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Procedures Conduct of Conformity Assessment Activities

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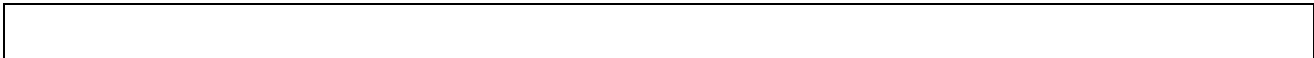
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1 SCOPE

These procedures establish guidance for the conduct of conformity assessment activities relating to ASME Survey, Review, Audit, Investigation and Interview Teams. These are the elements to carry out the ASME purpose to protect the ASME Mark and acceptance of the Applicant's demonstrated compliance with ASME Codes and Standards. For Conformity Assessment activities pertaining to AIA accreditation, additional guidance is provided under Appendix C.

1.1 GLOSSARY OF TERMS

Terms used in these procedures are defined as follows:

- (a) "Applicant" refers to an organization applying for any form of ASME accreditation / certification.
- (b) "ASME Conformity Assessment Activity" refers to those activities performed during Surveys, Reviews, Audits, Investigations and Interviews for the purpose of issuing or maintaining ASME Certifications or Accreditations.
- (c) "ASME Consultant" refers to an ASME Designee under contract to ASME.
- (d) "ASME Designated Organization" refers to an entity appointed by ASME to perform an administrative activity in accordance with an applicable Code or Standard.
- (e) "ASME Designee" An ASME Designee (referred to in this document as the Designee) is an individual authorized by ASME to perform administrative functions on its behalf and who has been qualified by ASME as either an Auditor or Lead Auditor.
- (f) "Audit" refers to a documented evaluation performed to verify, by examination of objective evidence, that those selected elements of a previously approved quality system have been developed, documented, and implemented in accordance with specific requirements. As used in this document, depending upon the context in which it appears;
 - (1) "Audits for Cause" refers to an audit that is the result of voted actions by the appropriate Conformity Assessment Committee or subcommittee.
 - (2) "Program audits" refers to an audit that covers selected elements of a previously accepted program and are scheduled on a programmed basis.
- (g) "Auditor" An ASME Designee who performs the auditing functions during conformity assessment activities.
- (h) "Authorized Inspection Agency" or "AIA" refers to an organization accredited by ASME in accordance with ASME QAI-1.
- (i) "Conduct" refers to an all-inclusive term encompassing the ASME staff and Team activities for formation, performance, and reporting of ASME surveys, reviews, audits, investigations, and interviews.
- (j) "Enforcement Authority" refers to a government entity that enforces regulations or laws and which formally recognizes an ASME Code or Standard as a means of compliance with those regulations or laws.

- (k) “Finding” refers to a deficiency in the quality system or its implementation that is based on an ASME Code, Standard, Procedure or Applicant’s quality system requirement. Findings are documented on forms prescribed by ASME Conformity Assessment Procedures.
- (l) “Internal Audits” refers to an audit performed according to procedures established by Committee on Conduct of Conformity Assessment Activities.(See paragraph 5.6)
- (m) “Interview” refers to verification done in lieu of a survey for an Applicant for a Nuclear Owner's Certificate.
- (n) “Observer” refers to a Team participant who is authorized by ASME to attend a review, survey, or interview to observe the Conformity Assessment activities of the Team (see paragraph 5.5) but who shall not evaluate an applicant’s quality program (unless the participation is for training purposes and is under direct supervision of a qualified individual), and does not contribute to the development of the Team’s consensus for a recommendation to ASME.
- (o) “Quality Management System”: an all-inclusive term that covers quality assurance, quality control, quality system, or quality program, depending on the requirements of the governing standard.
- (p) “Review” refers to the evaluation of an applicant’s Quality Management System, including a demonstration of compliance with Code requirements covered by the scope of the Certificate(s) being applied for, including as applicable, design, material, fabrication, examination, testing, inspection, and certification.
- (q) “Survey” refers to a documented evaluation of an applicant’s ability to perform Code activities as verified by objective evidence of the adequacy of the applicant’s quality management system and by a review of the implementation of that program at the location of the work.
- (r) “Team” refers collectively to those individuals authorized to participate in Team Activities consistent with their assigned role, which may be Team Members, Technical Experts and Observer(s).
- (s) “Team Activities” – Events described in this procedure during a review/survey where Team Members, Technical Experts, Trainees, and Observers may participate.
- (t) “Team Leader” refers to an ASME Designee who has overall responsibility for the conduct of the survey, review, audit, investigation or interview. This ASME Designee shall be qualified as an Auditor when leading activities under Appendix B (BPV Reviews) and shall be qualified as a Lead Auditor for all other surveys, audits or interviews.
- (u) “Team Member” refers to individuals authorized by ASME to participate on a Team and are limited to the Team Leader, Auditor(s), AIA representative(s) and Jurisdictional Authority representatives.
- (v) “Technical Expert” refers to a Team participant who, because of experience and unique qualifications, provides technical guidance to the Team Leader and Auditors while assessing an Applicant’s quality system but who does not contribute to the development of the Team’s consensus for a recommendation to ASME.
- (w) “Trainee” refers to an Observer attending a review/survey for the purpose of qualifying as an ASME Designee as either an Auditor or Lead Auditor.

