QUALITY ASIA

FREE QMS INTERNAL AUDITOR TRAINING

(As per ISO 9001:2015)

From Quality Asia Certifications Private Limited

Become a Certified Internal Auditor !!!

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COURSE OBJECTIVES

01 Introduction

02 Revision History and Purpose

03 Important Concepts

04 Cl. 1-4 Structure, scope, definitions, context of the organization

05 Cl. 5 Leadership and Cl.6 Planning

06 Cl. 7 Support

07 Cl. 8 Operation

08 Cl. 9 Performance Evaluation
Cl.10 Improvement

09 Impacts on Organization and Auditors

10 Internal Auditing

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OUTCOMES

Upon successful completion of this course, you will:

- Be able to understand the requirements of ISO 9001:2015.
- Have achieved the means to assess and improve your organization's QMS.
- Gain & sharpen your Internal Auditing skills
- Be Certified with Internal Auditor Credentials on ISO 9001 on successful clearance of the Exam

TRAINER INTRODUCTION

Mr. Atul Suri

BE (Electrical), MBA

- **Certified Lead Auditor:**
  ISO 9001, 14001, 45001, 50001, 22000, 27001, 13485, and 26000
- **BEE Certified Energy Auditor (CEA)**
- **Professional Experience:**
  - **30+ Years** in the industry, with a strong foundation in engineering and management.
  - **20+ Years** as a seasoned Management Systems Auditor and Trainer, delivering expertise across multiple sectors.
  - Worked with Various Top Notch Certification Bodies as a Lead Auditor and Reviewer like Quality Asia, Intertek, Apave, Moody International, IRQS, etc

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ABOUT QUALITY ASIA

Your Trusted Partner in ISO Certifications

- **Ethical Certifications**
  - We are committed to providing 100% audit and compliance services, ensuring transparency and integrity in every certification we issue.
- **Comprehensive Expertise**
  - We specialize in ISO 9001, ISO 14001, ISO 45001, and more, offering a full spectrum of certification services tailored to your organization's needs.
- **Free ISO 9001 Internal Auditor Training**
  - We empower your team with free training, helping you build internal expertise and maintain compliance with international standards.
- **Global Reach, Local Touch**
  - Serving clients across multiple Indian cities and international locations, we combine global expertise with personalized local service.
- **Commitment to Excellence**
  - Our mission is to support businesses in achieving and maintaining their certification, unlocking new opportunities and improving operational efficiency.

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ABOUT FREE LIVE INTERNAL AUDITOR PROGRAM

Empowering Your Team with ISO Expertise

- **Monthly Training Programs**
  - We offer a focused training session on a different ISO standard each month, ensuring continuous learning and up-to-date knowledge for your team.
- **Flexible Learning Options**
  - Missed a session? No problem! Our training programs are available for later viewing through the Quality Asia School on our website, allowing you to learn at your own pace. Log on to
- **Our Mission**
  - We are dedicated to increasing awareness about ISO standards and enhancing internal auditor competence. Our goal is to uplift industry operational standards by empowering professionals with the knowledge and skills they need to drive excellence in their organizations.

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ISO 9001:2015 – REVISION HISTORY AND PURPOSE

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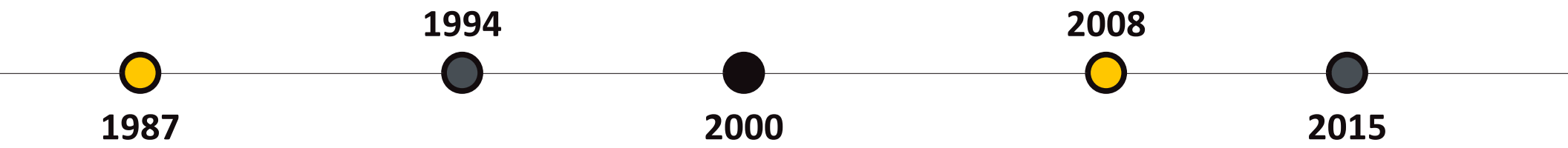
ISO 9001 REVISIONS

First published in 1987, ISO 9000 has consistently been ISO's most popular series of standards. The 1st edition of ISO 9001 was published, along with ISO 9002 and ISO 9003. Like all ISO standards, ISO 9001 generally undergoes a revision every five years.



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REVISION BACKGROUND

1994 A limited revision was published

The 1994 version (ISO 9000:1994) was an attempt to break from the practices which had somewhat clouded the use of the 1987 standard. It also emphasized quality assurance via preventive actions and continued to require evidence of compliance with documented procedures.

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REVISION BACKGROUND

- 2000: A major revision was published. ISO 9002, ISO 9003 were withdrawn; ISO 9001:2000 sought to make a radical change in thinking.

- The concept of process management was placed at the heart of the standard, making it clear that the essential goals of the standard - which had always been about 'a documented system' not a 'system of documents' - were reinforced.

- The goal was always to have management system effectiveness via process performance measures. This third edition makes this more visible and reduced the emphasis on having documented procedures if clear evidence could be presented to show that the process was working well. Expectations of continual process improvement and tracking customer satisfaction were also made explicit in this revision.

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REVISION BACKGROUND

- 2008: A minor amendment was published - the fourth and current edition of the standard (ISO 9001:2008) arrived on November 14th, 2008. This revision only contains minor amendments.
- The aim of this revision was to clarify existing requirements and to improve consistency of approach with other management standards, like ISO 14001:2004.
- 2012: The 2015 (major) revision was started in Bilbao.
- 2015: The current ISO 9001:2015 major revision was released September 15, 2015.

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SEVEN QUALITY MANAGEMENT PRINCIPLES

QUALITY PRINCIPLES

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ANNEX SL

- In an effort to ensure consistency of structure and terminology used across the available managements standards, so that they become more compatible and easier to use, ISO has developed what is now called Annex L.
    a) High-level structure
    b) Identical core text
    c) Common terms and key definitions

- All Management System Standards shall in the future, in principle, use consistent structure, common text and terminology so that they are easy to use and compatible with each other.
- Annex L, however, is not for management standards to have a “same look” only. More to that, it reinforces what is referred to as same “feel”.
- This brings the ISO 9001 standard into line with ISO's new harmonized and consistent structure.

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ANNEX SL

- The goal was to facilitate the integration of the different ISO standards and the development of integrated MS. Having a uniform structure as the basis of certification for MS will more likely improve the comprehensibility of standards and make combined certification more efficient.

- Based on the assumption, however, that Annex SL is not a static framework, but allows a change, prompted by the subject specific area of regulation, quality specific aspects have been added in the draft version. For example, planning of changes has been added to Annex SL (now Clause 6.3.) This has been stated to reflect the “recognition” in the quality world that things change.

- The revised standard comes with an uniformity of terms. Common terms and definitions are the same across all management systems standards.

- ISO 27001:2022, ISO 9001:2015 and ISO 14001:2015 have adopted Annex SL

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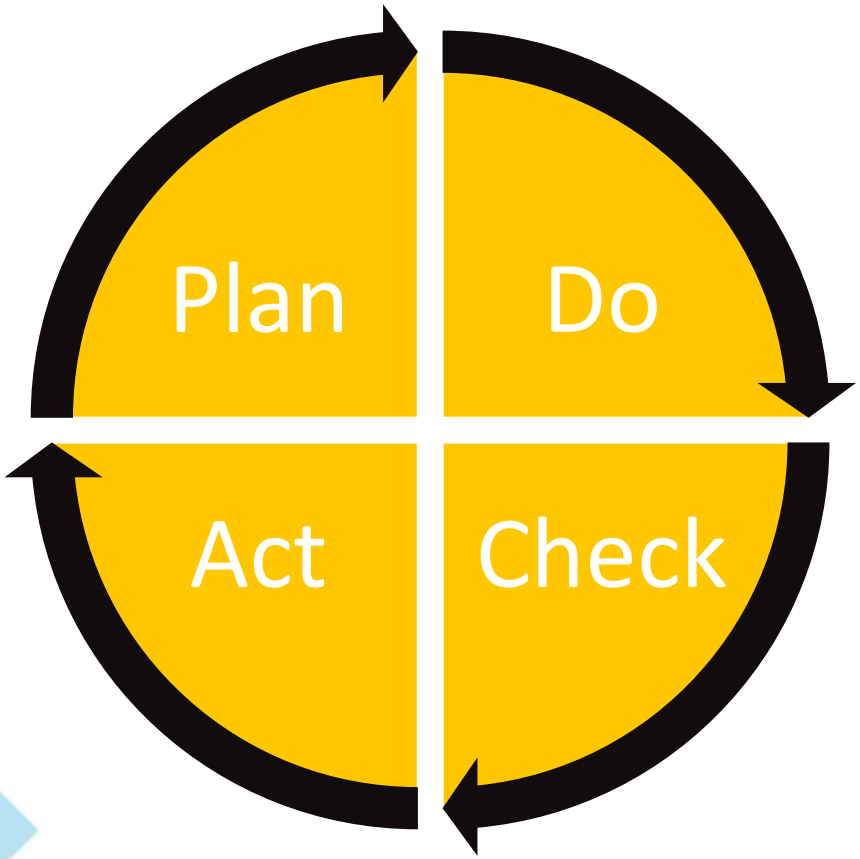
PDCA CYCLE



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IMPORTANT CONCEPTS IN ISO 9001:2015

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STRUCTURE

- Adopts the high-level structure of Annex SL, a general structure used for the development of all new ISO standards.

- There are 10 main clauses, with requirements set out in clauses 4-10.

- Facilitates the development of integrated management systems. Having a uniform structure as the basis of certification for MS will more likely improve the comprehensibility of standards and make combined certification more efficient.

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BASIC PRINCIPLES

- ISO 9001:2015 is based on 7 principles in line with the revision of the Quality Management Principles (see SC2/N1145)

- ISO 9000:2015 Standard provides a “statement” describing each principle, a “rationale” explaining why an organization should address the principle, potential key benefits and possible actions to address them.

BASIC PRINCIPLES

QMP 1 – Customer Focus

Statement: "The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations."

Rationale: "Sustained success is achieved when an organization attracts and retains the confidence of customers and other interested parties. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to the sustained success of an organization."

BASIC PRINCIPLES

QMP 2 – Leadership

Statement: "Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives."

Rationale: "Creation of unity of purpose and the direction and engagement of people enable an organization to align its strategies, policies, processes and resources to achieve its objectives."

BASIC PRINCIPLES

QMP 3 – Engagement of people

Statement: "Competent, empowered and engaged people at all levels throughout the organization are essential to enhance the organization's capability to create and deliver value."

Rationale: "In order to manage an organization effectively and efficiently, it is important to respect and involve all people at all levels. Recognition, empowerment and enhancement of competence facilitate the engagement of people in achieving the organization's quality objectives."

BASIC PRINCIPLES

QMP 4 – Process approach

Statement: “Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.”

Rationale: “The QMS consists of interrelated processes. Understanding how results are produced by this system, enables an organization to optimize the system and its performance.”

BASIC PRINCIPLES

QMP 5 – Improvement

Statement: “Successful organizations have an ongoing focus on improvement.”

Rationale: “Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.”

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BASIC PRINCIPLES

QMP 6 – Evidence-Based Decision Making

Statement: "Decisions based on the analysis and evaluation of data and information are more likely to produce desired results."

Rationale: "Decision making can be a complex process and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause and effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decision making."

BASIC PRINCIPLES

QMP 7 – Relationship management

Statement: “For sustained success, organizations manage their relationships with relevant interested parties, such as providers.”

Rationale: “Relevant interested parties influence the performance of an organization. Sustained success is more likely to be achieved when the organization manages relationships with all of its interested parties to optimize their impact on its performance. Relationship management with its provider and partner network is of particular importance.”

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PROCESS APPROACH

- The “process approach” is made more “explicit” in ISO 9001:2015. The current focus on effective process management is maintained but greater emphasis is placed on producing desired outputs and providing confidence in product.

- Clause 4.4 explicitly requires the identification of processes and their interactions.

