



Introduction to Quality Systems

NTMA Technology Team Best Practice

Quality systems are methodologies in which a manufacturer must establish and follow a system to help ensure that their products consistently meet applicable requirements and specifications. Many companies get overwhelmed when they talk about quality systems. What quality system is right for my company? If your customer base does not require or specify any quality standard, you need to ask your self a few questions. Before we get into defining your quality system it might be more helpful to review some quality systems and terms.

Quality Systems and Terms

Statistical Process Control (SPC)

Statistical Process Control is a process where you measure a process and using software calculate when the process is going to fail. A simple definition is SPC is a monitoring and recording tool to determine when you will have to make an adjustment to your process (e.g., replacing a cutting tool), before you begin producing bad parts. It is used to control many processes and is part of ISO and AS standards.

Total Quality Management (TQM)

Total Quality Management is an old system used before the interdiction of the ISO quality system. It took the quality principles and incorporated it into the management system. It was an improvement-focused program.

Six Sigma

Six Sigma is a tool used to trouble-shoot processes to locate the weakest link and to define the importance vs. the cost of implementation of corrective actions to eliminate the weak link. It is a never-ending process improvement program; as one link is repaired another one is next in line. There are two classifications for persons trained in Six Sigma. Black Belts, certified through successfully executing multiple projects, are primarily found in large companies whose principal job is leading Six Sigma projects. Green Belts are employees who are training in Six Sigma on their first project and participate on Six Sigma teams.

Mil-I 45208

Mil-I 45208 is an outdated government inspection system. It is replaced by the ISO 9001 standard but is sometimes still required for some contracts. It has 18 elements from contract review to statistical process control.

ISO 9001:2008

International Standards Organization is the International quality standard. It was first developed in Europe to standardize between separate country systems. It is now adopted as a world-wide standard. The ISO 9000 family is a series of documents that define requirements for the Quality Management System Standard. There are several documents in the set and we recommend buying a copy for your facility. Tech Street is a resource where you can purchase a download or hard copy of the following standards online: <http://www.techstreet.com/>

- ISO 9000:2005 Fundamentals and Vocabulary used in the ISO 9000 Standards
- ISO 9001:2008 contains the actual requirements an organization must comply with to become ISO 9001 Registered. People often say "ISO 9000" certified, but what they mean is they have met the requirements of the ISO 9001 standard.

Past (Obsolete) versions of ISO 9000 include:

- ISO 9001:2000 was revised in the year 2008.
- ISO 9001:2000 replaced the 1994 version(s):
- ISO 9001:1994 - Manufacturing with Design & Development
- ISO 9002:1994 - Production and Installation (No Design)
- ISO 9003:1994 - Final inspection and test

Industry Specific Quality Standards

QS/TS16949

This quality system is an enhanced version of ISO 9000 that reflects the needs of the automotive industry. The title is indicative of the current transition status from QS 9000 to TS 16949. This certification is required for all first-tier suppliers of the Big Three automakers. The goal of ISO TS 16949 is the development of a quality management system that provides for continual improvement, emphasizing defect prevention and the reduction of variation and waste in the supply chain.

This specification together with applicable customer-specific requirements, defines the fundamental quality management system requirements for those subscribing to it. The specification is intended to avoid multiple certification audits and provide a common approach to a quality management system for automotive production and relevant service part organizations. It can be applied throughout the automotive supply chain.

ISO 13485

ISO 13485 is the ISO 9000 for medical device manufacturers. Embracing the FDA's good manufacturing practices, this standard defines terms such as: medical device, active medical device, active implanted medical device, sterile medical device, and more.

This international standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

The primary objective of this standard is to facilitate harmonized medical device regulatory requirements for quality management systems. It includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Due to these exclusions, organizations whose quality management systems conform to this standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001.

AS 9100

AS 9100 is an Aerospace Standard that is in use in the aerospace industry whose requirements are above ISO 9001:2008. It is currently the highest level of quality system possible. When the aerospace industry realized that it was necessary to supplement the ISO quality management system model to satisfy internal, government and regulatory requirements for the aerospace industry, AS 9100 was established. This standard comprises the ISO 9001:2000 requirements augmented by aerospace industry requirements. It was the result of an international effort by aerospace companies with a common goal of establishing a quality management system for use within the aerospace industry.

