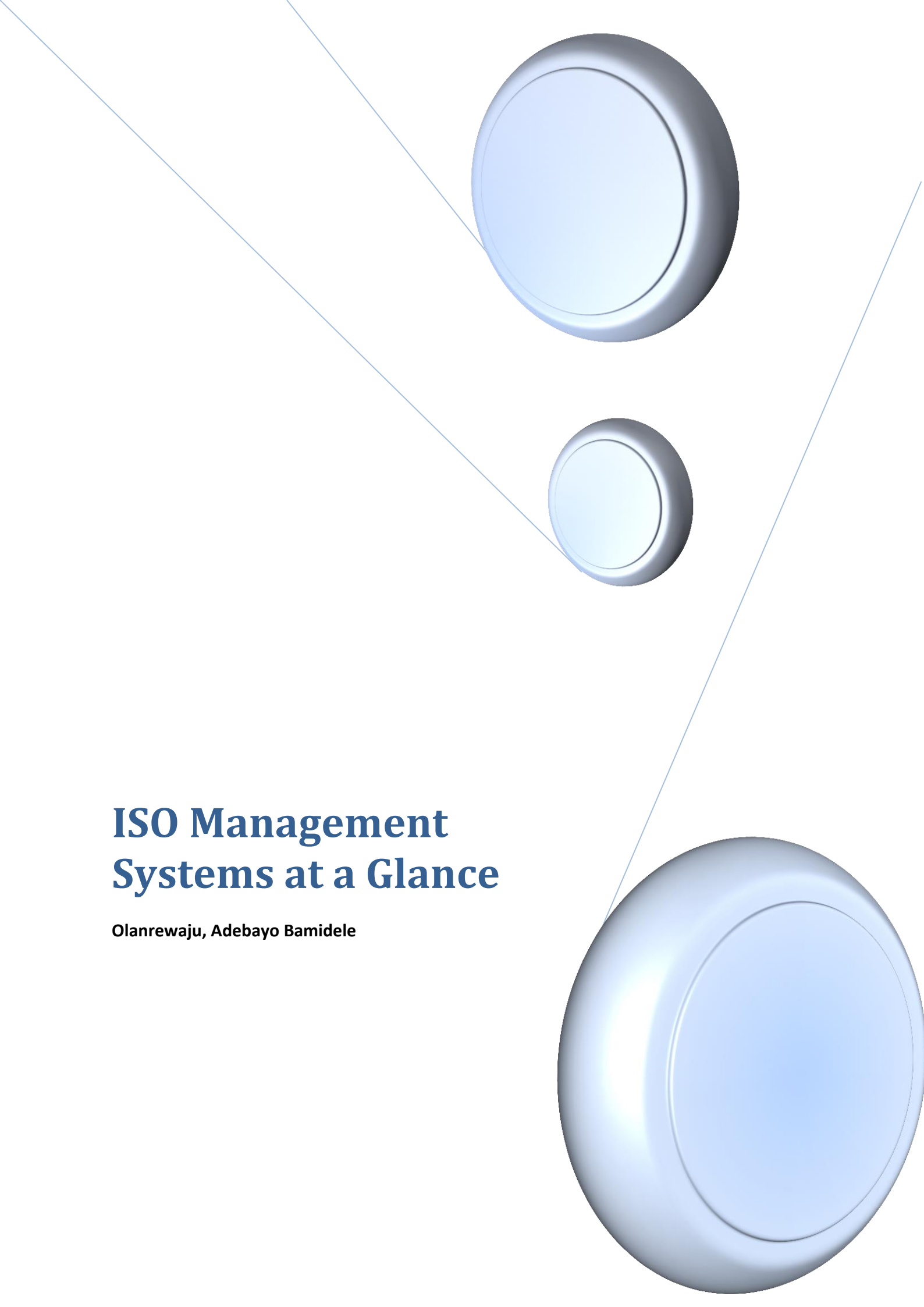

ISO Management Systems at a Glance

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Managing the Organization & its Context

Clause 4.1 of ISO 9001:2015 standard says ''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.''

Determining the external and internal issues involves:

- Studying the **influences** of various elements affecting the organization directly or indirectly.
- Understanding **how** the elements affect the management system.
- Studying the risks and opportunities regarding the business.

These elements are referred to as the interested parties with their attending issues, internal or external to the system and/or the organization.

