## TL 9000 Requirements Handbook, Release 5.0

Changes from Release 4.0



#### **Authors**

Special Thanks To

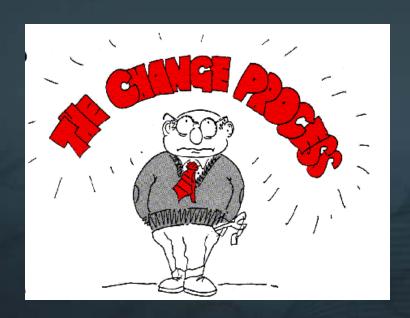
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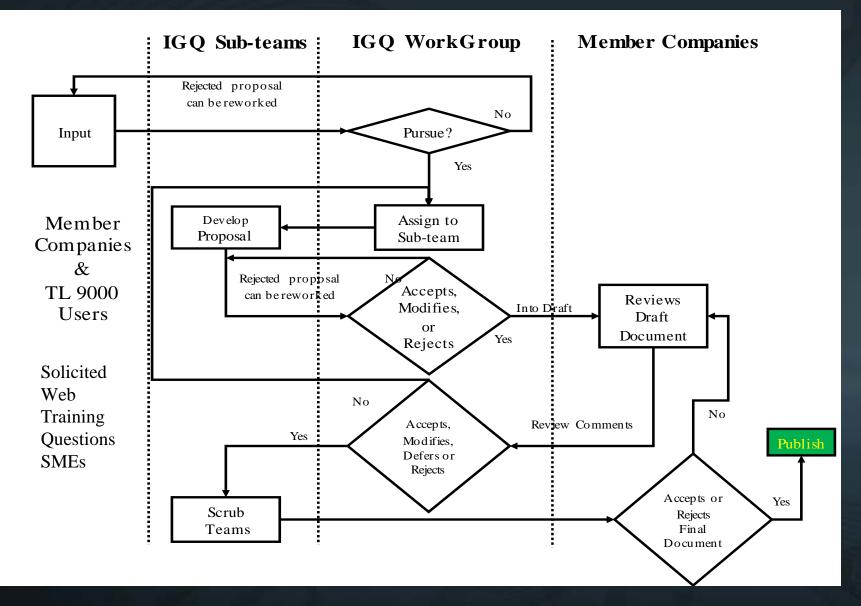
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Who prepared this presentation for the QuEST Forum In support of TL 9000 Requirements Handbook R5.0 Deployment

# Change Process



#### Handbook Production Process



#### **Current Status**

- Draft Handbook completed
- Full Forum Review conducted
- Comments were resolved Nov. 08 Mar. 09
- Final formatting and editing completed
- Official approval vote completed
- Final copy printed
- Available for purchase
- Formal delta training for auditors available on-line
- Effective date 11/15/2009



#### Usage

- May use for audits conducted on and after Nov. 15, 2009
- Must use for audits conducted on or after Nov.
   15, 2010
- May still use R4.0 until Nov. 15, 2010



Why are sub-teams important?

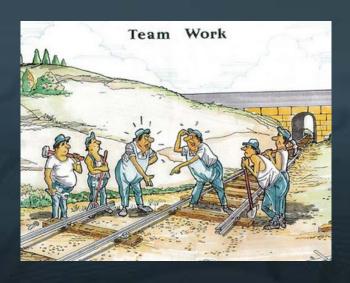


Sub-teams are where new ideas are developed...



### **Contributing Sub-teams**

- TS 16949 Comparison
- CMM-I Comparison
- In Process Quality Measures (IPQM)
- Sustainability
- Section sub-teams (member suggestions 169)
  - Section 1-4, Glossary, & Misc.
  - Section 5 & 6
  - Section 7.1 & 7.2
  - Section 7.3
  - Section 7.4
  - Section 7.5
  - Section 8



#### Why Join a Sub-team?

#### **Sub-teams:**

- Are where ideas are turned into reality
- Are key to enhancing TL 9000 and the Forum
- Meet "virtually" and don't require travel
- Are great opportunities for sharing, learning and networking
- Provide leadership opportunities
- Support professional growth
- Support requirements for individual TL certification
- Provide recognition

Thank-you to the many who participated in IGQ and Oversight Workgroups And sub-teams to make TL 9000 Requirements Release 5.0 Possible!

