ISO 9001:2015 FOR QUALITY MANAGEMENT SYSTEMS
AUDIT and DOCUMENTATION EXPECTATIONS

General Conditions
Although outsourcing of processes is part of the new standard, it specifies that processes must meet both legal and customer requirements. Even if the organization outsources, it is the organization's responsibility to ensure that all relevant processes meet regulations, obligations and customer requirements. The clause defines the organization's responsibilities to further assist you in identifying any incidents or problems that may occur between you and your supplier and to ensure that they are managed effectively in your main processes.

Senior Management
The ISO 9001:2015 standard defines that the management member must be a member of the organization's management team and cannot be an external member of management.

Infrastructure
It now includes "information systems" that enable the release of the product.

Working Environment
The definition of the working environment is further defined to include the physical environment and other factors that enable the fulfillment of product requirements, such as air, lighting, sound and heat.

Product Related Terms
ISO 9001:2015 defines what post-delivery is. This includes contractual obligations such as maintenance services and support services (recycling or disposal) and warranty terms.

Sources
The competence of personnel directly or indirectly affecting compliance with product requirements should be checked by the organization.

Design and Development
Additional guidance is provided to clarify the definition of this clause. The standard informs users that the activities listed in this clause may be performed as a single activity or separately, whichever best accomplishes product realization. An additional definition has also been added to define the meaning of providing services, including details for product protection.

Monitoring and Measurement Devices
Additional guidance has been added for extra guidance covering the ability to consistently monitor the effectiveness of the software used and to determine its fitness for purpose.

Customer Satisfaction
Additional guidance has been added to explain the different methods used to measure and monitor customer satisfaction, such as data analysis, surveys, complaints, guarantees, vendor reports, etc.

Internal Audits
The standard specifies requirements for keeping internal Audit records.

Monitoring and Measurement of Processes
Additional guidance has been added to explain "appropriate methods". The organization should indicate the need to consider the type and amount of monitoring and measurement of each process to determine its impact on conformity to product requirements and the effectiveness of the quality management system.

Product Monitoring and Measurement

The standard clearly states the release of products shipped to the customer. The organization should keep records of whoever is responsible for signing approval for product shipment.

Documentation
The organization now needs to determine the scope of the external documents it needs in control to maintain and operate its management system.

Certification Audit Expectations
Before the Certification Audit, YBM expects its customers to have realized the following points:

1. The quality policy, objectives and quality manual/procedures should have been reviewed by the YBM. The quality manual should cover the following items:

   a. The scope should be specified in the Quality Manual to show what is excluded from the requirements of the standard.

   The elements that can be excluded are listed under heading 7.

7.1	Product realization planning is always in scope and cannot be excluded
7.2	Identifying customer requirements is always in scope and cannot be excluded
7.3	It can be excluded if the design is not realized. However, the design is feasible if the functional requirements are characterized and specified.
7.4	It can be excluded if the supplier is not involved, but this is very rare.
7.5.1	Controlled conditions cannot be excluded as they are always necessary
7.5.2	May be excluded if no special process is involved
7.5.3	The definition is generally applicable if there are no immeasurable products such as services.
7.5.4	Can be excluded if the customer does not have the product supplied
7.5.5	In the case of immeasurable products that do not require physical protection, they may be excluded.
7.6	Excludable if no measuring and monitoring device is involved

Procedures prescribed by the customer for the effective operation of the quality management system may also be prepared separately.

   b. Explanation of the interaction between processes. The processes that are decided to be outsourced should be specified. The standard is oriented towards the establishment of the quality management system with a process approach. The process approach identifies and manages linked activities that together meet the requirements of the standard.

Processes are management, resource allocation, product realization and measurement of processes. The connection or interaction between processes can be shown with a process map. The interaction needs to be analyzed to show that all processes work as a network.

2. There should be at least three (3) months of records required by the quality management system.

If any of these conditions are not fulfilled before the audit date, please contact YBM Certification Manager to reschedule the audit.

Pre-Audit
In YBM, pre-inspections are an optional service. Their purpose is to sample the implementation of the management system, without a "certification decision" being made at the end of the day. They are informal but have the same content as a typical Phase II Certification Audit. We recommend that you select the elements to be audited in the pre-Audit based on your experience with your management system and the results of the internal Audit.