- **Interested parties – Who qualifies?**

Interested parties are entities that are directly or directly concerned with the performance of an organization's quality, occupational health & safety, environmental safety or food safety systems. They are the individuals, organizations or group that can influence or be influenced by your organization's processes or activities. They include the organization's management, community, contractors, and shareholders. These parties are qualified as interested parties for the management systems.

a. **Management & Shareholders:** These people are connected to all the business functions and strategic decisions affecting the well-being of the business. They set directions and take the lead in implementing the strategic goals of the organization.

b. **External Providers, Contractors & Service Parties:** The role of this group is also very important for the effectiveness of a management system since they can also be a source for introducing food safety risk in the supply chain of food *(for FSMS)*. The organization should develop proper controls to manage their performance to enhance the effectiveness of the system.

c. **Government, Regulatory or Legislative Bodies:** In the case of the fulfilment of legal requirements, these parties become interested in authority over organizations.

d. **Customers:** Customers are the most important interested party of a management system. They should purchase products of high quality, which should be manufactured in hygienic condition. In the absence of proper controls, they will suffer the negative impact of these products on health, including acute diseases.

Internal & External Issues

- **Internal Issues**

Internal issues of an organization make up the internal context of the organization. They are actions or products and services within the organization that may affect an organization's management systems performance.

Organizations have so much intensive and complex issues to consider when planning for the operation of their management system. When analyzing the business context, they should consider some common internal issues such as these:

- The competence of the organization's workforce for ensuring effective management system implementation.
- The commitment of the workforce regarding food safety, health & safety, quality etc.
- Organization's communication channels and means for the management system and their significance.
- The readiness to collaborate and remain within the declared scope of the management system.

- **External Issues**

External issues refer to factors influencing the organization's business and operations from the outside. They include legal, economic, social, or political issues susceptible to damage an organization's business and operational performance.

The following are some examples of external issues that an organization should consider while planning its management system.

- **Legislation & regional laws:** Legislation and regional laws are important to the organization's performance. The organization need to make their processes compliant with these laws. They should have a system in place to upgrade with any new laws as well.
- **Economic & Political Situations:** Both economic and political conditions of the sector in which an organization operates impact their business processes. While they may not be able to control the situation, they can adapt and respond to such changes in political and economic space. Response should go to the level in which organization

can maintain its effectiveness for business and the management system itself. These should be addressed in policy, objectives, and programs.

- **Shareholders Interest:** The expectations of the stakeholders must be taken care of. Since they are also concerned about business and the system performance.
- **Updates from International agencies:** They might need a restructuring of your business parameters for your specific system. An example is the FDA banning the usage, sales and distribution of seven artificial food flavorings (benzophenone, ethyl acrylate, methyl eugenol, myrcene, pulegone, or pyridine).

Haven determined the internal and external issues affecting an organization documenting the analysis of business context is recommended to to serve as an evidence to auditors and other stakeholders. Also, a consistent review of the issues should regularly be conducted to address changes in changing world.

ISO Management Systems: Vital Steps to Implement Risk-Based Thinking

ISO 9001 certification serves a way to prove that an organization has the ability to provide customers with conforming products and services consistently. Consistency can be ensured through adequate control of processes, but in the case of something unforeseen occurring, the concept proves to be relevant.

Newer versions of ISO standards such as ISO 9001:2015 and 14001:2015 are giving risk a more prominent place in quality and environmental management standards. These standards have made it a requirement for organizations getting certified to them to adopt risk-based thinking to their processes from planning to execution and performance evaluation.

Risk based thinking as a concept encourages proactive approach, rather than reactive approach in that, it requires systematic incorporation throughout the entire processes of an organization and its quality management system and not handling it as a standalone component, like the case of preventive action in previous version of ISO 9001 standard. The latest standard requires risk to be woven throughout the entire process of the organization, not a separate entity.

The specific areas where risk appears in the new standard requirements include the following:

- Organizational context

- Leadership
- Planning
- Operation
- Performance evaluation
- Improvement

Following a risk-based approach requires:

- Determining the risk and opportunities associated with an organization's processes.
- Planning effective actions to address them.
- Implementing them in an organization's processes and its quality management system.
- Evaluating their performance for effectiveness.

Implementing Risk-Based Thinking

- **Identification:** Identify the risk and opportunities associated with an organization's processes by taking into consideration the context of your organization..
- **Prioritization:** The next step is to analyze and prioritize the identified risks and opportunities to determine what is acceptable and what is not.
- **Planning:** Plan effective actions to address these risk, determining those that can be avoided, mitigated or eliminated
- **Implementation:** Taking actions to implement the planned actions to address risks.
- **Evaluation:** Evaluating the effectiveness of the actions.
- **Continual Improvement:** Striving for excellence by incorporating on a consistent basis, any necessary modification, and repeating the cycle.

ISO Management Systems: Identifying and Analyzing Risks & Opportunities

Clause 6.1 “actions to address risks and opportunities” of ISO 9001:2015 replaces the ‘’preventative actions’’ implicitly incorporated in the previous standard to mitigate and avoid risk.

