

Two Park Avenue
New York, NY
10016-5990 U.S.A
Tel 1.212.591.8500

The American Society of Mechanical Engineers® ASME®



Table of **Contents**

- **3** About ASME Nuclear Certification
- **4** Overview of Certification Process
- **7** General Survey Conformity Assessment Requirements for Applicants

The following sections are being developed:

- N Certificate of Authorization Demonstration Guidance
- NPT Certificate of Authorization Demonstration Guidance
- NA Certificate of Authorization Demonstration Guidance
- NS Certificate of Authorization Demonstration Guidance
- NV Certificate of Authorization Demonstration Guidance
- N3 Certificate of Authorization Demonstration Guidance
- Quality System Certificate (Metallic) Demonstration Guidance
- Quality System Certificate (Polyethylene) Demonstration Guidance
- Quality System Certificate (Non-Metallic) Demonstration Guidance

,

AboutASME Nuclear Certification

he American Society
of Mechanical
Engineers (ASME)
has played a vital
role in supporting the
nuclear industry since
the first publication
of the ASME Boiler and Pressure
Vessel Code, Section III, "Rules
for Construction of Nuclear
Facility Components" in 1963. The
commencement of the ASME Nuclear
Certification Program in 1968 has only
strengthened that support.

Certificates of Authorization and Quality System Certificates issued by ASME signify that an organization has been through a rigorous Survey to verify the adequacy and effective implementation of the organization's quality program. The N-type Certificates of Authorization (N, NA, NPT, NS, NV, and N3) allow Certificate Holders to certify and stamp newly constructed items with the Certification Mark in accordance with Section III of the ASME Boiler and Pressure Vessel Code.

Quality System Certificates (QSC) provide assurance that the organization's operations, processes, and services related to the procurement, manufacture, and supply of material, source material, and unqualified source material are performed in accordance with the requirements of the ASME Boiler and Pressure Vessel Code, Section III, NCA-3800 and NCA-3900.

The Certificates authorize the following scopes of activities:

- N Construction of vessels, pumps, valves, piping systems, storage tanks, core support structures and concrete containments
- NA Field installation and shop assembly of all items
- **NPT** Fabrication of parts, appurtenances, welded tubular products and piping subassemblies
- **NS** Fabrication of supports
- **NV** Construction of pressure relief valves
- **N3** Construction of transportation containments and storage containments
- **QSC** Manufacture and supply of material

For detailed Certificate scopes and other requirements concerning the issuance of N-Type Certificates of Authorization and Quality System Certificates, please refer to the Notice on Nuclear Scope Statements.

Overview of **Certification Process**

The Certification Process can be divided into four phases: preparation, application, assessment, and certification.

Preparation

In preparation for obtaining ASME Certification, applicants should review all of the information related to the certification program including the applicable forms, checklists, and associated fees. This will ensure that applicants have a thorough understanding of the certification program requirements prior to submitting an application. Things to do prior to submitting an application for a certificate:

- Review relevant information about the certification program on ASME's website, go.asme.org/certification
- Decide on the scope of work that will be certified by ASME
- Obtain required standards
- Enter into an agreement with an <u>Authorized</u>
 <u>Inspection Agency</u> if required by the applicable standard
- Prepare the quality manual, a written description of the quality program
- Indoctrinate and train personnel who will implement the quality program

Application

Organizations seeking ASME Certification are required to submit the proper application forms and fees prior to receiving a Survey date. New applicants will need to create a <u>CA Connect</u> account. For more information on this process, please see the <u>CA Connect User Guide</u>. Existing account holders should first ensure that the primary contact for the account is correct. To change the primary contact for your company, please reference <u>How to Change Primary Contact Information</u>. For more information about the process for existing account holders, please see the <u>CA Connect User Guide</u>.

As part of the CA Connect application, applicants must ensure that the following supplemental forms are uploaded:

- <u>Nuclear Components Supplemental Application</u>
 <u>Form</u> (for N-Type Certificate applicants)
- <u>Nuclear Material Organization Supplemental</u>
 <u>Application Form</u> (Quality System Certificate applicants)
- Accreditation/Certification Agreement

Overview of Certification Process (cont.)

Assessment

The purpose of the Survey is to evaluate the adequacy of the applicant's quality manual and the effective implementation of the quality program. The extent of the Survey will be determined by ASME based on a review of the applicant's intended scope of activities as described in the application.

This Survey ensures that the applicant's quality program has been effectively implemented and that it complies with the requirements of Section III of the Boiler and Pressure Vessel Code. After the Survey is completed, the Survey Team Leader will submit a written report to ASME.

