documenting surveillance activities at a supplier's facility considered lifetime records?

Reply: If the Surveillance Reports do not contain data meeting the criteria of ANSI/ASME NQA-1, 17S-1, para. 2.7.1, the reports do not have to be maintained as lifetime records.

File: QA89-002

Subject: ANSI/ASME N45.2.6-1978 and ANSI/ASME NQA-1-1986 Edition with Addenda through 1c-1998, 2S-1; Qualification of Inspection and Test Personnel - Applicability

Date Issued: November 21, 1989

Question (1): Does ANSI/ASME N45.2.6 and ANSI/ASME NQA-1 require certification for all personnel performing tests to verify conformance?

Reply (1): Yes, unless application of the standards are otherwise modified by regulatory commitments.

Question (2): Does ANSI/ASME N45.2.6 and ANSI/ASME NQA-1 apply to all personnel performing tests, regardless of departmental origin (i.e., I&C, Operations, etc.)?

Reply (2): Yes, unless application of the standards are otherwise modified by regulatory commitments.

Question (3): Does certification to ANSI/ASME N45.2.6 or ANSI/ASME NQA-1 supercede certifications by other agencies/societies (i.e, ASNT, etc.)?

Reply (3): No.

File: QA89-003

Subject: ANSI/ASME NQA-1-1986 Edition, and later Addenda through 1c-1988, S-1; 4S-1, Para. 2; 7S-1, Paras. 3.1 and 10; Commercial Grade Services – Subtier Suppliers

Date Issued: November 21, 1989

Question (1): Does ANSI/ASME NQA-1, 7S-1 require that suppliers of commercial grade calibration services for safety-related measuring and testing equipment be evaluated in accordance with para. 3.1?

Reply (1): ANSI/ASME NQA-1 defines commercial grade items in Supplement S-1 and addresses purchasing commercial grade items in Supplement 7S-1, para. 10 but commercial grade services are not defined.

However, ANSI/ASME NQA-1 does include requirements for the control of purchased services as defined by ANSI/ASME NQA-1, Supplement S-1, including supplier selection, bid evaluation, supplier performance evaluation, acceptance of services, and verification of conformance. Se Supplement 7S-1 for specific requirements.

Question (2): Do the requirements of ANSI/ASME NQA-1, 7S-1, para. 3.1 for evaluation of suppliers of services apply through succeeding levels of subtier suppliers?

Reply (2): Yes, procurement documents issued at all tiers of procurement shall include provisions deemed necessary by the purchaser at each tier. See ANSI/ASME NQA-1, 4S-1, para. 2.

File: QA89-006

Subject: ANSI/ASME NQA-1-1986 Edition, and later Addenda through 1c-1988, S-1, 4S-1, and 7S-1; Commercial Grade items

Date Issued: November 21, 1989

Question (1): In accordance with ANSI/ASME NQA-1, if we meet the requirements of 7S-1, para. 10, is this an acceptable alternate to all the other requirements of 4S-1 and 7S-1?
Reply (1): Yes.

Question (2): In accordance with ANSI/ASME NQA-1, 7S-1, para. 10, is it permissible to procure an item as commercial grade when the manufacturer does not have a written quality assurance program?
Reply (2): Yes.

Question (3): In accordance with ANSI/ASME NQA, S-1, if a manufacturer does not assign a catalog number or part number to an item but publishes a product description and it meets all the other criteria of a commercial grade item, can the item be procured as a commercial grade item?
Reply (3): Yes.

File: QA89-007

Subject: ANSI/ASME NQA-1-1986 Edition with Addenda through 1c-1989, Supplements S-1 and 11S-2; Computer Systems - Applicability

Date Issued: November 21, 1989

Question (1): Does ANSI/ASME NQA-1, Supplement 11S-1 apply to computer systems defined in Supplement S-1, Footnote 2?

Reply (1): Yes, when and to the extent specified by the organization invoking this Standard. See Supplement 11S-2, Section 1.

Question (2): Does ANSI/ASME NQA-1, Supplement 11S-2 apply to computer systems when no decisions affecting quality are made?

Reply (2): Yes, if the computer system is used as described in Supplement S-1, Footnote 2.

File: QA89-008

Subject: ANSI/ASME NQA-1-1986 Edition, 17S-1; Quality Assurance Records – Retention of

Date Issued: May 21, 1990

Question: Is it a requirement of ANSI/ASME NQA-1, 17S-1, to place copies of regulatory requirements, codes and standards, American National Standards, and Federal regulations used as design inputs into your records system?

Reply: No if such records can be readily retrieved from a public or other records system.

File: QA89-009

Subject: ANSI/ASME NQA-1-1986 Edition with Addenda through NQA-1c-1988, Supplement 17S-1, Para. 4.4.3; Temporary Storage of Records

Date Issued: December 1, 1989

Question (1): When are the provisions of ANSI/ASME NQA-1, 17S-1, para. 4.4.3 on temporary storage of records to be applied?

Reply (1): The provisions of 17S-1, para. 4.4.3 apply after the completion of the receipt control process of 17S-1, para. 3.2 and prior to submittal to the storage facility. In addition, records removed from the storage facility for processing, review or use, and are stored in a facility which does not meet 17S-1, para. 4.4.1, 4.4.2, or 4.4.4 must meet the requirements of para. 4.4.3.

Question (2): Do the requirements of ANSI/ASME NQA-1, 17S-1, para. 4.4.3 apply to all records for an incomplete project?

Reply (2): Yes, the requirements apply to records completed in accordance with 17S-1, para. 2.3.

Question (3): In accordance with ANSI/ASME NQA-1, 17S-1, para. 4.4.3 are duplicate copies of records in a different location also required to be placed in a 1 hr fire rated cabinet?

Reply (3): No, if you meet the requirements of ANSI/ASME NQA-1, 17S-1, para. 4.4.4, “Dual Facilities.”

File: QA89-010

Subject: ANSI/ASME NQA-1-1986 Edition with the 1b-1987 Addenda, Supplement 2S-3; Qualification Requirements for Technical Specialists

Date Issued: December 1, 1989

Question (1): Does ANSI/ASME NQA-1, 2S-3 provide amplified requirements for the qualification of technical specialists, management representatives, and auditors-in-training as indicated in para. 1?

Reply (1): Yes, ANSI/ASME NQA-1, 2S-3, para. 2.1 requires that the auditing organization establish the qualification of audit personnel. Paragraph 1 establishes that audit personnel (i.e., participants in an audit) are referred to as Auditors and include technical specialists, management representatives, and auditors-in-training.

Question (2): Does ANSI/ASME NQA-1, 2S-3 allow technical specialists to serve as advisors to duly qualified Auditors/Lead Auditors during the course of an audit?

Reply (2): ANSI/ASME NQA-1 does not address the use of advisors.

Question (3): Does ANSI/ASME NQA-1, 2S-3 allow technical specialists to serve as independent Auditors on their own?

Reply (3): Yes, ANSI/ASME NQA-1, 2S-3 does not permit technical specialists to serve as independent Auditors on their own. To do an independent audit the technical specialists would have to be qualified as a Lead Auditor. All audits are performed under the direction and supervision of a Lead Auditor. Members of the audit team can work separately provided they work under the direction of the Lead Auditor.

Question (4): Does ANSI/ASME NQA-1, 2S-3 address the qualification requirements for technical specialists?

Reply (4): Yes, ANSI/ASME NQA-1, 2S-3, para. 2.1 states that the responsible auditing organization shall establish the requirements for use of technical specifialists.

