

**GUIDE
FOR
ASME REVIEW TEAMS
FOR
REVIEW OF APPLICANTS
FOR
ASME CERTIFICATES OF AUTHORIZATION
{A, M, PP, S, E, H, HLW, U, UM, U2, U3, PRT and T}**

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INTRODUCTION

This Guide is prepared for the use of ASME Review Teams. It is not intended to replace or interpret the requirements of the ASME Boiler and Pressure Vessel Code (B&PVC).

In addition, to assist the ASME Review Team, this Guide will be provided to Applicants for ASME Certificates of Authorization for their use in cross referencing the paragraphs in their written description of the Quality Management/Quality Control ((QC)) Manual with the applicable control requirements of the Code, and as a guide as to what is expected for a demonstration of the QC System.

This Guide is based on Section I, Section IV, Sections VIII Divisions 1, 2 and 3, and Section XII of the B&PVC. The Guide is subject to revision based on changes made in the aforementioned Sections in the B&PVC.

A Review must cover a QC Manual and its implementation. It is recognized that the scope of work, QC Manual, and Manual implementation will vary from Applicant to Applicant. Therefore, the ASME Review Teams are advised that all aspects of this Guide may not apply and that this Guide may not outline all possible aspects of each Review. The Manual need not follow the format of this Guide.

Questions of possible need for Code interpretation raised by Review Teams shall be submitted to the ASME Director, Accreditation and Certification. When a request for an interpretation is to be submitted by an Applicant, the Team Leader shall advise the Applicant that all such inquiries must be submitted to the Secretary of the applicable Boiler and Pressure Vessel Book Section, and that a copy of the inquiry and reply should be provided by the inquirer to the Applicant's Authorized Inspection Agency and cognizant Jurisdiction, if appropriate.

Suggestions for revisions or clarification to this Guide should be directed to the ASME Director, Accreditation and Certification.

REVIEW DEMONSTRATION

The purpose of the Review Demonstration is to evaluate the Applicant's Quality Control System (QCS) and its implementation. For evaluation of the QCS, the Applicant must demonstrate to current Code rules sufficient administrative and fabrication functions of the QCS to show that they have the knowledge and ability to produce the Code items typical of those covered by the QCS.

It is expected that fabrication functions be demonstrated using typical Code work. However they may be demonstrated using current work, a mock up, or a combination of the two. Any current Code work ongoing at the time of the joint review is subject to the Team's review. Code work that is being fabricated or assembled at field site, the Applicant shall include the field site details on their application and inform ASME about the location of field site and whether the review can be performed by the team at the field site location.

While the Applicant must address each element of the QCS in the Code, the Applicant need only demonstrate those elements within the intended scope of activities that apply to their program.

Demonstration Item¹: An Applicant² requesting a single Certificate of Authorization (e.g. "A"; "S"; "PP"; "PRT"; etc.) must demonstrate on an item that will be fabricated for the requested Certificate Designator and scope of Certificate of Authorization. The demonstration must be an implementation of ALL aspects of the QC System and is to include a demonstration of actual welding if welding is included in the scope of Code activities. If computer calculations are to be used, the Applicant shall demonstrate that the computer program has the capability of producing acceptable calculations.

For Applicants requesting multiple Certificates of Authorization, it is not necessary to have a demonstration item with design calculations for each Certificate Designator. A demonstration item fabricated to any one of the requested Certificates may be used as the demonstration item for the implementation portion of the Review. The Applicant is advised to select a demonstration item based on type of code item normally and most frequently manufactured. However, please note that if the demonstration item selected does not cover all the Certificates requested, the applicant will be required to prepare and present to the Review Team design documents for those Certificate designators not covered by the selected demonstration item.

For example, an Applicant for U and U2, Class 1 or Class 2 Certificates could demonstrate its QCS on a Section VIII, Div. 1 demonstration item including design. However, since the Section VIII, Div. 1 demonstration item does not cover the U2 Class 1 or Class 2 Certificate Designator, the applicant will also be required to prepare and present to the Review Team design documents for Section VIII, Div. 2 Class 1 or Class 2 depending on the scope of the U2 Certificate of Authorization, such as, Examination and Inspection plan, Manufacturer's Design Report with supporting User Design Specification, Certification of the design documents by an Engineer, as applicable.