To assure customer satisfaction, aerospace industry organizations must produce, and continually improve safe, reliable products that meet or exceed customer and regulatory requirements. The globalization of the aerospace industry, and the resulting diversity of regional/national requirements and expectations, has complicated this objective. End-product organizations face the challenge of assuring the quality of, and integration with, product purchased from suppliers throughout the world and at all levels within the supply chain. Aerospace suppliers and processors face the challenge of delivering product to multiple customers having varying quality expectations and requirements.

There are also other AS 9100 support documents and systems. These include AS 9102, a 1st Article Inspection System for AS 9100 and AS 9003, an aerospace standard quality system subset of AS 9100 aerospace quality management system. It has 20 elements and is in the process of being rewritten. It is based on the old ISO 9100:1994 standard and is on its way to obsolescence.

ISO 14000

This specification is an environmental standard. It deals with environmental management system requirements such as documentation, training, auditing, defining environmental aspects and their impact, performance evaluation, life cycle assessments, leadership, and continuous improvement. It is the intention of this standard to protect the earth's environment while spurring international trade and commerce. The guidelines are intended to be practical, useful, and usable for companies of all sizes in manufacturing and service industries.

The benefits of implementing an Environmental Management System are many. Implementation of an Environmental Management System (EMS) can positively affect your company's bottom line. Potential savings can amount to millions of dollars in reduced fines and penalties alone. Other savings can approach the same amount, considering waste haulage, resource use reductions, material efficiencies, etc. In addition, you can measure your ongoing positive impact on the environment.

Two of the big three automotive manufacturers have stipulated that their suppliers be ISO 14001 certified, while the third is requiring either that or self-certification.

The Choice

When choosing to implement an AS or ISO system, your company needs to make a commitment in man-power and costs. Your company can try to implement the program on your own, but we suggest that you can hire a consultant. Resources are available at your local Manufacturing Extension Program (MEP). Quality System consultants are experts in the business and know what the auditors are looking for. Estimated costs are \$150 per hour for 8 hours per week, starting every other week for 2 months followed by every week for 4 to 6 months. You can expect funding requirements of \$30,000 to \$50,000; this does not include your employee's time (see funding below). These consultants can help you develop an implementation plan which nominally takes 8 to 12 months for the designing and proofing process. In most cases there is a preliminary documentation evaluation, a 1 to 2 day pre-audit followed by a 2 to 4 day certification audit a few weeks after. The audit runs about \$1,200 to \$1,600 per day or double that if more than one auditor is used. Most costs do not include travel and are based on number of employees. There will also be a recertification audit every year to maintain the certification. Every 4 to 6 years the specifications are revised and there are many companies that provide classes or webinars on the new revisions. As you can see, it takes a large commitment to implement these quality systems. If implemented correctly, they will save you money in the long run. Commitment of the necessary resources is critical to successfully complete the program. If not fully committed, an attempt at implementing a Quality System is a waste of your valuable time and resources.

Other System

There are also many other sub-system standards under ISO. Many industries also have their own requirements such as the FDA for food and medical related product and the FAA for commercial and private aircraft.

No System

If your company is a start up or small shop and if none of the above quality systems meet your needs, the NTMA can supply you with a blank quality manual that you can use to start a basic quality system. This manual / system will give you the basics and you will be able to adopt future upgrading as required.

Conforming

Many of your customers may only require that you can conform to one of the above specifications. A word of caution; in many cases your customer may also audit you themselves to see if you do what you say.

New Customer Requirements

With most of the above quality systems, in order to be evaluated by a new customer, the following information may be requested.

1. A copy of your quality manual.
2. A copy of you current certification
 - a. Some may request copies for the last five years.
3. They may have you complete a questioner.
4. Or all of the above.

If your company receives one or more of the above certifications, any new vendors added will also have to supply similar information.

Funding

If one of the above systems is what you need, but you do not have the funds for implementation, there is help available. Many states have funding available to small companies to aid in the implementation of an ISO quality system, through the MEP Manufacturing Extension Program. There are also state funds available for quality consultants and quality training; check with your state Department of Labor.

Summary

Implementing a quality system may seem like a lot to go through to get some work, but the higher quality requirements nominally get a higher shop rate. Shops without a quality system may only receive an approximate shop rate of \$50 per hour; ISO registered shops secure approximately \$80 per hour, and AS shops on the average contract over \$100 per hour. This is based on a 25-man shop with the same manufacturing capabilities. So in the long run quality does pay.

If you are still unsure what quality system is best for your company, attend a local NTMA chapter meeting or an NTMA National meeting and ask your fellow members. There is always someone available who can help make recommendations and provide guidance.