File: QA 89-011

Subject: ANSI/ASME NQA-1-1986 Edition, 6S-1, Para. 2; Document Control - Requirements

Date Issued: May 21, 1990

Question (1): Does ANSI/ASME NQA-1, 6S-1, para. 2(c) require documents, (e.g., work packages, engineering change orders/field change requires for design changes) which have been prepared but not yet issued for field work to be reviewed and approved prior to their issuance for field work?

Reply (1): Yes, ANSI/ASME NQA-1, 6S-1, para. 2(c) states that the control system shall provide for "review of documents for adequacy, completeness, and correctness prior to approval and issuance."

Question (2): Can the review and approver of documents addressed in ANSI/ASME NQA-1, 6S-1, para. 2(c), be the same person, or must a different individual from the reviewer approve documents?

Reply (2): Neither Basic Requirement 6 nor 6S-1 address whether the review and approver can be the same person. The user's procedures should define the review and approval requirements which must be consistent with the other sections of ANSI/ASME NQA-1 which address particular types of documents.

Question (3): Does ANSI/ASME NQA-1, 6S-1, para. 2(c) require that work documents (such as work packages, engineering change orders/field change requests) on which the field work is complete, but the documents are not yet signed as approved by the responsible individual, be reviewed and approved before they become records?

Reply (3): ANSI/ASME NQA-1, 6S-1 para. 2(c) does not require approval of completed documents after the work is complete. However, 17S-1, para. 2.2, states that documents shall be completed appropriate to the work accomplished before the documents became records. Additional requirements for record validation are found in 17S-1, para. 2.3, which states that "Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated."

File: QA89-012

Subject: ANSI/ASME NQA-1-1986 Edition, 17S-1, Para. 3.2; Records – Inspection of

Date Issued: May 21, 1990

Question (1): Does ANSI/ASME NQA-1, 17S-1, para. 3.2(c), require procedures for inspection of incoming records to assure that they are legible, identifiable, and retrievable?

Reply (1): Yes, ANSI/ASME NQA-1, 17S-1, para. 3.2(c) requires procedures for inspection to assure that incoming records meet the requirements of Basic Requirement 17 as well as the requirements of 17S-1, such as those defined in para. 2.2.

File: QA90-001

Subject: ANSI/ASME NQA-1-1986 Edition, Basic Requirement 2; Implementation of the Quality Assurance Program

Date Issued: November 15, 1990

Question (1): ANSI/ASME NQA-1, Basic Requirement 2, states, “Management for those organizations implementing the quality assurance 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,” Does this require that the assessment be conducted by personnel above or outside (independent) of the quality assurance organization?

Reply (1): No. For information, see interpretation QA86-002.

Question (2): In accordance with ANSI/ASME NQA-1, Basic Requirement 2, may the quality assurance organization assess that part of the quality assurance program for which they are responsible?

Reply (2): Yes. For further information see interpretation QA86-002.

File: QA90-002

Subject: ASME NQA-1-1989 Edition, 17S-1, Para. 4.4.4; Records Storage – Dual Facility

Date Issued: May 21, 1990

Question: In accordance with ASME NQA-1, 17S-1, para. 4.4.4, what is considered to be a “sufficiently remote” location to eliminate the chance of exposure to simultaneous hazard? May the dual facilities be located on the same site?

Reply: If there is a question concerning whether two locations are sufficiently remote, then an evaluation may be performed to determine the acceptability of the sites selected. The two locations may or may not be on the same site, depending on the inquirer’s specific situation and evaluation. Refer to ASME NQA-1, 17S-1, para. 4.4, for typical conditions which shall be considered in such an evaluation.

File: QA90-003

Subject: ASME NQA-1-1989 Edition, 2S-2, Para. 2.1; Nondestructive Examination Personnel – Edition of SNT-TC-1A

Date Issued: June 20, 1990

Question: Is ASME NQA-1989 Edition, Supplement 2S-2 correct with respect to the referenced edition of SNT-TC-1A, June 1980?

Reply: Yes, For your information, the NQA Committee is currently considering a revision to the edition date of SNT-TC-1S referenced in ASME NQA-1.

File: QA90-004

Subject: ANSI/ASME NQA-1-1986 Edition with Addenda through 1c-1988 and later Addenda 1a-1989, 17S-1, Paras. 4.4.3 and 4.4.4; Records Storage – Dual Facility

Date Issued: May 21, 1990

Question: When the alternative requirements of ANSI/ASME NQA-1, 17S-1, para. 4.4.4 are used, is it required to also meet the provisions of para. 4.4.3?

Reply: The intent of ANSI/ASME NQA-1, 17S-1, is not to require para. 4.4.4 to meet the requirements of para. 4.4.3 since para. 4.4.4 addresses permanent record facilities rather than temporary facilities. A change to ASME NQA-1, 17S-1, para. 4.4.4 is under consideration by the Committee to clarify these requirements.

File: QA90-005

Subject: ANSI/ASME NQA-1-1986 Edition, BR-1 and 2S-1; Quality Assurance Manual, Qualification of Inspection and Test Personnel – Applicable Edition

Date Issued: November 15, 19990

Question (1): In accordance with ANSI/ASME NQA, must quality assurance manuals for ANSI/ASME NQA-1 programs make specific reference to ANSI/ASME NQA (with applicable edition)?

Reply (1): No. ANSI/ASME NQA-1, Introduction, para. 2 requires that the application of NQA-1 be specified in written contracts, polices, procedures, or instructions. A specific reference int eh quality assurance manual would be one method of meeting this requirement

Question (2): In accordance with ANSI/ASME NQA-1, must personnel certifications for ANSI/ASME NQA-1 programs specifically state that the subject certification/qualification is in accordance with ANSI/ASME NQA-1 (with applicable edition)?

Reply (2): No. ANSI/ASME NQA-1, 2S-1 does not require that ANSI/ASME NQA-1 be specifically referenced in a personnel certification.

File: QA90-006

Subject: ANSI/ASME N45.2.6-1978 and ASME NQA-1-1998 Edition, 2S-1 and 2A-1; Qualification of Inspection and Test Personnel

Date Issued: November 15, 1990

Question (1): In accordance with ANSI/ASME N45.2.6 and ASME NQA-1, is a Level III required to certify or recertify a Level II or a Level III?

Reply (1): ANSI/ASME N45.2.6 requires that a Level III be capable of qualifying Level II and other Level III personnel. Certification and recertification is performed by an individual designated in the employer's program. ASME NQA-1 recommends the same thing.

Question (2): If in accordance with ANSI/ASME N45.2.6 and ASME NQA-1, a Level III is required to certify a Level III, how does a company certify its fist Level III inspection and test personnel?

Reply (2): ANSI/ASME N45.2.6, section 1.3, and ASME NQA-1, 2S-1, para. 2.1 both require that the responsible organization establish written procedures for the qualification of inspection and test

personnel. This procedure should delineate the parameter used to establish the qualification of the initial Level III in accordance with ANSI/ASME N45.2.6 and/or ASME NQA-1.

Question (3): In accordance with ANSI/ASME N45.2.6 and ASME NQA-1, does an individual lose his certification when changing employers?

Reply (3): Yes.

Question (4): In accordance with ANSI/ASME N45.2.6 and ASME NQA-1, does ASME administer an examination used to determine capability of inspection and test personnel?

Reply (4): No.

