

GUIDELINES FOR EVALUATION OF POTENTIAL NEW ASME CONFORMITY ASSESSMENT AND CREDENTIALING PROGRAMS

1 PURPOSE

These guidelines are intended to supplement the requirements and guidelines in the referenced documents as applied to evaluation, approval, and initiation of new conformity assessment and credentialing programs.

2 INTRODUCTION

2.1 Conformity Assessment

ASME conformity assessment independently ensures that products, services, systems or persons have required and consistent characteristics. ASME standards establish the required characteristics and the basis against which conformity is assessed. ASME serves as a conformity assessment body for product, management system, and personnel certification programs. ASME also serves as an accreditation body to assess the competence of other organizations to serve as conformity assessment bodies.¹ ASME does not “accredit” manufacturers, since manufacturers are not conformity assessment bodies. “Self-certification” is not independent certification. Similarly, ASME does not “accredit” training providers since training programs establish rather than just assess competencies and are therefore not considered conformity assessment programs. Finally, ASME cannot accredit itself, nor certify our own products, systems, or personnel. ASME serves as the certification body for all conformity assessment programs based on ASME standards², therefore independent accreditation of ASME is generally not necessary.

See Figure 1 for an overview of the conformity assessment program hierarchy. Presently ASME offers accreditation and conformity assessment programs. However, ASME's primary role is as a conformity assessment body (i.e., certification body), not an accreditation body. Evaluation of all future programs should consider ASME's role.

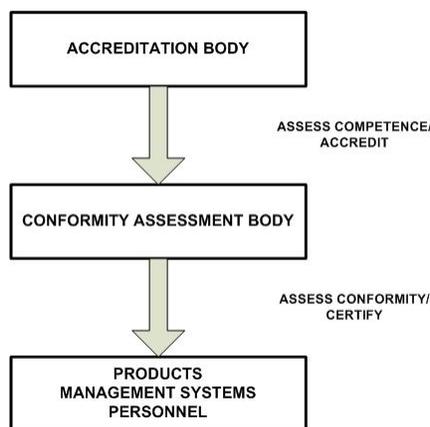


Figure 1 – Conformity Assessment Program Hierarchy

¹ Under the ISO/IEC-17000 [6] definition, accreditation bodies are not considered conformity assessment bodies.

² True with sunset of the ASME ISO9000 program.

2.2 Credentialing

There are other options outside Conformity Assessment for offering personnel credentials, including Certificate programs administered under ASME Training and Development. Credentialing of the technical workforce is an important element of ASME’s workforce development strategy, which includes fostering a broader, competent, vibrant and more diverse technical workforce, expanding the workforce capacity, and increasing technical competency. ASME credentials will recognize and acknowledge an individual’s attainment of qualification and certification. In light of the continuous development and deployment of technology, particularly in the energy area, and the corresponding specialization of personnel, ASME credentialing programs will help compensate for variations in education, training, and experience to both increase technical competency and expand the technical workforce. An ASME credential would be portable between employers. ASME’s direction is to become a credentialing organization. Figure 2 shows current and planned ASME conformity assessment and credentialing programs. Although ASME credentialing programs may lead to establishment or maintenance of personnel licensing, these licenses can only be issued by regulatory or jurisdictional authorities.

