

Introduction to Quality Systems

An NTMA Technology Team
Member Training Program



Intro to Quality

- 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. Most of our customers require some sort of quality system.
 - What is the system they require and how does it compare with other systems?
- If your customer does not require or specify any quality standard, you need to ask your self a few questions.
 - What benefits will a quality system give my company?
 - What quality systems are out there?
 - Which one will fit our companies needs?

General Standards

- When we talk about quality systems we are talking about a standard.
- In the past few years there are two quality system standards that are talked about.
 - Military
 - ISO

Mil-I-45208

- Is a out dated government inspection system.
- It is replaced by the ISO 9001 standard.
- May still be required for some contracts. It has 18 elements from contract review to statistical process control.

ISO 9000

- International Standards Organization (ISO) is the International quality standard.
- 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.
- [ISO 9000:2005](#)
 - Fundamentals and Vocabulary used in the ISO 9000 Standards.

ISO 9001:2008

- [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 ISO Standards

- Past (Obsolete) versions of ISO 9000 include:
 - ISO 9001:2000 was revised in the year 2008.
 - ISO 9001:2000 replaced the 1994 versions:
 - 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
- ISO 13485
- AS9100
 - AS9102
 - AS9003
- ISO 14000

ISO TS 16949



- This quality system is an enhanced version of ISO 9000 that reflects the needs of the **automotive industry**.
- 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.
- It is intended to:
 - Avoid multiple certification audits.
 - Provide a common approach to a quality management system for automotive production and relevant service part organizations.
 - Be applied throughout the automotive supply chain.

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.
- 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, you will not be able to claim conformity to ISO 9001.

AS 9100



- Aerospace Standard
- Is a requirement that is above ISO9001:2008, used in the aerospace industry. Currently the highest level of quality system possible.
 - 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, companies must produce and continually improve safe, reliable products that meet or exceed customer and regulatory requirements.
 - The globalization of the aerospace industry and resulting diversity of regional/national requirements and expectations, has complicated this objective.
 - Aerospace suppliers and processors face the challenge of delivering product to multiple customers having varying quality expectations and requirements.

AS 9100



- There are also other AS9100 support documents and systems, such as:
 - AS9102
 - 1st Article Inspection System for AS9100
 - AS9003
 - An Aerospace Standard that is a quality system subset of AS9100.
 - It has 20 elements and is in the process of being rewritten, it is based on the old ISO9100:1994 standard.
 - It is on it's way to obsolescence.

ISO 14001



- 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.

ISO 14001



- What are the benefits of implementing 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.

Recap

Industry Specific Quality Standards

- **QS/TS16949 Automotive**
- **ISO 13485 Medical**
- **AS9100 Aerospace**
- **ISO 14000 Environmental**

Other systems & programs

- SPC
- TQM
- Six Sigma

Statistical Process Control (SPC)

- Statistical Process Control is a process where you measure a process and through software calculate when the process is going to fail.
- A simple definition 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)



- This 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. 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 three classifications for Six Sigma trained employees;
 - Black Belts work full time on six sigma projects.
 - Green Belts are training in Six Sigma and participate on Six Sigma teams.
 - Brown Belts have learned the basics of Six Sigma and may participate with gathering data from management and employees.

No Quality System



- If your company is a start up or small shop and none of the above quality systems suite 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.
- Review the cost; if it's close consider getting certified.

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

Flow Down Requirements

- If your company receives one or more of the certifications, any new vendors added may also have to supply similar information required by your customer:
 - A copy of their quality manual.
 - A copy of their current certification.
 - Some may request copies for the last five years.
 - You may have to have them complete a questionnaire.
 - Or all of the above.

The Choice

- When choosing to implement an AS or ISO systems your company needs to make a commitment in man-power and costs.
- Locating a good consultant will be key to success.
- Locating funding will make the process less pain full.

Consultants

- Your company can try to implement the program on your own, but we suggest that you hire a consultant, perhaps through your local Manufacturing Extension Program (MEP).
- The consultants know the system and what the auditors are looking for.
- Consultants can help you develop a implementation plan. It 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.

Consultant Costs

- Estimated costs are \$150 per hour for 8 hours per week.
- Costs start every other week for 2 months followed by every week for 4 to 6 months. You can expect funding requirements of between \$30,000 to \$50,000, not including your employee's time.
- 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.
 - Costs are based on number of employees. There will also be a recertification audit every year to maintain the certification.
- It takes a large commitment to implement these quality systems. If done correctly they will save you money in the long run.
- **If not fully committed, an attempt at implementing a Quality System is a waste of your valuable time and resources.**

Maintaining The System

- There will also be a recertification audit every year to maintain the certification.
 - You can sign a three year audit contract.
- Every 4 to 6 years the specifications are revised.
 - Many audit companies provide classes or webinars on the new revisions.

Funding

- If one of the systems that we discussed is what you need, but 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.
- 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 shops secure approximately \$80 per hour.
 - 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.

Questions



- 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 around.
 - There is always someone available who can help make recommendations and provide guidance.

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Any Questions?