- ISO 9001:2015 Standard includes detail about the processes needed for a QMS, specifically at 4.4.1 “a) determine the inputs required and the outputs expected from these processes”. Outputs from one core process constitute inputs to other core processes. QMS procedures should describe these processes, from input to output, also describing the controlled conditions under which these processes operate.

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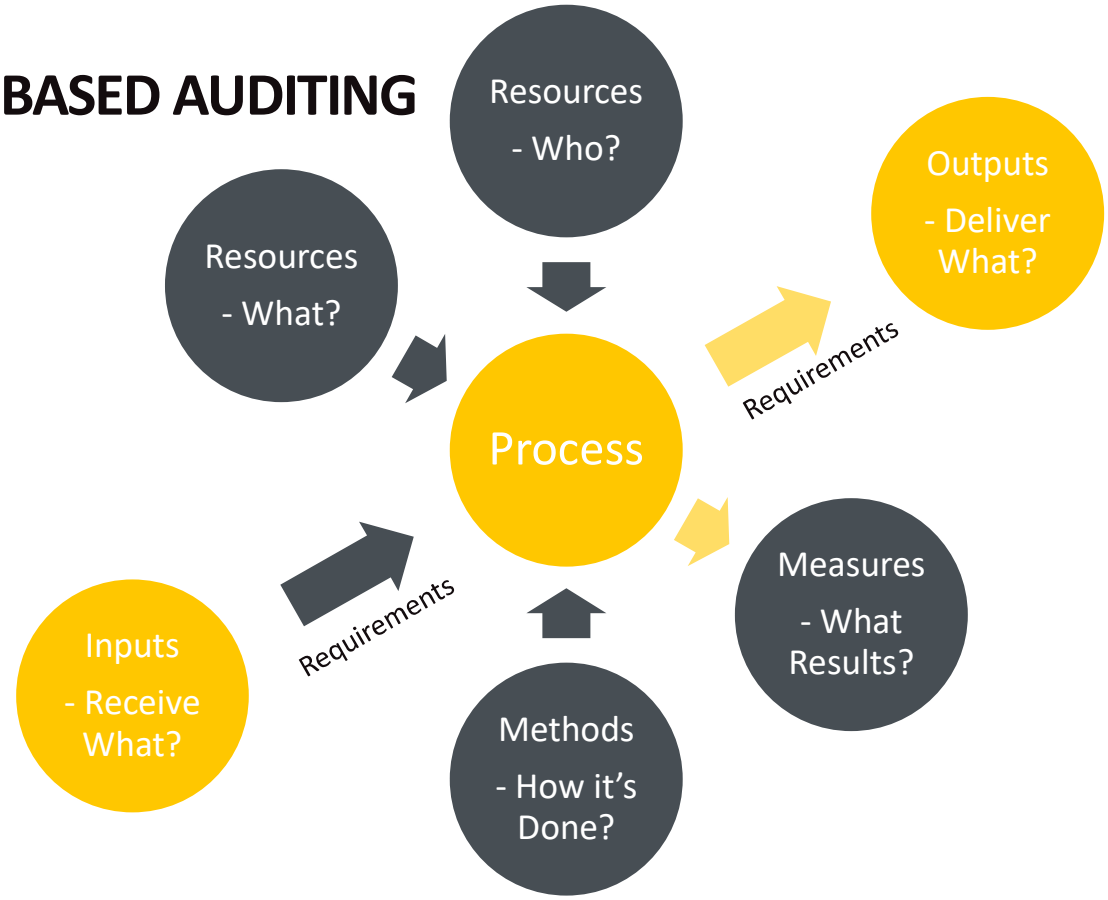
PROCESS APPROACH - PROCESS BASED AUDITING

Clause 5.1.1

"c) ensuring the integration of the quality management system requirements into the organization's business processes." That is to say that QMS should reside within, or be built into, the very processes that really output products. It is believed that this focus would "result in a holistic system with the primary objective of meeting customer requirements and enhancing customer satisfaction."



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RISK AND PREVENTIVE ACTION

- Preventive action has been removed from ISO 9001:2015 and is now replaced by the wider perspective of planning, risk management as a core element of planning, and having a management system in the first place.

- All references are made to risk, identification of risks and opportunities, and planning actions to address risks and opportunities identified. Risk-based thinking goes throughout the entire ISO 9001:2015.

- It stays in line with Annex SL that contains no specific requirements for ‘preventive action’ .

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CONTEXT OF THE ORGANIZATION

- Focus on the context of the organization. Clause 4 requires the organization to consider itself and its context, to understand the needs and expectations of interested parties, and to determine the scope of its management systems.

- Together these clauses require the organization to determine the issues and requirements that can impact the planning of the quality management system and can be used as an input into the development of the quality management system. This results in a broader business outlook that implies a more detailed operational planning.

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LEADERSHIP

- Top management is required to demonstrate that they engage in key management system activities as opposed to simply ensuring that these activities occur. This means that there is a need for top management to be actively involved in the operation of their management system.

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A GREATER EMPHASIS ON THE DEFINITION OF SCOPE

- ISO 9001:2015 puts a greater emphasis on the definition of scope, which has always been an important and critical aspect of a quality management system.

- It is up to the organization to determine the scope of their QMS.

IMPROVEMENT

- ISO 9001:2015 Clause 10 recognizes that incremental (continuous) improvement is not the only improvement profile.

- Improvement can also arise as a result of periodic breakthroughs, reactive change, or as a result of re-organization.

CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES

- Clause 8.4 addresses all forms of external provision, whether it is by purchasing from a supplier, through an arrangement with an associate company, through the outsourcing of processes and functions of the organization, or by any other means.

- The organization is required to take a risk-based approach to determine the type and extent of controls appropriate to each external provider and all externally provided products and services.

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ORGANIZATIONAL KNOWLEDGE

- Organizations should aim to take steps to capture and preserve knowledge and learning, which is necessary for the effective operation of their processes and for ensuring the conformity of their products and services.

- This is a broad requirement directed primarily at ensuring the organization has or obtains the knowledge resources necessary to respond to changing business environments referred to in clause 4.1, changing customer and interested party needs, and expectations referred to in clause 4.2, and, where applicable, related improvement initiatives.

- As such, this requirement has strong links with management review activities.

DOCUMENTATION REQUIREMENTS

- In line with Annex SL Appendix 2, ISO 9001:2015 contains general requirements for documentation only, with no reference to documented quality manuals, documented procedures, or to quality records.

- “Documented information” includes both documents and records which seems to be more accepting of electronic documents and document control approaches. The terms “document” and “record” are addressed throughout the standard by “documented information.”

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ANNEXES

- ISO 9001:2015 has two informative annexes.
  a) Annex A provides clarification on the structure, terminology, and concepts underpinning the Standard.
  b) Annex B details other international standards on quality management and quality management systems developed by ISO/TS 176.

- These are designed to provide assistance to organizations seeking to establish or improve their quality management performance.

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WORKSHOP #1: UNDERSTANDING THE KEY REQUIREMENTS

Explain **FIVE** key requirements found in the ISO 9001:2015 Standard as far as requirements to QMS are concerned.

Mention the implications that these requirements will have on your organization implementing the standard.

Please Comment your Responses in the Chat Box.

Your report should include your group's recommendations, observations, and decision to:

- Key ISO 9001:2015 Standard requirements
- Implications of these requirements on your organizations

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CLAUSES 1-4 STRUCTURE, SCOPE, DEFINITIONS, CONTEXT OF THE ORGANIZATION

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STRUCTURE

1.	Scope	8.	Operation
2.	Normative references	8.1.	Operational planning and control
3.	Terms and definitions	8.2.	Requirements for products and services
4.	Context of the organization	8.3.	Design and development of products and services
4.1.	Understanding the organization and its context	8.4.	Control of externally provided processes, products and services
4.2.	Understanding the needs and expectations of interested parties	8.5.	Production and service provision
4.3.	Determining the scope of the quality management system	8.6.	Release of products and services
4.4.	Quality Management System and its processes	8.7.	Control of nonconforming outputs
5.	Leadership	9	Performance evaluation
5.1.	Leadership and commitment	9.1.	Monitoring, measurement, analysis and evaluation
5.2.	Policy	9.2.	Internal audit
5.3.	Organizational roles, responsibilities and authorities	9.3.	Management review
6.	Planning	10.	Improvement
6.1.	Actions to address risks and opportunities	10.1.	General
6.2.	Quality objectives and planning to achieve them	10.2.	Nonconformity and corrective action
6.3.	Planning of changes	10.3	Continual improvement
7.	Support	Annex A	Clarification of new structure, terminology and concepts
7.1.	Resources	Annex B	Other International Standards on quality management and quality management systems developed by ISO/TC 176
7.2.	Competence	Bibliography	
7.3.	Awareness		
7.4.	Communication		
7.5.	Documented information		

QMS REQUIREMENTS - SCOPE

ISO 9001:2015 Clause 1 “This International Standard specifies requirements for a quality management system when an organization:

- needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- 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 term “product” or “service” only applies to products and services intended for, or required by, a customer.”

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

QMS REQUIREMENTS- SCOPE

ISO 9001:2015 Annex A A.5 recognizes that there may be circumstances where it is impossible for an organization to conform to a specific requirement – for example, where it does not operate a “required” process. In these instances, the organization can deem the requirement “not applicable” providing this does not affect its ability to supply conforming products or services, or compromise its aim to enhance customer satisfaction.

CLAUSE 2: NORMATIVE REFERENCES

For undated references, the latest edition of the referenced document (including any amendments) applies.

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

CLAUSE 3: TERMS AND DEFINITIONS

ISO 9001:2015

ISO 9001:2015 cites ISO 9000:2015 quality management systems – fundamentals and vocabulary as a normative reference. This means that these two documents were intended to be used as a pair.

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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: Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, cultural, social, economic and natural environment, whether international, national, regional or local.

Note 2: When understanding the internal context, the organization could consider those related to perceptions, values and culture of the organization."

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CONTEXT OF THE ORGANIZATION

- External issues such as legal, technological, competitive, cultural, social, economic and natural environment on international, national, regional or local levels related to the organization's strategic purpose shall be considered.

- Moreover, for interested parties' needs and expectations, not only from direct customers and regulators shall be considered. The needs and expectation from end users, suppliers, distributors, retailers or others involved in the supply chain and other relevant interested parties shall not be omitted.

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CONTEXT OF THE ORGANIZATION

- Together these clauses require the organization to determine the issues and requirements that can impact the planning of the QMS and can be used as an input into the development of the QMS. This results in a broader business outlook that implies more detailed operational planning. Since this reflects the greater business focus in the ISO 9001:2015 Standard, when determining the scope of QMS the organization shall consider not only internal issues.

- This requires auditors to look more broadly when determining the suitability of the QMS scope stated by the clients. This shall include the clients' external and internal issues, who are the clients' interested parties, and what are their requirements.

4.2 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

- The organization shall determine:
  a) the interested parties that are relevant to the quality management system,
  b) the requirements of these interested parties that are relevant to the quality management system.
- The organization shall monitor and review information about these interested parties and their relevant requirements."
- Relevant interested parties are groups or individuals who have the ability to impact (or potentially impact) the organization's ability to consistently supply products and services that meet customer and applicable statutory and regulatory requirements. Customers, shareholders, board members and competitors would all fit into this classification.
- Each organization will have its own set of relevant interested parties and this set will change over time.

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4.3 DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM

- The organization shall determine the boundaries and applicability of the quality management system to establish its scope.
- When determining this scope, the organization shall consider
  a) the external and internal issues referred to in 4.1, and
  b) the requirements of the relevant interested parties referred to in 4.2.
  c) the products and services of the organization.
- The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

4.3 DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM

- The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

- Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

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EMPHASIS ON THE DEFINITION OF SCOPE

- ISO 9001:2015 puts a greater emphasis on the definition of scope, which has always been important and critical aspect of a quality management system. Clients have always been required to specify the scope of their QMS. However, this must now be done in explicit consideration of the organizational context, as well as in terms of the products and services it intends to supply.

