PROQC
INTERNATIONAL

Internal Audit Checklist

for ISO 9001:2015 based Implementation Gap Analysis

2016

Pro QC International ISO 9001:2015 Gap Analysis Audit Tool

- **Disclaimer**
  - This audit is intended for use within one organization. The audit may be customized to suit your needs and preferences.
  - THE AUDIT IS DISTRIBUTED ON AN "AS IS" BASIS WITHOUT WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED.

- **Copyright**
  - This tool is created and copyrighted by PRO QC INTERNATIONAL & ART OF QUALITY CONSULTING
  - Copyrights of all the questions used in this presentation are held by their respective owners.

Current contact information can be found at proqc.com.

AUDIT PLAN	
Name of our organization audited:	
Audit Number:	
Date and Time of Audit:	
Functional Area covered:	All ISO 9001:2015 QMS related process areas
Name(s) of Auditor(s):	(Internal Auditor Team names)
Name(s) of Auditees/QMS Process Owners(s):	(QMS Process owners)

ISO 9001:2015 Quality Management System			Clause Overview	
Nr	**CLAUSE**	**PDCA CYCLE**	**309 Requirements**	**Requirement #**
4	Context of our Organization	Plan	1-24	24
5	Leadership	Plan, Do, Check, Act	25-50	26
6	Planning	Plan	51-77	27
7	Support	Do	78-120	43
8	Operation	Do	121-248	128
9	Performance Evaluation	Check	249-291	43
10	Improvement	Act	292-309	18

GAP ANALYSIS EVALUATION **Audit Result Summary** (Clausewise)	**Affected QMS Process**	**Gap Analysis Results Opportunity for Improvement (OFI) Recommendation**	**Responsibility (Who?)**	**Due Date (Until when?)**
Name the Clause	*Name the affected QMS Process (Existing/New)*	*(Write all justification artifacts like... Levels of current implementation at organization, Nonconformity to ISO 9001:2015 facts, Easy to implement or accomplish, potential remedy or solution to become compliant, etc...*	*Who will take care of that particular QMS upgrade?*	*Calculate due dates for the Implementation Project Plan*

Signature of Lead Auditor :…… Reviewed and Approved - Signature of CEO :……..…

Date: …… Date: ……..

Clause 4: CONTEXT OF OUR ORGANIZATION

4.1 Understanding our organization and its context

Sl.#	Audit Question	Audit Result	Describe the Gap
1	Has our organization determined the external and internal issues that are relevant to its purpose and its strategic direction and that affect our ability to achieve the intended result(s) of our quality management system? (Are documents available like Business Plans, SWOT Analysis, Stakeholder Analysis, etc…)		
2	Is our organization monitoring and reviewing information about these external and internal issues? How is it done?		

4.2 Understanding the needs and expectations of interested parties

Sl.#	Audit Question	Audit Result	Describe the Gap
1	Due to their effect or potential effect on our organization's ability to consistently provide products and services that meet our customer and applicable statutory and regulatory requirements, has our organization determined in documented format ... a) the interested parties that are relevant to our quality management system? b) the requirements of these interested parties that are relevant to our quality management system? (Any documentation available as evidence for that?)		
2	Whether and how our organization monitors and reviews information about these interested parties and their relevant requirements?		

4.3 Determining the scope of our quality management system

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Has our organization determined the boundaries and applicability of our quality management system to establish its scope? (Scope Statement available?)		
2	When determining this scope, did our organization consider: a) the external and internal issues referred to in 4.1? b) the requirements of relevant interested parties referred to in 4.2? c) the products and services of our organization.		
3	Did our organization apply all the requirements of the ISO 9001:2015 standard if they were applicable within the determined scope of our QMS?		
4	Is the scope of our organization's quality management system visually available and maintained as documented information somewhere?		
5	Does the scope state the types of our products and services covered, and provide justification for any requirement of the ISO 9001:2015 standard that our organization determines as not applicable to the scope of our quality management system?		
6	Are we aware that conformity to the ISO 9001:2015 standard may only be claimed if the requirements determined as not applicable do not affect our organization's ability or responsibility to ensure the conformity of our products and services and the enhancement of customer satisfaction?		

