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13 Concerns about ISO 9001:2015

Cathy Fisher, President of Quistem, LLC
July 9, 2015

QMS Certified?

ISO 9001:2015?????

You are in the right place!

Your ISO 9001 QMS Expert: **Cathy Fisher**

- Over 30 years industry experience
- Worked with ISO 9001 for over 20 years
- Hundreds of QMS implementations
- Thousands of management systems audit days
- A passion for Quality!

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My Promise to You:

- Answer all your questions about ISO 9001:2015
- Offer some resources to help you get started with your QMS transition
- Have some Quality fun!

FDIS 9001:2015 is finally HERE!

What is FDIS?

Final Draft International Standard

- 2nd to last step in ISO standards revision process
- Content = 99% of final standard
- ISO 9001:2015 publication scheduled for September, 2015

Get your copy today: (will add details on how to get copy)


GOOD
NEWS
ISO 9001:2015
Nothing new!

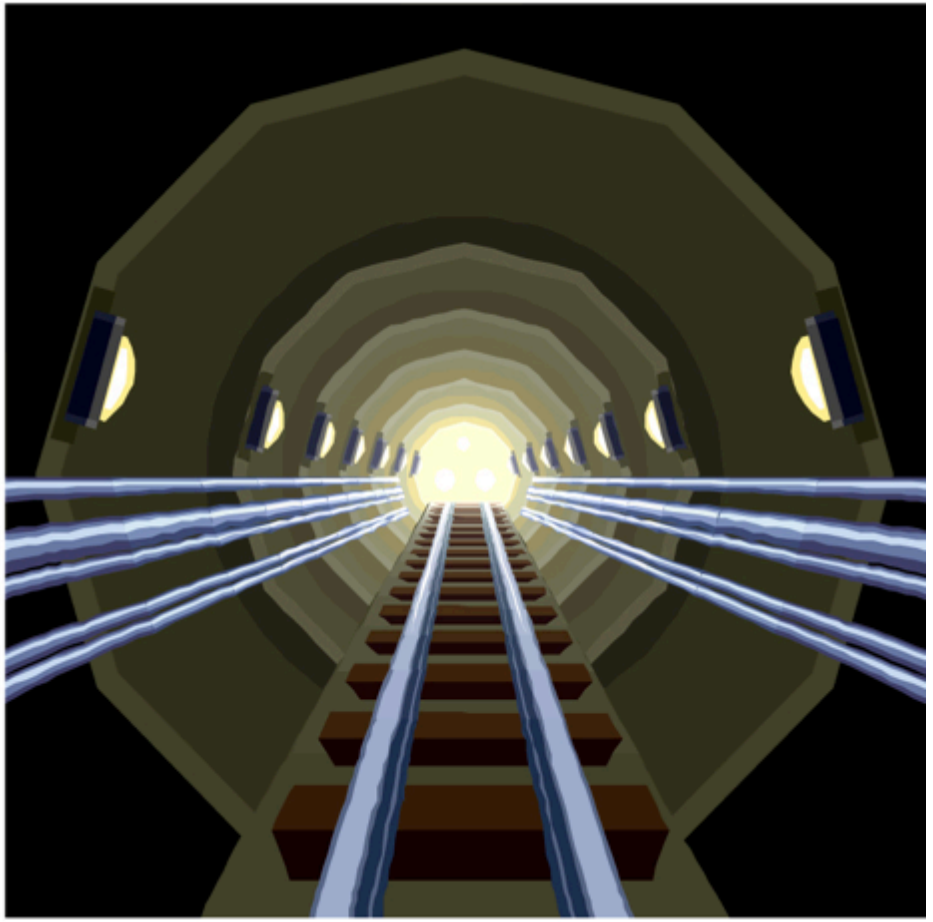
What we will cover. . .

Todays' Agenda

- 13 most common questions and concerns about ISO 9001:2015
- How you can get started on your organization's QMS transition
- BONUS: 5 important points to discuss with your registrar

Macro to Micro

- Question/Concern
- Truth
- Requirements
- Observations



Question #1: Do I have to re-do my entire QMS?

Question #1

Truth: No, as long as your QMS is currently working for your organization.

Observations

- Structure your QMS to reflect how your organization does business
- Map your organization's processes, (and possibly existing documentation), to updated ISO 9001 requirements numbering

Requirement:

- 4.4 QMS and its processes, (same as current 4.1)
- Process Approach still basis for QMS
- ISO high-level structure 10 sections of requirements

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ISO Management System Standards
High Level Structure

1. Scope
2. Normative References
3. Terms and Definitions, (see ISO 9000:2015)
4. Context of the Organization
5. Leadership
6. Planning for QMS
7. Support
8. Operation
9. Performance Evaluation
10. Improvement

Question #2: What happened to Permissible Exclusions?

