QUALITY MANUAL

EPC, UAE	**DISTRIBUTION LIST**	Manual Rev. No.	0
		Page issue No.	0
	SECTION - C	Page No.	1 of 1
		Date	06.08.2008

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The following abbreviations are used in the Manual

Abbreviation	Full Form/ Meaning
ISO	International Organization for Standardization
EPC	**Energy & Power Company (Fzc), UAE**
QA	Quality Assurance
Rev.	Revision
QM	Quality Manual
QSPM	Quality System Procedures Manual
QSPM	Quality Systems Management

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INTRODUCTION:

The Quality System documented in this manual describes the process used to continually improve and maintain the leading standards of quality and service delivered by **Energy & Power Company (FZC), UAE**

The Fabrication Division is a business entity of **EPC**. It is directed by the Board of Directors of **EPC** and is under the direct Supervision of the Managing Director.

EPC is engaged in Designing, Manufacturing, Erecting & Commissioning of Communication Towers, High Voltage & Low Voltage Transmission Towers, Sub-Stations, Telescopic poles for Transmission & Lighting. The factory houses large and dedicated production lines for its kind of operations, and has the relevant testing facilities.

The Quality System used at **EPC** complies with the requirements of ISO 9001: 2000.

This manual was prepared to comply with ISO 9001: 2000, Section 4.2.2 Quality Manual:

"The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2)

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

DISCLAIMER: The Quality System does not cover products which **EPC** deals in for trading purposes. Prepared By : _____ Reviewed By : _____		Approved By :_____

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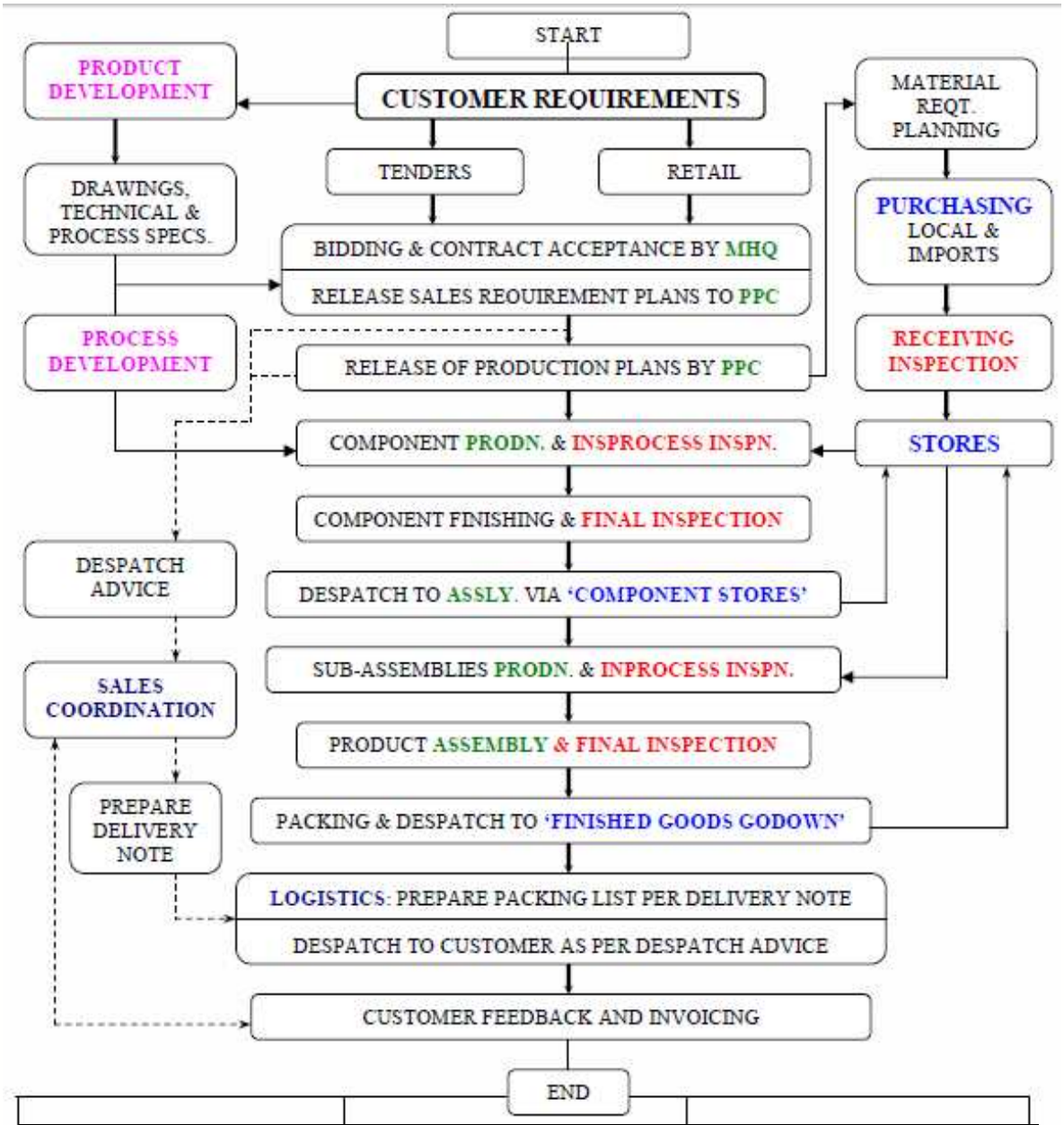