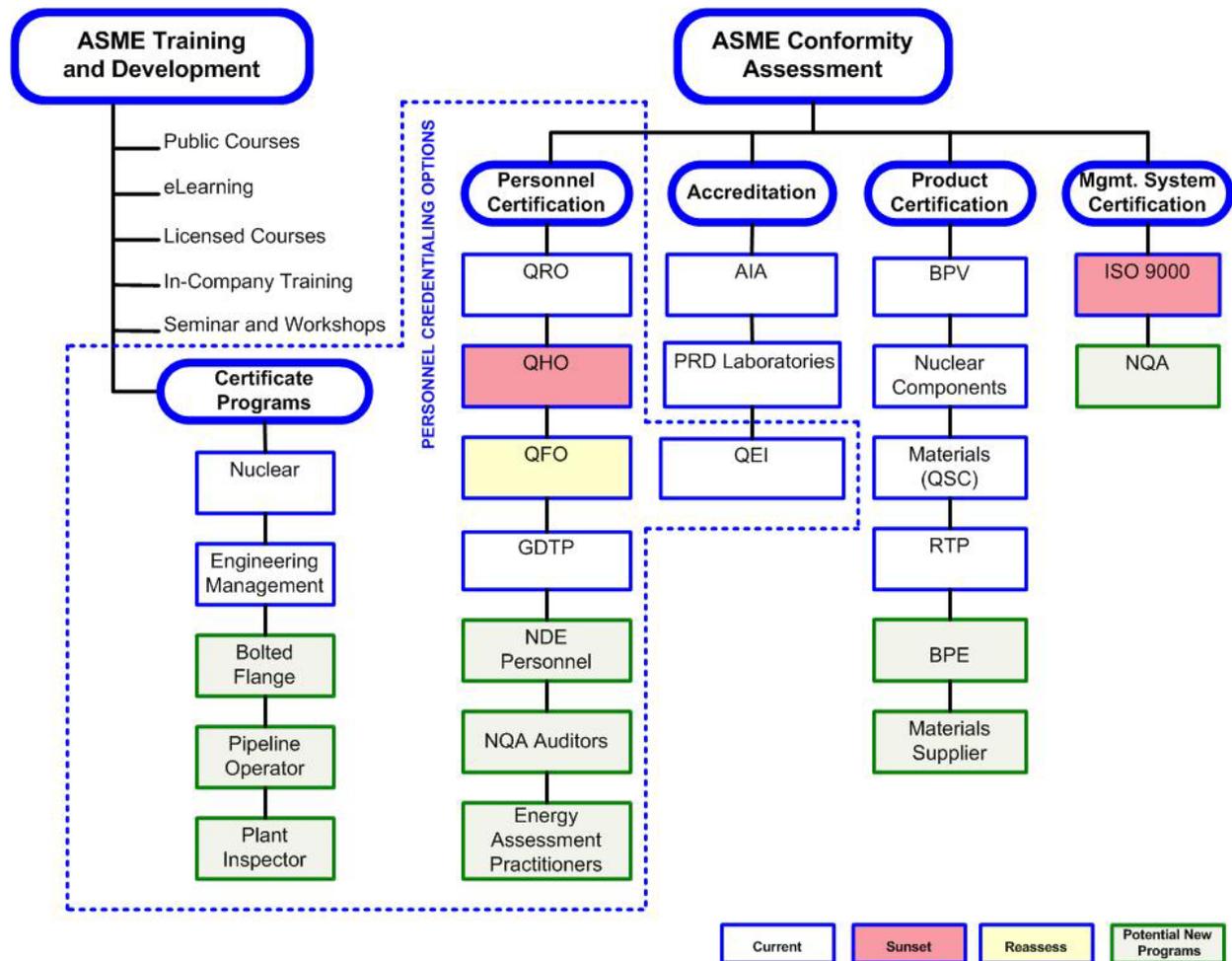


Figure 2 – ASME Conformity Assessment and Credentialing Programs

3 PROGRAM DESCRIPTIONS

Detailed descriptions of ASME conformity assessment programs can be found in references [3] and [4]. Brief summaries and discussion relative to existing programs are provided below to aid in the informed evaluation of potential new programs.

3.1 Accreditation

ASME Accreditation is an independent assessment and verification of an organization's competence to serve as a conformity assessment body. The accreditation assessment is performed by an ASME audit team which reviews quality system documentation and verifies implementation. The ASME-accredited organization may develop and administer a conformity assessment program (e.g., testing, inspection, or certification) in accordance with program requirements contained in an ASME standard developed through the consensus process. A "Certificate of Accreditation" is typically issued and organizations are referred to as "ASME-accredited". These programs are administered by ASME Conformity Assessment under the Board on Conformity Assessment (BCA). An associated Accreditation Committee is typically formed under BCA to provide guidance for the program. Current programs include:

- Authorized Inspection Agencies (AIA) – accredits organizations in accordance with the QAI-1 standard to perform third-party inspection as required by the ASME Boiler & Pressure Vessel (BPV) Code.
- Pressure Relief Device Laboratories (PRD) - accredits testing laboratories to perform capacity verification tests as required by the BPV Code. Tests are required to be conducted as specified in the ASME PTC 25 standard.
- Elevator Inspector Certification Organizations (QEI) – accredits organizations in accordance with the QEI-1 standard for certification of elevator inspection personnel.³

Discussion: an effective program at the accreditation level (see Figure 1) depends on the existence of a mature foundation of conformity assessment bodies over which to accredit. There should also be some value added by ASME accreditation, such as establishment of and assessment against a consistent set of criteria where none previously existed. The market size of potential conformity assessment bodies to be accredited is typically much smaller than the products, systems, and personnel these bodies would certify, test, or inspect; therefore, ASME's direct impact would be limited. Relative to personnel certification, each accredited certification body utilizes different assessment examinations with potentially large variations in rigor, validity, reliability, fairness and security; therefore, credentials provided are not ASME credentials and are not necessarily portable. ASME's future preference is to serve in the conformity assessment role, which would allow broader expansion of ASME's reach and impact.

