Future Developments of QMS

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Abstract: ISO technical committee ISO/TC 176 is responsible for the ISO 9000 family of standards for quality management and quality assurance. National delegations of 81 countries participate in its work, while another 21 (February 2009) countries have observer status. The ISO 9000 family of international quality management standards and guidelines (totally 18), has earned a global reputation as a basis for establishing effective and efficient quality management system. This paper show basic information about ISO 9001:2008, ISO 9004:2009 and future ISO TC 176 on advanced QMS model (probably ISO 9001:2015). Kay words: Quality Management, Quality Improvement, Quality Policy.

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1. Introduction

ISO standards represent an international consensus on the state of the art in the technology or good practice concerned. ISO's portfolio of more than 17 800 (in March 2009) standards and related documents addresses all three dimensions of sustainable development : economic, environmental and social. ISO's rules for the development of standards require their periodic review to decide if they need revising, maintaining or withdrawing. Compared to the 2000 revision of ISO 9001, ISO 9001: 2008 – the fourth edition of the standard – represents fine-tuning, rather than a thorough overhaul. It introduces clarifications to the existing requirements in ISO 9001:2000, based on user experience over the last eight years, and changes that are intended to improve further compatibility with the ISO 14001:2004 standard for environmental management systems. The new edition of ISO 9001 does not introduce additional requirements, nor does it change the intent of the ISO 9001:2000 standard. No new requirements have been introduced in the new edition, but in order to obtain the maximum benefit from the clarifications in ISO 9001:2008, the users of the 2000 edition must consider whether the clarifications have an impact on their current interpretation of ISO 9001:2000. ISO 9001:2008 has been developed in order to clarify the current requirements of ISO 9001:2000, and to introduce modifications that will improve its compatibility with ISO 14001:2004. ISO 9001:2008 does not contain any additional requirements, and in no way changes the intention of ISO 9001:2000. A certification to ISO 9001:2008 does not represent an increase in the level of quality to be expected, and any organizations certified to ISO 9001:2000 should be considered on the same level as those already holding a new certificate to ISO 9001:2008. For example, a large chemical processing company was required by its major customers to gain certification to ISO 9001 and to be environmentally friendly – ISO 14001. To address these issues, the company leadership planned a comprehensive management strategy linking their QMS and an environmental management system (EMS). A thorough review of their business processes indicated that all elements of ISO 9001 were applicable to their quality management system and the annex in ISO 9001 provided the information needed to effectively link it to the ISO 14001 EMS standard. This paper support references [1 - 10].

2. Activities on advanced QMS model

When applying the concept of multi dimensional Quality at the organization level, some difficulties are revealed in the process of understanding the "expectations and needs" of the customer. The last study of ASQ published recently concludes more explicitly that the future of Quality is moving from the single product quality dimension to a multi dimensional discipline which has to encompass the whole universe an organization is operating in and the different challenges it meets to satisfy the needs and expectations of all its customers. The difficulties origin from a preliminary step that is often overlooked by organizations. This step is the one of clearly defining the organization's customers. How could we understand and define customers' needs and expectations if we have no clear idea who they are? Only after clearly defining who are the organization's customers it can proceed to define their needs and expectation which, of course, will differ from one type of customer to the other. The group of customers of an organization (beyond the customers of its products/services) are usually referred to as the organizations stakeholders or its interested parties. The concept of interested parties is used also in the ISO 9000 Quality Management family of standards and is defined in paragraph 3.3.7 of ISO 9000:2005 as follows : "interested party - person or group having an interest in the performance or success of an organization. In a more descriptive language interested parties are described in ISO/FDIS 9004:2009 as : "Interested parties are individuals and other entities that add value to the organization, or are otherwise interested in, or affected by, the activities of the organization". As a general model was given on Figure 1.

Partners/Sups

Sustainable

Partnership

Social

Responsibility

ISO 14001



Profitability

ISO 2600018001ISO 22000Figure 1. Interested Parties expectations from the organization and related Management Systems Standards

OHSAS

Control or

autonomy Recognition Progress and development External rewards Decent working conditions Dignity

