

SCWI Study Guide QUALITY ASSURANCE

INTRODUCTION

In this module, the rationale and mechanics of Quality Assurance (QA) and Quality Management Systems (QMS) are reviewed. QA is a business philosophy. QA and QMSs are aimed at eliminating the opportunities for error that arise in all business environments. Poor communications between one level and another, working from obsolete drawings, using an incorrect material; all these are common occurrences in industry. They result in rework, delayed deliveries, and added costs. They strain relations between purchaser and supplier.

With an effective QMS, most of these problems can be avoided. This means reduced production time, better deliveries, improvement in the bottom line. In well-managed establishments, it also means better pay and conditions for personnel, and a congenial working environment. Internal political squabbles can be reduced and morale enhanced. If a problem develops, there is a mechanism in place for its solution.

Of course, this obviously desirable situation does not develop overnight, it takes time. Change is involved, and many people at all levels resist change on principle. This means that when a QMS system is to be introduced to an organization, it takes time and it takes 'selling.' It requires involvement at the very top level. A QMS cannot be introduced somewhere in the middle with any hope of success.

WHY DO WE NEED A QA SYSTEM?

There are a variety of reasons for an organization to introduce a QA system. The worst possible reasons are:

- I cannot keep my best customer without a QA system,
- My competition has it, so I better fall in line.

Rather, the reason should be based on a desire to produce a better product, with on-time deliveries. Of course, if you have the perfect product, with no rework ever required and no delayed deliveries, and you pay personnel top-dollar down the line, then you do not need a quality system. Otherwise, you do.

A question that may reasonably be asked is, why now? Why didn't industrial businesses of the last century need a quality system. The answer is, they had one—as do all businesses. It is just that it had not been recognized or accepted as a formal system. Until the modern era, industry was owned and controlled by entrepreneurs. Most were on-the-shop floor managers, with the right to hire and fire on the spot if a mistake was made. The 'quality system' was whatever this person thought it should be.

Common sense and unions did away with the industrial tyrant, the 'iron masters.' Industrial relations often become strained yet today, but in most cases accommodation is reached. A new job function for people was established, the 'inspectors.' Inspectors initially gave themselves credit for everything that was right, and blamed others when things went wrong. They tended in many cases to inhabit air conditioned chambers and emerged in their own good time. Many were good people, some were not.

Over time, it became apparent that 'quality,' whatever it means, is not inspected into the job. It must be built into the job. As we in the welding industry have known for years, certainly anyone involved with products made to ASME, Section VIII (or III), there is a relatively simple way to go about things. We check the design, use only certified materials, weld to qualified procedures, and use only qualified welders. We check weld preps, joint fit-up and back-gouging and we expect the finished job to be satisfactory and it usually is.

It may be contended that a pressure vessel or boiler are special cases. That is true, especially from the point of view of insurance companies who motivated the boiler and pressure vessel codes in the early 1900s. However, to a building owner, the safety and integrity of a structure is just as important. Likewise, a fan in a mine shaft or the cage carrying the product to the surface for processing can be just as critical. Everything needs some level of quality to adequately serve its purpose. Even the farm gate, because if the prize bull gets out, there could be real trouble.

ORIGINS OF QA SYSTEMS

Since early in the 20th century, industry has been conscious that while automation can produce things faster, it can also produce scrap equally fast. Systems were developed, based on the requirements of industries producing large numbers of identical products. Over time, what we now know as 'Statistical Process Control' (SPC) methods were introduced. Names such as Shewart were instrumental in the development of the mechanics. Tables showing sample numbers (of items for testing) for a given production 'lot' have been developed and are regularly used.

The principles employed are based on well known statistical techniques. There is always variation in the output of a machine. If these variations in a 'sample of a lot' are within certain limits, fixed beforehand and based on statistical theory, the process is said to be 'in control.' However, when a sample exhibits dimensions or attributes outside these limits, the process is said to be 'out of control' and corrective action is required.

In the case of small lots, involving multiple functions, a different approach was developed to obtain similar benefits. Over the last fifty years the method has become known as Quality Assurance and the methodology as Quality Management Systems.

INTRODUCTION OF QUALITY MANAGEMENT SYSTEMS IN THE USA

While in one sense, the origin of formal QMSs was in the United States, adoption as a formal 'system' here has been somewhat later than in other countries. The story is told of Edward Deming; he was involved in the development of the QA methodology during World War II and saw the great benefits to be derived from its wide application. He spoke to many industry leaders here in the U.S. and while most expressed interest, they were put off by the time frame of 2 to 5 years for completion. As a result, no significant action took place.

Just before the Korean War, Deming was invited to Japan by General McArthur and he spoke to industrialists there. They too expressed interest. When asked how long it would take to implement, the ever-cautious Deming suggested 10 to 15 years. The response was somewhat different from that of their U.S. counterparts. "When can we get started?" was the Japanese answer. It is interesting to note that the first Hondas

came to the USA in 1967. This was about 15 years after QA was first introduced in Japan. The effect of this on the American economy and on U.S. industry in particular, has been both revolutionary and in many areas, traumatic.

