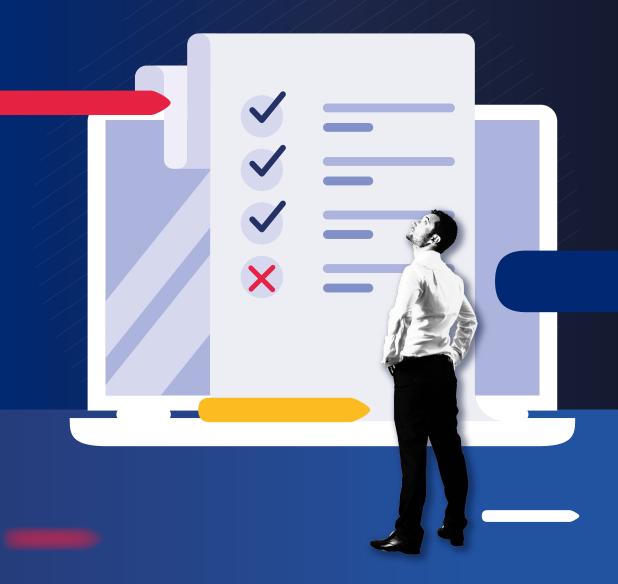


Process audit report



Guidance

Scoring criteria

The following audit scoring criteria have been used to identify the level of compliance with each requirement that is set out in the standard. In the ,Opportunities for Improvement' field, note down any situation or condition of the management system that may be weak, cumbersome, redundant, overly complex, or in some other manner, may, in the opinion of the auditor, offer an opportunity for the organization to improve its current status. In the 'Audit Evidence' field, fill in the evidence that you saw and your thoughts about the implementation and documentation. If any of the requirements are not applicable, please enter 'N/A' to denote that the particular requirement is not applicable to the organization.

Compliant	Yes, requirement fully documented and implemented. Adherence with the requirements of the standard or specification. No major or minor non-conformances found.
Opportunity for Improvement (OFI)	Minor gap, mostly documented and implemented The management system that may be weak, cumbersome, redundant, overly complex, or in some other manner, may, in the opinion of the auditor, offer an opportunity for an organization to improve its current status.
Minor Non-conformance	Requirement partially implemented but no documentation or partially documented but not implemented. A non-conformity that, based on the judgment and experience of the auditor, is not likely to result in the failure of the management system or reduce its ability to assure controlled processes or products. It may be either a failure in some part of the supplier's management system relative to a specified requirement or a single observed lapse in following one item of a company's management system.
Major Non-conformance	No provision, requirement not documented or implemented. The absence (omission, not addressed) or total breakdown (commission, failure, not implemented) of a system to meet a specified requirement. A number of minor non-conformities against one requirement can represent a total breakdown of the system and thus be considered a major non-conformity. Any non-compliance that would result in the probable shipment of a non-conforming product. Conditions that may result in the failure of or materially reduce the usability of the products or services for their intended purpose. A non-compliance that, in the judgment and experience of the auditor, is likely to either to result in the failure of the management system or to materially reduce its ability to assure controlled processes and products.

Requirements

An audit of customer related processes should be conducted at planned intervals in order to determine whether the process conforms 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 auditing requires the auditor to identify and record audit trails that will make a difference to the 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 are consistently fit for purpose and are efficiently managed. Do the customers agree with the outputs and the measures?

An audit of customer related processes is conducted at planned intervals to:

- Determine whether the process conforms to planned arrangements
- Determine whether the process is properly implemented and maintained
- Provide information on process performance to Top Management

Consider these points during the audit:

- Is there continuity between the various support processes?
- Is the task done consistently on a person-to-person or day-to-day basis?
- Do the interfaces between the departments operate smoothly?
- Does product information flow freely?
- Is the procedure right?
- Does it meet the requirements of the standard or specification?
- Is it helping the organization effectively?

Process audit turtle diagram



Equipment and facilities

- What equipment and resources are required?
- Is equipment suitable and properly maintained?
- Is the work environment maintained?
- Is there evidence of appropriate maintenance of all equipment used by this process?



Personnel

- What equipment and resources are required?
- · Review employee skill lists for the process. Are there lists of skills for each position? Do they show enough detail? This is often a finding, where lists are generic with inadequate detail. Training is a key process of any system.
- Are there particular skills you want to evaluate?



Control processes

- How is the process defined and who is responsible?
- How are customer requirements defined?
- What specifications apply defined?
- What objectives and targets apply process?
- What controls/check points are there?
- What acceptance criteria exist?