For guidance in the selection of the demonstration item recommended/required based on Certificate Designator requested, refer to Table 1 below:

¹ The demonstration item shall be based on the latest Code Edition in effect at the time a complete Application is received by ASME.

² This does not apply to an Engineering Contractor under Section I. For an Engineering Contractor Organization under Section I, without a fabricating facility, a physical demonstration item is not required. However, a design specification must be provided as well as additional administrative functions to demonstrate compliance with the organization's QCS.

Table 1
Demonstration & Certificate Coverage Matrix

Demonstration	Certificate Coverage
B31.1 [BEP]	PP
Section I (*)	PP, S, E, M, H, HLW
Section IV	H, HLW
Section VIII, Div. 1	PP, S, H, HLW, U, UM, T
Section VIII, Div. 2 Class 1	PP, S, H, HLW, U, UM, T, U2 Class 1
Section VIII, Div. 2 Class 2	PP, S, H, HLW, U, UM, T, U2 Classes 1 & 2
Section VIII, Div. 3	U3
Section XII	T

Note: For “PRT” or “A” Certificates, no design calculations are required. However the applicant shall demonstrate the QCS using a demonstration item representative of the Certificate scope (e.g. For “PRT” fabrication of a part shall be demonstrated and for “A” fabrication/assembly of a Section I boiler shall be demonstrated). When applying for PRT Certificate for multiple Codes of Construction, such as Section I, IV, VIII, etc., the applicant must show Code knowledge of the unique requirements of the different Code Sections (e.g. Heat Treatment requirements for Section I, VIII, Impact requirements for Section VIII, etc.)

If the demonstration item is based upon current work that is being fabricated to a previous Code edition, the Applicant shall address changes in the Code that would require different actions in the demonstrations to be in compliance with the current Code requirements.

(*) If the demonstration is Section I item and U and/or UM Certificate(s) is/are required to be covered, the Applicant shall demonstrate the QCS for compliance to requirements applicable to ASME Section VIII Division-1 stated under Drawings, Design Calculations, and Specification Control of this Guide.

QUALITY SYSTEM REVIEW CHECKLIST

Item No.	Quality Element and Sub-elements	QC Manual References
1.	<p><u>GENERAL QUALITY CONTROL SYSTEM REQUIREMENTS</u></p> <p>(a) QC System is documented in detail in a QC Manual that addresses all requirements of the applicable Code Section and includes:</p> <p style="padding-left: 40px;">(1) a cover sheet that contains the company name and physical address as it will appear on the requested Certificate of Authorization;</p> <p>Note: The cover sheet may also contain the effective date of the QC Manual, mailing address, phone number or other information desired by the Certificate Holder or Applicant.</p> <p style="padding-left: 40px;">(2) a brief description of the products being fabricated and/or work being accomplished under the Code including applicability of QC System to shop activities, field activities or both;</p> <p style="padding-left: 40px;">(3) control features to demonstrate Code compliance including sub-contracted activities;</p> <p style="padding-left: 40px;">(4) Manual revision control system;</p> <p style="padding-left: 40px;">(5) provision for review and approval of QC Manual to ensure it is current;</p> <p style="padding-left: 40px;">(6) provision for submittal of QC Manual revisions to the Authorized Inspector (AI) and T Class 3 for acceptance prior to implementation including timely updating of all copies to reflect accepted revisions; and</p> <p style="padding-left: 40px;">(7) provision for the custody and control of the Certification Mark to prevent loss or unauthorized use.</p> <p>(b) In the case where the QC Manual exists in more than one language, at least one version is in English and identified as the authoritative version.</p> <p>Note: A glossary of terms is desirable from the standpoint of clarity if abbreviated titles of personnel and control documents are used throughout the QC Manual. This, however, is not mandatory.</p>	
2.	<p><u>AUTHORITY AND RESPONSIBILITY</u></p> <p>(a) The authority and responsibility for QC by management is documented.</p> <p>Note: In practice, a Statement of Policy and Authority must be signed by a senior company official responsible for Code activities (e.g., President, Vice President, Plant Manager, etc.).</p>	

