

QUALITY Management System

ISO 9001

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Change history

Version	Author	Description
Current Issue - 1 dated 1 st JAN 2019	Sumit Dey	Initial issue

1 QMS- ISO 9001

1.1 Introduction

In this highly competitive world, every organisation wants to get associated with partners who are consistent in their performance and are keen to drive continual improvement to become trustworthy brand in the market. To be successful organisation in this era of Globalisation, business managers must understand their customers' requirements, then manage internal processes to fulfil those requirements in effective and efficient manner to meet customer satisfaction. To achieve this goal, Quality management system implementation is very effective

ISO 9001 - The Quality management system standard ISO 9001 is an internationally recognized standard, enables any company to achieve greater consistency in the activities involved in providing products or services, increase efficiency by improving use of time and resources, helps organisation to remain resilient and achieve sustainable growth. Thus, overall improve customer satisfaction.

1.2 Benefits

1. Promotes consistency in delivering products or services.
2. QMS certification helps Organizations in improving and monitoring all areas of their business.
3. Better internal management
4. Increase in efficiency, productivity and profit
5. Improved customer retention and acquisition
6. Suitable for both small and large organisations

1.3 Why Cotecna

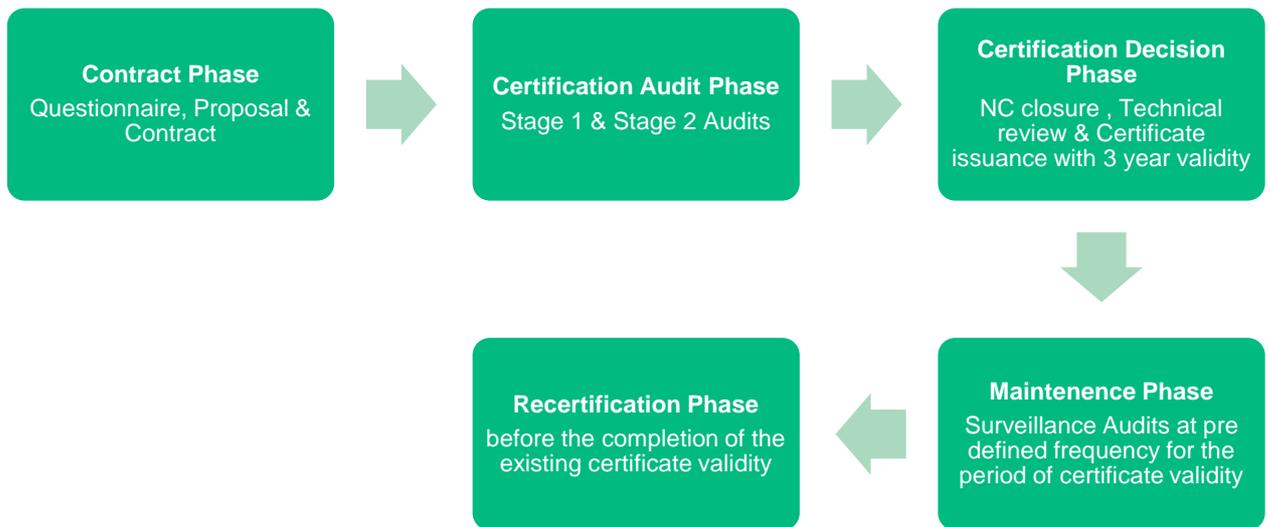
Swiss group founded in 1974. Extended network of over 100 offices & laboratories in 50 countries. The Group offers services to both governmental and commercial organizations. Cotecna is one of the world's leading testing, inspection and certification companies. Cotecna Inspection India Pvt Ltd has experienced experts on Quality management aspects and experienced auditor with multiple competency to provide one umbrella solution. COTECNA India can help an organisation as below

- Provides comprehensive training on all aspects of QMS
- Performs pre-assessment which helps the Organisation to understand their best route to certification
- Conducts the entire certification process to ensure compliance with Quality Management system standard.

1.4 Important Links

<https://www.iso.org/standard/62085.html>

1.5 Certification Process- ISO 9001



1.6 Application Process

To get Application / Questionnaire please contact indiacertification@cotecna.co.in

1.7 Audit

Opening meeting – Evaluation of the documentation – Site assessment and interviews of employees – Creation of the audit conclusions, Closing meeting

Initial Certification Audit is two stages of audit both Onsite, Stage-1 & Stage -2.

The Stage 1 audit, verifies that the system has been designed and developed in accordance with the organization's top management commitment to conform with Scheme requirements. The objective of this audit is to assess the preparedness of the applicant organization to proceed to the stage 2 audit.

The Stage 2 audit substantiates top management's claim by auditing implementation of the Quality management system. The activities subject to the proposed certification scopes shall be assessed during the initial certification audit. Once the gaps / deviation, identified during Stage-1 audit is satisfactory addressed by Audit site management - Stage -2 audit can be processed

Follow-up Audits (minimum annual surveillance) during the certification period to verify maintenance and continuous improvement will be conducted

1.8 Non-Conformity

Minor non-conformity - A minor non-conformity shall be issued when the finding does not affect the capability of the management system to achieve the intended results:

- 1) When a minor nonconformity is issued during an audit, the organization must provide the CB with objective evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan (CAP) within three (3) months after the audit.
- 2) Corrective action (CA) shall be implemented by the organization within 12 months after the audit.
- 3) The CB shall review the design of the corrective action plan, challenge it and approve it when acceptable.
- 4) Implementation of the corrective action plan shall be reviewed, at the latest, at the next scheduled on-site audit. The CB shall review the corrective action plan and determine its effectiveness of implementation
- 5) A major nonconformity is raised (on management responsibility and resource allocation) in the event of non-completion of the approved action plan at the next scheduled on-site audit.

Major nonconformity - A major nonconformity shall be issued when the finding affects the capability of the management system to achieve the intended results:

- 1) When a major nonconformity is issued during an audit, the organization must provide the CB with objective evidence of an investigation into causative factors, exposed risks and the proposed CAP. This shall be provided to the CB within 90 days after the audit.
- 2) Corrective action shall be implemented by the organization within 90 days after the audit. The major nonconformity shall be closed by the CB within a further 90 days after implementation of the corrective action by the organization. The organization shall submit objective evidence of implementation to the CB.
- 3) The CB shall review the corrective action plan and related objective evidence of implementation, challenge it if necessary and determine its effectiveness and approve the CAP and CA
- 4) The CB shall conduct a follow-up audit to verify the implementation of the CA to close the major nonconformity. In cases where documentary evidence is sufficient to close out the major nonconformity, the CB may decide to perform a desk review.
- 5) The completion of corrective actions might take more time depending on the potential severity of the major nonconformity and the amount of work necessary to eliminate the causative factors. In such cases the CAP shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented. A follow-up audit shall be conducted to verify the permanent corrective action and to close the major nonconformity.
- 6) A Major nonconformity is raised in the event of non-completion of the approved corrective action.

1.9 Transfer of Certification

Transfer of certification is done when the certification being transferred is in good standing, the certificate is valid and will be valid at the time of audit, all previous audits have been conducted at the appropriate intervals, there are no outstanding Major CARs and the scope remains the same. Copies of these documents shall be submitted with the proposal acceptance for further review and process