

ISO 9001:2015 Internal Audit Checklist

| The internal audit checklist ensures your internal audits concisely compare your management system against the requirements of ISO 9001:2015. |                             |             | Each ISO 9001:2015 'shall' requirement has been re-phrased as a question to elicit a response that can be represented as an 'x'. Answer questions 1 to 305 to determine conformance. The audit results are summarized in the 'Audit Results' worksheet. | The general guidance and examples shown in Column 'E' should be referred to when undertaking an internal audit as described by ISO 9001:2015, Clause 9.2.<br><br>This guidance is not intended to add to, subtract from, or in any way modify the stated requirements of ISO 9001:2015. The examples shown are things to consider when asking audit the questions and looking for objective audit evidence to record.   | Enter the letter 'x' into either Column 'F', 'G' or 'H', to express your answer to each audit question.<br><br>The scoring formula assumes each requirement conforms, until an 'x' is entered into Column 'G' or 'H'. | Any issues that are identified during the internal audit must be documented against the current ISO 9001:2015 requirements.<br><br>Provide a reference to documented information to justify each audit finding. Describe the nature of any <b>minor</b> or <b>major</b> nonconformance. | Note any process or practice that seems weak, cumbersome, redundant or complex - but which is <u>still conforms</u> .<br><br>An OFI may be an improvement to the QMS or something that could prevent future problems in an otherwise conforming area. | The error tracking cells in Column 'M' display an error message when more than 1 response is entered in Columns 'F', 'G' and 'H', or whether a response has yet to be entered. See the summary in Cell 'M3'. | Please not do amend the cells in Columns 'L' to 'Q'. |                          |             |   |                  |                   |             |           |
|---|-----------------------------|-------------|---|---|---|---|---|--|--|--------------------------|-------------|---|------------------|-------------------|-------------|-----------|
| Clause No   | Clause Title                | Question No | Audit Question  | Guidance & Suggestions  | Conforms  | Minor NC  | Major NC  | OFI  | Audit Evidence & Notes                               | Opportunities to Improve | Audit Score | 0 Entries yet to be entered<br>0 Errors | Section Subscore | Possible Subscore | % Compliant | OFI Count |
| 4   | Context of the Organization |             |   |   |   |   |   |  |  |                          |             |   |                  |                   |             |           |
| 4.1   | Organizational Context      | 1           | Has your organization determined external and internal issues relevant to its purpose and its strategic direction that affect its ability to achieve the intended result(s) of its quality management system?   | Sources of evidence could come from SWOT or PESTLE analysis results, business strategy plans; quality plans; information provided on your organization's website; annual reports; management meeting minutes; documented procedure; and lists of external and internal issues and conditions.<br><br>Records of meetings where context is routinely discussed and monitored, e.g. as part of the structured management review process or within each of the respective function of the organization (Purchase, HR, Engineering, Sales, Finance etc).<br><br>Interviews with relevant top management in relation to the organization's context and its strategic direction are also a good source of compliance evidence, such as: individual strategy or tactical plan documents written to underpin the organization's policies and provide a road map for achieving future goals.   | x   |   |   |  |  |                          | 100         |   |                  |                   |             |           |
| 4.1   | Organizational Context      | 2           | Does your organization monitor and review information about these external and internal issues?   | <b>External</b> issues, examples could include:<br>1. Reports relating to the your organization's competitive environment, new technologies, new markets, customer expectations, supplier intelligence, economic conditions, political considerations, investment opportunities, social factors;<br>2. Identification of factors relating to changing legislation and regulation;<br>3. Feedback relating to product/service performance and lessons learned;<br>4. Register of identified external risks and their treatment.<br><br><b>Internal</b> issues, examples could include:<br>1. Organizational structure, identification of roles/responsibilities and governance arrangements;<br>2. Reports on how well the organization is performing, statements relating to mission, vision and core values;<br>4. Feedback obtained from employees, e.g. survey results;<br>5. Information and processes for capturing and sharing knowledge and lessons learned;<br>6. Organizational capability studies: load/capacity, resource requirements to achieve demand;<br>7. Register of identified internal risks and their treatment. | x   |   |   |  |  |                          | 100         |   | 200              | 200               | 100.00      | 0         |