1.2 REVISION TO PROCEDURES

1.2.1 These procedures and revisions thereto, are the responsibility of the ASME Board on Conformity Assessment.

1.2.2 Proposed revisions shall be reviewed and accepted by the Committee on Conduct of Conformity Assessment Activities.

2 TEAM COMPOSITION

- 2.1 The Survey, Review, Audit and Interview Team make-up is shown in Appendix A.
- 2.2 Members of an ASME Conformity Assessment Committee and the Standards Committee to which it reports shall not be used as ASME Designees on Survey or Review Team organized to conduct surveys, reviews, or audits connected with conformity assessment activities for which such Conformity Assessment and Standards Committee have overseeing responsibility. An exception is the ASME Senior Consultant who may serve as a nonvoting member on the ASME Conformity Assessment Committee.
- 2.3 Members of an ASME Conformity Assessment Committee and the Standards Committee to which it reports may participate in surveys or reviews as
- (a) Observers (see 5.5); or as
 - (b) Representatives of an Authorized Inspection Agency, Enforcement and Regulatory Authority, an ASME Designated Organization (see 2.2 for limitations).

Representatives of the Applicant/Certificate Holder that hold such Committee membership shall not participate as a Team Member.

- 2.4 The ASME Policy and Procedures on Conflict of Interest and Confidentiality shall be followed by the Team Members.
- 2.5 ASME Designees shall not participate on a Survey, Review, Audit or Interview Team if within the last three years they have been involved in the following activities:
- a) They have been employed by the Applicant,
 - b) Provided inspection services to the applicant's location, or
 - c) Involved in providing consulting services to the Applicant, or
 - d) Involved in working with the Applicant in the same field for which the Applicant is being Surveyed, Reviewed, Audited or Interviewed.

It shall be the Designee's responsibility to disclose any activities or involvement that may have taken place within the three-year time frame, and to recuse him or herself voluntarily from any such assignment.

3 TEAM ASSIGNMENTS

- 3.1** It is the responsibility of the ASME staff to select an ASME Consultant as Team Leader, or where applicable, notify the Enforcement Authority or ASME Designated Organization to appoint an ASME Designee as Team Leader.
- 3.2** Selection of ASME Consultants to serve as Team Leaders and Team Members for surveys, reviews and audits shall be from a list of currently qualified personnel maintained by ASME staff.
- 3.3** Team Leaders and Team Members selected by Enforcement Authorities or ASME Designated Organizations shall be certified by ASME as ASME Designees.
- 3.4** Where an Authorized Inspection Agency is required, it is the responsibility of the Applicant to assure that the required representatives of the Authorized Inspection Agency are available for the survey, review or audit.
- 3.5** For Interviews for Nuclear Owner's Certificates, ASME staff will make arrangements to select the Team.

4 SCHEDULING

- 4.1** After fulfillment of application requirements, ASME Staff shall arrange for a Team visit to the Applicant's facility(ies). Refer to Appendix D, for the criteria (Section D.2), prerequisites (Section D.3), and factors (Section D.5) permitting a scheduled, or the scheduling of a, conformity assessment activity by which the Team's visit is through the use of technology producing live streaming data (audio, video, and files). The staff shall coordinate with organizations represented on the Team, in accordance with staff procedures.
- 4.2** It is the Applicant's responsibility to arrange for representation from their Authorized Inspection Agency, when required. ASME Staff shall invite the Enforcement Authority, when applicable.
- 4.3** The ASME staff is responsible for scheduling audits and involving such personnel as is necessary for the type of audit being performed.
- (a) The Program Audit frequency shall be established by the governing standard or applicable certification/accreditation committee.
 - (b) Audits for cause shall be scheduled within the time frame determined by the appropriate Conformity Assessment Committee or subcommittee requiring such an audit.
- 4.4** It is the responsibility of the Applicant for an ASME Nuclear Owner's Certificate of Accreditation to request ASME for an Interview with their Authorized Inspection Agency and an ASME Designee.
- 4.5** It is the responsibility of the Applicant to see that hotel arrangements are made for the ASME Team, or advise the ASME Designated Organization, Enforcement Authority and/or Team members concerning hotel information. The Authorized Inspection Agency representatives are responsible for making their own hotel arrangements.
- 4.6** It is the responsibility of ASME or the organization appointing the Team Leader to provide the Team Leader with all the information required for the conduct of the survey, review, Program Audit, audit for cause, investigation or interview. For other than new Applicants, this shall include the Team Report from the previous survey, review or interview (and audit(s) and investigation(s), where applicable).
- 4.7** It is the responsibility of ASME staff to provide the Applicant with a copy of the Due Process and Confidentiality notice at the time the Applicant is provided with the checklist relevant to the requested survey or review.
- 4.8** If a problem prevents a full Team (See Appendix A) from being available, such as health or travel issues just before a Survey, the Team may proceed with the Survey upon consultation with the company concerning possible extension of the survey, if necessary. The ASME staff shall be contacted and consulted for their approval. The applicable Conformity Assessment

Committee Officers shall be advised. The qualification and experience of the remaining Team should be considered by the staff in determining whether the survey should continue.

5 CONDUCT

5.1 SURVEYS AND REVIEWS

5.1.1 Team Leader Responsibilities. The Team Leader has complete responsibility for the conduct of the survey or review. This includes

- (a) obtaining the pertinent information from ASME staff and the Applicant;
- (b) assigning duties to each Team Member, as necessary;
- (c) speaking for the Team in official contacts with the Applicant's management.
- (d) coordinating the findings of the Team Members;
- (e) reviewing findings with the team and preparing the official Team Report and obtaining the required signatures, when applicable;
- (f) presenting an oral report to the Applicant including the Team's recommendation and a summary of findings observed during the survey or review (Note: A written copy of findings will be presented to the Applicant);
- (g) retaining Team Member notes as required in paragraph 8.3.;
- (h) transmitting to ASME staff the Team Report and expense report when required.
- (i) After 90 days, unless otherwise notified by ASME staff, all documentation associated with the completed survey, review, audit, and interview, such as survey report, QRR, notes, findings, etc. shall be deleted from Team Leader's electronic devices and any hardcopies destroyed.