4.4 Quality management system and its core processes

Sl. #	Audit Question	Audit Result	Describe the Gap
1	*(4.4.1)* Has our organization determined the main QMS related processes needed for our quality management system and their application throughout our organization?		
2	*(4.4.1)* Has our organization ... a) determined the inputs required and the outputs expected from these processes? b) determined the sequence and interaction of these processes? (Flow charts?) c) determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes? d) determined the resources needed for these processes and ensured their availability? e) assigned the responsibilities and authorities for these processes? f) addressed the risks and opportunities as determined in accordance with the requirements of 6.1 (planning)? g) evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results? h) tried to improve these processes and also our entire quality management system?		
3	*(4.4.2)* To the extent necessary, does our organization ... a) maintain documented information to support the operation of our QMS related processes? Please cite some examples like Core Process Map, Quality Manual, etc... b) retain documented information to have confidence that all QMS related processes are being carried out as planned? Records keeping? Please cite some examples.		

Clause 5: LEADERSHIP

5.1 Leadership and commitment

Sl. #	Audit Question	Audit Result	Describe the Gap
1	*(5.1.1 - General)* In order to demonstrate its leadership and commitment with respect to our quality management system, is our top management "Hands on"... a) taking accountability for the effectiveness of our quality management system? Please cite some examples. b) ensuring that our quality policy and quality objectives are established for our quality management system and are compatible with the context and strategic direction of our organization? Please cite some examples (Quality Policy signed, etc…?). c) ensuring the integration of our quality management system requirements into our organization's business processes? Please cite some examples. d) promoting the use of the process approach and risk-based thinking? Please cite some examples. (Quality training, E-newsletter, any other documented evidence, etc…) e) ensuring that the resources needed for our quality management system are available? Please cite some examples. Is there are Employee Handbook available? f) communicating the importance of effective quality management and of conforming to our quality management system requirements? Please cite some examples. g) ensuring that our quality management system achieves its intended results? Please cite some examples. Is there a List of Authorities/Responsibilities, Org-Chart available? h) engaging, directing and supporting persons to contribute to the effectiveness of our quality management system? Please cite some examples. i) promoting improvement? Please cite some examples. Improvement plans, etc… j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility? Please cite some examples. QMS Process owner plan, Master-list of approved SOP's, Records, Job descriptions, advanced quality training evidence records (Lean, Six Sigma, etc…)		

2	*(5.1.2 - Customer focus)* In order to demonstrate its leadership and commitment with respect to customer focus, is our top management ensuring that ... a) customer and applicable statutory and regulatory requirements are determined, understood, monitored and consistently met? b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed? (Risk plan?) c) the focus on enhancing customer satisfaction is maintained?		

NOTES:

5.2 Policy

Sl.#	Audit Question	Audit Result	Describe the Gap
1	*(5.2.1 - Establishing the quality policy)* Has our top management established, implemented and maintaining a quality policy that ... a) is appropriate to the purpose and context of our organization and supports its strategic direction? b) provides a framework for setting our quality objectives? c) includes a commitment to satisfy applicable requirements? d) includes a commitment to continual improvement of the quality management system?		
2	*(5.2.2 - Communicating the quality policy)* Whether the quality policy ... a) is available and is maintained as documented information? b) is communicated, understood and applied within our organization? Posters, e-newsletter? c) is available to relevant interested parties, as appropriate?		

5.3 Organizational roles, responsibilities and authorities

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our top management ensure that the responsibilities and authorities for relevant QMS related process roles are assigned, communicated and understood within our organization? (Responsibility Charts, Org-Chart, etc…)		
2	Has our top management assigned the responsibility and authority for ... a) ensuring that our quality management system conforms to the requirements of the ISO 9001:2015 standard? b) ensuring that all QMS related processes are delivering their intended outputs? c) reporting on the performance of our quality management system and on opportunities for improvement, in particular to our top management? d) ensuring the promotion of customer focus throughout our organization? e) ensuring that the integrity of our quality management system is maintained when changes to our quality management system are planned and implemented?		

