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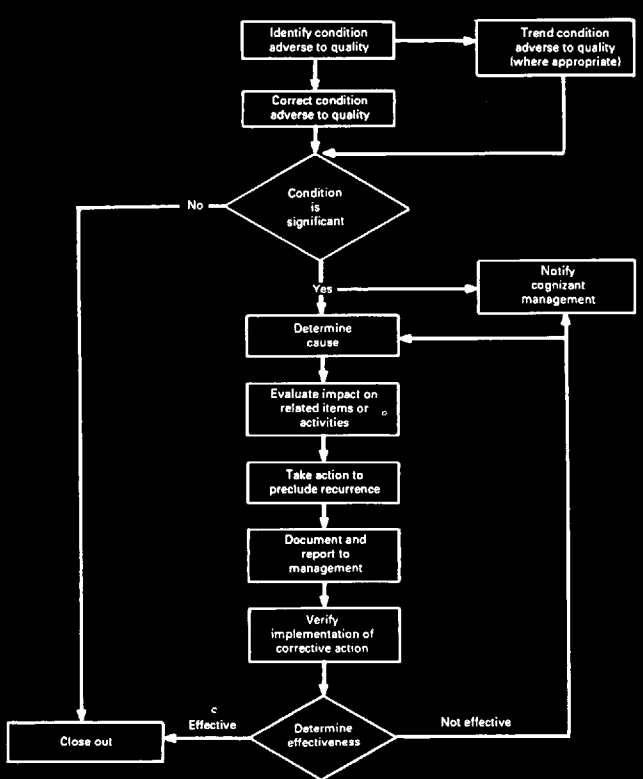
ASME NQA
TECHNICAL REPORT 1993

Comparison of ASME NQA-1 and ISO 9001



AN ASME TECHNICAL REPORT

The American Society of Mechanical Engineers

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Comparison of ASME NQA-1 and ISO 9001

The American Society of Mechanical Engineers

345 East 47th Street, New York, N.Y. 10017

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FOREWORD

(This Foreword is not part of the Task Group Report.)

The attached report takes each NQA-1 Basic Requirement and indicates the comparable paragraphs of ISO 9001. A summary of the requirments of each is provided. The Task Group has added a narrative comparison of the requirements of each and a conclusion noting if an NQA-1 program would meet the ISO 9001 requirement and vice versa.

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Task Group for NQA-1/ISO 9001 Comparison

(The following is the roster of the Task Group at the time of the preparation of this report.)

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Basic Requirement 1
Supplement 1S-1
Organization

Requires that a quality organization be established with a responsible level of management identified.

4.1.2.1 Responsibility and Authority
4.1.2.3 Management Representative

Requires that a quality organization be established with a responsible level of management identified.

COMPARISON

NQA-1 and ISO 9001 have equivalent requirements.

CONCLUSION

A quality program that meets the requirements of either standard would meet the requirements of both standards.

Basic Requirement 2
Quality Assurance Program

Requires that a quality program be developed, documented, and implemented.

4.2 Quality System

Requires that a quality program be developed, documented, and implemented.

COMPARISON

NQA-1 and ISO 9001 have equivalent requirements.

CONCLUSION

A quality program that meets the requirements of either standard would meet the requirements of both standards.

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Supplement 2S-1 through 2S-4
Personnel Indoctrination and Training

Requires that personnel be indoctrinated, trained, and evaluated. The indoctrination, training, and evaluation must be documented. Specific requirements are provided for indoctrination and training of audit and NDE personnel.

4.1.2.2 Verification Resources and Personnel
4.18 Training

Requires that all personnel receive training in accordance with written procedures.

COMPARISON

NQA-1 contains more specific requirements for the indoctrination, training, and evaluation of personnel.

CONCLUSION

A quality program that meets the requirements of NQA-1 will meet the requirements of ISO 9001. Conversely, a quality program that meets the requirements of ISO 9001 may not meet the requirements of NQA-1.

Basic Requirement 3
Supplement 3S-1
Design Control

Requires that the design process be defined, controlled, and documented. All designs must be verified and all changes reviewed and approved.