The term ‘’risk’’ as used in the standard is a deviation from the expected. This deviation can be positive or negative. This positive deviation can safely create a path to a new opportunity. Hence, addressing risk could result to pursuing a new opportunity. Effective risk management definitely results to effective preparation for uncertainties.

Opportunities can include such things as:

- Adoption of new customers,
- Manufacture of new products,
- Implementation of new technology or practices.

The following are some specific areas where risk appears and are mandatory in the new standard:

- **Organizational context:** Specifically, clause 4.4 ‘’quality management system and its processes’’ mandating the overall quality management system (QMS) to consider both risks and opportunities as part of its core planning processes.
- **Leadership:** Specifically, clause 5.1 ‘’leadership and commitment’’, mandating those leading the organization to promote risk-based thinking. And, clause 5.1.2 ‘’customer focus’’, ensuring that risks and opportunities that affect customers are determined and addressed.
- **Planning:** Specifically, clause 6.1 ‘’actions to address risks and opportunities’’ mandating determining and addressing risks and opportunities when planning for the QMS.
- **Performance evaluation:** Specifically, clause 9.1.3 ‘’analysis and evaluation’’ mandating evaluation of the effectiveness of actions taken to address risks and opportunities.
- **Improvement:** Specifically, clause 10.2 ‘’nonconformity and corrective action’’ mandating update of risks and opportunities determined during planning, if necessary.

Methods of Identifying and Addressing Risk

They include:

- Maintaining a risk register,
- Conducting FMEA study (Failure Mode Effects Analysis),
- Conducting FTA (Fault Tree Analysis),
- Applying a Probability and Impact Matrix.

Steps to Address Risks and Opportunities

Two metrics are needed to effectively evaluate risk and opportunities, they:

- **Probability:** The possibility that the risk would occur.
- **Severity:** The seriousness of the risk if it occurs.

Consider the following steps when addressing risks and opportunities:

- **Determine the type and source of risk and opportunity:** Does it originate from context, process and products/ services.
- **Determine Risk Category:** What category is the risk classified?
- **Determine Risk Impact and Probability:** Define the impact and the probability of the risk occurring.
- **Determine Risk Treatment and Action:** Determine how the organization will treat the risk and create a predefined list of treatments. Also, determine acceptable action to treat the risk.
- **Review and Documentation:** Regularly review risks and opportunities and ensure proper documentation at each stage of the process as evidence of actions taken.

Role of Top Management in Management Systems Implementation

There is an increased focus on top management to prove leadership and commitment with respect to its management system under implementation. They are required ensure that all responsibilities have been allocated, communicated and understood around organization. They have a duty to ensure that the significance of the management system is effectively communicated and comprehended by all internal and external stakeholders who impacts and/or impacted by the business.

They need to make sure that the organization attains its planned outcomes. Top management must ensure a leadership role and exhibit commitment towards the management system by observing the following elements:

- **Ownership:** They need to take complete responsibility and accountability for the management system.
- **Policy and Objectives:** The top management need to ensure that the policy and concerning objectives are identified and are related to the strategy of the company.
- **Business Integration:** They need to ensure the integration of the management system requirements into the business processes of the organization.
- **Provision of Resources:** The need to make sure that the required resources to develop, apply, sustain and enhance the management system are available.
- **Communication:** They are responsible for effective communication of the significance of implemented management system and its compliance to standard requirements.
- **Maintenance & Evaluation:** They need to make sure that the management system is evaluated and maintained to ensure its effectiveness.
- **Continual Improvement:** Top management need to ensure that review and results of review contribute to the continual improvement of the management system.
- **Empowerment of Roles:** They need to appoint and empower responsible persons which would assist in the implementation activities.
- **Culture:** The top management are responsible for establishing, leading and encouraging culture in the organization that assists the desired results of the management system.
- **Coaching:** Directing and supporting persons to contribute to the effectiveness of the food safety management system.

3 Tips for Conducting an Effective Management Reviews

Management Review refers to structured meeting involving top management of an organization with the goal of reviewing and evaluating the effectiveness of the Management System, helping you to determine its continued suitability and adequacy. This meeting holds

at regular intervals throughout the year. They are part of the requirement of running an ISO certified Management System.

The following are three (3) key steps required for the effectiveness of management reviews:

- Involvement of Top Management
- Speak in their terms
- Distribute responsibility

- **Involvement of Top Management**

The top management comprising of the chief operating officer (COO), chief executive officer (CEO), managing director, general manager and chief financial officer etc, are all concerned about the financial status of the organization. They believe that the operational and financial performance of the organization is vital for its overall success.

In the same way, the quality management system needs to be taken, in which all members of the top management believe that quality is an integral part of organizational success. This belief system will drive the involvement of all members of the top management which is actually necessary to accelerate improved business processes.

