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Management of Corrective and Preventive Actions

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Annotation: This article discusses the requirements of international and organizational standards for the correction, identification and prevention of inconsistencies identified in audits of management systems.

Key words: ISO 9000: 2015, ISO 14000: 2015, ISO 17025: 2017, ISO 22000: 2018, ISO 50001: 2018 and IATF 16949: 2016, defect, inconsistency, correction, corrective and preventive measures, root cause.

Timely identification and implementation of non-compliance and corrective, corrective and preventive measures to eliminate the root cause will allow the organization to develop competitive products. In order to achieve efficiency and effectiveness, it is important to identify the steps of corrective or preventive measures, the root causes of inconsistencies, to eliminate and prevent them. The international standard ISO 9000: 2015 defines corrective and preventive measures as follows:

3.12.1 Preventive action - actions taken to eliminate the causes of possible non-compliance (3.6.9) or other possible adverse events.

3.12.2 Corrective action is the action taken to eliminate the cause of a nonconformity (3.6.9) and to prevent its recurrence.

The international standard ISO 9001: 2015 sets the following requirements for the management of corrective and preventive measures:

10.2 Non-compliance and corrective action

10.2.1 The organization should be aware of any inconsistencies, including those identified in all of the objections:

a) elimination of inconsistencies, as well as the type to which it corresponds:

1) implementation of measures to manage and correct non-compliance;

2) implementation of measures against the consequences of non-compliance;

(b) Evaluate the necessary measures to eliminate the cause of the discrepancy on the basis of the following, to ensure that they do not recur or occur elsewhere:

1) inconsistency analysis;

2) finding the root causes of the discrepancy;

3) identify where and where similar inconsistencies exist or are likely to occur;

c) take all necessary measures;

d) analysis of the effectiveness of each corrective action taken;

e) identifying, if necessary, the risks and opportunities identified during the planning process;

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f) make changes to the quality management system as necessary.

Corrective measures should be appropriate to the degree of inconsistency identified.

10.2.2 The organization shall keep the documented information that serves as a witness:

a) a description of the nonconformity and all related measures;

b) results of all corrective measures.

One of the important goals of quality management systems is to apply methods to prevent the organization from operating tasks. Therefore, the ISO 9001: 2015 standard does not specify the quality of preventive measures as a separate section or band. The concept of preventive measures is characterized by the use of risk-oriented thinking in making demands on the quality management system. The concept of risk-oriented thinking is not explicitly stated in the previous version of the international standard ISO 9001: 2015, for example, in requirements, planning, analysis and improvements. This international standard sets out the requirements by which an organization defines its contextual concept (see environment in which its task is performed) and the quality of key requirements in risk identification planning (see 6.1). This reflects the application of risk-oriented thinking to the planning and implementation of processes in a quality management system (see 4.4) and helps to determine the amount of documented data.

The IATF 16949: 2016 International Standard for Automotive Quality Management Systems sets out the following requirements for preventive measures:

6.1.2.2 Precautions.The organization should identify and implement the causes of nonconformities and measures to address them. The precautionary measure should be appropriate to the significance of the potential problem (eliminating the root cause). The organization should develop a process to reduce the impact of adverse risks, including the following asp6.1.2.2 Precautions. The organization should identify and implement the causes of nonconformities and measures to address them. The precautionary measure should be appropriate to the significance of the potential problem (eliminating the root cause). The organization should develop a process to reduce the impact of adverse risks, including the following aspects:

a) identification of possible discrepancies and their causes;

b) assessment of necessary measures for possible inconsistencies;

c) identification and implementation of necessary measures;

d) documenting information on measures;

f) apply the accumulated experiments to similar processes to avoid duplication (see ISO 9001, 7.1.6).

The international standard ISO 14001: 2015 Environmental Management System states that corrective and preventive measures are aimed at environmental policy and must comply with the requirements of the corrective and preventive measures of the international standard ISO 9001: 2015.The ISO 50001: 2018 Energy Management System does not require any additional corrective and preventive measures from the international standard ISO 9001: 2015. This means that it is sufficient to comply with the corrective and preventive measures set by ISO 9001: 2015 in accordance with ISO 50001: 2018.The basic structure of ISO 50001 is similar to other management system standards and therefore it is easy to integrate into existing management systems in accordance with ISO 9001 or ISO 14001. This allows organizations to benefit from energy and apply common requirements in a common way. ISO 22000: 2018 International Standard for Food Safety Management Systems The following additions have been made to the corrective and preventive measures set by ISO 9001: 2015:

8.9.3 Corrective measures

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The application of necessary corrective measures should be evaluated in cases where the CSR-critical control points are out of bounds and / or within the limits set by the OPRP-initial environment management program. In order to prevent the recurrence of non-compliance and to return the process to a manageable state after non-compliance is identified, the organization should identify the cause of the non-compliance and take appropriate action to create a documented record and keep it in working condition.