On the other side of the Atlantic, late in the 1950s, the British Navy created a task force to explore ways of better assuring the quality of followed suit and a range of systems was developed. This has culminated in the 90-odd countries of the International Standards Organization (ISO) pooling their resources in what we know today as the ISO 9000 quality management specifications.

ISO 9000 SERIES STANDARD SPECIFICATIONS

There are many QA systems used in companies which perform welding. The most universally-accepted systems being used comply with the ISO 9000 Series standards. The ISO 9000 Series standards are international standards published by the International Organization for Standardization (ISO). ISO is also the symbol for equal in all directions, indicating that these standards are the same or equal for all.

Many of the ISO 9000 series standards have been adopted as American National Standards. These may contain some editorial changes to incorporate American language usage and spelling, but they are equivalent to the corresponding ISO Standards. The numerical designation of the American National Standards is the same numerical designation as the corresponding International Standard, with a prefix such as “Q.”

The ANSI/ISO/ASQC documents are published by the American Society for Quality (ASQC or ASQ). This organization is located at 611 East Wisconsin Ave., P.O. Box 3005, Milwaukee, WI 53202. These standards have been adopted by the American National Standards Institute (ANSI). ANSI is the U.S. member body of ISO.

The ANSI/ISO/ASQC Q9000 series of documents consists of three models plus several guidelines (the information in this module pertaining to ISO 9000 was taken from Q9001-1994). The three models are:

1. ANSI/ISO/ASQC Q9001 Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation and Servicing
2. ANSI/ISO/ASQC Q9002 Quality Systems—Model for Quality Assurance in Production, Installation and Servicing
3. ANSI/ISO/ASQC Q9003 Quality Systems—Model for Quality Assurance in Final Inspection and Test

These three models represent three distinct forms of quality system requirements suitable for a supplier to demonstrate its capability. They also provide for the assessment of that capability by external parties.

ISO/Q9001 is “for use when conformance to specified requirements is to be assured by the supplier during design, development, production, installation and servicing.” It is for manufacturers who design and build their own equipment, either as a cataloged item, or as a cataloged item modified to a purchaser’s requirements. General Electric would be an example; GE designs and builds railroad locomotives, aircraft engines, power generation equipment, along with other products, and they also install and service these products. The performance of their products is fully monitored with feedback to design, when appropriate.

ISO/Q9002 is “for use when conformance to specified requirements is to be assured by the supplier during production, installation and servicing.” It is applicable to a wide range of fabricators of welded products. Many welding shops might use this model.

ISO/Q9003 is “for use when conformance to specified requirements is to be assured by the supplier solely at final inspection and test.” This would be for mass producers, who buy raw materials, process these materials in appropriate machinery and sell the output. By and large, the only effective ‘inspections’ are those carried out on the raw materials and the finished product. Makers of bolts and nuts, paint, welding wire, electrodes, gases, all fall within this category. In the fabrication field, some makers of standard products such as gates, fences, windows, and so forth may also find this model suitable.

The requirements in the three models are intended to complement any technical or product specifications or requirements, such as codes or standards. These are quality system requirements which are not a replacement nor alternative to those codes and standards. These models provide the requirements which determine what elements a suppliers’ quality system should encompass. However, ANSI and ISO do not enforce uniformity of quality systems.

The varying needs of the supplier, such as the products, services and processes, will determine the actual design and implementation of its quality system. It is intended that the ISO/Q 9000 models will be adopted by the supplier, but may need to be tailored by adding or deleting certain requirements for the supplier’s needs (or for a specific contract).

The ISO/Q 9000 series standards also include two main guidelines. These provide guidance on how to select the appropriate quality assurance model (whether it should be Q9001, Q9002 or Q9003), what quality system elements to use, how to tailor the quality system requirements to specific company needs, etc.

The guidelines are:

1. ANSI/ISO/ASQC Q9000 Quality Management and Quality Assurance Standards
Part 1— Guidelines for Selection and Use
Part 2—Generic Guidelines for the Application of ISO 9001, ISO 9002 and ISO 9003

Part 3— Guidelines for the Application of ISO 9001 to the Development, Supply and Maintenance of Software

Part 4—Guide to Dependability Program Management

2. ANSI/ISO/ASQC Q9004-1 Quality Management and Quality System Elements

Part 1—Guidelines

Part 2—Guidelines for Services

Part 3—Guidelines for Processed Materials

Part 4—Guidelines for Managing Quality Improvement

The Quality System models from ISO 9001, 9002 and 9003 were, in large part, adopted from the British Standard BS 5750, which was originally used for two-party contractual situations. As such, they were used as conformance standards. The supplier was required to meet the provisions of the applicable specification. More lately, this has

changed where working in conformance to a given model can be regarded as a 'qualification.'

