Doc. No. DIC-SLM/QM/01



## DEPARTMENT OF INDUSTRIES AND COMMERCE

OFFICE OF THE
DISTRICT INDUSTRIES CENTRE,
SIDCO INDUSTRIAL ESTATE,
FIVE ROADS,
SALEM – 636 004.

**QUALITY MANUAL** 

## **QUALITY MANAGEMENT SYSTEM**

As per

IS / ISO 9001:2015

Issue no. 01 Revision Status:00, Date: 31.12.2020

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### 0.1 ISSUE & APPROVAL

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Doc. Name : Quality Management System Manual

 Doc. No.
 : DIC/QM/01

 Issue No.& Date
 : 01 / 31.12.2020

 Rev. No. & Date
 : 00 / 00-00-0000

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#### **PREFACE**

This QMS Manual describes the quality management system followed in District Industries Centre, Salem. This is developed to provide information to interested parties as well as guidance to all members of the organization. This First Issue is released for implementation on 31.12.2020.

This manual is a non-confidential, auditable document released with the approval and authorization of the General Manager, District Industries Centre. This manual is a property of Department of Industries and Commerce, and no extract may be reproduced, stored in a retrieval system or transmitted in any form or by any means – electronic, photo copying, recording or otherwise – without prior permission from the *Management Representative*.

#### **ISSUE & REVISION HISTORY**

#### **REVISION HISTORY:**

Clause No:	Rev. No.	Rev. Dt.	Description
All	00	_	NA

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**ORGANIZATION PROFILE: ABOUT US** 

### **VISION**

The District Industries Centre, Salem is functioning for the development of Industries in general and Micro, Small and Medium Enterprises in the Salem district.

#### **MISSION**

District Industries Centre, Salem give support facilities for starting and sustaining industrial enterprises by providing a variety of escort services to the MSMEs like identification of viable activities, preparation of project profiles, obtaining financial assistance from various banks/financial institutions and statutory clearances through Single Window Clearances from Government Departments and sanction and disbursement of eligible subsidies.

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#### MANAGEMENT REPRESENTATIVE

### **TO ALL CONCERNED**

**Management Representative is** appointed for the organization (hereinafter may be referred as 'MR', in this Manual, it's supporting Procedures, Work instructions, Plans, Formats etc...) **with effect from 21.12.2020**.

GM is responsible for ensuring the establishment, implementation review of the performance and maintenance of QMS in accordance with IS / ISO 9001:2015 standard and reporting to the Top Management.

MR's responsibilities will include: liaison with external parties on matters relating to the system.

#### **MANUAL IDENTIFICATION & DISTRIBUTION**

The manual is structured as per the IS / ISO 9001:2015 international standard and is identified by the relevant clause numbers.

The master and controlled copies of this manual are distributed as per this list with understanding that it is maintained in good condition and is controlled.

The General Manager, District Industries Centre, Salem approve this manual. It is issued and controlled by the MR. Any change to the manual is properly documented and is approved by the General Manager, District Industries Centre, Salem.

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# QUALITY MANAGEMENT SYSTEM MANUAL DISTRIBUTION LIST

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1.	General Manager	1
2.	Manager (Materials)	2
3.	Project Manager	3
4.	Assistant Director (Industrial Co-Operative)	4
5.	Office Manager	5
6.	Management Representative / Manager (Material) (Master copy)	6

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#### 1. SCOPE

#### 1.1 General

The quality management system detailed in this manual is established, documented, implemented and maintained to ensure that all operations and activities related with entrepreneurial development are carried out at the Department, conforms to the requirements of IS / ISO 9001:2015 international standard.

- a) This manual is developed to demonstrate the ability & commitment of the organization to:
  - consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
  - enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements
- b) This manual is applicable to all the activities carried out by the organization and applies to the Quality aspects of its activities, products and services to systematically improve its quality Management.

### Scope as per IS/ISO 9001:2015:

The District Industries Centre, Salem providing services to the customers like escort services for Single Window Clearance and incentives for the development of micro, small and medium enterprises and industrial co-operatives in Salem District.