Clause 6: PLANNING

6.1 Actions to address risks and opportunities

Sl. #	Audit Question	Audit Result	Describe the Gap
1	*(6.1.1)* When planning for our quality management system, did our organization consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine all risks and relevant new opportunities that need to be addressed to: a) give assurance that our quality management system can achieve its intended result(s)? Global Risk plan if needed? Inclusive Supplier risk evaluation? b) enhance desirable effects? c) prevent, or reduce, undesired effects? (FMEA, or any other Risk planning tool?) d) achieve improvement?		
2	*(6.1.2)* Has our organization planned ... a) actions to address these risks and opportunities? (Continuity/Contingency plan?) b) how to: 1) integrate and implement the actions into its quality management system processes (see 4.4)? Do we have a Risk and/or Safety Committee? 2) evaluate the effectiveness of these actions? Regular Risk status meetings?		
3	*(6.1.2)* Whether the actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services? Global and local?		

4	*(6.1.2)* Do the options to address all to our organization relevant risks include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision?		
5	*(6.1.2)* Has any opportunity led to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address our organization's or its customers' needs? Please cite some instances.		

NOTES:

6.2 Quality objectives and planning to achieve them

Sl. #	Audit Question	Audit Result	Describe the Gap
1	*(6.2.1)* Has our organization established and connected our quality objectives with relevant functions, levels and processes needed to achieve our quality management system objectives?		
2	*(6.2.1)* Whether the chosen quality objectives ... a) are consistent with our quality policy? Any SOP for QMS planning? b) are measurable and broken down visible in our QMS processes? c) take into account applicable requirements? Key Performance Indicator (KPI) Plan? d) are relevant to conformity of our products and services and focus on enhancement of customer satisfaction? e) are monitored? Do we have a Records keeping plan? f) are communicated throughout our organization? g) are updated, as appropriate?		
3	*(6.2.1)* Does our organization maintain documented information on the QMS quality objectives?		
4	*(6.2.2)* When planning how to achieve our quality objectives, does our organization determine ... a) what will be done? Do we collect and track monthly KPI Records for status update? b) what resources will be required? c) who will be responsible? Process owners responsible for tracking process interruptions? d) when it will be completed? Quarterly, Monthly, weekly? e) how the results will be evaluated? Is the Quality team tracking/analyzing KPI trends?		

6.3 Planning of changes

Sl. #	Audit Question	Audit Result	Describe the Gap
1	When our organization determines the need for changes to our quality management system, are the changes carried out in a planned manner? Any SOP for that available? Does our organization consider ... a) the purpose of the changes and their potential consequences? b) the integrity of our quality management system? c) the availability of resources to cover the changes? d) the allocation or reallocation of responsibilities and authorities?		

NOTES:

Clause **7**: **SUPPORT**

7.1 Resources

Sl. #	Audit Question	Audit Result	Describe the Gap
1	*(7.1.1 – General)* Has our organization determined and is providing the resources needed for the establishment, implementation, maintenance and continual improvement of our quality management system? Is that a constant item line of our QMS Management Reviews? Has our organization considered ... a) the capabilities of, and constraints on, existing internal resources? b) what needs to be obtained from external providers?		
2	*(7.1.2 - People)* Does our organization determine and provide the persons necessary for the effective implementation of our quality management system and for the operation and control of its relevant processes? Job Skill Matrix? Annual Training plan in place? etc...		
3	*(7.1.3 - Infrastructure)* Does our organization determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products & services? What is the status of the following infrastructure (if applicable) ... a) buildings and associated utilities? b) equipment, including hardware and software? c) transportation resources? d) information and communication technology?		

4	*(7.1.4 - Environment for the operation of our QMS processes)* Has our organization determined, provided and is maintaining the environment necessary for the operation of its processes and to achieve conformity of our products and services? What is the status of the following environmental factors (if relevant) ... a) social (e.g. non-discriminatory, calm, non-confrontational)? b) psychological (such as stress-reducing, burnout prevention, emotionally protective)? *c)* physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise)? SOP's for our Operations/business activities in place, Flow charts, etc…?		
5	*(7.1.5.1 Monitoring and measuring resources – general)* Has our organization determined and is providing the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements with focus on non-conformities? Who is doing Legal Watch and Statutory/Regulatory Watch in our organization?		
6	*(7.1.5.1 Monitoring and measuring resources – general)* Whether and how does our organization ensure that the resources provided ... a) are suitable for the specific type of monitoring and measurement activities being undertaken? b) are maintained to ensure their continuing fitness for their purpose?		
7	*(7.1.5.1 Monitoring and measuring resources – general)* Does our organization retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources? What documents are they?		

