



## **Introduction to Quality Assurance in Welding**

Certification Department

**Disclaimer:** this document is intended to provide introductory information on quality assurance. It does not reflect the official position or policies of the American Welding Society. Opinions expressed within are solely those of the author. The reader is advised to consult the latest edition of any standards mentioned in this introduction.

## Table of Contents

Introduction and Scope .....	4
General Principles of Quality Assurance .....	4
History of QA.....	5
QA versus QC.....	6
Elements of a QA Program for Welding.....	6
Program Plan/Management Responsibilities.....	6
Welding/Brazing Procedure Specifications .....	7
Qualification of Welding Procedures .....	7
General Welding Requirements.....	8
Qualification of Welders/Brazers.....	8
Filler Metal Procurement/Storage/Control .....	8
Preheat and Postweld Heat Treatment (PWHT) .....	9
Welding Inspection Requirements.....	9
NDE Procedures and Personnel Qualification.....	9
Records/Document Control .....	10
Internal Audits and Management Review.....	10
Nonconformances .....	11
Welding Coordination .....	12
Review of requirements.....	13
Technical review .....	13
Sub-contracting.....	13
Welding personnel .....	13
Equipment .....	13
Production planning .....	13
Qualification of the welding procedures.....	14
Work instructions.....	15
Welding consumables.....	15

Materials .....	15
Inspection and testing before welding.....	15
Inspection and testing during welding.....	15
Inspection and testing after welding.....	16
Postweld heat treatment (PWHT).....	16
Nonconformance and corrective actions .....	16
Calibration and validation of measuring, inspection and testing equipment.....	16
Identification and traceability .....	16
Health and safety and environment.....	17
Important Topics in Quality Management.....	17
Total Quality Management (TQM) .....	17
Lean Manufacturing .....	18
Six Sigma .....	18
Key Standards Affecting Quality Management.....	18
ISO 9001 series.....	18
ISO 14000 series.....	20
ISO 3834.....	20
Key Standards for Assessing NDE Agencies for QMS Systems .....	22
Industry Certification Programs in Quality Assurance .....	23
American Institute of Steel Construction (AISC) .....	23
Structural Steel Design and Construction Certification .....	23
American Petroleum Institute (API).....	23
American Society of Mechanical Engineers (ASME).....	24
ASME Boiler and Pressure Vessel Certification Program.....	24
ASME Nuclear Quality Assurance Program.....	25
ASME Quality Program for Suppliers (QPS).....	26
American Welding Society (AWS) .....	26
AWS B5.17, Specification for the Qualification of Welding Fabricators.....	26
AWS QC47, Specification for AWS Certification of Welders and Accreditation of Test Facilities.....	27
International Aerospace Quality Group (IAQG) .....	28
AS 9100 .....	28
National Board of Boiler and Pressure Vessel Inspectors (NBBI) .....	29

Performance Review Institute (Nadcap).....	29
Principles and Practices of Auditing .....	30
ISO 19011 Guidelines for Auditing Management Systems.....	30
Conducting Audits of Quality Systems.....	31
Useful References for Additional Study .....	33

## Introduction and Scope

This introduction is intended to provide basic information to prepare the reader to participate in quality assurance activities in the field of welding. The origins and rationale for the various approaches to quality assurance will be discussed as well as some treatment of significant industry standards that may impact welding operations. In addition, the commonly accepted principles and practices of auditing are also covered so the reader can prepare for being audited as well as performing as an internal auditor. For those wishing to continue a more in-depth study of quality assurance in welding, the reader is encouraged to visit the websites of the mentioned organizations which are listed at the end of this document.

The reader is cautioned that quality assurance activities in a company are extremely dependent upon standards compliance, regulatory requirements, and contract agreements with customers. The size of a company along with the complexity of manufacture are also important factors to consider. Designing and implementing a quality assurance system should come only after extensive research into all these areas.

The reader should also be aware that the standards mentioned in this guide are constantly being revised and the reader should bear responsibility for using the latest editions where appropriate.

## General Principles of Quality Assurance

**Quality assurance (QA)** is the term used in both manufacturing and service industries to describe the systematic efforts taken to assure that the product(s) delivered to customer(s) meet with the contractual and other agreed upon performance, design, reliability, and maintainability expectations of that customer. The core purpose of Quality Assurance is to prevent mistakes and defects in the development and production of both manufactured products, such as automobiles and shoes, and delivered services, such as automotive repair and athletic shoe design. Assuring quality and therefore avoiding problems and delays when delivering products or services to customers is what ISO 9000 defines as that "part of quality management focused on providing confidence that quality requirements will be fulfilled".

## History of QA

During the Middle Ages, guilds adopted responsibility for the quality of goods and services offered by their members, setting and maintaining certain standards for guild membership.

Royal governments purchasing material were interested in quality control as customers. For this reason, King John of England appointed William de Wrotham to report about the construction and repair of ships. Centuries later, Samuel Pepys, Secretary to the British Admiralty, appointed multiple such overseers to standardize sea rations and naval training.

Prior to the extensive division of labor and mechanization resulting from the Industrial Revolution, it was possible for workers to control the quality of their own products. The Industrial Revolution led to a system in which large groups of people performing a specialized type of work were grouped together under the supervision of a foreman who was appointed to control the quality of work manufactured.

During the time of the First World War, manufacturing processes typically became more complex, with larger numbers of workers being supervised. This period saw the widespread introduction of mass production and piece work, which created problems as workmen could now earn more money by the production of extra products, which in turn occasionally led to poor quality workmanship being passed on to the assembly lines. Pioneers such as Frederick Winslow Taylor and Henry Ford recognized the limitations of the methods being used in mass production at the time and the subsequent varying quality of output. Taylor, utilizing the concept of scientific management, helped separate production tasks into many simple steps (the assembly line) and limited quality control to a few specific individuals, limiting complexity. Ford emphasized standardization of design and component standards to ensure a standard product was produced, while quality was the responsibility of machine inspectors, "placed in each department to cover all operations ... at frequent intervals, so that no faulty operation shall proceed for any great length of time."

Out of this also came statistical process control (SPC), which was pioneered by Walter A. Shewhart at Bell Laboratories in the early 1920s. Shewhart developed the control chart in 1924 and the concept of a state of statistical control. Statistical control is equivalent to the concept of exchangeability developed by logician William Ernest Johnson, also in 1924, in his book *Logic, Part III: The Logical Foundations of Science*. Along with a team at AT&T that included Harold Dodge and Harry Romig, he worked to put sampling inspection on a rational statistical basis as well. Shewhart consulted with Colonel Leslie E. Simon in the application of control charts to munitions manufacture at the Army's Picatinny Arsenal in 1934. That successful application helped convince Army Ordnance to engage AT&T's George Edwards to consult on the use of statistical quality control among its divisions and contractors at the outbreak of World War II.

After World War II, many countries' manufacturing capabilities that had been destroyed during the war were rebuilt. General Douglas MacArthur oversaw the rebuilding of Japan. He involved two key people in the development of modern quality concepts: W. Edwards Deming and Joseph Juran. They and others promoted the collaborative concepts of quality to Japanese business and technical groups, and these groups used these concepts in the redevelopment of the Japanese economy.

Although there were many people trying to lead United States industries toward a more comprehensive approach to quality, the US continued to apply the Quality Control (QC) concepts of inspection and sampling to remove defective products from production lines, essentially unaware of or ignoring advances in QA for decades.