- ISO 9001:2015 makes it clear that if a requirement of the standard can be applied, given the organization's determined scope, then it must be included. Only in cases where meeting the requirement is impossible (and where the absence of meeting the requirement does not adversely impact the organization's ability to supply conforming products and services) is it permissible not to apply it.

- Auditors will need to verify that the organization's scope exists as documented information. They must gather evidence that it has been produced in consideration of the organization's context and products and services.

4.4 QUALITY MANAGEMENT SYSTEM

“The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. “

To the extent necessary, the organization shall:

a) maintain documented information to support the operation of its processes;

b) retain documented information to have confidence that the processes are being carried out as planned.”

4.4 QUALITY MANAGEMENT SYSTEM

"The organization shall determine the processes needed for the quality management system and their applications throughout the organization, and shall:

a) determine the inputs required and the outputs expected from these processes;

b) determine the sequence and interaction of these processes;

c) determine and apply the criteria and methods (including monitoring, measurements, and related performance indicators) needed to ensure the effective operation and control of these processes;

d) determine the resources needed for these processes and ensure their availability;

e) determine the responsibilities and authorities for these processes;

f) address the risks and opportunities as determined in accordance with the requirements of 6.1;

g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

h) improve the processes and the quality management system.

EMBEDDED PROCESS APPROACH

- The Process Approach is a must, not an option. All the clients shall ensure that their QMS is based on process approach, i.e., determining inputs and outputs from each process, the sequence and interaction of the process, etc. Training on process approach is a priority for those clients who do not have a well-developed process-based QMS.

- Clause 5.1.1 c) of the ISO 9001:2015 requires top management to make sure that QMS are integrated into business processes.

- QMS should reside within, or be built into, the very processes that really output product. It is believed that this focus would "result in a holistic system with the primary objective of meeting customer requirements and enhancing customer satisfaction."

EMBEDDED PROCESS APPROACH

- Because the process approach is explicitly required by the standard, it should make it easier to audit an organization's QMS by using a process-based approach. Less challenge from the clients could be expected when auditors writing nonconformity on "process approach."

- Auditors' knowledge and competence on process approach auditing shall be ensured.

WORKSHOP #2: CONTEXT OF THE ORGANIZATION

Mention 5 each of external and internal issues, that are relevant to the purpose of your own organization and its strategic direction and that affect its ability to achieve the intended outcome(s) of your quality management system.

Identify

- The interested parties that are relevant to your quality management system, and
- The requirements of these interested parties.

Mention Your Responses in the Chat Box

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GUEST SPEAKER
MR SANDEEP SHARMA (FLIPKART GROUP OF COMPANIES)

Flipkart

- Sandeep Kumar Sharma,
- Graduate Engineer in E & C and MBA (Marketing).
- Lead Auditor for ISO 9001 & ISO 14001.
- 24+ years experience in Service Operations & Quality Domain.
- F1 Info Solutions & Services Pvt Ltd & Jeeves Consumer Services Pvt Ltd (Flipkart Group of Companies) as Manager Quality Assurance.
- F1 into repairs of Mobiles, Laptops and other Electronic Products
- Jeeves is into Installation & Repairs of TV, AC, HA, Fur. & Other Products which are bought by Customers through Flipkart Portal.

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BENEFITS OF IMPLEMENTING ISO 9001 IN FLIPKART SUBSIDIARY F1 SOLUTIONS

1. Proper Documentation and streamlining of all the Processes.
2. Implementation of RCA & CAPA, which supports in finding the root cause of the issues and taking appropriate actions & preventing further occurrence.
3. Streamlining of Internal Quality Audits, which helps in maintaining the overall Quality of the Service offered.
4. Improvement in Customer Satisfaction.
5. Motivation to Team Members being working in ISO Certified Organization.
6. Enhancement in Business being ISO Certified Organization.
7. Continual Improvement in overall Process.

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BENEFITS FOR PROFESSIONALS FOR GAINING ISO 9001 INTERNAL AUDITOR CERTIFICATION

1. Qualified to do Internal Audits of the Functions and Branches.
2. Good Opportunity to gain knowledge about other Functions / Processes in depth through Internal Audits.
3. Self Development.
4. Additional Qualification for the Resume.
5. Will help to identify areas for Improvement, Increased Efficiency & Effectiveness.

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CLAUSE 5 LEADERSHIP, CLAUSE 6 PLANNING

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5.1 LEADERSHIP AND COMMITMENT

5.1.1 General

“Top management shall demonstrate leadership and commitment with respect to the quality management system by:

a) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
b) taking accountability of the effectiveness of the quality management system;
c) ensuring the integration of the quality management system requirements into the organization‘s business processes;
d) promoting the use of the process approach and risk-based thinking;
e) ensuring that the resources needed for the quality management system are available”
f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
g) ensuring that the quality management system achieves its intended results;
h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
i) promoting improvement; and
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility”

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LEADERSHIP

- Top management is required to demonstrate that they engage in key quality management system activities as opposed to simply ensuring that these activities occur.

- This means that there is a need for top management to be actively involved in the operation of their quality management system.

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LEADERSHIP

- ISO 9001:2015 requires top management to be “hands on” with respect to their QMS.

- Where the word “ensuring” is used in clause 5.1.1, top management may still assign this task to others for completion. Where the words “promoting”, “taking”, “engaging” or “supporting” appear, these activities cannot be delegated and must be undertaken by top management themselves.

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LEADERSHIP

- Auditors must seek evidence that top management has a “hands-on” approach to the management of their QMS.

- Auditors must understand which ISO 9001:2015 requirements top management can delegate and which they cannot.

- Auditors must ensure that they are equipped to challenge top management with respect to their commitment to their QMS. To be effective and gain the respect of top management, auditors will need to have a good understanding of management activities, be able to engage with top management on a range of subjects, and speak the language of top management.

QUALITY ASIA

5.1.2 CUSTOMER FOCUS

"Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
c) the focus on enhancing customer satisfaction is maintained."

5.2 POLICY

Top management shall establish, implement and maintain a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;
b) provides a framework for setting quality objectives;
c) includes a commitment to satisfy applicable requirements, and
d) includes a commitment to continual improvement of the quality management system.

The quality policy shall:

a) be available and be maintained as documented information;
b) be communicated, understood and applied within the organization;
c) be available to relevant interested parties, as appropriate

QUALITY ASIA

5.3 ORGANIZATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES

- “Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

- Top management shall assign the responsibility and authority for:
  a) ensuring that the quality management system conforms to the requirements of this International Standard;
  b) ensuring that the processes are delivering their intended outputs;
  c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;
  d) ensuring the promotion of customer focus throughout the organization;
  e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.”

QUALITY ASIA

MANAGEMENT REPRESENTATIVE NOT EXPLICITLY REQUIRED

- Senior management is now required to take a more active involvement in the quality management system. Stronger emphasis on the overall accountability of top management for the effectiveness of the quality management system.

- The figure of a management representative is no longer explicitly mentioned. In the absence of specific requirement for a management representative, the organization may choose a structure of assigning responsibilities as appropriate to ensure relevant responsibilities and authorities are assigned.

6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

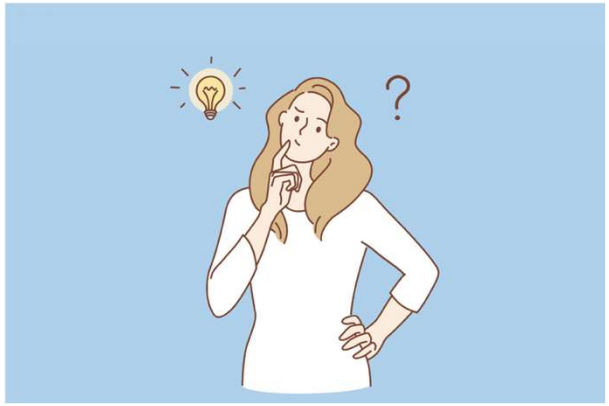
"When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance the quality management system can achieve its intended outcome(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects

d) achieve improvement."



6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

- "The organization shall plan:
  a) actions to address these risks and opportunities, and
  b) how to:
     1) integrate and implement the actions into its quality management system processes (see 4.4), and
     2) evaluate the effectiveness of these actions.

- Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

Note 1: Options to address risks can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

Note 2: Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

RISK AND PREVENTIVE ACTION

Risk-based thinking and risk-driven approach to preventive action is in the development and implementation of QMS.

RISK AND PREVENTIVE ACTION

- The Standard does not prescribe a risk methodology that the organization must adopt; instead, each organization is free to decide its own approach. The robustness of the risk approach must be proportionate to the consequences, should the risk be realized.

- This requires the clients to adopt risk-based thinking and risk-driven approach in their QMS. Risks and opportunities shall be determined to assure QMS achieving its intended results, products and service conformity and customer satisfaction; preventing or reducing undesired effects and achieving improvement. Actions to address risks and opportunities identified shall be planned and their effectiveness of the actions shall be evaluated.

- While no specific risk-management methodology is prescribed, risk management as an activity must be carried out.

QUALITY ASIA

RISK AND PREVENTIVE ACTION

- Risk-based thinking and risk-driven approach shall be required from the clients by auditors when auditing clients' QMS.

- The role of the auditor is not to carry out their own determination of risks and opportunities, but to ensure that the organization is applying their methodology consistently and effectively. However, where the auditor's knowledge of the context of the organization reveals that the organization has failed to identify a familiar known risk or opportunity, they may call into question the organization's approach.

6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

- "The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall:
  a) be consistent with the quality policy,
  b) be measurable,
  c) take into account applicable requirements,
  d) be relevant to conformity of products and services and to enhancement of customer satisfaction,
  e) be monitored,
  f) be communicated,
  g) be updated as appropriate.

- The organization shall maintain documented information on the quality objectives.

- When planning how to achieve its quality objectives, the organization shall determine:
  a) what will be done,
  b) what resources will be required,
  c) who will be responsible,
  d) when it will be completed, and
  e) how the results will be evaluated."

QUALITY ASIA

6.3 PLANNING OF CHANGES

When the organization determines the needs for changes to the quality management system, the changes shall be carried out in a planned manner. (See 4.4)

The organization shall consider:

- the purpose of the changes and their potential consequences
- the integrity of the quality management system;
- the availability of resources
- the allocation or re-allocation of responsibilities and authorities.

WORKSHOP #3: AUDITING LEADERSHIP

Please provide 2 things each that you would require your top management to do in order to comply with ISO 9001:2015 Standard requirements.

Please write your responses in Chat Box

QUALITY ASIA

CLAUSE 7 SUPPORT

For Training Purpose Only

QUALITY ASIA

STRUCTURE

1.	**Scope**	**8.**	**Operation**
2.	Normative references	8.1.	Operational planning and control
3.	Terms and definitions	8.2.	Requirements for products and services
4.	Context of the organization	8.3.	Design and development of products and services
4.1.	Understanding the organization and its context	8.4.	Control of externally provided processes, products and services
4.2.	Understanding the needs and expectations of interested parties	8.5.	Production and service provision
4.3.	Determining the scope of the quality management system	8.6.	Release of products and services
4.4.	Quality Management System and its processes	8.7.	Control of nonconforming outputs
5.	Leadership	9	Performance evaluation
5.1.	Leadership and commitment	9.1.	Monitoring, measurement, analysis and evaluation
5.2.	Policy	9.2.	Internal audit
5.3.	Organizational roles, responsibilities and authorities	9.3.	Management review
6.	Planning	10.	Improvement
6.1.	Actions to address risks and opportunities	10.1.	General
6.2.	Quality objectives and planning to achieve them	10.2.	Nonconformity and corrective action
6.3.	Planning of changes	10.3	Continual improvement
7.	Support	Annex A	Clarification of new structure, terminology and concepts
7.1.	Resources	Annex B	Other International Standards on quality management and quality management systems developed by ISO/TC 176
7.2.	Competence	Bibliography	
7.3.	Awareness		
7.4.	Communication		
7.5.	Documented information		

QUALITY ASIA

7.1. RESOURCES

"The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the Quality Management System.

The organization shall consider:

- the capabilities of, and constraints on, existing internal resources;
- what needs to be obtained from external providers."