The stage of the Pre-Audit must be before the Stage 1 Audit. Pre-Audit cannot be conducted after the first certification process has started.

Certification Process

Phase I Audit (Document and Preparation Review)
YBM performs a Phase I Audit to verify that your documented management system used in practice in the organization specifies the relevant requirements of the QMS standard and that your system is implemented and ready for the Phase II Certification Audit. Generally, Phase I Audits are performed on-site, but in some cases this process can be performed off-site. Please contact YBM to find out if your organization is eligible for an off-site Phase I Audit.

On the QMS side, Auditors examine the following aspects:

- Does your system (if documented) meet all relevant requirements of ISO 9001:2015?
- Your goals and objectives
- A complete QMS internal audit cycle and management review that you have completed (or plan to complete).

Phase II Certification Audit
The primary purpose of a Certification Audit is to audit the Management System against the applicable standard and to investigate the effective implementation of policies and procedures. For an effective Certification Audit, the following points should be considered:

- Provide sufficient evidence to the Audit team to demonstrate that your management system is fully documented and effectively implemented according to the relevant standard.
- Provide relevant records to the Audit team during the review of records that are crucial to the effectiveness of the practices in the system. In some cases, corrective actions taken in response to customer complaints and procedures and work instructions modified as a result of the action should also be available.
- Allow the audit team access to facilities, employees and records to verify that the Management System has been established and implemented,
- Cooperate in resolving any inconvenience.

The YBM will send a copy of the Audit Plan, including any additional requirements needed to achieve the relevant accreditation, to the client prior to the scheduled Audit date.

Surveillance
YBM conducts Surveillance Audits on a semi-annual and annual basis. Approximately (as a minimum) 25% of the companies that choose the semi-annual Surveillance Audit are reviewed in each Audit. Approximately (as a minimum) 50% of the companies that choose annual surveillance are reviewed in each Audit. The YBM reviews at least the following issues:

- Customer complaints and the organization's responses
- Customer internal Audit review, planning and results
- Management review results and activities
- Realized improvements for continuous improvement targets

YBM will inform you 30 days before the foreseen Surveillance Visit. The Surveillance Visit has the same structure as the Certification Audit but with a narrower content.

Special Surveillance Audits
YBM may carry out special Surveillance Visits for the continuation of certification in some necessary situations that arise. These situations may be the customer's wish to expand the Scope

of Certification, major changes in the Management System and Organizational Structure as a result of a merger or transfer, the requirement arising from your customer's sanction, or the detection of a major non-conformity.

Short Term Audits

If necessary, special audits can be carried out in companies outside the certification period. In these cases, it may be necessary to carry out a short-term Audit in cases such as change in the scope of certification, scope narrowing or expansion, change of address, change in company partners, complaints from third parties about the certified customer, follow-up of the suspended certificate, etc. Such special Audits can be carried out in a short time and only the situation/area requiring the Audit is investigated. At the end of the audit, an audit report is prepared and the research is recorded.

Corrective Action(s) resulting from the Audit Visit(s)

A Corrective Action Request arises if there are errors in the implementation of your system. During the Certification Audit or Surveillance Visit, the YBM Audit team may issue a Corrective Action Request. You are required to close these nonconformities, both minor and major, in all Audits. Corrective actions taken for all nonconformities are verified on-site for effectiveness at the next Audit.

Minor and Major non-conformities are described below:

MINOR nonconformity is a type of nonconformity that does not arise from the structure of the quality system and does not reduce the system's ability to provide controlled process and production.

1. Partial nonconformities with the company's documented quality system or requirements
2. Deviations in the implementation of the company quality system

Examples of MAJOR nonconformities are given below:

1. The system is not structured to meet the requirements. Numerous minor nonconformities related to a specific requirement that may indicate a system failure.
2. Any nonconformity that may cause an inappropriate product to reach the customer. Detection of conditions that may prevent the use of products or services in accordance with their intended use or
3. Nonconformities arising from the structure of the quality system that reduce the system's ability to provide controlled processes and production.