4.4 Design Control

Requires that the design process be defined, controlled, and documented. All designs must be verified and all changes reviewed and approved.

COMPARISON

NQA-1 contains more specific requirements for the identification of individuals and groups responsible for design activities (*i.e.,* review, approval, and verification). Also, NQA-1 requires more detailed design procedures. ISO 9001 does not address computer software.

CONCLUSION

A quality program that meets the requirements of NQA-1 will meet the requirements of ISO 9001. Conversely, a quality program that meets the requirements of ISO 9001 may not meet the requirements of NQA-1.

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Basic Requirement 4
Supplement 4S-1
Procurement Document Control

Requires that procurement documents be prepared, reviewed, and approved. Provides for specific items to be included in the procurement documents.

Requires that changes to procurement documents be reviewed and approved.

4.6.2 Assessment of Subcontractors
4.6.3 Purchasing Data
4.6.4 Verification of Purchased Product

Requires that procurement documents be prepared, reviewed, and approved. Provides for specific items to be included in the procurement documents.

COMPARISON

ISO 9001 does not provided for the control of changes to procurement documents. Also, the procurement documents are not required to include items addressing noncomformances or spare and replacement parts.

CONCLUSION

A quality program that meets the requirements of NQA-1 will meet the requirements of ISO 9001. Conversely, a quality program that meets the requirements of ISO 9001 may not meet the requirements of NQA-1.

Basic Requirement 5
Instructions, Procedures, and Drawings

Requires that activities be performed in accordance with documented procedures, instructions, or drawings. These documents must include or reference acceptance criteria of the activity.

4.2(b) Quality System
4.4.4(b) Design Output

Requires that activities be performed in accordance with documented procedures, instructions, or drawings. These documents must include or reference acceptance criteria for the activity.

COMPARISON

NQA-1 and ISO 9001 have equivalent requirements.

CONCLUSION

A quality program that meets the requirements of either standard would meet the requirements of both standards.

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Basic Requirement 6
Supplement 6S-1
Document Control

Requires that documents specifying quality requirements be identified, reviewed, approved, and controlled.

4.5 Document Control

Requires that documents specifying quality requirements be identified, reviewed, approved, and controlled.

COMPARISON

NQA-1 and ISO 9001 have equivalent requirements except that NQA-1 allows minor revisions to be made without the same review and approval required for the original document or major revisions. ISO 9001 requires a master list, or equivalent, be established to identify current revision of the documents and it recommends identification of the nature of the changes to the documents.

CONCLUSION

A quality program that meets the requirements of ISO 9001 will meet the requirements of NQA-1. Conversely, a quality program that meets the requirements of NQA-1 may not meet the requirements of ISO 9001.

Basic Requirement 7
Supplement 7S-1
Control of Purchased Items and Services

Requires that the purchase of items and services is controlled. Provides for source evaluation, evaluation of objective evidence, source inspection, audit, and examination.

4.6.1 General
4.6.2 Assessment of Subcontractors
4.6.4 Verification of Purchased Product
4.7 Purchaser Supplied Product

Requires that the purchase of items and services is controlled. Provides for source evaluation, evaluation of objective evidence, source inspection, and examination.

COMPARISON

NQA-1 contains additional requirements for external audits, control of nonconformances, procurment planning, and commercial grade items. Commercial grade items are not applicable to ISO 9001. NQA-1 provides specific requirements for the control of purchased items and services.

CONCLUSION

A quality program that meets the requirements of NQA-1 will meet the requirements of ISO 9001. Conversely, a quality program that meets the requirements of ISO 9001 may not meet the requirements of NQA-1.

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Basic Requirement 8
Supplement 8S-1
Identification and Control of Items

Requires that items be identified and controlled to prevent the use of nonconforming items.

4.10 Inspection and Testing
4.8 Product Identification and Traceability

Requires that items be identified and controlled to prevent the use of nonconforming items.

COMPARISON

NQA-1 contains additional requirements for the control of limited life items. The other requirements for identification and control of items are equivalent.

CONCLUSION

A quality program that meets the requirements of NQA-1 will meet the requirements of ISO 9001. Conversely, a quality program that meets the requirements of ISO 9001 may not meet the requirements of NQA-1.