Non-applicable clause: Clause 8.3 – Design and Development

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Abbreviations:-	
DIC-SLM	District Industries Centre, Salem
IS / ISO	International Organization for Standardization
QSM	Quality System Manual
QPM	Quality Procedure Manual
WI	Work Instructions
QP	Quality Plan
Rev.	Revision
Doc.	Document
MR	Management Representative
MRM	Management Review Meeting
MRC	Management Review Committee
IQC	Internal Quality Audit
PD	Production
QC	Quality Control
PS	Purchase & Store
MT	Maintenance
P&A	Personnel & administration
PR	Procurement

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### 4.0 CONTEXT OF THE ORGANIZATION

### 4.1 Understanding the organization and its context

The DIC-SLM has determined external and internal issues that are relevant to the purpose and strategic direction and that affect the ability to achieve the intended results of the DIC's quality management system.

The DIC-SLM implemented proper system to monitor and review information about these external and internal issues.

Issues identified and are include positive and negative factors or conditions for consideration.

The external issues may include; issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

The internal issues for consideration may include; issues related to values, culture, knowledge and performance of the DIC-SLM.

**Ref: Operations Manual** 

## 4.2 Understanding the needs and expectations of interested parties

The DIC has determined the interested parties that are relevant to the quality management system

- a) The interested parties that are relevant to the quality management system are; and may include:
  - 1. The Customer
  - 2. The Employees
  - 3. External Providers including Suppliers, Service providers, etc....
  - 4. The Statutory / regulatory authorities.
  - 5. Financial providers / insurers.
  - 6. The Public / Society / Environment.
  - 7. The Stake holders.
- b) The requirements (needs & expectations) of these interested parties that are relevant to the quality management system are determined and are monitored and reviewed for competence during the management review.

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## 4.3 Determining the scope of the quality management system

The DIC-SLM has determined the boundaries and applicability of the quality management system while establishing the scope.

The DIC-SLM has considered the following while determining its scope:

- a) the external and internal issues referred to in clause 4.1 above;
- b) the requirements of relevant interested parties referred to in clause 4.2 above;
- c) the products and services of the organization

All the activities, products and services of the DIC-SLM are included in to the scope the quality management system and provided proper justification for requirements of this International Standard that are not applicable to the scope of its quality management system.

This QMS manual applies to the following activities.

## The scope of quality management system:

The District Industries Centre, Salem providing facilities to the Entrepreneur like escort services for Single Window Clearance and subsidies and incentives for the development of micro, small and medium enterprises and industrial co-operatives in Salem District.

## **Exclusions / Non-Applicability to the Standard requirements:**

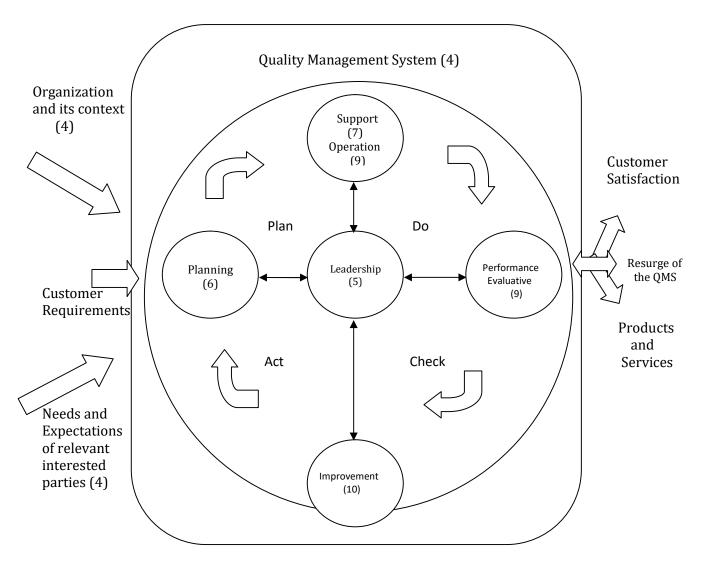
**Clause 8.3:** Design and Development is excluded from the scope of the Quality Management System, as no such activity is being performed in the Department of Industries and Commerce as per national / international standards.

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# 4.4 Quality management system and its processes

3.4.1The DIC-SLM has established, implemented, maintained and continually improves the quality management system, including the processes needed and their interactions, in accordance with the requirements of the IS / ISO 9001:2015 International Standard.



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The DIC – SLM has determined the processes needed for the quality management system and their application throughout the DIC- SLM, in order to achieve this DIC-SLM has:

- a) determined the inputs required and the outputs expected from the QMS processes;
- b) determined the sequence and interaction of these processes;
- determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) determined the resources needed for these processes and ensure their availability;
- e) assigned the responsibilities and authorities for each of the processes;
- f) addressed the risks and opportunities as determined in accordance with the requirements of clause 6.1 below;
- g) determined proper mechanism to evaluate these processes and implement any changes needed to ensure that QMS processes achieve their intended results;
- h) continually taken appropriate actions to improved the processes and the quality management system

## 4.4.2 To the extent necessary, as determined, the DIC-SLM:

- a) maintained documented information to support the operation of its processes;
- b) Retained documented information to have confidence that the processes are being carried out as planned.

