ISO 9001:2008 Overview

presented by Impact Washington

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So Who Are These ISO Guys Anyway?

- The International Organization for Standardization (ISO) was founded in Geneva, Switzerland in 1946.
- This organization develops manufacturing, trade, and communications standards to make international trade easier.
- The ISO receives input from governments, industry, and other interested parties before and during development of any standard. All standards developed by the ISO are strictly voluntary; no legal requirements force countries, industries or organizations to accept or adopt them.

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ISO Goal

"One of the most noteworthy accomplishments in keeping the price of Ford products low is the gradual shortening of the production cycle. The longer an article is in the process of manufacture and the more it is moved about, the greater is its ultimate cost."

Henry Ford, 1926

Get things done right the first time!!

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ISO Is Part of “Lean”

Lean is…….

A systematic approach

to identifying and eliminating waste

(non-value-added activities)

through continuous improvement

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Value

- Value is defined from the perspective of the customer

- To be considered value-added, an activity must meet these three criteria:
  - *The customer must care about it*
  - *It must modify the product or service (changing fit, form or function)*
  - *It has to be done right the first time*

ISO items are normally here.

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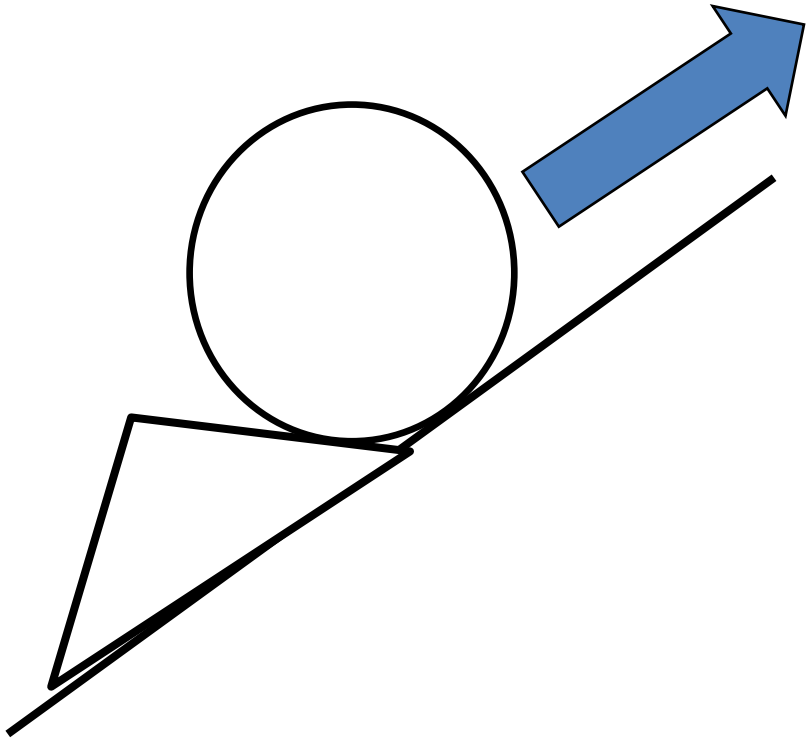
Why is Standardizing Processes Important?



The Lean Gurus would say if it isn't standardized, it isn't controlled, and there is no way you can improve the process.

The ISO guys agree and if you embark down this road, you should too.