CERTIFYING BODIES FOR QUALITY MANAGEMENT SYSTEMS

In the past several years a number of bodies, both from the public sector and the private sector, have set themselves up as certifying bodies for Quality Management Systems. Before this development, each purchaser would descend on prospective suppliers and conduct an audit, which sometimes became very combative. Gilbert and Associates in the U.S.A. and Lloyds in the U.K. took the lead, and based on experience and training, designated qualified persons as Lead Auditors and others as Auditors.

This greatly reduced tensions and led to a more professional approach to quality system conformance. In due time, the certifying bodies set up registers of organizations that had been found to satisfy the requirements of a particular Quality System model. These registers are administered by a 'Registrar' and the term is used in a broader sense to indicate the certifying body—be it Bureau Veritas or the American Bureau of Shipping (ABS).

Choice of a Registrar is a very important decision. It should be based on what potential Registrar purchasers are most likely to hold in the necessary esteem. Quality professionals are usually equipped to offer suitable advice. For firms seeking registration, it is advisable to engage an outside quality professional.

A QUALITY MANAGEMENT SYSTEM

Basic requirements for quality management systems include the requirement of being fully documented, generally in the following format:

1. Quality Manual—which sets out the manner in which an organization addresses each element of the QMS model
2. System Procedures—embodying all the procedures on how each element of the quality system is to be implemented in practice
3. Work Instructions and Quality Plans—detailing the manner in which specific activities are to be carried out
4. Quality Records—in which are filed all the documents supporting and/or pertaining to the quality system. This typically includes audit reports, system non-conformance reports, corrective action disposition and similar documents showing the current status of the system.

QUALITY MANAGEMENT SYSTEMS are DYNAMIC

Quality Management Systems, especially in respect to Procedures and Work Instructions, are subject to continual revision and upgrading. There are two basic reasons why a system element, and its documentation, may have to be changed:

- Deficiency revealed by an internal or external audit
- Deficiency revealed by ongoing non-conformance.

Internal audits of system elements are on-going, as is typically detailed in the QA Manual. External audits are carried out either by an appointed agency, the registering body or a prospective client. An external agency may be called upon to conduct annual audits by the organization. As an auditor cannot effectively carry out an official audit on his own department, smaller organizations usually need to retain an external auditor.

The quality system may be likened to the financial system with respect to audit rationale.

The dynamic nature of quality system elements is recognized by, and implemented under, "Document Change and Control." Any non-conformance can be traced back to some quality system deficiency. It is from this basis that the need to determine the 'real' cause of every non-conformance arises. In one sense, when its implications are local, and readily contained and corrected, this may seem to be making a big fuss about potentially insignificant occurrences. Yet it is the sum of small non-conformances that often lead to major problems down the road.

MEASUREMENTS

In determining and verifying the conformance of product 'measurements.' Quality Management Systems (QMS) typically stress the importance on the state of 'calibration' of the measuring and testing equipment used. While in general, 'accuracy' and 'tolerances' are well understood, this is not always the case with the concepts applicable to quality control methods. In this context, 'measurements' applies to 'characteristics,' which may be 'attributes' or 'variables.'

In the control of quality, what is known as the 'Method of Attributes' is defined as a method that notes the presence (or, if appropriate, the absence) of one or more characteristics of a product. The 'Method of Variables' is the measuring, to some defined scale, of one or more characteristics of a product.

It goes without saying that measurements made using an instrument or item of test equipment with doubtful accuracy is of little value. While a machinist's rule (scale) with finely divided graduations is unlikely to vary with use, most other instruments and gages may develop inaccuracies in service. Needless to say, some are more vulnerable than others. Periodic 'calibration' is the process of verifying the state of accuracy of the application item of measuring or test equipment. Logically, the interval between successive calibrations of a given item of measuring or test equipment will be influenced by its vulnerability.

Many instruments are supplied with appropriate items of calibration equipment. Micrometers, particularly those with interchangeable anvils, are a case in point. Reference blocks used in association with hardness testers are normal. These and other 'calibration blocks' are generally defined as having a given order of accuracy, based on an appropriate standard. In the United States, the National Institute for Standards and Testing (NIST) is considered and accepted as the ultimate authority. In other countries, corresponding organizations serve a similar purpose.

The general approach used in a QMS is to have a library of reference standards, from which may be verified the accuracy of each item of measuring and test equipment. This activity is typically under the direct control of the Quality Assurance Manager. In larger organizations, the mechanics of calibration are delegated to appropriately skilled and trained personnel. The reference standards are directly traceable to a NIST standard. These standards are appropriately housed, maintained, and periodically 'recalibrated' by a NIST-certified test laboratory.

Records of each item of measuring and test equipment are to be maintained. These records will show the recalibration, and the results. In service, should there be a

valid reason to question the accuracy of either measuring or test equipment, immediate recalibration is customarily required. Needless to say, a 'Procedure' is required to cover the mechanics of both internal or external recalibration.