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#### 5.0 LEADERSHIP

## 5.1 Leadership and Commitment

- 5.1.1 Top management has demonstrated the leadership and commitment with respect to the quality management system by:
  - a) taking accountability for the effectiveness of the quality management system;
  - b) ensuring that the quality policy and quality objectives are established and are compatible with the strategic direction and the context of the organization;
  - c) ensuring the integration of the quality management system requirements into the organization's business processes;
  - d) promoting the use of the process approach and risk-based thinking;
  - e) ensuring that the resources needed for the quality management system are available;
  - f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
  - g) ensuring that the quality management system achieves its intended results;
  - h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
  - i) promoting continual improvement;
  - j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

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#### **5.1.2 Customer Focus**

Top management has demonstrated leadership and commitment with respect to customer focus by ensuring that:

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained. Ref: Operations Manual

#### **5.2 POLICY**

## **5.2.1 Establishing the quality policy**

Top management has established, implemented and maintained the quality policy that, within the defined scope of quality management system:

While defining the QMS policy, it is ensured that, the policy;

- a) is appropriate to the purpose and context of the organization, and supports its strategic direction;
- b) provides a framework for setting quality objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) Includes a commitment to continual improvement of the quality management system.

### **QUALITY POLICY**

DIC-SLM has committed to achieve excellence in promulgation and implementation of various schemes for the accelerated cum prevalent Industrial Development in the Salem District by providing prompt services to the satisfaction of its Entrepreneurs.

It is also committed to lay down measurable standards for entrepreneur service and constantly improve its Quality Management System by the full involvement of the personnel at all levels and also meeting all the requirements.

DIC-SLM strived to execute timely delivery of decisions with due maintenance of hierarchy in a disciplined environment under proper review of performance and also meeting all the requirements of the Customer by continual improvement of the QMS and conforming to the standards and previling codes of practice. Ref: Operations Manual

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## 5.2.2 Communicating the quality policy

It is ensured by the management that the policy has been communicated to all levels of employees within the organization and is displayed in all the required places for information to interested parties.

## 5.3 Organization Roles, Responsibilities and Authorities

The Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management has properly assigned the responsibility and authority to:

- a) ensure that the quality management system conforms to the requirements of the IS / ISO 9001:2015 International Standard;
- b) ensuring that the processes are delivering their intended outputs;
- c) reporting on the performance of the quality management system and on opportunities for improvement (see clause 10.1 below), in particular to top management;
- d) ensuring the promotion of customer focus throughout the organization;
- e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

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#### 6. PLANNING

## 6.1 Actions to address Risks and Opportunities

6.1.1 While planning the quality management system, DIC-SLM has considered the issues referred to in clause 4.1 (understanding the organization & its context) and the requirements referred to in clause 4.2 (understanding the needs & expectations of interested parties) and determined the risks and opportunities that need to be addressed to:

- a) give assurance that the quality management system can achieve its intended result(s);
- b) enhance desirable effects;
- c) prevent, or reduce, undesired effects;
- d) Achieve improvement.

## 6.1.2 The organization has planned:

- a) actions to address the risks and opportunities;
- b) how to:
- 1) integrate and implement the actions into the quality management system processes (Ref. clause 4.4 above quality management system and its processes);
- 2) evaluate the effectiveness of the actions taken.

It is ensured that, the actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

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## 6.2 Quality objectives and planning to achieve them

6.2.1 The organization has established the quality objectives at relevant functions, levels and processes within in the organization.

While deciding the objectives the organization ensures to:

- a) be consistent with the quality policy;
- b) be measurable;
- c) take into account applicable requirements;
- d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) be monitored;
- f) be communicated;
- g) be updated as appropriate.

The organization maintains documented information on the quality objectives. (Ref. clause 0.7 above) Ref: Operations Manual

- 6.2.2 When planning to achieve the quality objectives, the organization determines:
  - a) what will be done;
  - b) what resources will be required:
  - c) who will be responsible;
  - d) when it will be completed;
  - e) How the results will be evaluated.

