How Did ISO 9000 & 9001: 2015 End up Like This

A Retrospective View on How ISO 9000 & 9001:2015 Was Developed, to Understand Why it is What it is.
Dec 2015
Key Players from Minnesota

Paul Palms
SC1 Chair of TC176
Incoming Chair of USTAG176

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Minnesota has a strong presence in ISO 9000 series revision.
Agenda

- Controversies related to the revision
- Key Drivers to the Revision
- Background of ISO TC176
- How Did I Get Involved
- How Are ISO Standards Developed
- The Right Expectation to ISO Standards
- Key Changes in ISO 9001:2015
- Responses of Related Industry Standards
- Remaining Challenges
- How Should Companies Respond to the Changes
- Useful Public Communications
How Do You Feel About 2015 Revision?

Good?
Bad?
Improved?
Dialed back?
Don’t know yet?
?
Highly Controversial – Still the Case

- Huge up roar during committee draft (CD) stage
- Significant improvement in draft standard (DIS) stage
- Controversy remains post publication - campaign letter
ISO9001:2015
7.1.4 Environment for the operation of processes
The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE A suitable environment can be a combination of human and physical factors, such as:
- a) social (e.g. non-discriminatory, calm, non-confrontational);
- b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

Quote from campaign letter:

The requirement for a “calm and emotionally protective” work environment… is entirely subjective, … impossible to comply, … an untouchable “third rail”, …determined impossible to legislate, … legislators and regulators have not accomplish, … how third party certification auditors approach, …

…legal entanglements if auditor write a finding being “discriminatory” … or “anti-discriminatory”, …

… how one implements -- and certifies -- "thinking."
Double Edge Sword of Relaxed Requirements

• A major change in this rev. is relaxed requirements in documentation.
• The user base seems welcome the direction.
• But cloud forms over uncertainty in auditing.

Relaxed requirements give more say to the auditors, potentially adding uncertainty in auditing.
Key Drivers to the Revision

- Keep up to the new development
- Annex SL – Common structure for all ISO standards
- Consultancy – E.g. auditing sector
- Generate revenue – Less known reality, an invisible hand

Some say:
Generating revenue drives for many wrong behaviors and bad decisions, that hinders jobs being done thoroughly.
Background Info of ISO TC176

• ISO Technical Committee (TC) 176 handles ISO 9000 standard family.
  • 85 participating countries (each with 1 vote)
  • 25 observing countries
  • 35 liaison bodies
  • 3 subcommittees (SC) with ~ 12 active working groups (WG)
  • 21 of 19,000 ISO standards are in ISO 9000 family.

St. Petersburg, RUS, Nov. 2012

Galway, Ireland, Nov. 2014
Background Info of ISO TC176

- **ASQ** manages US participation, on behave of ANSI.
- **ASQ** holds the *secretariat* post for SC1.
- US mirroring Technical Advisory Group TAG 176, managed by ASQ.
  - That’s where **US position is formed**.
  - That’s where **companies insert influences**.

**Hong Kong, Nov. 2015**

**Porto, Portugal Nov. 2013**
The Makeup of USTAG176 Membership

- Currently 162 members
- Everyone can participate (apply), subject to member approval via voting
- Auditors may potentially have the strongest interest
- $150 annual due.

![Participating Members Pie Chart]

- Company: 76 (47%)
- Consultant: 55 (34%)
- Government: 13 (8%)
- Individual: 13 (8%)
- Organization: 5 (3%)
Historically,

- ISO 9000 series has been European centric, BSI driven.
- US has not been in leading roles, nor driving force.
- US held no leadership positions, nor secretariat post.
- US isn’t the largest ISO 9001 certification market.

During this cycle,

- US gained **convenor** ship for WG1 (ISO9000) and lately WG24 (ISO9001) and many newer WG’s.
- US gained secretariat post and chairmanship for SC1.

US gained influence during this revision.
Gary Jing’s Background

- ASQ Fellow, MBA, PhD in IE, CQM / CQE
- Founding MBB @ Seagate TCO (1998 - 2005)
- Sr. Mgr., Global LS / Founding MBB @ Entegris (2005 - 2009)
- LDFSS Deployment Leader / MBB @ TE – ADC (2009 - 2011)
- LSS Leader / MBB @ TE / CS BNS (2011 - )

- US Delegation to ISO TC176 for ISO 9000 Revision
- Editorial Review Board of Six Sigma Forum Magazine
- IQPC LSS Award Judge Panel
- Development of ASQ BB Certification Program (participant)
- Delphi panel expert for SME/AME/Shingo Lean Certification Program

- Isixsigma DFSS Award (2011), Finalist of IQPC MBB of The Year (2008)
- Two patents in disc drive modeling from his Sigma work
- Series publications on Lean Sigma
How Did I Get Involved

• To many, standard work is dull, lack of excitement.
• Not typically in line with Lean Six Sigma type of work.
• Most time consumed on procedural type of activities or consensus building.
• Limited time on productive work.
• …
• But, I want to be part of the history…

Standard work moves like snail. Meetings are very bureaucratic - inefficient and less productive.
My Involvement
Started in 2012 – the beginning stage of this cycle

St. Petersburg, RUS, Nov. 2012
The Abnormally Fun 1st Meeting Hooked Me

Lavish gala
All of ice, cups too

Free beer in every room all day long

Swan Lake

Peter & Catherine the Great

Special brew for ISO 9000
The Abnormally Fun 1st Meeting Hooked Me

Special brew for ISO 9000 25th Anniversary
How Are ISO Standards Developed

Development Process

- A 4-year cycle.
- Still rushed in many cases.