Instruments and test equipment, with current calibration, are required for any quality control activity. This covers the range from incoming product inspection, through in-process inspection to final and/or acceptance inspections. With multiple product or large project orders, inspection using one or more statistical techniques may be employed. The use of such methods is usually agreed upon between buyer and seller, except where it is customary practice in the industry concerned. Mainly by virtue of a lack of understanding, statistical techniques are frequently overlooked in the verification of welded product quality.

In the present context, only a brief overview can be given. As a basic principle, 'variability' (of supposedly identical product) has been recognized from the beginning. It was noted by the builders of the pyramids and by the clock makers of the Middle Ages. The 19th century U.S. rifle and pistol makers began to quantify variability but it was Dr. Shewart and others at the Bell Laboratories in the 1920's and 30's who gave a finite dimension to it as an industrial problem.

The general method used control charts to differentiate between normal variations resulting from chance and variations resulting from assignable causes. When these latter became excessive for the activity involved, it was said to be 'out of control.' Such a condition signals that a corrective action is necessary to restore the requisite degree of control.

Control charts may be of various types but tend to be directed to determining either averages or deviations there from. Control charts, of whatever type, are developed from data provided by 'sampling.' A 'sample' is a finite part of a statistical 'population' whose properties are being studied to gain information about the population as a whole. A 'population' is all the individual characteristics of a single design available during the period of interest and from which one or more samples may be taken.

Other terms that may be encountered include the following: A 'lot' is a group of individual items that are produced or sold as a unit. 'Random sampling' is the taking of a sample from a 'lot' or 'population' in which each unit has the same chance of being included in the sample. A 'range' is the difference between the largest and smallest value in a given set of observations.

Sampling to determine conformance of a product or group of products as a whole is a well proven technique. Tables such as the Dodge-Romig and MIL-STD-105 have been around for more than 50 years. Certain unique terminology is used with such tables. It cannot be over emphasized that any inspection and subsequent conformance based on statistical techniques only be implemented with the buyers' approval.

THE QA AUDIT

While there are several types of and reasons for conducting audits of Quality Management Systems, the mechanics and the objectives are essentially the same. The aim is to establish the on-going integrity of the system in terms of ability to produce goods (or services) of the specified 'quality.' Audits may be comprehensive, where the

whole of a system, and its several parts, are reviewed in detail. Alternatively, a lesser 'sample' may be audited. This is frequently the form adopted for internal audits and some external audits.

Welding-related audits may include a check-list for such items as:

1. Use of approved and qualified welding procedures
2. Documentation of welder qualification and certification
3. Welder identification on welds
4. Certification of welding consumables
5. Use of approved and up-to-date drawings and specifications
6. Inspection status of product
7. Records of nonconformance

Quality system audits provide a check that the supplier is giving the appropriate attention to the details. The results of an audit will benefit the supplier in taking corrective and preventive action. Audits should not be viewed as bad, but rather as a positive means for the supplier's activities to improve.

SUMMARY

After the above overview of QA and QMS principles, we will now review an ISO model and portions of an ISO guideline to see what elements are required for a particular model.

OVERVIEW OF ANSI/ISO/ASQC Q9001 AND Q9004-1

The introductions to the Q9000 series standards state that they are complementary, not alternatives, to the technical or product specified rules. These standards are for quality systems. The technical standards, such as the AWS D1.1 or ASME Section VIII, still apply.

It must be recognized that this Manual is a training and reference source as preparation for the AWS Senior Certified Welding Inspector examination. As such, it should not be used to develop a quality system for a company. One must always refer to the actual ANSI/ISO/ASQC standards for that purpose. Also, recognize that these standards are revised at regular intervals, so make sure you are using the latest versions of these standards.

ANSI/ISOASQC Q9004-1

Q9004-1, Quality Management and Quality System Elements-Guidelines provides guidance on quality management and quality-system elements. It is one of the guidelines to help understand and implement the Q9001 through Q9003 models.

This guideline charts the relationships of the various organizations in the supply chain for the Q9001 through Q9003 standards. A "supplier" is the company or organization which is preparing the Quality System and providing the product. The organization which purchases or receives the final product is the "customer." Any organization from which the supplier purchases raw materials or parts is a "subcontractor."

The Q9004-1 standard discusses certain "elements" or requirements of the quality system and describes or provides guidance on them. These help describe or augment the requirements in the models, in this case Q9001. For example, Q9001 states that "the supplier's management with executive responsibility" is responsible for the

supplier's quality. Q9004-1, Section 4.1 states that "the responsibility for and commitment to a quality policy belongs to the highest level of management," not just any level of management

The Q9004-1 is a guide that helps explain and support Q9001. It provides details on what information might be used in each element to assure that all pertinent areas are addressed. Thus, certain information from Q9004-1 will be used to explain some of the requirements in Q9001. However, the majority of information which the SCWI should know comes from the Q9001 standard, with backup from Q9004-1.

Q9004-1 defines various "quality-system elements," the appropriate ones of which can be selected by an organization. The extent to which these elements are adopted and applied by an organization depends upon factors such as the market being served, nature of the product, production processes, and customer and consumer needs.

