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# ISO9001:2015

## Transition Audit Checklist

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**To be used to supplement the Audit Report Template QEF08**

Transition Audit for:

Company Name:

Address:

Audit Date:

Work Item I.D.:

## 4 Context of the organization

### 4.1 Understanding the organization and its context

The organization ☐ has ☐ has not determined 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 ☐ has ☐ has not monitored and reviewed the information about these external and internal issues.

Examples of the determined external and internal issues and how often the information about them is being monitored and reviewed include:

#### Notes for auditors:

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

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

### 4.2 Understanding the needs and expectations of interested parties

The organization:

- ☐ has ☐ has not determined the interested parties that are relevant to the quality management system.

List interested parties:

#### Notes for auditors:

Definition of interested party: person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity. Example: Customers, owners, people in the organization, suppliers, bankers, unions, partners or society that may include competitors or opposing pressure groups.

- ☐ has ☐ has not determined the requirements of these interested parties that are relevant to the quality management system.

Interested parties requirements:

### 4.3 Determining the scope of the quality management system

When determining the scope, the organization:

- ☐ has ☐ has not considered the external and internal issues referred to in 4.1.
- ☐ has ☐ has not considered the requirements of relevant interested parties referred to in 4.2.
- ☐ has ☐ has not considered the products and services of the organization.

The scope ☐ is ☐ is not available and maintained as documented information. It

- ☐ includes ☐ does not include products and services covered by the quality management

system

- ☐ Includes ☐ does not include justification for any instance where a requirement of this standard cannot be applied.

If applicable, list requirements of the standard that cannot be applied and justifications:

**Notes for auditors:**

Where a requirement can be applied within the scope of its quality management system, the organization cannot decide that it is not applicable. Where a requirement cannot be applied (for example where the relevant process is not carried out) the organization can determine that the requirement is not applicable. However, this not applicability cannot be allowed to result in failure to achieve conformity of products and services or to meet the organization's aim to enhance customer satisfaction.

#### 4.4 Quality management system and its processes

**Notes for auditors:**

The consequent changes in the structure and terminology do not need to be reflected in the documentation of an organization's quality management system.

The Organization can choose to use terms which suit their operations (for example: using 'records', 'documentation' or 'protocols' etc. rather than "documented information" and 'supplier', 'partner' or 'vendor', etc. rather than 'external provider'.

The organization ☐ has ☐ has not established, implemented, maintained and continually improved the processes needed and their interactions, in accordance with the requirements of ISO 9001:2015.

The organization:

☐ has ☐ has not determined the inputs required and the outputs expected from these processes.

☐ has ☐ has not determined the assignment of the responsibilities and authorities for these processes.

☐ has ☐ has not determined the risks and opportunities in accordance with the requirements of 6.1, and plan and implement the appropriate actions to address them.

**Notes for auditors:**

Although the risks and opportunities have to be determined and addressed there is no requirement for formal risk management or a documented risk management process.

☐ has ☐ has not determined evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results.

☐ has ☐ has not determined the opportunities for improvement of the processes and the quality management system.

The organization ☐ has ☐ has not maintained documented information to the extent necessary to support the operation of processes and ☐ has ☐ has not retained documented information to the extent necessary to have confidence that the processes are being carried out as planned.

The organization's processes and interactions checked and the observations noted during their review:

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## 5. Leadership

### 5.1 Leadership and commitment

#### 5.1.1 Leadership commitment for the quality management system

Top management:

- ☐ has ☐ has not taken accountability for the effectiveness of the quality management system.
- ☐ has ☐ has not ensured the integration of the quality management system requirements into the organization's business processes.
- ☐ has ☐ has not promoted the awareness of the process approach.
- ☐ has ☐ has not ensured that the quality management system achieves its intended results.
- ☐ has ☐ has not engaged, directed and supported persons to contribute to the effectiveness of the quality management system.
- ☐ has ☐ has not promoted continual improvement.
- ☐ has ☐ has not supported other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

The primary activities conducted by top management to demonstrate leadership and commitment are:

#### 5.1.2 Customer focus

Top management:

- ☐ has ☐ has not ensured that applicable statutory and regulatory (or legal) requirements are determined and met.
- ☐ has ☐ has not ensured that the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed.
- ☐ has ☐ has not ensured the focus on consistently providing products and services that meet customer and applicable statutory and regulatory (or legal) requirements is maintained.

