QuEST Forum
TL 9000 R6.0 Requirements & ISO 9001:2015
Inform, Educate and Define

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John Wronka – Alcatel-Lucent

June 2015
Presented at the QuEST Forum EMEA Regional Conference
TL 9000 HANDBOOKS - REQUIREMENTS

• Requirements Handbook Release 5.5: ISO 9001:2008 plus additional requirements that address requirements *specific to the ICT sector.*
  – Service Availability (24/7)
  – Program, product, project, and service planning
  – Continuity of supply
  – Maintenance, including long-term & end of life
  – Product security
  – Disaster recovery
  – More than hardware design & manufacturing - Services and Software

http://tl9000.org
Alerts, Rules, Guidance, Examples, References
Measurements Handbook Release 5.0: Defines comparable performance measurements for quality management system implementation, differentiating organizations based on: Problem Report handling; On-Time Delivery; System Performance (Outages); Quality of Hardware, Software, and Services.

http://tl9000.org
Alerts, Rules, Guidance, Examples, References
TL 9000 contains all of the auditable clauses of ISO 9001:2008

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**TL 9000 Informational Alert**

<table>
<thead>
<tr>
<th>1. Originating Workgroup:</th>
<th>2. Alert Number:</th>
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<tbody>
<tr>
<td>Workgroup: IGQ and OSWG</td>
<td>14-002A</td>
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<tr>
<td>Contact: <a href="mailto:contact@questforum.org">contact@questforum.org</a></td>
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<tr>
<th>3. Documentation Affected:</th>
<th>4. Issue Date:</th>
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<tbody>
<tr>
<td>Requirements Handbook</td>
<td>April 21, 2014</td>
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<tr>
<td>Code of Practice for TL 9000 Certification Bodies</td>
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<th>5. Reason for Alert:</th>
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<tr>
<td>A reminder of the relationship between ISO 9001:2008 and TL 9000</td>
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<td>Based on questions received by QuEST Forum and anecdotal reports, it appears the relationship between ISO 9001:2008 and TL 9000 is not clear to everyone. The TL 9000 Quality Management System is based on ISO 9001. The TL 9000 Quality Management System Requirements Handbooks R5.0 and R5.5 contain all of the auditable clauses of ISO 9001:2008. Therefore a certification to TL 9000 includes by default certification to ISO 9001:2008. A single certificate showing both may be issued and any contractual obligation to be ISO 9001 certified is fully met by TL 9000 certification. For simplification, the issuance of single certificate is highly encouraged.</td>
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http://tl9000.org/alerts/alerts.html#10
May 27, 2014

Re: ISO 9001:2015 and TL 9000

To Whom It May Concern:

Based on the released ISO 9001:2015 DIS, existing publication and implementation schedules, and other currently available information, QuEST Forum plans to continue to incorporate ISO 9001 as the base set of requirements within the TL 9000 Quality Management System.

Fraser Pajak

CEO
QuEST Forum
QuEST Forum is also a member of:

- ISO CASCO and ISO CASCO STAR
- USTAG Liaison Group
ISO 9001:2015 Status Update

International ballot on the DIS closed on Oct. 10, 2014 – Results were APPROVE DIS by 90%

When the FDIS is available, it will be posted in the Strategic Relationship Subteam folder and will be emailed to all workgroup members.

ISO/TS 9002 “Guidelines for the application of ISO 9001” AND the ISO Handbook “Guidelines for Small Businesses” will be Implemented

TC 176 SC 2/WG 23 Communication & Product Support – Ashok Dandekar (QuEST Forum Representative)

CD available 2013

DIS available 05/2014

FDIS available 07/2015

ISO 9001:2015 to be published 09/2015

3-Year Transition Agreed
What actions have QuEST Forum taken regarding ISO 9001:2015?

- Solicited, reviewed and submitted comments on ISO 9001:2015 CD: 08/2013
- QuEST Forum agreed continued alignment to ISO 9001: 06/2014
- Solicited, reviewed and submitted comments on ISO 9001:2015 DIS: 07/2014
- Mapped R5.5 TL 9000 Adders to ISO 9001:2015 DIS clauses (now 10!): 11/2014

May REPEAT upon release of the FDIS! For example, Nigel has already agreed to present an ISO 9001 FDIS webinar to QuEST Forum Academy in 07/2015!
IAF Informative Document

Transition planning guidance for ISO 9001:2015

• NOTE: Users should be aware that at Draft International Standard (DIS) stage technical changes may still occur, therefore it is recommended that, while preparation can be carried out at DIS, significant changes should not be implemented until the Final Draft International Standard (FDIS) is issued and the technical content is finalized.