**Ref: Operations Manual** 

## **6.3 Planning of Changes**

While determining the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

When planning for changes the organization shall considered:

- a) the purpose of the changes and their potential consequences;
- b) the integrity of the quality management system;
- c) the availability of resources:
- d) the allocation or reallocation of responsibilities and authorities.

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#### 7. SUPPORT

#### 7.1 Resources

#### 7.1.1 General

The organization has determined the resource requirements and provided for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization considers following while determining the resource requirements:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

### **7.1.2 People**

The organization determined and provided the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

#### 7.1.3 Infrastructure

The organization has determined, provided and maintained the infrastructure necessary for the operation of the processes and to achieve conformity of products and services.

Infrastructures include:

- a) buildings and associated utilities;
- b) equipment, including hardware and software; (AMC,ELCOT)
- c) transportation resources;
- d) information and communication technology.

## 7.1.4 Environment for the operation of processes

The organization has determined, provided and maintained the environment necessary for the operation of the processes and to achieve conformity of products and services.

A suitable environment has been provided considering the combination of human and physical factors, such as:

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- a) social (e.g. non-discriminatory, calm, non-confrontational);
- b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);
- c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

Any other factors deemed necessary, depending on the products and services provided by the organization from time to time.

Any additional environmental concerns are discussed in the MRM and provided as required.

## 7.1.5 Monitoring and measuring resources

#### 7.1.5.1 General

The organization has determined and provided the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization ensures that the resources provided:

- a) are suitable for the specific type of monitoring and measurement activities being undertaken;
- b) are maintained to ensure their continuing fitness for their purpose.

The organization retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

### 7.1.5.2 Measurement traceability

Where and when the measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

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- b) identified in order to determine their status;
- c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization will determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

## 7.1.6 Organizational knowledge

The organization has determined the knowledge necessary for the operation of its processes and to achieve conformity to the products and services, the organization offers.

This knowledge shall be maintained and be made available to the extent necessary to all the required levels within and external to the organization.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

- 1. NOTE: Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.
- 2. NOTE: Organizational knowledge can be based on:
- a) internal sources (e.g knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);
- b) External sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

### 7.2 Competence

The organization has:

- a) determined the necessary competence for personnel doing work under its control, that affects its quality performance and effectiveness of the quality management system;
- b) ensured that all the personnel are competent on the basis of appropriate education, training or experience;
- c) Where applicable, taken actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken.
- d) retained appropriate documented information as evidence of competence

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## 7.3 Awareness

The organization ensures that persons doing work under the organization's control are aware of:

- a) the quality policy;
- b) relevant quality objectives;
- c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- d) The implications of not conforming to the quality management system requirements.

### 7.4 Communication

The organization determines the internal and external communications relevant to the quality management system, including:

- a) on what it will communicate;
- b) when to communicate;
- c) with whom to communicate;
- d) how to communicate;
- e) who communicates.

#### 7.5 Documented information

### **7.5.1 General**

The organization's quality management system has included:

- a) documented information required by the IS / ISO 9001:2015 International Standard;
- b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

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### 7.5.2 Creating & Updating

When creating and updating documented information, the organization has ensured appropriate:

- a) Identification and description (e.g. Document title, Sub title, Issue No. Issue date, revision no. rev. date, other document references, etc...);
- b) format (e.g. Record title, revision no. rev. date) and media (e.g. paper, electronic);
- c) review and approval for suitability and adequacy.

#### 7.5.3 Control of Documented information

- 7.5.3.1 Documented information required by the quality management system and by the IS / ISO 9001:2015 International Standard has been controlled to ensure:
  - a) it is available and suitable for use, where and when it is needed;
  - b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).
- 7.5.3.2 For the effective control of documented information, the organization has implemented & addressed the following controls:
  - distribution, access, retrieval and use;
  - storage and preservation, including preservation of legibility;
  - control of changes (e.g. revision control);
  - retention and disposition.

The organization has identified & determined the requirements of documented information of external origin, necessary for the planning and operation of the quality management system, as appropriate, and controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

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### 8. OPERATION

## 8.1 Operation Planning & Control

The organization has planned, established, implemented, controlled and maintained the processes needed to meet requirements for the provision of products and services, and to implement the actions determined in Clause 6 – Planning, above by:

- a) determining the requirements for the products and services;
- b) establishing criteria for:
  - 1. the processes;
  - 2. the acceptance of products and services;
- c) determining the resources needed to achieve conformity to the product and service requirements;
- d) implementing control of the processes in accordance with the criteria;
- e) determining, maintaining and retaining documented information to the extent necessary:
- f) to have confidence that the processes have been carried out as planned;
- g) to demonstrate the conformity of products and services to their requirements.