Each of them giving a different meaning for the Quality of the organization: Customers (Internal and External), Shareholders/Owners, Employees, Society, Suppliers/Partners. Of course interested parties differ between organizations, industries, nations, cultures and may change over time. A new Task Group, for examining concepts and ideas for a future revision to ISO 9001, held its first meeting in Tokyo. Its meeting was well attended, and allowed for considerable brainstorming activity on new issues. Initial inputs from the TG members and other sources (e.g. the project review report from TG 1.19) were also reviewed and then combined with the brainstorming results to be categorized into a set of high level concept groupings. Following the report of the TG to the SC2 closing plenary some questions were raised about the timeline for a future revision of ISO 9001. The Secretary advised that two

streams of development activity needed to be brought together for the next revision: the work in the TG on new ideas and concepts for quality, as well as the work in the ISO/ TMB/Technical Advisory Group 13 – Joint Technical Co-ordination Group (ISO/TMB/ TAG13-JTCG), which is seeking to improve the alignment across all of ISO's management system standards. The Secretary presented a chart to show that if about 3 years were to be permitted for the two streams to come together into an approved project, and then a further 3 years were permitted for the drafting activity, we would be looking at a target of around 2015 for the publication of the next edition of ISO 9001. A separate new Task Group also held its first meeting, to update the ISO Handbook: ISO 9001:2000 for Small Businesses, to align it to ISO 9001:2008. This made very good progress in its work, and will submit a draft for

Service

ISO 9001

a 3 month comments review by the members of TC 176 in the near future, following editing. Once the received comments have been reviewed by the TG, it is intended that a final draft will be submitted to ISO Central Secretariat for publication. The submission to ISO is expected to be achieved around the 3rd quarter of 2009. While the current edition of the ISO Handbook contains the complete text of ISO 9001, the SC2 closing plenary meeting agreed that it was not necessary to include either Annex A "Correspondence between ISO 9001:2008 and ISO 14001:2004" or Annex B "Changes between ISO 9001:2000 and ISO 9001:2008" from ISO 9001:2008 in the new edition, but only to provide an explanation of why they are given in the standard.

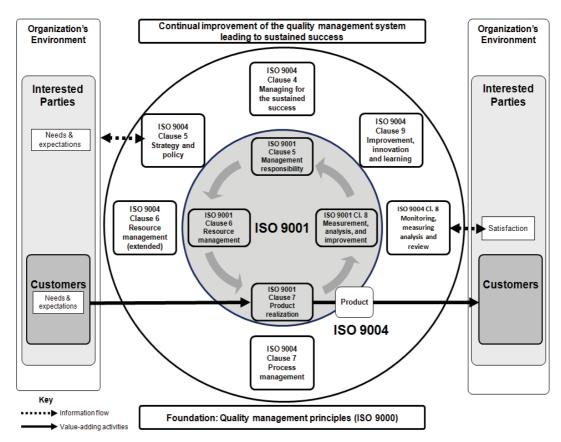
3. ISO 9004:2009

ISO 9004:2009 was prepared by Technical Committee ISO/TC 176, Quality Management and Quality Assurance, Subcommittee SC 2, Quality Systems. This third edition cancels and replaces the second edition (ISO 9004:2000) which has been technically revised. Managing for the sustained success of an organization is a major change in focus for this standard, leading to substantial changes to its structure and contents. The sustained success of an organization is achieved by its ability to meet the needs and expectations of its customers and other interested parties, over the long term and in a balanced way. Sustained success can be achieved by the effective management of the organization, through awareness of the organization's environment, by learning, and by the appropriate application of improvements and / or innovations. ISO 9004:2009 provides a wider focus on quality management than

ISO 9001; it addresses the needs and expectations of all relevant interested parties and provides guidance for the systematic and continual improvement of the organization's overall performance. An extended model of a process-based quality management system incorporating the elements of 9001:2008 and 9004:2009 is given in Figure 2.

This model have nine modules and three annexes. Main modules are: Managing for the sustained success of an organization; Strategy and policy; Resource management; Process management; Monitoring, measurement, analysis and review; Improvement and innovation and learning. Annexes are: A self-assessment tool; Quality management principles and Correspondence between ISO 9004:2009 and ISO 9001:2008. Interested parties are individuals and other entities that add value to the organization, or are otherwise interested in, or affected by, the activities of the organization. Meeting the needs and expectations of interested parties contributes to the achievement of sustained success by the organization. In addition, the needs and expectations of individual interested parties are different, can be in conflict with those of other interested parties, or can change very quickly. The means by which the needs and expectations of interested parties are expressed and met can take a wide variety of forms, including collaboration, cooperation, negotiation, outsourcing, or by terminating an activity.

