ISO 9001:2015: Change or Not to Change

or

How to Transition from ISO9001:2008 and ISO9001:2015

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HISTORY OF ISO 9001 Standard

(28 Years of ISO)

1987 Procedures

7 years

1994 Preventive Action

6 years

2000 Process Approach & PDCA

8 years

2008 Process Approach & PDCA

7 years

2015 Risk & Opportunities

ISO 9001:2008 Standard

- **4 Quality Management System**
  - Doc Control, Records, Quality Manual
- **5 Management Responsibility**
  - Commitment, Customer Focus, Quality Policy
- **6 Resource Management**
  - Training, Infrastructure, Work Environment
- **7 Product Realization**
  - Purchasing, Calibration, Design & Development
- **8 Measurement, Analysis and Improvement**
  - Nonconforming, Auditing, Corrective Action

ISO 9001:2015 Standard

- **4 Context of Organization**
  - QMS understanding, Scope, Organization & Context needs and expectations
- **5 Leadership**
  - Commitment, Customer Focus, Quality Policy
- **6 Planning**
  - Objectives, Planning Changes, ***Risk***

Bold and Italics means NEW for this standard

ISO 9001:2015 Standard

- **7 Support**
  - Training, Competence, Communication, Awareness, ***Organizational Knowledge***, ***Document Information***
- **8 Operation**
  - Purchasing, Release, Traceability, Design & Development
- **9 Performance Evaluation**
  - Auditing, Customer Satisfaction, Management Review, Analysis
- **10 Improvement**
  - Nonconforming, Corrective Action, Continual Improvement

ISO TIPS (from ISO.ORG)

1. Familiarize with NEW Standard
2. Identification gaps
3. Develop an implementation plan
4. Training and awareness
5. Update Quality Management System
6. Talk to your registrar about transition

Author Note: To save time and cost, switch steps 4 and 5. New standard and procedure training can be done at the same time.

www.iso.org/ISO/iso_9001_-_moving_from_2008_to_2015 (page 6 of 8)

TERMS THAT HAVE CHANGED

2008	2015
Documents & Records	Document Information (DI)
Documented Procedures	Maintain DI
Records	Retained DI
Work Environment	Environment for the Operation of Processes

TERMS THAT HAVE CHANGED

2008	2015
Purchased Product	Externally provided Product & Services
Product	Products & Services
Preventive Action	Risk Based Thinking (Replaced By)
Supplier	External Provider

NOTE: Supplier (2008) > External Provider (2015):
Can use: supplier, vendor, contractor, consultant, etc

Examples of Maintained DI

- Maintained Document Information
  - Number: 6
  - Clauses: See next slide
  - Documents that add value to the Quality System
  - Documents such as (but not limited to):
    - Scope, Docs necessary to support the operation processes, Quality Policy, Quality Objectives, Org Charts, Procedures, Specs, Scheduled, Approved Supplier List, Information required by the Standard, etc

Examples of Maintained DI

- Maintained Document Information
- Clauses:
  - 4.3 Scope of QMS
  - 4.4 QMS and Process
  - 5.2.2.a Quality Policy
  - 7.5.1.a Document Information
  - 7.5.1.b Document Information
  - 7.5.3.2 Document Information (Records)

Examples of Retained DI

- Retained Document Information
  - Number: 26
  - Clauses: See next 2 slides
  - Records such as (but not limited to):
    - Calibration, Design & Development, Evaluations, Training, Traceability, Property of customer, Release sheets, Nonconformities, Audit, Corrective Actions, Management Review, etc

Examples of Retained DI

- Retained Document Information Clauses:
- 5.1 Leadership and commitment
- 6.3 Planning and Changes
- 7.1.5 Monitoring and Measuring Resources
- 7.2.d Competence
- 8.1 Operational Planning and Control
- 8.2.1.e Customer Communication
- 8.2.3.2 Review of Requirements for Products & Services
- 8.3.1 Design & Development of Products & Services
- 8.3.5 Design and Development Outputs
- 8.3.6 Design & Development Changes
- 8.4.1 Control of Externally provided Processes, Products & Services

Examples of Retained DI

- Retained Document Information Clauses:
- 8.5.2 Identification and traceability
- 8.5.6 Control of Changes
- 8.6 Release of Product & Services
- 8.7.2 Control of Nonconforming Outputs
- 9 Performance Evaluation
- 9.1.1 Monitoring, Measurement, Analysis & Evaluations
- 9.2.2.f Internal Audit
- 9.3.2 Management Review
- 10.1 Nonconformity & Corrective Action
- 10.2.2 Nonconformity & Corrective Action

GENERAL CHANGES

- Risk Management Approach
- Leadership
  - No Management Representative required
  - Management needs to be stronger and more visible
  - Quality Policy & Goals MUST be aligned with company strategic orientation
  - QMS MUST be part of the Business Process

GENERAL CHANGES (Part 2)

- Focus on ALL industries instead of manufacturing
- NO EXCLUSIONS
- No Quality Manual required. However principles are still required
- Greater focus in Identification and understanding expectations

GENERAL CHANGES (Part 3)

- Knowledge is NOW a Resource
  - Must identify what knowledge is needed to carrying out the activity
  - Must maintain, protect & make available (as needed)
  - Must anticipate changes
    - What risk is associated
    - What would happened if the knowledge is NOT acquired in a timely manner

QUALITY MANUAL

2008: Required

2015: Not Required

Should you have a QUALITY MANUAL or NOT?