It is ensured that the output of this planning will be suitable for the organization's operations.

The organization will control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization ensures that outsourced processes are controlled (see clause 8.4 below).

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## 8.2 Requirements for products and services

#### **8.2.1 Customer communication**

Communication with customers includes:

- a) providing information relating to products and services;
- b) handling enquiries, contracts or orders, including changes;
- c) obtaining customer feedback relating to products and services, including customer complaints;
- d) handling or controlling customer property;
- e) establishing specific requirements for contingency actions, when relevant.

## 8.2.2 Determining the requirements for products and services

While determining the requirements for the products and services to be offered to customers, the organization ensures that:

- a) the requirements for the products and services are defined, including:
  - 1) any applicable statutory and regulatory requirements;
  - 2) those considered necessary by the organization;
- b) where the organization can meet the claims for the products and services it offers.

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#### 8.2.3 Review of the requirements for products and services

- 7.2.3.1 The organization ensures that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:
  - a) requirements specified by the customer, including the requirements for delivery and post delivery activities;
  - b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
  - c) requirements specified by the organization;
  - d) statutory and regulatory requirements applicable to the products and services;
  - e) contract or order requirements differing from those previously expressed.

The organization ensures that contract or order requirements differing from those previously defined are resolved.

The customer's requirements will be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

- 8.2.3.2 The organization retains documented information, as applicable:
  - a) on the results of the review;on any new requirements for the products and services.

### 8.2.4. Changes to requirements for products and services

The organization ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

### 8.3 Design and Development of Products and Services

Presently the department performs no design activity. Therefore the design and development clause is not applicable as of now.

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## 8.4 Control of externally provided processes, products and services

#### 8.4.1 General

The organization ensures that externally provided processes, products and services conform to requirements.

The organization has determined the controls to be applied to externally provided processes, products and services when:

- a) products and services from external providers are intended for incorporation into the organization's own products and services;
- b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;
- c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization has determined and applied criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization retains documented information of these activities and any necessary actions arising from the evaluations.

#### 8.4.2 Type and extent of control

The organization ensures that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization implemented controls to:

- a) ensure that externally provided processes remain within the control of its quality management system;
- b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) take into consideration:
  - 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
  - 2) the effectiveness of the controls applied by the external provider;
- d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

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## 8.4.3 Information for external providers

The organization ensure that the adequacy of requirements prior to their communication to the external provider.

The organization communicates to external providers its requirements for:

- a) the processes, products and services to be provided;
- b) the approval of:
  - 1) products and services;
  - 2) methods, processes and equipment;
  - 3) the release of products and services;
- c) competence, including any required qualification of persons;
- d) the external providers' interactions with the organization;
- e) control and monitoring of the external providers' performance to be applied by the organization;
- f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

## 8.5 Production and service provision

8.5.1 Control of production and service provision

The organization has implemented production and service provision under controlled conditions.

Controlled conditions includes, as applicable:

- a) the availability of documented information that defines:
  - 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
  - 2) the results to be achieved;
- b) the availability and use of suitable monitoring and measuring resources;
- c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

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- a) the use of suitable infrastructure and environment for the operation of processes;
- b) the appointment of competent persons, including any required qualification;
- c) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- d) the implementation of actions to prevent human error;
- e) the implementation of release, delivery and post-delivery activities.

## 8.5.2 Identification and traceability

The organization uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability

### 8.5.3 Property belonging to customers or external providers

The organization exercises care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization will identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization has made necessary arrangement to report this to the customer or external provider and retain documented information on what has occurred.

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### 8.5.4 Preservation

The organization implemented necessary arrangements to preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

## 8.5.5 Post delivery activities

The organization has arranged necessary facilities to meet the requirements for post-delivery activities associated with the products and services.

While determining the extent of post-delivery activities that are required, the organization has considered:

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with its products and services;
- c) the nature, use and intended lifetime of its products and services;
- d) customer requirements;
- e) Customer feedback.

### 8.5.6 Control of changes

The organization has made necessary arrangements to review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

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## 8.6 Release of products and services

The organization has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer will not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The organization retains documented information on the release of products and services. The documented information includes:

- a) evidence of conformity with the acceptance criteria;
- b) traceability to the person(s) authorizing the release.