5.1.2 Team Member Responsibilities. The Team Members have responsibility for:

- (a) carrying out assignments (made by the Team Leader).
- (b) summarizing the results for assigned areas of survey or review for inclusion in the Team Report;
- (c)* identifying any findings relative to the applicant's quality program in the areas assigned and reporting these to the Team Leader. Team Members shall base findings strictly according to applicable Code, Standard or Applicant's Quality System requirements;
- (d)* identifying any findings relative to the testing equipment, test procedures, personnel qualifications, and quality program, and reporting these to the Team Leader;
- (e) reviewing findings prior to exit meeting for concurrence with Team recommendation;
- (f)* submitting required expense report, when required.

*Note: Items (c), (d), & (f) are performed only by individuals qualified as an ASME Designee or a Trainee under the direct supervision of an ASME Designee.

5.1.3 Survey or Review Team Checklists and Presurvey Questionnaire. When a survey or review is scheduled, the Applicant receives an ASME survey or review announcement letter. A copy of the documents required by the applicable Accreditation and/or Certification program, such as checklists and presurvey questionnaires, are supplied by ASME staff. These

required documents must be completed by the Applicant who then provides them to the Team for review along with the Applicant's Quality Manual. If there are apparent conflicts between the applicable Code or Standard and the corresponding guide, the Code or Standard shall prevail.

5.1.4 Manual Review. Prior to the entrance meeting, the survey or review team shall review and critique the written description of the quality program, application from CA Connect, and other documents required by the program. Specific points to be considered include the following:

- (a) All controls and requirements specified by the Quality Program and the applicable Code and/or Standard are adequately described for the scope of work being requested.
- (b) The quality program is described in the Manual in a manner that renders it auditable.

The Team Leader shall remind those present of the rules of confidentiality attached to the deliberations (see 5.9). The Team should avoid, as much as possible, imposing personal stylistic preferences on the Manual as corrections to the program. Any changes recommended by the Team should be substantiated by a requirement of the applicable Code or Standard. As part of the manual review, the Team Leader will make team assignments for the implementation portion of the survey or review.

5.1.5 Entrance Meeting. An entrance meeting will be held with the applicant prior to the start of the survey or review. At this meeting, the Team Leader shall

- (a) encourage participation of executive/senior management at the meeting;
- (b) review the application obtained from CA Connect, if changes to the application are required the Team Leader shall submit a revised application with the survey / review report.
- (c) carry out introductions;
- (d) describe the manner in which the survey or review will be conducted, including the fact that the Team Leader will conduct a daily meeting to discuss the schedule and the team's concerns and possible findings with the Applicant, so that the Applicant can implement any appropriate corrective actions during the survey or review;
- (e) discuss and agree upon the scope of certification and/or accreditation being requested;
- (f) discuss any significant changes, as a result of the Team review of ASME/Applicant's submitted documents, needing Senior management's response;
- (g) verify Applicant's receipt and understanding of the Due Process and Confidentiality notice, and respond to any questions from the Applicant. If the Applicant does not have a copy of the notice, the Team Leader shall supply a copy;
- (h) request information on safety requirements and proprietary aspects so that the Team can comply in all respects;
- (i) request a brief tour of the facilities for familiarization of the Team, when appropriate.

5.1.6 Implementation Demonstration

- (a) Team's critique and comments concerning possible need for manual changes identified during the Manual Review shall be reported to the Applicant. The discussion shall take place following the shop tour, if conducted, or entrance meeting if the shop tour is not conducted. The Applicant shall be encouraged to complete any Manual revisions during the survey or review so that the revised Manual can be reviewed and accepted prior to the exit meeting.
- (b) The quality program described in the Quality Manual must be demonstrated in use. The program does not have to be demonstrated on Code/Standard work. Non Code/Standard work may be used provided it is representative of the Code/Standard work contemplated and is documented throughout as Code/Standard work. Any current Code work ongoing at the time of the Survey or Joint Review is subject to the Team's review.
- (c) The Team Leader shall ensure that the applicant provides appropriate personnel to accompany Team Members in their assigned portions of the survey or review.
- (d) The Team shall ensure that each building/facilities used by the Applicant to perform Code work is recognized in the Manual and reviewed by the Team.
- (e) Manual revisions made during the survey or review shall be verified to assure adequate Code requirements have been incorporated.
- (f) For renewals, re-surveys or re-reviews, corrective actions from the previous survey, review or audit shall be verified.
- (g) The Team shall verify that the program described in the Manual, including documents shown as exhibits, examples, or samples, is in fact the program being implemented.

5.1.7 Team Findings and Recommendation.

Meeting(s) of the Survey or Review Team shall be held prior to the exit meeting for the purpose of identifying findings and developing the Team recommendation to be submitted to ASME and for Applicant information. The Team Leader shall be responsible for the conduct of the meeting and shall

- (a) ensure that only the Team and Internal Audit Team Members assigned to the survey or review by ASME staff are in attendance;
- (b) remind those present of the rules of confidentiality attached to the deliberations (see 5.9.1);
- (c) ensure that the list of findings reflects the consensus of the team and includes findings that were resolved before completion of the implementation; and
- (d) provide dissenting Team Members, authorized to contribute to the consensus of the Team's recommendation, the opportunity to prepare a Minority Report and forward to the staff for inclusion in the Team Report.

The Team may choose not to cite in the Team Report as findings, items of a minor nature.