The major topics or "elements" listed in the Table of Contents of Q9004-1 are:

1. Scope
2. Normative References
3. Definitions
4. Management Responsibility
5. Quality-System Elements
6. Financial Consideration of Quality Systems
7. Quality in Marketing
8. Quality in Specification and Design
9. Quality in Purchasing
10. Quality of Processes
11. Control of Processes
12. Product Verification
13. Control of Inspection, Measuring, and Test Equipment
14. Control of Nonconforming Product
15. Corrective Action
16. Postproduction Activities
17. Quality Records
18. Personnel
19. Product Safety
20. Use of Statistical Methods

ANSI/ISO/ASQC Q9001

The following provides a review of ANSI/ISO/ASQC Q9001-1994, Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing. The Q9001 standard provides a model for quality assurance systems for companies which design, develop, and produce products, and also install and service them.

Section 1 is the scope of the Q9001 standard. This standard specifies quality system requirements for a supplier to demonstrate its capability to design, produce and supply product which conforms to the design. The purpose is to achieve customer satisfaction by preventing nonconformities through all stages from design to servicing.

Q9001 is applicable in situations when:

- Design is required and requirements for the product are in terms of its performance, or they need to be established
- Confidence in product conformance can be attained by adequate demonstration of a supplier's capabilities

Section 2 provides references (termed "normative references"). In Q9001 the only reference is ISO 8402:1994, Quality Management and Quality Assurance—Vocabulary.

Section 3 is definitions. This again references ISO 8402 for definitions, plus adds a definition for product as "Result of activities or processes." Several notes further define that a product may be:

- A service, hardware, processed materials, software, or a combination of these
- Tangible (e.g. materials or assemblies) or intangible (e.g. knowledge or concepts)
- The intended product but not an unintended by-product (such as that affecting the environment)

Other definitions include:

Tender—Offer made by a supplier in response to an invitation to satisfy a contract award to provide product (this is the term used for bid, proposal, etc.).

Contract—accepted order: Agreed requirements between a supplier and customer transmitted by any means.

4. QUALITY—SYSTEM REQUIREMENTS

Section 4 is the main portion of the standard. The following twenty subsections are included in Section 4. Each of these main topics typically would be addressed as a separate section in the companies' Quality System Manual:

- 4.1 Management Responsibility
- 4.2 Quality System
- 4.3 Contract Review
- 4.4 Design Control
- 4.5 Document and Data Control
- 4.6 Purchasing
- 4.7 Control of Customer-Supplied Product
- 4.8 Product Identification and Traceability
- 4.9 Process Control
- 4.10 Inspection and Testing
- 4.11 Control of Inspection, Measuring, and Test Equipment
- 4.12 Inspection and Test Status
- 4.13 Control of Nonconforming Product
- 4.14 Corrective and Preventive Action
- 4.15 Handling, Storage, Packaging, Preservation, and Delivery
- 4.16 Control of Quality Records
- 4.17 Internal Quality Audits
- 4.18 Training
- 4.19 Servicing

4.20 Statistical Techniques

4.1 MANAGEMENT RESPONSIBILITY

4.1.1 Quality Policy

This section states that the supplier's management with executive responsibility shall define and document its policy for quality. This is to include objectives for quality and the suppliers' commitment to quality. The quality policy must be relevant to the supplier's organizational goals and also to the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented, and maintained at all levels of the organization. This means that all employees understand and follow the quality policy.

Q9004-1 stated that this is to be the highest level of management, not just a lower level manager. Q9004-1 states that the quality policy should be consistent with other policies within the organization, and states that management should document objectives and commitments pertaining to quality.

4.1.2 Organization

4.1.2.1 Responsibility and Authority

This establishes that the supplier is to define and document the responsibility, authority, and the interrelationships of personnel who manage, perform, and verify work that affects the quality. This is particularly important for those personnel who need the organizational freedom and authority to:

- a) initiate action to prevent the occurrence of any non-conformities relating to product, process, and quality system;
- b) identify and record any problems relating to the product, process, and quality system;
- c) Initiate, recommend, or provide solutions through designated channels;
- d) verify the implementation of solutions;
- e) control further processing, delivery, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

4.1.2.2 Resources

The supplier is to identify resource requirements and provide adequate resources. This includes the assignment of trained personnel, for management, performance of work, and verification activities, including internal quality audits.

4.1.2.3 Management Representative

The management with executive responsibility is to appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for:

- a) ensuring that a quality system is established, implemented, and maintained in accordance with Q9001, and
- b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system.

This management representative may also serve as a liaison with external parties on matters relating to the supplier's quality system.

4.1.3 Management Review

The supplier's management with executive responsibility is to review the quality system at defined intervals. The frequency of these reviews is not specified, but they must be defined by the supplier. These reviews are to be at intervals that are sufficient to ensure the continuing suitability and effectiveness of the quality system in satisfying the requirements of Q9001 and the supplier's stated quality policy and objectives. Records of these reviews are to be maintained.