8	*(7.1.5.2 Monitoring and measuring resources - Measurement traceability)* When measurement traceability is a requirement, or is considered by our organization to be an essential part of providing confidence in the validity of measurement results, are the measuring equipment ... a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information? b) identified in order to determine their status? c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results?		
9	*(7.1.5.2 Monitoring and measuring resources - Measurement traceability)* Does our organization determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and take appropriate action as necessary?		
10	*(7.1.6 - Organizational knowledge)* Has our organization determined the knowledge necessary for the operation of its QMS processes and to achieve conformity of products and services?		
11	*(7.1.6 - Organizational knowledge)* Whether this knowledge is maintained within documented information and made available to the extent necessary?		
12	*(7.1.6 - Organizational knowledge)* When addressing changing needs and trends, does our organization consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates?		

13	*(7.1.6 - Organizational knowledge)* Whether our organizational knowledge is based on: a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services)? b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers)?		

7.2 Competence

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our organization ... a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of our quality management system? b) ensure that these persons are competent on the basis of appropriate education, training, or experience? Job Skill matrix, HR Competency plan for growth, etc… c) where applicable, take actions (for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons) to acquire the necessary competence, and evaluate the effectiveness of the actions taken? d) retain appropriate documented information as evidence of competence?		

7.3 Awareness

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Whether and how does our organization ensure that persons doing work under our organization's control are aware of: a) our quality policy? Training evidence? b) our relevant quality objectives? Training records? c) their contribution to the effectiveness of our quality management system, including the benefits of improved quality performance? d) the implications of not conforming with our quality management system requirements? Any training on Process owner's responsibility?		

7.4 Communication

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Has our organization determined the internal and external communications relevant to our quality management system including: a) on what we will communicate? Marketing Plan/Customer engagement? b) when to communicate? c) with whom to communicate? d) how to communicate? e) who communicates?		

7.5 Documented information

7.5.1 General

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our organization's quality management system include: a) documented information required by the ISO 9001:2015 standard? b) documented information determined by our organization as being necessary for the effectiveness of our quality management system?		

7.5.2 Creating and updating

Sl. #	Audit Question	Audit Result	Describe the Gap
1	When creating and updating documented information, does our organization ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number)? b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic)? c) review and approval for suitability and adequacy?		

7.5.3 Control of documented information

Sl. #	Audit Question	Audit Result	Describe the Gap
1	*(7.5.3.1)* Are the documented information (relevant to our quality management system and required by the ISO 9001:2015 standard) controlled to ensure that ... a) it is available and suitable for use, where and when it is needed? b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity)? Does our Email policy help to preserve emails?		
2	*(7.5.3.2)* For the control of documented information, has our organization addressed the following activities to maintain documented information, as applicable: a) distribution, access, retrieval and use? b) storage and preservation, including preservation of legibility? c) control of changes (e.g. version control)? d) retention and disposition?		
3	*(7.5.3.2)* Is the documented information of external origin necessary for the planning and operation of our quality management system identified (as appropriate)? Are they controlled in some form or way? Any SOP's/Records obsolete?		
4	*(7.5.3.2)* Are QMS related documented information retained as evidence of conformity protected from unintended alterations?		

Clause 8: OPERATION

8.1 Operational planning and control

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Has our organization planned, implemented and controlling the processes needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6 (Planning)?		
2	Are we are doing these by: a) determining the requirements for our products and services? Which SOP? b) establishing criteria for the processes and the acceptance of products and services? c) determining the resources needed to achieve conformity to the product and service requirements? (Supplier evaluations, Annual evaluation of all Third Party vendors?) d) implementing control of the processes in accordance with the criteria? e) determining, maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned, and, to demonstrate the conformity of products and services to their requirements?		
3	Is the output of this planning suitable for our organization's operations? Can we defend that with some examples from recent past?		
4	Whether and how our organization is controlling planned changes and reviewing the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary?		
5	How does our organization ensure that outsourced processes are controlled?		