3.2 Product Certification

ASME certification related to products means that a manufacturer is capable of constructing equipment and fulfilling requirements of a certain ASME standard. Certification is performed

³ The ASME Council on Standards and Certification (CSC) took action on February 15, 2012 to withdraw from accreditation of personnel certification bodies.

by an ASME audit team which reviews quality systems documentation and verifies implementation. The supplier is responsible for ensuring that individual products meet the requirements on which the certification is based. An ASME “Certificate of Authorization” is issued where there is an associated certification mark that may be placed on the product. These programs are administered by ASME Conformity Assessment under the BCA. An associated Conformity Assessment Committee is also typically formed under BCA, or the relevant technical standards committee, to provide guidance for the program. Current programs include:

- Boiler and Pressure Vessel (BPV, Non-Nuclear) - ASME BPV certification is a means of complying with the laws and regulations in most of the U.S. and Canada, as well as other countries throughout the world. There is a separate ASME certification designator used in conjunction with the certification designator for each type of equipment covered by the BPV Code, as summarized below:
 - Section I – Power Boilers (A, E, M, PP, S, V)
 - Section IV – Heating Boilers (H, LWH, HV)
 - Section VIII – Pressure Vessels (U, U2, U3, UD, UM, UV, UV3)
 - Section X – Fiber-Reinforced Plastic Pressure Vessels (RP)
 - Section XII – Transport Tanks (T, TD, TV)
- Nuclear Components (N-type Certificates) – Similar to BPV, N-type certification is a means of complying with the laws and regulations in most of the U.S. and Canada, as well as other countries throughout the world. Items stamped comply with the ASME Boiler and Pressure Vessel Code, Section III, Subsection NCA as well as other applicable Subsections and NQA-1. Programs include:
 - N - Nuclear vessels, pumps, valves, piping systems, storage tanks, core support structures, and concrete containments
 - NA - Field installation and shop assembly
 - NPT - Fabrication, with or without design responsibility, for nuclear appurtenances and supports
 - NV - Pressure relief valves
 - N3 - Containments used for transportation and storage of spent fuel and high level radioactive material and waste
 - NS - Nuclear component supports (no associated certification mark)
- Quality System Certificate (QSC) – ASME product certification program for nuclear materials. Holders of N-type Certificates are responsible for qualifying suppliers of materials either by evaluating the material organization's quality assurance system or by contracting with an organization certified by ASME under the QSC program. There is no QSC certification mark.
- Reinforced Thermoset Plastic Vessels (RTP) – ASME product certification covers reinforced thermoset plastic (RTP) vessels operating at pressures not exceeding 15 psig. Program criteria are included in RTP-1, Reinforced Thermoset Plastic Corrosion-Resistant Equipment.
- Bioprocessing Equipment (BPE) – ASME product certification for equipment used in the bioprocessing, pharmaceutical, and personal care product industries, including aspects

related to sterility and cleanability, materials, dimensions and tolerances, surface finish, material joining, and seals.

Discussion: ASME is transitioning to a single mark to be used for product certification stamping in lieu of the current multiple-mark system. ASME is evaluating a new Materials Supplier program based on QSC, but intended for non-nuclear applications. Unlike some product certification bodies (e.g., UL, CSA), ASME does not maintain a testing laboratory for product-specific assessment. The term “accreditation” had been improperly applied to some of ASME’s product certification programs in the past.

3.3 Management System Certification

ASME management system certification means that the management system of the organization conforms to specified requirements, is capable of consistently achieving its stated policy and objectives, and is effectively implemented. Management system certification does not include the certification of products, services, or personnel.

3.4 Personnel Certification

ASME Personnel Certification means that an individual’s qualifications have been reviewed, proficiency has been demonstrated, and the individual has been accepted by ASME as meeting all requirements of the relevant ASME Standard. ASME serves as the conformity assessment (certification) body and assesses the conformity of the personnel to requirements of the certification criteria document (an ASME standard), which includes independent job-specific assessment of an individual’s qualification (knowledge, skills, and abilities). Documented training and experience prerequisites are typically established to become eligible for the certification. The certification program is developed and maintained independent of related training to maintain the integrity of the certification. ASME training programs administered by ASME Training and Development may be developed based on the body of knowledge and skills to help personnel acquire the competencies necessary for the certification, but ASME training courses may not be specifically mandated. Standardized and secure written and practical assessment examinations are utilized and based on the required body of knowledge and skills contained in the referenced certification criteria document. The certification program criteria and assessment examinations are established using a psychometric⁴ approach to ensure validity, reliability, and fairness. An individual receives a Certificate or Certification Card upon successful completion and is referred to as “Certified”. Programs are administered by ASME Technology & Personnel Certifications under BCA. An associated Conformity Assessment Committee is typically formed under BCA or the relevant technical standards committee. Current programs include:

- Resource Recovery Facility Operators (QRO) - program criteria are contained in ASME QRO-1, Standard for the Qualification and Certification of Resource Recovery Facilities. These facilities are also referred to as “Waste-to-Energy” plants. QRO Certification is recognized by the U.S. EPA as a means of compliance with the Clean Air Act.

⁴ Psychometrics means “measurement of the mind.”

- High Capacity Fossil Fuel-Fired Facility Operators (QFO) – program criteria are contained in ASME QFO-1, Standard for the Qualification and Certification of Operators of High Capacity Fossil Fuel Fired Plants.
- Geometric Dimensioning and Tolerancing Professionals (GDTP) – program criteria are contained in ASME Y14.5.2, Certification of Geometric Dimensioning and Tolerancing Professionals.
- Hazardous Waste Incinerator Operators (QHO) – program criteria are contained in ASME QHO-1, Standard for the Qualification and Certification of Hazardous Waste Incinerator Operators.