4.2 QUALITY SYSTEM

4.2.1 General

This section defines the requirements for the suppliers' quality system. It states that the supplier shall establish, document, and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of Q9001. This quality manual shall include or make reference to quality system procedures and outline the structure of the documentation used in the quality system. (A note states that guidance on quality manuals is given in ISO 10013.)

4.2.2 Quality-System Procedures

The supplier shall prepare documented quality-system procedures consistent with the requirements of Q9001 and the supplier's quality policy. These procedures are used throughout the supplier's process from design through servicing. The supplier must also effectively implement the quality system and its documented procedures.

The details of the procedures will depend upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity. The procedures may make reference to work instructions that define how an activity is performed.

These require the supplier to have a quality system in place. This is to include a quality manual, with procedures and work instructions. review of a contract, order and the tender shall be done to ensure that all parties fully understand all requirements. If a verbal order is placed, the supplier must ensure that all requirements are understood and agreed before the order is placed.

The supplier is responsible to ensure that all differences between the contract or order and the tender are resolved before the order is placed. Finally, the supplier must make sure that it has the capability to meet all requirements.

Other requirements of contract review are that the supplier shall identify how an amendment to a contract will be made and how it will be properly communicated and transferred to all necessary people within the supplier's organization. Finally, it requires that records of contract reviews be maintained.

4.4 DESIGN CONTROL

This section is unique to Q9001 because it is the only model which includes design and associated functions. As such, each subsection within the Design Control will be discussed.

4.4.1 General

This requires the supplier to establish and maintain documented procedures to control and verify the design of the product. The purpose of this is to ensure that the specified requirements are met.

4.4.2 Design and Development Planning

The supplier is to prepare plans for each design and development activity, which are to describe or reference these activities. This also requires the supplier to define responsibility for implementation. These activities are to be assigned to people who are qualified and are equipped with adequate resources to perform the work. It also requires that the plans are to be updated as the design evolves.

4.4.3 Organizational and Technical Interfaces

This requires that there be organizational and technical communication (interfaces) between the various groups which have input into the design process. These interfaces are to be defined, and the necessary information must be documented, transmitted, and regularly reviewed.

4.4.4 Design Input

This subsection is concerned about the legal and technical design requirements for the product. The design-input requirements which relate to the product are to be identified, documented, and reviewed by the supplier for adequacy. If there are incomplete, ambiguous, or conflicting requirements, they shall be resolved with those responsible for imposing these requirements. This is also to take into consideration the results of any contract review activities.

4.4.5 Design Output

The design output is the outcome of the design process. It shall be documented and expressed in terms that can be verified against design input requirements and validated. The design output shall:

- a) Meet the design-input requirements;
- b) Contain or make reference to acceptance criteria;
- c) Identify the characteristics of the design that are crucial to the safe and proper functioning of the product (e.g., operating, storage, handling, maintenance, and disposal requirements).

These could include drawings, specifications, and other design-related documentation. The design output documents are to be reviewed before release.

4.4.6 Design Review

This requires formal documented reviews of the design results to be planned and conducted at appropriate stages of design. Representatives of all functions that are concerned with the design stage being reviewed are to be included, as well as other specialists, as required. Records of these reviews shall be maintained.

4.4.7 Design Verification

The differences between this subsection and the next one is important, because there can be confusion between them. This subsection concerns design verification, which is a verification that the design-stage output meets the design-stage input requirements. This occurs at appropriate stages of design, and the design- verification measures shall be recorded.

This may also include such items as: performing alternative calculations; comparing the new design with a similar proven design, if available; undertaking tests and demonstrations, and; reviewing the design-stage documents before release.

4.4.8 Design Validation

Design validation is different from verification in that it is the validation that the product conforms to defined user needs and/or requirements.

Several points are made here concerning validation:

- Design validation follows successful design verification
- It is normally performed under defined operating conditions
- It is normally performed on the final product, but may be performed during production
- Multiple validations may be performed if there are different intended uses

4.4.9 Design Changes

This is a very important point that is often overlooked. It requires all design changes and modifications to be identified, documented, reviewed, and approved by authorized personnel before they are implemented.

4.5 DOCUMENT AND DATA CONTROL

This section covers all types of documents and data that relate to the requirements of Q9001. It requires the supplier to establish and maintain documented procedures to control all documents and data, including any documents of external origin such as standards and customer drawings. It also notes that the documents and data can be in the form of any type of media, such as hard copy or electronic media.

All documents and data are to be reviewed and approved for adequacy by authorized personnel prior to issue. The supplier is to have a master list or equivalent document-control procedure identifying the current revision status of documents. This is to be established and be readily available to preclude the use of invalid and/or obsolete documents.

The purpose of this control is to ensure that:

- a) Pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;
- b) Invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
- c) Any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified

This section lastly covers changes to documents and data. Such changes shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations are to have access to pertinent background information upon which to base their review and approval. A note states that, where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

4.6 PURCHASING

4.6.1 General

This requires the supplier to have documented procedures to ensure that purchased product conforms to requirements.