File: QA 90-007

Subject: ASME NQA-1 -1 989 Edition, 1 S-1, Para. 2.1, and 1 OS-1, Para. 2.1; Inspection Personnel - Reporting Independence

Date Issued: November 15, 1990

Question: Where the department manager employs the operators, the inspectors, and the supervisors, does ASME NQA-1, 1 S-1, para. 2.1 (b) and 1 OS-1, para. 2.1 intend for the inspection personnel to report to someone other than the department manager?

Reply: No. The inspector may report to the department manager or supervisor, but may not report to a first line supervisor responsible for production.

File: QA 90-008

Subject: ASME NQA-1 -1 989 Edition, Basic Requirements 8 and 1 5, Supplements 7S-1 and 15S-1; Use of Nonconforming Items

Date Issued: November 15, 1990

Question (1): ASME NQA-1, 7S-1, para. 8.1 states in part that "Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use." Does ASME NQA-1 require items not meeting the above requirement due to nonavailability of the required documentary evidence to be processed per the requirements of Basic Requirement 15 and 15S-l?

Reply (1): Yes, provided Basic Requirement 15 and Supplement 15S-1 are invoked.

Question (2): Does ASME NQA-1 allow the use of conditional or any other method of release of indeterminate, unaccepted, or nonconforming items for the purpose of further processing, installation, or use?

Reply (2): Yes, ASME NQA-1, Supplement l5 S-1, para. 4.1 does permit a conditional release system, but in a limited and controlled manner.

File: QA 90-009

Subject: ANSI/ASME NQA-1-1986 Edition, 9S-1; Control of Processes

Date Issued: November 15, 1990

Question: In accordance with ANSI/ASME NQA-1, 9S-1, para. 3, is it a requirement to qualify the personnel, procedures, and equipment associated with a process if the acceptance criteria for the product are all measurable and verifiable according to the applicable code or standard?

File: QA90-010

Subject: ANSI/ASME NQA-1-1986 Edition, 7S-1, Para. 10; Commercial Grade Items - Acceptance Personnel

Date Issued: November 15, 1990

Question: Does receipt of a certificate of conformance (C of C) for a commercial grade item eliminate the need for inspection and/or testing in accordance with ANSI/ASME NQA-1, 7S-1, para. 10(d)?

Reply: No. It is the intent of ANSI/ASME NQA-1, 7S-1, that each of the four conditions of para 10(d) be satisfied.

As regards the third condition of para 10(d), where the Purchaser has determined that inspection and/or testing is necessary to establish the acceptability of a commercial grade item for its intended function, the inspection and/or testing must be performed. If a C of C is required by the Purchaser, it may contribute to satisfying the requirements of 7S-1, para. 10(d), condition four.

File: QA90-012

Subject: ASME NQA-1-1989, Supplement 18S-1; Records – Audit Checklists

Date Issued: September 13, 1991

Question: Does NQA-1 require that the completed checklists for an audit be retained as quality assurance records?

Reply: No, however, it should be noted that the records required for an audit are identified in 18S-1, para. 8 and these records must meet the requirements of 17S-1, para. 2.7.1 or 2.7.2.

File: QA91-001

Subject: ASME NQA-1-1989, Supplement 8S-1; Item Identification and Traceability Requirements

Date Issued: May 17, 1991

Question (1): What is the intent of ASME NQA-1, 8S-1, para. 2.1 regarding the specific methods or extent of identification of an item from initial receipt and fabrication of the items up to and including installation and use?

Reply (1): ASME NQA-1, 8S-1, para. 2.1 does not address the method or extent of identification or an item. Supplement 8S-1, paras. 2.2 and 2.3 provide requirements regarding physical identification and markings.

Question (2): If contracts, codes, or specifications do not specify traceability requirements, does ASME NQA-1, 8S-1 require the traceability of items to their origin (such as manufacturer’s lot, batch, test report, etc.)?

Reply (2): No. ASME NQA-1, 8S-1, para. 2.1 requires that items be identified to their origin only if specified by codes, standards, or specifications.

File: QA91-002

Subject: ASME NQA-1-1989, Supplement 3S-1; Documentation of Design Activities – Personal Computers

Date Issued: May 13, 1991

Question: What is meant by the term “computer type” as used in ASME NQA-1-1989, 3S-1, para. 3.1(b)(5) and what constitutes adequate documentation of “computer type?”

Reply: “Computer type” is meant to include the identification of the computer configuration (hardware and operating system) used to perform the design analysis with documentation of sufficient detail that a technically qualified person)(s) can review, understand and verify the adequacy of the design analysis.

File: QA91-003

Subject: ASME NQA-1-1989, Supplement 2S-3, Para. 4, Lead Auditor – Maintenance of Qualification

Date Issued: May 16, 1991

Question: Can credit be given to a Lead Auditor toward maintenance of proficiency for participation in a nuclear quality assurance program management assessment?

Reply: Yes. Participating in a nuclear quality assurance program management assessment may be utilized in the maintenance of a Lead Auditor Qualification as defined in ASME NQA-1, 2S-3, para. 4.1, if the assessment meets the parameters of the audit process as delineated in 18S-1 of ASME NQA-1.

File: QA91-004

Subject: ASME NQA-1-1989, Supplement 2S-3, Paras. 3 and 4; Qualification of Lead Auditors

Date Issued: May 13, 1991

Question: Can the Lead Auditor qualification maintenance documentation of a previous employer be utilized to meet the audit participation requirements of ASME NQA-1, 2S-3, para. 3.3?

Reply: Yes, if data utilized by the previous employer to maintain the individual’s qualification can be verified as meeting the parameters of the new employer’s Lead Auditor Qualification Program.

File: QA91-005

Subject: ASME NQA-1-1989, Supplement 17S-1, Paras. 2.2 and 2.3; Quality Assurance Records

Date Issued: April 13, 1992

Question (1): When a Quality Assurance document has been authenticated in accordance with ASME NQA-1, A17S-1, para. 2.3, does that act certify the record has been completed appropriate to the work accomplished?

Reply (1): Yes. For further information see interpretation QA82-11.

Question (2): If a pre-printed form is used to record information, and then, after authentication, becomes a QA record, is it required that those areas of the form not used to record information be identified in some fashion to indicate the area has been intentionally left blank?

Reply (2): No, the last sentence of 17S-1, para. 2.2 states that “Documents that are designated to become records shall be legible, accurate, and completed appropriate to the work accomplished.” Administration of this requirement shall be accomplished in accordance with the last sentence of para. 2.1 which states “the records system(s) shall be defined, implemented and enforced in accordance with written procedures, instructions, or other documentation.”

File: QA91-006

Subject: ASME NQA-1-1989, Supplement 17S-1, Para. 2.9; Corrected Information in Records

Date Issued: November 6, 1991

Question: Prior to authentication of a document as a QA record in accordance with ASME NQA-1, 17S-1, para. 2.3, “Record Validation,” is it required that corrections to the document be individually dated and the person making the correction identified?

Reply: No, however, once the document becomes a record, the requirements of 17S-1, para 2.9 apply.

File: QA91-007

Subject: ASME NQA-1-1989, Supplement 11S-1, Para. 2.2; In-Use Tests

Date Issued: November 6, 1991

Question (1): ASME NQA-1, 11S-2, para. 2.2 requires test problems to permit confirmation of acceptable performance of the computer program in the operating system. Is it the intent of this paragraph that the term “operating system” include both the operating system software and hardware?

Reply (1): Yes.

Question (2): ASME NQA-1, 11S-2, para. 2.2 requires that test problems be run whenever the computer program is installed on a different computer, or where significant hardware or operating system configuration changes are made. Is it the intent of the last sentence in this paragraph to additionally require periodic testing of computer programs within the operating system?