Question #2

Truth: Still in the standard!

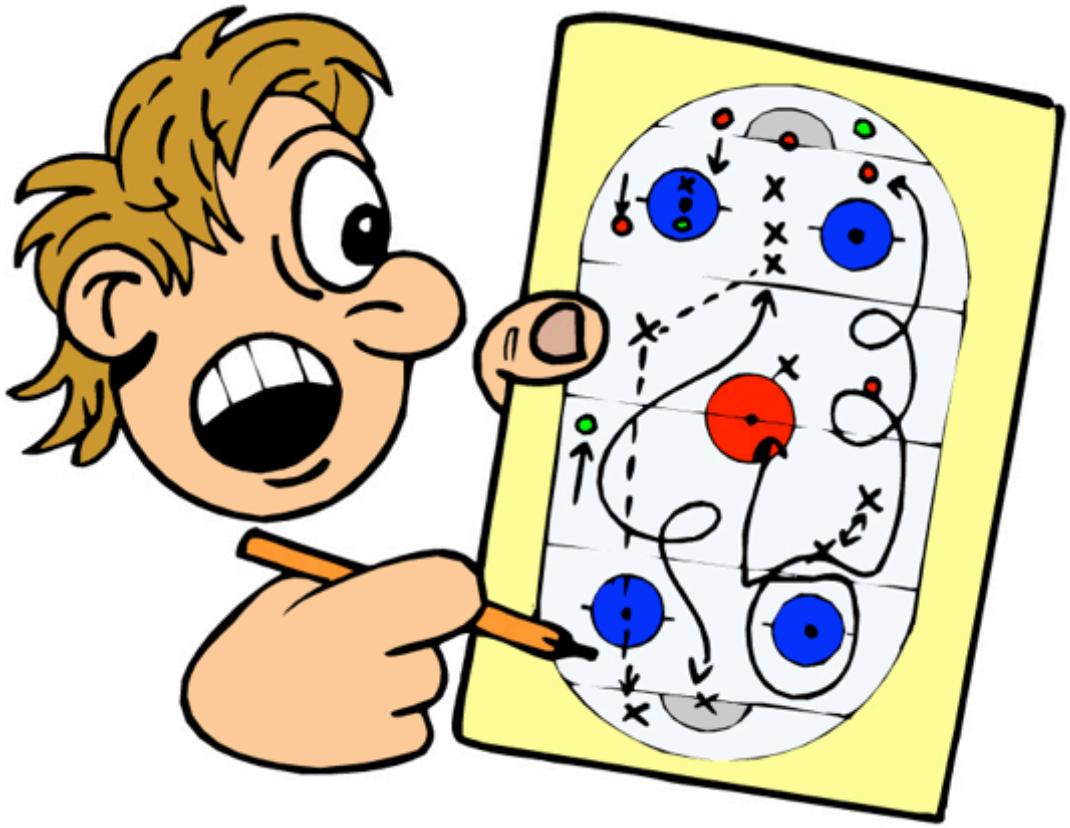
Observations

- Review your current QMS scope
- Consider which processes in your organization support each ISO 9001 requirement, (could be multiple)
- Revisit applicability of Design & Development requirements
- Be careful!

Requirement:

- 4.3 Determining the scope of the QMS
- 8.3.1 Design and Development of Products and Services General

Question #3:
What does “Context of Organization” really mean?



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Question #3

Truth: Consider QMS in relation to overall business strategy.

Observations

- How does business strategy affect ability of organization to achieve quality policy?
- Issues can be internal or external
- Issues can be acute or long-standing
- Monitor issues for consideration of impact on QMS

Requirement:

- 4.1 Understanding the Organization and its Context
- Internal considerations: values, culture, knowledge, organization performance
- External considerations: legal, technological, competitive, market, cultural, social, economic

Question #4:
Who are all these “interested parties”?

Question #4

Truth: Anyone or group with affect by/to your organization.

Observations

- Look beyond who you sell your products/services to; consider
  - Supply chain
  - Supporters
  - influencers
- Can be internal or external
- QMS commitment is to meet customer and applicable statutory/ regulatory requirements

Requirement:

- 4.2 Understanding the needs and expectations of interested parties

Question #5: What happened to "Outsourced Processes"?

Question #5

Truth: Still in there!

Observations

- Applies to all types of “external provision”, (products and services obtained from outside your organization)
- Consider arrangements with associate companies; could affect QMS scope!