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DISTRIBUTION, REVIEW AND APPROVALS

This manual is released under the authority of the Management Representative. Individual pages will be approved by the Management Representative, except the Quality Policy, which will be approved by the Managing Director.

The 'Revision Number' refers to the Quality Manual Revision. The 'Issue Number' refers to the Page Revision. Each Page Revision will be introduced by issue of new pages for each controlled copy in existence. The issue number of each revised page will be incremented and dated. When the complete manual is revised and reissued, the manual revision number will be incremented and all pages will commence with issue number Zero.

The manual will have a manual revision number indicated on the cover page along with Copy Number and the Department/ individual/ client it is assigned to.

Stock copies can be kept by the Management Representative and shall be updated at the time of issue as appropriate.

CONTROLLED COPIES:

Controlled copies are those copies which are assigned to customers or individuals within **EPC** and are not meant to be distributed to other organizations, unless approved by the Management Representative.

Controlled copies will bear the copy number and control stamp

UNCONTROLLED COPIES:

Uncontrolled copies will not bear the copy number; however 'uncontrolled copy' stamp will be affixed on it at the time of issue for tender pre-qualifications, proposals, customer off-site usage or where change control is not intended. **EPC** is not responsible for manuals marked as "Uncontrolled Copies" nor for any unofficial duplication. Holders of uncontrolled copies are to use the copies only for reference. Uncontrolled copies will not be updated.

REVISIONS:

This manual will be revised and added to as necessary to reflect changes in Quality Requirements. All revisions will be authorized by the Management Representative on the Issue/ Change record. It is the goal and purpose of the Quality Manual to assure the quality and reliability of our products.

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4.1 GENERAL REQUIREMENTS

A documented Quality System is established, maintained and implemented as a means of ensuring that product conforms to specified requirements during all stages of the Manufacturing process. The organization strives fully to continuously improve the effectiveness of the Quality Management System in accordance with the ISO 9001 – 2000.

The organization:
a) has identified the processes needed for the quality management system and their Application throughout the organization,
b) has determined the sequence and interaction of these processes,
c) has determined criteria and methods needed to ensure that both the operation and control of these processes are effective,
d) Continuously strives to ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
e) Monitors, measures and analyses these processes, and
f) Implements actions necessary to achieve planned results and continual improvement of these processes .
These processes are managed in conformance to ISO 9001-2000.
In addition to the above, whenever outsourcing of any process is taken up, proper control is ensured based on the respective procedures.

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4.2 DOCUMENTATION REQUIREMENTS

4.2.1 GENERAL

The Quality Management System documentation includes documented Quality System Procedures and instructions in accordance with the documented Quality Manual, stated Quality Policy & Quality Objectives and requirements of ISO 9001 – 2001.
The Quality Management System is supported by four different levels of documents, as follows:

First Level : A. ISO 9001 – 2001.
B. Quality Policy and Quality Objectives
C. **EPC**s Quality Manual

Second Level : Quality Systems Procedures contained in the Quality System Procedures
Manual (QSPM)

Third Level : Drawings/ Technical Specs. (applicable national & international standards,
codes of practice, guides and **EPC** specifications)/
Process Sheets/
Quality Plans/Work instructions/Specific-job procedures as per QSPM.

