ISO 9001 / ISO 22006

An Introduction To
Quality Management System Standards
To Understand Quality Standards, It Can Be Helpful To Start By Answering The Question; What Are Standards?
Standards are Very Common

Generally speaking, a standard is an established method for defining “acceptability.”

Standards are so common we don’t even notice them:
• Computer keyboards
• Paper size
• Physical shape and color of a stop sign

Some standards are actually written into law:
• Driving on the right-hand side of the road
• Electrical codes
• Height of a handrail on a stairway

✔ There are 10’s of thousands of standards in use every day.
Where Did Quality Management Standards Come From?
The Industrial Revolution (1750 to 1850) set the stage for Standards that Controlled and Assured *Product and Process Outcomes*
Driving Forces for Controlling
Product and Process Outcomes

Best Practices were needed to assure results. Achieving results became an increasing problem over time because:

• More and more people had to work together to produce a defined result

• Customer demand for quality increased

• The costs associated with a simple mistake grew larger

• Products and technology became more complex

• Production quantities grew
These Practices Evolved over time to Resolve Known Problems

Some Simple (and familiar) examples:

• “When a procedure or instruction is changed, it must be reviewed and approved prior to use to avoid unanticipated adverse consequences.”
• “Don’t assign someone to do something unless you know they are capable of performing the task.”
• “It is usually better to fix the cause of the problem than the symptom.”
• The organization will evaluate and select suppliers/vendors based on their capability not on their price
Evolution of Best Practices

Some Simple (and familiar) examples (cont):

• When making a measurement, make sure the tool that is used to make the measurement is sufficiently accurate.

• Make sure that the organization is capable of meeting customer requirements prior to making a commitment to customers.

• Make sure instructions and information are available (when needed) to the people who are performing work.

✓ These were often called “Best Practices”
Evolution Of Best Practices

These Best Practices evolved, over time into hundreds of specific preventive steps that are currently part of ISO 9001.

These “Best Practices” quickly became the optimum method for assuring results, for example;

- Automotive
- DOD
- NASA
- Aerospace
- Food and Drug Administration
Best Practices provide the **Lens** for organizations, their customers and regulatory bodies to continually evaluate an organization to **confirm the organization’s best practices**, thus providing confidence to all.
Best Practices Related to Agriculture

The following text has been extracted and paraphrased from ISO 22006.

• One or more people on the farm must review documents for adequacy.
• The farm operation ensures that personnel assigned to specific tasks are competent to perform those tasks.
• The farm operation must understand customer requirements related to crop identification, storage, traceability and transport.
• Vendor assessments must include as appropriate, service providers (including labor), purchased processes, equipment and materials.
• Quality objectives are established (for example, reduction of soil erosion and water use) and understood by farm personnel.
By the Late 1800’s, Best Practices for controlling Product and Process Outcomes had been well established and documented.
The Next Stage: Quality Management Systems
Problems With Implementing Best Practices

Ultimately World War II Drove “Best Practices” to the **Next Level**: **Quality Management Systems**!

- People and organizations did not follow identified “Best Practices” **consistently** over time:
  - Urgent production needs drew people’s attention elsewhere
  - People and organizations became complacent over time
  - Increasing numbers of people involved led to inconsistencies in methods and approaches across the organization and its supplier and customer networks
The Solution:

“Best Practices” for *Top Management* were needed to support *Best Practices for Product and Process Outcomes*. A brief list:

- Regularly and consistently *communicate* expectations to all personnel
- *Pay attention and monitor the details* and take action early – hopefully before a problem occurred
- *Assign responsibility and hold people accountable*
- *Have a plan and people need to know where they fit into the plan*
- *Many Others . . .*

“Best Practices” for Top Management
Specific Best Practices Related to Top Management

The following text has been extracted and paraphrased from ISO 22006;

• A person or a group of people is assigned to be the **final decision making authority on the farm**.

• A person or group of people is to be assigned to review the quality program on the farm at defined intervals.
The Result:

A Defined Role for Top Management
Ensuring Ongoing Discipline and Effectiveness Over Time
The Final Problem Was A Lack Of Transparency

- **Customers** needed to *see* what was happening so that they had the confidence to make purchasing decisions

- **Organizations** needed to clearly *see* and *confirm* what they were doing and what had been done

- **People** needed to *see* and clearly *know* what to do – what was expected of them
Best Practices For Transparency

- Products, Processes and Outcomes that were verified through an ongoing *Internal Audit Process*
- *Documents* (policy, manual, vision statements, plans, etc.)
- Documented *Procedures*
- Documented *Instructions*
- *Records* of what had been done

“Best Practices” for Transparency
Transparency is Supported by A Deliberately Planned Feedback Loop:

**Internal Audits (Self Checks)**

**Corrective Action To Fix Problems**

**Reviews By Top Management**

All effectively managed organizations regularly perform and manage this ongoing feedback loop.
Specific Best Practices Related to Transparency

The following text has been extracted and paraphrased from ISO 22006;

• Nonconforming crop must be identified and controlled to prevent shipment to customers

• Create and maintain appropriate records associated with planting, growing, field activities, harvest, storage, handling, traceability, food safety and those required by customers or regulatory bodies.
Transparency Provided

Confidence and Immediate Feedback to all Parties
Best Practices Evolved to Become Management Systems Standards

Best Practices to Control *Product and Processes Outcomes*

+ 

Best Practices For *Top Management*

+ 

Best Practices For *Transparency*

= 

**Quality Management Systems**

Best Practices For Operating a Business
ISO 9001 / ISO 22006

- Today, ISO 9001 is being used by over 1.2 million organizations round the world.