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Item No.	Quality Element and Sub-elements	QC Manual References
	<p>(b) The authority and responsibility of those in charge of the QC System are clearly established and documented.</p> <p>(c) Persons performing QC functions have sufficient and well defined responsibility, the authority, and the organizational freedom to identify quality control problems and to initiate, recommend and provide solutions.</p>	
3.	<p><u>ORGANIZATION</u></p> <p>(a) An organization chart showing the relationship between management and engineering, purchasing, manufacturing, production, field assembling, field construction, inspection and quality control, as applicable, exists and reflects the actual organization.</p> <p>Note: The purpose of this chart is to identify and associate the various organizational groups with the particular function for which they are responsible. The Code does not intend to encroach on the Certificate Holder's right to establish and, from time to time, alter whatever form of organization the Certificate Holder considers appropriate for their Code work.</p>	
4.	<p><u>DRAWING, DESIGN CALCULATIONS, AND SPECIFICATION CONTROL</u></p> <p>(a) Procedures exist which assure that the latest applicable drawings, design calculations (design calculations are not required for PRT or certificate scopes with no design responsibility), specifications and instructions, required by the Code, as well as authorized changes, are used for manufacture, assembly, examination, inspection and testing. Procedures include provision for:</p> <ol style="list-style-type: none"> (1)) review of customer supplied documents for Code compliance For Section VIII Div 1, provision exists for review and use of User's Design Requirements Form, or other document with equivalent information; (2) the preparation, review, approval and distribution of drawings, calculations, and specifications; <p>For manufacturers or assemblers of parts who do not perform or assume any design responsibility for the part they manufacture, the QCS must describe how design documents, including specifications, drawings and sketches, that are received from the purchaser of the part are controlled and how parts are controlled while in the custody of the parts manufacturer or assembler.</p> <ol style="list-style-type: none"> (3) {Applicable to U2 and U3 only} use of the Certified User's Design Specification including authorized changes; (4) {Applicable to U2 and U3 only} providing the Certified Manufacturer's Design Report including authorized changes; (5) {Applicable to U2 and U3 only} certification of User's Design Specification and Manufacturer's Design Report by a Certifying Engineer meeting the criteria defined in Section VIII Div. 2 and/or an Engineer meeting the criteria defined in Section VIII, Div. 3; 	

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(6) {Applicable to U2 Class 1}

provisions for Certification of Manufacturer's Design Report for Class 1 vessels by a Certifying Engineer in accordance with Annex 2-B or by a Designer or engineer in accordance with Annex 2-B when none of the conditions of Section VIII, Div. 2 paragraph 2.3.3.1(a)(1) through (4) applies.

(7) {Applicable to T Class 3 only}

provisions for Design Certifying Engineer.

(8) {Applicable to Section VIII Div. 1}

provisions for procedures that will ensure that any computer program used for preparing calculations or conducting analysis meets the requirements of the Code. The procedures shall ensure that prepared calculations or analysis is verified as follows:

(a) The computer program calculations or analysis shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.

(b) The encoded mathematical model shall be verified to show that it produces correct solutions to the physical problem associated with the particular application.

NOTE: For (a) and (b), verification against examples found in ASME PTB-4, ASME Section VIII, Division 1 Example Problem Manual may be sufficient to show that verification is met.

In lieu of (a) and (b) above, the computer programs may be verified by the results confirmed by design analysis for each application.

(9) {Applicable to Section VIII Div. 1}

Provisions exist for individuals engaged in design activity while under the responsible charge shall:

(a) be qualified to meet the following minimum requirements by the Manufacturer as described in the Quality Control System:

(1) Description of how knowledge is determined of the design requirements of this Division for the application of the Certification Mark with the appropriate Designator

(2) Description of how knowledge is determined of the Manufacturer's or Assembler's quality program

(3) have training commensurate with the scope, complexity, criticality, or special nature of the design activities to which oversight is to be provided

QUALITY SYSTEM REVIEW CHECKLIST

(b) Description of documentation generated and maintained containing objective evidence of meeting the qualifications for the experience and training obtained

(c) be permitted to engage in any design activity required by this Division or any supplemental User's Design Requirements provided on Form U-DR-1 or Form U-DR-2 (or equivalent document)

(10) (Applicable to Section VIII Div. 1)

(a) Description of minimum requirements for education, years of experience and frequency of activity required to maintain qualifications for those that are engaged in design activities, including those in responsible charge.

(b) The title of the document used to identify the persons that are qualified to exercise control of design work performed by others.