QUALITY MANUAL (Qman)

QUESTIONS TO ASK YOURSELF:

- Who is asking for your QMan?
- Do you really want to get rid of your QMan?
- Do you want to rewrite it to show that you have processes in place?
- Can you function without? There is nothing to saying that you can not have a QMan.
- What is best for your company?

Management Representative

2008: Required

2015: Not Required

Should you have a
Management Representative
or NOT?

Management Representative (MRep)

QUESTIONS TO ASK YOURSELF:

- What does your MRep do for your company?
- Who will be the contact point for the registrar?
- Who will make sure the QMS is working properly?
- Who will stand for the QMS?
- Pick up the tasks assigned to the current MRep?
- Can you function without?

There is nothing to saying that you can not have a MRep.

What is best for your company?

PROCEDURES

Required Procedures

- 2008 Std required
  - Document Control
  - Records
  - Nonconforming Product
  - Internal Audit
  - Corrective Action
  - Preventive Action: 2015: Not required.

DOCUMENT INFORMATION

Do you keep your current numbering system or change to the new numbering system?

Leaving the Numbering System As Is

- PRO
  - Limited Retraining
  - Only Procedures needing updating change
  - Internalize the QMS
  - Procedures added to cover new clauses in the Standard
  - COST
- CON
  - Not numbered the same as the Standard
  - No guarantee that all clauses are covered at a glance
  - Need for a Clause/SOP Matrix

Changing the Numbering System

- PRO
  - Guarantees all clauses are covered at a glance
  - Procedures align with the Standard
  - No need for a Clause/SOP Matrix
- CON
  - Retraining on ALL Procedures
  - Every document in the QMS must be updated and reapproved
  - COST

Clause/Procedure MATRIX (ISO 9001:2008)

	Doc Name	Doc #	4.2 Doc Req	4.2.1 General	4.2.2 Quality Man	4.2.3 Doc Control	4.2.4 Records	8.2.1 Customer Sat	8.2.2 Auditing	8.2.3 M&M Proc	8.2.4 M&M Prod	8.3 Nonconform
			0	0	1	1	1	0	1	0	0	1
1	Quality Manual				X							
1	Document Control	210				X						
1	Records	250					X					
1	Auditing	510							X			
1	Nonconforming	410										X
0	Management Review	110										

KEY: M& M: Monitoring and Measurement

Procedures

- If you have a Clause/Procedure Matrix, do you need to have clauses of a Standard listed in your Procedure?
  - Other than identification system for the procedure, format and prior approval before use, there is nothing required in a procedure.

Document Information

8 Procedures (total)	**Gen #:**	**2008 Std**	**2015 Std**
Document Control	210	422	750
Records	250	423	750
Management Review	110	560	930
Purchasing	310	740	840
Auditing	510	822	920
Nonconforming	410	830	870
Corrective Action	550	852	1020
Preventive Action	551	853	NA

PROCEDURES	Cost ($)	Docs	TC (No Change)	Docs	TC (Change)
Review (all) @*^	10	8	80	8	80
New SOP+	20	2	40	2	40
Rewrite/Reissue*	20	1	20	1	20
Delete^	10	1	10	1	10
Clause/SOP Matrix	10	1	10	0	0
Revise/Reissue@	20	0	0	6	120
ReApproval@	10	0	0	6	60
DOCUMENTS TOTAL:			160		330

@6 Procedures (no change)

*1 Procedure to be rewrite

^ 1 Procedure to be deleted

+2 Procedures to be written (Risk and Org Knowledge)

(Cost x Docs) = TC (Total Cost)

TRAINING	COST	Emp	TIME	Docs	TC (No Change)	Docs	TC (Change)
Awareness Development	20	1	5	1	100	1	100
Awareness Class	10	11	1	1	110	1	110
Procedure Training	10	11	1	3*+	330	9@*+	990
TRAINING Cost:					**540**		**1200**

@6 Procedures (no change) ^ 1 Procedure to be deleted

*1 Procedure to be rewrite +2 Procedures to be written (Risk and Org Knowledge)

10 Employees (Emp) + 1 Management Rep

(Cost x Emp x Time x Docs) = TC (Total Cost)

Numbering System:	No Change	Change
PROCEDURES	160	330
TRAINING	540	1200
TOTAL COST (Procedures/Training)	700	1530

CONCLUSION

It's up to you and HOW much you want to spend as to which path to take. Hopefully this presentation has added a few other things to think about before you jump into your transition to the new standard.

Whatever your path,

GOOD LUCK.