Discussion – ASME Personnel Certification programs follow the general practices of ISO17024 (Ref [8]), but ASME does not claim compliance and is not accredited by ANSI nor any other organization. The QHO program is being sunset. New Personnel Certification programs under development include ASME NDE and QC Personnel (ANDE) and NQA Auditors. Additional programs are under evaluation for Energy Assessment Practitioners and Pipeline Operators.

3.5 Certificate Programs

In contrast with Personnel Certification programs, ASME Certificate programs are training-based individual credentialing programs, and are not considered Conformity Assessment programs. Certificate programs include a series of rigorous and mandatory learning events (training) as well as individual assessments to determine attainment of learning objectives. A volunteer Oversight Group is typically established to support program development, perform peer review of the program plan, course material, and assessment exams, and provide due process for the certificate program. Authorized Training Providers (ATPs) may be engaged to administer programs. A common ASME curriculum is developed and administered by the ASME Training and Development to ensure consistency between ATPs. Individuals successfully completing the program receive a Certificate or Qualification Card and are referred to as “Qualified”. Current certificate programs include:

- Engineering Management Certificate program (EMCP) – includes a series of training modules addressing core engineering management, as well as specialized topics including marketing, sales, communications, design & development, leadership, strategic planning, finance, and legal issues.
- Nuclear Construction Certificate program (NCCP) – includes a series of training courses providing an overview of ASME Nuclear Codes & Standards including rules for plant design, construction, fabrication and examination.

Discussion – ASME Certificate programs follow the general guidelines of ASTM E2659, “Standard Practice for Certificate Programs” and ICE 1100-2010(E) “Standard for Assessment-Based Certificate Programs,” but ASME doesn’t claim compliance, and is not accredited by ANSI. However, ASME is accredited by the International Association for Continuing Education & Training (IACET) to offer Continuing Education Units (CEUs) for training courses, including Certificate programs. Certificate programs under development or consideration include Pipeline Operators, Plant Inspectors, and Bolted Flange Joint Assemblers.

3.6 Authorized Training Providers (ATPs)

ASME Training and Development may engage multiple Authorized Training Providers (ATPs) to administer elements of a Certificate program including knowledge and skills training and assessments based on a consistent ASME curriculum. ASME will review and approve the organization's facilities, processes and personnel in accordance with established program requirements. The organization is then "authorized" to administer the ASME curriculum. ASME does not "accredit" any training organizations.

Discussion - For Certificate programs where utilization of multiple ATPs is envisioned ASME requires all ATPs to utilize the same ASME approved curriculum and assessments in order to eliminate potential disparities between training providers and resultant non-portable ASME credentials.

Note: ASME participates on the Accreditation Board for Engineering and Technology (ABET), which is a federation of 30 member professional and technical societies. ABET is the recognized accreditor of degree-granting postsecondary programs in applied science, computing, engineering, and technology. ASME has lead responsibility for over 450 undergraduate degree programs related to Mechanical Engineering, Mechanical Engineering Technology, Engineering Mechanics, Drafting/ Design Engineering Technology. This activity is coordinated through ASME Public Affairs and Outreach (formerly Centers) and is not part of ASME's conformity assessment organization (<http://www.asme.org/groups/centers-committees/educational-programs/accreditation-board-for-engineering-and-technology>).

4 PERSONNEL CREDENTIALING OPTIONS

Figure 2 presents the general ASME credentialing options including current and potential programs. Table 1 includes a general comparison of current ASME credentialing program attributes. Generally, ASME is transitioning away from accreditation of personnel certification bodies (QEI model) toward serving as the certification body for new personnel certification programs. Key attributes between the preferred credentialing options are included in Table 2.

Table 1 – ASME Credentialing Program Comparison

Item	Program Feature	Conformity Assessment				Training
		Accreditation Program ⁵	Product Certification	Management System Certification	Personnel Certification	Certificate Program ⁶
1	Key program attributes	Assess an organization’s competency to serve as a Certification Body (testing, inspection, certification); Administered by ASME Conformity Assessment under BCA	Assess manufacturer’s capability of constructing equipment and fulfilling requirements of a certain ASME technical product standard; Administered by ASME Conformity Assessment under BCA	Assess an organization’s management system (quality assurance program) as meeting the requirements of the relevant ASME standard; certifying an organization’s process; Administered by ASME Conformity Assessment under BCA	Independent job-specific assessment of an individual’s qualification (knowledge, skills, and abilities); Stakeholders establish the certification criteria; Documented training and experience prerequisites; Certification independent of related training; Standardized and secure assessment examinations; psychometrics ⁷ (validity, reliability, and fairness) applied for development and maintenance, ASME is certification body; Administered by ASME Personnel Certifications under BCA	Learning events (training) and individual assessments; Curriculum developed and administered by the certificate issuer (ASME); Assess attainment of learning objectives; Administered by ASME Development and Training, including approval of ASME Authorized Training Providers (ATPs) competency. May include prerequisite education, training and experience requirements.
2	Pros/ Advantages	Independently confirms that conformity assessment programs operated by others meet certain minimum requirements	Provides confidence that ASME product standard rules are consistently fulfilled by the manufacturer	Enables consistent control of management processes where an ASME product standard does not exist	High pedigree, transportable credential; true “certification”	Provides training and credentialing; Common ASME curriculum minimizes disparities between training providers ⁸
3	Cons/ Disadvantages	Requires existing certification/ foundation for accreditation; potential disparities between programs; International convention that organizations	None	None	Does not include training; additional resources to develop assessment exams; additional costs for psychometrics; No involvement in training program	Not a “Certification”; Additional resources needed to develop ASME curriculum and assessments; Individuals are not assigned a designation/acronym.