| 4.2   | Relevant Interested Parties | 3           | Does your organization determine the interested parties that are relevant to the quality management system?   | Examples of interested parties include: customers, partners, end users, external providers, owners, shareholders, employees, trade unions, government agencies, regulatory authorities, and the local community.  | x   |   |   | x  |  |                          | 100         |   |                  |                   |             |           |
| 4.2   | Relevant Interested Parties | 4           | Does your organization determine the requirements of these interested parties that are relevant to the quality management system?   | Include those parties that add direct value to your organisation, or who are affected by your organisation's the activities. Use of surveys, networking, face-to-face meetings, association membership, attending conferences, lobbying, participation in benchmarking, etc., in order to gain stakeholder information and their requirements.  | x   |   |   |  |  |                          | 100         |   |                  |                   |             |           |
| 4.2   | Relevant Interested Parties | 5           | Does your organization monitor and review information about these interested parties and their relevant requirements?   | Records of meetings where interested parties and their requirements are routinely discussed and monitored, e.g. as part of the structured management review process, or within each of the respective function of the organization (Purchase, HR, Engineering, Sales, and Finance etc).   | x   |   |   |  |  |                          | 100         |   | 200              | 300               | 66.67       | 1         |
| 4.3   | Management System Scope     | 6           | Does your organization determine the boundaries and applicability of the quality management system to establish its scope?  | Consideration of boundaries and applicability of the QMS includes:<br>1. Range of products and services;<br>2. Different sites and activities;<br>3. External provision of processes, products and services.  | x   |   |   | x  |  |                          | 100         |   |                  |                   |             |           |
| 4.3   | Management System Scope     | 7           | When determining this scope, has your organization considered the external and internal issues referred to in 4.1?  | Ensure that issues relating to organizational context and the needs of interested parties encompassed in the scope. A lack of a documented process will require more reliance on objective evidence from interviews with Top management and the evaluation of <b>external and internal</b> issues (see 4.1).  |   |   | x   |  |  |                          | 25          |   |                  |                   |             |           |
| 4.3   | Management System Scope     | 8           | When determining this scope, has your organization considered the requirements of relevant interested parties referred to in 4.2?   | Ensure that issues relating to organizational context and the needs of interested parties encompassed in the scope. A lack of a documented process will require more reliance on objective evidence from interviews with Top management and the evaluation to the <b>requirements of relevant interested parties</b> (see 4.2).   |   | x   |   |  |  |                          | 75          |   |                  |                   |             |           |
| 4.3   | Management System Scope     | 9           | When determining this scope, has your organization considered all relevant products, services and work-related activities, functions and physical boundaries to the quality management system?  | Obtain evidence that clearly defines what your organisation sells, produces, or provides services for. Link this to the relevant standards or ACOPs that they are governed by.  | x   |   |   | x  |  |                          | 100         |   |                  |                   |             |           |
| 4.3   | Management System Scope     | 10          | Has your organization applied all the requirements of ISO 9001:2015 if they are applicable within the determined scope of the quality management system?  | Describe the application of ISO 9001 within the scope was determined, and how has it been applied by your organization.   |   |   | x   |  |  |                          | 25          |   |                  |                   |             |           |
| 4.3   | Management System Scope     | 11          | Does the scope state the types of products and services covered, and provide justification for any requirement of ISO 9001:2015 that your organization determines is not applicable to the scope of its quality management system?                      | Describe how the application of ISO 9001 within the scope was determined, and how any clause exclusions are justified. There must be alignment between the documented scope of the organization's QMS and their agreed scope of certification.  |   | x   |   |  |  |                          | 75          |   |                  |                   |             |           |
| 4.3   | Management System Scope     | 12          | Is the scope of your organization's quality management system available and maintained as documented information and available to interested parties and workers? (See 7.5.1a)  | Verify objective evidence that the scope of documented and available to interested parties. A statement from your organization that the scope will be provided upon request may be accepted as objective evidence.  | x   |   |   |  |  |                          | 100         |   | 500              | 700               | 71.43       | 2         |