Factors that are within the control of the organization and critical to its sustained success should be subject to performance measurement and identified as key performance indicators (KPIs). The KPIs should be



Manager

Figure 2. An extended model of a process-based quality management system

Interested party	Needs and expectations
Customers	Quality, price and delivery performance of products
Owners / shareholders	Sustained profitability Transparency
People in the organization	Good work environment Job security Recognition and reward
Suppliers and partners	Mutual benefits and continuity
Society	Environmental protection Ethical behaviour Compliance with statutory and regulatory requirements

Table 1. Examples of interested parties and their needs and expectations

quantifiable and should enable the organization to set measurable objectives, identify, monitor and predict trends and take corrective, preventive and improvement actions when necessary. Top management should select KPIs as a basis for making strategic and tactical decisions. The KPIs should in turn be suitably cascaded as performance indicators at relevant functions and levels within the organization to support the achievement of top level objectives. KPIs should be appropriate to the nature and size of the organization and to its products, processes and activities. They need to be consistent with the objectives of the organization, which should, in turn, be consistent with its strategy and policies. Specific information relating to risks and opportunities should be considered when selecting the KPIs. In selecting the KPIs, the organization should ensure that they provide information that is measurable, accurate and reliable, and usable to implement corrective actions when performance is not in conformity with objectives or to improve process efficiency and effectiveness. Such information should take into account: (i) the needs and expectations of customers and other interested parties, (ii) the importance of individual products to the organization, both at the present time and in future, (iii) the effectiveness and efficiency of processes, (iv) the effective and efficient use of resources, (v) profitability and financial performance, and (vi) statutory and regulatory requirements, where applicable.

The completion of a self-assessment should result in an action plan for improvement and/or innovation that should be used as an input to top management for planning and review, based on the elements of this International Standard. The information gained from the self-assessment could also be used to: (i) stimulate comparisons and share learning throughout the organization (the comparisons can be between the organization's processes and, where applicable, between its different units), (ii) benchmark with other organizations, (iii) monitor progress of the organization over time, by conducting periodic self-assessments, and (iv) identify and prioritise areas for improvement. During this step the organization should assign responsibilities for the chosen actions, estimate and provide the resources needed, and identify the expected benefits and any perceived risks associated with them, Table 2.

4. Future trends of developing MSs

ISO 9001:2008 will have the impact of the new version on the value chain, based on the following facts: (i) scope extended to: "any intended output resulting from product realization processes" i.e. intermediate products, and (ii) much more emphasis on outsourced processes ISO 9001 users may influence their supply chain. ISO 9001:20XX work started for next revision last meeting (February 2009) in Tokyo, with next steps: 1st issue: major changes allowed ("blue sky"-thinking), and 2nd issue: revision of any ISO MS requirements standard should follow a common structure and use identical key wordings, as ISO standards affected: 9001, 14001, 20000, 22000, 27001, 28000, 29001, 30000 and 31000. Harmonized ISO MS requirements, for a concept for 9001 and 14001 are: (i) Context of the organization (Consideration of the needs and expectations of interested parties (including customers and stakeholders)), (ii) Leadership (Commitment and actions by management), (iii) Support (Resources and other needs that enable the organization to

			Maturity level		
Key element	Level 1	Level 2	Level 3	Level 4	Level 5
7.1 (Process man- agement) General 7.2 Process plan- ning and control	Processes are planned and managed in an informal, ad-hoc man- ner.	Key processes, such as those relat- ing to customer satisfaction and product realiza- tion, are defined and managed. Interactions be- tween processes are defined and managed. The effectiveness of the processes is systematically measured and acted upon.	Process planning is integrated with strategy deployment. The needs and expecta- tions of identified inter- ested parties are used as inputs into process planning. Improvements in pro- cess efficiency can be demonstrated. Processes are delivering predictable results. The efficiency and ef- fectiveness of the orga- nization's processes is reviewed.	Improvements in agility, flexibility and processes in- novation can be demonstrated. All relevant inter- ested parties are considered in pro- cess planning. Interaction conflicts between processes are identified and resolved in an ef- fective way.	Process per- formance is compared to leading orga- nizations and the results are used in process plan- ning. The outcomes of key pro- cesses are above the organiza- tion's sector average.
7.3 Process responsibility and authority	Process re- sponsibilities are defined on an ad-hoc basis.	Clear responsibil- ity and authority for the manage- ment of processes is assigned (e.g. to "process owners").	A policy to avoid and resolve potential dis- putes in process man- agement exists.	Process owners' competences are continually im- proved.	Learning is shared be- tween process owners and interested parties.
Note The current maturity level	y level of the organiza	tion's individual elements is	of the organization's individual elements is the highest level achieved with no preceding gaps in the criteria up to that point	to preceding gaps in the criter	rria up to that point