⁵ ASME S&C presently accredits Personnel Certification bodies (QEI), Testing bodies (PRD), and Inspection bodies (AIA). The CSC took action on February 15, 2012 to withdraw from accreditation of personnel certification bodies.

⁶ Certificate Program column deals with Certificate Programs only; ASME does not prohibit other parties from running training on ASME Codes and Standards.

⁷ Application of psychometric practices is inherent in all ASME Personnel Certification programs.

⁸ ATPs for ASME Certificate programs must use the same curriculum in order for the ASME credential to be awarded.

Item	Program Feature	Conformity Assessment				Training
		Accreditation Program ⁵	Product Certification	Management System Certification	Personnel Certification	Certificate Program ⁶
		don't offer both accreditation and certification				
4	Existing ASME Programs	AIA, PRD, QEI	BPV, Nuclear Components, QSC, RTP	ISO9000	QRO, GDTP, QFO, QHO	Nuclear Construction, Engineering Management
5	Precedence/ best practice	ISO/IEC 17011 (General requirements for accreditation bodies accrediting conformity assessment bodies)	None	None	Uses best practices from ISO 17024 (General requirements for bodies operating certification of persons)	Uses best practices from ASTM E2659-09 (Standard Practice for Certificate Programs) and ICE 1100 2010(E) – (Standard for Assessment-Based Certificate Programs)
6	Facilities provider	Accredited Certification Bodies (ACB)	Manufacturer	Supplier	Subcontracted facilities (written and practical assessments, examiners)	ASME ATP - classroom and practical training and assessments
7	Training provider	Not mandated by ASME program	n/a	n/a	Not mandated by ASME program	ATP – knowledge and skills training
8	Exam (written and/or practical) provider	ACB	n/a	n/a	ASME	ATP – written and practical assessments
9	Credential	“Accredited”; Certificate of Accreditation; “Certification” by ACB	“Authorized” or “Certified”; Certificate of Authorization	“Registered” or “Certified”; Certificate of Registration	“Certified” (demonstrated required qualifications per certification criteria); ASME Certification	“Qualified” (achieved learning objectives); ASME Certificate
10	Volunteer resources	Committee to establish and maintain recommended guidelines for accreditation requirements	Conformity assessment committee	Conformity assessment committee	Personnel Certification committee (program oversight, written and practical assessment exam development and maintenance, due process)	Certificate program Oversight Group (develop, monitor, and approve the certificate program)
11	Audits scope	Approve prospective Certification Body’s process	Approve quality systems documentation and verifies implementation	Approve system documentation and implementation	Approve subcontracted facilities, personnel, process	Approve ATP personnel, process

Table 2 - Key Attributes of ASME Credentialing Programs

Certificate Programs	Personnel Certification Programs
<ul style="list-style-type: none"> – Learning events (e.g., training) and assessment are both developed and administered by the certificate issuer – Assess attainment of learning objectives – Participation in specific ASME training events is mandatory; alternative training and experience is not accepted – Written program plan, policies and procedures – No renewal requirements – May grant continuing education credits – ASME Certificates are issued to “Qualified” personnel – Administered by ASME Development and Training 	<ul style="list-style-type: none"> – Independent job-specific assessment of knowledge, skills, and abilities – Stakeholders establish the certification criteria, typically as an ASME standard through the consensus process – Formal application, evaluation, certification, surveillance, and recertification – Documented training and experience prerequisites – Certification is independent of related training; ASME training may not be mandated – Written and practical exams utilized for assessment <ul style="list-style-type: none"> • Validity, reliability, and fairness (psychometrics) • Administered in a standardized and secure environment – Certification is time limited; renewal requirements measure or enhance continued competence – ASME Certificates are issued to “Certified” personnel – Administered by ASME Personnel Certifications under the Board on Conformity Assessment (BCA)

5 DECIDING ON THE PROGRAM STRUCTURE

An important early step in evaluating any new ASME conformity assessment program or credentialing program is identifying the most appropriate structure for the conformity assessment and/or credentialing program. The most appropriate structure will depend on the specific conformity assessment or credentialing need, status of the industry, existing related conformity assessment activities, adoption of a relevant ASME standard, and the level of stakeholder participation and commitment. A review of existing programs is recommended and may serve to determine the best structure as well as example program against which to model the potential new program.⁹

5.1 General Guidelines for Program Structure

The following general guidelines are provided to assist with evaluation of a suitable program structure for a potential new program.