## QA versus QC

This defect prevention aspect of quality assurance differs from the defect detection aspect of quality control and has been referred to as a *shift left* since it focuses on quality efforts earlier in product development and production (i.e., a shift to the left of a linear process diagram reading left to right) and on avoiding defects in the first place rather than correcting them after the fact.

## Elements of a QA Program for Welding

### Program Plan/Management Responsibilities

Planning a quality management system requires inputs from several sources, and program planners must incorporate all of these inputs into an overall governing plan. Inputs to the program design must include any regulatory or licensing requirements, design considerations, construction code requirements, and company management and policy requirements.

The program plan is usually contained within a Quality Manual which sets out the manner in which a company addresses each element of the program plan. Although not considered as a formal element of a Quality Manual, the Manual should address how system procedures, work instructions, drawings, travelers and records are controlled and handled.

However the quality management system is expressed, there must be clear and unambiguous management support for the system with roles and responsibilities clearly defined. A useful way to demonstrate management commitment to the system is via an organization chart, where key positions and lines of responsibility are clearly defined. The Manual should also contain a statement of commitment signed by management to acknowledge their support.

AWS B5.17, *Specification for the Qualification of Welding Fabricators*, specifies the minimum content of a Quality Manual, which includes, but is not limited to, the following:

- Cover Page
- Management Support and Responsibilities
- Organization
- Document Control
- Material Control
- Welding
- Inspection
- Nonconformance
- Measuring and Testing Equipment
- Internal Quality Audits
- Sample Forms

## Welding/Brazing Procedure Specifications

Welding procedure specifications (WPSs) and brazing procedure specifications (BPSs) are documents that ensure repeatability of the welding performed by properly qualified welders or brazers, and welding operators. Properly qualified WPSs and BPSs should be readily available to personnel who are responsible for verifying that the welding/brazing is in accordance with those specifications.

## Qualification of Welding Procedures

System procedures should be in place to govern how welding and brazing procedures are qualified. Those procedures should specify the entire qualification process, including the base and filler materials used, the welding variables, how test coupons are tested and the individual(s) responsible for the qualification. Welding variables can be categorized as either essential or supplemental and there are rules that define what must happen when there are changes in the type of variable. The recording of these actual test variables is recorded on a Procedure Qualification Record (PQR) which forms the basis of the requirements contained in a WPS/BPS. There is not necessarily a one-to-one relationship between a supporting PQR and a specific WPS. Most codes permit a single PQR to support one or more WPSs and vice versa. Some construction codes permit the use of prequalified procedures, however, this use should be approved by the relevant engineering authority.

Various standards have been developed to govern how welding procedures are qualified. The reader should be familiar with these standards and whether they have been called out for a specific welding project. The following standards have been used world-wide:

*AWS B2.1, Specification for Welding Procedure and Performance Qualification*

*ASME Boiler and Pressure Vessel Code, Section IX, Qualification Standard for Welding, Brazing, and Fusing Procedures; Welders; Brazers; and Welding Brazing, and Fusing Operators*

*ISO 15609, Specification and qualification of welding procedures for metallic materials – Welding procedure qualification*

*ISO 15614, Specification and qualification of welding procedures for metallic materials – Welding procedure test*

The reader should be familiar with the different code requirements for the minimum welding parameters to be included on a WPS as well as which changes in those parameters would require the WPS to be requalified or revised.

### General Welding Requirements

While WPSs/BPSs specify the actual technical conditions required to deposit a sound weld, there may be many other work requirements that have to be separately defined. These would include, but not limited to, fitup, weld preparation, gas purging, the application of preheat, postweld heat treatment (PWHT), and weld repairs.

### Qualification of Welders/Brazers

Procedures should be in place to control all aspects of welder/brazer qualification and the individual responsible for the testing including qualification and training requirements. In addition to the technical requirements in place for procedure qualification, welder/brazer qualification procedures should include retest requirements, detailed qualification records that indicate the welders/brazers, processes used, position tested in, ranges of qualification, and how maintenance of qualification, renewal, and expiration is handled.

### Filler Metal Procurement/Storage/Control

Requirements for procurement of filler materials should be established. These procedures should specify all applicable code, contract, and technical requirements. Personnel handling the purchase of filler materials should be trained to verify that all materials received into the company are in conformance with stated requirements.

Control of filler materials should extend to storage and issue of said materials. Procedures should be in place to ensure that all filler materials are stored in accordance with the filler material's manufacturer recommendations and codes. Traceability of filler materials issued should extend beyond the issue location to the workstation of the welder. Filler materials should only be issued to personnel qualified to use them.



Records related to the issue of filler materials should include an identification of the applicable WPS, the weld and welder, the type and size of material issued, heat or lot number of material issued, and quantity issued.

### Preheat and Postweld Heat Treatment (PWHT)

Procedures concerning preheat and PWHT should address technical aspects that satisfy the requirements that may be required on the relevant WPS. These would include the methods of preheat and PWHT, rates of heating/cooling, hold times, and characteristics of company-owned PWHT equipment. In addition, the equipment used for measuring and recording temperature, how that equipment is calibrated, the thermocouple location(s) and what information is included on PWHT documentation should be defined.

### Welding Inspection Requirements

Because of the inability of visual weld examination to determine weld quality after welding is completed, it is important to establish hold points where welding is suspended pending the outcome of visual or other NDE procedures. These hold points should be carefully considered and uniformly applied. These requirements would be appropriately included in the welding instructions. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

When visual examination and NDE procedures are applied to in-process welds, both acceptance criteria and the qualification of inspection/NDE personnel should be clearly specified. The specification requirements should conform to any applicable code or customer requirements.

All welds are to be identified by suitable means to show the inspection and test status, that is, whether the welds are in conformance or nonconformance. This identification shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation, and servicing of the weldment to ensure that only welds that have passed the required inspections and tests are delivered.

Measurement devices play a key role throughout the welding process and many codes require that strict calibration procedures should be in place and implemented. Where available, calibration standards traceable to a national standard (i.e., the National Institute of Standards and Technology (NIST)) should be used. Records of all calibrations should be maintained.

### NDE Procedures and Personnel Qualification

NDE methods are generally grouped to those methods appropriate for detecting surface irregularities such as magnetic particle testing (MT) and liquid penetrant testing (PT) and those for volumetric examination such as radiographic testing (RT) and ultrasonic testing (UT). Both groups of methods have specific procedures that address the application of the method chosen. These procedures must be qualified and applied by personnel that are qualified for each specific procedure.

## Records/Document Control

Records are extremely important to verify that the quality management system is working correctly and that all work performed conformed to the requirements of the quality management system. Procedures should be in place to define how and who generates the record, how that record is maintained and how long that record is retained. These procedures should be in compliance with applicable code, regulatory or customer requirements.

At a minimum, the following records should be considered as integral to a welding quality management system:

- Procedure qualification records (PQRs)
- Welder qualification records (WQTRs)
- Welder maintenance of qualification records
- PWHT records
- Filler material issue records
- Records of weld examinations, visual and NDE
- Equipment calibration records
- Qualification records for visual and NDE inspectors
- Weld travelers
- Weld repair records
- Training records for all welding coordinators
- Internal audit reports

## Internal Audits and Management Review

Any quality management system can benefit from an internal self-assessment to identify potential problems with system procedures, communication, organizational effectiveness, and clarity of roles. Any assessments performed should have a goal of verifying that the system is effective in making sure that the welding is in conformance with all applicable code, regulatory, and customer requirements.