Reply (2): Yes, for those applications where computer failure or drift can affect performance. The term “drift” is intended to mean the accumulated effects of degradation of the computer system. “Computer failures” is intended to mean unidentified computer component failures.

File: QA91-008

Subject: ASME NQA-1-1989, Supplement 6S-1, Para. 3; Document Changes

Date Issued: November 6, 1991

Question: Does ASME NQA-1, 6S-1, paras. 3.1 and 3.2 permit the omission of an organization's review and approval of a revision to a document originally reviewed and approved by that organization?

Reply: Yes, provided the conditions for such omission are clearly delineated in accordance with 6S-1, para. 2(b).

File: QA91-009

Subject: ASME NQA-1-1989, Supplement 17S-1, Para. 4.4.3; Quality Assurance Records – Fire Protection

Date Issued: November 6, 1991

Question: Does NQA-1, Supplemental 17S-1, para. 4.4.2 permit a 1 hr fire rated container to be used in a single story trailer as an acceptable Alternative Single Storage Facility, provided that a person who is competent in the technical field of fire protection and fire extinguishing has certified that the single story trailer has less than 25 lb/ft² of combustible material and will burn out completely in less than 1 hr when left unattended?

Reply: No. Supplement 17S-1, para. 4.4.2 requires 2 hr fire protection regardless of the weight per square foot of combustible material or time period of burnout.

File: QA92-001

Subject: ASME NQA-1-1989, Supplement 2S-3, Para. 5.2, Lead Auditor Qualification Examination integrity

Date Issued: April 10, 1992

Question: ASME NQA-1, 2S-3, para. 5.2 states in part: "Integrity of the examination shall be maintained by the employer or the certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations." Is it acceptable for the certifying agency to retain each completed examination in its files (rather than in the employer's files)?

Reply: Yes, it is acceptable for the certifying agency to retain each completed examination.

File: QA92-002

Subject: ASME NQA-1-1989, Supplement 2S-3, Certification of Lead Auditors

Date Issued: April 13, 1992

Question: Can a present employer accept a Lead Auditor Certification from a previous employer as evidence that the requirements of ASME NQA-1, 2S-3 or ANSI N45.2.23 have been accomplished?

Reply: Yes. For further information see interpretations QA86-009 and QA91-004.

File: QA92-003

Subject: SME NQA-2-1989, Part 2.5; Table 5.6, "Required In-process Tests"
ANSI/ASME N45.2.5-1974; Table B, "Required In-Process Tests," Nonshrink Grout

Date Issued: April 10, 1992

Question (1): Do prepackaged shelf item nonshrink grout products fall under the jurisdiction of Table B of N45.2.5?

Reply (1): No. Testing of nonshrink grout does not fall under the jurisdiction of Table B of N45.2.5.

Question (2): If a prepackaged nonshrink grout does not fall under the jurisdiction of Table B of N45.2.5, what testing procedures and frequency is recommended for testing?

Reply (2): The designer is responsible for identifying necessary testing and frequency requirements.

File: QA92-005

Subject: ASME NQA-1-1989, Supplement 17S-1, Para. 3.2(c); Inspection of Records

Date Issued: October 5, 1992

Question (1): Does NQA-1, Supplement 17S-1, para. 3.2(c) mean that incoming records should be inspected in accordance with procedures that assure that they are identifiable in accordance with Supplement 17S-1, para. 2.6 and retrievable in accordance with Supplement 17S-1, Section 5?

Reply (1): Yes. Please refer to Inquiry QA89-012.

Question (2): If incoming records should be inspected in accordance with procedures that assure that they are identifiable in accordance with NQA-1, Supplement 17S-1, para. 2.6, does that mean that incoming records should contain sufficient information to permit them to be identified and indexed in the records system by the specific items and activities to which they apply so that such records can be retrieved in accordance with Supplement 17S-1, para. 5 by those associated items and activities?

Reply (2): Yes, per the requirements of para. 2.6.

File: QA92-008

Subject: ASME NQA-1-1989, Supplement 17S-1, Para. 4.2(c); Special Processed Records

Date Issued: October 5, 1992

Question: Do “special processed records,” referred to in NQA-1, Supplement 17S-1, para. 4.2(c), and “special process records,” as used in the standard, pertain to the same classification of records?

Reply: No. Special process records referred to in Supplement 9S-1 are records that provide documentary evidence of the qualification of personnel performing special processes and the results of the accomplishment of special processes.

The term, “Special Processed Records,” used in Supplement 17S-1, para. 4.2(c) refers to records such as magnetic media which require special preservation controls to assure absence from electromagnetic fields. The NQA Working Group will recommend a revision to clarify the standard.

File: QA 92-01 0

Subject: ASME NQA-1-1989, Supplement 17S-1, Para. 4.2(b); Records Preservation

Date Issued: October 5, 1992

Question: Do records that are stored in binders and on shelves meet the requirements of NQA1, Supplement 1 7S-1, para. 4.2(b)?

Reply: Yes, provided they are stored in containers.

File: QA92-011

Subject: ASME NQA-1-1989, Supplement 17S-1, Dual Storage – Computer Diskettes

Date Issued: October 5, 1992

Question: Does NQA-1, Supplement 17S-1 allow computer diskettes to be used as an acceptable second copy of a quality assurance record when the dual storage option is elected?

Reply: Yes. NQA-1, Supplement 17S-1, para. 4.2(c) does allow the storage of magnetic media as a quality assurance record.

File: QA92-013

Subject: ASME NQA-1-1989, Basic Requirement 15, Supplement 15S-1; Basic Requirement 16, and Appendix 16A-1

Date Issued: April 4, 1995

Question (1): Is it the intent of ASME NQA-1 Basic Requirement 15 to control nonconforming activities?

Reply (1): No. Basic Requirement 15 and Supplement 15S-1 address the control of nonconforming items only.

Question (2): Does NQA-1 Basic Requirement 16 apply to nonconforming items and activities?

Reply (2): Yes, to the extent that the nonconforming item or activity represents a condition adverse to quality.

Question (3): Does NQA-1 allow the use of individual nonconforming items while investigations are being performed to determine if other corrective actions are necessary?

Reply (3): Yes. Use of the individual item may proceed after the requirements of Supplement 15S-1 have been satisfied. Cause evaluation and corrective action as described by Basic Requirement 16 may be conducted separately.

File: QA93-003

Subject: ASME NQA-2a-1990, Part 2.7

Date Issued: August 13, 1993

Question (1): In regard to NQA-2, Part 2.7, is the verification review of Section 7 intended to be a design review beyond that required under Section 4?

Reply (1): No, provided the design verification requirements of NQA-1, Supplement 3S-1 are met.

Question (2): Is the term “ensure” as used in NQA-2, Part 2.7, Section 4, intended to be interpret as “provided adequate confidence,” “provided reasonable assurance,” or “guarantee” software performance?

Reply: The key term “ensure,

File: QA 94-002

Subject: ASME NQA-1-1989, Basic Requirement 18 and Supplement 18S-1

Date Issued: April 4, 1995

Question: In conducting an audit to NQA-1, is it permissible to use members of the line organization being audited as part of the audit team?

Reply: Yes, provided the line organization personnel performing the audit do not have direct responsibility for the activities being audited and meet the requirements of Supplement 25-3.

File QA 94-003

Subject: ASME NQA-lb-1991, Appendix 17A-1, Para. 3.1; Design Records

Date Issued: February 28, 1995

Question: Does the term "Approved design change requests" in Appendix 1 7A-1, para. 3.1, Design Records, mean the request sheet?

