Intertek

ISO 9001:2008 Implementation

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Introduction

While the changes in the ISO 9001:2008 standard are minor in nature, they may still require you to update your quality management system (QMS). With this article, you'll gain insight and information that will help you prepare for a seamless transition.

We'll start with a brief review of the changes published in ISO 9001:2008, as well as the concepts of Customer Satisfaction and the Process Approach. Next, we'll go through a case study example of "Review and Refresh" implementation. Finally, you'll be introduced to a useful process auditing tool for evaluating your QMS.

The changes in ISO 9001:2008

ISO 9001:2008 was published on November 15, 2008. As of November 15, 2009, all audits must be performed against the requirements of this new version of the standard. Any remaining ISO 9001:2000 certificates will become invalid on November 15, 2010. Until then, certificates to ISO 9001:2000 will be considered equal to certificates to ISO 9001:2008.

Compared to ISO 9001:2000, no new requirements have been introduced. Most of the changes are for ease of use and improved compatibility with ISO 14001:2004; these are in the form of "notes" at the end of certain elements/clauses. Information marked "NOTE" is not a requirement to be audited – it is guidance in understanding or clarifying the associated requirement.

Annex B of ISO 9001:2008 has a full, detailed list of the changes from ISO 9001:2000. The following is a brief outline of the most significant changes:

Clause	Revision
4.1	Notes 2 & 3 explain outsourced processes. The organization has to control outsourced processes.
4.2.1.c & .d	Added "Records" for documentation requirements. Also note 1.
4.2.3.f	Added clarification of documents for control.

Clause	Revision
5.5.2	Clarification of who can be the management representative.
6.2.2.b	Added "achieve necessary competence for personnel."
6.3.c	Added information systems as pertaining to the product. (See 7.6)
6.4	Note on clarification of work environment.
7.1.c & 7.2.1	Note word added and clarification of post delivery activities.
7.3.1	Note on what is verification & validation. See the Normative reference.
7.3.3	Note on product preservation.
7.5.3	Added clarification of identification of product from receiving to shipping.
7.5.4	Note on personal property from customer to be protected.
7.5.5	Wording change on preservation of product for conformity.
7.6.a & .c	Word changes, status of equipment identified and note on use of software for conformity of product. (See 6.3.c)
8.2.1	Note on sources for customer satisfaction.
8.2.2	Added corrections and corrective actions for Internal Audits and records of results of audits now required.
8.2.3	Word change and note added.
8.3.d	Added NC product after delivery.
8.5.2.e	Reviewing effectiveness of preventive action.
8.5.2.f	Reviewing effectiveness of corrective action.

Implementation of these changes should be easy and "transparent" to the organization and auditors.

Key concept: Customer satisfaction

Customer satisfaction is defined as:

The ability to consistently provide a product or service that meets customer and applicable statutory and regulatory requirements.

The purpose of ISO 9001 is to enhance customer satisfaction through the application of a quality management system. The QMS helps to measure and

manage customer satisfaction through the use of tools such as internal audit, management review, continual improvement, customer satisfaction reports, customer complaints, and measurable quality objectives.

Customer satisfaction can be measured from both from an External and an Internal viewpoint:

- *External* from customers and interested parties.
- *Internal* from shareholders and managers, to run the business efficiently for the owners.

Both of these factors have to be balanced in order to achieve success.

Key concept: The process approach

The process approach is a more holistic business approach to auditing, compared to the more traditional clause-based approach. It recognizes that while organizations are aligned by functional departments, usually including a "top down" hierarchy of reporting and responsibilities (organizational chart), those departments and functions come together to perform the work required – providing activities that form processes. By better understanding this "horizontal" interaction of the groups within your organization, you can ensure that all of their functions create real value for the customer.