- Accreditation – most appropriate where a conformity assessment system (testing or inspection) is already present and involves multiple organizations independently and perhaps inconsistently performing similar activities. Accreditation helps ensuring that the quality of conformity assessment activities performed by others against ASME requirements remains high, or at least meets minimum requirements.
- Product Certification – most appropriate where an associated ASME product standard exists and has been widely adopted and the consequences of nonconformity are significant such that confidence is needed that users of the standard are competent enough to consistently fulfill requirements.
- Management System Certification – most appropriate where an associated ASME product standard does not exist, but consistent control of management processes (such as quality assurance) is important to meeting minimum requirements.
- Personnel Certification – most appropriate where a rigorous independent job-specific assessment of an individual's qualification is desired, a portable credential is needed, and personnel may develop competency through multiple combinations of education, training, and experience.
- Certificate – most appropriate where a personnel credential is desired, but a specific curriculum of mandatory training is needed, as well as individual assessments to determine attainment of learning objectives.

5.2 Historical examples

- Accreditation (QEI) – prior to initial development a trend was observed among state and municipal governments to rely on private inspection agencies and self-inspection by elevator companies to perform inspections that had traditionally been done by the jurisdictional authorities. One of the prime concerns of the group was to develop a means for ensuring that the quality of the inspections remained at a high level. The group determined that addressing

⁹ ISO/IEC Guide 67, Fundamentals of product certification (Ref. [9]), is also useful in illustrating alternative models of product certification.

the qualifications of the persons performing the inspections was an important part of achieving this goal. Since multiple certification organizations already existed, and at the time (1981) ASME had a policy which prevented the direct certification of individuals, the accreditation structure was used. Today the QEI program has only 3 accredited organizations, and should not be used as a model for future programs. If today's environment existed when QEI was originally proposed, an ASME personnel certification program would likely have been considered as an alternative.

- Personnel Certification (QRO) - The original plan was to model the QRO standard after QEI. However, there were no organizations certifying resource recovery operators (1988). ASME policies were revised to allow direct certification of personnel, and the QRO was developed as a Personnel Certification program. QRO is presently ASME's most successful personnel certification program with over 1,500 personnel certified.

5.3 Recent Examples

- Personnel Certification (NDE and QC personnel) – The Boiler and Pressure Vessel Code (I, III, IV, V, VIII, X, XI, XII) includes requirements for owner qualification and certification on NDE personnel. Industry has identified the disparity between various owner-based programs, the need to improve performance, and the desire to expand the NDE workforce through a portable ASME credential. Emphasis was placed on third party assessment of individual competency. Industry also desired to preserve the availability of existing NDE training resources and allow personnel to development competency through multiple combinations of education, training, and experience. Additionally, the need was identified for standardized and secure assessment exams developed through a rigorous psychometric process. So the Personnel Certification platform was selected.
- Product Certification (BPE) – BPE follows the BPV code model for product certification. ASME BPE-2007 was originally issued without conformity assessment (product certification) requirements. Since the standard was new the need and opportunity emerged to ensure users were competent enough to consistently fulfill requirements. Product certification requirements covering limited applications (tubular products) were added in the ASME BPE-2009 following approval of the conformity assessment program. Further expansion to include other equipment covered by the BPE standard is expected.
- Management System Certification (NQA) – The Nuclear Quality Assurance (NQA) management system certification program, currently under development, will be based on the ASME NQA-1 standard. The program will address issues with quality products and associated documentation from suppliers of products and services needed for the construction of nuclear facilities that are outside the scope of BPV Section III and the existing N-type product certification program. Since no specific product standard is relevant, the management system approach was selected to certify suppliers.
- Certificate (Bolted Flange Jointing personnel) – Industry and the ASME PCC committee identified the need for training and qualification of bolted flange jointing personnel through knowledge and skills training combined with written and practical examinations. Multiple vendors were identified as potential training organizations, but there were no organizations providing certification. The original proposal was modeled after the QEI accreditation program, but it was observed that there existed no foundation upon which ASME could

impose an additional layer of conformity assessment. A Personnel Certification program was also considered, but a Certificate program was finally recommended due to the emphasis on training and desire for a consistent and portable ASME credential.

6 NEW PROGRAM EVALUATION PROCESS

To supplement the requirements of CSP-63 (Ref. [1]) each proposal for new Conformity Assessment program should include, address, and/or demonstrate the following:

- (a) Assign a senior S&C staff advisor

Due to the corporate responsibility associated with conformity assessment and credentialing programs, S&C staff leadership is essential for the timely and proper evaluation and subsequent initiation of new programs. Staff will work in partnership with volunteer subject matter experts close to the relevant industries in order to implement the referenced policies and the guidelines in this document. A staff Director or Managing Director will be designated as the advisor to perform the program evaluation, and may utilize additional staff resources as necessary. Authority, responsibility, and accountability remain with the designated staff advisor.

- (b) Select the most appropriate structure for the new program.