Process inputs

- What triggers the process?
- What inputs are required?
- Where do the inputs come from?
- Are they received in a timely manner?
- Are they fit for purpose?



Process name/description

- What steps are involved in the process?
- What happens at each step in the process?
- · What documents and records are generated?
- Is the process implemented in accordance with procedures, instructions or plans?
 - Are controls applied as described?



Process outputs

- What is the product produced by this process?
- Are product measures in place to ensure that product meets requirements?
- How are processes measured?
- Are product and process measures achieved?
- What feedback is received from customers?



Instructions and procedures

 Review the documents that describe and control the process. Review all the important steps and activities of the process being audited. This info must be documented within the QMS. Evaluate how effectively the process flows through the steps. Do you see roadblocks or issues?



Support process

• As you audit, you will see how it connects and interacts with other processes. Interactions with other processes are always important. As you audit the, you will see how it connects and interacts with other processes. Audit the relevant links to related processes and support processes.



Key performance indicators

 Review metrics and performance with Managers, Supervisors and operators. They should know how things are running, objectives, customer issues, problem areas. If they do not, the requirements were not met. Is there evidence that quality objectives and targets affected by this process are being achieved?



Audit checklist

Process definition

	question	Compliant	OFI	Minor M/C	Major M/C	Audit evidence Provide reference to documentation or records that justify the finding	Opportunities for Improvement (OFI) Provide suggestions for process improvement
1.	Is the process defined and documented?						
2.	Is the process owner identified? (Process map, procedure or work instruction, etc.)						
3.	Is there evidence that process inputs are accurately defined and understood by all employees involved?						
4.	Is there evidence that process activities are accurately defined and understood by all employees involved?						
5.	Is there evidence that process outputs are accurately defined and understood by all employees involved?						
6.	Are inputs defined and prioritized based on risk?						

Audit	question	Compliant	OFI	Minor M/C	Major M/C	Audit evidence Provide reference to documentation or records that justify the finding	Opportunities for Improvement (OFI) Provide suggestions for process improvement
7.	Have procedures, instructions, and forms been established as needed to control the process?						
8	Are procedures, instructions and forms used in controlling the process readily available?						
9	Do procedures, instructions and forms accurately reflect the practices? (Note: Requires the auditor review and observation!)						
10	Are there adequate plans in place to achieve the objectives?						
11	Is relevant customer feedback available? (Feedback from subsequent processes)						
12	Are documents understood by process participants?						
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Auditor signature:	Auditor name:	Date:
		DD / MM / YY

Process resources

Proc	ess resources	ı	ı	ı	ı	I	
Audit q	uestion	Compliant	OFI	Minor M/C	Major M/C	Audit evidence Provide reference to documentation or records that justify the finding	Opportunities for Improvement (OFI) Provide suggestions for process improvement
13.	Is there evidence of management commitment, involvement and allocation of resources?						
14.	How many people participate in the process, is this adequate to achieve process requirements?						
15.	Are participants adequately trained to carry out roles, responsibilities, and authorities?						
16.	Is equipment (e.g. manufacturing, measuring & monitoring equipment; transport/logistics; hardware/ software; PPE; etc.) adequate for its intended use?						
17.	Is equipment identified to allow participants to determine its readiness for safe use prior to and during the operation?						
18.	Are process owners accountable for the performance and compliance of their processes?						
19.	Are employees satisfied with their work area?						

Audit q	question	Compliant	OFI	Minor M/C	Major M/C	Audit evidence Provide reference to documentation or records that justify the finding	Opportunities for Improvement (OFI) Provide suggestions for process improvement
20.	Is the work area clean and safe?						
21.	Is there adequate equipment/ tools/IT support?						
22.	Are employees motivated and encouraged to make suggestions for process improvement?						
23.	Are all employees aware of the organizational objectives and the current status of these measurements?						
24.	Are all employees aware of who their customers are and whether they are satisfied?						
25.	Are employees aware of the process metrics which their activities can affect?						
26.	Are they aware of the current data analysis related to these metrics and the plans in place to achieve them?						

