ASME

NQA-1 CERTIFICATION PROGRAM

Requirements
for
ASME NQA-1 Certification

Q1.1
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1. Scope

1.1 This document establishes the certification requirements for an organization to obtain and maintain an ASME NQA-1 Quality Program Certificate, hereafter referred to as a Quality Program Certificate. It includes terms and conditions which form part of the certification agreement with the applicant or certified organization.

1.2 The term “organization” is used throughout this document and understood as:

- an “applicant” seeking certification that its Quality Assurance Program is in compliance with the ASME NQA-1 Standard; or
- a company that is in possession of a valid Quality Program Certificate, i.e. certified organization.

1.3 ASME audits for new issuance and renewals are performed to the requirements of the current edition/addenda of the ASME NQA-1 Standard unless the provision of paragraph 2.4 is elected. Audits will not be performed to editions/addenda of the NQA-1 Standard published prior to 2008.

1.3.1 The effective date is the date when the requirements of the latest published edition/addenda of the NQA-1 Standard become effective. The effective date shall be 6 months after the date of issuance. Upon the effective date, the latest published edition/addenda shall be known as the current edition/addenda.

1.3.2 Organizations are not prohibited from revising its Quality Assurance Program and implementing the requirements of the latest published edition/addenda prior to the effective date.

1.4 A Quality Program Certificate does not replace the certification requirements of applicable standards, jurisdictional authority, enforcement authority, or regulatory authority. The NQA-1 Quality Program Certificate does not permit the application of the ASME Mark.

1.4.1 The authorization to supply, manufacture, construct and fabricate items falling under the scope of Section III of the ASME Boiler and Pressure Vessel Code, is covered by a separate ASME certification program. The supply and manufacture of certified material to N-type Certificate Holders under Section III of the Code require a Quality System Certificate. The construction, fabrication and assembly of items under Section III of the Code require an N-type Certificate of Authorization.

1.5 A Quality Program Certificate does not prequalify or exempt an organization from a qualification audit being performed by the Purchaser of the items or services provided by the organization per Requirement 7 of the NQA-1 Standard.

1.6 A Quality Program Certificate is available to organizations implementing the NQA-1 Standard, Part I and Part II, or portions thereof, for the supply of items/services performing a safety function; an item or service necessary to achieve safe, reliable, and effective utilization of nuclear energy and nuclear material processing.

1.7 A Quality Program Certificate is not available to an organization in certifying the quality assurance program for:

1.7.1 Activities pertaining to weaponry.

1.7.2 Owners of nuclear facilities – facilities for power generation, spent fuel storage, waste management, fuel reprocessing, nuclear material processing, fuel fabrication, and other related facilities.

1.8 ASME may, at any time, change requirements concerning the issuance and use of the Quality Program Certificate as it deems appropriate, and all requirements shall become binding upon Quality Program Certificate holders.

2. Quality Assurance Program

2.1 It is a requirement for a Quality Program Certificate that an organization has a documented Quality Assurance Program meeting specified requirements in the ASME NQA-1 Standard that has been demonstrated, evaluated and accepted by ASME. The organization shall identify the specific quality requirements of the NQA-1 Standard, Part I and Part II applicable to the scope of activity performed by the organization by completing a Quality Assurance Manual Checklist and describe their Nuclear Quality Assurance Program in a Quality Assurance Manual. The Quality Program Certificate does not include evaluation or acceptance of any elements of an organization's Quality Assurance Program that is not a requirement of NQA-1 Standard or this document.

2.1.1 An organization that is unable to demonstrate its Quality Assurance Program, in its entirety for the supply of the following items/services for an owner of a nuclear facility may request to have its Quality Assurance Manual evaluated and accepted by ASME:

- construction activities
- decommissioning activities
- decontamination activities
- maintenance & operations activities

A “nuclear facility” is understood to be: 1) a facility in operation or under construction for the utilization of nuclear energy for the production of electricity; 2) a facility in operation or under construction for processing of nuclear material; or 3) a facility which performed a safety function that is being decommissioned.

An ASME audit of the implemented program will be conducted when the Quality Assurance Program has been implemented and an internal audit performed at the nuclear facility. A certificate shall not identify more than one nuclear facility.