5.1.8 Exit Meeting.

An exit meeting shall be held with the Applicant at the conclusion of the survey or review. At this meeting, the Team Leader shall

- (a) encourage participation of executive/senior management at the meeting;
- (b) present and discuss the Team's findings and recommendation (Note: A written copy of findings will be presented to the Applicant);

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- (c) when corrective action is to be taken by the Applicant and reported to ASME, explain the relevant procedures;
 - (d) provide the Applicant's representatives an opportunity to ask questions they may have concerning the survey or review, findings and/or the Team recommendation;
 - (e) remind the Applicant of the Due Process and Confidentiality notice and explain that:
 - (1) If they disagree with the findings, Team recommendation or general conduct of the survey or review, they may submit a written statement to the ASME Director, Auditing and Inspection, for consideration by ASME, as part of its evaluation of their application. In the event the applicant states intent to submit a statement to ASME, the Team Leader shall note this in the Team Report.
 - (2) The Team recommendation is not a final action. The determination to issue/renew their ASME certification and/or accreditation or recommend re-survey/re-review will be decided by the applicable Conformity Assessment Committee on the basis of the Team's recommendation, including consideration of Minority Reports by other Team Members, and statements presented by the Applicant, if submitted. If appropriate, the Team Report may include recommendation for AIA follow-up in lieu of re-survey/re-review.
 - (3) ASME staff shall notify the Applicant of the Committee's decision. If that decision is not to issue/renew the requested ASME certification and accreditation, the notification will include the applicable procedures for requesting a reconsideration of that decision and provisions for due process.
 - (4) If the Applicant has any questions about extension of the expiration date of Certificate(s), advise the Applicant to contact ASME staff.

5.1.9 Termination of Surveys or Reviews Before Completion. An ASME survey or review may be terminated before completion, by the Team Leader or ASME staff in an emergency situation, or upon written request from the Applicant. In such cases, a Report shall be prepared by the Team Leader concerning the summary of survey or review activities up to that point. The Report, together with the applicant letter, shall be sent to the applicable Conformity Assessment Committee for information. The Team shall not continue survey or review related activities subsequent to being advised that the applicant desires the survey or review to be terminated. The Team Leader shall advise the applicant that they should contact ASME staff concerning the consequences of early termination of a survey or review. If a problem such as health or an emergency during a survey prevents a full Team from being available, the Team may continue with the survey upon consultation with the applicant concerning possible extension of the survey, if necessary. The ASME staff should be contacted and consulted, if possible. The qualification and experience of the remaining Team should be considered in determining whether the survey should continue.

Note: The Team Leader shall advise the applicant that they must contact ASME staff concerning the rescheduling of their conformity assessment activity.

5.2 PROGRAM AUDITS

5.2.1 Companies which have Certificates, also known as Certificate Holders, subject to program audits shall have at least two audits during the term of the Certificate. Companies receiving more than two audits are chosen on a random basis as described under ASME internal Conformity Assessment Department procedures.

5.2.2 The Auditor has complete responsibility for the conduct of the audit. This includes

- (a) obtaining all the pertinent information from ASME staff.
- (b) arranging for a meeting with the Certificate Holder (Quality Systems Certificate for ASME Section III) prior to the start of the audit. At this meeting, the Auditor shall
 - (1) carry out introductions;
 - (2) describe the purpose of and manner in which the audit will be conducted;
 - (3) discuss confidentiality and appeal procedure;
 - (4) request information on safety requirements and proprietary aspects so the Auditor can comply in all respects;
 - (5) provide the applicant's representative(s) an opportunity to ask questions they have concerning the conduct of the audit.
- (c) performing audit in accordance with the checklist prepared by the Auditor. The checklist shall include verification of corrective actions from the last audit or survey.
- (d) arranging for a meeting with the applicant's management at the conclusion of the audit. At this meeting, the Auditor shall
 - (1) present an oral report including a summary of all findings observed during the audit;
 - (2) explain the relevant procedures to the representative(s) when corrective action is to be taken by them and reported to ASME;
 - (3) provide the applicant representatives an opportunity to ask questions concerning the audit and/or findings;
- (e) preparing the official Audit Report (all implementation and quality manual related findings in the Report shall be based on the applicable Code and/or Standard);
- (f) transmitting Audit Report and expense report to ASME staff.

5.3 AUDITS FOR CAUSE

5.3.1 An audit for cause may be announced or unannounced and may be required for one of the following reasons:

- (a) to verify completion of corrective actions required by ASME;
- (b) to review changes to the manual.

5.3.2 The Team Leader (or Auditor, where a single ASME Designee is assigned to conduct the audit) has complete responsibility for the conduct of the audit. In addition to the provisions of 5.2.2 (a) through (f), inclusive, the Team Leader shall

- (a) assign duties of each Team Member, when applicable;
- (b) speak for the Team in all official contacts with the representative(s);
- (c) coordinate finding(s) of the Team Members, when applicable.

5.3.3 Team Members have the same responsibility as outlined in 5.1.2.

5.4 INTERVIEWS FOR NUCLEAR OWNERS CERTIFICATES

5.4.1 The Interview Team shall meet with the Applicant to review and discuss the Applicant's Code responsibilities and duties relative to the Quality Assurance Program.

5.4.2 The Interview Team shall ascertain the Applicant understands Code responsibilities and that the Applicant has a documented policy statement, agreement, or letter from management to abide by these responsibilities.

5.4.3 After the interview, the Interview Team shall prepare a preliminary written report, including the team's recommendation. The contents of this report shall be discussed with the Applicant during the exit meeting.

5.4.4 The Team shall prepare and submit a final written report, including its recommendation, to the Director, Auditing and Inspection, after the exit meeting. The preliminary report may serve as the final report, provided no changes have been made.

5.5 OBSERVERS

5.5.1 Members and alternates of ASME Conformity Assessment Committees, Standard Committees to which a Conformity Assessment Committee reports, Board on Conformity Assessment, ASME Designee, ASME Designee Trainees, members of the ASME staff, members of the Committee on Conduct of Conformity Assessment Activities and Internal Auditors may be observers on ASME surveys, reviews, audits, investigations or interviews for the purpose of familiarizing themselves with the ASME Conformity Assessment activities. (see 5.7.1).