Reply: Yes, if the approved design change request sheet contains design input or design output requirements. In such instances, a design change request sheet is a design record in accordance with Basic Requirement 17 and Supplement 17S-1.

File: QA 94-004

Subject: ASME NQA-2-1989, Part 2.2, Para. 6.4.2 (a)

Date Issued: February 24, 1995

Question (1): Must pipe and tubing (without weld preps) that is stored in at least Level B storage as defined in para. 6.1.2, be covered, plugged, capped or sealed?

Reply (1): Yes.

Question (2): Are fittings considered piping per para. 2.2.4(i)? If so, should they be plugged, capped, or sealed?

Reply (2): Yes. Yes,

File: QA94-005

Subject: ASME NQA-1-1989, Supplement lOS-1, Para. 4.2

Date Issued: February 24, 1995

Question (1): Can a preestablished sampling plan as provided for in NQA-1-1989, Supplement l0 S-1, para. 4.2 be used for acceptance inspection activities such as those described NQA-2-1989, Part 2.8, paras. 4.3(a) through 4.3(l)?

Reply (1): Yes.

Question (2): Where a sampling plan per NQA-1-1989, Supplement l0 S-1, para. 4.2 is used to verify acceptability of activities on an item under repair (such as bolt tightening on a safety related component), must the sample population be limited to such operations on the specific item undergoing repair?

Reply (2): No.

Question (3): Referencing NQA-2-1989, Part 2.8, paras. 4.3(a) through 4.3(l), must acceptance inspection activities described in paras. 4.3(a) through 4.3(l) be by independent quality inspection personnel?

Reply (3): The Committee is unable to answer this question as stated. However, NQA-1, Basic Requirement 10 and Supplement 10 S-1 state respectively that those accepting activities must be independent from those performing or supervising the activities. Supplement 1 OS-1 contains the requirements for the qualification of personnel performing acceptance activities.

File: QA 94-006

Subject: ASME NQA-1-1989, Supplement S-1; Terms and Definitions

Date Issued: February 28, 1995

Question: According to the definition of "quality assurance record" of NQA-1-1 989, Supplement S-1, is every revision of a calculation a "completed" document?

Reply: Yes, when it has been approved in accordance with the approved quality assurance program.

File: QA94-007

Subject: ASME NQA-1-1989, Supplement 17S-1, Section 4; Storage, Preservation, and Safe-keeping

Date Issued: February 24, 1995

Question: Do the records storage requirements outlined in Section 4 of Supplement 17S-1, apply to the storage of quality assurance records after submission to the records organization and not to quality assurance records maintained in the office or working environment prior to submission to the records organization?

Reply: Yes. The storage requirements outlined in Section 4 of Supplement 17S-1 apply to the storage of quality assurance records after submission to the records organization. Please refer to Inquiry QA89-009.

File: QA98-001

Subject: ASME NQA-1-1989, Supplement 2S-1, Para. 2.6, Evaluation of Performance

Date Issued: April 22, 1999

Question (1): Does the phrase “performing inspection and testing activities” in NQA-1, Supplement 2S-1, para. 2.6 limit activities to field-performed inspection or testing functions?

Reply (1): No. See Appendix 2A-1, Sections 2.1, 2.2, and 2.3.

Question (2): Can inspection and testing activities include planning inspections and tests, setting up tests including preparation and set-up of related equipment, supervising or maintaining surveillance over the inspections and tests, supervising and evaluating the validity and acceptability of inspection and test of same and lower level personnel?

Reply (2): Yes. Inspection and testing activities is to be defined in the user’s implementing procedures. See Appendix 2A-1, Sections 2.1, 2.2, and 2.3.

Question (3): Does an annual review of an individual’s inspection and testing activities in his qualified areas performed by a designated certifying authority on or before the anniversary date of the original certification date satisfy the requirements of NQA-1, Supplement 2S-1, para. 2.6 in assuring the individual is performing in his qualified areas for a period of 1 year?

Reply (3): The annual evaluation is only to determine if the certified inspection or test personnel have performed inspection or test activities in those areas for which they are qualified. This evaluation should be documented and dated at 1-year intervals from the initial certification date.

File: QA98-010

Subject: ASME NQA-1-1989, Supplement 17S-1, Para. 4.2(b); Records Preservation

Date Issued: October 5, 1992

Question: Do records that are stored in binders and on shelves meet the requirements of NQA-1, Supplement 17S-1, para. 4.2(b)?

Reply: Yes, provided they are stored in containers.

File: QA99-01

Subject: ASME/ANSI N45.2.11-1974

Date Issued: June 22, 1999

Question (1): Are inputs to design analysis that are developed by one or more individuals required to be documented by ASME/ANSI N45.2.11-1974?

Reply (1): Yes.

Question (2): Are the originators of design inputs and design analysis required to be identified and documented in accordance with ASNE/ANSI N45.2.11-1974?

Reply (2): Yes.

File: QA99-02

Subject: ASME NQA-1-1994, Supplement 3S-1 and Supplement 15S-1

Date Issued: July 6, 1999

Question: In accordance with NQA-1-1994, do nonconformances to design requirements dispositioned as “Use-As-is” or “Repair” require the application of design control measures commensurate with the original design?

Reply: Yes. Refer to NQA-1-1994, Supplement 3S-1, para. 5, and Supplement 15S-1, para. 4.4. In addition, refer to NQA-1-1997, Requirement 15, para. 404.

File: QA99-03

Subject: ASME NQA-1-1997, Subpart 2.15, para. 403.1

Date Issued: July 5, 2001

Question (1): Does the vertical impact requirement of para. 403.1(a)(5), apply to the scenario of the cable breaking and the load falling and hitting a stop?

Reply (1): No. The impact load requirement of this section applies to the structural design for normal operation, and not for an accident condition as caused by a cable breaking.

Question (2): Does the minimum 10% vertical impact load requirement of para. 403.1(a)(5), if applied to a test load of 100 lb, require the impact load to be 110 lb, or 10 lb?

Reply (2): Neither. As stated in this section, the minimum vertical impact load is applied only to the maximum load to be handled, excluding test loads. If the maximum load handled, excluding test load, was 100 lb, then the minimum vertical impact load to be considered would be 10% of the 100 lb, which is 10 lb.

File: QA00-001

Subject: N45.2.11-1974, Para. 5.2.4 – Transmitting Design Information

Date Issued: April 6, 2001

Question (1): Does para. 5.2 of ANSI N45.2.11-1974 apply to information exchanged within the subdivisions of disciplines of a design organization?

Reply (1): Yes. Organization units that report to different supervisors or managers should have interfaces identified as prescribed by para. 5.2.1 to control the flow of design information.

Question (2): Do the documentation requirements of ANSI N45.2.11-1974 include:
(a) identification by name of those who provide design inputs to a design analysis?
(b) if so, is a signature of the provider required?

Reply (2): No. The method of identifying individuals that provide, verify, or approve design inputs shall be documented in the design organization’s procedures. A signature or initial, however, is an acceptable method of authentication.

File: QA01-003

Subject: ASME NQA-1-1989 Edition; 1S-1, Para. 2.1; and 10S-1, Para. 2.1; Inspection Personnel – Reporting Independence

Date Issued: June 19, 2001

Question (1): How is production defined?

Reply (1): Production is not defined, but means the activity the supervisor is responsible for achieving.

Question (2): Does production apply to the first line supervisor in the store's warehouse?

Reply (2): Yes.

Question (3): What are the limits of production "influence boundaries" so the "reporting independence" is clear?