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## 5.2 Quality policy

Top management ☐ has ☐ has not established, reviewed and maintained a quality policy that ☐ is ☐ is not appropriate to the context of the organization.

### 5.2.2 The quality policy:

- ☐ has ☐ has not been made available as documented information.
- ☐ has ☐ has not been applied within the organization.
- ☐ has ☐ has not been made available to relevant interested parties, as appropriate.

## 5.3 Organizational roles, responsibilities and authorities

Top management:

- ☐ has ☐ has not ensured that the processes are delivering their intended outputs.
- ☐ has ☐ has not ensured reporting on the need for change or innovation.
- ☐ has ☐ has not ensured that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

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## 6. Planning for the quality management system

### 6.1 Actions to address risks and opportunities

**6.1.1** The organization ☐ has ☐ has not considered the requirements referred to in 4.2 and determined the risks and opportunities that need to be addressed to give assurance that the quality management system can achieve its intended result(s); prevent or reduce, undesired effects; and achieve continual improvement.

**6.1.2** The organization:

- ☐ has ☐ has not planned actions to address risks and opportunities.
- ☐ has ☐ has not planned how to integrate and implement the actions into the quality management system processes.
- ☐ has ☐ has not evaluated the effectiveness of these actions.

Examples of risks and opportunities identified and planned actions:

### 6.2 Quality objectives and planning to achieve them

**6.2.1** The Quality objectives

- ☐ are ☐ are not been relevant to conformity of products and services and the enhancement of customer satisfaction.
- ☐ have ☐ have not been monitored.
- ☐ have ☐ have not been communicated.
- ☐ have ☐ have not been updated as appropriate.

The organization ☐ has ☐ has not retained documented information on the quality objectives.

**6.2.2** When planning how to achieve its quality objectives, the organization:

- ☐ has ☐ has not determined what will be done.
- ☐ has ☐ has not determined what resources will be required.
- ☐ has ☐ has not determined who will be responsible.
- ☐ has ☐ has not determined when it will be completed.
- ☐ has ☐ has not determined how the results will be evaluated.

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### 6.3 Planning of changes

Where the organization determines the need for a change to the quality management system, the change ☐ is ☐ is not carried out in a planned and systematic manner.

The organization:

- ☐ has ☐ has not considered the purpose of the change and any of its potential consequences.
- ☐ has ☐ has not considered the availability of resources.
- ☐ has ☐ has not considered the allocation or reallocation of responsibilities and authorities.

Examples of some planned changes to the quality management system and observations noted on the above criteria:



## 7. Support

### 7.1 Resources

#### 7.1.1 General

The organization:

- ☐ has ☐ has not considered the capabilities of, and constraints on, existing internal resources.
- ☐ has ☐ has not considered what needs to be obtained from external providers.

External providers used and their purpose of use:

#### 7.1.2 People

To ensure that the organization can consistently meet customer and applicable statutory and regulatory (or legal) requirements, the organization ☐ has ☐ has not provided the persons and processes necessary for the effective operation of the quality management system.

#### 7.1.4 Environment for the operation of processes

The organization ☐ has ☐ has not provided and maintained the environment necessary for the operation of its processes and to achieve conformity of products and services.

#### Notes for auditors:

Environment for the operation of processes can include physical, social, psychological, environmental and other factors (such as temperature, humidity, ergonomics and cleanliness).

#### 7.1.5 Monitoring and measuring resources

The organization ☐ has ☐ has not determined the resources needed to ensure valid and reliable monitoring and measuring results.

The organization ☐ has ☐ has not ensured that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken; and are maintained to ensure their continued fitness for their purpose.

The organization ☐ has ☐ has not retained appropriate documented information as evidence of fitness for purpose of monitoring and measurement resources.

Examples of evidence checked and observations:

#### 7.1.6 Organizational knowledge

The organization ☐ has ☐ has not determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge ☐ has ☐ has not been maintained, and made available to the extent necessary.

When addressing changing needs and trends, the organization ☐ has ☐ has not considered its current knowledge and determined how to acquire or access the necessary additional knowledge.