Minor corrective actions are minor errors in the implementation of your system and are not considered critical. Major corrective actions are typical systematic errors and can seriously affect the system. Corrective actions can be closed in the time intervals given below.

Minor Corrective Actions:	60 days to close
Major Corrective Actions:	14 days to submit action plan - 90 days to close

In ISO 22000 Food Safety Management Systems, there is also a CRITICAL classification for nonconformities.

Critical: In the unlikely event of a critical deficiency in meeting Food Safety or legal requirements.

Critical Corrective Action:	7 days to submit action plan - 60 days to close

Certification

Accreditation requirements specify that the entire system must be audited at least once every three years. Each surveillance Audit is a re-examination of a part of the system and the

recertification Audit takes place at the beginning of the three-year cycle, depending on the issue date of the current certificate.
At the end of the certification process, YBM issues a new Certification Certificate as a result of the successful passing of the recertification Audit. YBM has the right to perform the recertification Audit of your system longer than the minimum requirement of the standard if (with the recommendation of the lead Auditor) the practices continue at a low level.

Customer Support
As part of the certification process, you can guide us on the following issues:

- Providing a guide for each Auditor when conducting an on-site Audit.
- It is important that your Management Representative is present at all stages of the Certification Audit.
- Provide a room or area and telephone for the use of the Audit team during the on-site Audit.

Privacy
YBM, its employees and agents shall keep confidential all information of any kind that comes into their possession during the Audit processes described herein, except for the requirements arising from National Laws and the relevant Accreditation Authorities. YBM shall not disclose any information to third parties without the prior written consent of the client.

Having Observers and Guides during Examinations:
The Applicant Company shall allow the accreditation Auditors to observe the YBM Auditors in order to witness the performance of the YBM Auditors in case of need or request. However, if the Accreditation Body wishes to visit the Applicant Company, it undertakes to accept this and to provide the necessary convenience.

4 Context of the organization

4.1 *Understanding the organization and its context* Have internal and external issues been identified that are relevant to the organization, its purpose and strategic direction and that affect the ability of the QMS to achieve its intended results? These may include positive or negative factors for assessment. In the external context, it may be possible to consider factors arising from the legal, technological, competitive, market, cultural, social and economic environment. This can be international, national, regional and local. In the internal context, it may be possible by looking at elements related to the organization's values, cultural knowledge and performance.

4.2 *Understanding the needs and expectations of interested parties* " due to the impact or potential impact on the organization's ability to continuously provide products and services that meet customer and applicable legal and regulatory requirements;
Has it identified the relevant parties involved in the QMS and their requirements?"
Has the organization monitored and reviewed information about these interested parties and their requirements?

4.3 Determining *the scope of the quality management system* Has the organization determined its boundaries and applicability for establishing the scope of the QMS by evaluating the internal and external considerations and the requirements of the relevant parties?
Does the organization maintain the scope of the QMS as documented information?
Is the inapplicable scope justified (in case it does not affect the ability and capability of the product and service to assure conformity and enhance customer satisfaction)?

4.4 *Quality management system and processes* Has the organization established the QMS system, including the processes needed and their interaction with each other (Desired inputs and outputs, interaction, criteria and methods, assignment of resources, authority - responsibilities, risks and opportunities, changes - updates and improvement have been determined within the scope of this QMS?

4.4.1 Is documented information maintained to support the implementation of processes ?

4.4. 2 Is the continuity of documented information controlled?

5 Leadership

5.1 *Leadership and commitment*

5.1.1 General "Does the top management of the organization have a commitment that it fulfills the following? Does it audit the QMS?
Are the policies and objectives in line with the organization's vision and mission?
Are QMS requirements integrated with processes?
Is a process approach and risk-based thinking encouraged?
Is the effectiveness and importance of the QMS sufficiently shared?
Is the QMS supported to achieve its intended results?
Are there sufficient personnel with the competence to follow QMS practices?
Is remediation encouraged?
Are all levels of management supported with the necessary authorization to fulfill their responsibilities?"