8.2 Requirements for our products and services

8.2.1 Customer communication

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our communication with customers include: a) providing information relating to products and services? And how? b) handling enquiries, contracts or orders, including changes? And how? c) obtaining customer feedback relating to products and services, including customer complaints? And how? Any Customer Survey records? d) handling or controlling customer property? And how? e) establishing specific requirements for contingency actions, when relevant? And how?		

8.2.2 Determining the requirements for products and services

Sl. #	Audit Question	Audit Result	Describe the Gap
1	When determining the requirements for our products and services to be offered to customers, does our organization ensure that ... a) the requirements for our products and services are defined, including any applicable statutory and regulatory requirements, and, those considered necessary by our organization? b) our organization can meet the claims we make for our products and services we offer? Sales terms/Purchase order terms recent version?		

8.2.3 Review of the requirements for products and services

Sl. #	Audit Question	Audit Result	Describe the Gap
1	*(8.2.3.1)* How does our organization ensure that it has the ability to meet the requirements for products and services to be offered to our customers?		
2	*(8.2.3.1)* Does our organization conduct a documented review before committing to supply products and services to a customer?		
3	*(8.2.3.1)* Does this review include ... a) requirements specified by our customer, including the requirements for delivery and post-delivery activities? b) requirements not stated by the customer, but necessary for the specified or intended use, when known? c) requirements specified by our organization? d) statutory and regulatory requirements applicable to our products and services? e) contract or order requirements differing from those previously expressed?		
4	*(8.2.3.1)* How does our organization ensure that contract or order requirements differing from those previously defined are resolved?		

5	*(8.2.3.1)* Do the customer's requirements be confirmed by our organization before acceptance, when the customer does not provide a documented statement of their requirements?		
6	*(8.2.3.1)* In situations such as internet sales, does our organization review the coverage of relevant product information, such as catalogues?		
7	*(8.2.3.2)* Does our organization retain documented information, as applicable, ... a) on the results of the review? Please show some samples. b) on any new requirements for our products and services? Please show some samples.		

8.2.4 Changes to requirements for products and services

Sl. #	Audit Question	Audit Result	Describe the Gap
1	How does our organization ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for our products and services are changed?		

8.3 Design and development of products and services

8.3.1 General

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Has our organization established, implemented and is maintaining a design and development process that is appropriate to ensure the subsequent provision of our products and services?		

8.3.2 Design and development planning

Sl. #	Audit Question	Audit Result	Describe the Gap
1	In determining the stages and controls for design and development, does our organization consider ... a) the nature, duration and complexity of all design and development activities? b) the required process stages, including applicable design and development reviews? c) the required design and development verification and validation activities? d) the responsibilities and authorities involved in the design and development process? e) the internal and external resource needs for the design and development of products and services? f) the need to control interfaces between persons involved in the design and development process? Is our ERP handling that process? g) the need for involvement of customers and users in the design and development process?		

	h) the requirements for subsequent provision of our products and services? i) the level of control expected for the design and development process by customers and other relevant interested parties? j) the documented information needed to demonstrate that all design and development requirements have been met?		

NOTES:

8.3.3 Design and development inputs

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our organization determine the requirements essential for the specific types of our products and services to be designed and developed?		
2	Does our organization consider ... a) functional and performance requirements? b) information derived from previous similar design and development activities? c) statutory and regulatory requirements? d) standards or codes of practice that our organization has committed to implement? e) potential consequences of failure due to the nature of our products & services?		
3	How do you make sure that the inputs are adequate for design and development purposes, complete and unambiguous? And who approves this?		
4	In case of conflicting design and development inputs, how do we resolve them before proceeding further?		
5	Does our organization retain documented information on all design and development inputs? Please show some samples.		