| 4.4   | Management System Processes | 13          | Has your organization established, implemented, maintained and continually improved its quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO 9001:2015?                         | ISO 9001 includes specific requirements necessary for the adoption of processes when developing, implementing and improving your QMS. This requires your organization to systematically define and manage its processes, and their interactions, in order to achieve the intended results in accordance with both the policy and strategic direction of your organization.  | x   |   |   |  |  |                          | 100         |   |                  |                   |             |           |
| 4.4   | Management System Processes | 14          | Has your organization determined the process required for the quality management system, including their interactions, in accordance with requirements and their application throughout the organization?   | A process is set of interrelated or interacting activities which transforms inputs into outputs. A procedure is a specified way of fulfilling an activity within a process. QMS processes should be defined to address: suppliers, manufacturers, internal or external customer issues, resources, design, operation, production, logistics, products, and services, customers and end-users.   | x   |   |   |  |  |                          | 100         |   |                  |                   |             |           |
| 4.4   | Management System Processes | 15          | Has your organization determined the inputs required and the outputs expected from these processes?   | What are the expected inputs and outputs from each of the identified processes, together with assignment of responsibilities and authorities e.g. Process Owner, Process Champion, Lead Process User and Process User?  | x   |   |   |  |  |                          | 100         |   |                  |                   |             |           |

**ISO 9001:2015 Internal Audit Checklist**

| The internal audit checklist ensures your internal audits concisely compare your management system against the requirements of ISO 9001:2015. |                             |             | Each ISO 9001:2015 'shall' requirement has been re-phrased as a question to elicit a response that can be represented as an 'x'. Answer questions 1 to 305 to determine conformance. The audit results are summarized in the 'Audit Results' worksheet.                                 | The general guidance and examples shown in Column 'E' should be referred to when undertaking an internal audit as described by ISO 9001:2015, Clause 9.2.<br><br>This guidance is not intended to add to, subtract from, or in any way modify the stated requirements of ISO 9001:2015. The examples shown are things to consider when asking audit the questions and looking for objective audit evidence to record.  | Enter the letter 'x' into either Column 'F', 'G' or 'H', to express your answer to each audit question.<br><br>The scoring formula assumes each requirement conforms, until an 'x' is entered into Column 'G' or 'H'. | Any issues that are identified during the internal audit must be documented against the current ISO 9001:2015 requirements.<br><br>Provide a reference to documented information to justify each audit finding. Describe the nature of any <b>minor</b> or <b>major</b> nonconformance. | Note any process or practice that seems weak, cumbersome, redundant or complex - but which is <u>still conforms</u> .<br><br>An OFI may be an improvement to the QMS or something that could prevent future problems in an otherwise conforming area. | The error tracking cells in Column 'M' display an error message when more than 1 response is entered in Columns 'F', 'G' and 'H', or whether a response has yet to be entered. See the summary in Cell 'M3'. | <b>Please not do amend the cells in Columns 'L' to 'Q'.</b> |                          |             |   |                  |                   |             |           |
|---|-----------------------------|-------------|---|--|---|---|---|--|---|--------------------------|-------------|---|------------------|-------------------|-------------|-----------|
| Clause No   | Clause Title                | Question No | Audit Question  | Guidance & Suggestions   | Conforms  | Minor NC  | Major NC  | OFI  | Audit Evidence & Notes                                      | Opportunities to Improve | Audit Score | 0 Entries yet to be entered<br>0 Errors | Section Subscore | Possible Subscore | % Compliant | OFI Count |
| 4   | Context of the Organization |             |   |  |   |   |   |  |   |                          |             |   |                  |                   |             |           |
| 4.4   | Management System Processes | 16          | Has your organization determined the sequence and interaction of these processes?   | Describe the identification of the processes needed for the QMS, including their sequence and interaction, e.g. E.g. process framework, process model, process groupings, process flow diagram, process mapping, value stream mapping, Turtle diagrams, SIPOC (Supplier, Input, Process, Output, and Customer) charts and process cards.   | x   |   |   | x  |   |                          | 100         |   |                  |                   |             |           |