Evaluations of subcontractors are also covered in this section. The supplier is responsible to:

- a) Evaluate and select subcontractors on the basis of their ability to meet subcontract requirements including the quality system and any specific quality-assurance requirements;
- b) Define the type and extent of control exercised by the supplier over subcontractors. This depends upon the type of product, the impact of subcontracted product on the quality of the final product, and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors;
- c) Establish and maintain quality records of acceptable subcontractors.

The purchasing documents are to contain data which clearly describes the product ordered, including where applicable:

- a) The type, class, grade, or other precise identification;
- b) The title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions, and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment, and personnel;
- c) The title, number, and issue of the quality system standard to be applied.

The purchasing documents are to be reviewed and approved by the supplier prior to release.

Section 4.6.4 covers verification of purchased product. If the supplier is going to verify purchased product at the subcontractor's premises, the supplier shall specify verification arrangements and the method of product release in the purchasing documents.

If specified in the contract, the supplier's customer or customer's representative shall be given the right to verify at the subcontractor's premises and at the supplier's premises that subcontracted product conforms to specified requirements.

This verification is not to be used by the supplier as evidence of effective control of quality by the subcontractor. Verification by the customer also does not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

4.7 CONTROL OF CUSTOMER-SUPPLIED PRODUCT

If the customer supplies product for incorporation into the final product, the supplier is to have documented procedures for the control of verification, storage, and maintenance of this product. Any customer-supplied product that is lost, damaged, or is otherwise unsuitable for use shall be recorded and reported to the customer. Acceptance or verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.

4.8 PRODUCT IDENTIFICATION AND TRACEABILITY

Where it is appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery, and installation. Where traceability is a specified requirement, the supplier shall establish and maintain documented procedures for

unique identification of individual product or batches. This identification shall be recorded.

4.9 PROCESS CONTROL

This is the method by which quality is manufactured into the product. This requires the supplier to identify and plan the production, installation, and servicing processes which directly affect quality and the supplier shall ensure that these processes are carried out under controlled conditions. Controlled conditions include the following:

- a) Documented procedures defining the manner of production, installation, and servicing,
where the absence of such procedures could adversely affect quality;
- b) Use of suitable production, installation, and servicing equipment, and a suitable working environment;
- c) Compliance with referenced standards/codes, quality plans, and/or documented procedures;
- d) Monitoring and control of suitable process parameters and product characteristics;
- e) The approval of processes and equipment, as appropriate;
- f) Criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples, or illustrations);
- g) Suitable maintenance of equipment to ensure continuing process capability.

This section further defines process controls. Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations, including associated equipment and personnel, shall be specified.

It refers to such processes that require prequalification of their process capability as special processes. Welding procedures often fit into this category. Records are required to be maintained for qualified processes, equipment, and personnel, as appropriate.

4.10 INSPECTION AND TESTING

This requires the supplier to establish and maintain documented procedures for inspection and testing. The purpose of this is to verify that the specified requirements for the product are met. The section discusses inspection and testing at various stages of processing.

4.10.2 Receiving Inspection and Testing

This requires the supplier to ensure that all incoming product is not used or processed (except as allowed in 4.10.2.3, below) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of the specified requirements shall be in accordance with the quality plan and/or documented procedures. This also discusses how to determine the amount and nature of inspection, based on the controls used by, or

evidence of conformance by the subcontractor.

A special exception is made in 4.10.2.3. If incoming product is required for urgent production purposes before it can be inspected, this subsection allows it to be released. However, it must be positively identified and recorded in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.

4.10.3 In-process Inspection and Testing

This requires the supplier to perform in-process inspection and testing on the product as required by the quality plan and/or documented procedures. The product must be held until the required inspection and tests have been completed or necessary reports have been received and verified. The exception to this is when product is released under the positive-recall procedures of 4.10.2.3. Release under the positive-recall procedures does not eliminate the need for in-process inspection and testing requirements.

4.10.4 Final Inspection and Testing

Final inspection and testing are to be performed in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.

No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.

4.10.5 Inspection and Test Records

This subsection requires the supplier to maintain records which provide evidence that the product has been inspected and/or tested. These records are to show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. If the product fails to pass any inspection and/or test, the procedures for control of nonconforming product are to apply. Records are to identify the inspection authority responsible for the release of product.

4.11 CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT

This section covers requirements to control, calibrate, and maintain inspection, measuring, and test equipment (including test software) that is used by the supplier to demonstrate conformance of the product. This measuring equipment (or devices) are to be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability. If technical data pertaining to the measurement equipment is a specified requirement, this shall be made available to the customer for verification that the equipment is functionally adequate.

If test software or comparative references are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, and shall be rechecked at prescribed intervals. The supplier

shall establish the extent and frequency of such checks and shall maintain records as evidence of control.