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Item No.	Quality Element and Sub-elements	QC Manual References
5.	<p><u>MATERIAL CONTROL</u></p> <p>(a) Procedures for material control exist to assure that the material received is properly identified and has documentation, including, as applicable, required material certifications or material test reports, to satisfy Code requirements as ordered.</p> <p>(b) The material control system assures that only the intended material is used in Code construction. For Section XII only, material shall satisfy the applicable modal appendices requirements.</p> <p>(c) If substitution of materials is allowed, the applicable procedures for control of this activity are documented, including designation of the individual authorized to approve substitutions.</p> <p>(d) The title of the individual responsible for identifying the need for material test reports or certificate of compliance is designated.</p> <p>(e) The title of the individual responsible for performing a receiving inspection of Code materials is designated.</p> <p>(f) Information to be provided to the receiving inspector concerning the characteristics to be checked is documented.</p> <p>(g) A procedure exists for handling materials that are found to be nonconforming at receiving inspection.</p> <p>(h) If further material testing is required to be performed at receiving inspection or during manufacturing operations, the applicable procedures for control of this activity are documented.</p> <p>(i) Measures are established to assure the proper marking, handling and storage of materials.</p>	

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Item No.	Quality Element and Sub-elements	QC Manual References
6.	<p><u>EXAMINATION AND INSPECTION PROGRAM</u></p> <p>(a) Fabrication operations, including examinations and test procedures are described in sufficient detail to permit the Authorized Inspector (AI) to determine at what stages specific inspections are to be performed. Specifically:</p> <p style="padding-left: 40px;">(1) Provisions for the use of checklists, process sheets, travelers, etc., for listing of examinations and tests to be performed and for designation of inspection points;</p> <p style="padding-left: 40px;">(2) Such checklists, process sheets, travelers, etc., are made available to the Authorized Inspector prior to the start of fabrication; and</p> <p style="padding-left: 40px;">(3) {Applicable to UIG} A basic production flow diagram exists and includes in-plant inspection and check-off points and means of recording the same.</p> <p>(b) Material test reports or certificates of compliance, examination reports, test records, and other fabrication records are available to the Authorized Inspector.</p> <p>(c) Measures provide for transferring markings to assure traceability is maintained.</p> <p style="padding-left: 40px;">(1) If a coded marking system is used, it is documented and acceptable to the Authorized Inspector.</p> <p>(d) Measures to ensure that the Authorized Inspector is informed of approaching inspection points.</p> <p>(e) AI concurrence is obtained for repairs to material. {Not applicable to T Class 3}</p> <p>(f) Measures are established to assure that a final inspection is performed to assure all specified requirements have been met prior to obtaining AI's concurrence for application of the Certification Mark. {Not applicable to T Class 3}</p> <p>(g) Measures are established to provide for the preparation, certification, and distribution of the applicable Data Reports.</p> <p>(h) Measures are established to control field activities, when applicable.</p> <p>(i) {For operations under UG-90(c)(2), HG-515.4(b), or TS-200.7} Documented procedures exist and are accepted by the Authorized Inspection Agency (AIA), Jurisdictional Authority, and ASME Designee.</p>	

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Item No.	Quality Element and Sub-elements	QC Manual References
	<p>Note: Procedures should fully describe AI coverage of ASME Code work on all shifts. Also, percentage of AI time spent inspecting vessels or boilers that may not qualify for handling under UG-90(c)(2), HG-515.4(b), or TS-200.7 should be addressed.</p> <p>(j) {Applicable to UIG (Graphite)}</p> <p>(1) For U (Graphite) pressure vessels hydrostatic tests are conducted as required in UIG-99 and there are means of identifying acceptable graphite pressure vessel parts.</p> <p>(k) {Applicable to UIG}</p> <p>(1) Resin or cement mixing procedures are specified; and</p> <p>(2) Measures are established covering storage, issuance, handling, and disposal or resins, catalysts, fillers, pigments or cements.</p> <p>(3) Procedures exist covering:</p> <p>(i)) assembly and fit-up of the pressure vessel and parts; and</p> <p>(ii) adhesive-bonding of components.</p> <p>(l) {Applicable to E and UM only}</p> <p>Certified Individual (C.I) qualifications:</p> <p>i. Is an employee of the Applicant</p> <p>ii. meets knowledge and training requirements and is qualified and certified by the Applicant; and</p> <p>iii. records are available, maintained, certified by the Applicant and contain objective evidence of the Certified Individual's qualification.</p> <p>Measures are established to assure that the Certified Individual performs all required duties specified in the applicable Code.</p> <p>Note: For UM, U3, and T Class 3 qualification and duties for the C.I. shall be in accordance with QAI-1, Part 8.</p>	