Procedures should be in place to define the frequency of internal audits and the scope of the audits desired. Audits can focus on specific activities (i.e., welder qualification) or interdepartmental programmatic controls which specify the interfaces between departments. Audit checklists should be part of the self-assessment process so that all personnel understand the process.

ISO 19011 considers internal audits to be “first party” audits and a best practice would specify that the internal auditor be qualified to conduct properly designed audits and be independent of the activities being audited in the company. The primary responsibility of an internal auditor is to report to management on the effectiveness of the quality assurance system in place. It is up to management to make any changes in the procedures included in the quality assurance system.

The method of communication between the internal auditor and management is typically through a management review. A management review is performed or directed by senior-level management to assure and validate the overall effectiveness of the organization, personnel and procedures by establishing the overall expectations for implementation of the quality assurance program and taking responsibility for obtaining the desired end result. Management should believe that quality is achieved and maintained by those assigned responsibility for performing the work and verified by those not directly responsible for performing the work. Management reviews are performed at a frequency sufficient to maintain adequate control and documented as well as any corrective actions taken.

#### Nonconformances

This requires the fabricator to have procedures to ensure that nonconforming product is prevented from unintended use or installation. This control shall provide for such things as: identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned.

The resolution of nonconformances requires the fabricator to establish and maintain documented procedures for implementing corrective and preventive actions. Any corrective or preventive action that is taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered. The fabricator should implement and record any changes to the documented procedures resulting from corrective or preventive actions.

Procedures to address corrective actions should include the following elements:

- Effective handling of customer complaints and reports of product nonconformities;
- Investigation of the cause of nonconformities relating to product, process, and quality system, and recording the results of the investigation;
- Determination of the corrective action needed to eliminate the cause of nonconformities;
- Application of controls to ensure that corrective action is taken and that it is effective.

Procedures to address preventive actions should include the following elements:

- Use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports, and customer complaints to detect, analyze, and eliminate potential causes of nonconformities;
- Determination of the steps needed to deal with any problems requiring preventive action;
- Initiation of preventive action and application of controls to ensure that it is effective;
- Ensuring that relevant information on actions taken is submitted for management review.

Procedures should be in place to prevent nonconforming products are prevented from unintended use or installation. This control shall provide for such things as: identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned.

### Welding Coordination

ISO 14731 *Welding coordination – Tasks and responsibilities* introduces a new term for an existing concept; that certain individuals in a welding manufacturing company make crucial welding decisions and must be qualified to make those decisions. ISO 3834 (see below) addresses the human factor in making welding decisions by calling out ISO 14731.

A company seeking certification to ISO 3834 must employ individuals who are qualified to do the tasks outlined in Annex B of ISO 14731 for the level of ISO 3834 that they are seeking. For some companies, a single welding coordinator may be sufficient to cover all of the required tasks. For more complex manufacturing, a team of welding coordinators may be necessary. The audit of the company will check that someone is qualified for each of the tasks in Annex B, even though a single individual may not be qualified to do the entire list of tasks. For companies seeking certification at the comprehensive level (ISO 3834-2) the criticality of the weldments and metallurgical complications will probably require a welding coordinator who possesses an undergraduate degree in welding engineering, an AWS Certified Welding Engineer (CWEng), or an International Welding Engineer (IIW IWE) qualification. This welding coordinator was previously referred to as the Responsible Welding Coordinator (RWC).

The following tasks are a synopsis of tasks identified in Annex B of ISO 14731 and a quality assurance system should identify individuals and their qualification to properly carry out the tasks.

## Review of requirements

The review of the governing standard, the customer requirements, and any supplementary requirements shall be used and considered with regards to the capability of the fabricator to meet those requirements.

## Technical review

A technical review of the welding shall be conducted which considers the desired service conditions of the weld, the design and joint configuration of the weld, and the specification of base and filler metals. Acceptance criteria should be verified as well as the location and accessibility of the welds with regards to inspection and nondestructive testing.

## Sub-contracting

For any subcontracted work, the ability of the subcontractor to meet the fabrication requirements shall be considered.

## Welding personnel

With regards to welding personnel, the qualification of welders and welding operators shall be considered and in conformance with the relevant contract requirements.

## Equipment

Equipment that is used for the welding should be selected to ensure suitability to deliver the desired welds in accordance with a welding procedure specification. Such equipment shall be adequately maintained and calibrated where applicable. Personal protective gear for equipment operators should be available and in good condition.

## Production planning

The following elements shall be considered with regard to production planning:

- reference to the appropriate procedure specifications for welding and related processes;
- the sequence in which the welds are to be made;
- environmental conditions (e.g. protection from wind, temperature and rain);
- the allocation of competent personnel;
- equipment for preheating and post-heat treatment, including temperature indicators; and
- the arrangement for any production test.

Production planning shall ensure that only qualified procedures and personnel are utilized for all welding and allied processes. Sequencing of the welding should be clear to all personnel and the welding should be performed in environmental conditions that permit proper welding. All equipment necessary to apply preheat and postweld heat treatments should be available and in good working order.

#### Qualification of the welding procedures

With regard to the qualification of the welding procedures, the method and range of qualification and all variables shall be considered against the relevant contract requirements.

## Work instructions

With regard to work instructions, the issuing and use of work instructions shall be considered.

## Welding consumables

The selection and purchase of welding filler materials shall consider compatibility with procedures and equipment, the conditions of delivery inspection and the storage and issue of such materials.

## Materials

Base materials used in fabrication should be reviewed to ensure that any supplementary requirements are addressed, the weldability of the base materials has been considered, how such material will be stored and issued, and what procedures are in place for traceability.

## Inspection and testing before welding

The following elements shall be considered with regards to inspection and testing before welding:

- the suitability and validity of welders' and welding operators' qualification certificates;
- the suitability of the welding procedure specification;
- the identity of the base materials;
- the identity of welding consumables;
- joint preparation (e.g. shape and dimensions);
- fit-up, jiggling and tacking;
- any special requirements in the welding procedure specification (e.g. prevention of distortion); and
- the suitability of working conditions for welding, including the environment.

## Inspection and testing during welding

The following elements shall be considered with regards to inspection and testing during welding:

- essential welding parameters (e.g. welding current, arc voltage, and travel speed);
- the preheating/interpass temperatures;
- the cleaning and shape of runs and layers of weld metal;
- back gouging;
- the welding sequence;

- the correct use and handling of welding consumables;
- control of distortion; and
- any intermediate examination (e.g. checking dimensions).

### Inspection and testing after welding

The following elements shall be considered with regards to inspection and testing after welding:

- the use of visual inspection (for completeness of welding, weld dimensions, shape);
- the use of non-destructive testing;
- the use of destructive testing;
- the form, shape, tolerance and dimensions of the construction; and
- the results and records of post-operations (e.g. postweld heat treatment, ageing).

### Postweld heat treatment (PWHT)

All PWHT activities shall be in conformance with the welding procedure specification, PWHT equipment shall be in good order, and only qualified technicians shall apply the treatment.

### Nonconformance and corrective actions

With regards to nonconformance and corrective actions, the necessary measures and actions (e.g. weld repairs, re-assessment of repaired welds, corrective actions) shall be considered.

### Calibration and validation of measuring, inspection and testing equipment

With regards to the calibration and validation of measuring, inspection and testing equipment, the necessary methods and actions shall be considered.