QUALITY ASIA

7.1.2 PEOPLE

“The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.”

7.1.3 INFRASTRUCTURE

“The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes to achieve conformity of products and services.

Note: Infrastructure can include:

a) buildings and associated utilities,

b) equipment including hardware and software;

c) transportation resources;

d) information and communication technology”

QUALITY ASIA

CLAUSE 7.1.4 ENVIRONMENT FOR THE OPERATION OF PROCESSES

"The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE: A suitable environment can be a combination of human and physical factors, such as:

social (e.g. non-discriminatory, calm, non-confrontational);

psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided."

CLAUSE 7.1.5 MONITORING AND MEASURING RESOURCES – 7.1.5.1 GENERAL

- "The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.
- The organization shall ensure that the resources provided:
  a) are suitable for the specific type of monitoring and measurement activities being undertaken;
  b) are maintained to ensure their continuing fitness for their purpose.
- The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources."

7.1.5 MONITORING AND MEASURING RESOURCES – 7.1.5.2 MEASUREMENT TRACEABILITY

- "When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results; measuring instruments shall be:

  a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

  b) identified in order to determine their status;

  c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

- The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary."

7.1.6 ORGANIZATIONAL KNOWLEDGE

“The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary.

Where addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.”

QUALITY ASIA

7.1.6 ORGANIZATIONAL KNOWLEDGE

"NOTE 1: Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2: Organizational knowledge can be based on:

a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b) external sources (e.g. standards; academia; conferences, gathering knowledge from customers or external providers)."

QUALITY ASIA

ORGANIZATIONAL KNOWLEDGE

This requirement aims at ensuring that organizations take steps to capture and preserve knowledge and learning, which is necessary for the effective operation of their processes and for ensuring the conformity of their products and service.

ORGANIZATIONAL KNOWLEDGE

- Clients should ensure that they introduce processes to address the requirements in this clause.
- The notes to clause 7.1.6 give good examples of what “organizational knowledge” can include as well as to how additional knowledge can be obtained.
- Auditors should ensure that organizations have taken steps to identify the organizational knowledge necessary to establish the continuing conformity of their products and services.
- Auditors should also ensure that organizational knowledge has been communicated as necessary within the organization and that it is being maintained and protected.

7.2 COMPETENCE

"The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system:

b) ensure that these persons are competent on the basis of appropriate education, training, or experience;

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

d) retain appropriate documented information as evidence of competence.

NOTE: Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons."

7.3 AWARENESS

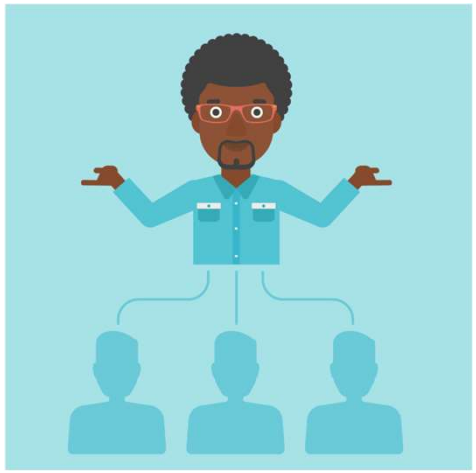
"The organization shall ensure that persons doing work under the organization's control are aware of:

a) the quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;

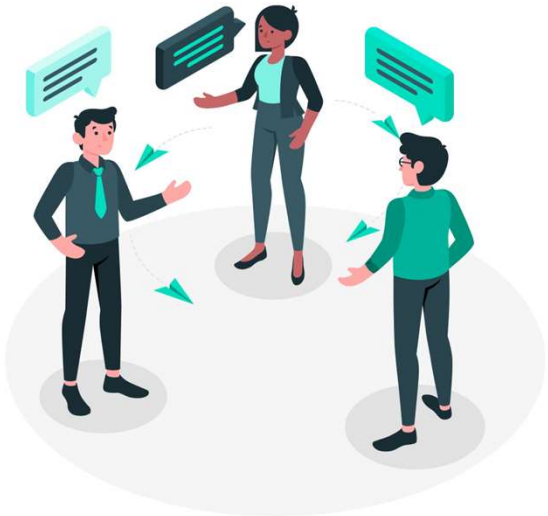
d) the implications of not conforming with the quality management system requirements."



7.4 COMMUNICATION

“The organization shall determine the internal and external communications relevant to the quality management system, including:

a) on what it will communicate;
b) when to communicate;
c) with whom to communicate;
d) how to communicate;
e) who communicates.”



7.5 DOCUMENTED INFORMATION – 7.5.1 GENERAL

"The organization's quality management system shall include:

a) documented information required by this International Standard;

b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

NOTE: The extent of documented information for a quality management system can differ from one organization to another due to:

- the size of organization and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons."

QUALITY ASIA

7.5.2 CREATING AND UPDATING

"When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number);

b) format (e.g. language, software version, graphics) and media (e.g. paper; electronic);

c) review and approval for suitability and adequacy."

QUALITY ASIA

7.5.3 CONTROL OF DOCUMENTED INFORMATION – 7.5.3.1

"Documented information required by the quality management system and by this International Standard shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3 CONTROL OF DOCUMENTED INFORMATION – 7.5.3.2

- For the control of documented information, the organization shall address the following activities, as applicable:
  a) distribution, access, retrieval and use;
  b) storage and preservation, including preservation of legibility;
  c) control of changes (e.g. version control);
  d) retention and disposition.
- Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and controlled."
- "Documented information retained as evidence of conformity shall be protected from unintended alterations.

Note: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information."

DOCUMENTED INFORMATION

- There is no mandatory documented procedure required nor is there a minimum number of documented procedures.

- The clients shall be familiar with the term of “documented information” which includes both documents and records and is more accepting of electronic documents and document control approaches. The terms “document” and “record” are addressed throughout the standard by “documented information.”

QUALITY ASIA

WORKSHOP #4: AUDITING CLAUSE 7 SUPPORT

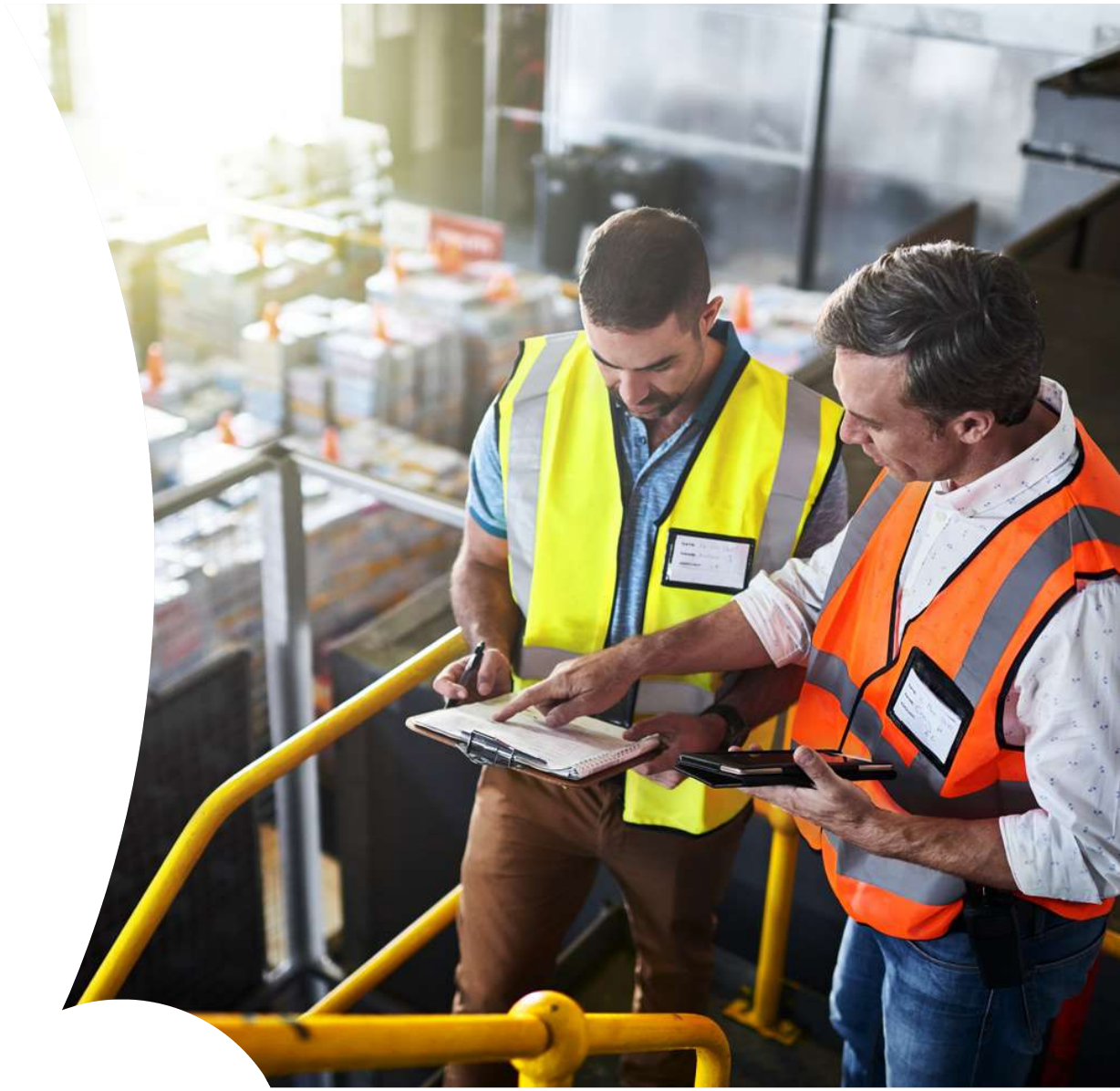
Please provide 5 types of resources that you would need in your ISO 9001:2015 quality management system programs and explain why.

Please suggest 3 methods on how to evaluate competence of the person(s) doing work under your organization's control that affects the performance and effectiveness of the quality management system. Please rank them in an order with highest rate of effectiveness to the least rate of effectiveness and explain why.

Please Write your Responses in Chat Box

QUALITY ASIA

CLAUSE 8 OPERATION



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QUALITY ASIA

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8.1 OPERATIONAL PLANNING AND CONTROL

"The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6 by:

a) determining the requirements for the product and services;
b) establishing criteria for:
   1) the processes;
   2) the acceptance of products and services;
a) determining the resources needed to achieve conformity to the product and service requirements;
b) implementing control of the processes in accordance with the criteria; e) determining, maintaining and retaining documented information to the extent necessary:
   1) to have confidence that the processes have been carried out as planned
   2) to demonstrate the conformity of products and services to their requirements."

QUALITY ASIA

8.1 OPERATIONAL PLANNING AND CONTROL

“The output of this planning shall be suitable for the organization's operations.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

Has your organization had any unintended changes, if so, how were the consequences reviewed?

The organization shall ensure that outsourced processes are controlled (see 8.4).”

8.2 REQUIREMENTS FOR PRODUCTS AND SERVICES – 8.2.1 CUSTOMER COMMUNICATION

"Communication with customers shall include:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property:

e) establishing specific requirements for contingency actions, when relevant."

8.2.2 DETERMINING THE REQUIREMENTS FOR PRODUCTS AND SERVICES

"When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

a) The requirements for the products and services are defined, including:
   1) any applicable statutory and regulatory requirements;
   2) those considered necessary by the organization;
b) the organization can meet the claims for the products and services it offers."

QUALITY ASIA

8.2.3 REVIEW OF THE REQUIREMENTS FOR PRODUCTS AND SERVICES

8.2.3.1 “The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

a) requirements specified by the customer including the requirements for delivery and post-delivery activities;

b) requirements not stated by the customer, but necessary for the specified or intended use, when known; documented information

c) requirements specified by the organization;

d) statutory and regulatory requirements applicable to the products and services;

e) contract or order requirements differing from those previously expressed. “

8.2.3 REVIEW OF THE REQUIREMENTS FOR PRODUCTS AND SERVICES

- "The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

- The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

- Note: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues."