Auditor signature:	Auditor name:	Date:
		DD / MM / YY

Process execution

Proc	ess execution	I	L	ı	I	I	I
Audit q	uestion	Compliant	OFI	Minor M/C	Major M/C	Audit evidence Provide reference to documentation or records that justify the finding	Opportunities for Improvement (OFI) Provide suggestions for process improvement
27.	Is the observed process activity consistent with approved plans and procedures?						
28.	Is the process flow constructed to avoid unnecessary movement of materials and personnel?						
29.	Are redundant and non-value adding activities minimized?						
30.	Is material usage maximized to avoid waste?						
31.	Is waste material effectively removed and segregated from the process?						
32.	Are unused materials returned to the correct location in conditions suitable to allow re-use?						
33.	Are process outputs passed on to subsequent processes only when all planned process activities are completed?						

Audit q	uestion	Compliant	OFI	Minor M/C	Major M/C	Audit evidence Provide reference to documentation or records that justify the finding	Opportunities for Improvement (OFI) Provide suggestions for process improvement
34.	Is there evidence of continuity between the various support processes?						
35.	Do the interfaces between the departments operate smoothly?						
36.	Does product information flow freely between the support processes?						
37.	Is there evidence for the reduction in measurement system and process variation?						

Auditor signature:	Auditor name:	Date:
		DD / MM / YY

Process monitoring

Proc	ess monitoring	I	I		l	I	
Audit q	uestion	Compliant	OFI	Minor M/C	Major M/C	Audit evidence Provide reference to documentation or records that justify the finding	Opportunities for Improvement (OFI) Provide suggestions for process improvement
38.	Is the process monitored, measured, analyzed and improved?						
39.	Are monitoring activities carried out according to approved plans and procedures?						
40.	Is process monitoring compared against standards to determine the current status of the process?						
41.	Is process status communicated to appropriate members of the process team?						
42.	Are records of process monitoring maintained according to approved procedures?						
43.	Have key performance indicators (KPI) been established to allow the effectiveness of the process to be evaluated?						
44.	Are KPI consistent with quality and business objectives?						

Audit q	uestion	Compliant	OFI	Minor M/C	Major M/C	Audit evidence Provide reference to documentation or records that justify the finding	Opportunities for Improvement (OFI) Provide suggestions for process improvement
45.	Are KPI consistent with customer requirements?						
46.	Are KPI reviewed and communicated to the process team, as appropriate, by process leaders?						
47 .	Is the process measured for effectiveness and efficiency?						
48.	When a process is not performing, is there evidence of data analysis to determine the root cause?						
49.	When a process is not performing, is there evidence that the cause(s) are dealt with in accordance with procedure?						
50.	When a process is not performing, is there evidence that the cause(s) are dealt with in accordance with procedure?						

Auditor signature:	Auditor name:	Date:	
		DD / MM / YY	

Process improvement

Proc	Process improvement						
Audit q	uestion	Compliant	OFI	Minor M/C	Major M/C	Audit evidence Provide reference to documentation or records that justify the finding	Opportunities for Improvement (OFI) Provide suggestions for process improvement
51.	Is the performance of the process reviewed at an appropriate frequency by top management?						
52.	Are process improvement objectives aligned with organizational objectives, e.g. the business plan?						
53.	Is there evidence of an effective PDCA cycle?						
54.	Can the process owner demonstrate how PDCA applies to their process?						
55.	Can the process owner to show examples of improvements driven by their PDCA cycle?						
56.	Can employees demonstrate areas of previous continual improvement?						
57.	Are records of process upsets and actions taken reviewed to determine the need for corrective/preventive action?						

Audit question		Compliant	OFI	Minor M/C	Major M/C	Audit evidence Provide reference to documentation or records that justify the finding	Opportunities for Improvement (OFI) Provide suggestions for process improvement
58.	Where corrective/preventive actions have been implemented, have the action(s) taken been demonstrated as effective?						
59.	Where opportunities for improvement have been implemented, have the action(s) taken been demonstrated as effective?						
60.	Are all process participants encouraged to be involved in identifying improvements?						

Auditor signature:	Auditor name:	Date:
		DD / MM / YY

Findings summary

Non-conformance

Question No.	ISO/Specification Ref.	Summary	Root Cause	NCR No.	Rectification Date
					DD / MM / YY
					DD / MM / YY
					DD / MM / YY

Corrective action

Question No.	ISO/Specification Ref.	Summary	Root Cause	NCR No.	Rectification Date
					DD / MM / YY
					DD / MM / YY
					DD / MM / YY

Preventive action and OFI

Question No.	ISO/Specification Ref.	Summary	Root Cause	NCR No.	Rectification Date
					DD / MM / YY
					DD / MM / YY
					DD / MM / YY

Observations

Comments and notes



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