### Identification and traceability

The following elements shall be considered with regards to identification and traceability:

- the identification of production plans;
- the identification of routing cards;
- the identification of weld locations;
- the identification of non-destructive testing procedures and personnel;
- the identification of the welding consumable (e.g. designation, trade name, manufacturer of consumables and batch or cast numbers);



- the identification and/or traceability of base material (e.g. type, cast number);
- the identification of the location of repairs;
- the identification of the location of temporary attachments;
- traceability for fully mechanized and automatic welding units to specific welds;
- traceability of welder and welding operators to specific welds; and
- traceability of welding procedure specifications to specific welds.

With regards to quality records, the preparation and maintenance of the necessary records (including subcontracted activities) shall be considered.

#### Health and safety and environment

With regards to health and safety and environmental issues, all relevant rules and regulations shall be considered.

### Important Topics in Quality Management

#### Total Quality Management (TQM)

Total quality management (TQM) consists of organization-wide efforts to "install and make permanent climate where employees continuously improve their ability to provide on demand products and services that customers will find of particular value." "Total" emphasizes that departments in addition to production (for example sales and marketing, accounting and finance, engineering and design) are obligated to improve their operations; "management" emphasizes that executives are obligated to actively manage quality through funding, training, staffing, and goal setting. While there is no widely agreed-upon approach, TQM efforts typically draw heavily on the previously developed tools and techniques of quality control. TQM enjoyed widespread attention during the late 1980s and early 1990s before being overshadowed by ISO 9000, Lean manufacturing, and Six Sigma.

There is no widespread agreement as to what TQM is and what actions it requires of organizations, however a review of the original United States Navy effort gives a rough understanding of what is involved in TQM.

The key concepts in the TQM effort undertaken by the Navy in the 1980s include:

- "Quality is defined by customers' requirements."
- "Top management has direct responsibility for quality improvement."
- "Increased quality comes from systematic analysis and improvement of work processes."
- "Quality improvement is a continuous effort and conducted throughout the organization."

## Lean Manufacturing

Lean manufacturing is a production method aimed primarily at reducing times within the production system as well as response times from suppliers and to customers. It is closely related to another concept called just-in-time manufacturing (JIT manufacturing in short). Just-in-time manufacturing tries to match production to demand by only supplying goods which have been ordered and focuses on efficiency, productivity (with a commitment to continuous improvement) and reduction of "wastes" for the producer and supplier of goods. Lean manufacturing adopts the just-in-time approach and additionally focuses on reducing cycle, flow and throughput times by further eliminating activities which do not add any value for the customer. Lean manufacturing also involves people who work outside of the manufacturing process, such as in marketing and customer service.

## Six Sigma

Six Sigma ( $6\sigma$ ) is a set of techniques and tools for process improvement. It was introduced by American engineer Bill Smith while working at Motorola in 1986.

Six Sigma strategies seek to improve manufacturing quality by identifying and removing the causes of defects and minimizing variability in manufacturing and business processes. This is done by using empirical and statistical quality management methods and by hiring people who serve as Six Sigma experts. Each Six Sigma project follows a defined methodology and has specific value targets, such as reducing pollution or increasing customer satisfaction.

The term *Six Sigma* originates from statistical quality control, a reference to the fraction of a normal curve that lies within six standard deviations of the mean, used to represent a defect rate.

## Key Standards Affecting Quality Management

### ISO 9001 series

The ISO 9000 family is a set of five quality management systems (QMS) standards by the International Organization for Standardization (ISO) that help organizations ensure they meet customer and other stakeholder needs within statutory and regulatory requirements related to a product or service. ISO 9000 deals with the fundamentals of QMS, including the seven quality management principles that underlie the family of standards. ISO 9001 deals with the requirements that organizations wishing to meet the standard must fulfill. ISO 9002 is a model for quality assurance in production and installation. ISO 9003 for quality assurance in final inspection and test. ISO 9004 gives guidance on achieving sustained organizational success.

The global adoption of ISO 9001 may be attributable to several factors. In the early days, the ISO 9001 (9002 and 9003) requirements were intended to be used by procuring organizations, such as contractors and design activities, as the basis of contractual arrangements with their suppliers. This helped reduce the need for subcontract supplier quality development by establishing basic requirements for a supplier to assure product quality. The ISO 9001 requirements could be tailored to meet specific contractual situations, depending on the complexity of the product, business type (design responsibility, manufacture only, distribution, servicing, etc.), and risk to the procurer. If a chosen supplier was weak in the controls of their measurement equipment (calibration), and hence QC/inspection results, that specific requirement would be invoked in the contract. Adopting a single quality assurance requirement also leads to cost savings throughout the supply chain by reducing the administrative burden of maintaining multiple sets of quality manuals and procedures.

It is important to note that the ISO 9001 standard has undergone revisions over the years. The authoring committee for this standard is ISO/TC 176. Below is a summary of the relevant changes to the standard.

1994. The first revision emphasized preventive action and made a first attempt at slowing down the documentation paper mill.

2000. The second revision was a complete rewrite and did away with the three separate standards. It focused on process management instead of reactive quality assurance and quality control. It placed a higher burden on senior management to integrate quality management into business management.

2008. This revision introduced clarifications from the ongoing work of TC 176 and began harmonization with ISO 14001:2004.

2015. Another complete rewrite of the standard, this version introduced a new era of Quality Management Systems. It suggested replacing preventive action with risk-based thinking. Further, it created a focus on business performance instead of quality metrics and greatly streamlined the required documentation.

The organization of ISO 9001:2015 is as follows:

1. Process approach
2. Plan-Do-Check-Act cycle
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvements

The International Organization for Standardization (ISO) does not certify organizations themselves. Numerous certification bodies exist that audit organizations and issue ISO 9001 compliance certificates upon success. Although commonly referred to as "ISO 9000" certification, the actual standard to which an organization's quality management system can be certified is ISO 9001:2015 (ISO 9001:2008 expired around September 2018). Many countries have formed accreditation bodies to authorize ("accredit") the certification bodies. Both the accreditation bodies and the certification bodies charge fees for their services. The various accreditation bodies have mutual agreements with each other to ensure that certificates issued by one of the accredited certification bodies (CB) are accepted worldwide. Certification bodies themselves operate under another quality standard, ISO/IEC 17021, while accreditation bodies operate under ISO/IEC 17011.

### ISO 14000 series

ISO 14000 is a family of standards by the International Organization for Standardization (ISO) related to environmental management that exists to help organizations (a) minimize how their operations (processes, etc.) negatively affect the environment (i.e. cause adverse changes to air, water, or land); (b) comply with applicable laws, regulations, and other environmentally oriented requirements; and (c) continually improve in the above.

ISO 14000 is similar to ISO 9000 quality management in that both pertain to the process of how a service/product is rendered, rather than to the service/product itself. As with ISO 9001, certification is performed by third-party organizations rather than being awarded by ISO directly. The ISO 19011 and ISO 17021 audit standards apply when audits are being performed.

### ISO 3834

Welding is a special process in that the final result may not be able to be verified by testing. The quality of the weld is manufactured into the product, not inspected after the fact. This means that welding normally requires continuous control or that specific procedures be followed, or both. ISO 3834 deals with quality requirements in welding and has been prepared in order to identify those controls and procedures.

One of the significant aspects of ISO 3834 is that it is one of the first standards to place emphasis on the human factor in welding. It identifies, through using ISO 14731 as a reference, essential tasks that require correct decisions based on the qualifications of the individual making those decisions.

ISO 3834 is not a quality system standard intended to take the place of ISO 9001, but a useful, additional tool for use when ISO 9001 is applied by manufacturers, in which case the meeting of its requirements needs to be recorded in certificates or documentation.