• Evaluation activity undertaken by the CB during the DIS stage cannot be taken into account as part of the formal transition process. Any early evaluation must be re-assessed and fully verified before transition to ISO 9001:2015.

• The International Accreditation Forum (IAF) and the ISO Committee on Conformity Assessment (CASCO) have agreed a three year transition period from the publication date of ISO 9001:2015.
Time to update the TL 9000 Requirements Handbook!
TL 9000 R6.0 Requirements Handbook
Timeline Summary (revised 20150330)

• Map R5.5 adders to ISO 9001:2015 DIS Q4 2014
• Review ISO content vs TL adders Q4 2014/Q1 2015
• Collect general feedback/suggestions Q1 2015
• Section teams work on alignment/wording Q1/Q2 2015
• FDIS published Q3 2015
• Review impact of changes in FDIS on draft Q3 2015
• Full Forum review Q1 2016
• Scrub, Forum vote, and publish Q2/Q3 2016
• Effective Q3 2016
• Mandatory (NOTE 2 YEAR TRANSITION) Q3 2018
A New TL 9000 Measurements Handbook is anticipated in 2018
An Alert will be issued clarifying the TL 9000 R6.0 Requirements Handbook implementation

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<td>Clarify the rules for the implementation of the R5.5 Release of the TL 9000 Requirements Handbook</td>
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<td>The newly released R5.5 Requirements Handbook has a publication date of December 31, 2013 to ensure adequate time for organizations to complete delta training and seamlessly upgrade to the new release. Section 1.7 of the Handbook states: “When a new release of this handbook is published, all changes become effective on the date of publication shown below. Organizations seeking to achieve or maintain certification may continue to use the previous release of the handbook for 12 months after the date of publication of the new release. At that point, the old release becomes obsolete and may no longer be used for any certification or surveillance activities.”</td>
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What can you do to prepare for TL 9000 R6.0 Requirements Handbook Changes

✓ Provide comments to improve TL 9000 Requirements
  – Some comments have already been provided through review of the ISO 9001:2015 CD and DIS along with feedback from “Contact Us”
✓ Participate on an IGQ Clause/Section Sub-team
✓ Review the ISO 9001:2015 FDIS and provide feedback to QuEST Forum
  • Contact your CB to discuss transition planning
  • Attend QuEST Forum Academy webinars and other learning opportunities
✓ Provide comments on R6.0 draft during Full Forum review (1Q16)
✓ Vote on the changes for TL 9000 R6.0 Requirements (2Q16)
  – QuEST Forum Member Companies Only
✓ Implement and comply with TL 9000 R6.0 Requirements

This is your opportunity for your voice to be heard
ISO 9001:2015 follows a new “high-level structure” called Annex SL that will be used for all future management system development.
Conceptual Changes

- a shift to risk-based thinking to support and improve the process approach
- fewer prescribed requirements
- less emphasis on documents
- improved applicability for services
- a requirement to define the boundaries of the QMS
- increased emphasis on organizational context
- increased leadership requirements
- greater emphasis on achieving desired outcomes to improve customer satisfaction
Detailed Changes

- New version of Figure 1; ISO 9001 still follows PDCA
- “procedures” and “records” are not mentioned instead “maintain documented information” and “retain documented information”
- A quality manual and a management representative are no longer required
- “products and services” replaces products
  - ISO 9000 will be updated to address changes in terms & definitions
- “applicability” replaces “exclusions”
- risks are to be determined and addressed, but there is no requirement for formal risk management or risk approach
- New/different requirements from ISO 9001:2008 include organizational context and knowledge management
- Annex A to provide general guidance on implementation and other Annexes will be included such as a summarized analysis of key enhancements between ISO 9001:2008 and ISO 9001:2015
CURRENTLY 10 ADDERS HAVE BEEN PROPOSED TO BE DELETED DUE TO NEW VERBIAGE IN ISO 9001:2015

CURRENT TEXT OF ADDER PROPOSED TO BE DELETED BECAUSE IT IS NOW COVERED IN ISO 8.5.1. C.1 Continual Improvement Program(s) - The organization shall establish and maintain a continual improvement program(s) that includes a focus to improve
a) customer satisfaction,
b) quality and reliability of the product, and
c) other processes/products/services used within the organization.

NEW ISO TEXT IN SECTION 10 WHICH COVERS IMPROVEMENT

10.1 General The organization shall determine and select opportunities for improvement and implement necessary actions to meet customer requirements and enhance customer satisfaction. This shall include, as appropriate:
a) improving processes to prevent nonconformities;
b) improving products and services to meet known and predicted requirements;
c) improving quality management system results.

