

ASME

NQA-1 CERTIFICATION PROGRAM

Instructions for ASME NQA-1 Certification

1. Scope

1.1 This document establishes the instructions for an organization to obtain and maintain an ASME NQA-1 Quality Program Certificate, hereafter referred to as a Quality Program Certificate.

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.
- A Quality Program Certificate is not available to an organization in certifying the quality assurance program for activities pertaining to weaponry

1.3 ASME audits for new issuance and renewals are performed to the requirements of the organizations requested edition of the ASME NQA-1 Standard. Certificates will not be issued to editions/addenda of the NQA-1 Standard published prior to 2008.

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.

Note: The authorization to supply, manufacture, construct, fabricate and assemble 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 metallic/nonmetallic material to N-type Certificate Holders under Section III of the Code require a Quality System Certificate or an N-type certificate with furnishing metallic/nonmetallic material in the scope of the certificate.

1.5 A Quality Program Certificate may not prequalify or exempt the Purchaser from performing a qualification audit for the items or services provided, in accordance with NQA-1 Requirement 7.

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 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 evaluated, demonstrated 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 (Form Q2.1) 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.

2.1.1 An organization that does not have a demonstrated or implemented Quality Assurance Program covering the full scope of its item or service supply may request that its Quality Assurance Manual be evaluated and accepted by ASME. In such cases, ASME may issue a Quality Program Certificate based solely on the results of a Quality Assurance Manual review performed by an ASME Audit Team.

2.1.2 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, under construction or being decommissioned for processing of nuclear material; or 3) a facility which performs a safety function.

2.1.3 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 Quality Program Certificate shall not identify more than one nuclear facility.

2.1.4 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 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.

2.2 An organization shall have and maintain a Quality Assurance Program which

meets the current edition of the ASME NQA-1 Standard or may elect to freeze its Quality Assurance Program to a specific edition/addendum of the ASME NQA-1 Standard published in 2008 or later.

- 2.3** Organizations that maintain and update their Quality Assurance Program to the current edition of ASME NQA-1 shall identify it as “NQA-1 (current edition).” Organizations that elect to freeze their Quality Assurance Program shall instead specify the exact edition and addenda to which the program is fixed.
- 2.4** Organizations that have an established quality management system in accordance with ISO 9001 and additionally need to meet the requirements of NQA-1 may refer to ASME NQA-1, Subpart 4.1.1, Guidance to Modification of an ISO 9001:2015 Quality Management System for Compliance With NQA-1, Part I.

3. Changes to the ASME Accepted Quality Assurance Program

- 3.1** 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
- 3.2** The organization shall supply ASME with a signed and approved controlled copy of the revised Quality Assurance Manual for acceptance.
- 3.3** 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 shall be performed by correspondence. 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.

3.4 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:

3.4.1 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.

3.4.2 Location and/or Address Changes. With the exception of installation activities occurring at a Purchaser's facility when authorized in the scope of its Quality Program 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

3.4.3 Certificate Scope. Scope statements for Quality System Certificates shall be in accordance with ASME Q1.2, Notice on NQA-1 Quality Program Certificate Scope Statements.

3.4.4 Certificate Scope Changes. ASME shall be notified of any change in the organization's scope of activities. Each change shall be incorporated into a revision of the Quality Assurance Manual, submitted to ASME for acceptance, and may require an implementation audit by ASME. Following ASME acceptance, any necessary revisions to the scope statement will be reflected on the Quality Program Certificate.

4. Quality Assurance Manual

4.1 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.

4.1.1 Detailed technical procedures, work instructions, travelers, and forms are not required to be included within the Quality Assurance Manual. Instead, the manual shall describe the applicable controls—either through written narrative or by incorporating referenced forms as exhibits—to demonstrate how the governing documents satisfy the NQA-1 requirements that establish quality requirements or prescribe activities affecting quality.

4.1.2 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.