Reply (3): The reporting levels of inspectors should be at a sufficient level to ensure that any influence from "production" will have no undue effect on the inspectors' decisions related to quality or acceptability. The reporting levels should be established by management who have overall responsibility for the effectiveness of the QA program.

Question (4): May a Quality Control Inspector report to a First Line Supervisor responsible for the "Stores Warehouse" who also supervises store personnel?

Reply (4): No, not if the Quality Control Inspector is inspecting production work of their first line supervisor.

File: QA01-005

Subject: ASME NQA-1-1997, Programmable Logic Control Systems

Date Issued: November 2, 2001

Question (1): Is ASME NQA-1-1997, Subpart 2.7 applicable to the computer-programmed portion of a programmable logic control system?

Reply (1): Yes. See Subpart 2.7, para. 100, General, for applicability.

Question (2): Is ASME NQA-1-1997, Part I, Requirement 3, Design Control, applicable to the computer-programmed portion of a programmable logic control system?

Reply (2): Yes. See Requirement 3, para. 800, Software Design Control.

Question (3): Is ASME NQA-1-1997, Part I, Requirement 11, Test Control, applicable to the computer-programmed portion of a programmable logic control system?

Reply (3): Yes.

Interpretation: QA01-006

Subject: ASME NQA-1–1994, Part I — Terms and Definitions

Date Issued: December 4, 2001

Question: May textual and/or pictorial documents be on other than paper media, such as magnetic media?

Reply: Yes. The definition of *document* in the ASME NQA-1–1994 edition has been revised in the ASME NQA-1–2000 edition to eliminate the term *any written or pictorial information*, and provides more descriptive details to electronic records.

Interpretation: QA02-001

Subject: NQA-1–2000; Requirement 2, Para. 303.3 — Audit Participation

Date Issued: August 13, 2002

Question: Can an activity that meets all aspects of the definition of an “audit” but are identified or described using a different term be used to meet the requirements of NQA-1-2000, Requirement 2, para. 303.3?

Reply: Yes, provided the activity is consistent with the definition of audit, contained in NQA-1-2000, and meets the applicable requirements (or provisions) of Requirement 18.

Interpretation: QA02-003

Subject: NQA-1–1994; Subpart 2.2, Para. 3.7.2

Date Issued: November 20, 2003

Question: Does para. 3.7.2 require equipment in excess of 500 lb to be crated and skid-mounted?

Reply: No. Crates and/or skids, as appropriate, are acceptable.

Interpretation: QA04-001

Subject: NQA-1–1989; Supplement 3S-1, Section 5, Change Control

Date Issued: April 26, 2005

Question: Does Section 5 allow for the design organization to issue changes to the design without obtaining the review and approval of all of the original groups?

Reply: Yes. Section 5 requires that “Changes shall be approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the Owner or his designee shall designate a new responsible organization which could be the Owner’s engineering organization.”

Interpretation: QA04-003

Subject: NQA-1–1989; Application of Basic Requirement 10 to Special Processes

Date Issued: April 26, 2005

Question: For Requirement 9, was it the intent of the ASME Committee to apply Basic Requirement 10, Inspection, to NDE Special Processes to ensure their independence?

Reply: No. The organizational structure and responsibility assignment to achieve and verify quality is identified in NQA-1–1989 Basic Requirement 1, Organization and Section 2.1, Supplement 1S-1, Supplementary Requirements for Organization.

Interpretation: QA05-001

Subject: NQA-1–1989; Supplement 12S-1, Para. 3.2, Control

Date Issued: April 6, 2005

Question (1): Does the term “out-of-calibration” refer solely to equipment found to be outside the acceptable accuracy range?

Reply (1): No. The term “out-of-calibration” not only refers to measuring and test equipment (M&TE) found to be outside the established accuracy range, but also to M&TE for which the established calibration interval has expired.

Question (2): The requirements state that out-of-calibration devices shall be tagged or segregated. Does the expired due date listed on the calibration sticker meet the out-of-calibration tagging requirements?

Reply (2): No. A standard calibration status does not satisfy the requirement that out-of calibration M&TE be tagged or segregated, or both.

Question (3): The guidelines state that out-of-calibration devices may not be used until they have been calibrated. May equipment that has exceeded its calibration due date interval be used for informational purposes only (not supporting qualification testing or qualified processes) without being recalibrated?

Reply (3): NQA-1–1989 applies to quality related items and activities. This question falls outside the scope of this Standard.

Interpretation: QA05-002

Subject: NQA-1–2004; Part I, Introduction, Para. 400, Terms and Definitions

Date Issued: April 6, 2005

Question: In some cases reexamination and/or retest of *reworked* items may need to be performed at a different location, and by different procedures, instrumentation, personnel and/or organizations. Is this permissible as long as the item meets the original acceptance criteria?

Reply: Yes. The use of different inspection/test personnel working at a different locality is permissible, provided

(a) the personnel performing the reexamination meet the specified qualification requirements

(b) the reworked items meet the original acceptance criteria

(c) acceptance is determined using the original test or inspection procedures, unless alternate procedures have been technically evaluated and approved by authorized personnel

Interpretation: QA06-001

Subject: NQA-1–1994; Basic Requirement 17 and Supplement 17S-1 As Described in Sections 2.7 and 2.7.1

Date Issued: December 20, 2006

Question (1): Does a Purchase Order (PO) issued, but not yet accepted by the supplier, meet the criteria as a lifetime record in accordance with Section 2.7.1 of Supplement 17S-1 of NQA-1–1994?

Reply (1): No, since the terms and conditions of the PO have not been accepted by the supplier, nothing exists to furnish evidence of the quality of items and/or activities affecting quality. According to the definition of *QA Record* — "a completed document that furnishes evidence of the quality of items and/or activities affecting quality" (ref. NQA-1–1994, Introduction, Section 4) — the PO is not complete and does not become a record. Also, Section 1, "General," of Supplement 17S-1, NQA-1–1994 states, "The requirements of this Supplement apply to quality assurance records which have been completed." Since the PO has not been completed, Section 2.7.1 of NQA-1–1994, Supplement 17S-1 is not applicable to this PO.

Question (2): Does an issued PO that has been accepted by the supplier, but the item or service has not been received or processed, meet the criteria as a Quality Record in accordance with Section 2.7.1 of Supplement 17S-1 of NQA-1–1994?

Reply (2): Yes, since the terms and conditions of the PO have been accepted by the supplier, the document furnishes evidence of the quality of items and/or activities affecting quality. This meets the definition of a Quality Record. The classification of the record in accordance with Section 2.7 of NQA-1–1994, Supplement 17S-1 will determine if the record is a Lifetime or Nonpermanent Record.

Question (3): Are supplier documents required by the PO that have been received by the purchaser and verified as meeting the PO requirements classified in accordance with Section 2.7 of Supplement 17S-1 of NQA-1–1994?

Reply (3): Yes, the documents provided by the supplier are to be classified against the criteria of Section 2.7, once they satisfy the authentication requirements for completion.

Question (4): Is it acceptable to place a PO in temporary storage, per Section 4.4.3 of Supplement 17S-1 of NQA-1–1994, until such time as the item or service has been received by the purchaser and verified against requirements of the PO?

Reply (4): Yes, it is acceptable, provided the procedure(s) address temporary storage of records, including the maximum time permitted in temporary storage.

Interpretation: QA07-001

Subject: NQA-1-2004, Subpart 2.15, Paragraph 601.4, Re-rated Equipment

File#: Record #07-1830

Date Issued: November 21, 2008

Question (1): Does the term "special lifts" refer to any lift in excess of the hoisting equipments current rated capacity?