Top management should be helped to understand that quality is an essential element in the organization's overall success. They need to understand that all employees, including functional managers, supervisors and other member of the organization have a vital role in the success of quality management systems. They need to believe that quality should be taken as a critical business activity. Management reviews are very essential to meet the goals of an organization and the top management needs to show ownership and engagement in the system to make it effective.

- **Speak in their terms**

Haven seen the need for the involvement of the top management in management reviews, how can you ensure that they are enthusiastically involved?

One key way is to speak in their terms - in business linguistics. That means helping them to see convincingly, that an ineffective management system can result to increase in the cost of running the business and an effective quality management system can help improve internal processes that can result in profitability of the business.

You should ponder over the key impacts quality management systems have had on to the organization outside audits, inspections, and system certificates placed on the wall. Quality

managers and coordinators must speak in the language the top management understands, just like the finance and accounting managers when discussing the company's monetary achievements.

They need to be enabled to see how the organization's economic activities are affected by the effectiveness of its management systems. The management review is a vital way for validating the business value that quality management systems have on the organization.

For example, has it helped to improve the company's market share? And, in what way has it done so? This attribution follows the cause-and-effect principle.

- **Distribute the Responsibility**

Quality is not just the concern of the quality manager but every individual member of organization – from the top management to the shop floor engineer. Although, the quality manager or QMS coordinator is responsible for coordination of the whole routine operation of the quality management system, all executives, members and their teams are also liable for system to be operational. As the saying goes that **"Quality is every one's responsibility".**

In view to this, quality managers must endeavor to allocate responsibilities to the appropriate department heads or managers, that way responsibility can be shared.

ISO 9001 Quality Management Systems and the PDCA Model

The Plan-Do-Check-Act (PDCA) model is a cyclic process conceptualized by Walter Shewhart and widely promoted by Edward Deming. The two are referred to as the founders of most of the quality philosophies that are widely in use today.

The PDCA concept is simply a cycle for effecting change which, when implemented and repeated, would yield repeated improvements in any process. It is an iterative four-step managing technique utilized in industry for the continuous improvement of their processes.

Phases of the PDCA Model

- **Plan**

This phase involves the establishment of the objectives and processes essential to provide outcomes that are in line with needed output. It include planning on how to realize the

product or service, including what resources are required and how they will be used, is the last step in the early planning.

- **Do**

In this phase, the execution of the plan, performance of the process, and/or production is carried out. It is at this stage that, an organization gathers process statistics for recording and examination in the next steps of Check & Act. This stage includes sourcing and purchasing raw materials against requirements, monitoring, testing and validating processes etc.

- **Check**

This stage involves examining the actual results of the 'Do' phase, and assessing it against the expected results of the plan phase. It is mandatory to check and measure not merely the product to make sure it fulfils requirements, but to also assess and measure the processes as well. The check phase includes the following: analysis of process data, internal /external audits and management review.

- **Act**

If the check phase of the PDCA cycle reveals that the Plan applied in the Do phase is a progressive improvement to the earlier results, the present 'Do' then becomes the new standard for how the organization should 'Act' going forward. However, if the result of the check phase analysis reveals that the Plan applied in Do phase is not an improvement, then the prior standard remain.

In both cases, more understanding of the process is needed which will serve as a basis for the next PDCA cycle. Corrective actions and action plans that resulted from output of management review meetings and internal audits acts as part of the Act phase of PDCA cycle.

When to Use PDCA Model

PDCA cycle can be used under the following circumstances:

- When initiating a new improvement project.
- When opting for continuous improvement.
- When modifying or designing a new part of a process, product or service.
- When defining a repetitive work process.

- When collating or analysing data so as to verify and prioritize problems or root causes.
- When applying any change.

PDCA Cycle and ISO 9001

The PDCA model is an integral part of ISO 9001 Quality Management System. It is embedded into the standard. Organizations opting for ISO 9001 automatically adopts PDCA cycle.

- **Plan**

Planning is a major part of the quality management system which begins with **realizing the context** of the organization and the expectations of interested parties, captured at Clauses 4.1 & 4.2 of ISO 9001 standard, and then utilized to define QMS scope and processes according to Clauses 4.3 & 4.4 standard.

Then **commitment of leadership** in the company guides the organization to a customer focus by outlining organizational roles and responsibilities and by instituting a quality policy to focus on QMS according to Clauses 5.1, 5.2 & 5.3 of ISO 9001 standard.

Planning also helps **identify and address the risks and opportunities** of the quality management systems. The planning includes setting and planning for quality objectives and changes to support continual improvement as outlined at Clauses 6.1, 6.2 & 6.3 ISO 9001 standard.

The final layer of planning involves **recognizing and defining the support structure** to perform the plans, which includes the resources (Clause 7.1), recognizing competence (Clause 7.2), awareness (Clause 7.3), communication (Clause 7.4) and to have the system for creation and control of documented information (Clause 7.5).

