ISO 9001:2015 Management Overview Executive Summary

**Quality management systems — Requirements**

# Introduction

## General Overview

The adoption of a quality management system is a strategic decision for an organization that can help improve its overall performance and provide a sound basis for sustainable development initiatives. ISO 9001:2015 enables organizations to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, facilitate opportunities to enhance customer satisfaction, address risks and opportunities associated with organizational context and objectives, and demonstrate conformity to specified quality management system requirements.

## Process Approach and PDCA Cycle

This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. The process approach enables organizations to plan processes and their interactions, ensure processes are adequately resourced and managed, and determine and act on opportunities for improvement. The PDCA cycle provides a systematic framework for continual improvement and organizational learning.

## Risk-Based Thinking

Risk-based thinking enables organizations to determine factors that could cause processes and quality management systems to deviate from planned results, put in place preventive controls to minimize negative effects, and make maximum use of opportunities as they arise. This approach represents a fundamental shift from reactive to proactive management, embedding prevention throughout organizational operations.

## Quality Management Principles

The standard is based on seven quality management principles: customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision making, and relationship management. These principles form the foundation for organizational excellence and sustainable success.

# Section 1: Scope

ISO 9001:2015 specifies requirements for quality management systems when organizations need to demonstrate their ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aim to enhance customer satisfaction through effective application of the system. All requirements are generic and intended to be applicable to any organization, regardless of type, size, or products and services provided.

# Section 2: Normative References

The standard references ISO 9000:2015 (Quality management systems — Fundamentals and vocabulary), which provides essential background for proper understanding and implementation of quality management system requirements.

# Section 3: Terms and Definitions

All terms and definitions are provided in ISO 9000:2015, ensuring consistency across the quality management system family of standards and providing comprehensive understanding of quality management concepts and terminology.

# Section 4: Context of the Organization

## Understanding Organizational Context

Organizations must determine external and internal issues relevant to their purpose and strategic direction that affect their ability to achieve intended quality management system results. This includes consideration of legal, technological, competitive, market, cultural, social, and economic environments at international, national, regional, or local levels, as well as internal factors related to values, culture, knowledge, and performance.

## Interested Parties Requirements

Organizations must determine interested parties relevant to the quality management system and their requirements due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

## QMS Scope Determination

Organizations must determine the boundaries and applicability of the quality management system to establish its scope, considering external and internal issues, interested party requirements, and organizational products and services. The scope must be available as documented information, stating types of products and services covered and providing justification for any requirement determined as not applicable.

## Quality Management System Establishment

Organizations must establish, implement, maintain, and continually improve quality management systems, including needed processes and their interactions, in accordance with standard requirements. This includes determining process inputs and outputs, sequence and interaction, criteria and methods for effective operation and control, resource requirements, responsibility and authority assignments, risk and opportunity addressing, process evaluation, and improvement implementation.

# Section 5: Leadership

## Leadership and Commitment

Top management must demonstrate leadership and commitment with respect to the quality management system by taking accountability for effectiveness, ensuring policy and objectives establishment, ensuring integration into business processes, promoting process approach and risk-based thinking, ensuring resource availability, communicating importance, ensuring intended results achievement, engaging and directing personnel, promoting improvement, and supporting other management roles.

## Customer Focus

Top management must demonstrate leadership and commitment with respect to customer focus by ensuring customer and applicable statutory and regulatory requirements are determined, understood, and consistently met; risks and opportunities affecting conformity and customer satisfaction are determined and addressed; and focus on enhancing customer satisfaction is maintained.

## Quality Policy

Top management must establish, implement, and maintain quality policy that is appropriate to organizational purpose and context, provides framework for setting quality objectives, includes commitment to satisfy applicable requirements, and includes commitment to continual improvement. The policy must be available as documented information, communicated and understood within the organization, and available to relevant interested parties.

## Organizational Roles and Responsibilities

Top management must ensure responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization, including ensuring quality management system conformity, ensuring processes deliver intended outputs, reporting on performance and improvement opportunities, ensuring customer focus promotion, and ensuring system integrity maintenance during changes.

# Section 6: Planning

## Risk and Opportunity Actions

When planning for the quality management system, organizations must consider organizational issues and interested party requirements to determine risks and opportunities needing attention to give assurance that the system can achieve intended results, enhance desirable effects, prevent or reduce undesired effects, and achieve improvement. Actions must be planned to address these risks and opportunities with integration into system processes and effectiveness evaluation.