5.5.2 Representatives of ASME Designated Organizations, Authorized Inspection Agencies, and/or Enforcement Authorities, may accompany Survey or Review Teams as observers for indoctrination, training or overview.

5.5.3 All Observers on ASME surveys, reviews, audits, investigations or interviews shall

- (a) report directly to the Team Leader and provide complete cooperation to the Team Leader;

- (b) hold all information relative to findings, recommendations, discussions, reports, and Applicant's operation as confidential;
- (c) communicate only to the Team Leader or Team Members on matters relative to the survey or review.
- (d) not participate in the development of the Team's consensus for a recommendation to ASME.

5.6 INTERNAL AUDITS

5.6.1 Internal Audits shall be conducted in accordance with the current Internal Audit Team procedures, approved by the Committee on Conduct of Conformity Assessment Activities. Members of the ASME Board on Conformity Assessment, Internal Audit Team (IAT), ASME staff, or other so designated, may periodically attend ASME surveys, reviews, audits, and interviews as observers to the internal audit process.

5.6.2 Internal Audit Team Members, while performing audits of ASME surveys, reviews, audits, and interviews, shall

- (a) be under the direct control and supervision of the Internal Audit Team Leader;
- (b) communicate only with the Internal Audit Team Leader on matters relative to the internal audit;
- (c) not participate in any function of a survey, review, audit or interview;
- (d) hold all information relative to survey or review findings, observations, recommendations, discussions, reports, and Applicant's operation as confidential.

5.6.3 The conduct of the Internal Audit Team shall in no way, nor at any time during the audit, be performed in a manner that can be construed as either a parallel survey or review of the Applicant.

5.7 ARRANGEMENTS FOR OBSERVERS AND INTERNAL AUDITORS

5.7.1 The ASME Conformity Assessment staff shall be responsible for making all arrangements with the applicant to avoid potential conflicts of interest and an excessive number of observers and Internal Auditors on a survey, review, audit, investigation or interview. Consequently, no more than two observers should be assigned to any Team unless ASME staff determines it is beneficial to the process.

5.7.2 Assignment as an observer or Internal Auditor(s) is contingent upon the following:

- (a) acceptance by the applicant for observer(s) or Internal Auditor(s) to be present during the survey, review, audit, investigation or interview; and
- (b) determination by each individual observer or Internal Auditor that a potential conflict of interest does not exist with the applicant being surveyed, reviewed, audited, investigated or interviewed.

5.8 RULES OF DECORUM

5.8.1 Team Members shall at all times perform their duties and conduct themselves in a professional manner during surveys, reviews, audits, investigations or interviews.

5.8.2 Any apparent violations, misconduct, or extreme or inappropriate behavior shall be reported in writing to the ASME Committee on Designees. At least two individuals shall have witnessed the incident so that the allegation can be validated.

5.9 CONFIDENTIALITY

5.9.1 All discussion held in the process of arriving at a consensus with regard to the Team's recommendation to be reported to ASME and the position taken by each Team Member with regard to the recommendation, is strictly confidential.

5.9.2 Unauthorized communication of confidential information to the applicant or any non-Team Member shall be considered in violation of the confidentiality policy and shall be reported in writing to the ASME Committee on Designees.

5.10 LANGUAGE

The Quality Document 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.

Oral communication shall be made in the English language. In those situations where all participants in an audit, review or survey 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.

6 INVESTIGATIONS

6.1 INITIATION

- 6.1.1** When a written complaint is received by ASME alleging Code violations in items produced and/or activities performed under an ASME instrument of certification or accreditation, an investigation may be required. Investigations, if conducted, shall determine if items or activities as identified in the complaint are in compliance with Code requirements and if the Certificate Holder's Quality Program requires corrective action.
- 6.1.2** ASME staff shall acknowledge receipt of a complaint in writing to the originator if known with notification that review and processing of the complaint will be in accordance with ASME procedures.
- 6.1.3** If a complaint is identified involving an organization which is not a current Certificate Holder, the issue may be referred to the ASME's legal counsel and/or appropriate jurisdictional authority(s) for action as may be warranted.
- 6.1.4** The ASME staff shall coordinate investigation activities with the ASME Designee, ASME Designated Organizations, Jurisdictions, Authorized Inspection Agencies, owners/users, and other affected parties, as appropriate to the scope of an investigation and involvement of the organization.

6.2 AUTHORIZATION

- 6.2.1** The initiation of an investigation shall be by authorization of the Director, Auditing and Inspection with written notification of the investigation given to the appropriate Conformity Assessment Committee Chair or by the appropriate Conformity Assessment Committee.
- 6.2.2** A determination by the ASME staff that an allegation lacks sufficient information or an appropriate basis to conduct an investigation, or that an investigation is otherwise not warranted, shall be reported to the responsible Conformity Assessment Committee Chair.

6.3 PERSONNEL

- 6.3.1** Assignment of an organization or personnel for the conduct of investigations shall be by the ASME staff. Normal sources for investigators will include Authorized Inspection Agencies, Jurisdictions, ASME Designated Organizations, ASME Designees, and the ASME staff.

6.3.2 If an outside organization (i.e., persons other than ASME Designee or staff) is to perform an investigation on behalf of ASME, the assigned investigation personnel shall be acceptable to ASME. Investigators shall not be selected from an organization contracted as an Authorized Inspection Agency of the organization being investigated.