Requirement:

- 8.4.1 Control of externally provided products and services
- Apply risk-based approach in determining type and extent of controls

Question #6: How is my QMS Scope affected?

Question #6

Truth: Could be impacted by clarifying language in certain requirements.

Observations

- Now QMS scope formalized as requirement in ISO 9001
- Review applicability of 8.3 Design & Development of products and services as well as 8.4 Control of externally provided products and services requirements

Requirement:

- 4.3 Determining the scope of the QMS
- "Determine boundaries and applicability of QMS"

Question #7: Since the Management Rep requirement is gone, do I lose my job?

Question #7

Truth: Don't worry; your job is safe!

Observations

- Activities of Management Rep still described in ISO 9001
- These may be accomplished by multiple functions/persons in the organization
- Leadership looks for people in the organization to "champion" Quality and maintain customer focus

Requirement:

- 5.3 Organizational roles, responsibilities and authorities
- "Top management shall assign the responsibility and authority for: . . "

Leadership balances multiple Management Systems

Quality

Environment

Technology

Security

Safety

Financial

Other. . .

Knowledge

Question #8:
Should we throw out our Quality Manual?

Question #8

Truth: No, as long as your organization sees value in maintaining this information.

Observations

- A well-prepared Quality Manual defines an organization's business relative to Quality
- Roadmap for navigating the business from a customer requirements perspective
- Basis for Quality decision-making and improvement

Requirement:

- 7.5.1 Documented Information
- a) required by this International Standard
- b) determined by the organization as being necessary for QMS effectiveness

Question #9: What is "Documented Information"?

Question #9

Truth: "Information required to be controlled and maintained".

Observations

- Includes policies, procedures, instructions, formats, recorded results
- Can be "controlled" internally or externally
- Essential information that defines "what", "how", or "what happened"

Requirement:

- 7.5.1 Documented Information
- a) required by this International Standard
- b) determined by the organization as being necessary for QMS effectiveness

Question #10: How can we audit without any procedures?

Question #10

Truth: Look for the Process! It is always there even without paperwork.

Observations

- Think **INPUT-STEPS-OUTPUT**
- Observe
- Follow supporting process audit trails
- Create questions based on available outcomes/results
- Ask “what if?”, “what happens when?”

Requirement:

- 9.2 Internal Audit
- “take into consideration quality objectives, importance of processes, customer feedback, results, etc.
- 7.5.1 Documented Information

Question #11: What do I do with our Preventive Action Process?

Question #11

Truth: If its working for your organization, keep it!.

Observations

- If not, identify other means of Risk-based Thinking in your business.
- "Risk = effect of uncertainty on an expected result"
- Occurs at strategic organizational level down to process/operational level

Requirement:

- 6.1 Actions to address risks and opportunities
- Risk-based thinking is reflected throughout ISO 9001 requirements, (4.4f, 5.1.2b, 6.1, 6.3, 7.1.5, 7.3, 8.1, 8.2.1, 8.3.3, 8.3.6, 8.4.2, 8.5.5a, 8.7, 9.2.2a, 9.3)

What Risk-based Thinking may look like

- SWOT analysis in business planning
- FMEA, FTA in product/ process planning
- Risk review of changes
- Other?

Question #12: What's up with the Knowledge requirement?

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Question #12

Truth: Highlighting the importance of knowledge preservation in any business.