QUALITY ASIA

8.2.3 REVIEW OF THE REQUIREMENTS FOR PRODUCTS AND SERVICES

8.2.3.2 The organization shall retain documented information, as applicable:

a) on the results of the review

b) on any new requirements for the products and services

QUALITY ASIA

8.2.4 CHANGES TO REQUIREMENTS FOR PRODUCTS AND SERVICES

"The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed."

8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES - 8.3.1 GENERAL

“The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.“

QUALITY ASIA

8.3.2 DESIGN AND DEVELOPMENT PLANNING

"In determining the stages and controls for design and development, the organization shall consider:

a) the nature, duration and complexity of the design and development activities;
b) the required process stages, including applicable design and development reviews;
c) the required design and development verification and validation activities;
d) the responsibilities and authorities involved in the design and development process;
e) the internal and external resource needs for the design and development of products and services;
f) the need to control interfaces between persons involved in the design and development process;
g) the need for involvement of customer and user groups in the design and development process;"
h) the requirements for subsequent provision of products and services;
i) the level of control expected for the design and development process by customers and other relevant interested parties;
j) the documented information needed to demonstrate that design and development requirements have been met.

QUALITY ASIA

8.3.3 DESIGN AND DEVELOPMENT INPUTS

- "The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

  a) functional and performance requirements;
  b) information derived from previous similar design and development activities;
  c) statutory and regulatory requirements;
  d) standards or codes of practice that the organization has committed to implement;
  e) potential consequences of failure due to the nature of the products and services;

- Inputs shall be adequate for design and development purposes, complete, and unambiguous. Conflicting design and development inputs shall be resolved."

- The organization shall retain documented information on design and development inputs.

8.3.4 DESIGN AND DEVELOPMENT CONTROLS

"The organization shall apply controls to the design and development process to ensure that:

a) the results to be achieved are defined;

b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;

f) documented information of these activities is retained.

NOTE: Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization."

QUALITY ASIA

8.3.5 DESIGN AND DEVELOPMENT OUTPUTS

"The organization shall ensure that design and development outputs:

a) meet the input requirements;

b) are adequate for the subsequent processes for the provision of products and services;

c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d) Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs."

QUALITY ASIA

8.3.6 DESIGN AND DEVELOPMENT CHANGES

“The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization shall retain documented information on:

a) design and development changes;
b) the results of reviews;
c) the authorization of the changes;
d) the actions taken to prevent adverse impact.”

8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES - 8.4.1. GENERAL

- "The organization shall ensure that externally provided processes, products and services conform to requirements.
- The organization shall determine the controls to be applied to externally provided processes, products and services when:
  a) products and services from external providers are intended for incorporation into the organization's own products and services;
  b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;
  c) a process or part of a process, is provided by an external provider as a result of a decision by the organization."
- The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.
- The organization shall retain documented information of these activities and any necessary actions arising from the evaluations."

8.4.2 TYPE AND EXTENT OF CONTROL

- "The organization shall ensure that externally provided process, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

- The organization shall:

  a) ensure that externally provided processes remain within the control of its quality management system;

  b) define the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

  c) take into consideration:

    1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

    2) the effectiveness of the controls applied by the external provider;

  d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

QUALITY ASIA

8.4.3 INFORMATION FOR EXTERNAL PROVIDERS

- "The organization shall ensure the adequacy of requirements prior to their communication to the external provider
- The organization shall communicate to external providers its requirements for:
  a) the processes, products and services to be provided;
  b) the approval of:
     1) products and services;
     2) methods, processes and equipment;
     3) the release of products and services;
  c) competence, including any required qualification of persons;
  d) the external providers' interactions with the organization;
  e) control and monitoring of the external provider's performance to be applied by the organization;
  f) verification or validation activities that the organization, or its customer, intends to perform at the external provider's premises."

CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES

- The client shall determine what forms of external provision of products and services they are using now – through suppliers, associate companies, or outsourcing of certain processes and functions to sub-contractors.

- Then, evaluate the potential impact of the externally provided processes, products, or services and determine what type and extent of control shall be applied to external providers and externally-provided processes, products and services.

- Auditors shall have a good understanding about what forms of external provision are being used by the clients, e.g., suppliers, associate companies, outsourcing of processes and functions, and assess whether the clients have done their potential impact analyses and apply appropriate controls in external provision of products and services.

8.5 PRODUCTION AND SERVICE PROVISION - 8.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

"The organization shall implement production and service provisions under controlled conditions. Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:
   - the characteristics of the products to be produced, the services to be provided, or the activities to be performed
   - the results to be achieved;
b) the availability and use of suitable monitoring and measuring resources;
c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
d) the use of suitable infrastructure and environment for the operation of processes;
e) the appointment of competent persons, including any required qualification;
f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production of service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
g) the implementation of actions to prevent human error;
h) the implementation of release, delivery and post-delivery activities."

QUALITY ASIA

8.5.2 IDENTIFICATION AND TRACEABILITY

- “The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.
- The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.
- The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.”

8.5.3 PROPERTY BELONGING TO CUSTOMERS OR EXTERNAL PROVIDERS

- “The organization shall exercise care with property belonging to the customers or external providers while it is under the organization's control or being used by the organization.

- The organization shall identify, verify, protect and safeguard customers’ or external providers’ property provided for use or incorporation into the products and services.

- When property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE: A customer’s or external provider’s property can include materials, components, tools and equipment, premises, intellectual property and personal data.”

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8.5.4 PRESERVATION

"The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection."

8.5.5 POST-DELIVERY ACTIVITIES

- "The organization shall meet requirements for post-delivery activities associated with the products and services.

- In determining the extent of post-delivery activities that are required, the organization shall consider:
  a) statutory and regulatory requirements;
  b) the potential undesired consequences associated with its products and services;
  c) the nature, use and intended lifetime of its products and services;
  a) customer requirements;
  b) customer feedback.

NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal."

8.5.6 CONTROL OF CHANGES

- “The organization shall review and control changes for production and service provision, to the extent necessary to ensure continuing conformity with requirements.

- The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.”

8.6 RELEASE OF PRODUCTS AND SERVICES

- “The organization shall implement the planned arrangements, at appropriate stages, to verify that the products and service requirements have been met.
- The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.
- The organization shall retain documented information on the release of products and services. The documented information shall include:
    a) evidence of conformity with the acceptance criteria;
    b) traceability to the person(s) authorizing the release.

8.7 CONTROL OF NONCONFORMING OUTPUTS

- “The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

- The organization shall take appropriate actions, based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, or during and after the provision of services.”

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8.7.1 CONTROL OF NONCONFORMING OUTPUTS

“The organization shall deal with nonconforming outputs in one or more of the following ways:

a) correction;
b) segregation, containment, return or suspension of provision of products and services;
c) informing the customer;
d) obtaining authorization for acceptance under concession

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 CONTROL OF NONCONFORMING OUTPUTS

“The organization shall retain documented information that:

a) describe the nonconformity;
b) describes the actions taken;
c) describes any concessions obtained;
d) identifies the authority deciding the action in respect of the nonconformity.

WORKSHOP#5: CHALLENGES IN AUDITING CLAUSE 8 OPERATION

Develop 5 checklist questions that can help your organization to check whether your QMS is in compliance with Cl. 8 Operation of ISO 9001:2015 Standard.

Please Write your Responses in the Chat Box

GUEST SPEAKER
MR SHRIDHAR DANGETY (RIA ADVISORY LLC)

RECOGNIZE > INNOVATE > ACCELERATE

Hello, my name is Shridhar Dangety – working a Senior Operations Manager for global locations at RIA Advisory LLC. With over 25 years of industry experience and having successfully lead teams and worked independently at multinational companies and 3 start-ups, I have the knowledge and experience in setting-up operations processes from brick and mortar to reviewing compliance documents.

RIA Advisory is a Business and Technology Advisory Consulting firm that specializes in the field of implementing ORMB & CC&B software at Financial Services, Utilities, Healthcare and Public Sector/Tax companies. Headquartered in Florida, USA, the company has a global reach in 5 additional international locations - Australia, Canada, India, Philippines and UK.

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BENEFITS OF IMPLEMENTING ISO 9001:2015 IN RIA ADVISORY LLC

1. **Enhanced Customer Satisfaction:**
   - Consistently meet customer requirements and expectations.
   - Improve product and service quality
2. **Improved Process Efficiency:**
   - Streamline operations and reduce inefficiencies
   - Implement standardized processes that enhance productivity
3. **Increased Market Opportunities:**
   - Access to new markets and customer segments
   - Meet regulatory and contractual requirements more effectively
4. **Risk Management:**
   - Identify and manage risks more effectively
   - Improve decision-making and resilience through better planning
5. **Continuous Improvement:**
   - Establish a framework for ongoing enhancement of processes and services
   - Use data-driven insights to drive improvements
6. **Compliance and Standardization:**
   - Ensure compliance with industry standards and regulations
   - Standardize processes across the organization for consistency

QUALITY ASIA

CAREER BENEFITS OF ISO 9001 INTERNAL AUDITOR CREDENTIALS FOR PROFESSIONALS

1. Enhanced Career Opportunities: Increase your employability with a sought-after certification. Open doors to roles in quality management and auditing.

2. Improved Skill Set: Develop advanced auditing skills and knowledge of ISO 9001:2015 standards. Gain expertise in assessing and improving quality management systems.

3. Networking Opportunities: Connect with other professionals and experts in the field. Participate in industry forums, seminars, and workshops.

4. Better Job Performance: Apply auditing techniques to identify and address inefficiencies. Contribute to organizational improvements and compliance.

5. Increased Value to Employers: Help your organization maintain ISO 9001:2015 certification. Drive improvements in quality management processes and performance.

6. Personal Satisfaction: Achieve a recognized professional milestone. Gain confidence in your ability to conduct effective internal audits.

7. Continuous Learning: Stay current with industry best practices and standards. Engage in ongoing professional development and learning.

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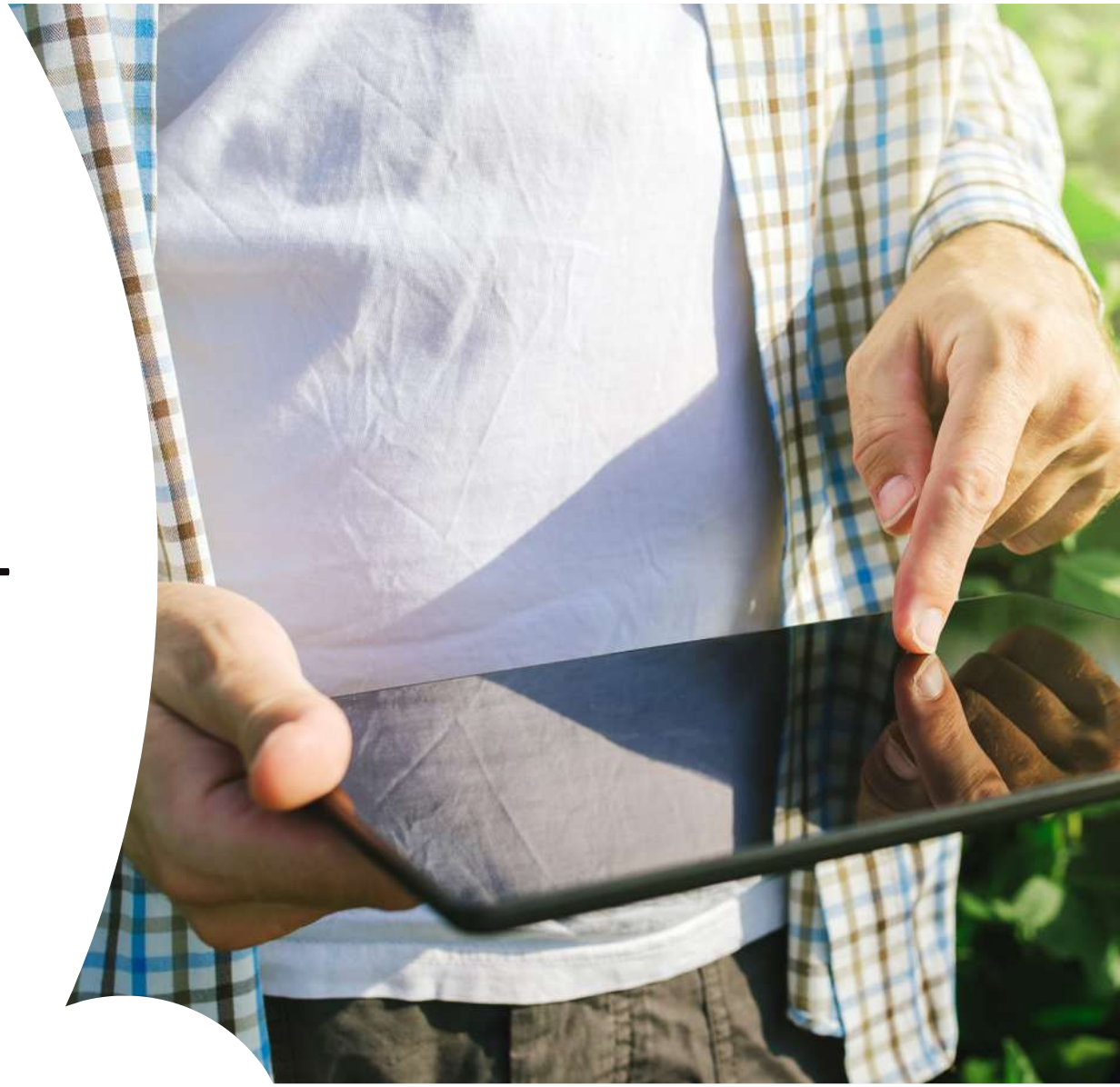
CLAUSE 9 PERFORMANCE EVALUATION, CLAUSE 10 IMPROVEMENT