The Survey is conducted in five phases or segments as follows:

 Manual Review: Shall be performed by the Survey Team and observers authorized by ASME only, on the first day of the Survey. This review will normally be held in a location remote from the applicant's facility. Manual Review may continue on subsequent days at the applicant's facility as necessary. Pre-Survey questionnaires and manual checklists must be presented to the Survey Team at this time.

The Quality Program Manual programmatic controls as mandated by **NCA-3800/3900/4000** means who, what, where, when, and how. The terms who, what, when, where, and how are defined as follows:

What: The Manual identifies the activities which affect quality in the supply of the product (items/services).

Who: The Manual identifies the individual by title within the organization, at any level, that is responsible for performing the activity? This includes activities which are being delegated; the title of the delegate is to be identified. (In-lieu of a title, providing a clear description of knowledge, experience, training, and edition requirements of the individual required to perform the activity is permissible).

When: The Manual indicates the point of time the activity is required to be performed.

Where: The Manual identifies the location(s) at which the activity is performed or indicates if the activity is being subcontracted to an approved supplier/vendor.

When: The Manual indicates the point of time the activity is required to be performed.

How: The QA Manual identifies the technique (planning & accomplishment) used to achieve quality, e.g. drawings, procedures, work instructions, forms, travelers and/or tags. A graphic representation of the typical comparison of information contained in the Quality Program Manual vs Instructions, Procedures, and Drawings is shown below.

Quality Manual vsInstructions, Procedures, and Drawings	
What	
Who	
When	
Where	
How	

- 2. Entrance Meeting / Facility Tour: Will be held on the second day. The entrance meeting will provide the Applicant and the Survey Team an opportunity to: introduce themselves, review the Certificates and Scopes applied for, and to establish the Survey agenda. During the entrance meeting the applicants should identify the specific interfaces to fully support a timely, effective and efficient Survey. ASME fully encourages executive/senior management to attend the entrance meeting. During this meeting the Applicant may, if they wish, give a presentation of the company, products, personnel, etc.
- 3. Implementation: The Applicant is expected to demonstrate the implementation of the Program on Code work, demonstration item(s), or a combination thereof. If any deficiencies are discovered during the Survey, they will be immediately identified to the Applicant in order to provide them an opportunity to correct them prior to the conclusion of the Survey.
- 4. Team Closed Meeting: This meeting will be held at the Applicant's facilities prior to the exit meeting. This meeting will be attended only by the Survey Team and observers authorized by ASME. During this meeting, the Survey Team will review the results of the Survey and vote on the recommendation that the team will present to the Committee on Nuclear Certification (CNC).
- 5. Exit Meeting: This meeting will be held with the Applicant's management and will review the results of the Survey. ASME fully encourages executive/ senior management to attend the exit meeting. If there were any findings issued, they will be reviewed, and the Applicant will be advised of their status. The Survey Team's recommendation to the Committee on Nuclear Certification (CNC) will be made known. The Applicants will be allowed to ask any questions relative or pertinent to the Survey. At the conclusion of the exit meeting, the Survey is officially ended and there will be no more discussion of the Survey.

Certification

A Certificate will be granted by ASME only after the applicant successfully demonstrates the adequacy and effective implementation of their quality program to the ASME Survey Team. Survey reports are reviewed by the ASME Committee on Nuclear Certification (CNC). The CNC is composed of subject-matter experts who are stakeholders in the nuclear industry, including manufacturers and regulators. After the CNC reviews the report submitted by the Survey Team, they will either authorize the issuance of the Certificate or request additional action by the applicant.

Certificates are valid for three years. A renewal application and applicable fees must be submitted at least six months prior to the certificate expiration date to begin the certificate renewal process.

General Survey Conformity Assessment Requirements for Applicants

pplicants applying for initial issue or renewal of an ASME Certificate of Authorization should be aware that the ASME Survey will require that implementation of the Quality Assurance Program be demonstrated.

Applicants applying for initial issue or renewal of an ASME Quality System Certificate should be aware that the ASME Survey will require that implementation of the Quality System Program be demonstrated.

The extent of the Survey will be determined by the Society based on a review of the applicant's intended scope of Code activities described in the application, including but not limited to the specific information contained in this handbook.

The ASME Policies and Operating Procedures require the Survey Team to make a full review of the Applicant's Quality Assurance Manual/Quality
System Manual prior to visiting the
Applicant's facilities. This review is
performed by the full Survey Team
on the first day of the Survey. This
manual review is normally performed
remote from the Applicant's facility,
usually in a hotel but may be continued
at the Applicant's facility. In some
rare instances and under certain
circumstances it may be performed
at the Applicant's facility and will only
be done with the concurrence of the
Survey Team Leader.