Processes describe how work is performed and evaluated to the customer's and organization's expectations, including:

- Inputs: how many and from where?
- Outputs: how many and where to?
- Evaluation criteria: is this process working effectively for the business?
- Competent personnel
- Method or sequence to be followed

"Review and refresh" implementation: A sample case study

The following is a composite case study based on the experience of Intertek auditors and clients. The intent is to provide guidance and understanding for an initial review of implementation, and a refresher for those who have already completed implementation. Be creative with your own implementation, since in the end, it needs to meet the needs of *your* business.

Process interaction
Our sample organization has identified the following processes: Planning, Product[*] Design, Process Design, Production & Service, Assessment & Action, and Resource Procurement. Now, evaluate how those processes interact with one another:

Planning is the beginning, and is then linked to…
Product Design is the stage of determining what is to be produced, linked to…
Process Design reveals the details of how to produce, linked to…
Production & Service is the actual creation of the product by the design, linked to…
*Assessment & Action* is the feedback mechanism for evaluation of compliance for external and internal satisfaction.

Resource Procurement supports all of the processes by obtaining the resources (materials, suppliers, equipment, personnel, outside services, etc.) required for achieving the planned results of the processes.

You may notice that the process interaction mapped above is *descriptive* in nature. A diagram is not required, although some people can find them helpful. Such a diagram might look like this:

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[*] Note that in this implementation example, "service" could be substituted for "product."

Process Macro
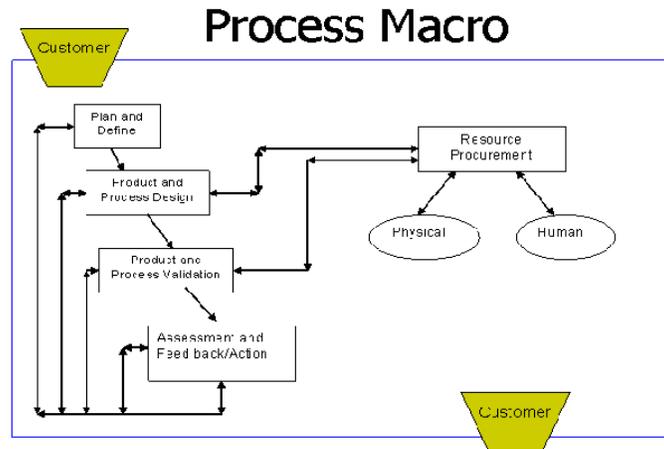
Individual process evaluation

Next, evaluate each process based on the process approach outlined above: Inputs, Outputs, Evaluation of Effectiveness, Competent Personnel, and Sequence. An example follows:

Process	Inputs	Outputs	Effectiveness	Competent Personnel	Sequence
Planning	Market analysis, Customer requirements, Warranty, customer reports, statement of work & CATIA drawings, and request for quote.	Design objectives, reliability goals, quote, estimates, & BOM.	Quotes on time, no open issues after production, quotes accepted.	Senior Mgt., Marketing/Sales, Engineering, Manufacturing, & Finance.	Form team, timing plan, feasibility assessment, approval/denial decision, finances available, & respond to customer
Product Design	Design goals, customer statement of work, reliability targets, product function requirements, and drawings.	Design & development review records, specifications, material specifications, log of changes, measuring equipment.	Timing plan completion, open issues resolved, product testing accepted and on time.	Engineering Mgr., design engineers, engineering techs., purchasing mgr., Q.A. mgr, plant mgr.	Kickoff mtg., timing plan assignments, select resources, create & review design, test results analysis, and approval of design.
Process Design	Design requirements for product, BOM, equipment, test equipment, specifications, and test methods.	Mfg. flow chart, quality plan, work instructions, floor plan, test equipment calibration/verification, and production goals.	Timing plan completion, open issues resolved, productivity is acceptable to estimates.	Mfg. Mgr., plant mgr., Q.A. mgr., Maint. Mgr., process engineer.	Review inputs from design, obtain mfg. & test equipment for mfg., review process parameters, allocate floor space, create maint. program, and install equipment.