- **Do**

An unimplemented plan only remains a plan. Plans are meant to be implemented. While implementing the plans, Controls need to be put in place for the operations, product or service requirements (clause 8.2). For designs to be developed (clause 8.3), controls needs to be placed on external providers according to clause 8.4. The course of producing the product or service needs to be applied with control of product and service release according to clause 8.5 & 8.6, and non-conformities in the course of running the operations needs to be addressed as outlined at clause 8.7 of ISO 9001 standard.

- **Check**

There are numerous places in the standard to check the effectiveness of the quality management system. The ISO standard requires enterprises to monitor, measure, analyze and evaluate the products or services to make sure that the processes employed are satisfactory and effective, and that customer satisfaction is achieved as outline at Clause 9.1 of ISO 9001 standard. Internal audits according to Clause 9.2, acts as a means for measuring the effectiveness of the quality management system. The Management Review procedure as stated at Clause 9.3 of ISO 9001 standard is aimed at analysing and evaluating all the collected information related to the quality management system and helps to identify solutions to resolve any issues or problems.

- **Act**

This phase of ISO 9001 quality management systems includes the required actions to address any concerns revealed at the check phase. Improvement according to Clauses 10.1 & 10.3 of ISO 9001 is the main purpose for these action items outlined at Clause 10.1 of the standard. This action occurs when removing nonconformity and taking Corrective Actions according to Clause 10.2 of the standard in order to eradicate the reasons for current and foreseeable nonconformities.

At the end of the “Act” phase, some changes are likely to surface at the initial “Plan” of the quality management system; this then marks the beginning of the cycle again. As already stated, the cycle is a repetitive one.

ISO Management Systems Document Control

Document control is a key aspect of ISO standards. A good document control is required for companies who wish to demonstrate quality, reliability, and other important traits related to their products, services, and processes.

What is Document Control?

Document control simply means a series of practices to ensure that documents are developed, reviewed, distributed, retrieved, and discarded in a systematic, traceable and/or verifiable manner.

The concept of document control is most widely known in the context of ISO standards, and especially within ISO 9001 standard.

For instance, clause 7.5.3 (control of documented information) of ISO 9001:2015 standard requires organizations to establish a documented procedure to control several aspects of their documents, including:

- Identification
- Storage
- Protection
- Retrieval
- Retention
- Review
- Approval
- Disposition
- Legibility
- Change tracking

These procedures can assist an organization to maintain stability, and organized as it grows. Good document control practices can assist in maintaining the integrity and traceability of documents, which are aspects that are necessary for effective business operation.

Why you Need an Effective Document Control

There are many possible answers to this question, and the following provides some core reasons.

- **Enhancements of organizational productivity**

Proper documentation is vital in any organization. Having procedures to manage them improves their quality and integrity, as well as the organization's productivity and performance.

- **Requirement for organizational processes**

Organizations need proper documentation on a constant basis in order to efficiently run their processes in order to meet expectations of their customers and stakeholders. An example is documenting formulations, company's policies, products requirements and others for future reference and use.

- **Requirement of ISO standards**

The third reason is that, documentation is one of the specific and unavoidable requirements of the standards of International Organisational for Standardisation (ISO). In such cases, document control must be in place in order to meet the requirements of a desired ISO certification.

Documentation Best Practices

Maintaining document control requires adhering to the procedures established for that purpose by the organization. A point to note is the importance of traceability and clear access for documentation.

A document should be accessible and traceable, anything short of this leads to procedural failure. The following steps are some initiatives that can facilitate the task of maintaining proper documentation. They are:

1. Hiring effective document controllers.
2. Establishing clear procedures.
3. Training team members to follow the formulated procedures.
4. Pick the right software tools for document control.
5. Review the results on a periodic basis, and adjust.

Automating Documentation

A fast and smart way of maintaining good documentation is automating them. Documentation doesn't have to be in paper form. The disadvantage with paper-form documents is that, they could become cumbersome overtime and can be lost at any time. This is aside from the safety hazard they pose such as, acting as source of fire outbreak in a facility. To avoid this, automated documentation is strongly recommended.

6 Simple Guides for Writing a Good Quality Policy

When implementing a Quality Management System using the requirements of the ISO 9001 standard it is required by the standard (ISO 9001:2015) to write a Quality Policy for the intending organization.

The responsibility of establishing, reviewing and maintaining the ISO quality policy and quality objectives which should developed on corporate objectives and values and be appropriate to the purpose and context of the organization lies with the Top Management of an organization. A vital point to note is that, the policy should demonstrate a commitment to continual improvement, communicated, understood and applied throughout the organization.