4.2 The Quality Assurance Manual shall describe the scope of the items, products and services provided by the organization. When the scope of certification includes multiple locations the Quality Assurance Manual shall identify the locations and the activities performed at each location.

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

4.4 The Quality Assurance Manual and supporting procedures/records shall be in English. If another language Manual is prepared, the English Manual shall govern for certification or accreditation of the organization by ASME.

4.5 Oral communication shall be made in the English language. In those situations where all participants in an audit fluently speak and understand a common language other than English, the Team Leader or leading Auditor may authorize oral communication in that common language provided it facilitates a more effective and efficient activity..

- 4.6 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.
- 4.7 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.
- 4.8 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.

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

5. Application for Certification

- 5.1 An organization desiring a Quality Program Certificate shall complete an application on forms issued by ASME. All information requested shall be provided in the English language.
- 5.2 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.
- 5.3 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.
- 5.4 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.
- 5.5 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.

6. Locations

6.1 All locations where activities are controlled, managed, and administered shall be audited by ASME and listed on the Quality Program Certificate. The terms 'location', 'primary location', and 'adjunct location' are used in the ASME Certification Process and are defined as follows:

6.2 Location - may refer to a single address or building(s) with multiple addresses on a common company complex/site that operates under the same company management and Quality Assurance Program. It is an all-inclusive term which identifies where activities are performed and include the terms, 'primary location' and 'adjunct location'.

6.3 All locations where hardware activities (e.g., construction, manufacturing fabrication, material receipt, receipt inspection, examination, testing, etc.) are being performed shall be audited by an ASME and identified on the Quality Program Certificate. When these locations are buildings within the same common company complex/site, these buildings may be identified on the Quality Program Certificate under a single complete/site address.

6.4 Primary Location - refers to the address identified at the top portion of the Quality Program Certificate and, at a minimum, is the location where:

- management responsible for the effective implementation of the quality program is located, and
- certification occurs
 - A shop/location-specific Quality Program Certificate or
 - A Quality Program Certificate (Corporate), the certification activities performed at the corporate location which has been extended to a shop or field location.
 - When the Quality Assurance Program with Quality Program Certificates (Corporate) are extended to shop or field locations, the Quality Program Certificate will include a location qualifier such as "at the xxx Power Plant (field site address)" and are numbered with the Quality Program Certificate (Corporate) number followed by a -1, -2, -3, and -n for the 1st, 2nd, 3rd, and nth extension.

- 6.5** Adjunct Location – refers to building(s) with multiple addresses used to assist or supplement activities and are identified in the Quality Assurance Manual. These adjunct locations in and of themselves do not produce finished items, but rather furnish incremental activities to augment the item during the construction/manufacturing process. It is neither a field location nor a “multi-plant” company, where each plant is established to operate autonomously in the fabrication or construction of finished items; each field location or plant established to operate autonomously is required to have its own Quality Program Certificate.
- 6.6** Multiple adjunct locations of an organization performing only procurement, quality assurance, and/or engineering may be identified on one Quality Program Certificate provided these activities are described and controlled in the same Quality Assurance Manual and audited by ASME. Adjunct locations of an organization performing only procurement, quality assurance, and/or engineering activities need not be audited nor listed on the Quality Program Certificate provided the following conditions are met:
- (1) Their activities are controlled and authorized by audited location,
 - (2) The output documents produced can be prepared at the non-audited location, but require all other reviews and approvals to be from an audited location,
 - (3) They shall be available to communicate with the ASME Audit Team e.g. (in person, by video conference, or telephone conference).
- 6.7** One Quality Program Certificate shall include in the scope statement the address of all adjunct locations used to augment construction/manufacturing activities provided the audit can be performed by ASME within seven (7) days.
- 6.8** For Organizations that perform services not associated with hardware activities (e.g., auditing, examination, testing, etc.) are not required to be audited by ASME at the various locations where those services are conducted. The Quality Assurance Manual shall define the controls governing such services. Each service and the location shall be identified on the Quality Program Certificate.

