

Assessing the business for MIR specific ISO 9001 conformance (a globally proven standard for a Quality Management System)



By

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Focus for Sustainable development and growth

Whether a micro, small, medium or large enterprise, the subject of quality management is a vast topic where, each organization's endeavors to meet the need for quality is a journey by itself.

It needs to be said that knowledge, experience and commitment can help an organization meet this challenge, but the needs of the hour are strategies that help capitalize on investment and simplify the learning curve.

Organizations are increasingly looking to ISO standards to provide a framework to ensure alignment and consistency both nationally and internationally.



A. About ISO standards

ISO International Standards and related normative documents provide consumers, regulators and organizations in both public and private sectors with tools that satisfy the following expectations:

1. They are **technically credible** as ISO standards represent the sum of knowledge of a broad pool of international expertise and stakeholders
2. They **fulfill stakeholder needs** as the ISO standards development process is based on international input and consensus

3. They **facilitate the development of uniform requirements** as the ISO standards development process is built on participation by its national member institutes from all regions of the world

4. They **promote efficiencies when the same standards are implemented** across markets, sectors, and/or jurisdictions

5. They **support regulatory compliance** when the standards are used to meet market and regulatory needs

6. They **enhance investor confidence** because the standards can be used for conformity assessment such as by audit, inspection or certification. This enhances confidence in products, services and systems that can be demonstrated to conform to ISO standards and provides practical support for regulation

All this **seems promising** but **very detailed** for an average business owner. The complexity in incorporating a standard sometimes alienates business owners from the need.

In this assessment, we try to reduce some of this complexity as we uncover the details that one needs to know about one of the ISO standards.

We look under the hood to understand the ISO 9001 standard for Quality management.



B. What is a quality management system about?

A quality management system is a management system that is made up of a set of elements that help an organization

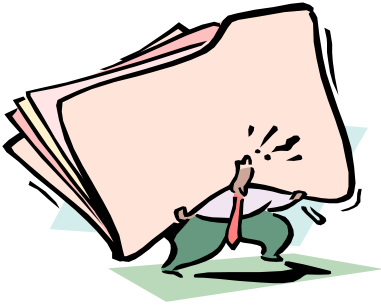
- (1) Establish a globally acceptable policy for quality adherence
- (2) Define objectives that can be used to systematically achieve these policies and
- (3) Develop indicators to check whether these objectives are being met satisfactorily.

It is a management system that can direct and control an organization with regard to its efforts to design and develop quality adherence.

There are different ways to design and develop such quality assurance. There are many businesses that have adopted their own ways to achieve quality and are seen as success stories for others.

However, today the business world is affected by many issues such as rising costs, global expectations for quality and innovation, cutting edge competition, climate change, global warming and unforeseen shortages that together are making it difficult for a business to stay profitable and sustainable.

By implementing the ISO 9001:2008 standard, an organization can establish and ensure product or service conformance for specified requirements on a strategic, industry-wide acceptable and continual manner.



The ISO 9001:2008 standard makes the task of identifying, maintaining and managing data that is needed to run business operations (with quality assurance), simpler and well defined.

The standard makes it possible to establish and maintain a quality management system that has organization-wide orientation, where this orientation does apply to any business, irrespective of whether it is a one-man show or is one with 1 to 100 or more employees.

The normative reference for the standard does focus on 20 or more vital areas:

1. General requirements
2. Documentation requirements
3. Policy for Management commitment
4. Policy for Customer focus
5. Policy for Quality assurance
6. Policy for Planning within the organization
7. Policy for Responsibility, Authority and Communication
8. Policy for Management Review
9. Policy for Provisioning of Resources
10. Policy for Human Resources
11. Policy for Infrastructure

12. Policy for Work environment
13. Policy for Planning of service realization
14. Policy for Customer related processes
15. Policy for Purchases
16. Policy for Operations and service provision
17. Policy for Control of monitoring and measuring equipment
18. Policy for Measurement, Analysis and Improvement
19. Policy for Monitoring and Improvement
20. Policy for Control of non-conformity
21. Policy for Control of non-conforming services
22. Policy for Improvement

Many industry sources and authors of books have tried to uncover the normative reference. There are previews, checklists and guides available. All these are very good.

This article and the author's "**Sustainable Development toolkit**" steers through the normative reference to open up a set of questions that can be answered by a management representative or panel via **Yes, No or Partially Yes** responses.

The responses are thereon compared as against a reporting template, prepared based on ISO 9004 (for continual excellence). This thereon generates a simple report that can be used by a planning committee to plan action and remedial involvement based on budgeting, approvals and milestones set for the organization's vision.



C. What does this assessment expect to achieve?

This assessment expects to start Well-planned Quality management.

Well-planned Quality management is a solution that permits a business owner or management panel interact with standards for quality, high performance and sustainability without actually investing deep-pocket funds that may later never be capitalized upon.

Well-planned Quality management permits a business owner to enter into or exit from the exercise of incorporating adherence for a standard, norm and best practice **quite early on**. The approach helps businesses perform for sustainable development and growth, where there is no-one-size-that-fits-all kind of solution.