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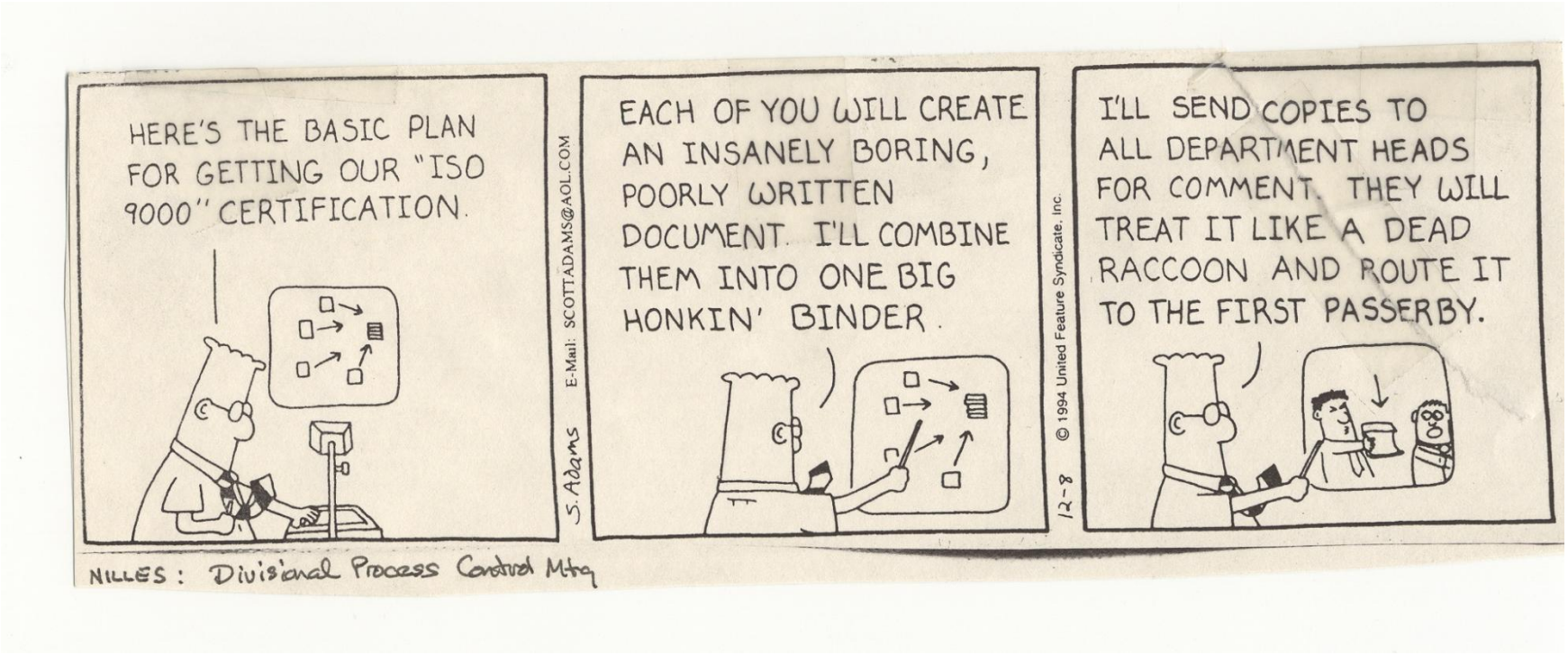

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In a Nut Shell……

- ISO 9001:2008 asks that you define and standardize your processes so you can effectively plan, operate and control **YOUR** processes.

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What This Means

- Your organization is the only one that can define adequate control. Others will have industry experience, but if it works for you that is okay.
- Canned programs/borrowed programs **DO NOT WORK**

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Let's Look at What is Required

- Section 4.2.1 General
  - Documented statements of the a quality policy and quality objectives
  - A quality manual
  - Documented procedures and records required by the ISO standard.
  - Documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

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What's Important to Remember

ISO 9001:2008 only requires 7 documents.

1) Quality Manual
2) Document Control
3) Record Control
4) Non-Conforming Product
5) Internal Audits
6) Corrective Action
7) Preventative Action

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What's Important to Remember

13 Quality Records Are Required

1) Management reviews
2) Education, training, skills and experience
3) Evidence that the realization processes and resulting product fulfill requirements.
4) Results of the review of the requirements relating to the product and actions arising from the review
5) Results of supplier evaluations and actions arising from evaluations
6) As required by the organization to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring and measurement
7) The unique identification of the product, where traceability is a requirement
8) Customer property that is lost, damaged or otherwise found to be unsuitable for use.
9) Validity of previous results when measuring equipment is found not to conform with its requirements
10) Results of calibration or verification of measuring equipment
11) Internal audit results
12) Evidence of product conformity with the acceptance criteria and indication of the authority responsible for the release of the product
13) Corrective and Preventive Action