However, ISO 3834 can be used independently of ISO 9001. Users seeking certification should be aware that the assessment of requirements in accordance with ISO 3834 requires highly competent welding professionals and the mere fact that an ISO 9001 certified company also performs welding does not certify that company to ISO 3834.

ISO 3834 is intended for the fusion welding of metallic materials, and its application is independent of the products manufactured. However, its principles and many of its detailed requirements are also relevant for other welding and welding-related processes.

One of the aims of ISO 3834 is to define requirements in the field of welding so that contracting parties or regulators do not have to do this themselves. A reference to a particular part of ISO 3834 should be sufficient to demonstrate the capabilities of the manufacturer to control welding activities for the type of work being done.

ISO 3834 does not in itself require external assessment or certification. However, assessments by customers and certification by independent bodies are growing trends in commercial relations and the standard can serve as a basis for these purposes, as well as for the demonstration of performance by those manufacturers implementing it.

It is strongly recommended that potential users of ISO 3834 purchase those parts of ISO 3834 that are applicable to the level of control desired (ISO 3834-2, 3834-3, or 3834-4). ISO 3834-1 is a good start to understand which level of quality requirements may be appropriate for the welded products of a particular company.

*ISO 3834, Quality requirements for fusion welding of metallic materials – Part 1: Criteria for the selection of the appropriate level of quality requirements*

This part of ISO 3834 provides a general outline of ISO 3834 and criteria to be taken into account for the selection of the appropriate level of quality requirements for fusion welding of metallic materials, among the three levels specified in ISO 3834-2, ISO 3834-3 and ISO 3834-4. It applies to manufacturing, both in workshops and at field installation sites.

*ISO 3834, Quality requirements for fusion welding of metallic materials – Part 2: Comprehensive quality requirements*

This part of ISO 3834 defines comprehensive quality requirements for fusion welding of metallic materials both in workshops and at field installation sites.

*ISO 3834, Quality requirements for fusion welding of metallic materials – Part 3: Standard quality requirements*

This part of ISO 3834 defines standard quality requirements for fusion welding of metallic materials both in workshops and at field installation sites.

*ISO 3834, Quality requirements for fusion welding of metallic materials Part 4: Elementary quality requirements*

This part of ISO 3834 defines elementary quality requirements for fusion welding of metallic materials both in workshops and at field installation sites.

*ISO 3834, Quality requirements for fusion welding of metallic materials – Part 5: Documents with which it is necessary to conform to claim conformity to the quality requirements of ISO 3834-2, ISO 3834-3, or ISO 3834-4*

The ISO 3834 series of standards call out a number of ISO standards to govern welder and procedure qualification, inspection, and NDE requirements. For companies that use national standards other than ISO, provisions are available for those technically equivalent standards to be used. Part 5 also delineates between Type A and Type B ISO standards which define quality requirements for fusion welding.

*ISO 3834, Quality requirements for fusion welding of metallic materials – Part 6: Guidelines on implementing ISO 3834*

This part of ISO 3834 is a Technical Report that gives guidelines for the implementation of requirements given in the other parts of ISO 3834 and is intended to help manufacturers and users select that part of ISO 3834 appropriate to their needs. It is expected that they will already be familiar with ISO 3834 as a whole.

There have been reports that quality system registrars have been issuing ISO 3834 compliance certificates solely on the basis of the company meeting ISO 9001 requirements. This is a disservice to those companies expecting a detailed welding-oriented audit of their manufacturing systems. In practice, ISO 9001 and ISO 3834 are two different standards and the audits for each should be detailed for the requirements of each respective standard. As different standards, companies can choose one over the other, or both if required. End-users seeking companies that must demonstrate compliance to ISO 3834 should not accept compliance to ISO 9001 as evidence of meeting ISO 3834.

For those companies that implement both ISO 9001 and ISO 3834, readers are advised to consult ISO 3834-1 clause 6 to see ISO 9001 QMS requirements that should be addressed to support ISO 3834.

### Key Standards for Assessing NDE Agencies for QMS Systems

ASTM International has published three standards that can be used to determine and assess whether an agency performing NDT operations is capable of performing those operations in a competent manner. All of the ASTM standards below cross-reference each other extensively as well as the ISO 9000 and 17000 series standards.

*ASTM E0543, Standard Specification for Agencies Performing Nondestructive Testing* covers the minimum requirements for agencies performing NDT. It is intended to be

used to evaluate both testing and inspection agencies and can be used in conjunction with ASTM E1359.

ASTM E1212, *Standard Practice for Establishing Quality Management Systems for Nondestructive Testing Agencies* establishes the general requirements for QMS systems utilized by agencies performing NDT activities. The practice utilizes criteria expressed in ANSI/ISO/ASQ 9001 and references ASTM E0543 and E1359, as well as ASNT SNT-TC-1A and ASNT CP 189.

ASTM E1359, *Standard Guide for Auditing and Evaluating Capabilities of Nondestructive Testing Agencies* establishes areas for review based on industry accepted practices and provides an audit checklist. Areas of review include facilities, organization, documentation of policies, contract review, equipment calibrations, and personnel qualification.

### Industry Certification Programs in Quality Assurance

American Institute of Steel Construction (AISC)

Structural Steel Design and Construction Certification

The AISC *Governing Requirements for Certification Programs* (GRs) provide for the administration of the audit program from application to certification, and they apply to every participant or applicant. The AISC Supplemental Requirements are additional requirements that are tailored for a specific certification or endorsement. For example, a Certified Bridge Fabricator must adhere to the GRs and the *Supplemental Requirements for Bridge Fabricators* - similar to how they must meet the criteria of Chapter 1 & 4 of the *Standard for Certification Programs*.

Governing Requirements for Certification Programs

Supplemental Requirements for Building Fabricators (BU)

Supplemental Requirements for Bridge Fabricators (SBR, IBR, ABR)

Supplemental Requirements for Highway Component Manufacturers (CPT)

Supplemental Requirements for Fabricators of Hydraulic Steel Structures (HYD, HYDA)

Supplemental Requirements for Erectors (CSE)

Supplemental Requirements for Fracture Control Endorsement (FCE)

Supplemental Requirements for Complex Coatings Endorsement (CCE)

Useful Reference: Download AISC 207-20 from website: [aisc.org](http://aisc.org)

American Petroleum Institute (API)

API Specification Q1 *Specification for Quality Management System Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industry*

This specification has been developed to address quality management systems for organizations that manufacture products or provide manufacturing-related services under a product specification for use in the petroleum and natural gas industry. It defines the fundamental quality management system requirements for those claiming conformity to the requirements of this specification.

API Q1 establishes the minimum quality management system requirements for organizations that manufacture products or provide manufacturing-related processes under a product specification for use in the petroleum and natural gas industry.

This specification specifies the requirements of a quality management system for an organization to demonstrate its ability to consistently provide reliable products and manufacturing-related processes that meet customer and legal requirements.

If an organization performs activities addressed by this specification, no claims to exclusion of those activities are permitted. Where any requirement of this specification cannot be applied due to the nature of an organization, the requirement can be considered for exclusion. Where exclusions are made, the basis for claiming exclusions is to be identified. Furthermore, such exclusions cannot affect the organization's ability, or responsibility, to provide products and related servicing that meet customer and applicable regulatory requirements. Exclusions are limited to the following sections:

- Design and Development
- Servicing
- Validation of Processes for Production and Servicing
- Customer-supplied Property
- Control of Testing, Measuring, and Monitoring Equipment

API has also introduced a second quality management specification for supply organizations, API Specification Q2, *Quality Management for Service Supply Organizations for the Petroleum and Natural Gas Industry*.