| 4.4   | Management System Processes | 17          | Has your organization 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?  | Describe how what are the criteria, methods, measurement and related performance indicators needed to operate and control those processes? Criteria and methods to ensure effective operation and control of the identified processes, e.g. process monitoring indicators, process performance indicators, target setting, data collection, performance trends, and internal or external audit results.  | x   |   |   | x  |   |                          | 100         |   |                  |                   |             |           |
| 4.4   | Management System Processes | 18          | Has your organization determined the resources needed for these processes and ensure their availability?  | Describe how resources are determined and how they are made available, this might doing operational planning or management reviews.  | x   |   |   |  |   |                          | 100         |   |                  |                   |             |           |
| 4.4   | Management System Processes | 19          | Has your organization assigned responsibilities and authorities for these processes?  | Describe how are responsibilities and authorities assigned for those processes. Information needed to ensure effective operation and control of the processes, e.g. defined process requirements (shall), good practice (should), defined roles, required competencies, associated training, and guidance.   | x   |   |   |  |   |                          | 100         |   |                  |                   |             |           |
| 4.4   | Management System Processes | 20          | Has your organization addressed the risks and opportunities as determined in accordance with the requirements of 6.1?   | Describe how risks and opportunities are considered and what plans are made to implement actions to address them? Risks and opportunities relating to the process, resource needs, user training/competency, continual improvement initiatives, frequency of reviews, agenda, minutes, and actions.  | x   |   |   |  |   |                          | 100         |   |                  |                   |             |           |
| 4.4   | Management System Processes | 21          | Has your organization evaluated these processes and implement any changes needed to ensure that these processes achieve their intended results?   | Describe the methods that are used to monitor, measure and evaluate processes and, if needed, what changes are made to achieve intended results?   |   | x   |   |  |   |                          | 75          |   |                  |                   |             |           |
| 4.4   | Management System Processes | 22          | Does your organization improve the processes and the quality management system?   | Describe how opportunities to improve the processes and the QMS are determined. Examples include risk and opportunity matrices, corrective action and non-conformance records. Describe the approach towards improvement and action taken when process performance is not meeting intended results.  | x   |   |   |  |   |                          | 100         |   |                  |                   |             |           |
| 4.4   | Management System Processes | 23          | To the extent necessary, does your organization maintain documented information to support the operation of its processes?  | Documentation identified and retained by the organization to show that processes are carried it as planned, e.g. physical hard copy records, electronic media (data servers, hard drives, CDs).  | x   |   |   |  |   |                          | 100         |   |                  |                   |             |           |
| 4.4   | Management System Processes | 24          | To the extent necessary, does your organization retain documented information to have confidence that the processes are being carried out as planned?   | Documentation created and maintained that includes a description of relevant interested parties (4.2), scope of the QMS including boundaries and applicability (4.3), description of the processes needed for the QMS, their sequence, interaction and application and assignment of responsibilities for the processes.   | x   |   |   |  |   |                          | 100         |   | 1175             | 1200              | 97.92       | 2         |
| 5   | Leadership                  |             |   |  |   |   |   |  |   |                          |             |   |                  |                   |             |           |
| 5.1   | Leadership & Commitment     |             |   |  |   |   |   |  |   |                          |             |   |                  |                   |             |           |
| 5.1.1   | General                     | 25          | Has Top Management demonstrated leadership and commitment to the quality management system by taking accountability for the effectiveness of your organization's quality management system?   | Describe how Top management has a 'hands-on' approach to managing the QMS through interviews and auditing other requirements e.g. Context of the organization, quality policy and objectives, management review minutes, assignment of resources etc. e.g. established measures, system/process performance monitoring, management review, realization of planned activities, achievement of planned results and taking action when process performance is not meeting intended results. |   | x   |   |  |   |                          | 75          |   |                  |                   |             |           |