2.2 The scope of certification may include multiple locations when all locations are operating under the same company name (including division/department, if it appears on the certificate). The certification of an organization’s Quality Assurance Program is limited to the locations that have been audited by ASME and identified on the certificate. All locations identified on the certificate and the activities affecting quality shall be controlled, administered and managed from one location.

2.2.1 The certification of multiple locations is recognized through issuance of a:

2.2.1(a) Certificate with multiple addresses identified under the scope statement appearing on the certificate; or

2.2.1(b) Corporate certificate and Site certificates. The addresses identified on a Corporate certificate are locations that control quality activities or provide services which support activities performed at another location. One Quality Assurance Manual controls the activities affecting/controlling quality for all locations. Locations not identified on the Corporate certificate are certified through the issuance of a Site certificate(s). Site certificates are dependent upon the Corporate certificate.

2.2.1(c) For certificates issued at a nuclear facility, para 2.1.1, multiple locations may be identified on the certificate, when the locations provide services which support the activities performed at the nuclear facility.

2.3 An organization shall perform internal audits on an annual basis on its quality assurance program in its entirety.

2.4 An organization shall have and maintain a Quality Assurance Program which meets the current edition of the ASME NQA-1 Standard or elect to freeze its Quality Assurance Program to a specific edition/addenda of the ASME NQA-1 Standard published in 2008 or later. For Quality Assurance Programs frozen to a specific edition/addenda of the ASME NQA-1 Standard, refer to paragraph 8.2.1.

2.5 A Certificate of Conformance which references the Quality Program Certificate number, indicates that the item was supplied under the certified program and shall include:

2.5.1 The expiration date of the Quality Program Certificate;

2.5.2 The date of the Quality Assurance Manual, and as appropriate, the Issue/Edition and Revision level;

2.5.3 The specific NQA-1 edition/addenda as permitted by the Quality Program Certificate, refer to paragraphs 1.3, 2.4 and 8.2.1.

2.5.3(a) The citation of an NQA-1 edition/addenda earlier than NQA-1-2008 along with the NQA-1 Quality Program Certificate number is prohibited.

3. Quality Assurance Manual

3.1 The Quality Assurance Manual shall not be a reiteration of the NQA-1 Standard, but rather, a detailed written document which clearly describes the controls for each element of the Nuclear Quality Assurance Program as to who, what, when, where and how the program is being implemented. The Quality Assurance Manual need not be in the same format or sequential arrangement as in the NQA-1 Standard, as long as all the applicable requirements have been covered. The Manual accepted by ASME is the guide for performing the audits and determining continued compliance with the accepted Quality Assurance Program.

3.1.1 It is not a requirement nor desirable that detailed written technical procedures, work instructions, travelers, and/or forms be a part of the Quality Assurance Manual, but rather, the manual satisfactorily address the controls of the applicable NQA-1 Standard requirements for documents that specify quality requirements or prescribe activities affecting quality.

3.1.2 A Quality Assurance Manual dedicated to describing the controls for the NQA-1 Quality Assurance Program is encouraged. However, when there is a combined Quality Assurance Manual (a manual that describes the controls for

other types of programs) it shall clearly indicate and/or identify the controls which apply to the ASME NQA-1 Program that are subject to acceptance only by ASME.

3.2 The Quality Assurance Manual shall describe the scope of the items, products and services provided by the organization**.**

3.3 The Quality Assurance Manual shall include a statement of policy and authority indicating upper management support and responsibility for obtaining the desired end result.

3.4 The Quality Assurance Manual shall be in English. The organization is not prohibited from having a Quality Assurance Manual in another language; however, the English version shall govern when there is a discrepancy.

3.5 A copy of the organization's Quality Assurance Manual shall be provided and retained by ASME. ASME shall be provided a copy of all Quality Assurance Manual revisions issued during the effective period of the Quality Program Certificate. The revised Quality Assurance Manual shall be submitted to ASME within 30 days.

3.6 The Quality Assurance Manual and revisions to it shall be signed and approved for use by the individual responsible for establishing and executing the Quality Assurance Program.

3.6.1 Additional approvals to sections of the Quality Assurance Manual are permitted.

3.6.2 When the scope of certification includes multiple locations the Quality Assurance Manual shall identify the locations and the activities performed at each location.