It should be noted that API has restructured its program for certifying auditors for both the API Q1 and API Q2 programs. The API website should be consulted for the current requirements for certifying auditors for these two specifications.

American Society of Mechanical Engineers (ASME)

ASME Boiler and Pressure Vessel Certification Program

The ASME BPVC Certification Program conforms to the rules governing the design, fabrication, assembly, and inspection of boiler and pressure vessel components during construction. In 1916, shortly after the first publication of the *Rules for the Construction of Stationary Boilers and for Allowable Working Pressures* (known today as the ASME BPVC), ASME began offering certification to companies in the pressure equipment industry to certify their quality control systems comply. Products manufactured by ASME



BPVC Certificate Holders are certified and stamped with the Certification Mark in accordance with the applicable ASME BPVC Section. The ASME Certification Mark can only be applied by fabricators which possess a Certificate of Authorization issued by ASME. Today there are more than 6,800 Certificate Holders in the ASME BPVC Certification Program.

Scopes offered by the ASME BPVC Certification Program vary and include but are not limited to: power boilers, heating boilers, pressure vessels, fiber-reinforced plastic vessels, transport tanks and valves.

### ASME Nuclear Quality Assurance Program

The ASME Nuclear Quality Assurance (NQA-1) Certification Program provides centralized, independent, third-party certification for quality assurance programs in conformance with the ASME NQA-1 standard, *Quality Assurance Requirements for Nuclear Facility Applications*. It entails a full audit of the Quality Assurance Program performed by trained ASME auditors with an extensive background in quality assurance. A successful audit will yield a NQA-1 Quality Program Certificate. Examples of nuclear facilities can include reactors such as, nuclear power plants (NPP), small modular reactors (SMR), microreactors, and advanced reactors, and the handling of radioactive and/or fissionable materials for fuel processing, and fuel recycling.

The ASME NQA-1 Certification Program seeks to meet the needs of the nuclear industry by expanding the supply chain with organizations who are committed to understanding quality and providing high quality products and services.

ASME will not perform audits or certify:

- to the ASME NQA-1 Standard published prior to the 2008 edition.
- activities pertaining to weaponry; and
- owners of nuclear facilities - facilities for power generation, spent fuel storage, waste management, fuel reprocessing, nuclear material processing, fuel fabrication, and other related facilities.

In order to obtain and maintain an ASME NQA-1 Quality Program Certificate, the Applicant must comply with requirements given in the ASME NQA-1 Standard and the conformity assessment requirements document titled, *Requirements for ASME NQA-1 Certification*. This document can be found on the Nuclear Quality Assurance (NQA-1) Certification web page.

ASME, by using Audit Teams, audits the Applicant's Quality Assurance Manual and its implementation. Any findings noted during the audit, are discussed between the Applicant and the Team, and a written report of the audit is submitted to ASME. This report is to be reviewed by ASME, which either authorizes the issuance of a Certificate valid over a three-year period or requests additional action by the Applicant. The Certificate does not authorize the use of the ASME Certification Mark; therefore, the

stamp for the ASME Certification Mark will not be issued with the Certificate. Two announced interim audits will be performed by ASME over the three-year life of the certificate. A copy of all audit reports will be furnished to the Applicant when ASME has completed its evaluation of the reports.

### ASME Quality Program for Suppliers (QPS)

The QPS Standard and its Certification program have been developed to be a supplement to technical standards that do not have a dedicated section that addresses quality and their requirements. Applying QPS to these standards will enhance quality of items supplied to general industry.

The QPS Certification Program is for any general industry organization regardless of type of product they are producing or the size of the company. Typical companies that would benefit from QPS would be, but are not limited to:

- raw material manufacturers - Ingots, slabs, additive materials
- material manufacturers - forgings, piping, fittings, castings, bolts and nuts, plates, filler metal (materials for welding)
- manufacturers with or without design responsibility - Valve Manufacturers, Oil & Gas, Power Generation, Additive Manufacturing, Hydrogen industries, Green Industries
- Service providers - NDE, Auditing, Heat Treating, Welding (Cladding), Machining, Coating

QPS is not limited to only working with ASME standard and will work as the quality program for most general industry standards. (It should be noted that the QPS program is not a replacement for any existing ASME certification programs.)

QPS is different from the typical ASME certification program. After the application has been submitted and accepted, the company undergoes a two-stage survey/review process. Survey Stage I: Document Review, determines an organization's readiness for the Survey Stage II: Implementation Review.

### American Welding Society (AWS)

#### AWS B5.17, Specification for the Qualification of Welding Fabricators

This specification establishes the minimum requirements for the Welding Quality Program for welding fabricators. It is intended to be used by welding fabricators regardless of the welding processes or materials used. It does not cover weldment design or non-welding related fabrication processes, such as bolting and coatings. It can offer assistance to the customers of welding fabricators who purchase weldments in various industry sectors in assessing the firm's capability to satisfy project quality needs.

The welding fabricator may be accredited by AWS as an AWS Certified Welding Fabricator, providing the fabricator meets the requirements of AWS QC17, *Standard for Accreditation of Welding Fabricators for AWS Certified Welding Fabricator Program*.

#### AWS QC47, Specification for AWS Certification of Welders and Accreditation of Test Facilities

This specification describes the accreditation of AWS Accredited Test Facilities (ATF), the qualification and testing of welders, and the certification of welders desiring to be listed in the AWS National Registry of Certified Welders (NRCW). The specification supersedes AWS QC4, *Standard for Accreditation of Test Facilities for AWS Certified Welder Program*, AWS QC7, *Standard for AWS Certified Welders* and all of its supplements. The elements of this program establish requirements for:

- (1) Certified Welders
- (2) Accredited Test Facilities
- (3) Qualifiers

Users wishing to set up welder test facilities not leading to AWS accreditation are advised to consult AWS B5.4, *Specification for the Qualification of Welder Test Facilities*. Users wishing to obtain AWS accreditation as an AWS ATF and certify welders for entry into the AWS NRCW shall meet the requirements of this Specification.

QC47 shall be used by welders, Qualifiers, Certified Welding Inspectors (CWI), Senior Certified Welding Inspectors (SCWI), employers, NDE technicians, and AWS Accredited Test Facility personnel to recognize and implement their responsibilities in the Program. Certification under the AWS Certified Welder Program for inclusion in the NRCW shall be conducted using AWS *B2 Standard Welding Procedure Specifications* (SWPSs) or an alternative WPS, as described in Annex A. Performance testing methods and visual acceptance criteria are derived from the governing standard chosen by the candidate or candidate's employer. It is the responsibility of the candidate or candidate's employer to select the SWPS and governing standard that is suitable for the work planned for production. When no governing standard is specified, the performance testing method and acceptance criteria shall be selected from the current revisions of AWS B2.1, *Specification for Welding Procedure and Performance Qualification*, or AWS B2.2, *Specification for Brazing Procedure and Performance Qualification*, or AWS B2.4, *Specification for Welding Procedure and Performance Qualification for Thermoplastics*. Participants (Accredited Test Facilities [ATFs] and Qualifiers) in this program conduct performance qualification tests that can result in certification in the AWS Certified Welder Program. Participants in this program may also conduct performance qualification tests that do not result in certification in the AWS Certified Welder Program.