7. Issuance

- 7.1** Issuance of a Quality Program Certificate is based upon ASME’s evaluation of the ASME audit report and payment of outstanding invoices.

- 7.2** It is a requirement for the organization to permit ASME to conduct two announced

interim audits during the 3-year period for which the Quality Program Certificate is valid.

- 7.3** It is a requirement for the organization to permit ASME to conduct an audit for cause when deemed necessary by ASME.
- 7.4** The organization shall agree that the Quality Program 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 Quality Program Certificate promptly to ASME upon demand, or when the organization discontinues the scope of activities covered by the Quality Program Certificate. The organization shall not permit any other party to use the Quality Program Certificate

8. Renewal

- 8.1** Not later than 6 months prior to the date of expiration on the Quality Program Certificate, the organization shall apply for renewal.
- 8.2** Failure to have a renewal audit scheduled prior to the expiration date on the Quality Program Certificate will result in the Quality Program Certificate expiring upon the expiration date.
- 8.3** An extension letter extending the expiration date shown on the Quality Program 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.
- 8.4** An organization shall perform internal audits on its quality assurance program in its entirety within a period of time not to exceed 12 months.

9. ASME Audits

- 9.1** 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.
- 9.2** 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.

9.3 ASME Audit Teams are established for:

- audits for new issuance and Renewal Audits,
- interim audits, and
- audits for cause.

9.4 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.

9.5 Interim Audits. Interim audits are performed twice during the 3 year period of a valid Quality Program 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. 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 Quality Program Certificate. Acceptance of revisions made to a Quality Assurance Manual are not be performed during an interim audit.

9.6 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 Quality Program Certificate.

9.7 The size and makeup of the audit team and length of the audit will be determined by ASME based on performance, the type of audit, location(s) and requested scope of activities.

9.8 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.

- 9.9** 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.
- 9.10** 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 Quality Program Certificate and may eventually lead to the withdrawal of the Quality Program Certificate. An extension letter extending the expiration date of the Quality Program Certificate will not be issued.
- 9.11** 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 Quality Program Certificate .
- 9.12** The audited organization may request 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 Quality Program Certificate .

10. NQA-1 Quality Program Certificate

- 10.1** ASME NQA-1 Quality Program Certificates are not transferrable.
- 10.2** The Quality Program Certificate is valid for a three-year period. The Quality Program 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).
- 10.3** Quality Program Certificate Site certificates are not valid when the Quality Program Certificate Corporate has been suspended, withdrawn or not renewed. The relationship between the Quality Program Certificate Corporate and Quality Program Certificate Site is through the Quality Program Certificate number.
- 10.4** 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.

10.5 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 Quality Program 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.

10.6 A Quality Program Certificate holder whose certificate has not been suspended or withdrawn is permitted to cite the ASME certificate number on Certificate of Conformance 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.

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

- The expiration date of the Quality Program Certificate;
- The date of the Quality Assurance Manual, and as appropriate, the Issue/Edition and Revision level;
- The specific NQA-1 edition/addenda as permitted by the Quality Program Certificate, refer to paragraphs 1.3, 2.4 and 8.2.1.
- The citation of an NQA-1 edition/addenda earlier than NQA-1-2008 along with the NQA-1 Quality Program Certificate number is prohibited.

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

10.8 ASME reserves the right to cancel, or refuse to renew a Quality Program Certificate .

- 10.9** Upon withdrawal, suspension, or expiration of the Quality Program Certificate, the organization shall discontinue the use of all advertising and other matter which contains any reference to ASME certification.

11. Suspension, Withdrawal, Withholding or Reinstatement of Certificate

- 11.1** 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.

- 11.2** 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.

- 11.3** 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.

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

- 11.4** A certificate cannot be reinstated for an organization that has let its Quality Program Certificate expire.