[Organization logo]

[Organization name]

Commented [16A1]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR INTERNAL AUDIT

Commented [16A2]: If you want to find out more about internal audit, see:

13 Steps for IATF 16949:2016 Internal Auditing using ISO 19011
http://advisera.com/16949academy/knowledgebase/13-steps-for-iso-16949-internal-auditing-using-iso-19011/

Commented [16A3]: Adapt to the existing practice in organization.

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Version:	0.1
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	0.1	16949Academy	Basic document outline

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1. Purpose, scope and users

The purpose of this procedure is to describe all audit-related activities: writing the audit program, selecting an auditor, conducting individual audits and reporting.

The Internal Audit determines if the QMS is effectively implemented and maintained. Internal audits use a process approach and verify compliance to IATF 16949 and customer-specific requirements.

This procedure is applied to all processes and/or areas (parts of the organization) within the QMS.

Users of this document are [members of top management] of [organization name], as well as internal auditors.

2. Reference documents

- IATF 16949:2016 standard, clauses 7.2.3 and 9.2.
- Quality Manual
- Procedure for Nonconformities and Corrective Action

3. Conducting of internal audit

3.1. Types of audits

[Organization name] performs 3 types of audits:

- Quality management system audit
- [illegible]
- [illegible]

The purpose of the internal QMS audit is to determine:

- [illegible]
- [illegible]

The purpose of the manufacturing process audit is to determine:

- Effectiveness and efficiency of the manufacturing process
- [illegible]
- [illegible]

[illegible]

- Product conformity to requirements at different stages (including delivery)

- Product safety requirements

3.2. Internal audit planning

[Job title] approves an annual program for internal audits. This takes into consideration the status and importance of the process and/or areas (part of the organization) that is audited. It also considers the risks and criticality of processes, as well as results of previous audits. The annual audit program schedules each QMS process to be audited at least once within a three year period. Internal audits are usually conducted before management reviews, and the audit program must cover the entire QMS, and all process and products.

Additional internal audits may be conducted in the case of:

- Significant reclamation from client (decision about whether the reclamation is significant and requires additional audit is made by [job title])
- Significant non conformity in process or repetition of the same non conformity (decision about whether the conformity is significant and requires additional audit is made by [job title])
- Significant change in system, in process and products - the decision about whether the change in system is significant and demands additional audit is made by [job title]
- Increased risks or criticalities within the processes, unsatisfactory internal and external performance trends of the QMS processes, production process and products.

[Job title] is responsible for planning the internal audit, reporting the results of internal audits and maintaining records. When planning the internal audit, [job title] must consider results from previous audits, importance of the processes, and changes affecting the organization.

3.3. Appointing internal auditors

[Job title] appoints internal auditors and a leader of the auditor team (if there are more internal auditors) from a List of Qualified Internal Auditors.

An internal auditor may be someone from the organization or a person outside the organization. Criteria for appointing internal auditors are:

- Knowledge of principles of auditing
- Possession of general knowledge for specific areas of an audit
- Knowledge of standards ISO 19011 and IATF 16949, other standards and/or norms related to process audits
- Necessary competence – achieved through education and/or experience
- Understanding of process approach and risk based thinking
- Understanding the customer-specific requirements regarding audited product, process and/or system
- Experience and knowledge of core tools applicable to audited process
- Experience and knowledge in audit reporting

- Understanding of product-process related documents for process auditors (P FMEA, D FMEA, Control Plan.)
- [illegible]

Training records are retained by [organization name]'s HR department according to the Procedure [illegible] related documents.

Commented [16A5]: Adapt here to your organization internal rules.

Internal auditors must be selected in such a way as to ensure objectivity and impartiality (i.e. to avoid [illegible] internal auditors into the List of Qualified Internal Auditors.

3.4. Conducting individual internal audits

The team leader and/or members of the auditor team defines criteria, audit scope and methods of audit.

[illegible]

- Document audit
- [illegible]

Commented [16A6]: Audit of all documents related to standard ISO 9001 and identified processes in organization.

Commented [16A7]: Audit that shows whether the processes are executed in accordance with corresponding procedure.

Criteria of the audit can be compliant with IATF 16949:2016 and/or aligned with legal requirements and previously agreed-upon requirements of external parties.

Methods of internal audit that will be applied during the internal audit are [write in the methods]. [illegible]

Commented [16A8]: E.g. vertical check (by hierarchical levels of QMS documents) and horizontal check (by processes, backwards and forwards) or other methods that organization establishes.

A checklist for an internal audit can be used for conducting the internal audit according to audit type/level.

Manufacturing process audits are performed by the audit team, using a customer-specific approach [illegible] Checklist.

Commented [16A9]: For example, it can be VDA 6.3 manufacturing process audit, FIEV.

3.5. Internal audit reporting

On the basis of the audit findings, the internal auditor (or internal audit team leader if there are more [illegible]

[illegible]

- Non-conformities (major and/or minor) that require corrective actions,
- [illegible]
- [illegible]

- Any areas within the audit scope that are not covered
- Recommendations for improvement of the QMS.

[illegible]

Results of the manufacturing process audit are recorded by [job title] in the Manufacturing Process Audit Checklist.

[illegible] in the Product Audit Checklist.

The effectiveness of the internal audit process is presented in management review as input by a [illegible]

3.6. Follow-up activities

The owner of the process in which the non-conformities are identified must ensure that all necessary [illegible]

Corrective actions are undertaken without undue delay, according to the Procedure for Nonconformities and Corrective Actions.

[illegible] Procedure for Nonconformities and Corrective Actions in order to assess the effectiveness or verification of corrective actions.

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Internal Audit Program	19.1	2 years	[office of [job title]]	[job title]
Internal QMS Audit Checklist	19.2	2 years	[office of [job title]]	[job title]
Manufacturing Process Audit Checklist	19.3	Product end of life + n years	[office of [job title]]	[job title]

Commented [16A10]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

Commented [16A11]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

Product Audit Checklist	19.4	Product end of life + n years	[office of [job title]]	[job title]
Second Party Audit Checklist	19.5	Product end of life + n years	[office of [job title]]	[job title]
Internal Audit Report for QMS Audits	19.6	2 years	[office of [job title]]	[job title]
List of Qualified Internal Auditors	19.7	2 years	[office of [job title]]	[job title]

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Commented [16A13]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

Only [job title] can grant other employees the right to access the Internal Audit Program, the Internal Audit Report and the Internal Audit Checklist.

5. Appendices

- Appendix 1 – Internal Audit Program
- Appendix 2 – Internal QMS Audit Checklist
- Appendix 3 – Manufacturing Process Audit Checklist
- Appendix 4 – Product Audit Checklist
- Appendix 5 – Second Party Audit Checklist
- Appendix 6 – Internal Audit Report for QMS Audits
- Appendix 7 – List of Qualified Internal Auditors