Table 2. Self-assessment of the detailed elements of clause 7 - Process management

function), (iv) Operations (Activities / processes that make the organization achieve its purpose), (v) Performance evaluation (Measurement and data gathering, analysis and use), and Improvement (Action to enhance the organization's performance). But, Risk Management also increasing attention within ISO & in general, because: (i) Word "risk" contained in 9001 the first time in 2008, (ii) Ongoing discussions about future "risk based" 9001 & 14001, (iii) Global financial crisis is enforcing discussions about RM, (iv) FDIS 31000 (RM Guidance) since February 18, 2009, and (v) ISO 31000 (not certifiable) awaited by September 2009. According previous considerations - Risk based auditing, may be considered in a future ISO 19011, because: (i) Think about our PAP method (available since years - 2009), and (ii) "Professional Auditing Practice" PAP includes: (a) identification of 2 major goals (opportunities), (b) identification of 5 risks related to the goals, and (c) auditing of the risks within the network of processes. Also, new DIS/prEN 14005 Guide for the phased implementation of an EMS – including the use of environmental performance evaluation, based on: (i) project following an EU mandate, (ii) "staged implementation" (as in BS 8555) only informative option, and (iii) thus no recommendation for a "14001 minus" certification. We can see structure similar to a "maturity model", as used in the future ISO 9004:2009 (awaited in October) October), and potential usage of 14005 in Stage 1 EMS audits. Next interesting document is ISO Working Draft 14006 Environmental management systems - Guide on Eco-design, with following characteristics: (i) Work ongoing since September 2008, (ii) Need expressed by certain sectors (building construction, Energy Using Products because of an EU Directive), (iii) Merging ISO 14001 with ISO 9001, Chapter 7.3, and (iv) Potential later usage for assessments (14001 plus). Also, joint usage of 9001 & 14001 preferred vs a potential new assessment-certification scheme. ISO also working on Energy Management Systems - prEN 16001 & ISO/PTC 242, with following characteristics: (i) prEN 16001: clearly a 14001 derivate -"environment" simply replaced by "energy", and (ii) A similar approach is discussed also regarding a "Greenhouse-Gas Management System". 14001 users may easily fulfill these additional requirements if a need for certificates would arise. In Security Management Systems, ISO also have a lot of standardization activities, such as: (i) ISO 27001 (IT security) since 2005, (ii) ISO 28000 (Supply chain security) since 2007, (iii) BS 25999-2 (Business Continuity Management) since 2007, and (iv) ISO WD 22301 (Emergency preparedness & BCM) in process preparation. Excellent organizations can put following question - Which of our customers are "security sensitive" ? In field of CSR, ISO 26000, have following activities: (i) International Standard awaited by 2010, (ii) Guidance on social responsibility ("CSR"), (iii) A specific writing process - 6 International Stakeholder Groups: Industry, Government, Labor, Consumer, NGOs, Others, and (iv) Committee Draft stage reached of the end 2008. ISO CD 26000 Content of following modules: (a) Chapters 1-4: Scope, Definitions, Understanding, Principles - What is Societal Responsibility?, (ii) Chapter 5: Recognizing SR & engaging stakeholders - Stakeholder processes (process certification already present), (iii) Chapter 6: "CORE ISSUES" - in future likely to be considered in "sustainability reports", (iv) Chapter 7: Guidance on integration practices

- "system" and awaiting of "assurance", "recognition", "certificate". ISO CD 26000 Core Issues are related on: Organizational governance, Human rights, Labor practices, The environment, Fair operating practices, Consumer issues, and Community involvement and development. Finally, ISO 26000 – an outlook are: (i) Standard still in development, (ii) It is intended as a guide (not for certification), (iii) It should not become a Management System Standard, (iv) Followup-certification likely but path-forward not clear, (v) Content is long and challenging, and (vi) But: Social Responsibility is an issue in the global crisis.

5. Conclusions

ISO TC 176 working very hard last time on the new version ISO 9004:2009 and advance version ISO 9001:2015. On the last meeting, was held in February 2009, the closure of the validation programme meant that the SC2/WG18/TG 1.21 had completed its formal activities. Consequently the TG spent time in Tokyo to develop its project review

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report, so that SC2 can learn from its activities and improve its processes in the future for the control of design specifications and for conducting verification and validation programmes. The project review report will be circulated to SC 2 in due course. In support of the publication of ISO 9001:2008, SC2/ WG18/TG 1.22 had updated the "ISO 9000 Introduction and Support Package" documents, with the assistance of ISO/TC176/ SC1. The member bodies of both SC1 and SC2 had been invited to submit comments on these documents, and the TG reviewed these before producing final versions of the texts. Additionally, the TG focussed its attention on providing supporting documents for ISO 9004:2009. It continued the development of: (i) a brochure on quality for Top management, (ii) a guide on the use of the ISO 9004 Self-Assessment tool, as well as starting new projects, (iii) an ISO 9004:2009 "Implementation" guide, (iv) a "Journey to Organizational Sustained Success" guide, and (v) a "How to sell and promote ISO 9004" guide for national standards bodies.

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