5.1.2 Customer focus "Is top management committed to customer satisfaction? Customer needs; expectations and conditions are understood and fulfilled, risks and opportunities related to the product or service are continuously monitored and evaluated while meeting customer demand, Is customer satisfaction continuously ensured?"

5.2 *Policy*

5.2.1 Establishment of a quality policy "Has senior management established and maintained a Quality Policy? Within the scope of the Quality Policy; It should support strategic direction appropriate to the organization's purpose and context, provide a framework for setting quality objectives, include a commitment to fulfill applicable requirements, include a commitment to continuous improvement of the QMS."

5.2.2 Publicizing the quality policy "Does the Quality Policy exist as documented information? Is the Quality Policy communicated, understood and implemented? Is it easily accessible to all employees?"

5.3 Corporate duties, authorities and responsibilities "Has the senior management determined and announced the authorities and responsibilities of the relevant officials? Are the following issues specified in the authorities and responsibilities? Giving the competence to meet the requirements of the QMS standard, Giving the necessary competence to those concerned to ensure that the processes produce the desired results, Giving the competence to report and access data on QMS performance and opportunities for improvement, Giving competence to encourage customer-oriented work of all employees, Giving the necessary competence and competence to ensure that the QMS system does not deviate from the standard and organizational expectations."

6 Planning

6.1 *Activities to identify risks and opportunities* Has the organization identified risks and opportunities to ensure that the QMS achieves the desired results, to prevent/minimize undesirable effects, and for continuous improvement? Have necessary preventive actions been implemented?

6.2 *Quality objectives and planning to achieve them Has the organization* set its Quality Objectives? Are these objectives in line with the Quality Policy? Are they measurable? Are they appropriate to improve the conformity of products and services and customer satisfaction? Can they be monitored? Are they announced? Are they updated appropriately? In order to achieve the Quality Objectives; Has it determined what will be done, what resources will be required, who will be responsible, when it will be completed and how the results will be evaluated?

6.3 *Planning for changes* When the organization needs to make changes to the QMS, does it assess the purpose and potential outcomes, the integrity of the QMS, the availability of resources, and the identification or redefinition of authorities and responsibilities in order to make these changes in a planned manner?

7 Support

7.1 *Sources*

7.1.1 General Has the organization identified the capabilities and constraints of its existing internal resources and what will be procured from external suppliers?

7.1.2 Contacts Has the QMS appointed and provided the necessary personnel for effective operation and control of the processes as required?

7.1.3 Infrastructure Has the organization designated the necessary infrastructure for the operation of processes and to establish the conformity of products and services? This infrastructure may include buildings, machinery equipment including hardware and software, transportation resources, information and communication technologies.

7.1.4 *Environment for the operation of processes Has the organization* designated the environment (working environment) necessary for the operation of processes and to establish the conformity of products and services? This environment should be assessed in terms of its social (non-discriminatory, calm, non-confrontational), psychological (stress reducing, burnout preventing, emotionally protective) and physical (temperature, heat, humidity, light, ambient air, hygiene, noise) elements.

7.1.5 *Monitoring and measurement of sources* Does *the organization* calibrate all measurement equipment to ensure the validity of measurement results? Are the instruments identified for traceability? Has the organization developed a system to be confident of the measurement results?

7.1.6 Has *the organization* identified the information needed to operate processes and to establish the conformity of products and services? Is this knowledge(s) sustainable and accessible? Is there a system in place for the necessary updates and access to the knowledge to enable its modification, improvement and addition of experience? Organizational knowledge should be considered as internal and external sources.

7.2 Qualification Has the organization determined the competence of its personnel? Has it ensured the competence of these persons, taking into account their education, training and experience? Has it carried out the necessary activities (training) for the personnel to acquire competence when necessary? Has it evaluated these activities? It is recommended that staff training practices should cover continuity, necessary and up-to-date scope, right person and time in order to ensure appropriate product and service.

7.3 *AwarenessDoes the organization* ensure that its personnel are aware of the Quality Policy, Quality Objectives, their contribution to the QMS, and their authority to intervene when the QMS conditions are violated through announcements, information and trainings?

7.4 *Communication* Has *the organization* determined what, when, with whom, how and who will establish internal and external communication related to the QMS?