**Notes for auditors:**

Organizational knowledge can include information such as intellectual property and lessons learned.

To obtain the knowledge required, the organization can consider:

- a) internal sources (e.g. learning from failures and successful projects, capturing undocumented knowledge and experience of topical experts within the organization);
- b) external sources (e.g. standards, academia, conferences, gathering knowledge with customers or providers).

### 7.3 Awareness

Persons doing work under the organization's control:

- ☐ are ☐ are not aware of the quality policy.
- ☐ are ☐ are not aware of benefits of improved quality performance.
- ☐ are ☐ are not aware of the implications of not conforming with the quality management system requirements.

List ways in which the organization has promoted awareness for the above requirements and how effective it was:

### 7.4 Communication

The organization ☐ has ☐ has not determined the internal and external communications relevant to the quality management system, including: what, when, with whom and how to communicate.

## 8. Operation

### 8.1 Operational planning and control

The organization:

- ☐ has ☐ has not implemented and controlled the processes, as outlined in 4.4, which are needed to meet the requirements for the provision of products and services.
- ☐ has ☐ has not implemented the actions determined in 6.1.
- ☐ has ☐ has not established the criteria for the processes and for the acceptance of products and services.
- ☐ has ☐ has not implemented control of the processes in accordance with the criteria.
- ☐ has ☐ has not retained documented information (i.e. records) to the extent necessary to have confidence that the processes have been carried out as planned.

The organization ☐ has ☐ has not controlled planned changes and reviewed the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization ☐ has ☐ has not ensured that outsourced processes are controlled in accordance with 8.4.

Outsourced processes and how they are controlled:

### 8.2 Determination of requirements for products and services

#### 8.2.1 Customer communication

The organization ☐ has ☐ has not established the processes for communicating with customers in relation to:

- ☐ Information relating to products and services.
- ☐ Enquiries, contracts or order handling, including changes.
- ☐ Obtaining customer views and perception, including customer complaints.
- ☐ The handling or treatment of customer property, if applicable.
- ☐ Specific requirements for contingency actions, when relevant.

#### 8.2.2 Determination of requirements related to products and services

The organization ☐ has ☐ has not established, implemented and maintained a process to determine the requirements for the products and services to be offered to potential customers.

The organization:

☐ has ☐ has not ensured that product and service requirements (including those considered necessary by the organization) and applicable statutory and regulatory requirements are defined.

☐ has ☐ has not ensured that it has the ability to meet the defined requirements and substantiate the claims for the products and services it offers.

### 8.2.3 Review of requirements related to products and services

The organization, as applicable:

☐ has ☐ has not reviewed requirements specified by the customer, including the requirements for delivery and post-delivery activities.

☐ has ☐ has not reviewed requirements not stated by the customer, but necessary for the customer's specified or intended use, when known.

☐ has ☐ has not reviewed any additional statutory and regulatory requirements applicable to the products and services.

☐ has ☐ has not reviewed contract or order requirements differing from those previously expressed.

#### Notes for auditors:

Requirements can also include those arising from relevant interested parties.

Documented information describing the results of the review, including any new or changed requirements for the products and services, ☐ has ☐ has not been retained.

Observations :

## 8.3 Design and development of products and services

### 8.3.1 General

Where the detailed requirements of the organization's products and services are not already established or not defined by the customer or by other interested parties, such that they are adequate for subsequent production or service provision, the organization ☐ has ☐ has not established, implemented and maintained a design and development process.

### 8.3.2 Design and development planning

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

☐ has ☐ has not considered the nature, duration and complexity of the design and development activities.

- ☐ has ☐ has not considered requirements that specify particular process stages.
- ☐ has ☐ has not considered the need for involvement of customer and user groups in the design and development process.
- ☐ has ☐ has not considered the necessary documented information to confirm that design and development requirements have been met.

### 8.3.3 Design and development Inputs

The organization:

- ☐ has ☐ has not determined standards or codes of practice that the organization has committed to implement.
- ☐ has ☐ has not determined internal and external resource needs for the design and development of products and services.
- ☐ has ☐ has not determined the potential consequences of failure due to the nature of the products and services.
- ☐ has ☐ has not determined the level of control expected of the design and development process by customers and other relevant interested parties.