Basic Requirement 9
Supplement 9S-1
Control of Processes

Requires that all processes affecting be controlled. Special processes must be performed in accordance with written procedures by qualified individuals using qualified equipment.

4.9 Process Control

Requires that all processes affecting be controlled. Special processes must be performed in accordance with written procedures by qualified individuals using qualified equipment.

COMPARISON

NQA-1 and ISO 9001 have equivalent requirements.

CONCLUSION

A quality program that meets the requirements of either standard would meet the requirements of both standards.

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Basic Requirement 10
Supplement 10S-1
Inspection

Requires that inspections performed to verify conformance of items to specified criteria be controlled. Items may not be used until after any required inspection has been successfully accomplished.

4.10 Inspection and Testing

Requires that inspections performed to verify conformance of items to specified criteria be controlled. Items may not be used until after any required inspection has been successfully accomplished.

COMPARISON

NQA-1 contains additional requirements for the qualification of inspection personnel. NQA-1 contains more specific requirements for records.

CONCLUSION

A quality program that meets the requirements of NQA-1 will meet the requirements of ISO 9001. Conversely, a quality program that meets the requirements of ISO 9001 may not meet the requirements of NQA-1.

Basic Requirement 11
Supplement 11S-1 and 11S-2
Test Control

Requires that tests performed to verify conformance of items to specified criteria be controlled. Items may not be used until after any required test has been successfully accomplished.

4.10 Inspection and Testing

Requires that tests performed to verify conformance of items to specified criteria be controlled. Items may not be used until after any required test has been successfully accomplished.

COMPARISON

NQA-1 contains additional requirements for the evaluation of test results by personnal that have specific authority. NQA-1 contains more specific requirements for records.

CONCLUSION

A quality program that meets the requirements of NQA-1 will meet the requirements of ISO 9001. Conversely, a quality program that meets the requirements of ISO 9001 may not meet the requirements of NQA-1.

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Basic Requirement 12
Supplement 12S-1
Control of Measuring and Test Equipment

Requires that measuring and test equipment be controlled and calibrated.

4.11 Inspection, Measuring and Test Equipment

Requires that measuring and test equipment be identified, controlled, and calibrated. Also, the measurements to be taken must be identified and documented.

COMPARISON

ISO 9001 contains a more comprehensive and detailed definition of the requirements for the control of inspection, measuring and test equipment. It also includes specific provisions for checking the capability of test hardware (such as jigs, fixtures, templates, patterns) and test software. While the intent of NQA-1 is the same, it does not contain similar explicit requirements.

CONCLUSION

A quality program that meets the requirements of ISO 9001 will meet the requirements of NQA-1 (Basic Requirement 12 and Supplement 12S-1). Conversely, a quality program that meets the requirements of NQA-1 may not meet the requirements of ISO 9001.

Basic Requirement 13
Supplement 13S-1
Handling, Storage, and Shipping

Requires that product be controlled to prevent damage, loss, or deterioration.

4.15 Handling, Storage, Packaging and Delivery

Requires that product be controlled to prevent damage, loss, or deterioration. Also, requires specific assessment of the effectiveness of the control procedures used.

COMPARISON

ISO 9001 requirements are more programmatic in nature, NQA-1 requirements more specific. ISO 9001 includes a requirement for detecting deterioration of product(s) through periodic assessment of the condition of products in storage.

CONCLUSION

A program meeting NQA-1 may not completely meet the requirements of ISO 9001. Similarly, a program meeting ISO 9001 may not completely meet the requirements of NQA-1.

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Basic Requirement 14
Inspection, Test, and Operating Status

Requires that items be identified as to their conformance to specified requirements to prevent the use of nonconforming items. Also, the authority to identify the status of the items must be documented.

4.12 Inspection and Test Status

Requires that items be identified as to their conformance to specified requirements to prevent the use of nonconforming items. Also, the authority to identify the status of the items must be documented.

COMPARISON

NQA-1 and ISO 9001 have equivalent requirements.

