



# ISO 9001:2008

Quality Management System

ISO 9001:2008, Ver. 2010

## ISO 9001:2008's Process Approach Compatibility

Special points of interest:

- Page 1: ISO 9001 process Approach... Adding Value Assessment and some changes that the 2008 version brings...
- Documents and Documentation
- Competency
- Auditing, the Process Approach
- Guidelines to Continual Improvement

### Assessment comprises of...

- Application (questionnaire and quote)
- Selection of Team Members
- Phase I Planning
- Phase I Assessment, on-site
- Phase II Planning
- Phase II Assessment, on-site
- Progression, and
- Review & advance

ISO 9001:2008 requires, as its predecessor required, the process approach. The process approach is one in which the organization flows ISO 9001 as it operates; its activities and processes and interrelation to each other. With supporting evidence and means to plan and benefit from its actions in improving its processes. (see page 3).

Our experience is that the process approach truly links the nature of the organization's activities with the ISO 9001. And it further assists the organizations in truly understand the intent and purpose of an internationally recognized management system. Previous versions of ISO 9001 tend to be mistakenly implemented by answering its elements and addressing the standard in "pockets".

Customer satisfaction is one of the focus of attention within the process approach promoting continuous im-

provement in the relation and expectation with customers and the market.

ISO 9001:2008 requires documentation that is reasonable and that the organization needs to implement, maintain and assist to update and improve its own management system. Yes there are a few specific documents that ISO 9001 requires at procedural level, but these are most likely the same that an organization needs to implement a fundamentally sound managerial practices and methods. These require the application of contemporary methods and progression of technology to improve competitively and that through diagrams, electronic media, models, pictography can be expressed... What is essential is that the documents truly provides evidence that sound fundamentals have been implemented and that propitiate improvement *over* and *over* concurrent with the organization's objectives and goals.

ISO 9001 and the organization's objectives are not mutually exclusive, need be integral.

Records and control for organizations determines whether the organization prosper financially, protects its intellectual property, captures knowledge, or risk non-compliance and litigation, and meets legal obligations. Our uniquely certified professionals, supported by a global team, applies best practices during assessments contributing to effectiveness in management of records from creation to communication and distribution, retrieval, archiving and to flawless final disposition. The peace of mind that BRS certification carries is unparalleled, regardless of any other certification imposed to your organization.

## BRS ... Process Approach Since 1984, now ISO 9001:2008

The process approach has assisted to establish and implement our adding-value-assessment methodology, AVA.

BRS fuses adding-value-assessment to the process focus approach requiring, as deemed beneficial and concurrent with client-organization objectives and including methods, princi-

ples and techniques tied to JIT, Kaizen, Six Sigma, ERP, risk and "Lean Manufacturing" - Further, BRS carries competency on "Lean Manufacturing", which turns into an assessment protocol leading to a certification.

The BRS process approach is unique and focuses on how will ISO 9001 can best service the organization to iden-

tify, evaluate, act and control improvements as it is to protect consumers.

Some changes to the 2008 version encompass adding *applicable* legal requirements, as in 7.2... 6.2.2 *ensure* that competence is achieved... 6.3 *information systems... initiates calibration within 7.3...* and BRS consumer-centric obligation.

## Documents and Documentation



Organizations are already reaping the benefit from the changes in documentation requirements brought by ISO 9001:2008. It is essential that the standard be analyzed not only from a clause-by-clause perspective but from a “panoramic” view for effectiveness. The 8 principles noted elsewhere in the ISO 9000 series and on which ISO 9001 is based:

1. Customer-focused organization
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to management
6. Continual improvement
7. Factual approach to decision-making
8. Mutually beneficial supply-chain relationships

Organizations implementing ISO 9001 on the basis of the organization’s experiences and knowledge (not in guessing what the standard implies) will implement an effective managerial system assisting toward meeting (market) expectations and improving business performance within a consumer-centric obligation. *ISO 9001 must work for your organization and not the other way.*



**“... the combination of training, consciousness, implementation, analysis, actions... are all fundamental toward a progressively competent organization.”**

## ISO 9001:2008, Competency

Investment in training and implementing “consciousness” is a requirement of the standard as components to achieve competency. Further, training will serve as a basis to maintain implementation and improve practices and methods of processes (namely “process approach”)...

improving knowledge.