Section 1 above provides guidelines for deciding on the appropriate structure. Note, if a Certificate program is selected, CSP-63 does not apply. The guidelines below should still be helpful. Since any new credentialing program represents a corporate commitment by ASME, the decision to initiate a new Certificate program will fall within the ASME senior staff.

- (c) Confirm that the new program aligns with ASME enterprise and S&C priorities.

- (d) Establish through multiple rigorous methods a clear market/industry need.

In its simplest form, marketing includes identifying the potential market and determining how best to reach it. Many of these activities may already be accomplished qualitatively through the development of the initial concept; however, a further quantitative analysis is essential to development of estimated program financials justifying viability of the program.

Market analysis has been performed in the past through staff analysis, volunteer/project team analysis, formal industry surveys, and even engagement of professional marketing firms. No single method has consistently resulted in or can guarantee success. It is understood that market analysis is not an exact science, and that ultimately the decision to initiate a new program will involve some commercial risk by ASME and therefore confidence must be established. A realistic market analysis will help establish this confidence and increase the comfort level of decision makers. It is suggested that the market analysis address, but not be limited to, the following:

- Determine current related practices for conformity assessment or credentialing
- Estimate market size, including the number of potential certificate holders
- Ability to clearly articulate the value added by ASME

- Confirmation that ASME is the right organization to host the new program
 - Willingness of users to pay for the services. This includes both the additional cost to purchasers of certified products and employers of certified personnel.
 - Perform environmental scanning of similar existing programs serving the same or similar industries. Collect data on number of certificate holders and average fees for similar services.
 - Determine the willingness of industry/government stakeholders to fund program development
 - Determine the potential for regulatory adoption
- (e) Identify and quantify all resources to be utilized for development, launch, and operation of the new program.

It is understood that some initial ASME investment (including financial, volunteer, and staff resources) will be necessary to initiate any new conformity assessment or certificate program. A detailed financial analysis based on the market analysis, program attributes, and required resources is necessary to inform the decision on program viability within the overall ASME enterprise. The cost estimates should include an estimate of staff costs using average loaded labor rates.

Although ASME is a not-for-profit, new programs should be developed to ultimately cover all direct and indirect costs through operations with a reasonable return on the initial investment. It is recognized that many ASME enterprise programs do not cover costs and must be subsidized by the surplus of successful program; however, new Conformity Assessment or Certificate programs expecting to operate at a loss will likely not be initiated, without strong alignment with ASME's mission.

Any new program relies on the availability of resources, primarily staff and consultants. All new programs will demand some degree of staff and volunteer resources at start-up; however, the degree will depend on the variation from current practices. Availability and training of consultants who perform conformity assessment-related audits is largely dependent on whether ASME has an established presence in corresponding industry and can utilize an existing group/network rather than seeking new people from a new industry.

- (f) Establish the relative prioritization of the proposed new program within all new initiatives under consideration.

Figure 2 shows the existing and potential new ASME conformity assessment and credentialing programs. A potential new program's relative ranking within this framework should be established to allow informed decisions where resource constraints may exist. This ranking should consider alignment with strategies, financials, liabilities, facilities, and resources (staff, volunteer, and contractors).

- (g) Evaluate incremental risk/reward

Conformity assessment and credentialing programs can potentially introduce significant corporate risk. This risk must be assessed and balanced against the potential rewards

both financial and in terms of impact in achieving ASME's mission. Volunteer subject matter experts can help identify the potential areas of concern, consequences, probability, as well as possible mitigation plans; however, the ultimate decision on whether the risk is acceptable is a corporate decision to be made by senior staff in consultation with legal counsel, as necessary. ASME corporate liability and risk should always be considered.

(h) Establish major decision milestones

Presuming the above analysis results in approval to proceed with program development; this approval should not preclude re-evaluation in the event actual conditions or performance varies significantly from expectations. The program development plan should include milestones and criteria allowing for validation of original assumptions or reassessment of the "Go- No Go" decision to initiate the new program. These milestones should also be considered in the execution of any formal agreements (contracts) with sponsors, partners, or contractors.

(i) Exit strategy

All programs need to be evaluated periodically during development to determine whether they are continuing to accomplish their intended purposes. The consequences of discontinuing a program that is ineffectual needs to be considered from its inception. As a general rule, positive action toward development should be taken within three years of Council action otherwise the development project should be terminated.

(j) Consideration of the direction and trends in Section 8 below.

7 REVIEW AND APPROVAL

To supplement and clarify the requirements of CSP-63 (Ref. [1]) relative to review and approval of new conformity assessment and credentialing programs, the review and approval flow presented below is generally recommended.