Process	Inputs	Outputs	Effectiveness	Competent Personnel	Sequence
Production & Service	Mfg. flow chart, quality plans, work instructions, set up instructions, test equipment, packaging, and personnel.	On time delivered product meeting customer's requirements. Test records, non-conforming reports, training records,	Labor & material variances, premium freight, on-time delivery, and scrap costs	Plant Mgr., mfg. supvs., process engs., tool makers, maint. Mgr., production workers.	Schedule issue, production run, material & tool set up, product tests, packaging, and shipping.
Resource Procurement	Material and equipment requirements, employee requirements & training, and requirements from all other processes.	Physical resources to all affected processes. Qualified Human resources to all processes.	Supplier performance, turnover, accidents, and training completion per plan.	H.R. mgr., Purchasing mgr., Senior mgrs., and Materials mgr.	Select & evaluate sources, approve sources, provide training, and issue resources to processes.
Assessment & Action	Production data, costs to mfg., customer performance reports, internal evaluations of processes, status of corrective actions, and follow ups.	Customer satisfaction achieved and Business plan objectives attained.	Customer performance reports, internal metrics reports, measures of all processes, and progress of continual improvement.	Senior managers, General mgr., management representative, and plant mgr.	Review customer & internal performance, review of external & internal audits, business objectives, and system effectiveness. Management Review.

Review and Refresh

During this review, ensure that the process evaluations are close to the business objectives. Inputs/Outputs/Personnel/Sequence should be easy and simple. Be flexible! "More" is not always "better" – start small and add processes as necessary in the future. If you have too many processes, you might end up spending too much time on maintaining unnecessary documentation.

Audits – whether internal, second-party, or third-party – are used as an assessment of your system. An audit will show you if a process is not performing "up to par" – and if that is the case, you should focus efforts to correct any issues. Management Review will be the key for actions and prevention measures.

Process auditing tool

This matrix is one of many methods that can be used to aid in the evaluation of the QMS. It takes into account all of the characteristics of each process, and helps to analyze the risk to the customer at each step.
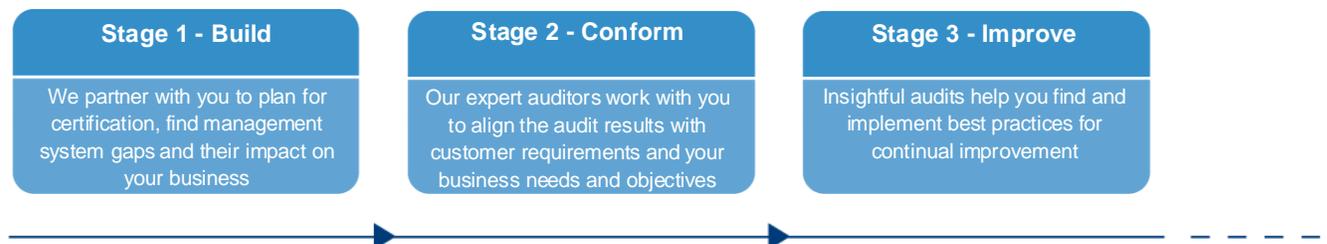
With What? Are physical resources present? Are they maintained?	**Impact to the customer** What are the risks for customer satisfaction?	**With Who?** Does the process owner know the process? Are people qualified and trained?
INPUTS Where do they originate? Can you find evidence of all inputs?	**PROCESS** Does the sequence operate as documented? Where do the support processes contribute?	**OUTPUTS** What are they? Where do they go? Is there an acceptance criteria?
How Many? Are the metrics tracked? Do they have goals? Are there actions for goals not achieved?	**Support processes** Who supports and how? Are they linked to other processes? Have you checked the linkages? Remote sites?	**How?** What is used to control this process? What are the monitoring methods? What are the records?

About the author

Ray Ness is a lead auditor and project manager for Intertek. With over 40 years of experience in the automotive, commercial, and aerospace industries, his areas of expertise include Automotive Quality Systems, Plant Management, Purchasing & Supplier Management, and Process Engineering. He is a certified lead auditor for the ISO 9001, ISO 14001, and ISO/TS 16949 standards.

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