# 8.7 Control of non-conforming outputs

8.7.1 The organization ensures that the outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The organization will take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This will also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The organization deals with nonconforming outputs in one or more of the following ways:

- a) correction:
- b) segregation, containment, return or suspension of provision of products and services;
- c) informing the customer;
- d) obtaining authorization for acceptance under concession.

  Conformity to the requirements shall be verified when nonconforming outputs are corrected.
- 8.7.2 The organization retains documented information that:
  - a) describes the nonconformity;
  - b) describes the actions taken;
  - c) describes any concessions obtained;
  - d) Identifies the authority deciding the action in respect of the nonconformity.

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### 9. PERFORMANCE EVALUATION

## 9.1 Monitoring, measurement, analysis and evaluation

#### 9.1.1 General

The organization has implemented necessary arrangements to monitor, measure, analyse and evaluate its quality performance.

The organization determined:

- a) what needs to be monitored and measured;
- b) the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;
- c) when the monitoring and measuring will be performed;
- d) when the results from monitoring and measurement shall be analysed and evaluated.

The organization periodically evaluates the performance and the effectiveness of the quality management system at planned intervals.

The organization retains appropriate documented information as evidence of the results.

### 9.1.2 Customer satisfaction

The organization continuously monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization has determined the methods for obtaining, monitoring and reviewing this information.

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## 9.1.3 Analysis and evaluation

The organization analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis will be used to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the quality management system;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the quality management system.

### 9.2 Internal Audit

- 9.2.1 The organization conduct internal audits at planned intervals to provide information on whether the quality management system:
  - a) conforms to:
    - 1) the organization's own requirements for its quality management system;
    - 2) the requirements of this International Standard;
  - b) is effectively implemented and maintained.

Internal Audit: Annexure I

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## 9.2.2 The organization implemented necessary actions to:

- a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which will take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
- b) define the audit criteria and scope for each audit;
- c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensure that the results of the audits are reported to relevant management;
- e) take appropriate correction and corrective actions without undue delay;
- f) retain documented information as evidence of the implementation of the audit programme and the audit results.

## 9.3 Management Review

#### 9.3.1 General

Top management at periodic intervals, review the quality management system, to ensure the continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

### Ref: 1. www.indcom.tn.gov.in

2. Minutes of MRM - Annexure II

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## 9.3.2 Management review inputs

The management review will be planned and carried out taking into consideration:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the quality management system;
- c) information on the performance and effectiveness of the quality management system, including trends in:
  - 1) customer satisfaction and feedback from relevant interested parties;
  - 2) the extent to which quality objectives have been met;
  - 3) process performance and conformity of products and services;
  - 4) nonconformities and corrective actions;
  - 5) audit results;
  - 6) the performance of external providers;
- d) the adequacy of resources;
- e) the effectiveness of actions taken to address risks and opportunities (see clause 6.1 above);
- f) Opportunities for improvement.

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### 9.3.3 Management review output

The outputs of the management review includes decisions and actions related to:

- a) opportunities for improvement;
- b) any need for changes to the quality management system;
- c) resource needs.

The organization retains documented information as evidence of the results of management reviews.

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#### 10 IMPROVEMENT

### 10.1 General

The organization determines and selects the opportunities for improvement and implemented necessary actions to meet customer requirements and enhance customer satisfaction.

These may include:

- a) improving products and services to meet requirements as well as to address future needs and expectations;
- b) correcting, preventing or reducing undesired effects;
- c) Improving the performance and effectiveness of the quality management system.

## 10.2 Non-Conformity & Corrective Action

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization take appropriate actions to :

- a) react to the nonconformity and, as applicable:
  - 1) take action to control and correct it;
  - 2) deal with the consequences;
- b) evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - 1) reviewing the nonconformity;
  - 2) determining the causes of the nonconformity;
  - 3) determining if similar nonconformities exist, or could potentially occur;
- c) implement any action needed;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during planning, if necessary;
- f) make changes to the quality management system, if necessary.

It will be ensured that the Corrective actions taken shall be appropriate to the effects of the nonconformities encountered.

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10.2.2 The organization retains documented information as evidence of:

- the nature of the nonconformities and any subsequent actions taken;
- the results of any corrective action.

# **10.3 Continual Improvement**

The organization takes all measures to continually improve the suitability, adequacy and effectiveness of the quality management system.

The organization considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

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