Fourth Level : Records in the form of Documents/ Log books/ files/ registers/ forms as referred in the Second or Third Level Quality System Documentation.

The range and detail of the procedures that form part of the Quality Management System depend upon the complexity of the processes and their interaction, the methods used, and the competence, skills and training needed by personnel involved in performing the activity

The documentation is in two forms depending upon the necessity –

a) Hard Copies – prints or drawings etc. on paper
b) Soft Copies – documents on the Electronic media such as Personal Computers, floppies, Compact Discs etc..

4.2.2 QUALITY MANUAL

This Quality Manual has been established and maintained and includes

a) The scope of the Quality Management System (QMS),
b) Reference to the documented procedures established for the QMS,
c) Description of the interaction between the processes of the QMS.

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4.2.3 CONTROL OF DOCUMENTS

All documents required by the quality management system are controlled. Documented procedures exist which define the controls needed

a) to approve documents for adequacy prior to issue
b) to review and update as necessary and re-approve documents
c) to ensure that changes and the current revision status of documents are identified
d) to ensure that relevant versions of applicable documents are available at points of use
e) to ensure that documents remain legible and readily identifiable
f) to ensure that documents of external origin are identified and their distribution controlled
g) and to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 CONTROL OF RECORDS

Records are established and maintained to provide evidence of conformity to requirements
and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

NOTE: QSP – 4.2 – 01, Quality System Procedure for coding practices details the procedure for establishing traceability of all documents.

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5 MANAGEMENT RESPONSIBILITY

5.1 MANAGEMENT COMMITMENT

The management of **EPC** is committed to the development and implementation of the Quality Management System and continually improving its effectiveness by:

a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
b) Establishing and upgrading the quality policy in line with the continuous Improvement in the organization,
c) Ensuring that quality objectives are established and achieved,
d) Conducting management reviews
e) Ensuring the availability of resources – men, money, material and machinery.

5.2 CUSTOMER FOCUS

E L T E L's Management is committed to ensuring that the customer requirements are determined and are met with the aim of enhancing customer satisfaction, in line with the Quality Policy of the Organization.

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5.3 - QUALITY POLICY

The following Quality Policy, established by **EPC.** (Organization/ facility), has been posted in conspicuous locations throughout the facility and delivered to all the employees of the Division.

QUALITY POLICY

IF YOU CARE ... YOU CAN

EPC., *shall manufacture quality products to customers' and international specifications, at the right time, to the total customer satisfaction. This shall be achieved through continuously striving to improve the Quality Management System within the organization, investment in advanced technologies, involvement of all the employees, suppliers and customers.*

DATE :
PLACE:

Maher Dassouki
Managing Director

A continuous effort exists from **EPC** Management to ensure a good understanding of this policy by all employees through:

A. Explanation of the policy during instruction sessions.
B. Periodic interviews with randomly selected employees.

5.4 PLANNING

5.4.1 QUALITY OBJECTIVES

Top management ensures that the Quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the organization. It is ensured that the quality objectives are measurable and consistent with the Quality Policy.

5.4.2 QUALITY MANAGEMENT SYSTEM PLANNING

Top management ensures that

a) the planning of the Quality Management System is carried out in order to meet the requirements as well as the Quality Objectives, and
b) the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

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5.5 RESPONSIBILITY, AUTHORITY & COMMUNICATION

5.5.1 RESPONSIBILITY AND AUTHORITY:

Top management has defined and communicated the responsibilities and authorities of the employees. The responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality are shown in the enclosed

organizational chart. Following are descriptions of the Top, Middle and Lower level management positions as given in the Organization chart.

MANAGING DIRECTOR:

Directs the entire Towers Division – Manufacturing and Marketing, apart from directing all the other divisions of **EPC.** Is responsible for providing the Quality Policy of the Organization apart from the policies related to individual departments like Personnel, Administration, Commercial and Marketing functions of the Organization. He is also authorized to review and approve them.