4. Application for Certification

4.1 An organization desiring a Quality Program Certificate shall make application on forms issued by ASME. All information requested shall be provided in the English language.

4.2 For initial certification, an internal audit of the Quality Assurance Program in its entirety shall have been conducted in accordance with NQA-1, Part I, Requirement

18, and a decision made by management that the Quality Assurance Program is adequate and effectively implemented, prior to the scheduled ASME audit. Organizations which have not fully implemented its Quality Assurance Program on an actual purchase order are permitted to perform an audit on a demonstration item (fictitious order) for processes which have not been implemented. The demonstration item shall be prepared in manner to be a mock-up of an order which is required to be processed under the Quality Assurance Program. Sufficient copies of the internal audit report shall be provided to the ASME Audit Team on the first day of the audit.

4.3 For initial certification, a copy of the Quality Assurance Manual describing the Program which is to be audited by ASME shall be provided with the application forms.

4.4 ASME will arrange for an audit for new issuance or an audit for renewal of the organization's Quality Program for the scope of activities at the location(s) listed on the application. ASME will attempt to schedule audits on date(s) requested by the organization. If this is not possible, it will be scheduled at the earliest possible date acceptable to the organization that ASME auditors are available.

5. Issuance

5.1 Issuance of a Quality Program Certificate is based upon ASME's evaluation of the ASME audit report and payment of outstanding invoices.

5.2 It is a requirement for the organization to permit ASME to conduct two announced interim audits during the 3 year period for which the certificate is valid.

5.3 It is a requirement for the organization to permit ASME to conduct an audit for cause when deemed necessary by ASME.

5.4 The organization shall agree that the certificate is at all times the property of ASME. Organizations not in compliance with the requirements established under this document and/or the NQA-1 Standard will be requested to return the certificate promptly to ASME upon demand, or when the organization discontinues the scope of activities covered by the certificate. The organization shall not permit any other party to use the certificate.

6. Renewal

6.1 Not later than 6 months prior to the date of expiration on the Quality Program Certificate, the organization shall apply for renewal.

6.2 Failure to have a renewal audit scheduled prior to the expiration date on the certificate will result in the Quality Program Certificate expiring upon the expiration date.

6.3 An extension letter extending the expiration date shown on the certificate may be issued under certain hardship circumstance at ASME's discretion. Failure to accept available renewal audit dates prior to the expiration date or to submit the renewal application 6 months prior to the date of expiration are not considered to be a hardship.

7. ASME Audits

7.1 ASME Audit Teams are established for:

- audits for new issuance,
- renewal audits,
- interim audits, and
- audits for cause.

7.1.1 ASME audits are announced audits. Audits are a planned and documented activity performed by an ASME Audit Team to determine by investigation, examination, review, and evaluation of objective evidence the adequacy of the Quality Assurance Program and its effectiveness and compliance with established procedures, instructions, drawings, and other applicable documents as described in the Quality Assurance Manual. The Audit Team will utilize audit findings to identify conditions adverse to quality found during the audit. A corrective action plan shall be proposed by the organization and performed in accordance with the organization's Quality Assurance Manual. An audit finding(s) identified as a condition(s) adverse to quality will be provided to the organization at the completion of the audit by the Audit Team.

7.1.1(a) Audits for New Issuance and Renewal Audits. All elements of the Quality Assurance Program are audited. The Audit Team may identify audit findings in the adequacy of the Quality Assurance Manual in meeting the NQA-1 standard and in the demonstration/implementation of the Quality Assurance Program.

7.1.1(b) Interim Audits. Interim audits are performed twice during the 3 year period of a valid certificate to verify that the Quality Assurance Program is being maintained and that selected elements of the previously accepted Quality Assurance Program are being demonstrated in accordance with specified requirements. The Audit Team will also verify that the corrective action(s) taken to close out an audit finding(s) from a previous audit was effective in correcting the audit finding and in the prevention of its recurrence. Acceptance of revisions made to a Quality Assurance Manual may be performed during an interim audit. Failure to maintain an acceptable Quality Assurance Program, as determined by the significance of the identified audit findings may result in the suspension or withdrawal of the certificate.