Two stages (CD & DIS) have public comment cycle built in.

That’s when public can exert influence.
How Are ISO Standards Developed (cont.)

- Participants – Delegates of member bodies.
- Working groups – Those who actually craft the contents.
- How are decisions made – Compromise.
  - Very much like United Nation (or Congress).
  - Always have opposite views.
  - Possibly hundreds of different ways for one line.
  - High level decisions done through voting.
  - Major milestones requires 2/3 of votes to pass.
  - Working decisions via compromise & consensus.

If you are there, your voice will be heard.
If not there, you are at the mercy of whoever are there.
The Right Expectation to ISO Standards

- Industry best practice?
  — A typical trap many standard writers fall into.

- A vehicle for teaching (text book)?

- Minimum requirements?

- ???

Result of Compromise.
Major Changes in ISO 9001:2015

• **Major structural change**, different look. - Clauses and requirements restructured to follow Annex SL (the structure governs all future ISO standards).

• **Major requirement changes.** – Loosened (flexibility) documentation requirement. No longer requires 6 basic procedures documented. They are as in rev 2008:
  
  – Document Control (clause 4.2.3)
  – Control of Quality Records (clause 4.2.4)
  – Internal Audit (clause 8.2.2)
  – Control of Nonconformity (clause 8.3)
  – Corrective Action (clause 8.5.2)
  – Preventive Action (clause 8.5.3)
Major Changes in ISO 9001:2015 (cont.)

- Various less significant changes to catch up with evolution of the world and current state of technologies, e.g.
  - Context of the organization
  - Interested parties
  - Risk based thinking instead of preventive action
  - Documented information
  - No more “Exclusions”
  - Quality management principles reduced to 7 from 8
  - ISO 9000 doc becomes normative reference
  - Improved applicability for service organizations

- Transition period - 3 years (Complete in 2018).
Related Industry Standards

- Many relevant industry standards have liaisons to TC 176 and are actively responding to and preparing for the changes of ISO 9000 series. They provide updates @ TAG 176 meetings.


- Telecom TL9000 - Currently harmonized with ISO 9001 certifications. Full speed in revision; plan to release R6.0 in 2016 and synchronize the transition with ISO 9001.

- Aviation AS9100 - Currently harmonized with ISO 9001 certifications. Full speed in revision; plan to publish in April 2016.
Related Industry Standards

- **Automotive TS16949** – Changed heart (major !). Strongly resisted the change at the beginning. Position softened after DIS. **Now**, after surveying supplier base worldwide, decide to adopt ISO 9001:2015, and to publish in 2016. Key messages:
  - Even top 100 suppliers are not solely automotive.
  - “Moving away from alignment with ISO9001 would increase complexity and costs to suppliers”.

- **Medical Devices ISO 13485** – Changed course. Will adopt the change and upgrade, but struggled to make Annex SL structure work. Eventually decided to abandon Annex SL, but will adopt ISO 9001:2015.

- **Railway IRIS** – They don’t have representation @ TAG176, so no update received. Unlikely to be harmonized with ISO 9001:2015.
Many challenges remain to be resolved

1. The campaign letter.

2. A rising issue: Current Annex SL text and structure proved to be especially challenging for regulatory type of standards. It becomes clear that those standards will have to deviate from it.
   - E.g. ISO 13485 Medical Device, ISO 45001 OHSMS, …
   - Revision of Annex SL will start in 2017.

3. Some terminologies proved to be difficult to standardize, e.g.:
   - Audit – US standard adoption has issue with wording of ”documented” process.
   - Annex SL Definition of ‘Requirement’.

4. There are talks to make the terminology part of revision on-going and on-line, and blur the line of revisions.
How Should Companies Respond to the Changes

Externally

- **Influence the changes** - Closely monitor the proposed changes, actively provide feedbacks during public comment cycles, to advocate your position and interests. (Passed this phase now.)
  - Being actively executed. *Collectively changed the course.*
  - Committee Draft (CD) was very *controversial*
    - Too much subjectivity to auditors, auditing unpredictable.
    - Lots of concerns on redoing QMS docs to align new structure.
  - DIS was widely praised, swinging the pendulum back.

- **Closely monitor** the move of related *Industry Standards*.
  - Most vow to retain the *more strict requirements*. Worth to see how the gaps bridged.
How Should Companies Respond to the Change

Internally – Preparedness

• Anticipate changes.
  – For existing certifications
    • Established companies can largely retain their existing more strict practice. They are not in conflict.
    • May not need to remap the clauses solely for documentation purpose. – Not settled yet. More details in development as a “implementation guide”.
  – The certification body may have it’s own interpretation in some areas. - They’ve 3 months to prepare themselves.

• Start high level communication within company to anticipate and prepare for the changes.
  – ASQ started the public campaign with series publications to raise the awareness and prepare the public.
1. ISO 9001:2015 Revision Overview - General users (PPT)

2. ISO 9001:2015 “Risk Based Thinking” (PPT)

3. ISO/DIS 9001 Correlation Matrix (Doc)

4. ISO/DIS 9001:2015 Transition Guidance (PPT), published by IAF (International Accreditation Forum, which governs certification bodies):
   - Primarily for certification bodies.
Some Public Communication Campaign from ASQ

1. **ASQ** Standard site: [http://asq.org/standards](http://asq.org/standards)

2. **ASQ April & October 2015 Member Gift**:


7. **ASQ Standards Channel** has many great videos explaining things from the basics of the ISO 9001 revision to key changes by topic.
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