## International Aerospace Quality Group (IAQG)

### AS 9100

AS9100 Rev D is an aerospace standard (AS) that was released by the International Aerospace Quality Group (IAQG) based on the internationally recognized standard ISO 9001. Both AS9100 and ISO 9001 are standards that include requirements for implementing a Quality Management System (QMS) in your organization; however, AS9100 is modified for aviation, space, and defense organizations.

The AS9100 standard is a set of guidelines for implementing a Quality Management System for use by aviation, space, and defense organizations (often referred to as the aerospace industry). The standard is produced by the International Aerospace Quality Group, which includes representatives from aerospace companies worldwide. The document is sometimes mistakenly referred to as “ISO 9100”; however, AS9100 is not maintained by the International Organization for Standardization (ISO). Instead, it builds on the requirements for a Quality Management System as defined in the ISO 9001 Quality Management System requirements. While the ISO 9001 standard is generally accepted by any industry around the world, AS9100 is specifically modified for aerospace companies, including some regulatory requirements. What the IAQG has done is to take the ISO 9001:2015 requirements in their entirety, and then add in specific aerospace Quality Management System requirements without removing any existing requirements, thereby creating the AS9100 Revision D standard.

When considering AS9100 vs. ISO 9001, it is the additional aerospace requirements that you want to focus on. The AS9100 standard follows the clauses in the ISO 9001 standard exactly. The content of the standard is identical to that of ISO 9001 with no deletions; however, additional requirements have been added that relate to the needs of stakeholders in the aerospace industry. In order to make the additions easy to recognize, they are in bold and italics in the document. The main additions in AS9100 occur in the primary sections on “Product Realization” and “Measurement, Analysis and Improvement.” The main sections added are for Project Management, Risk Management, Configuration Management, and Control of Work Transfers. Additional focus is placed on product safety, management of counterfeit parts, ethical behavior and human factors. Additionally, there are many updates to the requirements for the Design and Development, Purchasing, Production, and Non-conforming Product processes. The main point to remember on this standard is that it is designed by the aerospace industry specifically for aerospace companies and has little application outside this industry.

Prior to development of AS9100 standards for Quality Management Systems, the U.S. military applied two specifications to supplier quality and inspection programs, respectively, MIL-Q-9858A, *Quality Program Requirements*, and MIL-I-45208A, *Military Specification: Inspection System Requirements*. For years these specifications had represented the basic tenets of the aerospace industry. However, when the U.S. government adopted ISO 9001, it withdrew those two quality standards. Large

aerospace companies then began requiring their suppliers to develop quality programs based on ISO 9001.

The term product assurance (PA) is often used instead of quality assurance in the aerospace industry and is, alongside project management and engineering, one of the three primary project functions. Quality assurance is seen as one part of product assurance. Due to the sometimes catastrophic consequences a single failure can have for human lives, the environment, a device, or a mission, product assurance plays a particularly important role here. It has organizational, budgetary and product developmental independence meaning that it reports to highest management only, has its own budget, and does not expend labor to help build a product. Product assurance stands on an equal footing with project management but embraces the customer's point of view.

#### National Board of Boiler and Pressure Vessel Inspectors (NBBI)

NBBI administers three accreditation programs for organizations that perform repairs and alterations on pressure equipment (R, VR, NR) and one program for organizations that test pressure relief valves (T/O). Accreditation involves thorough evaluation of an organization's quality system manual and requires a demonstration of its ability to implement the system. Authorized repair organizations are issued an NBBI stamp that is applied to the equipment nameplate. The stamp signifies strict repair and/or alteration requirements have been met and verified by an NBBI Commissioned Inspector. For certain jurisdictions in the US, the National Board will maintain a registry for all pressure equipment constructed by accredited companies.

The National Board offers a *Certificate of Authorization* and NR symbol stamp for the repair and replacement of nuclear components, the R symbol stamp for the repair and/or alteration of boilers, pressure vessels, and other pressure-retaining items, the T/O mark for the in-service testing of pressure relief valves, and the VR Stamp for the repair of pressure relief valves.

The inspection and repair of installed pressure devices is governed by the *National Board Inspection Code* (NBIC) which covers post-construction activities. The NBIC is published every two years and consists of four parts covering installation, inspection, repairs and alterations, and pressure relief devices.

#### Performance Review Institute (Nadcap)

The Nadcap program is administered by the Performance Review Institute (PRI). Nadcap was established in 1990 by SAE International. Nadcap's membership consists of "prime contractors" who coordinate with aerospace accredited suppliers to develop industry-wide audit criteria for special processes and products. Through PRI, Nadcap provides independent certification of manufacturing processes for the industry. Welding is considered a special process under Nadcap rules and has its own accreditation category.

PRI schedules an audit and assigns an industry approved auditor who will conduct the audit using an industry agreed checklist. At the end of the audit, any non-conformity issues will be raised through a non-conformance report. PRI will administer and close out the non-conformance reports with the Supplier. Upon completion PRI will present the audit pack to a 'special process Task Group' made up of members from industry who will review it and vote on its acceptability for approval.

## Principles and Practices of Auditing

### ISO 19011 Guidelines for Auditing Management Systems

Since the second edition of this document was published in 2011, a number of new management system standards have been published, many of which have a common structure, identical core requirements and common terms and core definitions. As a result, ISO 19011 considers a broader approach to management system auditing that includes a risk-based analysis, as well as providing guidance that is more generic. Audit results can provide input to the analysis aspect of business planning, and can contribute to the identification of improvement needs and activities.

An audit can be conducted against a range of audit criteria, separately or in combination, including but not limited to:

- requirements defined in one or more management system standards;
- policies and requirements specified by relevant interested parties;
- statutory and regulatory requirements;
- one or more management system processes defined by the organization or other parties;
- management system plan(s) relating to the provision of specific outputs of a management system (e.g. quality plan, project plan).

This document provides guidance for all sizes and types of organizations and audits of varying scopes and scales, including those conducted by large audit teams, typically of larger organizations, and those by single auditors, whether in large or small organizations. This guidance should be adapted as appropriate to the scope, complexity and scale of the audit program.

This document concentrates on internal audits (first party) and audits conducted by organizations on their external providers and other external interested parties (second party). This document can also be useful for external audits conducted for purposes other than third party management system certification. ISO/IEC 17021-1 provides requirements for auditing management systems for third party certification; this document can provide useful additional guidance.

## Conducting Audits of Quality Systems

Conducting an audit requires close communication between the auditors and auditee. For larger audits, an audit team may be required. A designated audit team leader will make the initial contact with the auditee and the following issues should be discussed. The means of communication between the audit team and the auditee should be established. The authority under which the audit will be conducted and access to relevant information should be granted. Any regulatory or statutory requirements that are applicable should be disclosed. Any information transmitted should be considered as confidential and protections should be established. Audit fees and a schedule for conducting the audit as well as the auditee's acceptance of the composition of the audit team should be documented.

An important step in preparing for an onsite audit is a review of the documentation of the auditee. The document review serves to familiarize the audit team with a company's operations and which management system documents and reports would be useful in the audit. Previous internal audit reports and corrective actions also would be useful. An audit plan should be developed and ISO 19011 emphasizes that the audit plan should be risk-based, meaning an analysis is done on the effect of the audit itself on the company's operations and processes.

Any audit plan should clearly state both the objectives and the scope of the audit. How the evidence will be sampled and the criteria by which that evidence will be evaluated has to be included in the plan. Should there be a need for observers or translators, that also has to be planned in advance.