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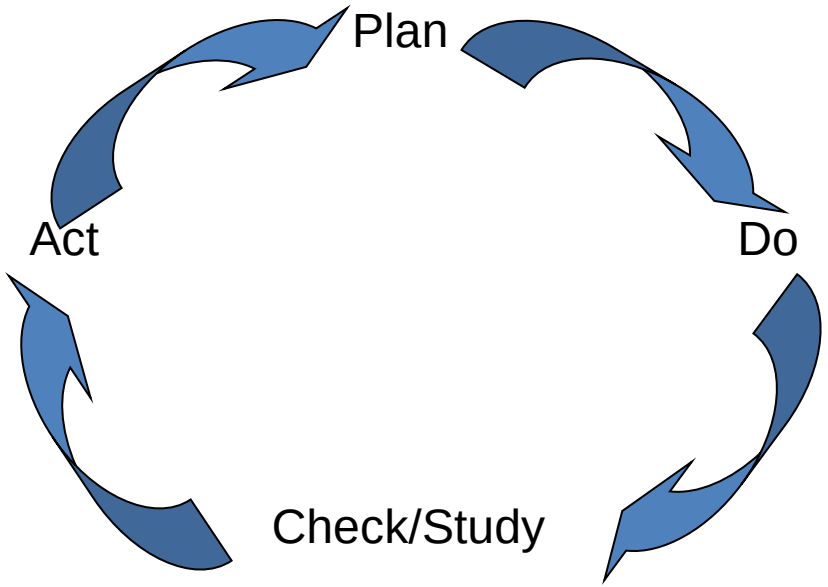
Where Did These Documents and Records Come From?



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How Much Control?

- That is up to you
- There are industry standards
- There is the hinky test
- It is a business decision

Perhaps now you can see where ISO starts to get hard as biases and opinions of adequate control start to get discussed in your organization.

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Implementing ISO 9001 Best Practices

It’s simple really……

- Canned systems do not work (nor does just tell me what to do)
- Delegating defining the standard work to one person does not work
- Where does it make sense to create standard work to ensure things are done right the first time (eliminate waste)?
- How do you measure, analyze, and improve your processes continuously?

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1)
2)
3) Decide which processes need more formal documentation or forms.
4) Review the processes to understand whether all 7 of the ISO required.
5) Review the required forms to understand whether all 13 are implemented
6) Develop implementation plan
7) Decide who is going to be the process leader.

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Implement ISO 9001 Best Practices

If EVERYONE in your organization does not embrace these 4 things. ISO 9001 is going to be VERY difficult.

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So Why Bother?

- Less Stress
- Less Mistakes
- Streamlined processes with less waste
- Customers are asking for it
- There is some research that it makes companies more profitable

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Audit Process

- Registration means a formal audit from an outside source.
- There are:
  - Internal Audits
  - Pre-Audits
  - Certification Audit
  - Maintenance Audits

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Audit Findings

- **Observations**-Based on the auditor's years in industry the process feels hinky and there may be an opportunity for a defect.
- **Minor Non-Conformances**-The process isn't broken, but the auditor found 1 or more instances where the standard work wasn't followed
- **Major Non-Conformances**-You didn't address in your system a required document or record, or the process **you** defined is broken and out of control.

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ISO 9001:2008 Is Not ONLY About Making Product

- It's mostly about the processes needed before you even get to production.
  - Quoting
  - Contract Acceptance
  - Supplier Management

They call it a Quality Management System but really it is a Business Management System because it includes all processes.

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Section 4.0-Quality Management System

- What processes are necessary for you to meet your customers requirements? How do they fit together?
- Which of these processes (in addition to those required by the standard) need to be formally documented to ensure adequate control.
- What forms (in addition to those required by the standard) do you think you need to control your processes?
- How will ensure people have the correct version of these documents and forms? **Required Procedures (2)**

Remember: You said you needed them. If you don't, stop using them.