7.5 *Documented information*

7.5.1 *General Is the organization* assigned documented information according to its size, type of activity, processes, products and services, complexity of processes and their interactions, competence of people?

7.5.2 *Establishment and updatingDoes the organization* consider the system of identification and description, format, conformity, review and approval when establishing documented information?

7.5.3 *Control of documented information* Is documented information accessible when needed? Is appropriate protection provided to ensure confidentiality? To this end, the organization should identify activities such as distribution, access, use, preservation of quality, archiving, change control, retention and disposal of documented information.

8 Operation

8.1 *Operational planning and control Has the organization* planned the processes needed to deliver the product or service? Has it established, implemented and controlled the necessary processes? Has the organization assigned documented information to ensure that processes are operated as planned and that products and services comply with requirements? Is the continuity of this information ensured? Does the organization control outsourced processes?

8.2 *Requirements for products and services*

8.2.1 Has the necessary measures been taken and practices established by taking into account the provision of the necessary information within the scope of communication with the customer, the contract and its terms, feedback on products and services including complaints, control of customer property, unexpected situations?

8.2.2 *Has the organization* defined the requirements for the offer?

8.2.3 *Review of terms and conditions for Products and* ServicesDoes *the organization* meet the terms and conditions for the offer? Has the organization documented information on the products and services to be offered to the customer within the scope of the sale? Are these requirements reviewed for adequacy and fulfillment?

8.2.4 *Changing requirements for Products and Services* Does the organization check that when there are changes to the terms of the tender, the new terms are also changed in the documents? How are staff informed of changes?

8.3 *Design and development of products and services*

8.3.1 *Has the organization* established a design and development process to ensure satisfaction in the subsequent delivery of its products and services?

8.3.2 Planning *design and development* "When planning the design;
Has the structure of the design, time complexity, process stages, verification of the design, authorities and responsibilities, internal and external resources needed, design controls, knowledge of the customer in the design where necessary, conditions of the product and service, control conditions, establishment of documents proving that the design meets adequate conditions been taken into account? "

8.3.3 *Design and development* inputs "Design inputs;
functional and performance requirements, previous similar design information, primary and secondary legislation requirements, committed standards and codes of practice, potential consequences of failure?"

8.3.4 *Control of design and* developmentDid the *design* process check whether the design is capable of meeting expectations?

8.3.5 *Design and development* outputsAre *the* results of *the design*, compared with the design inputs, specified as meeting the requirements, covering the required criteria and specifying some mandatory features?

8.3.6 *Design and development changesIf the* need for changes is identified during the *design* process or when considering the outputs of the design, is it specified how these changes will be made?

8.4 *Control of outsourced processes, products and services*

8.4.1 *Does the organization* control the processes, products and services procured from external suppliers for compliance with the requirements? For this purpose, does it document the control criteria and the results of control practices? Also, are supplier performances evaluated? Are these evaluation criteria determined? Are they documented?

8.4.2 *Type and extent of control* Has *the organization* communicated to the external supplier how and under what conditions it will control outsourced processes, products and services and the control criteria? Has the external supplier provided the necessary verifications that it will comply with these control conditions?

8.4.3 *Information for external* suppliersDoes *the organization review the* appropriateness of the terms it will share with external suppliers?

8.5 *Production and service delivery*

8.5.1 *Control of production and service provision* Does *the organization* control production and service provision under the conditions it has determined? Are control criteria defined? Does it use appropriate measurement and monitoring tools? Does it use appropriate infrastructure and environment? Has it assigned sufficient personnel with the necessary qualifications? Is it capable of achieving the planned results in production and service delivery? Has it taken measures to prevent personnel errors? Does it implement product launch, delivery and post-delivery activities?

8.5.2 *Identification and traceability* Can *the organization* identify its products and services? If there is a traceability requirement, has the necessary identification and method been determined for each of the outputs?

8.5.3 *Customer and external supplier* propertyDoes it have *customer* and external supplier property? Does it identify it? Does it protect it? Does it report when customer property is damaged? Does it maintain these documents?

8.5.4 PreservationDoes *the organization* preserve the outputs of products and services in accordance with the requirements?