Observations

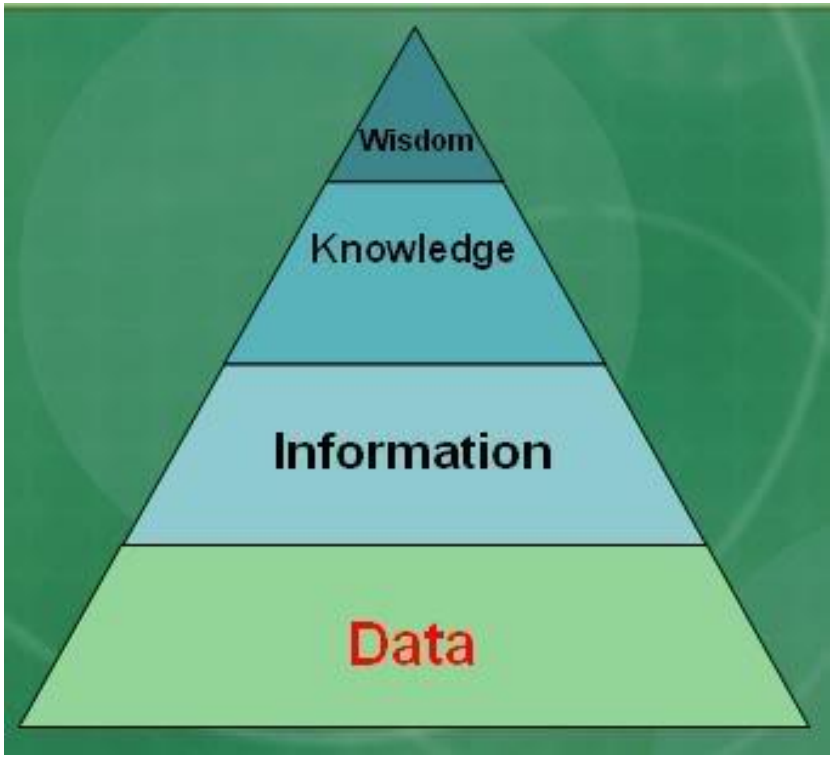
- Loss of knowledge is a leading cost to organizations today!
- Organizations tend to have lots of data and information but these are only useful when put into practice, (which requires knowledge)
- Consider internal, (intellectual property, lessons learned, etc.), as well as external knowledge sources
- Capture Explicit, Implicit and Tacit Knowledge

Requirement:

- 7.1.6 Organizational Knowledge
- Determine knowledge necessary for operation of processes, to achieve conformity of products and services
- Maintain, keep available

What Organizational Knowledge may look like

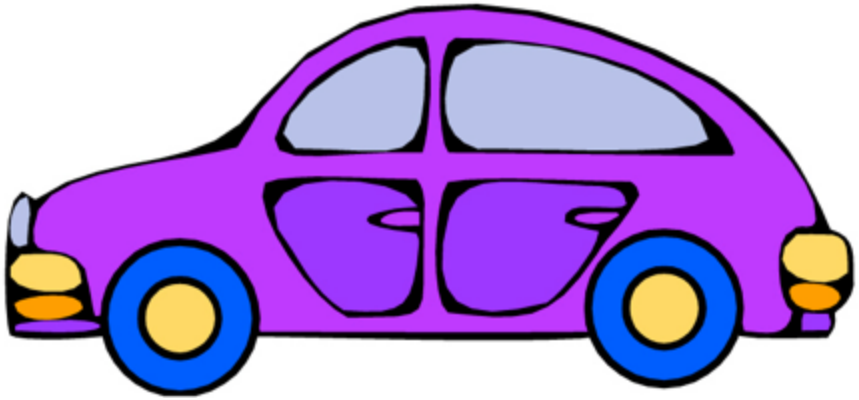
- Directory of SMEs
- Lessons Learned database
- FMEAs
- SOPs
- Design standards
- Other?



Bottom line. . .

- Keep what you have already
- Don't throw anything out that is working for your organization
- Evaluate how you can improve your QMS during transition to ISO 9001:2015

Question #13:
What is going to happen with sector-specific QMS standards?



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Sector-Specific QMS Standards based on ISO 9001

- **ISO/TS 16949** – Automotive: target 2016 for release of update to this international automotive industry standard led by IATF
- **AS9100** – Aerospace: IAQG 9100; target April, 2016 series publication of update to this international aerospace standard
- **ISO 13485** – Medical Device; currently in DIS2 revision stage; not planned to align with High Level Structure
- **TL 9000** – Telecommunications; for global information and communication technologies industry; R6.0 available 2017/2018

Other?

Transition Your QMS: Get Started NOW!

FREE Webinar

- **"5 Steps to Transitioning your QMS to ISO 9001:2015"**
- Monday, July 13, 2015 10-11:30AM EDT
- Register at www.QuistemQMS.com to register

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BONUS

Have a conversation with your registrar!

- Scope of QMS
- Applicability of Design & Development requirement
- External provision/ outsourced processes
- Transition timing
- Transition expectations

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Smithers Quality Assessments

425 West Market Street
Akron, OH 44303

www.smithersregistrar.com

Transition Your QMS: Get Started NOW!

Your Best Next Actions:

1. Get a copy of the FDIS 9001:2015, (will add details to how)
2. Join Cathy's FREE webinar on July 13 **"5 Steps to Transitioning your QMS to ISO 9001:2015**"; go to www.QuistemQMS.com to register
3. Schedule discussion with your registrar

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With Change comes Opportunity!

- Up-level your QMS
- Get leadership more directly involved
- Integrate your organization's management systems
- Focus your business activities towards consistently satisfying your customers

Thank You!

Cathy Fisher
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www.QuistemQMS.com