Reply (1): Yes. The term special lifts in NQA-1-2004 refer to lifts exceeding the rated capacity.

Question (2): Do the requirements of paragraph 601.4 apply any time facility hoisting equipment is re-rated to new rated capacity in excess of its current rated capacity?

Reply (2): Yes. The guidelines set forth in paragraph 601.4 refer specifically to re-rated hoisting equipment.

Interpretation: QA08-003

Subject: NQA-1-1994; Subpart 2.8, Paragraph 4.3(j)

File#: Record #08-965

Date Issued: October 23, 2008

Question: Is it a requirement of Subpart 2.8 Paragraph 4.3 (j) that every installation and repair weld be inspected for materials, process controls, and when the weld procedure requires purging, adequate purging and removal of purge dams on completion?

Reply: No. Inspections shall be performed in accordance with governing technical requirements

Interpretation: QA07-001

Subject: NQA-1–1994, Subpart 2.8, Para. 4.3(j)

Date Issued: October 23, 2008

Question: Is it a requirement of Subpart 2.8, para. 4.3(j), that every installation and repair weld be inspected for materials, process controls, and when the weld procedure requires purging, adequate purging and removal of purge dams on completion?

Reply: No. Inspections shall be performed in accordance with governing technical requirements.

Interpretation: QA08-001

Subject: NQA-1–2004, Subpart 2.15, Para. 601.4, Rerated Equipment

Date Issued: November 21, 2008

Question (1): Does the term "special lifts" refer to any lift in excess of the hoisting equipment's current rated capacity?

Reply (1): Yes. The term "special lifts" in NQA-1–2004 refers to lifts exceeding the rated capacity.

Question (2): Do the requirements of para. 601.4 apply anytime facility hoisting equipment is rerated to new rated capacity in excess of its current rated capacity?

Reply (2): Yes. The guidelines set forth in para. 601.4 refer specifically to rerated hoisting equipment.

ASME NQA-1 Interpretations

Replies to Technical Inquiries as of 2009

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 ASME NQA-1, Quality Assurance Requirements for Nuclear Facility
Applications.

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. vi of ASME NQA-1).

File #: **08-578**

Subject: **Supplementary Requirements for Design Control**

Applicability: ASME NQA-1-1994, 3S-1

Date Issued: October 8, 2009

Question: Is it necessary to retain actual computer input and output files or file images associated with the use of controlled computer software as part of the Design Analysis Quality Assurance record in order to meet the documentation requirements of ASME NQA-1-1994, Supplement 3S-1, Section 3.1, (b5)?

Reply: Yes, ASME NQA-1-1994, supplement 3S-1, Section 3.2 (b-5) states that "Documentation of design analysis shall include identification of any computer

calculation, including computer type, computer program, revision identification, inputs, outputs…"

It is further understood that the use of file scans of computer program input and output files is an acceptable approach provided the electronic record meets the NQA-1 requirements for authentication and maintenance of quality records.

File #: **08-587**

Subject: **Part III – Appendix 2A-1**

Applicability: ASME NQA-1-1994

Date Issued: October 13, 2009

Question: When following the guidance of the 1994 Edition of NQA-1, do the capabilities of Level I Inspection Personnel as discussed paragraph 2.1, "performing and documenting inspection and test results" include the acceptance or acceptability of an item as identified in Supplement 10S-1, paragraph 7.3?

Reply: No. Appendix 2A-1, paragraph 2.2 identifies under the Level II capabilities a provision where the Level II must have demonstrated capabilities to evaluate the validity and acceptability of inspection and test results. The provision is that a qualified Level II would evaluate the validity and acceptability of the inspection and test results documented by a Level I Inspector.

File #: **08-1419**

Subject: **Requirement 15 - Control of Nonconforming Items, Paragraph 300(b)**

Applicability: ASME NQA-1-2000

Date Issued: November 5, 2009

Question (1): Can an electronic process be used as a method of controlling the movement (further processing) of nonconforming items?

Reply (1): Yes. Electronic processes can be used to control the further processing, delivery, installation, or use of nonconforming items.

Question (2): Is an evaluation of extent of condition of the nonconformance required by Requirement 15?

Reply (2): No. However, Requirement 16 applies to all conditions adverse to quality. See Nonmandatory Appendix 16A-1 Para. 301 for further guidance on extent of condition.

File #: **08-1420**

Subject: **Design Control**

Date Issued: October 8, 2009

Applicability: ASME NQA-1-2000

Question: If the software is on a LAN system, is the server manufactures make, model, serial number information sufficient? If you are using a LAN, do you need both - Server and Desk Computer information (make, model, serial number etc.)?

Reply: Determine what level of detail of documentation is required to be compliant to the standard. These requirements were added to the standard many years ago. Computer use and technology has advanced - has the standard kept up with these changes? We use LAN's in today's engineering world. We did not exclusively use that type of technology when these requirements were added to the standard.

File #: **08-1730**

Subject: **Supplement 3S-1, Para. 4, Design Verification.**

Date Issued: November 5, 2009

Applicability: ASME NQA-1 1994

Question: For Supplement 3S-1, Para. , if an individual is involved in the review and approval of the design analysis per section 3.1(b)(6), can that person also be the design reviewer per section 4?

Reply: Yes, as per Inquiry File # 86-012 response.

File #: **08-1772**

Subject: **Part 2, Subpart 2.2, Section 200**

Date Issued: October 8, 2009

Applicability: ASME NQA-1-2000

Question: Can a valve be stored in other than Level C storage as specified in NQA-1, 2000 Edition, Part 2, Subpart 2.2, Paragraph 202.3?

Reply: Yes. Valves are to be stored as Level C unless a classification evaluation justifying otherwise has been performed, and documented, by the buyer or the contractor in accordance with Paragraph 202 of the Standard. Additionally, the manufacturer's documented standard or minimum requirements shall be considered when classifying the items.

File #: **09-596**

Subject: **Requirement 3, Section 500, Design Verification**

Date Issued: November 5, 2009

Applicability: ASME NQA-1-2008

Question: For Requirement 3, Section 500, where it says, “The results of design verification shall be documented”, is a signature by the verifier sufficient documentation?

Reply: Yes; the use of a “signature” only of the verifier on the design document is sufficient when the verification is done in accordance with the verification procedures that comply with the NQA-1 requirements.

Interpretation: QA06-001

Subject: NQA-1–1994; Basic Requirement 17 and Supplement 17S-1 As Described in Sections 2.7 and 2.7.1

Date Issued: December 20, 2006

Question (1): Does a Purchase Order (PO) issued, but not yet accepted by the supplier, meet the criteria as a lifetime record in accordance with Section 2.7.1 of Supplement 17S-1 of NQA-1–1994?

Reply (1): No, since the terms and conditions of the PO have not been accepted by the supplier, nothing exists to furnish evidence of the quality of items and/or activities affecting quality. According to the definition of *QA Record* — "a completed document that furnishes evidence of the quality of items and/or activities affecting quality" (ref. NQA-1–1994, Introduction, Section 4) — the PO is not complete and does not become a record. Also, Section 1, "General," of Supplement 17S-1, NQA-1–1994 states, "The requirements of this Supplement apply to quality assurance records which have been completed." Since the PO has not been completed, Section 2.7.1 of NQA-1–1994, Supplement 17S-1 is not applicable to this PO.

Question (2): Does an issued PO that has been accepted by the supplier, but the item or service has not been received or processed, meet the criteria as a Quality Record in accordance with Section 2.7.1 of Supplement 17S-1 of NQA-1–1994?