6.3.3 The qualification of the assigned investigator(s) shall relate to the scope of the investigation. In most cases, qualifications for an ASME Designee will suffice. However, there may be times when investigations must be conducted in a specific area and therefore other qualifications as considered necessary by the ASME staff may be appropriate. In all cases, the ASME staff shall assure that assigned investigation personnel acknowledge compliance with the ASME's policies on confidentiality, conflict of interest and code of conduct.

6.4 CONDUCT OF INVESTIGATIONS

6.4.1 Notification. Upon action to initiate an investigation, the ASME staff shall notify the affected organization(s) of the action. When determined appropriate by the Director, Auditing and Inspection or appropriate Conformity Assessment Committee, investigations may be conducted on an unannounced basis. Jurisdictional Authorities, eligible to serve as members of the Survey or Review Team, shall be notified of the conduct of the investigation.

Details and preparations for performance of the investigation will be arranged with the involved parties by the assigned investigator(s). The owner's authorization shall be secured as necessary for review of installed or in-service items.

Instructions provided by ASME staff to the Investigator(s) shall include pertinent information related to the area of investigation, as well as the time period for which the investigation is to be conducted.

6.4.2 Entrance Meeting. The investigator(s) shall meet with representatives of the applicant at the beginning of the investigation to explain the purpose and scope of the investigation review. The responsibility of the investigator(s) shall be clearly stated, that is, to perform the investigation review, document findings, and provide recommendations for consideration in accordance with procedures of ASME. The investigator(s) shall explain that a verbal report of findings and proposed recommendations will be provided to the applicant prior to conclusion of the investigation and that a written report will be provided to the responsible Conformity Assessment committee. Affected parties will be requested to advise the Investigator(s) if they disagree with any reported finding so that it may be rechecked and agreement reached, if possible. It should be made clear that they have this right, and that they are invited to contact the ASME staff if agreement cannot be reached on an issue.

6.4.3 Implementation. Performance of the investigation shall include review of relevant portions of the Quality Program, inspection of items and equipment, examination of records, and evaluation of activities affecting Code or Standard compliance, as appropriate

to the purpose and scope of the investigation. The aforementioned evidence shall be examined as necessary to determine the nature, extent, and validity of alleged Code or Standard violations. This may include examination of items at the applicant's facility, field sites, or in service at the location of installation. Any deficiencies identified in implementation of the Quality Program or in Code or Standard compliance of items shall be brought to the attention of the applicant. The affected parties shall be provided the opportunity to respond to identified deficiencies prior to conclusion of the investigation.

6.4.4 Exit Meeting. The findings of the investigator(s) shall be verbally reported to the applicant at the completion of the investigation. The report must be clear, and accurate, with opportunity for questioning of findings and reverification, if necessary, as stated during the opening meeting.

6.5 WRITTEN REPORT

6.5.1 Submittal. The Investigator(s) shall forward a written report on the results of the investigation to the Director, Auditing and Inspection, for distribution and consideration by the appropriate Conformity Assessment Committee in accordance with Committee procedures. The written report shall be submitted as soon as possible, but no later than fifteen days, after completion of the investigation.

6.5.2 Content. The written report shall include a description of conditions found relative to the purpose and scope of the investigation. This should include conditions found at the Certificate Holder's facilities and at the location of installation, as appropriate. The report should also include a discussion of any items or conditions not part of the original complaint, but relevant to the investigation; recommendations as considered appropriate for resolution of identified concerns; and any response, action, or documentation provided by the organization or as part of the original complaint.

6.6 RESULTS

6.6.1 Follow-up. After the appropriate Conformity Assessment Committee has made its determination relative to an investigation, the Committee Secretary shall notify the Certificate Holder of the actions taken by the Committee. Follow-up action shall be in accordance with Committee procedures.

6.6.2 Where applicable, the Committee Secretary shall notify the Jurisdictional Authority in which the item subjected to the investigation is located, of actions taken by the Committee.

6.6.3 When determined appropriate by the Committee or Director, Auditing and Inspection, a summary of the investigation results may be provided by the Committee Secretary to the Investigator(s), Authorized Inspection Agency, Jurisdiction, ASME Designated Organization, owner/user, and the individual reporting the original complaint, if known.

7 REPORTS

- 7.1** The Team Report shall include sufficient detail to record location, scope, duration, and nature of the conformity assessment activity; Team Members, observers, and other participants; findings, observations, and conclusions; and Team recommendations, as appropriate.
- 7.2** If the Survey or Review Team recommendation is to resurvey/re-review, the deficiencies in the Applicant's quality program shall be included in the Team Report, so that ASME staff can extract the deficiencies for inclusion in correspondence to the applicant surveyed or reviewed.
- 7.3** If a Team Member does not agree with the decisions of the consensus of the Team, the Member may file a Minority Report. Minority Reports shall define the areas of disagreement and present reasons for the disagreement. Minority Reports shall be included with the Team Report by ASME staff for review and consideration by the applicable Conformity Assessment Committee.
- 7.4** The Team Report shall be transmitted to ASME by the Team Leader for consideration and appropriate action within fourteen (14) days of the completion of the visit. Minority Reports shall be submitted by the Team Member writing the Report to the ASME Director, Auditing and Inspection, within ten (10) days of the completion of the visit for submittal to the applicable Conformity Assessment Committee.
- 7.5** At the exit meeting for a program audit, the Auditor shall advise the applicant of the requirement to respond to corrective actions. The date of response will depend on the requirements of each ASME program. The audit findings will be given in the Audit Report and a written report submitted to the applicant by the ASME staff upon receipt of the Audit Report. Corrective actions to be taken by the applicant shall be transmitted to the ASME staff for submittal to the Auditor for review and acceptance. In the event that the corrective actions are not accepted, the ASME staff will then submit the Auditor's response to the applicant and take what further action may be required.
- 7.6** The Team recommendation on new issuance or renewal surveys or reviews shall generally be selected from variations of the following options, as applicable to each program:
- (a) issue requested Certificate(s) to the location(s) indicated;
 - (b) issue Certificate(s) after receipt and acceptance of a follow-up Report (from Applicant or Authorized Inspection Agency);
 - (c) issue Certificate(s) subject to an ASME certification's or accreditation's audit program,; or
 - (d) re-survey or re-review.