## Quality Objectives and Planning

Organizations must establish quality objectives at relevant functions, levels, and processes that are consistent with quality policy, measurable, consider applicable requirements, relevant to conformity and customer satisfaction enhancement, monitored, communicated, and updated appropriately. Planning must determine what will be done, required resources, responsibilities, completion timing, and result evaluation methods.

## Change Planning

When organizations determine the need for quality management system changes, changes must be carried out in a planned manner considering change purpose and potential consequences, system integrity, resource availability, and responsibility and authority allocation or reallocation.

# Section 7: Support

## Resource Management

Organizations must determine and provide resources needed for establishment, implementation, maintenance, and continual improvement of the quality management system, considering capabilities and constraints of existing internal resources and what needs to be obtained from external providers.

## Personnel and Infrastructure

Organizations must determine and provide persons necessary for effective implementation and process operation and control. Infrastructure necessary for process operation and product and service conformity achievement must be determined, provided, and maintained, including buildings, equipment, transportation resources, and information and communication technology.

## Environmental and Monitoring Resources

Organizations must determine, provide, and maintain the environment necessary for process operation and product and service conformity achievement. Resources needed to ensure valid and reliable monitoring and measurement results must be determined and provided, including appropriate resources for specific activities and maintenance for continuing fitness. Measurement traceability requirements must be addressed when required.

## Organizational Knowledge

Organizations must determine knowledge necessary for process operation and product and service conformity achievement. This knowledge must be maintained and made available to the extent necessary, with consideration of current knowledge and determination of how to acquire additional knowledge and required updates when addressing changing needs and trends.

## Competence and Awareness

Organizations must determine necessary competence of persons doing work under organizational control that affects quality management system performance and effectiveness, ensure competence based on appropriate education, training, or experience, take actions to acquire necessary competence, and retain appropriate documented information as evidence. Personnel must be aware of quality policy, relevant objectives, their contribution to effectiveness, and implications of non-conformity.

## Communication and Documentation

Organizations must determine internal and external communications relevant to the quality management system, including content, timing, recipients, methods, and communicators. Quality management systems must include required documented information and organization-determined necessary information for effectiveness, with appropriate controls for creation, updating, and control.

# Section 8: Operation

## Operational Planning and Control

Organizations must plan, implement, and control processes needed to meet requirements for provision of products and services and implement planned actions by determining requirements, establishing criteria for processes and acceptance, determining required resources, implementing process control, determining and maintaining documented information, controlling planned changes, reviewing unintended change consequences, and ensuring outsourced process control.

## Customer Requirements and Communication

Communication with customers must include providing information relating to products and services, handling enquiries and orders including changes, obtaining customer feedback including complaints, handling customer property, and establishing contingency action requirements when relevant. Organizations must ensure requirements for products and services are defined and that they can meet claims for offered products and services.

## Requirements Review and Changes

Organizations must ensure ability to meet requirements for products and services to be offered to customers through review before commitment, including customer-specified requirements, unstated but necessary requirements, organizational requirements, statutory and regulatory requirements, and differing contract or order requirements. Relevant documented information must be retained, and relevant persons must be made aware when requirements are changed.

## Design and Development

Organizations must establish, implement, and maintain design and development processes appropriate to ensure subsequent provision of products and services. This includes planning with stages and controls, determining inputs including functional and performance requirements, applying controls to ensure result definition and requirement meeting, ensuring outputs meet input requirements, and identifying, reviewing, and controlling changes.

## External Provider Control

Organizations must ensure externally provided processes, products, and services conform to requirements through appropriate control determination, criteria establishment for evaluation and selection, and information communication to external providers including requirements, approval needs, competence requirements, interactions, performance control, and verification activities.

## Production and Service Provision

Organizations must implement production and service provision under controlled conditions including documented information availability, suitable resource availability, monitoring and measurement implementation, suitable infrastructure and environment use, competent person appointment, process validation, human error prevention, and release and post-delivery activity implementation.

## Product and Service Release

Organizations must implement planned arrangements at appropriate stages to verify that product and service requirements have been met, with release not proceeding until arrangements are satisfactorily completed unless otherwise approved. Documented information must be retained including evidence of conformity and traceability to authorization persons.

## Nonconforming Output Control

Organizations must ensure nonconforming outputs are identified and controlled to prevent unintended use or delivery, taking appropriate action based on nonconformity nature and effects. This includes correction, segregation, containment, return or suspension, customer information, and authorization for acceptance under concession, with conformity verification when corrected.