These actions should include:

a) whether the nonconformity analysis is identified in the customer or end consumer complaint or in the report of the controlling organization;

b) analysis of trends in monitoring results, which could lead to loss of management;

c) identification of reasons for non-compliance (s);

d) identify and take action to ensure that inconsistencies are not repeated;

e) documenting the results of corrective action taken;

f) verification of corrective measures taken to confirm their effectiveness.

The organization should maintain documented information on all corrective actions.

ISO 17025: 2017 General requirements for the competence of testing and calibration laboratories International standard 7.10 Non-compliant work management clause: 7.10.3 When the assessment of non-compliant work shows its recurrence or the laboratory doubts the adequacy of its management activities, corrective measures should be taken.

The organization should develop, implement and ensure the validity of documents in identifying existing and potential inconsistencies and implementing corrective and preventive measures to address the root causes.An organizational standard for the automotive industry has been developed in accordance with the management requirements of corrective and preventive measures set by the above international standards, and it includes the following procedure: acts:

CORRECTIVE AND PREVENTIVE MEASURES MANAGEMENT

1. Purpose

This standard establishes the procedure for identifying and implementing corrective, corrective, and preventive measures. In achieving effectiveness, the focus is on identifying the steps of corrective and preventive measures, eliminating and preventing the causes of inconsistencies.

2. Scope of application

This standard applies to all inconsistencies identified in quality management system (SMT) processes. This standard must be applied by all departments / processes / processes of the enterprise.

3. Normative sources

3.1 Ц 22838117-02: 2019 Document management

3.2 Ц 22838117-03: 2019 Records Management

3.3 Ts 22838117-04: 2019 Incompatible product management

3.4 Ts 22838117-05: 2019 Internal Audit Management

4. Terms and definitions

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4.1 Non-compliance - non-compliance with the requirements set by internal enterprise documents, or external standards ISO 9001, ISO 17025, ISO 50001 and IATF 16949, laws and regulations.

4.2 Correction is an action taken to eliminate a identified discrepancy.

4.3 Corrective action is an action taken to eliminate the cause of a identified nonconformity or other adverse event.

4.4 Preventive measures are preventive actions aimed at eliminating the cause of non-compliance or other adverse events that may occur.

4.5 Consumer complaint - a consumer's dissatisfaction with non-compliance by the enterprise with the requirements for product quality or the terms of the contract.

5. Responsibilities and rights

5.1 Enterprise Manager

- Analysis of the activities of the SMT, ensuring the effectiveness of corrective and preventive measures;
- Carrying out continuous improvement work at the enterprise.

5.2 Quality Management System (SMT) Management Manager

- ensure the effectiveness of corrective and preventive measures;
- report the level of implementation of corrective and preventive measures to senior management for analysis.

5.3 Department / shop / process managers

- Ensuring the timely development and implementation of corrective and preventive measures; -analyze corrective and preventive measures and improve activities based on them; - Eliminate the causes of inconsistencies.

5.4 Auditors - fair assessment of non-compliance; -recommendations in the development of corrective and preventive measures; -improve their knowledge and skills.

6. Job content

6.1 Detection and recording of discrepancies

6.1.1 Inconsistencies or possible inconsistencies may be identified as a result of:

- analysis of quality policy and implementation of objectives;
- conducting internal and external audits;
- Evaluation of the activities of processes and their effectiveness;
- analysis of risks and opportunities;
- analysis of used documents and records;
- analysis of suggestions and objections from consumers and other stakeholders.

6.1.2 All identified risks and opportunities (each process owner in Annex 1), as well as corrective and preventive measures for non-conformities, shall be completed by department / shop / process managers and responsible personnel in accordance with Annex 2. Reports of non-compliance identified in all audits or other inspections shall be recorded in the logbook by process officials in accordance with Annex 3.

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6.1.3 Elimination of discrepancies identified as a result of the audit shall be carried out by the auditors in accordance with Annex 2.

6.1.4 Proposals, objections, demands, etc. received by the consumer and other stakeholders are received by the sales department and submitted to the quality control department for review and elimination. Their review and elimination by the relevant department / shop / process officials will be carried out in accordance with Annex 4.

6.1.5 Identified discrepancies are included in the results of the analysis of the SMT activities of process managers and appropriate decisions are made on the corrections.

6.1.6 Management of non-compliant raw materials, materials and products is carried out in accordance with the requirements of the standard "Management of non-compliant products" (Ts 22838117-04: 2019).

6.2 Analysis of inconsistencies and identify their causes.

6.2.1 All registered risks (opportunities) and opportunities, as well as non-conformities listed (in paragraph 6.1) should be analyzed to determine the extent of impact on SMT.

6.2.2 The department / process / process managers who identified the discrepancy should identify the causes of the discrepancy and take corrective, corrective and preventive measures.

6.2.3 Suggestions and objections received by the Consumer and others shall be analyzed by the relevant officials. The identification and elimination of appropriate corrective and preventive measures shall be carried out in accordance with Annex 4 and shall be registered by the responsible officer of the Quality Control Department in accordance with Annex 5.

6.2.4 Suggestions and objections received from the consumer must be answered in writing or orally by the responsible staff.

6.2.5 From the Consumer

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