Proper understanding of the quality policy entails that employees are able to relate the impact of their job on product quality and quality control, and the overall success of the company. It involves the employees being aware that their individual contribution directly or indirectly affects the company's commitment to quality and are important to the company's overall success.

ISO 9001:2015 requires that an organization's quality policy and objectives be appropriate to its strategic and operational direction. The implication of this is that, determining the context of an organization, its interested parties and their relevant requirements, necessitates a review of the policy to ensure continued relevance to any changes or updates of an organization's system or process.

Establishing the Quality Policy

This requirement of ISO 9001:2015 for establishing a quality policy can be compared to that of ISO 9001:2008 Clause 5.3. To ensure an adequate quality policy, the requirements of the standard needs to be considered, this includes the following six (6) points:

1. **Appropriateness & Compliance to ISO 9001:** Is the policy appropriate to the organization and ISO implementation? The quality policy needs to show the company's commitment to the requirements of ISO 9001 and to improve the effectiveness of the QMS.

2. **Commitment to Requirements:** Does the policy include a commitment to requirements of the standard and customer? A key to an effective quality policy includes understanding the requirements of the customers. This is important to succeed in ensuring customer satisfaction. The requirements may come directly from customer specification, through industry standards, or some legal requirements regarding your products or services.

3. **Inputs of Internal Interested Parties:** The quality policy should be usable by all employees as a focus for their job, hence it is important to gather relevant input from every part of the organization to ensure relevance of the policy to all those areas. The employee should see within the policy how the policy relates to their job.

4. **Establishment of objectives:** The policy should be written in such a way as to provide a basis for establishing the quality objectives.

5. **Communication:** The policy should be adequately communicated and understood within the organization. Means such as the company website, noticeboards, postcards etc. can be used to effectively communicate the policy.

6. **Review:** What plans are in place to periodically review it for continued suitability?

The policy should be kept simple, meaningful and relevant to the organization*. It is not a document that should be written merely to satisfy the requirements of ISO 9001:2015. It should align with the strategic direction of the organization* acting as a driver for continual improvement. As processes evolves within an organization, reviewing and aligning the policy to the changes are required to ensure that the changes are appropriately captured and the degree to which the organization's products and services meet customer requirements are further enhanced.

Communicating the Quality Policy

Clause 7.5.1a of ISO 9001:2015 requires that the quality policy be maintained as documented information. The internal auditors are to check whether the quality policy has been applied throughout the organization and are well understood by all relevant interested parties. Understanding the policy is essential for ISO certification.

Remote Audit: Benefits and Tips for Effectiveness

Remote audit refers to the use of technology to evaluate the level of an organization's compliance with set criteria. It is also known as virtual audit, using electronic methods such as video conferencing, email and telephone to obtain audit evidence, just as in an on-site audit. Remote audit replaces face-to-face interaction, either internally or between a company and an external certifying body.

Benefits of Remote Audits

Some benefits of remote audit include the following:

- It frees up onsite resources.

- It is less disruptive to daily work processes.
- It supports maximized efficiency by allowing audit teams to work from different locations.
- It promotes an agile auditing process through the use of security-enhanced cloud computing which supports easy document sharing and video conferencing software.
- Increases risk mitigation.

What happens in a remote audit?

Remote audit is agile, responsive and dynamic in nature that evolves as it unfolds. It is led and guided by auditor requiring constant adjustments to audit questions, documenting requests as the audit progresses. In remote audit, interviews are conducted in real-time via video conferencing applications such as Zoom or Skype. During the audit process, documents and data are shared and reviewed on file-sharing apps.

Getting ready for remote auditing

A successful remote audit entails the following:

- Updating existing management systems (QMS, FSMS etc.)
- Determining an appropriate tool and infrastructure for the process,
- And, in the case of an internal audit, defining and developing the audit process. Security evaluations of shared tools, documents and networks may be required to support a remote audit. Updating policies and procedures relating to document and data access is essential to protecting the integrity of your organization.

Tips for Effective Remote Audits

The following are a few recommendations to support organization's remote audit program:

1. Appoint an onsite facilitator to manage the audit logistics. He/she will support in resolving any technical itches that may occur during the exercise.
2. Clearly define the scope, purpose, timing, requirements and method of each audit.

3. Establish clear-cut rules of engagement between the organization and the compliance or audit team. This should include covering expectations regarding the availability of role players, the frequency of status updates and engagements between defined points of contact.

4. The audit exercise should be arranged so that audit activities do not disrupt the daily workflow.

5. Regular check-in times with the auditors should be scheduled in enable easy track and evaluation of the audit progress, resolve problems and streamline the flow of communication.

CASE STUDIES

▪ ISO 10012 and ISO 17025

The difference between ISO 10012 and ISO 17025 lies majorly in their scope.