8.3.4 Design and development controls

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our organization apply controls to our design and development process to ensure that ... a) the results to be achieved are defined? b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements? c) verification activities are conducted to ensure that our design and development outputs meet the input requirements? d) validation activities are conducted to ensure that our resulting products and services meet the requirements for the specified application or intended use? e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities? f) documented information of these activities is retained?		

8.3.5 Design and development outputs

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our organization ensure that all design and development outputs ... a) meet the input requirements? b) are adequate for the subsequent processes for the provision of our products and services? c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria? d) specify the characteristics of our products and services that are essential for their intended purpose and their safe and proper provision?		

2	Does our organization retain documented information on all design and development outputs?		

8.3.6 Design and development changes

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our organization identify, review and control all changes made during, or subsequent to, the design and development of our products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements?		
2	Whether and what documented information does our organization retaining on ... a) design and development? b) the authorization of all changes? c) the actions taken to prevent adverse impacts? Do we have Flow Charts/Routing for customer complaints for our internal routing?		

8.4 Control of externally provided processes, products and services

8.4.1 General

Sl. #	Audit Question	Audit Result	Describe the Gap
1	How does our organization ensure that externally provided processes, products and services conform to the proposed product and service requirements? Non-conformity Register in place?		
2	Has our organization determined the controls to be applied to externally provided processes, products and services when ... a) products and services from external providers are intended for incorporation into our organization's own products and services? b) products and services are provided directly to the customer(s) by external providers on behalf of our organization? c) a process, or part of a process, is provided by an external provider as a result of a decision by our organization?		
3	Whether and how does our organization determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers? Is it based on their ability to provide processes or products and services in accordance with requirements?		
4	What documented information does our organization retain for these activities and any necessary actions arising from these evaluations?		

8.4.2 Type and extent of control

Sl. #	Audit Question	Audit Result	Describe the Gap
1	How does our organization ensure that externally provided processes, products and services do not adversely affect our organization's ability to consistently deliver conforming products and services to our customers?		
2	Does our organization ... a) ensure that externally provided processes remain within the control of our quality management system? b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output? c) take into consideration: 1) the potential impact of the externally provided processes, products and services on our organization's ability to consistently meet customer and applicable statutory and regulatory requirements? 2) the effectiveness of the controls applied by the external provider? d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet all requirements?		

NOTES:

8.4.3 Information for external providers

Sl. #	Audit Question	Audit Result	Describe the Gap
1	How does our organization ensure the adequacy of requirements prior to their communication to the external provider?		
2	Does our organization communicate to external providers its requirements for ... a) the processes, products and services to be provided? b) the approval of: 1) products and services? 2) methods, processes and equipment? 3) the release of products and services? c) competence, including any required qualification of persons? d) the external providers' interactions with our organization? e) control and monitoring of the external providers' performance to be applied by our organization? f) verification or validation activities that our organization, or its customer, intends to perform at the external providers' premises?		

8.5 Production and service provision

8.5.1 Control of production and service provision

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Has our organization implemented production and service provision under controlled conditions?		
2	Do these controlled conditions include, as applicable ... a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed? 2) the results to be achieved? b) the availability and use of suitable monitoring and measuring resources? c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met? Calibration Log? Etc… d) the use of suitable infrastructure and environment for the operation of processes? e) the appointment of competent persons, including any required qualification? f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement? g) the implementation of actions to prevent human error? h) the implementation of release, delivery and post-delivery activities?		

8.5.2 Identification and traceability

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our organization use suitable means to identify all outputs when it is necessary to ensure the conformity of our products and services?		
2	How does our organization identify the status of all outputs with respect to monitoring and measurement requirements throughout production and service provision?		
3	How does our organization control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability?		

8.5.3 Property belonging to customers or external providers

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our organization exercise care with property belonging to customers or external providers while it is under our organization's control or being used by our organization?		
2	Does our organization identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into our products and services?		

3	When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, does our organization report this to the customer or external provider and retain documented information on what has occurred?		
4	Does your definition (and coverage) of customer's or external provider's property include materials, components, tools and equipment, premises, intellectual property and personal data?		