10.3 Continual improvement
The organization shall continually improve the suitability, adequacy, and effectiveness of the quality management system.
The organization shall consider the outputs of analysis and evaluation, and the outputs from management review, to confirm if there are areas of underperformance or opportunities that shall be addressed as part of continual improvement.
Where applicable, the organization shall select and utilise applicable tools and methodologies for investigation of the causes of underperformance and for supporting continual improvement.
ANOTHER EXAMPLE OF A PROPOSED DELETION

CURRENT TEXT OF ADDER PROPOSED TO BE DELETED BECAUSE IT IS NOW COVERED IN ISO

7.2.3.C.3 Problem Report Feedback - The organization shall provide the customer with feedback on their problem reports in a timely and systematic manner.

NEW ISO TEXT IN SECTION 8 WHICH COVERS CUSTOMER FEEDBACK

8.2.1 Customer communication - The organization shall establish the processes for communicating with customers in relation to:

a) information relating to products and services;

b) enquiries, contracts or order handling, including changes;

c) obtaining customer views and perceptions, including customer complaints;

d) the handling or treatment of customer property, if applicable;

e) specific requirements for contingency actions, when relevant.
All are still under discussion and are subject to change or removal

2 in section 4 - Requirements for TL 9000 certification

1 in section 8 - Requirements Communication

1 in section 9 - Internal Audit Coverage (below)

Example of a proposed new adder under discussion

9.2.2.C.1 Internal Audit Program Planning - The internal audit program shall include all applicable Requirements and Measurement Handbook requirements at least once during every certification cycle. In planning the internal audit program, the organization shall assess the risks and opportunities which may have an impact on the effectiveness of the QMS. The results of this assessment shall be taken into consideration when planning the scope of the internal audit program to determine the sites, processes, and other applicable requirements to be included and prioritized in the program, and the need for subject matter expert participation in the audit team
Many adders have changed only to reflect the change in ISO 9001:2015 from ‘documented procedures’ to ‘documented information’

Example of change:

CURRENT

7.2.3.HS.3 Notification About Critical Problem Reports - The organization shall establish a documented procedure to notify all customers who may be affected by a critical problem report.

PROPOSED CHANGE TO DOCUMENTED INFORMATION

8.2.1.HS.2 Notification About Critical Problem Reports - The organization shall maintain documented information to notify all customers who may be affected by a critical problem report.
In the case of Disaster Recovery, the team felt it was important to have a documented plan and no change to ‘documented information’ was made.

CURRENT

7.1.C.2 Disaster Recovery - The organization shall establish and maintain documented plans for disaster recovery, infrastructure, and security restoration to ensure the organization’s ability to recreate and service the product throughout its life cycle. Disaster recovery plans shall include at a minimum, crisis management, business continuity, and information technology. Disaster recovery and infrastructure security restoration plans shall be periodically evaluated for effectiveness and reviewed with appropriate levels of management.

NO CHANGE IN REQUIREMENT FOR DOCUMENTED PLAN

7.1.1.C.1 Disaster Recovery - The organization shall establish and maintain documented plans for disaster recovery, infrastructure, and security restoration to ensure the organization’s ability to recreate and support the product or service throughout its life cycle. Disaster recovery and infrastructure security restoration plans shall be periodically evaluated for effectiveness and reviewed with appropriate levels of management.
Structure of ISO 9001:2015

4 Context of organization
- Understanding of the organization and its context
- Needs & Expectations of interested parties
- Scope of the QMS
- QMS and its Processes

5 Leadership
- Leadership and commitment
- Quality policy
- Roles, responsibilities and authorities

6 Planning
- Actions to address risk and opportunity
- Quality objectives
- Planning of changes

7 Support
- Resources
- Competence
- Awareness
- Communication
- Documented information

8 Operation
- Operation planning and control
- Determination of requirements for products/services
- Design and development
- Control of externally provided products and services
- Production & service provision
- Release of products and services
- Control of Nonconforming process outputs, products and services

9 Performance evaluation
- Monitoring, measurement, analysis and evaluation
- Internal audit
- Management review

10 Improvement
- Nonconformity and corrective action
- Continual improvement

(Slide Courtesy of Alan Daniels; Boeing)
3 Core Concepts

• Identify the *processes needed to achieve* the planned results
• Continually monitor the *risks* ("Risk-based thinking")
• Understanding “Cause and effect”
• Manage the processes and the system using “PDCA”
Acknowledgements

We would like to thank the following who helped make this workshop possible:

• Nigel Croft who has graciously shared his ISO 9001:2015 overview presentation with the QuEST Forum and

• The QuEST Forum IGQ Work Group leadership team for their contributions to this presentation:
  – Mike Gaines – AT&T
  – Sheronda Jeffries - Cisco
  – Nancy Patterson – Alcatel-Lucent
  – Bill Jibby – Pace Americas
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