D. A peek into ISO 9001's MIR specific areas

We preview some questions that help an organization understand the need for a Quality management system. We start by looking at the policy for documentation requirements and end with the policy for improvement.

D.1 Policy for Documentation requirements (select questions)

1.Does the organization have a documented statement of a quality policy?
Yes/No/Partially

2.Does the organization have a documented statement of quality objectives? Yes/No/Partially

3.Does the organization have a quality manual? Yes/No/Partially

4.Does the organization have documented procedures/processes?
Yes/No/Partially

5.Has the organization identified documents (and records) determined as important to ensure the effective planning, operation and control of the organization's processes? Yes/No/Partially

6.Does the organization maintain such documents (and records)?
Yes/No/Partially

7.Does the quality manual include the scope of the quality management system? Yes/No/Partially

8.Does the quality manual mention details of and justification for any exclusion from the quality of service requirement? Yes/No/Partially

9.Does the quality manual include a documented procedure in the quality management system for the reference of these exclusions?
Yes/No/Partially

10.Does the quality manual include a description of the interaction between the processes of the quality management system?
Yes/No/Partially

11. Does the organization maintain records to provide evidence of conformity to standards and of the effective operation of the quality management system? Yes/No/Partially

12. Are records of the organization legible? Yes/No/Partially

13. Are records of the organization readily identifiable and retrievable? Yes/No/Partially

D.2 Policy for Management commitment (select questions)

1.Has the top management communicated to the organization the importance of meeting customer as well as statutory and regulatory requirements? Yes/No/Partially

2.Has the top management established a quality policy? Yes/No/Partially

3.Has the top management ensured that quality objectives are established? Yes/No/Partially

4.Has the top management conducted management reviews? Yes/No/Partially

5.Has the top management ensured the availability of resources? Yes/No/Partially

D.3 Policy for Quality assurance (select questions)

1.Is the quality policy appropriate to the purpose of the organization? Yes/No/Partially

2.Does the quality policy include a commitment to comply with the requirements? Yes/No/Partially

3.Does the quality policy include a commitment to continually improve the effectiveness of the quality management system? Yes/No/Partially

4.Does the quality policy provide a framework for establishing quality objectives? Yes/No/Partially

5.Does the quality policy provide a framework for reviewing quality objectives? Yes/No/Partially

6.Is the quality policy communicated all through the organization? Yes/No/Partially

7.Is the quality policy understood within the organization? Yes/No/Partially

8.Is the quality policy reviewed for continuing suitability? Yes/No/Partially

D.4 Policy for control of non-conformity (select questions)

1.Does the organization determine, collect and analyze data for conformity? Yes/No/Partially

2.Does the analysis of data provide information related to customer satisfaction? Yes/No/Partially

3.Does the analysis of data provide information relating to conformity to standards, regulations and quality levels? Yes/No/Partially

4.Does the analysis of data provide information relating to incidences, sudden emergencies and other unforeseen occurrences? Yes/No/Partially

5.Does the analysis of data provide information relating to inadequate planning, negligence, oversight, and near-misses? Yes/No/Partially

D.5 Policy for improvement (select questions)

- 1.Does the organization continually improve the effectiveness of its Quality management system? Yes/No/Partially
- 2.Does the organization take corrective action? Yes/No/Partially
- 3.Are corrective actions always or nearly always appropriate to the effects of non-conformities encountered? Yes/No/Partially
- 4.Is a documented procedure established for corrective action? Yes/No/Partially
- 5.Is the documented procedure inclusive of defined requirements for reviewing non-conformities and customer complaints? Yes/No/Partially
- 6.Is the documented procedure inclusive of defined requirements for determining causes for non-conformities? Yes/No/Partially
- 7.Is the documented procedure inclusive of defined requirements for evaluating the need for action to ensure non-conformities do not occur? Yes/No/Partially
- 8.Is it inclusive of defined requirements for determining and implementing the corrective action needed? Yes/No/Partially
- 9.Does it include defined requirements for records of results for corrective action taken? Yes/No/Partially
- 10.Is the documented procedure inclusive of defined requirements for reviewing the effectiveness of the corrective action taken? Yes/No/Partially
- 11.Does the organization maintain records of corrective action? Yes/No/Partially

12.Does the organization determine preventive action? Yes/No/Partially

13. Does the organization share the results and learning from such preventive action (within the organization from time to time) to foster proactive involvement? Yes/No/Partially

A point to be noted

For a business owner, the selected questions all need an answer of Yes to indicate conformance for Sustainable Development with continual Quality assurance.

The complete ISO 9001 standard has a whole gamut of points that when considered and incorporated with right monitoring, measurement, analysis and remedial action, do ensure that the organization's policy for quality management is acceptable from a national and international perspective.



E. Acknowledging all this and more

The author of this assessment has designed a “**Sustainable Development toolkit**” that helps a medium, or small, or micro enterprise assess itself for gaps, lacunae and also use a ISO 9004 template to generate reports for further decision-making, action planning and steering.

The author’s “**Sustainable Development toolkit**” can help a management team prioritize what an organization must take as most relevant steps to implement well-planned and continual Quality management.

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