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STRUCTURE

1.	Scope	8.	Operation
2.	Normative references	8.1.	Operational planning and control
3.	Terms and definitions	8.2.	Requirements for products and services
4.	Context of the organization	8.3.	Design and development of products and services
4.1.	Understanding the organization and its context	8.4.	Control of externally provided processes, products and services
4.2.	Understanding the needs and expectations of interested parties	8.5.	Production and service provision
4.3.	Determining the scope of the quality management system	8.6.	Release of products and services
4.4.	Quality Management System and its processes	8.7.	Control of nonconforming outputs
5.	Leadership	9	Performance evaluation
5.1.	Leadership and commitment	9.1.	Monitoring, measurement, analysis and evaluation
5.2.	Policy	9.2.	Internal audit
5.3.	Organizational roles, responsibilities and authorities	9.3.	Management review
6.	Planning	10.	Improvement
6.1.	Actions to address risks and opportunities	10.1.	General
6.2.	Quality objectives and planning to achieve them	10.2.	Nonconformity and corrective action
6.3.	Planning of changes	10.3	Continual improvement
7.	Support	Annex A	Clarification of new structure, terminology and concepts
7.1.	Resources	Annex B	Other International Standards on quality management and quality management systems developed by ISO/TC 176
7.2.	Competence	Bibliography	
7.3.	Awareness		
7.4.	Communication		
7.5.	Documented information		

9 PERFORMANCE EVALUATION - 9.1 MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION

"9.1.1 General

- The organization shall determine:
  a) what needs to be monitored and measured;
  b) what methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
  c) when the monitoring and measuring shall be performed;
  d) when the results from monitoring and measurement shall be analyzed and evaluated;"

- The organization shall evaluate the performance and the effectiveness of the quality management system.
- The organization shall retain appropriate documented information as evidence of the results."

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9.1.2 CUSTOMER SATISFACTION

“The organization shall monitor customers’ perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

Note: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products or services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.”

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9.1.3 ANALYSIS AND EVALUATION

"The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement. The result of analysis shall be used to evaluate:

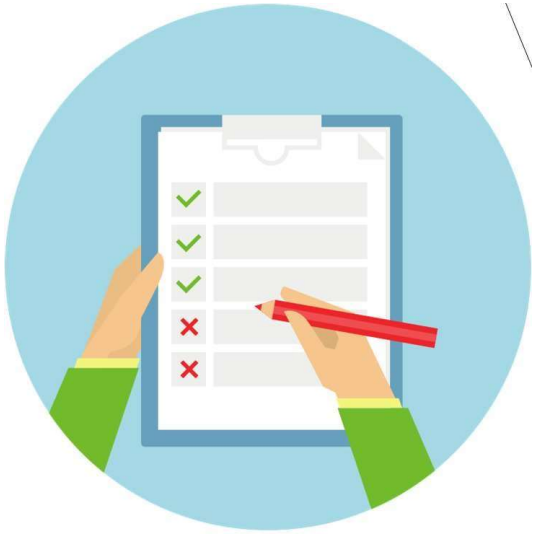
a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.

NOTE: Methods to analyze data can include statistical techniques.

9.2 INTERNAL AUDIT

9.2.1 “The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:
   1) the organization‘s own requirements for its quality management system;
   2) the requirements of this International Standard;
b) is effectively implemented and maintained.”



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9.2 INTERNAL AUDIT

"The organization shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) define the audit criteria and scope for each audit;

c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) ensure that the results of the audits are reported to relevant management,;

e) take appropriate correction and corrective action without undue delay;

f) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE: See ISO 19011 for guidance."

9.3 MANAGEMENT REVIEW – 9.3.1 GENERAL

"Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization."

9.3 MANAGEMENT REVIEW – 9.3.2 MANAGEMENT REVIEW INPUTS

"The management review shall be planned and carried out taking into consideration:

a) the status of actions from previous management reviews;
b) changes in external and internal issues that are relevant to the quality management system;
c) information on the performance and effectiveness of the quality management system, including trends in:
    1) customer satisfaction and feedback from relevant interested parties;
    2) the extent to which quality objectives have been met;
    3) process performance and conformity of products and services;
    4) nonconformities and corrective actions;
    5) monitoring and measurement results;
    6) audit results;
    7) the performance of external providers;
d) the adequacy of resources
e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
f) opportunities for improvement.

9.3 MANAGEMENT REVIEW – 9.3.3 MANAGEMENT REVIEW OUTPUTS

"The outputs of the management review shall include decisions and actions related to:

a) opportunities for improvement;

b) any need for changes to the quality management system;

c) resource needs.

The organization shall retain documented information as evidence of the results of management reviews."

10. IMPROVEMENT - 10.1 GENERAL

"The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

This shall include:

a) improving products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing or reducing undesired effects;

c) improving the performance and effectiveness of the quality management system."

NOTE: Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

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IMPROVEMENT

- Organizations should ensure that they have systems in place to review their processes, products and services, and the performance of their quality management system as a whole, with the objective of making improvements.

- Auditors should continue to seek objective evidence that improvement is taking place. They should note, however, that while improvement does not need to be continual, it does need to be evidenced as occurring.

- Auditors should look for evidence that the organization is considering improvement in respect of its processes, products and services, and the performance of the quality management system overall.

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10.2 NONCONFORMITY AND CORRECTIVE ACTION

10.2.1 “When a nonconformity occurs, including any arising from complaints, the organization shall:

a) react to the nonconformity and, as applicable:
   1) take action to control and correct it;
   2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
   1) reviewing and analysing the nonconformity;
   2) determining the causes of the nonconformity;
   3) determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;
d) review the effectiveness of any corrective action taken;
e) update risks and opportunities determined during planning, if necessary;
f) make changes to the quality management system, if necessary.”

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10.2 NONCONFORMITY AND CORRECTIVE ACTION

"Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.2.2 The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;
b) the results of any corrective action."

10.3 CONTINUAL IMPROVEMENT

- “The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

- The organization shall consider the outputs of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.”

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IMPACTS ON ORGANIZATION AND AUDITORS

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IMPACTS

- The ISO 9001:2015 standard is to be felt and perceived as an effort to encourage a business case where a QMS resides within, or is built into, the very processes that really output product, which results in a holistic system with the primary objective of meeting interested parties' requirements and enhance their satisfaction.

- Risk-based thinking becomes the very basis of the improvement agenda, the QMS is now more risk sensitive, more outward oriented, more flexible to innovation and improvement opportunities. This is the change that organizations need to understand and use to further reinforce the current approaches to addressing risks and opportunities.

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IMPACTS

- Without appropriate leadership and commitment, implementation of a QMS may bring desired outcomes only accidentally with limited, if any chances for sustained improvement.

- Auditors will need to become familiar with the ISO 9001:2015 standard and so training may need to be considered. Furthermore, auditors will need to understand the rationale behind the requirements, with particular emphasis put on process and risk-based management approach. This will also involve an effort to trace the new paradigm of the complexities of the relationship between the organization and its context and their interdependence and interference. The business agenda and the broader business outlook will have to be reinforced by the QMS and this is an aspect an auditor shall be aware of.

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IMPACTS

- Within her/his own mandate, the ISO 9001:2015 auditor will need to make an effort to bring a value added to the auditee organization. This will be especially difficult in organizations that have dealt primarily with older versions of ISO 9001 and that have limited experience in developing and implementing other risk management systems. Thus, an ISO 9001:2015 auditor will have to reinforce an understanding that the new revision is not simply a change of structure, some terms and definitions.

- The ISO 9001:2015 standard comes with a business oriented, risk-based thinking that implicitly reinforces a process approach and requires consistency in relating various elements to the PDCA cycle. At the end of the day, the QMS audited will need to demonstrate this new organizational thinking, feeling and outlook. The role of the QMS auditor in this process is to be understood as an 'agent of change', no matter how many and serious limitations may apply.

PUBLICATION OF EXPECTED OUTCOMES

- The International Accreditation Forum (IAF) and the International Organization for Standardization (ISO) published a document that sets the expected outcomes resulting form accredited management systems certification.
- The intent of the documents is to promote a common focus throughout the conformity assessment chain in order to enhance the value and relevance of accredited certification.

- The document provides a high-level overview of what organizations should expect from accredited certification as well as what they should not expect.
- This document is available at https://www.iaf.nu/upFiles/CASCO_Expected_Outcomes2018final.pdf

Source: IAF CASCO Expected Outcomes

EXPECTED OUTCOMES OF ACCREDITED CERTIFICATION TO MANAGEMENT SYSTEM STANDARDS (ISO) FROM AN INTERESTED PARTY PERSPECTIVE

- For a defined scope of certification an organization that has a certified management system has policies and processes in place to achieve objectives defined by the scope of the specific management system standard

Source: IAF CASCO Expected Outcomes

EXPECTED OUTCOMES QUALITY MANAGEMENT SYSTEM CERTIFICATION

For example:

“An organization with a certified quality management system is managing its systems and processes so as to :

a) consistently provide products and services that meet customer and applicable statutory and regulatory requirements ;

b) facilitate opportunities to enhance customer satisfaction.”