8.5.4 Preservation

Sl. #	Audit Question	Audit Result	Describe the Gap
1	How does our organization preserve the outputs during production and service provision, at least to the extent necessary to ensure conformity to requirements?		
2	Does our definition (and coverage) of preservation include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection?		

8.5.5 Post-delivery activities

Sl. #	Audit Question	Audit Result	Describe the Gap
1	How does our organization meet requirements for post-delivery activities associated with our products and services?		
2	In determining the extent of post-delivery activities that are required, does our organization consider ... a) statutory and regulatory requirements? b) the potential undesired consequences associated with our products and services? c) the nature, use and intended lifetime of our products and services? d) customer requirements? e) customer feedback?		
3	Does our definition (and coverage) of post-delivery activities 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

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our organization review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with all requirements?		
2	Does our organization retain documented information describing the results of the review of any changes, the person(s) authorizing the change, and any necessary actions arising from the review?		

8.6 Release of products and services

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Has our organization implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met?		
2	How do we ensure that the release of our products and services to the customer do not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by our customer?		
3	Does our organization retain documented information on the release of our products and services? Are the records up-to-date? Please show some samples.		
4	Does the documented information include ... a) evidence of conformity with the acceptance criteria (inspection / test results)? b) traceability to the person(s) authorizing the release (i.e., who has authorized the release)?		

8.7 Control of nonconforming outputs

Sl. #	Audit Question	Audit Result	Describe the Gap
1	*(8.7.1)* How does our organization ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery?		
2	*(8.7.1)* Does our organization take appropriate action based on the nature of the nonconformity and its effect on the conformity of our products and services?		
3	*(8.7.1)* Does this also apply to nonconforming products and services detected after delivery of products, during or after the provision of services?		
4	*(8.7.1)* Is our organization dealing in appropriate ways with nonconforming outputs in one or more of the following ways ... a) correction? Corrective Action tools? Please give some examples. b) segregation, containment, return or suspension of provision of our delivered products and services? Please give some examples. c) informing the customer? Please give some examples. d) obtaining authorization for acceptance under concession? Please give some examples.		

5	*(8.7.1)* Is the new conformity to the requirements verified when nonconforming outputs are corrected (i.e., re-inspection)?		
6	*(8.7.2)* Does our organization retain documented information that ... a) describes the nonconformity? b) describes the actions taken? c) describes any concessions obtained? d) identifies the authority deciding the action in respect of the nonconformity?		

NOTES:

Clause 9: PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Has our organization determined ... a) what needs to be monitored and measured within our QMS? b) the methods for monitoring, measurement, analysis and evaluation of our QMS needed to ensure valid results within our QMS? c) when the monitoring and measuring of our QMS shall be performed? d) when the results from monitoring and measurement shall be analyzed and evaluated?		
2	Whether and how does our organization evaluate the performance of our QMS and the effectiveness of our quality management system?		
3	Does our organization retain appropriate documented information as evidence of the results? Please show some samples.		

9.1.2 Customer satisfaction

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Whether and how does our organization monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled?		
2	Has our organization determined the methods for obtaining, monitoring and reviewing this information? Do we evaluate also Internal Customer satisfaction? How?		
3	Does your system / method of monitoring customer perceptions include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports?		

9.1.3 Analysis and evaluation

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Whether and how does our organization analyze and evaluate appropriate data and information arising from monitoring and measurementof our QMS?		
2	Do we use the results of analysis to evaluate ... a) conformity of products and services? b) the degree of customer satisfaction? c) the performance and effectiveness of our quality management system? d) if planning of all QMS related activities has been implemented effectively? e) the effectiveness of actions taken to address risks and opportunities? f) the performance of external providers (Suppliers, vendors, etc.)? g) the need for improvements to the quality management system?		
3	Does our organization use any statistical techniques to analyze our QMS related data? Are our people trained on using statistical techniques for QMS related data analysis?		