Conflicts among inputs ☐ have ☐ have not been resolved.

Observations :

### 8.3.4 Design and development controls

The controls applied to the design and development process: ☐ have ☐ have not clearly defined the results to be achieved by the design and development activities.

### 8.3.5 Design and development outputs

The organization:

- ☐ has ☐ has not ensured that the design and development output is adequate for the subsequent processes for the provision of products and services.
- ☐ has ☐ has not included or referenced monitoring and measuring requirements.

The organization ☐ has ☐ has not retained the documented information resulting from the design and development process.

## 8.4 Control of externally provided products and services

### Notes for auditors:

This 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 particular external providers and externally provided products and services.

### 8.4.1 General

The specified requirements for the control of externally provided products and services:

- ☐ have ☐ have not been applied for products and services which are provided by external providers for incorporation into the organization's own products and services.
- ☐ have ☐ have not been applied for products and services which are provided directly to the customer(s) by external providers on behalf of the organization.
- ☐ have ☐ have not been applied for a process or part of a process which are provided by an external provider as a result of a decision by the organization to outsource a process or function.

The organization ☐ has ☐ has not monitored and retained appropriate documented information for the monitoring of the performance of external providers.

### 8.4.2 Type and extent of control of external provision

The organization:

- ☐ has ☐ has not taken into consideration 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.
- ☐ has ☐ has not taken into consideration the perceived effectiveness of the controls applied by the external provider.

### 8.4.3 Information for external providers

The organization ☐ has ☐ has not communicated to external providers applicable requirements for the following:

- ☐ the products and services to be provided or the processes to be performed on behalf of the organization;
- ☐ competence of personnel;

☐ the control and monitoring of the external provider's performance to be applied by the organization.

## 8.5 Production and service provision

### 8.5.1 Control of production and service provision

The organization ☐ has ☐ has not implemented controlled conditions for delivery and post-delivery activities.

Controlled conditions:

☐ have ☐ have not included (as applicable) the availability of documented information that defines the activities to be performed and the results to be achieved.

☐ have ☐ have not included (as applicable) the monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and that the acceptance criteria for products and services, have been met.

☐ have ☐ have not included (as applicable) the use, and control of suitable infrastructure and process environment.

☐ have ☐ have not included (as applicable) the appointment of competent persons.

☐ have ☐ have not included (as applicable) the validation, and periodic revalidation, of the ability to achieve planned results of any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement.

### 8.5.2 Identification and traceability

Where necessary to ensure conformity of products and services, the organization ☐ has ☐ has not used suitable means to identify process outputs.

#### Notes for auditors:

Process outputs are the results of any activities which are ready for delivery to the organization's customer or to an internal customer; they can include products, services, intermediate parts, components, etc.

### 8.5.3 Property belonging to customers or external providers

The organization ☐ has ☐ has not exercised care with property belonging to the customer or external provider while it is under the organization's control or being used by the organization.

The organization ☐ has ☐ has not identified, verified, protected and safeguarded the customers' or external provider's property provided for use or incorporation into the products and services.

When property of the customer or external provider was incorrectly used, lost, damaged or otherwise found to be unsuitable for use, the organization ☐ had ☐ had not reported this to the customer or external provider.

**Notes for auditors:**

Customer property can include material, components, tools and equipment, customer premises, intellectual property and personal data.

### 8.5.5 Post-delivery activities

In determining the extent of post-delivery activities that are required, the organization:

- ☐ has ☐ has not considered the risks associated with the products and services.
- ☐ has ☐ has not considered the nature, use and intended lifetime of the products and services.
- ☐ has ☐ has not considered customer feedback.
- ☐ has ☐ has not considered statutory and regulatory requirements.

**Notes for auditors:**

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 ☐ has ☐ has not reviewed and controlled unplanned changes essential for production or service provision to the extent necessary to ensure continuing conformity with specified requirements.

The organization ☐ has ☐ has not retained documented information for the personnel authorizing the change.

### 8.7 Control of nonconforming process outputs, products and services

The organization ☐ has ☐ has not taken appropriate corrective action based on the nature of the nonconformity and its impact on the conformity of products and services. This applies also to the nonconforming products and services detected after delivery of the products or during the provision of the service.

