

Nuclear Certification Program

CONFORMITY ASSESSMENT
REQUIREMENTS

The American Society of Mechanical Engineers®
ASME®

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





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- 1.1 Applicants applying for the initial issue or renewal of an ASME Certificate of Authorization or Quality System Certificate should be aware that the ASME Survey will require that implementation of the Quality Program (Quality Assurance or Quality System, as applicable) be demonstrated.
- 1.2 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 applicable supplemental application(s), including but not limited to the specific information contained in this handbook.
- 1.3 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.
- 1.4 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 company-approved 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.



- 1.5** Any N-Type Certificate Applicant's Quality Assurance Manual not based solely on NCA (HAB)-4134 is acceptable only if it also includes all the controls necessary to establish compliance with NCA (HAB)-4134. Quality System Certificate applicant's programs not solely based on NCA-3300 are acceptable only if the program also includes all the controls necessary to establish compliance with NCA-3300 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.
- 1.6** 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.
- 1.7** 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 aspects of each Certificate scope shall be demonstrated. For those program scopes that include design responsibility, the controls for design processes shall be demonstrated for a component to be included on the N (NV) Certificate of Authorization. For Applicants not requesting an N (NV) Certificate of Authorization, then design process controls shall be demonstrated for an NPT appurtenance and, if only an NS Certificate is requested, a component support. It is unnecessary to repeat demonstrations (e.g. construction, fabrication or material activities) of each Certificate, provided that the demonstration includes the unique aspects of each certificate to be demonstrated. For instance, if material activities, welding and/or Non-Destructive Examination (NDE) process controls are demonstrated as part of the NPT demonstration, there is no need to repeat these activities for other certificate demonstrations.
- 1.8** When using suppliers of subcontracted services (NCA-3125) or approved suppliers (NCA-4255), 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.



1.9 A demonstration shall be to the highest Code Class to be included in the scope of the Certificate and as identified in the application. For demonstration purposes the highest class of metallic construction in descending order shall be considered as follows: Class A, Class 1, Class CS, Class B, Class 2, Class MC, Class SM, Class 3. Demonstrations for Division 2, Class CC and Division 5, Class SN for the G and GC Certificates require work demonstrations specific to that Class of Construction. Demonstrations for Classes A, B and SM shall be for elevated temperature service, unless these Classes will be limited to "Low Temperature Service" and noted in the Certificate Scope. Demonstrations shall not be planned to exclude any type of Code activity except as provided below:

- a. For N-Type Certificate or Quality System Certificate applicants using a demonstration item that does not implement fracture toughness requirements, the applicant shall provide another actual or mock-up demonstration using materials that are subject to fracture toughness requirements, unless excluded from the scope of the Quality Assurance Manual.
- b. For N-Type Certificate applicants, operations affecting chemical composition, mechanical properties, and/or product form, utilization of unqualified source material, certification of material, qualification of material organizations, shipment of material from qualified material organizations to other parties and approval and control of suppliers shall be demonstrated unless excluded in the Quality Assurance Manual.
- c. If any activities in paragraph 1.9 a. or b. above are excluded from the program, the exclusion statement in the Quality Manual shall include provisions to require the Certificate Holder or QSC Holder to notify ASME if they desire to remove an exemption from their program

- d. For applicants requesting Certificates which include design responsibility and who subcontract stress analysis or complete design, as permitted in NCA-3125 (b), shall demonstrate retention of responsibility for the design of the component and for the design output documents. Demonstration Design Reports shall be certified on behalf of the Certificate Holder by a Certifying Engineer that was qualified by the Applicant in accordance with Section III Appendix XXIII.
- e. For applicants requesting a Certificate which includes design responsibility for Division 5 Class A Elevated Temperature, a demonstration for the design of a component including the design output documents shall be provided. The demonstration Design Report shall be certified on behalf of the Certificate Holder by a Certifying Engineer that was qualified by the Applicant in accordance with Section III Appendix XXIII. It is not acceptable to present a “mock-up demonstration” of the qualification of the Certifying Engineer.
- f. For applicants requesting Certificate(s) which do not include design responsibility for Division 5 Elevated Temperature, a demonstration of the unique elements of the Certificate shall be provided.
- g. For Quality System Certificate applicants or applicants for N-Type Certificates with “furnishing metallic material” in the certificate scope, NCA-4251.2 activities shall be demonstrated unless excluded in the Quality System Manual or Quality Assurance Manual. For applicants requesting Division 5 be included to the Quality System Certificate, no additional demonstration is required as long as the scope of the manual includes Division 5.
- h. For Applicant’s requesting a Certificate to include the Supply of Services, a demonstration of a service shall be provided to demonstrate how the service is to be certified.



- 1.10** 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, that for N-Type Certificate applicants, the demonstration shall cover all of the NCA-4134 requirements addressing all applicable elements of the program, including NCA-3300. If the Applicant has no design responsibility, demonstration for design control need only establish how the Applicant receives and controls customer-supplied design documents.
- 1.11** For Quality System Certificate applicants, all applicable elements of NCA-3300 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 the implementation of those activities.
- 1.12** 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 elements of the Program, then a 'mock-up demonstration' shall be used to address the missing elements of the Program. Mock-up demonstrations may be non-Code, treated as though they were code, to address the missing elements of the program.
- 1.13** 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.