The tests to evaluate quality management system and its ability to work
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Claims about Quality Management Systems

• There is no real impact on performance of the organization
• It’s just needless paper work
• It’s done for certification, not for real work
• We have no ideas why we need these papers
• We were doing our work earlier without papers, now we continue to do same work with new papers
Main reason of problem

There are two different (parallel) management systems in the organization:

• **Real-Life Management System** – used by managers to collect and analyze information, to make, implement and standardize decisions; could be non-formalized and non-documented

• **Quality Management System (or Integrated Management System)** – developed, documented and audited accordingly to ISO 9001 or other standards
Creation of ‘parallel’ QMS - example

Requirement of ISO 9001: Quality Police

Simple decision: To develop new document, named Quality Police

Complex, but effective decision:
• To analyze existing strategy statements and documents (mission, vision, strategy goals, strategy, etc.), procedures of their development and review
• To understand relations between these documents, if necessary – to simplify and to harmonized their structure, content and review procedure
• To decide, which existing document or their combination could be considered as Quality Policy, or decide that creation of new document within this system could add value
Focus on internal customers of QMS

Internal customers of Quality Management Systems – people, who make management decisions, especially CEO

Ask them:

• What information do you need to monitor organization and to make decisions?
• How is it comfortable for you to get and to analyze this information?
• How is it comfortable for you to communicate your decision to people?

Don’t start with “ISO 9001 requires you to do…”
Test System

• Focused to identify gaps between Quality Management System and True-Life Management System
• 20 tests, structured by PDCA Cycle
• Specific questions, not just general ideas
• Piloted in companies from Ukraine, Russia, Belorussia, Kazakhstan
Tests: Plan

To top management: What are your top priorities, goals and challenges? Compare with quality policy. How do you develop common view on them? Compare with procedure of quality police review.

To top management: In which documents your describe your objectives and actions to achieve them? Compare with documents pointed in QMS as quality objectives and quality plans.

To CEO and process owners: What is your understanding of ‘good status’ of different processes? How you discuss and align this understanding? Compare with process monitoring/process objectives.

To CEO: What are main changes in the strategy during last years? Look for related changes in QMS.
Tests: Do (1)

To process owners: What are your additional roles, responsibilities and actions, comparing to roles of department managers? Check if there is understanding of process ownership

To managers and people: Which documents do you use to describe your requirements to different activities (or to find requirements for your activities)? Compare with QMS documents

Check QMS documents (relates to purchasing, selling, R&D, improvement, etc.): Do they include any requirements, related to their financial provision?
Tests: Do (2)

To managers and people: What are main problems and uncertain situations in you activity? Check QMS documents about guidelines for such situations

To managers: How do you resolve internal conflicts, related to different understanding of roles and responsibilities? Check using of QMS documents for resolving conflicts and standardizations of decisions

Check QMS documents (few years after QMS implementation): Do they cover areas beyond standards (financial management, partnership, people motivation)?
Tests: Check (1)

For top management: Which information do you analyze to monitor situation and to make improvement decisions? Compare with QMS monitoring system

For top management: Are there examples of significant improvements based on audit results?

For managers and people: What are main problems or unwanted situations you faced? How were they resolved? Compare with procedures of non-conformity management and corrective actions
Tests: Check (2)

For managers and people, who communicate with customers: What are main customers problems or situations, when customers were not satisfied, you faced? How were they resolved? Compare with procedures of non-conformity management and corrective actions

For top management: What are main risks or challenges, you forecast for the organization? What do you do to be prepared for them? Compare with procedure of preventive actions

For CEO: What are your main approaches or events for holistic analysis of organization’s activity? Compare with QMS procedure of management review
Tests: Act

For managers: What do your do if you want to implement improvement? Compare with procedures of corrective and preventive actions, with records for them.

Check management orders, protocols, etc.: Do they contain decisions about fulfillment of regular activity? How these decisions are reflected in QMS documents?

Check different documents, which contain management decisions (plans, protocols, etc.): Do they content decision about improvement of processes realization procedures?

Check examples of significant process changes: Compare dates when changes where implemented in reality and when they were reflected in QMS documentation.