

Indian Standard
QUALITY MANAGEMENT SYSTEMS — REQUIREMENTS
(Fourth Revision)

1 Scope

This International Standard specifies requirements for a quality management system when an organization:

- a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this International Standard, the terms "product" or "service" only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

4 Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

Indian Standard Quality Management Systems Fundamentals

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Table of Contents Indian Standard Quality Management Systems Fundamentals

1. Understanding the eBook Indian Standard Quality Management Systems Fundamentals
 - The Rise of Digital Reading Indian Standard Quality Management Systems Fundamentals
 - Advantages of eBooks Over Traditional Books
2. Identifying Indian Standard Quality Management Systems Fundamentals
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Indian Standard Quality Management Systems Fundamentals
 - User-Friendly Interface
4. Exploring eBook Recommendations from Indian Standard Quality Management Systems Fundamentals
 - Personalized Recommendations
 - Indian Standard Quality Management Systems Fundamentals User Reviews and Ratings
 - Indian Standard Quality Management Systems Fundamentals and Bestseller Lists
5. Accessing Indian Standard Quality Management Systems Fundamentals Free and Paid eBooks
 - Indian Standard Quality Management Systems Fundamentals Public Domain eBooks
 - Indian Standard Quality Management Systems Fundamentals eBook Subscription Services
 - Indian Standard Quality Management Systems Fundamentals Budget-Friendly Options

6. Navigating Indian Standard Quality Management Systems Fundamentals eBook Formats
 - ePub, PDF, MOBI, and More
 - Indian Standard Quality Management Systems Fundamentals Compatibility with Devices
 - Indian Standard Quality Management Systems Fundamentals Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Indian Standard Quality Management Systems Fundamentals
 - Highlighting and Note-Taking Indian Standard Quality Management Systems Fundamentals
 - Interactive Elements Indian Standard Quality Management Systems Fundamentals
8. Staying Engaged with Indian Standard Quality Management Systems Fundamentals
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Indian Standard Quality Management Systems Fundamentals
9. Balancing eBooks and Physical Books Indian Standard Quality Management Systems Fundamentals
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Indian Standard Quality Management Systems Fundamentals
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Indian Standard Quality Management Systems Fundamentals
 - Setting Reading Goals Indian Standard Quality Management Systems Fundamentals
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Indian Standard Quality Management Systems Fundamentals
 - Fact-Checking eBook Content of Indian Standard Quality Management Systems Fundamentals
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements

- Interactive and Gamified eBooks

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