ISO 10012 *specifies the quality management requirements of a measurement management system that can be used by an organization performing measurements as part of the overall management system, and to ensure metrological requirements are met, while* ***ISO 17025*** *is for use by laboratories in developing their management system for quality, administrative and technical operations.*

The focus of ISO 10012 is on the requirements of the measurement management system. It can be seen as a system within the quality management system defining the requirements applicable to the measurement management system in a way that illustrates the interrelations with other parts of the quality management system.

It is a guidance document that is not intended for certification. For example, a company may choose to have a quality management system certified to ISO 9001:2015. Even if such company chooses to follow the requirements of ISO 10012, getting certified to ISO 9001 isn't the same as getting certified to the requirements of ISO 10012. ISO 17025 on the other hand describes the requirements for a quality management system that can be accredited through a process that is comparable with certification but actually different from it.

ISO 17025 requirements covers all aspects of the laboratory of any type and/or size. An aspect of ISO 17025 requirements refers competence, this relates to the competence of the entire system – not just training of laboratory personnel, addressing such factors as contracts with customers, purchasing, internal auditing, and management review of the entire quality management system. However, ISO 10012 does not.

Rounding it all…

ISO 10012 is a guidance document that addresses one element (i.e. managing the measurement system) of a quality management system, while ISO 17025 defines requirements for the entire quality management system of laboratories that can be accredited, **not** certified to.

- **ISO 10012-1:2003 - Management Systems Requirements for Measuring Equipment**

ISO 10012-1:2003 is measurement management systems standard containing requirements for ensuring that measurements are made with intended accuracy. The standard contains all the necessary guidance on the implementation of the requirements. It also specifies the main features of the confirmation system. This management systems standard applies to measurement equipment used in the demonstration of conformance with a specification, not to other measuring equipment, records of measurement, or competence of personnel.

The standard applies to laboratories dedicated for testing, which include those providing a calibration service. It includes laboratories operating a quality system in accordance with ISO/IEC 17025 covering those who must meet the requirements of ISO 9001. ISO 10012 spelt out an integral part of the quality system which is the documentation of the control of inspection, measurement, and test equipment which must be specific in terms of which items of equipment are subject to the provisions, allocation of responsibilities, and actions to be taken.

The standard mandates that objective evidence must be available to validate that the required accuracy is achieved. This article lists some basic summaries of what must be accomplished to meet the requirements for a measurement quality system by ISO (and many other) standards. They include:

- **Records and Documentation:** All measuring equipment must be identified, controlled, and calibrated and records of the calibration and traceability to national standards must be kept. The methods and actions used to confirm the measuring equipment and devices must be documented.
- **Development of SOPs:** The system for evaluating measuring equipment to meet the required sensitivity, accuracy, and reliability must be defined in written procedures.
- **Evaluation of Calibration System:** The calibration system must be evaluated on a periodic basis by internal audits and by management reviews.

- **Calibration Action Plan:** The actions involved with the entire calibration system must be planned. This planning must consider management system analysis.
- **Determination of Measurement Uncertainty:** The uncertainty of measurement must be determined, which generally involves gage repeatability and reproducibility and other statistical methods.
- **Retention Time of Records:** Records must be kept on the methods used to calibrate measuring and test equipment and the retention time for these records must be specified.
- **Handling of Nonconforming Products:** Suitable procedures must be in place to ensure that nonconforming measuring equipment is not used.
- **Identification of Measuring Equipment:** A labelling system must be in place that shows the unique identification of each piece of measuring equipment or device and its status.
- **Calibration Frequency:** The frequency of recalibration of measuring devices must be established, documented, and be based upon the type of equipment and severity of wear.
- **Sealing of Adjusting Devices:** Where adjustments may be made that may logically go undetected, sealing of the adjusting devices or case is required.
- **Controls of External Calibration Services:** Procedures must define controls that will be followed when any outside source is used regarding the calibration or supply of measuring equipment.
- **Traceability of Calibration Systems:** Calibrations must be traceable to national standards. If no national standard is available, the method of establishing and maintaining the standard must be documented.
- **Handling of Measuring Equipment:** Measuring equipment will be handled, transported and stored according to established procedures in order to prevent misuse, damage and changes in functional characteristics.
- **Calculation of Uncertainties:** Where uncertainties accumulate, the method of calculation of the uncertainty must be specified in procedures for each case.
- **Storage Conditions of Measuring Equipment:** Gages, measuring equipment, and test equipment will be used, calibrated, and stored in conditions that ensure the stability of the equipment. Ambient environmental conditions must be maintained.

- **Procedures for Training Personnel:** Documented procedures are required for the qualifications and training of personnel that make measurement or test determinations.