| 5.1.1   | General                     | 26          | Has Top Management demonstrated leadership and commitment to the quality management system by ensuring that your organization's environmental policies and objectives are established and documented, and are compatible your organization's goals (See 6.2) and its context (See 4.0)? | Describe how Top management aligns policy and objectives are aligned with the strategic direction of organization and the internal and external issues covered in 4.1.   |   | x   |   |  |   |                          | 75          |   |                  |                   |             |           |
| 5.1.1   | General                     | 27          | Has Top Management demonstrated leadership and commitment to the quality management system by ensuring that quality requirements are integrated into your organization's business processes?  | Evidence may include Top management reviewing QMS KPI's as part of a regular business review process. Integrated quality requirements into the organizations business processes include e.g. system architecture, business model, process model, organization footprint, functional alignment (Engineering, Purchasing, IT, Finance, HR etc.)  |   |   | x   |  |   |                          | 25          |   |                  |                   |             |           |
| 5.1.1   | General                     | 28          | Does Top management demonstrate leadership and commitment with respect to the quality management system by promoting the use of the process approach and risk-based thinking?   | Describe how Top management considers risks and opportunities and what plans are made to implement actions to address them. Determine how Top management promotes the use of the process approach; e.g. process modelling, process mapping, inputs, outputs, activities, interactions, interfaces, resources, controls, risk management (identification, severity, ownership, and treatment etc.)  |   |   | x   |  |   |                          | 25          |   |                  |                   |             |           |
| 5.1.1   | General                     | 29          | Has Top Management demonstrated leadership and commitment to the quality management system by ensuring that your organization has the required resources to implement it?   | Describe how Top management have enabled the resources (including people) required for an effective QMS e.g. resource planning, workload, priorities, constraints, balance, organization flexibility, business benefits and organization growth.   |   | x   |   |  |   |                          | 75          |   |                  |                   |             |           |
| 5.1.1   | General                     | 30          | Does Top management demonstrate leadership and commitment with respect to effective quality management system by communicating the importance of effective quality, environmental and health and safety management and of conforming to the quality management requirements?            | Describe how Top management communicate the importance of conformity to the QMS and effective quality management e.g. meetings, briefs, e-mail, intranet, campaigns, roadshows, focused training, voice of the regulator/customer, consequence of non-conformity.  |   | x   |   |  |   |                          | 75          |   |                  |                   |             |           |
| 5.1.1   | General                     | 31          | Does Top management demonstrate leadership and commitment with respect to the quality management system by ensuring that the quality management system achieves its intended results?   | Describe how Top management systematically defines and manages processes, and their interactions, in order to achieve the intended results in accordance with both the policy and strategic direction of your organization.  | x   |   |   |  |   |                          | 100         |   |                  |                   |             |           |
| 5.1.1   | General                     | 32          | Does Top management demonstrate leadership and commitment with respect to the quality management system by engaging, directing and supporting persons to contribute to the effectiveness of the quality management system?  | Describe how Top management support other relevant management roles e.g. organization hierarchy, trust, empowerment, responsible delegation, coaching, sharing knowledge, removing barriers, or route to escalation.   | x   |   |   |  |   |                          | 100         |   |                  |                   |             |           |
| 5.1.1   | General                     | 33          | Does Top management demonstrate leadership and commitment with respect to the quality management system by promoting improvement?   | Describe how opportunities to improve the processes and the QMS are determined. Examples include risk and opportunity matrices, corrective action and non-conformance records.   | x   |   |   | x  |   |                          | 100         |   |                  |                   |             |           |
| 5.1.1   | General                     | 34          | Does Top management demonstrate leadership and commitment with respect to the quality management system by supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility?   | Describe how Top management support process owners in their process management activities e.g. deployment, governance, process evaluation and process improvement.   |   |   | x   |  |   |                          | 25          |   | 675              | 1000              | 67.50       | 1         |