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Item No.	Quality Element and Sub-elements	QC Manual References
7.	<p><u>CORRECTION OF NONCONFORMITIES</u></p> <p>(a) A procedure exists for the correction of nonconformities. Where AI involvement is required by the Code, the procedure is agreed upon with the AI. The procedure provides for:</p> <ol style="list-style-type: none"> (1) identifying those responsible for the resolution of nonconformities; (2) identifying and controlling further processing of nonconforming items until final disposition; (3) documenting the nonconformance and its disposition; and (4) informing the AI of nonconforming conditions. {Not applicable to T Class 3} <p>Note: A nonconformity is any condition which does not comply with the applicable rules of the Code, QC Manual or other specified requirements. Nonconformities must be corrected before the completed component can be considered to comply with the Code.</p>	
8.	<p><u>WELDING/CEMENTING</u></p> <p>(a) Welding/cementing conforms to requirements of Section IX and Construction Code, as applicable to the scope of work.</p> <p>(b) Provisions exists for personnel performing supervisory activities be designated with responsibility for supervision, control, evaluation, and acceptance of qualification testing.</p> <ol style="list-style-type: none"> (1) have a satisfactory level of competence in accordance with the Manual. As a minimum, they shall be qualified by education, experience, or training in the following areas: <ol style="list-style-type: none"> (a) Description of how knowledge of the requirements of Section IX is determined for the qualification of procedures and personnel (b) Description of how knowledge of the QC Manual is determined (c) the scope, complexity, or special nature of the activities to which oversight is to be provided (2) Description of documentation generated and, maintained by the organization, containing objective evidence of the qualifications, training or experience. <p>(c) WPS's/CPS's are available to the welder/cementing technician in the work area.</p> <p>(d) Measures assure continued welder/cementing technician qualification in accordance with Section IX and when required, Section VIII, Div. 1, UIG-80(d).</p>	

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| <ul style="list-style-type: none">(e) Those responsible for assuring that only qualified welders/cementing technicians are assigned to perform Code welding or cementing are identified.(f) Measures provide for the storage and conditioning, as required, of covered electrodes and conditioning of cements and their ingredients.(g) Measures are established for the control, issuance and return of welding material or disposal of cementing material to assure proper materials are used.(h) Measures are established for removing or inspecting tack welds.(i) Measures provide for the right, at any time, of the AI to call for and witness tests of the welding/brazing/cementing procedures and/or call for and witness the ability of welders, welding operators, braziers or brazing operators, or cementing technicians to perform their assigned tasks as required by the Code.(j) Measures provide for a system to identify work completed by each welder/cementing technician.(k) Applicable to Section I only<ul style="list-style-type: none">(1) Measures are provided to ensure preheating requirements of PW-38 are met(2) Measures are provided to ensure no thermal cutting or welding is performed on material with a metal temperature below 50 °F (10 °C)(3) Measures are provided that the required interpass temperature is not exceeded during welding(4) Measures are provided for interruption of welding | |
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Item No.	Quality Element and Sub-elements	QC Manual References
9.	<p><u>NONDESTRUCTIVE EXAMINATION</u></p> <p>(a) Provisions exist for identifying the appropriate NDE procedures applicable to the scope of Code work. These provisions assure that:</p> <ul style="list-style-type: none"> (1) NDE personnel are qualified in accordance with the applicable Code Section requirement; (2) NDE {{UT, MT, PT, RT and VT (UIG)}} examinations are performed in accordance with written procedures when required; (3) The AI can require demonstration by NDE personnel of an NDE examination or NDE procedures for cause; (4) NDE interpretation reports and RT films, as applicable, are retained in accordance with the applicable Code requirement; and (5) NDE equipment is calibrated. 	
10.	<p><u>HEAT TREATMENT</u></p> <p>{Not applicable to UIG}</p> <ul style="list-style-type: none"> (a) Controls provided to assure that heat treatment as required by the Code for the scope of Code work is applied. (b) Measures are established to assure proper placement of thermocouples and use of charts. (c) When heat treatment is subcontracted, measures are established to assure that procedures are followed and that heat treatment charts are provided. (d) Means are provided to satisfy for the AI that Code heat treatment requirements are met, (e.g., review of furnace time-temperature records or other methods as appropriate). 	