8.5.5 *Post-delivery activitiesDoes the organization* meet requirements after delivery of products and services, taking into account aspects such as primary and secondary legislation requirements, potential unintended consequences, use and intended life, customer requirements and customer feedback?

8.5.6 *Control of changes Does the organization* implement necessary changes to maintain conformity with the requirements for product and service delivery? Does the organization create and maintain documents describing the activities related to the changes?

8.6 *Does the organization* check that products and services meet the required requirements? Does the final checks of the products and services before delivery to the customer check their conformity with the acceptance criteria and ensure the traceability of the products and services delivered to the relevant persons?

8.7 *Control of non-conforming* outputDoes *the organization* identify and control non-conforming outputs in order to prevent their unwanted use or delivery? Are the necessary activities organized to ensure compliance after nonconformity detection? Are the non-conforming outputs checked again for compliance with the requirements?

9 Performance evaluation

9.1 *Monitoring, measurement, analysis and evaluation*

9.1.1 *General* Has *the organization* identified what needs to be monitored and measured for the purpose of performance evaluation? Has it identified the necessary monitoring, measurement and analysis methods for the same purpose? Has the timing of monitoring and measurement been planned for the same purpose? Has the period and time planning for analyzing and evaluating the results been determined for the same purpose?

9.1.2 *Customer* satisfactionDoes *the organization* conduct customer satisfaction measurements (surveys, feedback, customer meetings, market share analysis, compliments, warranty system, vendor reports)?

9.1.3 *Analysis and evaluation* Does *the organization* make evaluations by analyzing all kinds of data and information from monitoring and measurement? Are the conformity of products and services, the degree of customer satisfaction, QMS performance and effectiveness, whether planning is carried out effectively, the effectiveness of activities carried out to identify risks and opportunities, the performance of external suppliers presented in a report by identifying the improvement needs of the QMS?

9.2 *Internal Audit Does* the *organization* periodically audit the performance of the QMS for compliance with the requirements and standards? Does the plan, program, announcement, relevant criteria, prevention and correction, reporting and retention of documents of all activities meet the expectations of the standard? Are internal audits conducted by trained personnel, ensuring impartiality?

9.3 *Management review*

9.3.1 *GeneralDoes senior* management meet periodically and evaluate the relevant reports in terms of maintaining the organization's QMS fitness for purpose, adequacy and effectiveness and its alignment with strategic plans?

9.3.2 *Management review inputs Has the management* review been conducted in a planned manner? Within the scope of the review; previous meeting result status, changes in internal and external issues in QMS, customer satisfaction feedback, degree of achievement of quality objectives, conformity of products and services, nonconformities and corrective actions, monitoring and measurement results, audit results, external supplier performances, availability of resources, status of risks and opportunities, opportunities for improvement.

9.3.3 As a result of the FGD, has the *senior* management documented the opportunities for improvement, the needs for changes and resources needed for the QMS, and the decisions taken in response to the items discussed, and responsibilities have been determined and followed up by making the necessary announcements?

10 Improvement

10.1 *General* Has *the organization* assigned improvement activities? Improvement processes (correction, corrective action, continuous improvement, modifications, innovation and organizational changes) can be included in the scope of improvement to meet

requirements, increase customer satisfaction, improve product and service offerings, correct, prevent or reduce undesirable effects, and increase the effectiveness of QMS performance.

10.2 *Nonconformity and corrective action* Does *the organization* ensure that nonconformity detection and nonconformity elimination activity and control are taken under control? Does the organization take necessary measures to prevent recurrence of nonconformity? Is the nonconformity also analyzed and evaluated and root causes investigated? Has the general analysis of nonconformities led to the need for changes in planned processes? Does it document nonconformity processes?

10.3 *Continuous improvementDoes the organization monitor the* conformity, adequacy and effectiveness of the QMS through continuous improvement activities? The organization should evaluate improvement by examining analysis and assessment results, FGD outputs, needs and opportunities.

Note: The information provided on the standard clauses is a guide. In case of an incomplete or non-compliant situation for the auditee, YBM cannot be held responsible in this case.