- (a) Initial concept - The initial concept for a potential new conformity assessment or credentialing program may originate from multiple sources including ASME S&C staff, stakeholders, an S&C volunteer committee, staff or volunteers from another ASME enterprise group, and S&C supervisory or advisory board, or the Council on Standards & Certification.
- (b) Endorse concept- The S&C staff advisor shall present the concept to S&C senior staff for discussion as early as possible in the process; ideally prior to significant investment of volunteer or staff resources toward development of the business plan. S&C senior staff will provide initial feedback, including concerns or recommendations, and an endorsement to continue with program development. Alternatively, S&C senior staff may elect to terminate further development if it becomes clear the program does not appropriately fit within ASME.
- (c) Develop business plan - The S&C staff advisor will coordinate with the initiating group to establish and populate a project team to evaluate the concept and develop the corresponding proposal and business plan (or project plan). Formation of the project team does not necessarily require an action by any S&C committee, board, or the council but such formation may be appropriate in order to raise the priority or visibility of the

activity or facilitate engagement of stakeholders. Stakeholder and volunteer feedback will be necessary during development of the business plan. As a courtesy it may also be appropriate to solicit feedback from board members who must later approve the program provided it is understood intermediate approval milestones must also be satisfied.

- (d) Draft plan review - The S&C staff advisor shall present the complete draft business plan to S&C senior staff for review prior to any board action. Feedback shall be incorporated into revisions to the plan. Concerns and recommendations should be provided. Alternatively, S&C senior staff may elect to terminate further development if it has become clear the program does not appropriately fit within ASME.
- (e) Final plan review and approval - The S&C staff advisor and the project team will finalize the business plan, and the formal review sequence below will be followed. S&C senior staff shall be informed of any significant program modifications resulting from review and comment at each level.
 - Review and comment:
 - Relevant ASME standards committee(s)
 - Corresponding Supervisory Board
 - Board on Conformity Assessment (BCA)
 - Board on Codes & Standards Operations (BCO)
 - Approvals:
 - ASME S&C senior staff
 - Recommendation from appropriate Supervisory Board
 - Council on Standards & Certification (CSC)

8 FUTURE DIRECTION AND TRENDS

- Take conformity assessment requirements out of code books.
- Utilize the consensus standards development process to create conformity assessment program requirements and criteria, but do not issue conformity assessment criteria documents as consensus standards.
- Form conformity assessment committees under BCA rather than as subcommittees for technical standards committees.
- ANSI accreditation of Certification or Certificate programs is not required, but may be appropriate on a case-by-case basis. ANSI accreditation only evaluates compliance with the general requirements of References [8] and [5], respectively.
- The CSC took action on February 15, 2012 to withdraw from accreditation of personnel certification bodies.

- Future growth of ASME S&C is anticipated to be in conformity assessment (product and personnel certification) and training, and will include establishing ASME as a premier Credentialing organization.
- There is an industry trend toward central third-party personnel certifications rather than owner certifications. Owner certifications are essentially “self-certification”, which has inherent conflicts. ASME can serve a valuable role in central certification, but presence of established programs should be carefully considered.
- There is an industry trend toward mandatory training and credentialing (i.e., Certificate program) rather than just assessment.
- Staff and volunteer committees may both participate in accreditation and certification decisions.

9 REFERENCES

- [1] Codes & Standards Policies
(<http://cstools.asme.org/csconnect/pdf/CommitteeFiles/7614.pdf>) including:
- CSP-5 “Code Symbol Stamps and ASME Marking”
 - CSP-20 “Policy on Conformity Assessment”
 - CSP-53 “Policy on Protection of ASME Marks”
 - CSP-55 “Joint Conformity Assessment Activities”
 - CSP-58 “Review of Conformity Assessment Requirements”
 - CSP-63 “Guide for Establishing New ASME Conformity Assessment Programs”
- [2] Conformity Assessment Policies
(<http://cstools.asme.org/csconnect/pdf/CommitteeFiles/3729.pdf>) including:
- CAP-13 “Establishment of Conformity Assessment Programs”
- [3] S&C online Training Modules (<http://cstools.asme.org/trainingmodules.cfm>)
- A2 “Codes & Standards Products”
 - B3 “Conformity Assessment: Roles and Responsibilities”
 - B9 “ASME Conformity Assessment Programs”
- [4] Conformity Assessment Training Manual, Part 1: Overview of Programs and Policies (Rev 0, December 5, 2008)
- [5] ASTM E2659-09 Standard Practice for Certificate Programs¹⁰
- [6] ISO/IEC 17000 Conformity assessment -Vocabulary and general principles
- [7] ISO/IEC 17011 Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
- [8] ISO/IEC 17024 General requirements for bodies operating certification of persons¹¹
- [9] ISO/IEC Guide 67 Fundamentals of product certification

¹⁰ ASME Training & Developing is developing a new best practices document for Certificate programs that bounds the requirements of ASTM E2659 and includes ASME-specific guidance.

¹¹ ASME Technology & Personnel Certification is developing a new best practices document for Personnel Certification programs that bound the requirements of ISO/IEC 17024 and includes ASME-specific guidance.

Record of Revisions

<u>Revision</u>	<u>Description</u>	<u>Issue Date</u>
0	Initial Issue	January 19, 2012
1	Revised per CSC action on February 15, 2012 to withdraw from accreditation of personnel certification bodies; new BPE program launch; revised management system certification	February 24, 2012