Source: ISO CASCO Expected Outcomes

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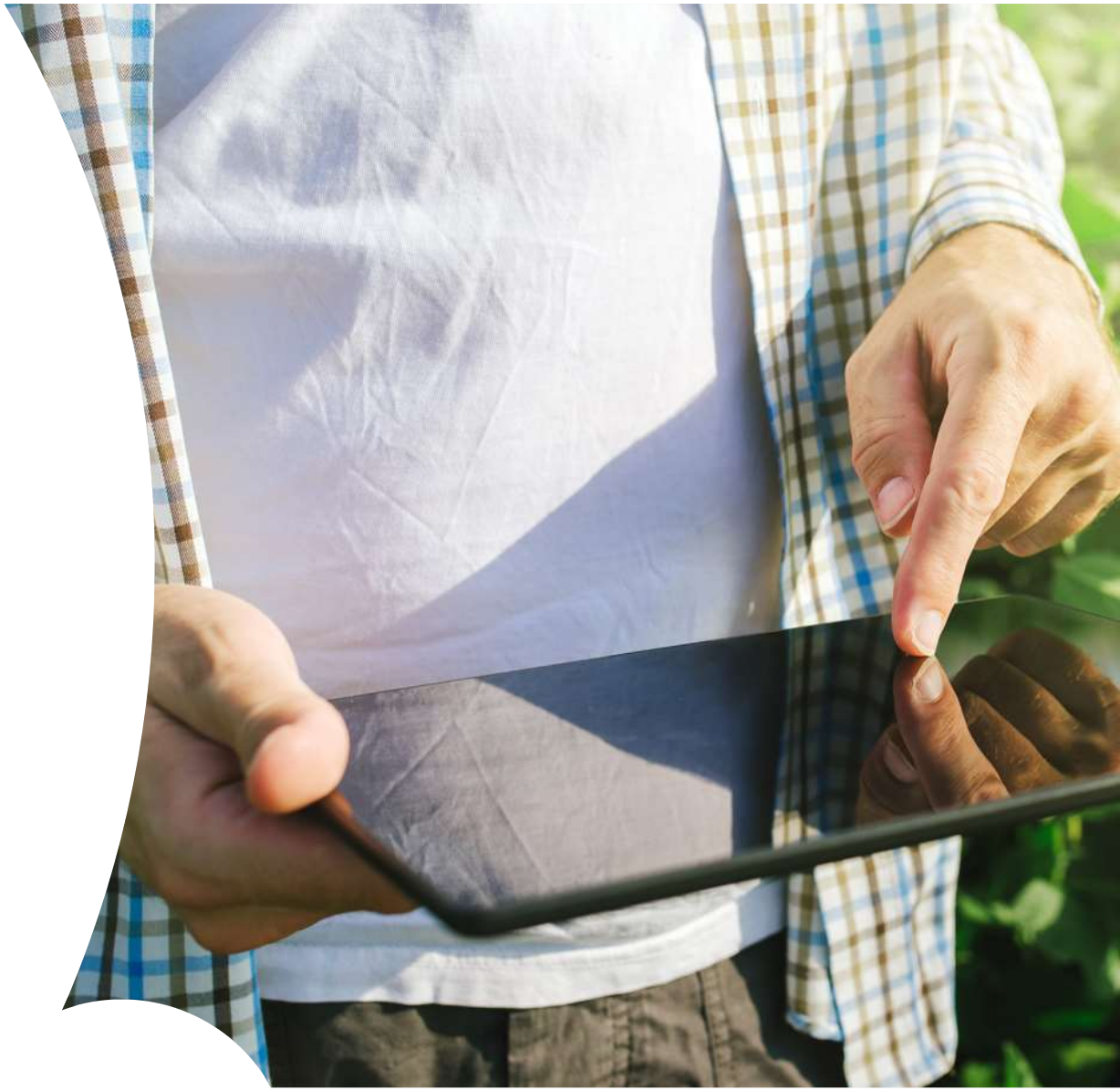
AUDITS: DEFINITION, PRINCIPLES, AND TYPES



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QUALITY ASSURANCE AUDIT/ASSESSMENT

ISO 9000:2015 Definition of "Audit":

"Systemic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled."

Alternative Definitions:

- Impartial documented activity
- Follows written checklists and documentation
- Uses examination of audit evidence to determine the existence of objective evidence
- Verifies that applicable processes of a QMS have been identified and are effectively controlled.

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EFFECTIVE AUDITS - REQUIREMENTS

- Timely access to facilities, documents and personnel, including top management
- Defined auditing procedures
- Support/involvement of management
- Competent audit team
- Impartial and objective audit team

TYPES OF AUDITS:

First Party (Internal Audit)

Definition:

An audit by the organization of its own systems and procedures.

Objective:

To assure maintenance and development of the quality system.

Third Party (External Audit)

Definition:

An assessment by a body which is independent of the organization, its suppliers and customers.

Objective:

To determine that an organization's quality system has been documented and implemented according to a specified standard.

Second Party (External Audit)

Definition:

An audit performed by the organization on suppliers and sub-contractors

Objective:

To determine suitability of suppliers and sub-contractors, and to appraise suppliers' and sub-contractors' performance.

PHASES OF AN AUDIT

Phases of an Audit

- Planning
- Preparation
- Performance
- Reporting and Follow Up

Planning the Audit Stage

- Frequency and timing
- Responsibility
- Criteria
- Scope
- Methods
- Duration

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AUDIT PLANNING

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PLANNING INTERNAL AUDITS

Frequency and timing:

- Based on status and importance

Responsibility:

- Competent auditor with technical knowledge

Criteria:

- Organization's own procedures, specifications, documents, etc.
- Internal Standards e.g. ISO 9001:2015

Scope:

- A process
- An area of the company, e.g. distribution

Duration

- Depends on the size of the scope

PLANNING SECOND PARTY AUDITS

Frequency and timing:

- As determined by the organization

Responsibility:

- Competent auditor with technical knowledge

Criteria:

- Contractual obligations
- Organization's quality management system
- ISO 9001 or other agreed standards

Scope:

- The entire facility
- An area of the company, e.g. a product line

Duration

- Depends on the size of the scope

PLANNING THIRD PARTY AUDITS

Frequency and timing:

- As determined by the accreditation

Responsibility:

- Qualified auditor with technical knowledge & experience

Criteria:

- ISO 9001 or other standards

Scope:

- Entire organization
- Management system operations as defined by applicable standard

Duration

- Depends on accreditation requirements

WORKSHOP 6: PREPARE AN AUDIT PLAN

Prepare an Audit Plan for Auditing a Manufacturing Organization involved in the Production of any Product you know about.

Please type your responses in the Chat Box

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AUDIT PREPARATION

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AUDIT PREPARATION

- Notify person to be audited and agree to a date and time
- Review documents: procedures, forms, previous reports, corrective action requests, work instructions, etc.
- Prepare/review/update checklists
- Brief auditor/team

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THE CHECKLIST

The Checklist

- To be used as a working document and as a record
- Tool to audit company processes, not standard
- Should follow the natural process of the organization

The Purpose of the Checklist

- To provide guidance to the auditor
- To ensure that the audit scope is covered (processes, activities)
- To reinforce the objectives and scope of the audit
- To act as a record

Risks of the Checklist

- Too focused on a single area
- Insufficient information included to evaluate conformance in interviews
- Not customized to reflect company's practices

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PREPARING THE CHECKLIST

Consider:

- The Quality Policy
- Objectives associated with the area to be audited
- Interactions between the processes
- Activities which are under way (audit according to the flow of the business)
- Relevant procedures
- Other documents being used
- Records being maintained
- Staff competence requirements
- Requirements of ISO 9001
- “Horizontal”(Clause-Based)/”Vertical” (Process-Based) auditing techniques

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WORKSHOP 7: PREPARE AN AUDIT CHECKLIST

Produce an audit checklist on specific processes identified on the audit plan in Case Study 6.

Identify the relevant clauses of the ISO 9001:2015 Standard that apply to the audit checklist questions.

Type your Responses in the Chat Box

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CONDUCTING THE AUDIT

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AUDIT PERFORMANCE

- Opening meeting
- Conduct the audit
- Review findings
- Closing meeting

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OPENING MEETING

- Introduce auditors or audit team
- Discuss audit scope and process
- Explain reporting and follow-up procedures
- Necessary for:
  a) Good communication
  b) Co-operation
  c) Openness

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THE AUDITOR'S APPROACH

The auditor must:

- Deal with top management
- Understand the key issues in the organization
- Focus on the critical processes
- Audit for business improvement
- Meet the area representative first
- Always talk to those performing the task
- Explain the purpose of the visit
- Be calm, polite, reassuring
- Never talk down
- Never act superior
- Speak clearly and carefully

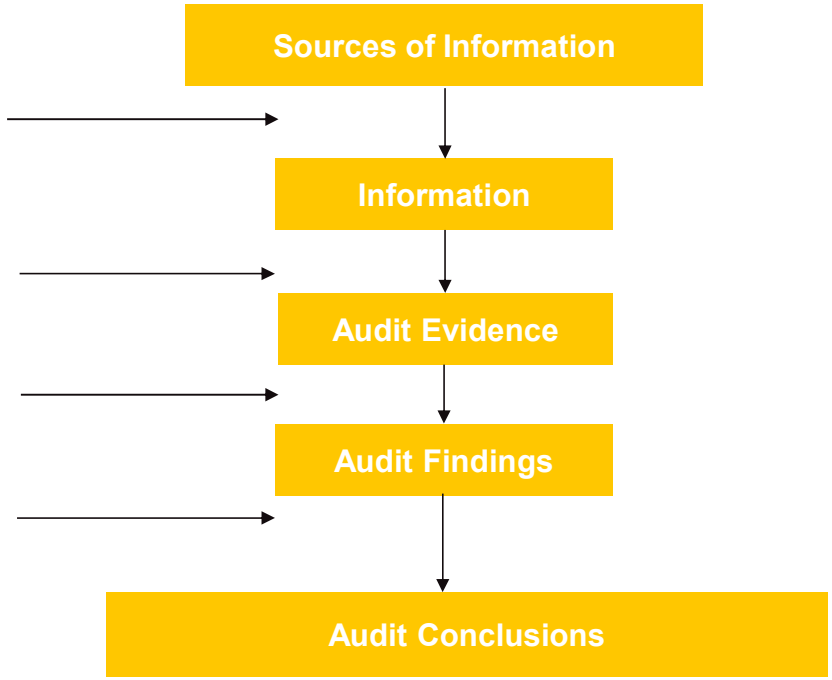
THE AUDITOR PROCESS

Gathering & selecting
(by document review, interviewing,
observing, etc.)

Verification

Comparison with audit criteria

Review



AN AUDITOR "VERIFIES" BY …

Obtaining Objective Evidence

ISO 9000:2015 definition for "Objective Evidence":

"*data* (3.8.1) supporting the existence or verity of something"

Note 1 to entry: Objective evidence can be obtained through observation, *measurement* (3.11.4), *test* (3.11.8), or by other means.

Note 2 to entry: Objective evidence for the purpose of *audit* (3.13.1) generally consists of *records* (3.8.10), statements of fact or other *information* (3.8.2) which are relevant to the *audit criteria* (3.13.7) and verifiable.

OBTAINING OBJECTIVE (AUDIT) EVIDENCE

May be gathered from:

- Interviews with people
- Observation of activities
- Interactions between functions, activities, processes
- Measurement of processes and programs
- Documents/records
- Data summaries, reports from other sources (e.g. customer feedback)

People:

- Does anyone understand the systems and documentation?
- Are the employees competent?
- Is there co-operation?
- Are there any system problems?

OBTAINING OBJECTIVE (AUDIT) EVIDENCE

Observation of activities

- Are the processes efficient? Effective?
- Are things in logical sequence?
- Are the interactions between processes defined?
- What is the significance of links between processes?
- Can inputs and outputs be identified?

Measurement of processes and programs

- Capacity of processes
- Product measurements
- Accuracy
- Dependability
- Cycle times
- Resource utilization
- Productivity

OBTAINING OBJECTIVE (AUDIT) EVIDENCE

Documents/records

- Issue status?
- Complete and concise?
- Condition?
- Legibility?
- Identity?
- Approval?
- Availability?

Data summaries

- Customer feedback
- Vendor analysis
- Internal Audits
- Financial measurements
  - Preventive, appraisal and failure cost analysis (Cost of quality)
  - Cost of nonconformity

EXAMINE OBJECTIVE EVIDENCE

Examine:

- Documents/data
  - Fully complete
  - Accurate data
  - Check for authorization
  - Review analysis of data
- Physical Evidence
- Environmental Conditions

Establish:

- Extent of conformity/nonconformity
- Nature for nonconformity
- Sample: According to the amount and variety of evidence

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USE THE CHECKLIST

- To record conformity/nonconformity
- To track where you are and manage time
- To control the pace of the audit and manage auditee personalities
- To ensure all areas are covered
- To make notes for follow-up in other areas
- For future reference

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QUESTIONING TECHNIQUES

Who?

What?

When?

Where?

Why?

How?