The requirements invoked as to collect, analyze and act upon market and customer data is critical in the sense that it is best when it *flows* into information > knowledge, and thus to implement as a fundamental basis integral to the managerial system from which bene-

fits are on-going (continual improvement).

The combination of training, consciousness, knowledge, implementation, analysis, actions... are fundamental toward a progressively competent organization and thus improving performance.

*individuals to the profile, propitiating training and other components thus the profile and the individual concur such that performance of the activities support the objectives of the organization and ultimately competence.*

## Auditing, The Process Approach—BRS



One of the biggest challenges that ISO 9001 year 2008 exposes the organization it is not the transition or implementation by organizations, but the lack of assessment-auditors having focus on the clause-by-clause approach—and not in the process approach). Wherein seen worst in effectively assessing through process

approach is within third party registration bodies with questionable purpose.

Assessment-Auditors must plan with care such that the process becomes integral component of the assessment. Briefly stated, view the organization’s processes, evaluate each requirement as it applies to each process activity, thus auditing is by process concurrent with the objectives of the enterprise. Yet not all, the assessment team must decide on the effectiveness of the interrelation to

the management system, business objectives, challenges, issues of risk and competitiveness as a whole... indeed it is easier said than done.

*ISO 9001:2008 brings challenges to assess a management system to audit, specifically to third party than its predecessor standards.*

The BRS professionals undergo a process integrating mission, values and vision with the value-adding-assessment through the process approach such that the organization obtain true benefits of ISO 9001:2008. Assessing an organization the BRS way requires a high degree of competence to the standard and industry knowledge, advance methodologies, knowledge of the *enterprise* within consumer-centric obligations .

**Continuous improvement is** highly dependent on team effort, not individualistic efforts. Whether improvement focuses on quality, efficiency, safety, minimization of wasteful resources, reduction in cycle-times, competitiveness... top management must champion the improvement initiatives by defining objectives and parametric values within the realm of consumer protection. Herein we include some matters to consider:

- Identify the opportunity (as other may refer to the “problem”).
- Define what is that your organization wishes to accomplish focusing on the objective and the objective be measurable.
- Mapping or process mapping can be a helpful tool to identify wherein gains of improvement can be accomplished by identifying wasteful efforts, resources, bottlenecks, *et* others. Consider aspects and issues “outside the paradigms” (black-box).
- Make measurable parametric values that are easily *express* in cost (\$\$, €...); cost is a common language that all levels within an organization can understand.
- When planning do so through a team that develops an objective / mission statement with milestones whether the achievement is short, medium or long range.
- Gather and analyze data such that it flows into information such that information converts to knowledge (*by applying the information*). Many techniques have proven useful such as Pareto charting, cause-an-effect and like many other within the realm of statistics and probability. We shall remember that often true roots for improvement or cause of problems are not in *plain sight*.
- Seek several paths based on root improvement or problem based on the cause potentials. All ideas have value if not directly it may do so indirectly – get out of the thoughts of common beliefs, paradigms.
- Solutions or improvements can be at times put to the test, test them; it can be an initial hypothesis. Situation dependent, compare and evaluate the paths for improvement or basis to a solution.
- Based on the outcomes (hypothesis and analysis outcome), choose.
- For the purpose of control, once the new path has proven to meet the intent then standardize through documents, non documented or documented procedures changing, modifying or eliminating operations and activities that will result in benefit. Procedure changing will require training and awareness (consciousness) of personnel affecting the activities and processes.
- Then quantify, quantify, quantify...
- Monitor progression (progressive success) ...and fine tune as a means to update and improve.
- Last, present the results, which should include an explanation of the what, where, how and why.
- And in continuing shall we ask... What knowledge has been acquired, else have we learned, that is applicable to other processes, products and experiences?

**Do not hesitate to contact BRS to answer questions and approach to 3rd Party Assessment,**

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