Subsection 4.11.2 covers control procedures for the inspection, measuring and test equipment. It is to ensure that accurate and precise measurements are made. It requires the supplier to:

- a) Determine the measurements to be made and the accuracy required, and select equipment that is capable of the necessary accuracy and precision:
- b) Identify all equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented;
- c) Define the process employed for calibrating the equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory;
- d) Identify equipment with a suitable indicator of calibration status;
- e) Maintain calibration records for equipment:
- f) Assess and document the validity of previous inspection and test results when equipment is found to be out of calibration.
- g) Ensure that the environmental conditions are suitable for the calibrations, inspections, measurements, and tests being carried out;
- h) Ensure that the handling, preservation, and storage of equipment is such that the accuracy and fitness for use are maintained;
- i) Safeguard inspection, measuring, and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

4.12 INSPECTION AND TEST STATUS

All product is to be identified by suitable means to show the inspection and test status, that is, whether the product is 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 product to ensure that only product that has passed the required inspections and tests (or that has been released under an authorized concession per

4.13.2) is used or installed.

4.13 CONTROL OF NONCONFORMING PRODUCT

This requires the supplier 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.

Subsection 4.13.2 states that the responsibility for review and authority for the disposition of nonconforming product shall be defined. Any nonconforming product shall be reviewed in accordance with documented procedures. Several options are then presented for what to do with nonconforming product. It may be:

- a) Reworked to meet the specified requirements
- b) Accepted with or without repair by concession

- c) Regraded for alternative applications
- d) Rejected or scrapped

If required in the contract, any proposed use or repair of product (b, above) which does not conform to requirements shall be reported for concession to the customer or customer's representative. The description of the nonconformity that has been accepted, and of repairs, are to be recorded to denote the actual condition. Repaired and/or reworked product is to be reinspected in accordance with the quality plan and/or documented procedures.

4.14 CORRECTIVE AND PREVENTIVE ACTION

This section requires the supplier to establish and maintain documented procedures for implementing corrective and preventive action. 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 supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

4.14.2 Corrective Action

Corrective action is used to correct a problem that already exists. This subsection states that the procedures for corrective action shall include:

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

4.14.3 Preventive Action

Preventive action is that taken to avoid a problem from occurring. This subsection states that the procedures for preventive action shall include:

- a) 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;
- b) Determination of the steps needed to deal with any problems requiring preventive action;
- c) Initiation of preventive action and application of controls to ensure that it is effective;
- d) Ensuring that relevant information on actions taken is submitted for management review

4.15 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

As evident from the title of this section, it deals with the supplier's responsibilities for handling, storage, packaging, preservation, and delivery of product. It requires the supplier to establish and maintain documented procedures for these. These include proper handling and use of designated storage areas or stock rooms to prevent

damage or deterioration of the product, pending use or delivery. This also requires appropriate methods for authorizing receipt to and dispatch from such areas. The condition of the product in stock is to be assessed at appropriate intervals to detect deterioration.

The supplier shall control packing, packaging, and marking processes, and the methods for preservation and segregation of the product. Finally, the supplier is responsible to arrange for the protection of the quality of product after final inspection and test. When specified in the contract, this protection shall be extended to include delivery to the destination.

4.16 CONTROL OF QUALITY RECORDS

This section requires the supplier to establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records. These records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from subcontractors are part of these data.

All quality records are to be legible and stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period. A note shows that the records may be in the form of any type of media, such as hard copy or electronic media.

4.17 INTERNAL QUALITY AUDITS

A key item in assuring that a quality control system is working properly is to perform internal quality audits. This section requires the supplier to have documented procedures for planning and implementing internal quality audits. The purposes of these audits are to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Two main items covered are that the audits shall be scheduled based on the status and importance of the activity to be audited, that is, based on how that activity affects the quality of the product. The second main item is that the audits are to be carried out by personnel independent of those having direct responsibility for the activity being audited, so the audit is truly independent.

The results of the audits are to be recorded and brought to the attention of the personnel having responsibility in the area audited. It is then the responsibility of the management personnel responsible for that area to take timely corrective action on deficiencies found during the audit. Finally, follow-up audits are to be performed to verify and record the implementation and effectiveness of the corrective action taken.

The results of internal quality audits form an integral part of the input to management review activities. (Q9001 notes that there are several ANSI/ISO/ASQC documents which provide guidance on quality-system audits.)

4.18 TRAINING

A very important part of a quality system is proper training of personnel. In this section, the supplier is required to establish and maintain documented procedures for

identifying training needs and provide for the training of all personnel who perform activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained.

4.19 SERVICING

Since Q9001 also covers servicing of the product after it is installed, this section describes that when servicing is required in the contract, the supplier shall establish and maintain documented procedures for performing, verifying, and reporting that the servicing meets the specified requirements.

4.20 STATISTICAL TECHNIQUES

The final section in Q9001 covers statistical techniques. These methods can be used to monitor and control manufacturing processes and to appropriately select the quantity of product to be inspected. This section states that the supplier shall identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics. If used, the supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified

SUMMARY

An SCWI might be one of the management personnel whose functions include many of the activities described above. As such, it is important for the SCWI to understand these Q9000 standards.