ISO 22000 & FSSC 22000

Any food organization may choose to implement any out of ISO 22000 or FSSC 22000, putting in mind that every company is unique. The effectiveness of the Food safety Management System relies on how religiously company implements the requirements of the standard.

An organization can choose either ISO 22000:2018 or FSSC 22000 as the requirements for organization's food safety management system. It is the company's commitment to improve food safety performance that matters the most.

While any of the standards may be implemented by any food organization, this article outlines some things to note about the two standards that should be considered when deciding which one to implement out of the two.

- **Eligibility**

Food companies, compliant with ISO 22000 standard, can attain the certificate of FSSC 22000 with some additional measures. FSSC 22000 is accepted by the Global Food Safety Initiative (GFSI). Some additional steps include compliance with technical industrial specifications and additional scheme requirements. FSSC 22000 is a certification scheme that contains ISO 22000.

Along with ISO 22000, it also includes specific technical standards. ISO 22000 offers less rigid requirements for the certification authority. Also, the requirements for food organization are less tough compared with FSSC 22000. FSSC specifies in details, requirements on infrastructure and documentation as well.

For FSSC 22000 certification, preparing and implementing the same procedures and documents as for ISO 22000 is mandatory. A**dditional requirements** will also be implemented as per FSSC 22000.

- **Needs of Interested Parties**

If a company has a legal or customer requirement to implement FSSC 22000, then the decision may not be there for the company to select. In that case, FSSC 22000 is the only way forward with no other choice.

- **Auditing Practice**

The procedure of certification is not much different. However, the needs of the FSSC 22000 scheme are more specific and rigid. So the certification under this scheme is a very extensive and labour-oriented process. ISO 22000:2018 audit is being carried out by certification bodies that are recognized by a country's national accreditation bodies.

These certification bodies follow ISO auditing standards and IAF (International Accreditation Forum) rules. FSSC 22000 also follows the same auditing practice like that of ISO 22000 only that, fewer numbers of FSSC 22000 auditors exists compared with ISO 22000 auditors.

▪ Integrated ISO Management Systems (IMS)

Integrated Management System can be defined as a single structure for management system utilized by companies to manage their organization's processes or activities that converts inputs into a product or service which comply the organization's objectives and equitably satisfy the interested party's quality, health & safety, environmental, security, ethical etc.

It refers to the integration of quality (QMS), environment (EMS) and occupational health, safety (OH&SMS) and where necessary, any other management systems. Common practice is, companies integrating three systems such as QMS, EMS, OH&SMS. However, no defined rule restricts a company from integrating as many systems they want as per their needs. The key variables that determine the levels of integration include the operations, size, competition, institutional setting and type of system.

These depend on the needs of the organization. Companies can attain numerous management systems the following that are classified as commonly used and industry-specific standards.

- **Common and Widely Used MSS**

Some widely used management system standards include the following:

- ISO 45001 (Occupational Health and Safety Management System)
- ISO 14001 (Environmental Management System)
- ISO 9001 (Quality Management System)
- ISO 50001 (Energy Management System) etc.

- **Industry-Specific or Application-Specific MSS**

Other management system standards (MSS) which are industry-specific or application based include:

- ISO 22000 (Food Safety)
- ISO 13485 (Medical devices)
- ISO 21001 (Education)
- ISO 27001 (Information Security)
- ISO 37001 (Anti-bribery Management Systems) etc.

Benefits of Integrated Management Systems

- **Increased Management System Requirement**

Many organizations often adopt more than one international management system standards as a result of intense pressure and presence of some sector-specific standards and, some other organizations, as a result of enforcement by their group headquarters, mother company or customer standards. The organization may then also be exposed with the quest to be competitive complying with all the system requirements. The only way to respond to all these challenges is to have a single integrated management system.

- **Improved Effectiveness**

IMS enhances a system to be more logical from a complete assessment of economy, functionality and transparency for the management system users. Here, the standards are comprehended more clearly in a manner that the company complies with both the system requirements and the organization's need. The company-wide missions, goals and objectives are developed through one management system. As a result of a single well designed management system, company can manage all requirements with improved effectiveness.

- **Cost Reduction**

A highly integrated management system will avoid the repetitive costs, additional cost or resources, external audits etc. If the company is managing various management systems separately, it will have separate system for Quality Management System likewise a separate system for health and safety and environment. Also all internal audits, document control, management review, and other common functions of management system will be managed separately. This means that there will be more resources required to manage these systems

individually, more processes, more interactions, more external audits, more paper work, more document reviews etc.

- **Less Redundancy and Conflicting Elements**

Integration manages the extensive business needs of a company by eradicating redundancies and conflicting processes that are usually present when multiple separate management systems are utilized individually. Environmental department can take advantage of developed QMS core systems like calibration, document control, roles and responsibilities, and record management.

About the Author

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