GENERAL MANAGER & MANAGEMENT REPRESENTATIVE:

Manages the entire Fabrication Division of **EPC,** including the Commercial, Operations and the HRD.
Directs the DGM – Commercial, AGM – Operations, HRD, Product Design & Development Dept., Planning Section, Tool Room and Maintenance Dept.
Is responsible for ensuring that the ISO 9001 Standards' requirements are implemented and maintained, throughout the organization. Is responsible and authorized for deciding and reviewing the Quality Objectives.

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DEPUTY GENERAL MANAGER - COMMERCIAL:

Directs the Accounts Dept., Marketing Dept. including the domestic sales and exports, Procurement Dept. and the Stores Section. Is responsible for the proper functioning of all the Commercial Sections including the Information Technology Dept. and Logistics Dept.
Is authorized to review all the policies related to Accounts & Finance and Commercial
functions of running the business of **EPC.**

ASST. GENERAL MANAGER – OPERATIONS

Is responsible for ensuring that the customers receive the material as per the required specifications & quality standards and that the Quality Management Systems are implemented in too. The AGM Operations directs the Production and QA Departments.

ASSISTANT GENERAL MANAGER: HUMAN RESOURCES DEVELOPMENT

Directs the Human Resources Development Dept. including the Personnel & Administration, Recruitment & Training, Legal & Insurance, Security, Health & Employee Welfare Sections. Is responsible for maintaining high employee morale, Employee Welfare, discipline, Training & Development and for Manpower Planning.

PRODUCT DESIGN & DEVELOPMENT ENGINEER:

Is responsible for ensuring that the Tower Division's Products' Engineering document Changes are reviewed, approved, issued, controlled and properly distributed. He is also responsible, when necessary, to review, reject or approve all deviations against specified drawings or Technical Specifications, to ensure that our customers receive reliable and quality products.

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TOOL ROOM MANAGER:

Is responsible for providing equipment, gages, tooling and effective planning of processes and support the manufacturing facility to improve the quality of the product and the efficiency of the plant equipment.

PROCUREMENT MANAGER:

Is responsible for the materials requirement planning, purchasing and expediting of import of materials to facilitate cost effective manufacturing and for providing a cost effective, timely delivery service to the manufacturing facility with quality products.

STORES MANAGER:

Is responsible for the materials requirement planning, purchasing, expediting of locally available materials and consumables; he is also responsible for the control of imported and locally purchased materials.

PLANNING ENGINEER :

Is responsible for Production Planning and Control, ensuring availability of material for Production. Is the liaison between Marketing Dept. and Manufacturing facility. Responsible for providing feasible production schedules and a timely delivery service to customers.

TOWERS MANUFACTURING: PRODUCTION ENGINEER:

Is responsible for the production of Telecommunication Microwave towers, Electrical Transmission Line towers, Lighting masts, Telescopic Polygonal Poles, Signage Gantries, other Heavy Steel Structures and the Finishing & Treatment Line.
Is responsible for coordination, motivation and utilization of resources to ensure cost effective, on-time achievement of production schedules to the required quality standards.

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QUALITY ASSURANCE ENGINEER:

Is responsible for the definition, maintenance and implementation of quality standards for the Towers and Telecom Divisions, to the Company's specifications and the requirements specified by individual customers.
Is the liaison between E L T E L, Customers' Inspectors and Independent Testing Labs & Inspection Agencies.

MAINTENANCE ENGINEER :

Is responsible for identification of critical machines and for scheduling their preventive maintenance in coordination with concerned departments. He is also responsible for spare parts planning of all machines & equipment.
He is the liaison between E L T E L and the Suppliers of new machines and equipment for machines installation/ commissioning.

SALES COORDINATOR:

Is responsible for coordinating with PPC, Logistics Supervisor and Marketing Dept. for the follow up/ correspondence related to Material Delivery and Cash Receivables.

LOGISTICS SUPERVISOR (EXPEDITER) :

Is responsible for the control of products to be delivered to the customers and for the type of transportation to be used. He is also responsible for the control of material sent to the suppliers (sub-contractors).

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5.5.2 MANAGEMENT REPRESENTATIVE

The Managing Director has appointed the official Management Representative, with responsibility and authority for

1st.ensuring that the processes required for ISO 9001 – Quality Management System requirements are established, implemented and maintained.

2nd.reporting on the performance of the Quality Management System to **EPC's** management for review and for improvement of the Quality Management System.