# Section 9: Performance Evaluation

## Monitoring and Measurement

Organizations must determine what needs to be monitored and measured, methods for monitoring, measurement, analysis, and evaluation, when monitoring and measuring shall be performed, and when results shall be analyzed and evaluated. Performance and effectiveness evaluation must be conducted with appropriate documented information retained as evidence.

## Customer Satisfaction

Organizations must monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled, determining methods for obtaining, monitoring, and reviewing this information through various approaches including surveys, feedback, meetings, market-share analysis, compliments, warranty claims, and dealer reports.

## Analysis and Evaluation

Organizations must analyze and evaluate appropriate data and information arising from monitoring and measurement, using results to evaluate conformity of products and services, customer satisfaction degree, performance and effectiveness, planning implementation effectiveness, risk and opportunity action effectiveness, external provider performance, and improvement needs for the quality management system.

## Internal Audit

Organizations must conduct internal audits at planned intervals to provide information on whether the quality management system conforms to organizational requirements and standard requirements and is effectively implemented and maintained. Audit programs must be established including frequency, methods, responsibilities, planning requirements, and reporting, with auditor selection ensuring objectivity and impartiality.

## Management Review

Top management must review the quality management system at planned intervals to ensure continuing suitability, adequacy, effectiveness, and alignment with strategic direction. Reviews must consider previous review actions, external and internal changes, performance information including trends, feedback, objective achievement, process performance, nonconformities and corrective actions, monitoring results, audit results, and external provider performance, with outputs including improvement opportunities, change needs, and resource requirements.

# Section 10: Improvement

## General Improvement

Organizations must determine and select opportunities for improvement and implement necessary actions to meet customer requirements and enhance customer satisfaction, including improving products and services, correcting and preventing undesired effects, and improving performance and effectiveness through various approaches including correction, corrective action, continual improvement, breakthrough change, innovation, and reorganization.

## Nonconformity and Corrective Action

When nonconformities occur, including those arising from complaints, organizations must react appropriately including taking control and correction action, dealing with consequences, evaluating elimination needs, determining causes, determining if similar nonconformities exist or could occur, implementing needed actions, reviewing corrective action effectiveness, and making quality management system changes if necessary.

## Continual Improvement

Organizations must continually improve quality management system suitability, adequacy, and effectiveness, considering analysis and evaluation results and management review outputs to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

# Annex A: Clarification of New Structure, Terminology and Concepts

## Structure and Terminology

The clause structure and terminology have been changed to improve alignment with other management system standards, with no requirement for organizations to apply the specific terminology or structure to their documented information. Organizations can choose terms that suit their operations while meeting standard requirements.

## Products and Services

The standard uses "products and services" to include all output categories, with specific inclusion of "services" to highlight differences in application of some requirements. Most outputs include both products and services, with characteristic differences in realization and delivery.

## Risk-Based Thinking

Risk-based thinking has been implicit in previous editions and is now explicitly specified, representing application to planning and implementing quality management system processes. This enables reduction in prescriptive requirements and replacement with performance-based requirements, providing greater flexibility than previous versions.

# Annex B: Other International Standards on Quality Management

Various supporting standards have been developed by ISO/TC 176 to provide guidance for organizations applying this International Standard and for those choosing to progress beyond its requirements, including standards addressing customer satisfaction, quality plans, project management, configuration management, measurement management, documentation, financial benefits, training, statistical techniques, people involvement, and consultant selection.

## Key Success Factors

1. **Strong Leadership Commitment**: Top management must demonstrate visible commitment and provide necessary resources for quality management system success
2. **Process Approach**: Systematic process approach ensuring consistent product and service realization and customer satisfaction
3. **Risk-Based Thinking**: Proactive identification and management of risks and opportunities throughout organizational operations
4. **Customer Focus**: Systematic understanding and meeting of customer requirements and enhancement of customer satisfaction
5. **Continual Improvement**: Regular monitoring, measurement, and improvement processes ensuring system effectiveness and organizational excellence

## Implementation Benefits

* **Enhanced Customer Satisfaction**: Systematic approach to understanding and meeting customer requirements and expectations
* **Improved Operational Efficiency**: Process approach providing clear understanding of organizational operations and improvement opportunities
* **Risk Management**: Systematic identification and management of risks and opportunities affecting organizational success
* **Market Access**: International recognition facilitating market access and customer confidence
* **Competitive Advantage**: Quality management system providing market differentiation and operational excellence
* **Regulatory Compliance**: Framework supporting compliance with applicable statutory and regulatory requirements
* **Organizational Learning**: Systematic approach to knowledge management and organizational development