It is the responsibility of the Applicant to have sufficient copies of their Manual (Uncontrolled) and at least one (1) copy of implementing procedures for the Survey Team's use at the time of the manual review. The Manual must be the Manual presently in use. For N-Type Certificate Applicants, the companyapproved manual also must be accepted by the Applicant's Authorized Nuclear Inspector Supervisor (ANIS). If the QSC or N-Type Certificate Applicant is proposing changes to the Manual, copies of the proposed changes shall be provided for review by the Survey Team. The Applicant will be expected to demonstrate the proposed changes during the implementation portion of the Survey.

Any N-Type Certificate Applicant's Quality Assurance Manual not based solely on NCA-4134 is acceptable only if it also includes all the controls necessary to establish compliance with NCA-4134. Quality System Certificate applicant's program not solely based on NCA-3800/3900 are acceptable only if the program also includes all the controls necessary to establish compliance with NCA-3800/3900 as applicable. When the quality manual addresses multiple codes, standards, or regulatory requirements, the manual shall indicate those portions which are not applicable for the implementation of the ASME Section III Code requirements.

For forms exhibited in the Quality
Assurance Manual or Quality
System Manual, the Survey Team
will find it beneficial to have the
completed example forms provided
for their review at the time of the
Manual Review.

The Applicant will be required to demonstrate the implementation of their Program for each Certificate applied for. If an applicant is applying for an N, NPT, NA, NS, N3, or NV Certificate of Authorization, the unique features of each Certificate scope shall be demonstrated. It is not necessary to repeat processes, e.g. if welding and NDE are demonstrated as part of the NPT demonstration there is no need to repeat it for the N, NA, or NS demonstration.

When using suppliers of subcontracted services (NCA-3125) or approved suppliers (NCA-3855), such as NDE, design activities, auditing, etc., the supplier's qualification procedure and records as required by NCA-4255.5 and/or NCA-4000 shall be made available for review by the Survey Team at the location of the Survey.

All demonstrations shall be to the most restrictive Code Class to be included in the scope of the Certificate and as identified in the application. For example, applicants applying for Class 1, 2 & 3 shall provide a demonstration to the Survey Team that is based on Class 1 Code requirements.

Demonstrations shall not be planned to exclude any type of Code activity:

- 1. For N-Type Certificate applicants using a thin-walled vessel demonstration item, the applicant shall provide another demonstration to implement fracture toughness requirements for thicker walled items, unless excluded from the scope of the Quality Assurance Manual.
- For N-Type Certificate applicants, utilization of unqualified source material, certification of material, qualification of material organizations, and approval and control of suppliers shall be demonstrated unless excluded in the Quality Assurance Manual.
- 3. For N-Type Certificate Holders and N-Type with design in their scope applicants utilizing subcontracted suppliers for design activities, these applicants shall demonstrate the requirements of NQA-1 Requirement 3 Paragraph 500, Design Verification. This demonstration activity cannot be subcontracted.
- 4. For Quality System Certificate applicants or applicants for N-Type Certificates with Material Organization in the certificate scope, NCA-3851.2 activities shall be demonstrated, unless excluded in the Quality System Manual or Quality Assurance Manual.

General Survey
Conformity
Assessment
Requirements for
Applicants (cont.)

If in 1, 2, 3 or 4 above activity is excluded, the exclusion statement shall include provisions to require the Certificate Holder or QSC Holder to notify ASME if they desire to remove this exemption from their program.

The purpose of the demonstration is to allow the Applicant to provide evidence of their knowledge of requirements for each Certificate and scope being requested. All elements of the ASME Section III Program must be described in the Quality Assurance Manual or Quality System Manual and shall be demonstrated. This means, for N-Type Certificate applicants, the demonstration shall cover all of the NCA-4134 requirements addressing all applicable elements of the program, including NCA-3800 and NCA-3900. If the Applicant has no design responsibility, demonstration for design control need only establish how the Applicant receives and controls customer-supplied design documents.

For Quality System Certificate applicants, all applicable elements of NCA-3800 and/or NCA-3900 must be described in their Quality System Manual and the demonstration shall include the implementation of material operations and certification of the results to the material specification and Section III. When the scope only includes furnishing material certified by other parties or qualified source material, then the demonstration shall include implementation of those activities.

It is expected that the demonstration of the Quality Program be implemented using actual Code work. If actual Code work is not sufficient to demonstrate all aspects of the Program, then a 'mock-up demonstration item' shall be used to address the missing elements of the Program. The demonstration shall be to the highest class of construction requested on the application. Mock-up demonstration items may be non-Code items treated as though they were Code items.

It is permissible to implement the Quality Program on Code work to the requirements of a previous Code Edition and addenda other than the current Code Edition and addenda, as long, as the Applicant also demonstrates their knowledge of the requirements of the most current Code Edition.