The internal audit checklist is just one of the many tools available from the auditor's toolbox. The checklist ensures each audit concisely compares the requirements of ISO 9001:2015, and your EQMS against actual business practice.

ISO 9001:2015 Internal Audit Checklist

System & Process Compliance Auditing

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Guidance

About this Checklist

The audit checklist is just one of the many tools which are available from the auditor's toolbox that help ensure your audits address the necessary requirements. It stands as a reference point before, during and after the audit process and if developed for a specific audit and used correctly will provide the following benefits:

- Ensures the audit is conducted systematically;
- Promotes audit planning;
- Ensures a consistent audit approach;
- Actively supports your organization's audit process (ISO 9001:2015, Clause 9.2.1);
- Provides a repository for notes collected during the audit;
- Ensures uniformity in the performance of different auditors;
- Provides reference to objective evidence.

This audit checklist comprises tables of the certifiable ('shall') requirements, from Section 4.0 to Section 10.0 of ISO 9001:2015, each required is phrased as a question. This audit checklist may be used for element compliance audits and for process audits. If you wish to create separate process audit checklists, select the clauses from the tables below that are relevant to the process and copy and paste the audit questions into a new audit checklist. We suggest that you retain this audit checklist as your 'master copy'.

Audit Scoring Criteria

A risk-based internal audit approach allows the internal audit to concentrate on reviewing the major risks to your organization. The audit's role is to provide assurance that key risks to your organization's objectives are being well controlled.

The audit findings 'traffic lights' are intended to visually communicate the risk posed by the audit finding of any system or processes being audited. The rating system is stratified from 'compliant' to 'major non-conformance' to convey a concise and consistent method for scoring each audit finding. At the end of the audit, you can transfer the findings into an Excel spreadsheet to create charts, summary tables and trend data to paste into your audit report or management review documentation.

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This methodology should be uniformly applied to all types of internal audit (gap analysis, system audits and process audits) that your organization will likely undertake.

Finding	Definition/Impact	Action/Mitigation
COMPLIANT	Compliant means adherence with the requirements of the standard and the EQMS. The process is implemented and documented and records exist to verify this.	Continue to monitor trends/indicators.
OFI	A **low risk issue** that offers an opportunity to improve current practice. Processes may cumbersome or overly complex but meet their targets and objectives. Unresolved OFIs may degrade over time to become non-compliant.	Review and implement actions to improve the process(es). Monitor trends/indicators to determine if improvement was achieved.
MINOR N/C	A medium risk, minor non-conformance resulting in deviation from process practice not likely to result in the failure of the management system or process that will **not** result in the delivery of non-conforming products nor reduce the effectiveness of the EQMS.	Investigate root cause(s) and implement corrective action by next reporting period or next scheduled audit.
MAJOR N/C	A high risk, major non-conformance which **directly impacts** upon customer requirements, **likely** to result in the customer receiving non-conforming products or services, or which may reduce the effectiveness of the EQMS.	Implement immediate containment action, investigate root cause(s) and apply corrective action. Re-audit in 4 weeks to verify correction.

Principles of Auditing

Auditing relies on a number of principles whose intent is to make the audit become an effective and reliable tool that supports your company's management policies and procedures whilst providing suitable objective information that your company can act upon to continually improve its performance. Adherence to the following principles are considered to be a prerequisite for ensuring that the conclusions derived from the audit are accurate, objective and sufficient. It also allows auditors working independently from one another to reach similar conclusions when auditing in similar circumstances. The following principles relate to auditors.

1. **Ethical conduct:** Trust, integrity, confidentiality and discretion are essential to auditing;
2. **Fair presentation:** Audit findings, conclusions and reports reflect truthfully and accurately the audit activities ;
3. **Professional care:** Auditors must exercise care in accordance with the importance of the task they perform;
4. **Independence:** Auditors must be independent of the activity being audited and be objective;
5. **Evidence-based approach:** Evidence must be verifiable and be based on samples of the information available.