Reply (2): Yes, since the terms and conditions of the PO have been accepted by the supplier, the document furnishes evidence of the quality of items and/or activities affecting quality. This meets the definition of a Quality Record. The classification of the record in accordance with Section 2.7 of NQA-1–1994, Supplement 17S-1 will determine if the record is a Lifetime or Nonpermanent Record.

Question (3): Are supplier documents required by the PO that have been received by the purchaser and verified as meeting the PO requirements classified in accordance with Section 2.7 of Supplement 17S-1 of NQA-1–1994?

Reply (3): Yes, the documents provided by the supplier are to be classified against the criteria of Section 2.7, once they satisfy the authentication requirements for completion.

Question (4): Is it acceptable to place a PO in temporary storage, per Section 4.4.3 of Supplement 17S-1 of NQA-1–1994, until such time as the item or service has been received by the purchaser and verified against requirements of the PO?

Reply (4): Yes, it is acceptable, provided the procedure(s) address temporary storage of records, including the maximum time permitted in temporary storage.

Interpretation: QA07-001

Subject: NQA-1–1994, Subpart 2.8, Para. 4.3(j)

Date Issued: October 23, 2008

Question: Is it a requirement of Subpart 2.8, para. 4.3(j), that every installation and repair weld be inspected for materials, process controls, and when the weld procedure requires purging, adequate purging and removal of purge dams on completion?

Reply: No. Inspections shall be performed in accordance with governing technical requirements.

Interpretation: QA08-001

Subject: NQA-1–2004, Subpart 2.15, Para. 601.4, Rerated Equipment

Date Issued: November 21, 2008

Question (1): Does the term "special lifts" refer to any lift in excess of the hoisting equipment's current rated capacity?

Reply (1): Yes. The term "special lifts" in NQA-1–2004 refers to lifts exceeding the rated capacity.

Question (2): Do the requirements of para. 601.4 apply anytime facility hoisting equipment is rerated to new rated capacity in excess of its current rated capacity?

Reply (2): Yes. The guidelines set forth in para. 601.4 refer specifically to rerated hoisting equipment.

Interpretation: QA08-002

Subject: NQA-1–1994, 3S-1, Supplementary Requirements for Design Control

Date Issued: October 8, 2009

File: 08-578

Question: Is it necessary to retain actual computer input and output files or file images associated with the use of controlled computer software as part of the Design Analysis Quality Assurance record in order to meet the documentation requirements of NQA-1–1994, Supplement 3S-1, Section 3.1(b5)?

Reply: Yes. NQA-1–1994, Supplement 3S-1, Section 3.2(b-5) states that "Documentation of design analysis shall include identification of any computer calculation, including computer type, computer program, revision identification, inputs, outputs..." It is further understood that the use of file scans of computer program input and output files is an acceptable approach provided the electronic record meets the NQA-1 requirements for authentication and maintenance of quality records.

Interpretation: QA08-003

Subject: NQA-1–2000, Design Control

Date Issued: October 8, 2009

File: 08-1420

Question: Does the level of detail for computer type in Requirement 3, para. 402(e) need to include the manufacturer name, serial number, model number, and server and desk computer information?

Reply: No. However, the level of detail to describe the computer type shall provide enough information to verify the adequacy of the results without recourse to the originator as required by Requirement 3, Section 400.

Interpretation: QA08-004

Subject: NQA-1–2000, Part II, Subpart 2.2, Section 200

Date Issued: October 8, 2009

File: 08-1772

Question: Can a valve be stored in other than Level C storage as specified in the NQA-1–2000 Edition, Part 2, Subpart 2.2, para. 202.3?

Reply: Yes. Valves are to be stored as Level C unless a classification evaluation justifying otherwise has been performed, and documented, by the buyer or the contractor in accordance with para. 202 of the Standard. Additionally, the manufacturer's documented standard or minimum requirements shall be considered when classifying the items.

Interpretation: QA08-005

Subject: NQA-1–1994, Part III, Appendix 2A-1

Date Issued: October 13, 2009

File: 08-587

Question: When following the guidance of the NQA-1–1994 Edition, do the capabilities of Level I Inspection Personnel as discussed in para. 2.1, "performing and documenting inspection and test results," include the acceptance or acceptability of an item as identified in Supplement 10S-1, para. 7.3?

Reply: No. Appendix 2A-1, para. 2.2 identifies under the Level II capabilities a provision where the Level II must have demonstrated capabilities to evaluate the validity and acceptability of inspection and test results. The provision is that a qualified Level II would evaluate the validity and acceptability of the inspection and test results documented by a Level I Inspector.

Interpretation: QA08-006

Subject: NQA-1–2000, Requirement 15, Control of Nonconforming Items, Para. 300(b)

Date Issued: November 5, 2009

File: 08-1419

Question (1): Can an electronic process be used as a method of controlling the movement (further processing) of nonconforming items?

Reply (1): Yes. Electronic processes can be used to control the further processing, delivery, installation, or use of nonconforming items.

Question (2): Is an evaluation of extent of condition of the nonconformance required by Requirement 15?

Reply (2): No. However, Requirement 16 applies to all conditions adverse to quality. See Nonmandatory Appendix 16A-1, para. 301 for further guidance on extent of condition.

Interpretation: QA08-007

Subject: NQA-1–1994, Supplement 3S-1, Para. 4, Design Verification

Date Issued: November 5, 2009

File: 08-1730

Question: For Supplement 3S-1, para. 4, if an individual is involved in the review and approval of the design analysis per Section 3.1(b)(6), can that person also be the design reviewer per Section 4?

Reply: Yes, as per the response to Interpretation QA86-012.

Interpretation: QA08-008

Subject: NQA-1–2008, Requirement 3, Section 500, Design Verification

Date Issued: November 5, 2009

File: 09-596

Question: For Requirement 3, Section 500, where it says, "The results of design verification shall be documented," is a signature by the verifier sufficient documentation?

Reply: Yes. The use of a "signature" only of the verifier on the design document is sufficient when the verification is done in accordance with the verification procedures that comply with the NQA-1 requirements.

Interpretation: QA08-009

Subject: NQA-1–2000 Edition With the NQA-1a–2002 Addenda, Requirement 2, Section 301, SNT-TC-1A Qualification Requirements

Date Issued: October 12, 2010

File: 09-1617

Question (1): Do the SNT-TC-1A qualification requirements of NQA-1–2000, Requirement 2, Section 301, Nondestructive Examination apply to all inspections or tests to be performed?

Reply (1): No. Section 301 applies only to the qualifications of personnel performing the listed nondestructive examination methods.

Question (2): Do the SNT-TC-1A qualification requirements of NQA-1–2000, Requirement 2, Section 301, Nondestructive Examination only apply when specified codes, customer order requirements, or the responsible organization mandates it?

Reply (2): Yes.

Question (3): Is it the responsibility of the organization that commits to the requirements of NQA-1–2000, Requirement 2 to establish and document criteria for the capabilities of personnel performing the inspection and tests?

Reply (3): Yes. NQA-1–2000, Sections 300, Qualification Requirements, and 302, Inspection and Test, provide requirements on the qualification of inspection and test personnel. Part III, Nonmandatory Appendix 2A-1provides guidance on the Qualification of Inspection and Test Personnel.

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[1] Subparts 2.1, 2.2, 2.5, 2.7, 2.8, 2.15 were formerly Parts 2.1, 2.2, 2.5, 2.7, 2.8, and 2.15, respectively, in NQA-2.

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