#### TS 16949

- Compared TL 9000 with TS 16949
- First identified requirements in TL that are not in TS
- Then identified requirements in TS that would be good additions to TL
- Goal harmonizing the two standards





#### CMM-I

- Compared TL 9000 with CMM-I (Level 3)
- First identified requirements in TL not considered by CMM-I
- Then identified areas in CMM-I that would be good additions to TL
- Goal harmonizing the two





# In Process Quality Measures (IPQM) Sub-team

- Standing IGQ sub-team to consider improvements in the design and development process especially pre-deployment measures
- Proposed several changes to the Requirements Handbook wording concerning the use measures within the design and development process

## Sustainability Sub-team

- New IGQ sub-team to consider incorporation of sustainability concepts and requirements into TL 9000
- Proposed several changes to the Requirements Handbook wording concerning sustainability

## Suggestion Process



- IGQ Feedback Sub-team solicited change suggestions from QuEST Forum member companies (169 received)
- Separate sub-teams set up for each major section of the Handbook
- Suggestions reviewed and formal proposals for changes submitted to IGQ (45 proposed)
- IGQ reviewed proposals (13 changes accepted in R5 draft)

# Changes





#### TL 9000 R5.0 Requirements Changes

- Changes presented here are final based on the version of R5.0 that has been approved by the QuEST Forum membership
- This presentation covers only TL 9000 adder changes; changes to ISO 9001:2008 (included as part of R5.0) are NOT included here
- Measurements Handbook is not changing at this time



## Summary of Changes

<b>Type</b>	<u>Adders</u>	<b>Notes</b>
New	2	11
Expanded Scope	2	1
Renumbered	2	2
Reworded	25	11
Deleted	0	1
Unchanged	61	16
TOTAL	92	42

#### **New Requirements**

 7.3.1.C.4 Risk Management Plan – The organization shall develop and document a plan for the identification, analysis, and control of risks to the project that can impact cost, schedule, product quality or product performance.

### New Requirements – cont'd

- 7.4.1.C.2 Supplier Performance Management The organization shall plan and perform supplier performance management and development activities so that:
  - a) suppliers are qualified to established criteria,
  - b) evaluation results are considered during supplier selection activities,
  - c) suppliers are periodically re-evaluated using established criteria,
  - d) supplier quality performance is tracked, and feedback is provided to suppliers to drive continual improvement,
  - e) for identified key suppliers, alignment toward conformity to TL 9000 requirements and measurements or other appropriate quality management systems for the supplier's products occurs, with a preference toward TL 9000.

#### **New Notes**

 5.5.3.C.1-NOTE Sensitive organizational information may be excluded from this requirement.



- 7.1.C.1-NOTE 1 A Life Cycle Model may include consideration and development of alternative solutions evaluated against selected criteria.
- 7.1.C.1-NOTE 2 The Life Cycle Model should take into consideration sustainability practices such as reduction of energy and resource consumption, ecologically-responsible disposal and proper end-oflife treatment.

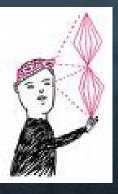
- 7.3.1.C.4-NOTE Risk Management should be performed during all phases of product development and should include:
  - a) the means to determine risk sources, categories, and priorities
  - b) identification of significant or critical characteristics and failure modes, including customer experience
  - a definition of risk parameters (e.g., probability of occurrence, severity of impact) to be used in determining risk priorities and any scoring mechanisms to be used (e.g. FMEA - Failure Mode Effects Analysis)
  - how risks will be managed (e.g., tools to be used, actions to reduce risk, mitigation strategies, monitoring and reporting requirements),
  - e) inputs from appropriate functional disciplines and
  - f) a mechanism for capturing and applying lessons learned.