7.1.1(c) Audit for Cause. Audit for Cause may be performed anytime for the following reasons:

(1) To audit the changes of a previously accepted Quality Assurance Program. The Audit Team will identify any audit findings in the revised Quality Assurance Manual and in the demonstration of the revised Quality Assurance Program.

(2) As a follow-up verification activity on an audit finding which could not be satisfactory closed.

(3) When deemed appropriate by ASME as a means to protecting the integrity of the ASME Certificate.

7.2 The size and makeup of the audit team and length of the audit will be determined by ASME based on performance and the type of audit. A Pre-assessment Questionnaire for audits for issuance and renewal audits shall be completed by the organization and will be used as a guide for ASME to determine the size and makeup of the team and the length of the audit.

7.3 The organization shall provide appropriate support personnel to the team including designated personnel knowledgeable and responsible for the development or demonstration of the Quality Assurance Program. Appropriate management personnel responsible for the Quality Assurance Program shall be available to the team.

7.4 The organization shall ensure that the audit team has free access to all quality assurance documentation and records, and all areas of the organization's facilities for which the scope of activities applies.

7.5 Documentation which supports understanding of the program by the audit team shall be in English.

7.6 A translator(s) is to be provided by the organization when the organization does not have a staff person(s) who is conversant in the English language.

7.7 An audit may be aborted only at the written request of the organization. For a certified organization, an aborted audit will result in the immediate suspension of their certificate and may eventually lead to the withdrawal of the certificate. An extension letter extending the expiration date of the certificate will not be issued.

7.8 All audit findings resulting from the ASME audit, both the implementation of the Quality Assurance Program and the Quality Assurance Manual review, are required to be corrected and closed within a reasonable amount of time agreed upon between the Audit Team Leader and organization (typically within 30-60 days of the audit exit meeting). Failure to correct and close out audit findings within the agreed upon time may result in an ASME decision to suspend, withdraw or withhold the certificate.

7.9 The audited organization shall be provided with a copy of the audit report when ASME has completed its evaluation of the audit report, corrective action reports, if any, and a decision made as to the issuance, suspension, withdrawal, or withholding of the certificate.

8. NQA-1 Quality Program Certificate

8.1 ASME NQA-1 Quality Program Certificates are not transferrable.

8.2 The certificate is valid for a three year period. The certificate shall identify the name of the organization, the location(s) covered, the NQA-1 Standard edition/addenda year, and the scope of activity(ies).

8.2.1 The certificate shall identify the specific edition/addenda of the ASME NQA-1 Standard for organizations which have elected to freeze its Quality Assurance Program under the provision of paragraph 2.4. Certificates which indicate "NQA-1 (current edition)" are issued to organizations which continually maintain and update its Quality Assurance Program to the current edition of NQA-1, refer to paragraph 1.3.

8.2.2 Site certificates and its corresponding Corporate certificate are not required to have the same dates of issuance or expiration. Site certificates are not valid when the Corporate certificate has been suspended, withdrawn or not renewed. The relationship between the Corporate certificate and Site certificate is through the certificate number; the Site certificate will have the same certificate number as the Corporate certificate followed by a serialized dash number.

8.2.3 An organization that is unable to demonstrate its Quality Assurance Program in its entirety for the supply of items/services performed at a nuclear facility, refer to paragraph 2.1.1, until established operations have commenced at the nuclear facility shall have a scope statement identifying the locations where additional ASME audits are required to be performed.

8.3 To prevent or mitigate a lapse in certification, the organization shall notify ASME of changes to the company name, address, and scope of activities as soon as possible, with subsequent submittal of a revised Quality Assurance Manual.

8.4 ASME does not "approve," "certify," "rate," or "endorse" any item, construction, or activity and there shall be no statements or implications that might so indicate. It is the aim of ASME to provide recognition of organizations that have attained and retained a Quality Program Certificate. A certified organization may state in advertising literature, that its quality assurance program is in conformity with the NQA-1 Standard and shall not use its certificate to imply that any items/services are approved or certified by ASME. Certified organizations may state in advertising literature that items, constructions, or activities "are built (produced or performed) or activities conducted under a Quality Assurance Program in conformity with the ASME NQA-1 Standard." The year of the edition/addenda shall be identified if it is cited on the Quality Program Certificate.

