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 taking about a standard.

- In the past few years there are two quality system standards that are talked about.
  - Military
  - ISO
Mil-I-45208

- Is an outdated government inspection system.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 its way to obsolescence.
ISO 14001

- This specification is a 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.
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 your 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 you 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 questioner.
  - 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?