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11.	<p><u>CALIBRATION OF MEASUREMENT AND TEST EQUIPMENT</u></p> <p>(a) A procedure exists for the calibration of examination, measuring and test equipment used in fulfillment of applicable Code requirements.</p> <p>(b) Measures are established that assure calibration records are maintained and that status indicators are used to indicate the current calibration status of equipment.</p>	
12.	<p><u>RECORDS RETENTION</u></p> <p>(a) Procedures exist for the maintenance of Manufacturer's Data Reports, radiographs and records as required by the applicable Section of the Code.</p>	
13.	<p><u>SAMPLE FORMS</u></p> <p>(a) Forms used to control functions relative to quality are included within the QC Manual and their use explained in the text of the QC Manual.</p>	
14.	<p><u>AUTHORIZED INSPECTOR (AI)</u> {Not applicable to T Class 3}</p> <p>(a) An inspection agreement is established and maintained with an ASME accredited Authorized Inspection Agency. For Section XII Class 2 this could be a Qualified Inspection Organization (QIO), as defined in QAI-1. Part 6.</p> <p>(1) All required inspections are to be performed by the AIA of Record (the AIA identified on the application).</p> <p>(2) Alternatively, if an AIA other than the AIA of Record is to perform inspections, the Certificate Holder is required to submit to ASME a request for use of an additional AIA. ASME may grant the use of an additional AIA in lieu of the AIA of Record when:</p> <p style="padding-left: 40px;">(a) The AIA of Record confirms they are unable to perform their required inspections, or</p> <p style="padding-left: 40px;">(b) The item will be supplied to a second party, who is a valid ASME Certificate Holder, and as part of the contract requirements requires the use of the second party's AIA of Record.</p> <p>(3) When additional AIAs perform required inspections, the Certificate Holder's QC Manual shall include the following:</p> <p style="padding-left: 40px;">(a) Description of how different AIA's will perform activities under their Quality Management System;</p> <p style="padding-left: 40px;">(b) Evidence that the AIA performing the field or shop activities, or both, has a contract or agreement with the Certificate Holder.</p> <p style="padding-left: 40px;">(c) Evidence that this Quality Management System has been accepted by the AIA of Record.</p>	

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| | <p>(4) The provisions for the use of an AIA other than the AIA of Record are not permitted for facilities operating under the Mass Productions provisions of the Code.</p> <p>(5) All additional AIAs performing work other than the AIA of Record during a three-year certification period may be required to be present during the Certificate Holder's renewal and/or make available diaries.</p> <p>(6) At the discretion of ASME, ASME is permitted to audit the activities at shop or field sites performed by the Certificate Holder and the additional AIA, at the expense of the Certificate Holder.</p> <p>(b) A controlled copy of the QC Manual is available to the AI at the plant and all field site locations controlled by the Code shop where Code activities are being carried out.</p> <p>(c) The AI has access to all drawings, calculations, specifications, procedures, process sheets, repair procedures, records, test results, and any other documents as necessary for the AI to perform their duties.</p> <p>(d) Provisions exist for providing a liaison between the AI and the Manufacturer/Installer.</p> <p>(e) Provisions exist for free access for the AI and the Inspector Supervisor to all areas involving Code activities.</p> <p>(f) Provisions exist to assure that all Code required inspections by the AI are performed.</p> <p>(g) ASME is notified whenever the agreement is cancelled or changed to another accredited Authorized Inspection Agency</p> <p>(h) Provisions exist for AIA's periodic inspection of the E Stamp Holder Code activities per PEB 18.2.2</p> <p>(i) Provisions exist for the reviews for UM certification renewal after the first and second years of each 3 year review cycle to be performed by the Authorized Inspector Supervisor and report submitted to ASME.</p> | |
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Item No.	Quality Element and Sub-elements	QC Manual References
15.	<p><u>CERTIFICATIONS</u></p> <p>(a) Provisions exists for written certifications, authorizations and approval that require written signature and written date.</p> <p>(b) Provisions exists for certification methods other than written, when used, describing the controls and safe guards that are employed to ensure the integrity of the certification, authorization or approval.</p>	