Additional recommendations may be made if required by circumstances.

8 RECORDS

- 8.1** Team Reports for current certificate period shall be retained in ASME files.
- 8.2** Team Reports which recommend against issuance or renewal of Certificates shall be retained in ASME files until superseded by a complete report of a re-survey or re-review and voted action of the cognizant ASME Conformity Assessment Committee recommending issuance of a Certificate; until the application is withdrawn by the Applicant; or after a fixed time established by ASME policy has elapsed.
- 8.3** The personal notes of Team Members shall be retained and held confidential by the Team Leader for reference during a re-survey/re-review or to respond to queries raised by the relevant Conformity Assessment Committee. They shall be destroyed 90 days after completion of the activity unless otherwise notified by ASME staff.
- 8.4** Team Reports based on an audit for cause, or investigation, shall be retained in ASME files in accordance with the ASME record retention policy. If it has been determined that the applicant has been found to be in violation of the Code or Standard, the Team Report shall be retained in ASME files until the violations have been remedied.

APPENDIX A
ASME SURVEY, REVIEW, AUDIT, AND INTERVIEW TEAM MEMBERSHIP

- A.1. The membership on ASME Survey, Review, Audit and Interview Teams shall be based on the procedures of the responsible Conformity Assessment Committee when included in their procedures, or as mandated in the Code or Standard, which is the basis of the program.
- A.2. When not included in the Code, Standard or applicable procedures, membership shall be as follows:

TYPE	ASME Team Leader	ASME Auditor
New Issuance	*	(1)
Renewal	*	(1)
Resurvey	*	(1)
Relocation Audit	*	--
Expansion of Certificate Scope Audit	*	--
Unannounced Audit	*	--
Audit for Cause	*	(1)
Interview	*	(1)

(*) Required ASME Designee

(1) Decision on need for an Auditor(s) to be determined by ASME Staff or the responsible Conformity Assessment Committee.

APPENDIX B
ADDITIONAL REQUIREMENTS RELATING TO BOILER AND
PRESSURE VESSEL REVIEWS

B.1 SCOPE

This appendix establishes guidance for the conduct of certification and accreditation activities relating to ASME Review, and audit teams for Certificates of Authorization and Certificates of Acceptance administered by the Committee on Boiler and Pressure Vessel Accreditation (CBPVCA).

B.2 REVIEW TEAMS

The Review Team shall be in accordance with the Team Assignments described in the base procedures, with the exception of the specific Team assignments for each type of Certificate listed below.

B.3 SUPPLEMENTAL REQUIREMENTS

B.3.1 UM Certificate of Authorization (Valid for 1 year)

B.3.1.1 For other than initial issuance and the triennial review, the Authorized Inspection Agency representative shall conduct and document the renewal reviews after the first and second year.

B.3.1.2 The Authorized Inspection Agency representative shall provide written verification to ASME prior to the expiration date verifying that the review has been performed and that the AIA representative has accepted the Certificate Holder's Quality Control System for use of the ASME Certification Mark with the UM designator.

B.3.2 Section UG-90(c)(2); Section HG-515.4(b), Section X RI-160 Mass Production / Multiple Duplicate Certificate of Authorization

B.3.2.1 The review shall be conducted by an ASME Designee appointed by ASME or an ASME Designated Organization.

B.3.2.2 The Review Team shall also include the Authorized Inspection Agency and the Jurisdiction, where applicable.

B.3.3 H (Cast Iron and Cast Aluminum) Certificate of Authorization

B.3.3.1 The review shall be conducted annually (approximately 12 months), by an ASME Designee appointed by ASME. The Designee shall provide a report to ASME verifying that the Applicant's Quality Control System has been accepted prior to issuance of the Certificate.

B.3.4 V, UV, HV, UD and UV3 Certificate of Authorization

B.3.4.1 The review shall be conducted by an ASME Designee appointed by ASME Designated Organization in accordance with 5.1 of the procedures except that the Manual review (see 5.1.4) may be conducted following the Entrance meeting (see 5.1.5).

B.3.4.2 For each V, UV, HV, UD, and UV3 Certificate of Authorization, the Applicant shall demonstrate implementation of their Quality Control System by producing sample Pressure Relief Devices of a model/type that has been capacity certified in accordance with the applicable section of the ASME BPV Code.

B.3.4.3 The ASME Designated Organization shall provide a report to ASME verifying that the Applicant's Quality Control System has been accepted and that the capacity certification of at least one of the Applicant's Pressure Relief Devices model/type has been verified in accordance with the applicable section of the ASME BPV Code prior to issuance of the Certificate.

B.3.5 PRD – Testing Laboratory Certificate of Acceptance

B.3.5.1 The review shall be conducted by an ASME Designee appointed by ASME or by an ASME Designated Organization in accordance with 5.1 of the procedures except that the Manual review (see 5.1.4) may be conducted following the Entrance meeting (see 5.1.5).

B.3.5.2 For each service fluid, one or more Pressure Relief Devices and other flow devices (nozzle or other object with a fixed flow path) shall be flow tested by the Applicant and then comparison flow tested at an ASME Accepted Laboratory.

B.3.5.3 The ASME Designee either directly or through an ASME Designated Organization shall provide a report to ASME verifying that the Applicant's Quality Control System has been accepted and that the comparison testing between laboratories was acceptable.