Once the audit plan has been developed and accepted by the auditee, the audit team leader can make assignments to the audit team so that they can collect the required information. Such assignments should take into account the impartiality and specific qualifications of the audit team members. The audit team may be comprised of individuals who have auditing expertise, technical experts who have specific knowledge sets relevant to the audit, and observers or translators. Members of the audit team shall not have professional relationships with the auditee and the auditee must approve, in advance, the composition of the audit team.

The onsite audit will commence with an opening meeting. The opening meeting has several purposes, including but not limited to confirming the scope and objectives of the audit, who is the management representative, the criteria by which the evidence will be evaluated, how progress on the audit will be reported, and how the auditee can respond to any findings developed during the audit.

Evidence collected during the audit should be evaluated based on the degree of verification that is possible. Any evidence that would lead to a formal finding should be adequately retained or documented.

Audit evidence should be evaluated against the audit criteria in order to determine audit findings. Audit findings can indicate conformity or nonconformity with audit criteria. When specified by the audit plan, individual audit findings should include conformity and good practices along with their supporting evidence, opportunities for improvement, and any recommendations to the auditee. ISO 19011 defines nonconformances that are related to regulatory requirements can be termed “non-compliances.” Any possible nonconformances should be discussed with the auditee to ensure that the evidence is accurate and the nonconformances understood. Prior to the closing meeting, the audit team should confer on the findings generated during the audit, how they will be presented to the auditee, any recommendations for improvement, and any follow-up actions that are necessary.

The primary purpose of a closing meeting is to present the audit findings and relevant conclusions. The attendees of the closing meeting should be the audit team, management representatives, and those responsible for the audited functions. The agenda for the closing meeting should include an explanation of the evidence sampling conducted during the audit, a presentation of the nonconformances in a manner that they can be understood and accepted, and an action plan for addressing the findings.

The conclusion of the audit process should be evidenced by the production of an audit final report.



## Useful References for Additional Study

<b>Document</b>	<b>URL</b>
<b>AISC Standard for Certification Programs</b>	<a href="https://www.aisc.org/globalassets/aisc/publications/standards/a207-20w.pdf">https://www.aisc.org/globalassets/aisc/publications/standards/a207-20w.pdf</a>
<b>API Q1, 9th Edition</b>	API Specification Q1, Specification for Quality Management System Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industry, 9th Edition, June 2013
<b>ASQ CQA Body of Knowledge</b>	<a href="https://www.asq.org/cert/resource/pdf/certification/2019_CQA_BOK_MAP.pdf">https://www.asq.org/cert/resource/pdf/certification/2019 CQA BOK MAP.pdf</a>
<b>ASQ Quality Resources: Auditing</b>	<a href="https://asq.org/quality-resources/auditing">https://asq.org/quality-resources/auditing</a> (free website info)
<b>AWS B2.1:2021</b>	<a href="https://pubs.aws.org/Download_PDFS/B2.1-B2.1M-2014-AMD1-PV.pdf">https://pubs.aws.org/Download_PDFS/B2.1-B2.1M-2014-AMD1-PV.pdf</a>
<b>AWS B5.17</b>	<a href="https://s3.amazonaws.com/pubs-www.aws.org/docs/AWS_B5.17-2014_SPECIFICATION_FOR_QUALIFICATION_OF_WELDING_FABRICATORS.pdf">https://s3.amazonaws.com/pubs-www.aws.org/docs/AWS_B5.17-2014 SPECIFICATION FOR QUALIFICATION OF WELDING FABRICATORS.pdf</a>
<b>AWS QC17</b>	<a href="https://pubs.aws.org/content/free_downloads/AWS_QC17-2015_Standard_for_Accreditation_of_Welding_Fabricators_for_AWS_Certified_Welding_Fabricator_Program.pdf">https://pubs.aws.org/content/free_downloads/AWS_QC17-2015 Standard for Accreditation of Welding Fabricators for AWS Certified Welding Fabricator Program.pdf</a>
<b>AWS QC47</b>	
<b>BPV-GUI-03 Issue 1, Rev. 2</b>	<a href="https://www.asme.org/getmedia/0cd8732b-fdfb-4c09-94ac-12a730a0c3cb/bpv-certification_form_checklist-accreditation_1-(2)_1.pdf">https://www.asme.org/getmedia/0cd8732b-fdfb-4c09-94ac-12a730a0c3cb/bpv-certification form checklist-accreditation 1-(2) 1.pdf</a>
<b>INPO Engineering Program Guide: Welding Program</b>	<a href="https://www.inpo.info/">https://www.inpo.info/</a>
<b>ISO 14731-2019</b>	<a href="https://www.iso.org/standard/68893.html">https://www.iso.org/standard/68893.html</a>
<b>ISO 15607 - 2003</b>	<a href="https://www.iso.org/obp/ui/#iso:std:iso:15607:ed-2:v1:en">https://www.iso.org/obp/ui/#iso:std:iso:15607:ed-2:v1:en</a>
<b>ISO 19011</b>	<a href="https://www.iso.org/standard/70017.html">https://www.iso.org/standard/70017.html</a>
<b>ISO 3834-1</b>	<a href="https://www.iso.org/standard/81650.html">https://www.iso.org/standard/81650.html</a>
<b>ISO 3834-2</b>	<a href="https://www.iso.org/standard/81651.html">https://www.iso.org/standard/81651.html</a>
<b>ISO 3834-3</b>	<a href="https://www.iso.org/standard/35146.html">https://www.iso.org/standard/35146.html</a>
<b>ISO 9001</b>	<a href="https://www.iso.org/iso-9001-quality-management.html">https://www.iso.org/iso-9001-quality-management.html</a>

<b>Nadcap Supplier Support Committee Handbook</b>	<a href="https://cdn.p-r-i.org/wp-content/uploads/2019/05/24090106/SSC-Handbook-Final-23May2019.pdf">https://cdn.p-r-i.org/wp-content/uploads/2019/05/24090106/SSC-Handbook-Final-23May2019.pdf</a>
<b>NB-57 National Board and ASME Guide</b>	<a href="https://www.nationalboard.org/SiteDocuments/NB-57.pdf">https://www.nationalboard.org/SiteDocuments/NB-57.pdf</a>
<b>NBIC</b>	<a href="https://www.nationalboard.org/index.aspx?pageID=4">https://www.nationalboard.org/index.aspx?pageID=4</a>
<b>Quality Auditor Certification CQA Pamphlet</b>	<a href="https://www.asq.org/cert/quality-auditor">https://www.asq.org/cert/quality-auditor</a>
<b>Reference Requirements for ASME NQA-1 Certification</b>	<a href="https://www.asme.org/getmedia/5200b2f8-8bea-42c9-aba5-b3f86f70cca9/nqa-certification_forms-and-resources_requirements-for-asme-nuclear-quality-assurance.pdf">https://www.asme.org/getmedia/5200b2f8-8bea-42c9-aba5-b3f86f70cca9/nqa-certification_forms-and-resources_requirements-for-asme-nuclear-quality-assurance.pdf</a>
<b>Welding Handbook, Volume 1</b>	<a href="https://www.aws.org/publications/page/10th-edition-volume-1">https://www.aws.org/publications/page/10th-edition-volume-1</a>
<b>Welding Quality Assurance and Inspection Manual (1998)</b>	<a href="https://app.aws.org/certification/docs/SCWI_studyguide.pdf">https://app.aws.org/certification/docs/SCWI_studyguide.pdf</a>