- ISO 22006 contains, word for word, all of the requirements in ISO 9001.

- ISO 22006 contains additional specific guidance related to Agricultural Crop Production.
A Recent Study by Harvard University Confirms the Benefits of Quality Management Systems

The Harvard Study compared 1000 organizations who had adopted a ISO 9001 with 1000 organizations that had not. The study found;

- Organizations that adopt and certify to ISO 9001 improved corporate survival and profit.
- Revenue increases nearly 9% after adoption as compared with non-adopters.
- The study found a ten percent increase in the number of employees compared to non-adopters while at the same time increasing profit. Total payroll in ISO firms grew 17.7% more than non-adopters.
- ISO 9001 adoption required a higher level of employee competence. The data shows an annual wage increase for the workers of 7.7%.
A Recent Study by Harvard University Confirms the Benefits of Quality Management Systems

Study Results Continued:

- Management systems standards return bottom-line financial value larger than any investment or time incurred.

- Certification to management systems results in benefits to the organization and its employees; businesses become more profitable, and they pay their employees more.

- The Harvard study also indicates that “the benefits achieved with implementation of ISO 9001 were statistically higher in smaller organizations than in larger organizations”.
Management Systems Standards Transform Organizations

Reactive Management Practices

Preventive Management Practices
When It Comes To Standards Published By ISO, It Is Important To Remember:

• ISO does not allow standards to be developed by “outsiders”.

• ISO requires that new standards be developed by users, potential users and their stakeholders – they are always developed within the industry. If a standard is created, then a noteworthy proportion of the industry decided it was needed.

• Also, it is important to remember, compliance with an ISO standard is VOLUNTARY. ISO does NOT publish REQUIREMENT STANDARDS.

• Over 1.2 million organizations are certified to ISO 9001. The use of ISO 9001 is increasing because it works!
Summary

• ISO 9001 / ISO 22006 is used because customers and stakeholders are increasingly asking for it – it provides **focus** and it **produces results**.

• ISO Certification provides confidence and thus becomes a required entry point for some customers.

• ISO 9001 / ISO 22006 is a required component of ISO 17026 which is used for **Product Certification**.
Conclusion:

ISO 9001 Works!!
Other Reasons Why ISO 9001 Certification a Good Idea
**External Verification** is part of the ISO Certification Process

Remember, ISO 9001 **Certification is Optional** but may be required by some customers or stakeholders

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**IAF**

*IAF (International Accreditation Forum)*
assures competence and consistency of National Accreditation Bodies such as ANAB

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**ANAB**

*ANAB* assures competence and consistency of Certification Bodies

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**CBs: Certification Bodies**

Certification Bodies conduct audits and issue Certificates to qualified organizations

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**Customers / Stakeholders**

Organizations and their customers receive assurance related to the effectiveness of their supplier’s “certified” Management System
About the International Organization for Standardization or “ISO”

- ISO was founded in 1947 to respond to market needs.

- The term ISO was originally derived from the Greek root word ISOS, meaning equal.

- Today, ISO stands for the International Organization for Standardization (not an abbreviation).

- Over time, people became aware of the increasing need for standards that would apply everywhere.
Who is Using ISO 9001?
Evolution of ISO 9001

• 1987 – 2000; Traditional Manufacturing
• In the 1990’s Industry Specific Standards were published to accommodate specific needs in:
  – Medical Device
  – Aerospace
  – Automotive
  – Oil and Gas production

• In 2000 the ISO 9001 scope was expanded to include Service (non manufacturing) creating a significant increase in usage in:
  – Government
  – Healthcare
  – Food Production
Continued Evolution of ISO 9001

• Specific ISO 9001 based Standards have been developed, with unique language for:
  – Agricultural Crop Production
  – Snow removal
  – Body Armor

• Specific ISO 9001 based standards are currently under development with unique language for:
  – Police Organizations
  – Local Government
  – Electoral Bodies - Control and Management of Elections
  – Crime Scene Investigations
  – Educational Organizations

• Under discussion – potential future standards
  – Livestock
  – Finance
  – Healthcare
What Management Systems Standards do for Organizations

Management Systems Standards:

• **Provide organizations (and their customers) with confidence**

• Help organizations *communicate their readiness* to produce consistent results – “*we are certified therefore we are ready and able to meet your needs.*”

• Helps assure results by preventing problems

• Helps reduce costs (prevention is less expensive than correction)

• Helps ensure that internal processes are clearly defined and controlled

• **Conclusion:** Quality Management Systems provide a well defined, peer reviewed, systematic methodology for achieving results!!!
Presented By:

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Thank You!