9.2 Internal audit

Sl. #	Audit Question	Audit Result	Describe the Gap
1	*(9.2.1)* Does our organization conduct internal audits at planned intervals?		
2	*(9.2.1)* Do our internal audits provide information on whether our quality management system ... a) conforms to: 1) our organization's own requirements for its quality management system? 2) the requirements of the ISO 9001:2015 standard? b) is effectively implemented and maintained?		
3	*(9.2.2)* Does our organization ... a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration the importance of the processes concerned, changes affecting our organization, and the results of previous audits? b) define the audit criteria and scope for each audit with focus on improvement? c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process? Annual Audit Plan? Lessons Learned plan? etc… d) ensure that the results of the audits are reported to relevant management? e) take appropriate correction and corrective actions without undue delay? f) retain documented information as evidence of the implementation of the audit program and the audit results?		
4	*(9.2.2)* Are our internal auditors aware of / trained on the audit standard (i.e., ISO19011:2011)?		

9.3 Management review

9.3.1 General

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our top management review our organization's quality management system at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of our organization?		

9.3.2 Management review inputs

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Is the QMS management review planned/carried out taking into consideration ... a) the status of actions from previous QMS management reviews? b) changes in external and internal issues that are relevant to our quality management system? c) information on the performance and effectiveness of the quality management system, including trends in: 1) customer satisfaction and feedback from relevant interested parties? 2) the extent to which quality objectives have been met? 3) process performance and conformity of products and services? 4) non-conformities and corrective actions? 5) monitoring and measurement results? 6) other audit results? 7) the performance of external providers (Supplier evaluations, etc.)? d) the adequacy of resources? e) the effectiveness of actions taken addressing risks and opportunities? f) opportunities for improvement?		

9.3.3 Management review outputs

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Do the outputs of our last QMS management review include top management decisions and concise actions with responsibilities and due date for accomplishment related to ... a) opportunities for improvement of our QMS? b) any need for changes to our quality management system? c) Resources or any other needs?		
2	Does our organization retain documented information as evidence of the results of management reviews? Please show some sample.		

NOTES:

Clause10: IMPROVEMENT

10.1 General

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Does our organization have a system in place to determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction?		
2	Does this system include focus on ... a) improving products and services to meet requirements as well as to address future needs and expectations? b) correcting, preventing or reducing undesired effects? c) improving the performance and effectiveness of our quality management system?		
3	Can we show evidence and cite some examples of improvement our organization has achieved through correction, corrective action, continual improvement, breakthrough change, innovation, or, re-organization at least over the last three months?		

10.2 Nonconformity and corrective action

Sl. #	Audit Question	Audit Result	Describe the Gap
1	*(10.2.1)* When a nonconformity (NC) occurs, including any nonconformity arising from complaints, whether internal or external complaint nature, does our organization ... a) react to the nonconformity and, as applicable: 1) take action to control and correct it? 2) deal with the consequences / b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: 1) reviewing and analyzing the nonconformity? 2) determining the causes of the nonconformity? 3) determining if similar non-conformities exist, or could potentially occur? c) implement any action needed to solve the nonconformity/problem/complaint? d) regular review the effectiveness of any corrective action taken? e) update risks and opportunities determined during QMS planning, if necessary? f) make changes to the quality management system, if necessary?		
2	*(10.2.1)* How does our organization make sure that all corrective actions are appropriate to the effects of the non-conformities encountered? Any follow-up done to check whether the corrective actions were effective?		
3	*(10.2.2)* What documented information does our organization retains as evidence of ... a) the nature of the non-conformities and any subsequent actions taken? b) the results of any corrective action?		

10.3 Continual improvement

Sl. #	Audit Question	Audit Result	Describe the Gap
1	How does our organization continually improve the suitability, adequacy and effectiveness of our quality management system?		
2	Does our organization consider the results of analysis and evaluation, and the outputs from our QMS management reviews, to determine if there are needs or opportunities that shall be addressed as part of continual improvement?		
3	Can our organization show any trend charts / graphs to prove that our organization is showing efforts for continual improvement on critical parameters of our QMS (such as material rejections management, field-failures management, warranty claims-, repairs-, reworks-, customer complaints management, and service response time management, etc.)?		

Signature of Auditors: (1) …… (2) …… (3) …… (4) ……

Date: ……..

Signature of Auditees: (1) …… (2) …… (3) …… (4) ……
(Optional)

Date: ……..