As applicable, the organization ☐ has ☐ has not dealt with nonconforming process outputs, products and services in one or more of the following ways:

- ☐ segregation, containment, return or suspension of provision of products and services;
- ☐ informing the customer.



The organization ☐ has ☐ has not retained documented information on the person or authority that made the decision regarding dealing with the nonconformity.

## 9. Performance evaluation

### 9.1 Monitoring, measurement, analysis and evaluation

#### 9.1.1 General

The organization:

- ☐ has ☐ has not determined what needs to be monitored and measured.
- ☐ has ☐ has not determined the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results.
- ☐ has ☐ has not determined when the monitoring and measuring shall be performed.
- ☐ has ☐ has not determined when the results from monitoring and measurement shall be analysed and evaluated.

The organization ☐ has ☐ has not retained appropriate documented information as evidence of the results.

The organization ☐ has ☐ has not evaluated its quality performance and the effectiveness of the quality management system.

#### 9.1.2 Customer Satisfaction

The organization ☐ has ☐ has not obtained information relating to customer view and opinions of the organization and its products and services.

#### Notes for auditors:

Information related to customer views can include customer satisfaction or opinion surveys, customer data on delivered products or service quality, market-share analysis, compliments, warranty claims and dealer reports.

#### 9.1.3 Analysis and evaluation

The organization ☐ has ☐ has not analysed and evaluated appropriate data and information arising from monitoring measurement and other sources.

The output of analysis and evaluation:

- ☐ has ☐ has not been used to ensure conformity and effectiveness of the quality management system.
- ☐ has ☐ has not been used to demonstrate that planning has been successfully

implemented.

- ☐ has ☐ has not been used to determine the need or opportunities for improvements within the quality management system.

The results of analysis and evaluation ☐ have ☐ have not been provided as inputs to management review.

## 9.2 Internal Audit

### 9.2.2 The organization:

- ☐ has ☐ has not planned, established, implemented and maintained an audit programme(s) which took into consideration the quality objectives, the importance of the processes concerned, customer feedback, changes impacting on the organization, and the results of previous audits.
- ☐ has ☐ has not ensured that the results of the audits are reported to relevant management.

## 9.3 Management review

### 9.3.1 The management review:

- ☐ has ☐ has not included changes in external and internal issues relevant to the quality management system including its strategic direction;
- ☐ has ☐ has not included information on the quality performance.
- ☐ has ☐ has not included trends and indicators in: nonconformities.
- ☐ has ☐ has not included trends and indicators in: monitoring and measurement results
- ☐ has ☐ has not included trends and indicators in: issues concerning external providers and other relevant interested parties.
- ☐ has ☐ has not included trends and indicators in adequacy of resources required for maintaining an effective quality management system.
- ☐ has ☐ has not included the effectiveness of actions taken to address risks and opportunities.
- ☐ has ☐ has not included new potential opportunities for continual improvement.

**9.3.2** The organization ☐ has ☐ has not retained documented information as evidence of the results of management reviews.

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## 10. Improvement

### 10.1 General

The organization ☐ has ☐ has not determined and selected opportunities for improvement and implemented necessary actions to meet customer requirements and enhance customer satisfaction.

This includes, as appropriate:

- ☐ improving processes to prevent nonconformities;
- ☐ improving products and services to meet known and predicted requirements;
- ☐ improving quality management system results.

### 10.2 Nonconformity and corrective action

**10.2.1** When a nonconformity occurs, including those arising from complaints, the organization:

- ☐ has ☐ has not reacted to the nonconformity i.e. taken action to control and correct it and deal with the consequences
- ☐ has ☐ has not made changes to the quality management system, if necessary.

### 10.3 Continual improvement

The organization ☐ has ☐ has not continually improved the suitability and adequacy of the quality management system.

The organization ☐ has ☐ has not considered the outputs of analysis and evaluation, and the outputs from management review, to confirm if there are areas of underperformance or opportunities that shall be addressed as part of continual improvement.

Where applicable, the organization ☐ has ☐ has not selected and utilized applicable tools and methodologies for investigation of the causes of underperformance and for supporting continual improvement.