B.3.6 PRD – Authorized Observer Certificate of Acceptance

B.3.6.1 The review shall be conducted by an ASME Designee appointed by ASME or by an ASME Designated Organization. The applicant shall demonstrate to an ASME Designee that the minimum education and experience requirements have been met and the applicant has the ability to conduct and supervise flow laboratory testing.

B.3.6.2 The ASME Designee, either directly or through an ASME Designated Organization, shall provide a report to ASME verifying that the Applicant's demonstration was acceptable.

B.4 SHOP REVIEW TIME GUIDELINES

The time spent on the implementation portion of Shop Reviews should normally be between 4 and 12 hours. When the time spent is outside of this range, an explanation shall be included in the report.

- (a) Some examples of rationale for short implementation review times include the following:
 - (1) Small number of employees;
 - (2) No or very few certified items fabricated within the past three years;
 - (3) Mature quality program and experienced staff;
 - (4) Limited certification scope.

- (b) Some examples of rationale for long implementation review times include the following:
 - (1) Large site or additional buildings at other non-contiguous locations;
 - (2) Language – interpreter required;
 - (3) New applicant and/or inexperienced staff;
 - (4) Significant number of findings.

APPENDIX C
ADDITIONAL REQUIREMENTS RELATING TO
AIA ACCREDITATION SURVEYS

C.1 SCOPE

This Appendix establishes guidelines for the conduct of accreditation activities relating to ASME Survey, and Audit Teams for Authorized Inspection Agency (AIA) Certificates of Accreditation administered by the Committee on AIA Accreditation (CAA).

C.2 GENERAL

The requirements of the base procedure apply except as noted herein:

- (a) Paragraph 2.3(b) is not applicable.
- (b) In Addition with Paragraph 5.1.5: If the Applicant is delegating part or all of the functions to an agent organization, then both the Applicant and the delegated organization should be represented during the survey or audit.

APPENDIX D

Conduct of ASME Conformity Assessment Activities via Video Conference

D.1 Scope and DefinitionsD.1.1 Scope

a) This Appendix establishes the requirements for ASME conformity assessment activities to be completed by the ASME Team when an on-site visit cannot be performed. When permission is granted, ASME Designees are allowed to conduct ASME conformity assessment activities without being physically on site at the applicant's facility through the use of different technologies to facilitate live streaming of video & audio, and sharing of documents.

D.1.2 Definitions

- a) On-site – activities that take place physically at the shop
- b) Shop- The location indicated on the ASME Certificate and where the activities being assessed are controlled and performed
- c) Video Conference - a conference in which participants in different locations are able to communicate with each other in sound and vision
- d) Visit – A visit on-site or visit via video conferencing

D.2. Criteria:

D.2.1 Holding paramount the safety, health and welfare of the ASME Team, use of these procedures is permitted when the ASME Designee(s) is prohibited from traveling to any country or area of the world containing war, civil unrest, natural disasters, pandemics etc., which has been deemed to be unsafe by ASME Staff for the ASME Designee(s) to conduct an on-site visit.

D.3. Prerequisites:D.3.1 Applicant:

- a) Shall have knowledge and the ability to use video conferencing.
- b) Shall have the capability to stream live video and audio from the shop.
- c) Shall have knowledge of sharing and receiving documents electronically.
- d) If the program includes AIA oversight, the applicant must coordinate with their AIA of record, so that AIA personnel can participate in the Conformity Assessment activity. If

possible, one AIA representative should be at the shop during the scheduled visit. For new applicants, at least one AIA representative shall be on-site during the scheduled visit.

e) Shop personnel implementing the program shall be available during time of Conformity Assessment activity.

f) Personnel performing activities on physical items shall be available on-site.

D.3.2 ASME Team shall have:

a) video conferencing capability.

b) capability to maintain a stable live stream of video and audio.

c) knowledge of sharing and receiving documents electronically.

D.3.3 ASME Conformity Assessment

a) ASME Staff shall review the criteria, prerequisites and factors concerning an Applicant's facility to determine scheduled conformity assessment activities for which permission is granted to ASME Designees to use this procedure.

b) For nuclear surveys, at least one member of the Team shall be physically onsite for certification activities.

D.4. Procedure

D.4.1 The requirements of the base procedure apply as augmented herein:

D.4.2 Once the Team Leader has been given permission by ASME Conformity Assessment staff to conduct the conformity assessment activity using this procedure, the Team Leader will contact the applicant and AIA personnel (if applicable) to set up the necessary video conferencing schedule.

D.4.3 The Team Leader may terminate the conformity assessment activity at any time during the process, if they are unable to clearly see and/or hear the necessary people and/or activities necessary to complete the conformity assessment activity. The Team Leader should consult with ASME Conformity Assessment staff if possible prior to the termination of the activity.

D.4.4 The Team Leader is responsible for all their duties in addition to those items clarified below:

a) documenting Entrance and Exit Meetings attendance in the activity report,

b) assuring confidentiality of conformity assessment activities are maintained throughout the Video Conferencing Activity

D.5. Factors for consideration when using this procedure

D.5.1 The best method of determining and verifying an applicant's capabilities is by having the ASME Team be physically present at the time of the scheduled assessment, however, there are circumstances, as described under D.2, which may prevent the ASME Team from traveling to the applicant's facility. The factors identified below shall be taken into consideration when determining the appropriateness of using video conferencing equipment.

- a) Safety of Participants
- b) Compliance with the base procedures of the Conduct document
- c) Ability of the Team to actually view the implementation demonstration activities and documentation comparable to an on-site visit
- d) Ability of the Team to ask questions of shop personnel
- e) All documents concerning the implementation are available for review and evaluation
- f) Ability of applicant to implement the entire program