CONCLUSION

A quality program that meets the requirements of either standard would meet the requirements of both standards. One exception is that ISO 9001 specifically addresses test software while NQA-1 does not provide specific requirements.

Basic Requirement 15
Supplement 15S-1
Control of Nonconforming Items
and Supplement 7S-1, Section 9
Control of Supplier Nonconformances

Requires that nonconforming items be identified and controlled until final disposition.

4.13 Control of Nonconforming Product

Requires that nonconforming items be identified and controlled until final disposition.

COMPARISON

NQA-1 and ISO 9001 have equivalent requirements. However, NQA-1, Supplement 15S-1 contains more detailed requirements concerning identification, segregation, and dispositioning of nonconforming items.

CONCLUSION

A quality program that meets the requirements of NQA-1 will meet the requirements of ISO 9001. Conversely, a quality program that meets the requirements of ISO 9001 may not meet the requirements of NQA-1.

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Basic Requirement 16
Corrective Action

Requires that conditions adverse to quality be identified and corrected. For significant conditions adverse to quality, corrective actions must be documented and reported to management, and the cause of the condition must be determined and corrected.

4.14 Corrective Action

Requires that all systems, records, and procedures be analyzed to detect and eliminate potential causes of nonconforming product. Nonconformances must be identified and corrected, and the cause must be identified, documented, and corrected.

COMPARISON

Both standards take a programmatic approach to the identification and elimination of conditions that lead to nonconformance. ISO 9001 is more comprehensive in the identification of sources of information that are to be used for detection and elimination of causes of nonconforming product. NQA-1 is more specific in requirements for reporting to management, and for corrective action to be applied to any condition adverse to quality of services, operations, etc., as well as product.

CONCLUSION

The programmatic and reporting requirements of the two standards are somewhat different. A quality program that meets the requirements of one of the standards may not meet the requirements of the other standard.

Basic Requirement 17
Supplement 17S-1
Quality Assurance Records

Requires that a documented system be implemented to generate, validate, store, retrieve, and dispose of records.

4.16 Quality Records

Requires that records be identified, stored, maintained, and disposed of in accordance with written procedures.

COMPARISON

NQA-1 contains more specific requirements for storage facilities and for indexing, distribution, identification, classification, and storage of records. NQA-1 provides requirements for generation, validation, and receipt of records not included in ISO 9001.

CONCLUSION

A quality program that meets the requirements of NQA-1 will meet the requirements of ISO 9001. Conversely, a quality program that meets the requirements of ISO 9001 may not meet the requirements of NQA-1.

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Basic Requirement 18
Supplement 18S-1
Audits

Requires that a system of planned and documented internal and external audits be conducted.

4.1.2.2 Verification Resources and Personnel
4.17 Internal Quality Audits
4.18 Training

Requires that a system of planned and documented internal audits be conducted.

COMPARISON

NQA-1 contains more additional requirements for external audits, audit plan, and selection of the audit team. NQA-1 provides more specific requirements for scheduling, personnel, performance, and documentation.

CONCLUSION

A quality program that meets the requirements of NQA-1 will meet the requirements of ISO 9001. Conversely, a quality program that meets the requirements of ISO 9001 may not meet the requirements of NQA-1.

ISO 9001 Requirements Without Specific NQA-1 Counterparts

ISO 9001 also contains the following requirements. These requiremnts are addressed by NQA-1 throughout the document as part of the quality program but are not treated explicitly as separate sections.

4.3 Contract Review

Requires that each contract be reviewed to determine if the organization can adequately fulfill its contractual responsibility.

4.19 Servicing

Requires that procedures be established for servicing products.

4.20 Statistical Techniques

Allows for statistical techniques to be used for verification (inspection and test).

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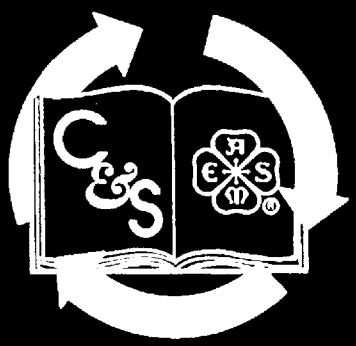

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