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Section 5.0-Management Responsibility

- How will you ensure the organization is
  - Meeting customer requirements
  - Effectively planning, operating and controlling the processes.
  - Measuring and analyzing data so you know there is an opportunity for improvement.
- How will you communicate to the organization whether they are successful or not.
- **Required Record**

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Section 6.0-Resource Management

- How does the organization ensure the resources are being managed to ensure effective planning, operation, and control
  - Are people competent? **Required Record**
  - If not, how do you make sure people get trained and the training worked. **Required Record**
- How do you know your work environment and infrastructure is adequate to ensure effective planning, operation, and control

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Section 7.1-Product Realization

- How do you make sure you are meeting your customer's technical requirements. **Required Record** (aka First Article)?
- How are changes to product handled to ensure effective control?

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Section 7.2-Determining and Reviewing Customer Requirements

- How do you know you can meet your customers requirements technically and from a delivery stand point BEFORE you accept the order?
- How do you record that you reviewed the order and any actions you took once you reviewed the order? **Required Record**

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Section 7.3-Design and Development

- If you design your own products, how do you control the design process including changes. How do you get the design right the first time.
  - What is your plan? When will you have design reviews? What are you going to test and when? What are you going to do to validate the design with the customer? **Required Record**
  - What are the design inputs? **Required Record**
  - What are the outputs so people can purchase items and make it in production? **Required Record**
  - What actions came out of the review. How do you make sure they don't get lost? **Required Record**
  - What are the test and validation results? **Required Record**

Lots of documentation to make sure you follow Engineering 101

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Section 7.4.-Purchasing

- How do you select your vendors so you know they can do what they say they can do? **Required Record** How will you monitor this over time? **Required Record**
- How will you measure and analyze data to know when a supplier is in trouble and action needs to be taken?
- How will people know that it is no longer okay to purchase from a supplier?

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7.4.3-Receiving

- How do you know you got what you ordered?
- What will you do if it is not correct?

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Section 7.5-Production

- Defines how product is controlled in production. (Traceability? Handling? Fixtures? Equipment? Instructions? Product Flow? You decide!!!!!)
- If I can't measure the results of the process after it is complete, how do I control the process? How are changes handled? (Heat treat, welding, paint etc.)

Yup! That's it! You decide!

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Section 7.6-Control of Inspection, Measuring and Test Equipment

- How do you know your are measuring things correctly the first time? **Required Record**
- If a gauge is not measuring correctly, how will you assess whether you shipped bad product?

If a measurement is important enough to take, why would you not want it done right the first time?

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Section 8.3-Non-Conforming Product

- How will you keep from accidentally moving bad product though the process? **Required Procedure**
- How will you record what action you took with the bad product? **Required Record**
- It's not required, but most companies choose to use the number of instances of non-conforming product as a way to measure success.

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Section 8.0-Measuring, Analyzing, and Improving

- What data will you measure and analyze to identify opportunities for improvement.
- You get to pick them, but one of them has to be Customer Perception, product conformity, suppliers.
- Normally the other objectives measure on-time delivery, returns, \

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Section 8.2.2-Internal Audits

- How will you ensure the standard work **YOU** defined is being followed? **Required Record and Procedure**
- How will you control the process to ensure this is happening and that things are getting corrected?

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Section 8.5.2-Corrective Action

• When things go wrong, how do you make sure the problem gets fixed? **Required Record and Procedure**

- Definition
- Root Cause
- Action Taken
- Verification of effectiveness

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Section 8.5.3-Preventive Action

- How do you define opportunities for improvement before something bad happens
- Once identified, how do you make sure the actions identified to keep the bad thing from happening are completed. **Required Record and Procedure**
  - Definition
  - Root Cause
  - Action Taken
  - Verification of effectiveness

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So What Makes This Hard?

- Organizations Try to Delegate to An ISO Cop
- Discussions about what controlled means and what is adequate finally have to take place.
- The 13 required records can take a bit of time to manage if you intend to use Excel and/or a paper system.
- When you add control to a process, it can take longer.

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Questions

- How much does an audit cost?
- What is important in choosing an auditor?
- Where do I find a company?
- How long can I expect this to take?
- I just want to implement the bare minimum, is that okay?

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