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Audit Methodology

Introduction

The adoption of the 'process approach' is mandated by ISO 9001:2015 and is one of the most important concepts relating to quality management systems. Process auditing is about auditing your organization's processes and their interactions, which together comprise the quality management system.

The process approach is one of the core quality management principles, which is defined as a 'consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system'.

The process audit provides assurance that the processes have been implemented as planned and provides information on the ability of the process to produce a quality output. Done properly, a process audit is much more than verification that processes are being followed. Although preparation can take a day or two, actual audit time is about two hours per shift.

A process is a set of interrelated activities that transform inputs, such as materials, customer requirements and labor, via a series of activities into outputs, such as a finished product or service. Various stages of the process must meet various applicable clauses of the standard. There are six characteristics to look out for when auditing a process:

1. Does the process have an owner?
2. Is the process defined?
3. Is the process documented?

4. Are links between other processes established?
5. Are processes and their links monitored?
6. Are records maintained?

As part of the process approach, the process audits must be scheduled according to the processes defined by your management system. The audit schedule should not be based on the clauses of the standard, but it should instead be based upon the importance and criticality of the process itself. The process approach to auditing should cover three vital stages:

1. Preparing for the audit; (desk review)
2. Auditing the process and its linkages;
3. Preparing the summary and audit report;

An audit of customer related processes should be conducted at planned intervals in order to determine whether the processes conform to planned arrangements in order to determine whether the process is properly implemented and maintained and to provide process performance information to top management.

Effective process auditing requires the auditor to identify and record audit trails that will make a difference to your organization. The audit should begin with the process owner in order to understand how the process interacts with the other process inputs, outputs, suppliers and/or customers.

The auditor should be able to determine whether the outputs are complete and that process measurements demonstrate whether all of the outputs

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Internal Audit Checklists

Part 1: Context of the Organization

Clause No.	Question No.	Audit Question	Audit Findings (Score '1' per box)				Audit Evidence	Opportunities for Improvement (OFI)
			Compliant	OFI	Minor N/C	Major N/C	Provide reference to documented information to justify the finding	Provide suggestions for process improvement
4.1	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 EQMS?						
4.1	2	Does your organization monitor and review information about these external and internal issues?						
4.2	3	Does your organisation determine the interested parties that are relevant to the EQMS?						
4.2	4	Does your organisation determine the requirements of these interested parties that are relevant to the EQMS?						
4.2	5	Does your organization monitor and review information about these interested parties and their relevant requirements?						
4.3	6	Does your organization determine the boundaries and applicability of the EQMS to establish its scope?						
4.3	7	When determining this scope, has your organization considered the external and internal issues referred to in 4.1?						

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Clause No.	Question No.	Audit Question	Audit Findings (Score '1' per box)				Audit Evidence	Opportunities for Improvement (OFI)
			Compliant	OFI	Minor N/C	Major N/C	Provide reference to documented information to justify the finding	Provide suggestions for process improvement
4.3	8	When determining this scope, has your organization considered the requirements of relevant interested parties referred to in 4.2?						
4.3	9	When determining this scope, has your organization considered the products and services of your organization?						
4.3	10	Has your organization applied all the requirements of this International Standard if they are applicable within the determined scope of its EQMS?						
4.3	11	Is the scope of your organization's EQMS available and maintained as documented information? (See 7.5.1a)						
4.3	12	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 EQMS?						
4.4.1	13	Has your organization established, implemented, maintained and continually improved an EQMS, including the processes needed and their interactions, in accordance with the requirements of ISO 14001:2015?						

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Audit Findings Summary

Manually transfer any adverse audit findings from the audit checklist in Part 1 into the audit findings summary table below. At the end of the audit, you can transfer the findings into an Excel spreadsheet to create charts, summary tables and trend data to paste into your audit report.

Clause ▶	4.1		4.2		4.3								4.4		4.4.1								4.4.2	
Question No. ▶	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Criteria ▼																								
OFI																								
MINOR N/C																								
MAJOR N/C																								