8.5 A Quality Program Certificate holder whose certificate has not been suspended or withdrawn is permitted to cite the ASME certificate number on documents accompanying items/services that had been built, produced, or performed under the Quality Program Certificate. General usage is permitted only when all of the certified organization's items/services are built, produced, or performed under the Quality Program Certificate.

8.6 An ASME Corporate logo shall not be used by any organization other than ASME.

8.7 ASME reserves the right to cancel, or refuse to renew a certificate.

8.8 Upon withdrawal, suspension, or expiration of the certificate, the organization shall discontinue the use of all advertising and other matter which contains any reference to ASME certification.

9. Changes to the ASME Accepted Quality Assurance Program

9.1 The organization is not prohibited from making changes to its Quality Assurance Program which had been accepted by ASME. Changes to an ASME accepted quality assurance program could be the result of, but not limited to, the following:

- Company name change
- Administrative organizational changes (title or department name changes)
- Address change (postal redesignation, relocations, additional sites)
- Change in scope of activity as established by the Quality Program Certificate
- Process changes, corrective actions or effectiveness improvements
- Meeting the current edition of the NQA-1 Standard

9.2 The organization shall supply ASME with a signed and approved controlled copy of the revised Quality Assurance Manual for acceptance.

9.3 Revisions to a Quality Assurance Manual shall be submitted to ASME. A summary of the changes and a description on how to locate the changes shall accompany the revised Quality Assurance Manual. ASME acceptance of the changes may be performed either by correspondence or at the time of a scheduled audit. When an audit is determined to be necessary to accept the changes, ASME shall determine whether the changes can be reviewed and accepted at an interim audit, an audit for cause, or if an early renewal audit is required. Administrative changes that do not affect the effectiveness of the Quality Assurance Program should not result in an audit.

9.4 Revisions to a previously accepted Quality Assurance Manual which do not result in the issuance of revised Quality Program Certificate (Name Change, Location Qualifiers, Certificate Scope Change) will not require ASME acceptance prior to implementation of the revised Program. However, the revised Quality Assurance Manual shall still be submitted to ASME. Changes which will require ASME acceptance prior to implementation are as follows:

9.4.1 Company Name Changes. Company name changes are permitted if objective evidence is provided to ascertain that the Quality Assurance Program requirements remain intact with no significant organizational changes in Quality Assurance staffing and all past liabilities under the former name are assumed under the new name. The statement of policy and authority (paragraph 3.3) shall identify the former name(s) of the company for which items/services had been provided under the Quality Program Certificate

9.4.2 Location and/or Address Changes. With the exception of installation activities occurring at a Purchaser's facility when authorized in the scope of its certificate, ASME shall be informed of location and/or address changes where activities addressed in the Quality Assurance Manual are being performed. The following types of changes are considered location and/or address changes:

- Postal Redesignation (physical location has not moved, just renamed/renumbered),
- Relocation of activities,
- Addition of new location, and
- Closure of an existing location

9.4.3 Certificate Scope Changes. ASME shall be informed of changes in the scope of activities which will result in a revision to the scope statement on a Quality Program Certificate.

10. Suspension, Withdrawal, Withholding or Reinstatement of Certificate

10.1 An organization may at any time suspend its certification by advising ASME in writing of its intention to do so. A suspension will permit the organization to retain its certificate; however, they are prohibited from using their certificate number or making any statements on documents or literature which conveys having a Quality Assurance Program in conformity with the ASME NQA-1 Standard.

10.2 An organization may at any time withdraw its certification by advising ASME in writing of its intention to do so and returning the ASME Quality Program Certificate. The organization is prohibited from using the certificate number or making any statements on documents or literature which conveys having a Quality Assurance Program in conformity with the ASME NQA-1 Standard. No prorated cost refund will be provided by ASME.

10.3 ASME may suspend, withdraw or withhold a certificate for cause. ASME maintains an impartial and nondiscriminatory appeals process to evaluate consideration of appeals against its decisions. The organization shall be provided with information on appearing before ASME at an appeal hearing.

10.4 ASME may reinstate a certificate that has been suspended or withdrawn. The reinstatement of such certificate may be based upon an audit or the outcome of an appeal hearing.

10.4.1 A certificate cannot be reinstated for an organization that has let its certificate expire.