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CONTROLLING THE AUDIT

- Insist that people being questioned answer for themselves
- Do as little talking as possible
- Do not let others dictate the pace
- Rephrase misunderstood questions
- Give compliments
- Say, “Thank you”
- Be aware of hidden agendas and emotional blackmail

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SOME BASIC ISSUES

- Establish that the company is demonstrating control over the operation
- Involve management in the audit process
- Observe work progression when possible
- Evaluate physical objective evidence
- Examine inputs and outputs
- Make comprehensive notes

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SOME BASIC RULES

Seek verification

- Do not assume people will lie, but seek to verify statements if necessary
- Recall ISO 9000:2015 definition of objective evidence

Do not accept pre-prepared samples

- Choose your own

GENERAL PRINCIPLES OF AUDITING

The following principles relates to all auditors:

- **Integrity** – the foundation of professionalism
- **Fair presentation** – the obligation to report truthfully and accurately
- **Due professional care** – the application of diligence and judgment in auditing
- **Confidentiality** – security of information
- **Independence** – the basis for the impartiality of the audit and objectivity of the audit conclusions
- **Evidence-based approach** – the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process

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AUDITOR'S PERSONAL ATTRIBUTES

Ethical – Fair, truthful, sincere, honest and discreet

Open-minded – willing to consider alternative ideas or points of view

Diplomatic – tactful in dealing with people

Observant – actively observing physical surroundings and activities

Perceptive – aware of and able to understand situations

Versatile – able to readily adapt to different situations

Tenacious – persistent and focused on achieving objectives

Decisive – able to reach timely conclusions based on logical reasoning and analysis

Self-reliant – able to act and function independently whilst interacting effectively with others

GENERAL KNOWLEDGE AND SKILLS OF MANAGEMENT SYSTEM AUDITORS

- Audit principles, procedures and methods
- Management system and reference documents
- Organizational context
- Applicable legal and contractual requirements and other requirements that apply to the auditee
- Discipline and sector-specific knowledge and skills of management system auditors

GENERIC KNOWLEDGE AND SKILLS OF AUDIT TEAM LEADERS

Audit team leaders should be able to:

- Balance the strengths and weaknesses of the individual audit team members
- Develop a harmonious working relationship among the audit team members
- Plan audits and effectively use audit resources
- Manage the uncertainty of achieving audit objectives
- Protect the health and safety of the audit team members including compliance with the requirements
- Organize and direct the audit team members
- Provide direction and guidance to auditors-in-training
- Prevent and resolve conflicts as necessary
- Represent the audit team
- Lead the audit team to reach the audit conclusions
- Prepare and complete the audit report

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GOOD PRACTICES FOR AUDITORS

- Introduce self and/or audit team
- Ensure agenda is understood
- Keep to agenda
- Keep control of the audit and time
- Avoid arguments
- Listen
- Keep records
- Remain polite, calm, professional

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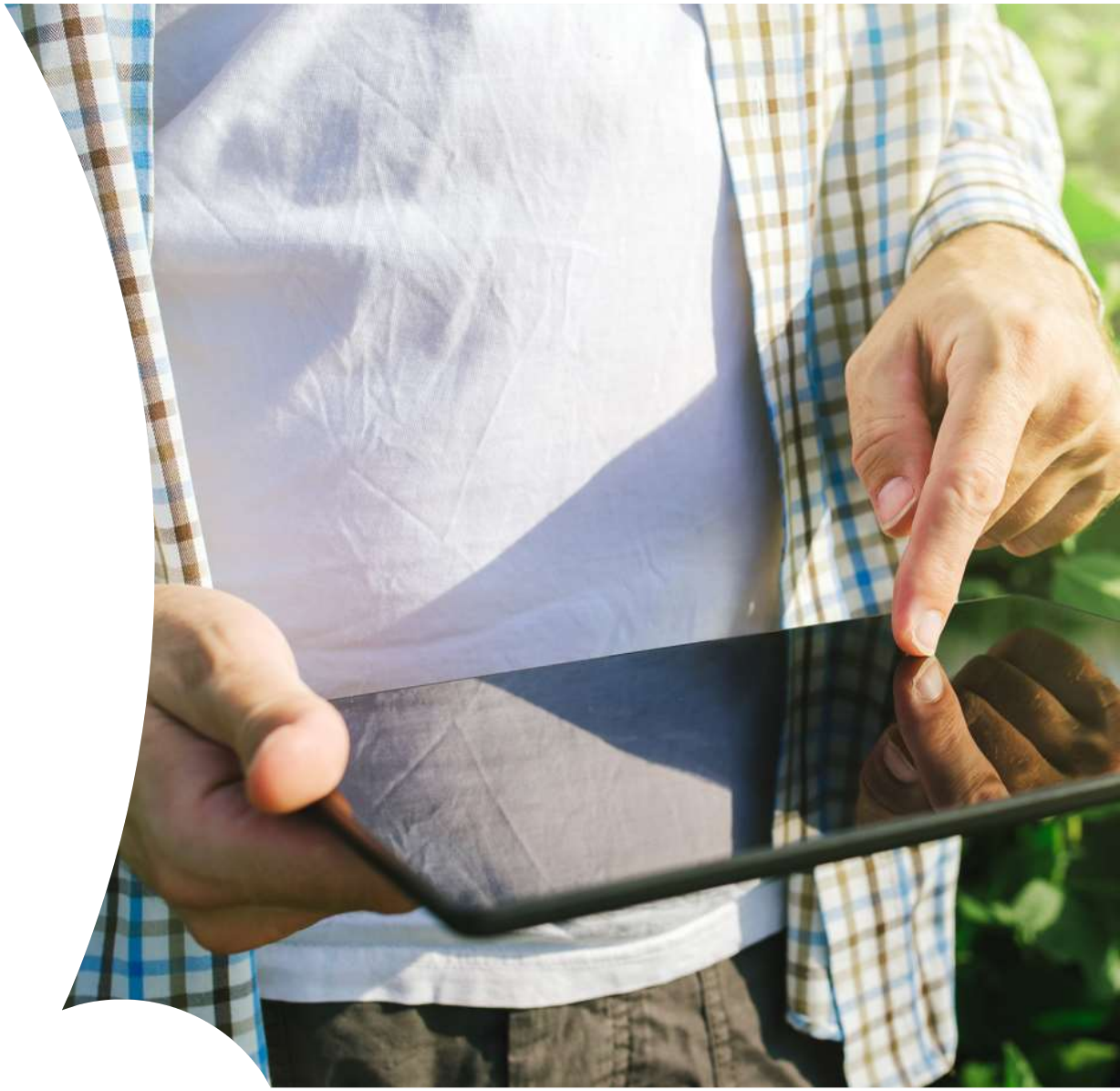
AUDIT REVIEW



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AUDIT REVIEW

- Conduct a private review when the audit is finished
- Interim or “end of the day” reviews (or both) may be appropriate
- Review and complete checklists
- Study and compare notes (team)
- List nonconformities

ANALYZING RESULTS

Review if:

The deficiency is an isolated error or a breakdown of a system

Auditee is aware of the problem

The deficiency has been reported before

CLOSING MEETING

- Explain/discuss the findings
- Obtain agreement
- State overall degree of conformity
- Mention the positive points

Internal Audit

- Informal
- Constructive
- System improvement

Second Party

- Contracts at stake
- Reports used as future reference
- More emotional situation than first party audit meeting
- Be prepared to be challenged

Third Party

- Certification at stake
- Findings issued
- Corrective actions timeline
- Based on accreditation requirements and interpretation of standard

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NONCONFORMANCE STATEMENT

A short statement describing the nonconformity including:

- What - The issue in question

  (a statement of nonconformity)

- Why - What the statement is raised against?

  (the requirement, or specific reference to the requirement)

- Objective Evidence - The objective evidence found

  (the objective evidence observed that supports statement of nonconformity)

EXAMPLE OF NONCONFORMANCE STATEMENT

A statement of nonconformity:

The system for recording the contract review results was not effective.

The requirement, or specific reference to the requirement:

ISO 9001:2015 Clause 8.2.3.2 Review of Requirements for Products and Services “The organization shall retain documented information, as applicable: a) on the results of the review;…….”

The objective evidence observed that supports statement of nonconformity:

No contract review results records were retained for customers’ contracts of ABC Company and YYZ Company

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AUDIT REPORTING, FOLLOW UP, AND REGISTRATION PROCESS

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AUDIT REPORTING

The audit report should include:

- Auditors, contracts, scope
- Overall conclusions
- Deficiencies, observations, supporting objective evidence
- Follow-up details

Exclude from Report:

- Confidential information given in interviews
- Matters not raised or discussed at the closing meeting
- Subjective opinions – use only verifiable facts / objective evidence
- Ambiguous statements
- Antagonistic words or phrases

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AUDIT FOLLOW-UP

- Verify that action(s) are implemented
- Ensure short and long term effectiveness
- Record follow-up details & objective evidence reviewed
- Sign off forms

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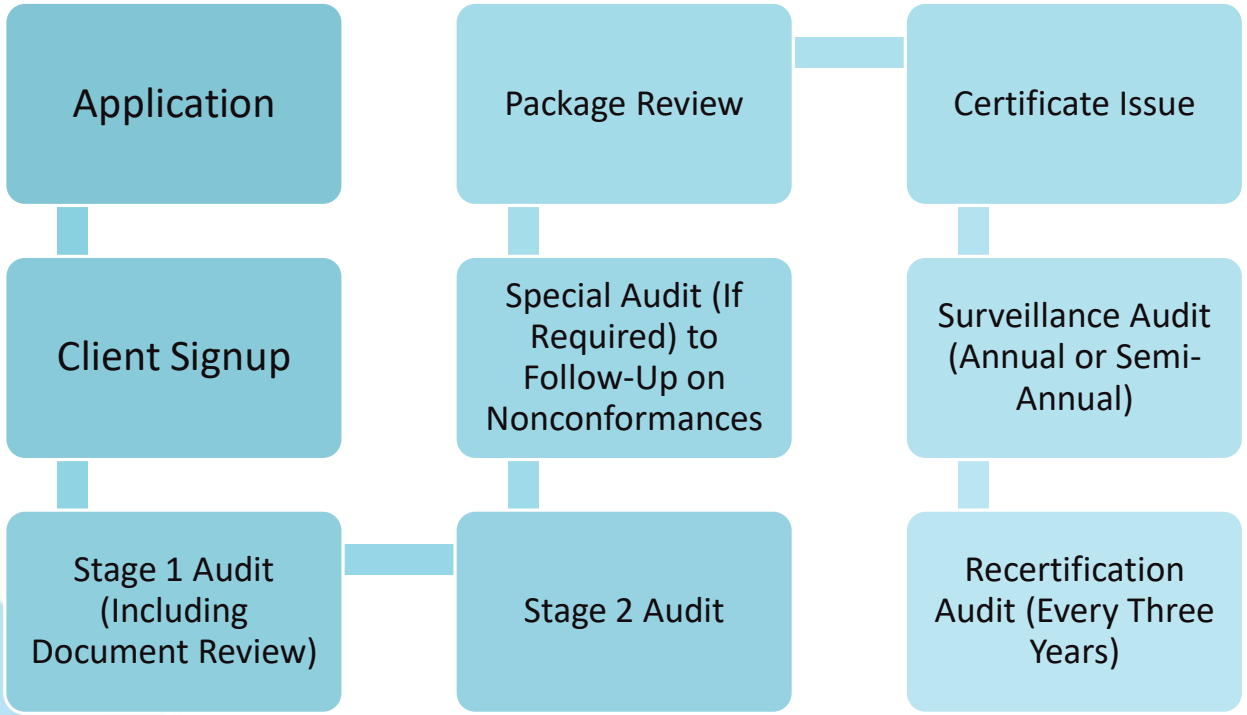
REGISTRATION PROCESS FLOW



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COURSE SUMMARY

- Understand the interpretation of ISO 9001:2015 Standard, the quality management system and its application to their own companies;
- Learn the principles and practices of the quality management systems (QMS);
- Develop skills in planning, preparing and performing value-added ISO 9001:2015 audits; preparing audit reports and conducting follow-up verification audits.

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Q & A

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TRAINING EXAM & FEEDBACK

Training & Feedback Form

https://forms.gle/1jZijFKnL2gTaxZz9

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