- 7.4.1.C.2 NOTE 1 Supplier performance management planning and activities should be in conjunction with the organization improvement processes of Section 8.5.
- 7.4.1.C.2 NOTE 2 It is recognized that it is not possible for an organization to provide the same level of interaction with all suppliers. The level provided may depend on the amount of business with a supplier, the criticality of products, history of problems, organization expectations, significance of a supplier within the supply chain or other factors.
- 7.4.1.C.2 NOTE 3 Examples of alignment toward conformity to appropriate quality management systems may include: surveys, supplier questionnaires, supplier education and training regarding conformance to standards; the use of the TL 9000 requirements and measurements, in full or in part; second-party audits evaluating TL 9000 conformance or conformance to an appropriate quality management system; and TL 9000 or other quality standards certification. Examples include ISO 9001, AS9100, CMMI, ISO/TS 16949, etc.

- 7.3.2.C.1-NOTE In conjunction with customer and supplier inputs, the organization should also consider results from competitive analyses.
- 7.3.2.C.2-NOTE Design and development requirements should be defined with a focus on preventing errors.

#### **Expanded Scope**

- 7.3.1.C.5 Integration Planning The organization shall develop and document a plan to integrate the hardware, software, and/or service components into the product to ensure they interact as designed. The plan shall include:
  - a) methods and documented procedure(s),
  - b) responsibilities,
  - c) schedule for integration, and
  - d) test requirements. [9]



### Expanded Scope – cont'd

- 7.3.1.C.6 Estimation The organization shall establish and maintain a method for estimating and tracking project factors against the project plan throughout the project life cycle.
- 7.3.1.C.6-NOTE Project factors should include product size, complexity, requirements changes, effort, staffing, schedules, cost, quality, reliability, and productivity. Data from the estimation process should be analyzed to compare original estimates to actuals.

#### Renumbered

The following requirements and notes are renumbered with no change in text or title:

Old	<u>New</u>
7.1.C.1-Note	7.1.C.1-Note 3
7.2.2.C-Note	7.2.2.C.2-Note
7.3.1.S.3 Computer Resources	7.3.1.S.1 Computer Resources
7.3.1.S.3 Note	7.3.1.S.1 Note
7.3.1.S.4 Regression Test Planning	7.3.1.S.2 Regression Test Planning
7.3.1.S.3 Note	7.3.1.S.1 Note

#### Reworded Adders

25 adders were reworded; some of these changes are minor for clarification purposes but others result in new requirements:

• 7.1.C.2 Disaster Recovery – Added 'Disaster recovery plans shall include, at a minimum, crisis management, business continuity, and information technology. Disaster recovery and security restoration plans shall be periodically evaluated for effectiveness and reviewed with appropriate levels of management.'

- 7.3.1.C.1 Project Plan Added requirement for consideration of:
  - k) design for 'x' plans as appropriate to the product life cycle. Plan examples include, but are not limited to, Manufacturability, Reliability, Regulatory, Serviceability, Safety, Sustainability, and Testability.

 7.3.1.HS.2 Design and Development Process **Quality Measurement Planning and** Implementation – Added minimum requirements for design and development process quality measures: 'The measures should cover the areas of project schedule (life cycle phase transition or milestone monitoring), test execution, and test phase defect monitoring.'

 7.4.1.C.1 Purchasing – Deleted some requirements based on new adder 7.4.1.C.2
 Supplier Performance Management

#### Thank You!

#### Questions?

 Use the Contact Us function on any page of questforum.org or tl9000.org.

#### Or

Contact: John Wronka,
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 (note that the Contact Us function is useful for Any question or problem you may have and is Continually monitored to ensure a response)