3rd.Liaising with external parties on matters relating to **EPC's** Quality System.

5.5.3 INTERNAL COMMUNICATION

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the Quality Management System.

5.6 MANAGEMENT REVIEW

5.6.1 GENERAL

The Quality Management System will be reviewed at least once a year by the members of senior management to ensure its suitability, adequacy and effectiveness and assure its compliance with ISO 9001. This review includes assessing opportunities for improvement and the need for changes to the Quality Management System, including the Quality Policy and Quality Objectives.

Minutes of the formal Management Review meeting are to be taken and maintained.

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5.6.2 REVIEW INPUT

As a minimum Management Review includes issues related to:

a) Results of internal and external audits
b) Customer feedback
c) Process performance and product conformity
d) Status of Preventive and Corrective Actions
e) Follow-up actions from previous management reviews
f) Changes that could affect the Quality Management System and
g) Recommendations for improvement
h) Effectiveness of meeting the objectives of Quality Policy
i) Quality Training
j) Review of any unresolved quality problems

5.6.3 REVIEW OUTPUT

The output from the management review shall include any decisions and actions related to:

a) improvement of the effectiveness of the Quality Management System and its processes,

b) improvement of the product related to customer requirements and
c) resource needs The procedure for Management Review is detailed in Quality Systems Procedure
d) QSP – 4.1-01

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6.0 RESOURCE MANAGEMENT

6.1 PROVISION OF RESOURCES

The organization determines and provides the resources needed
a) to implement and maintain the Quality Management System and continually improve its effectiveness and
b) to enhance customer satisfaction by meeting customer requirements

6.2 HUMAN RESOURCES

6.2.1 GENERAL

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 COMPETENCE, AWARENESS AND TRAINING

The organization shall

a) Determine the necessary competence for personnel performing work affecting product quality,
b) Provide training or take other actions to satisfy these needs
c) Evaluate the effectiveness of the actions taken
d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the Quality Objectives and
e) Maintain appropriate records of education, training, skills and experience

6.3 INFRASTRUCTURE

The organization has determined, provided and maintains the infrastructure needed to achieve conformity to product requirements, infrastructure includes, as applicable

a) Buildings, workspace and associated utilities
b) Process equipment (both hardware and software) and
c) Supporting services (such as transport or communication)

6.4 WORK ENVIRONMENT

The organization has determined the norms and manages the work environment needed to achieve conformity to product requirements.

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7. PRODUCT REALISATION

7.1 PLANNING OF PRODUCT REALISATION

The organization plans and develops the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the Quality Management System.
In planning product realization, the organization shall determine the following, as appropriate:

a) Quality objectives and requirements for the product
b) The need to establish processes, documents, and provide resources specific to the product
c) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance
d) Records needed to provide evidence that the realization processes and resulting product meet requirements

The output of this planning is in a form suitable for the organization's method of operations.

7.2 CUSTOMER-RELATED PROCESSES

7.2.1 DETERMINATION OF REQUIREMENTS RELATED TO THE PRODUCT

The organization determines
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 specified or intended use, where known,
c) Statutory and regulatory requirements related to the product, and
d) Any additional requirements determined by the organization.

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7.2.2 REVIEW OF REQUIREMENTS RELATED TO THE PRODUCT

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g.; submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined
b) contract or order requirements differing from those previously expressed are resolved
c) and the organization has the ability to meet the defined requirements

Records of the results of the review and actions arising from the review shall be maintained. Where the customer provides no documented statement of requirement, customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
Where formal review of each order is not practical, in such situations the review can cover relevant product information such as catalogues or advertising material.

7.2.3 CUSTOMER COMMUNICATION

The organization is keen on involving and ensure continuous communication with the customers and hence has embarked upon the following:

a) product information
b) enquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints.

7.3 DESIGN AND DEVELOPMENT

7.3.1 DESIGN AND DEVELOPMENT PLANNING

The organization plans and controls the design and development of product.
During the design and development planning, the organization shall determine

a) the design and development stages,
b) the review, verification and validation that are appropriate to each design and development stage, and
c) the responsibilities and authorities for design and development

The organization manages the interface between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.
Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 DESIGN AND DEVELOPMENT INPUTS

Inputs relating to product requirements are determined and records are maintained. These inputs shall include

a) Functional and performance requirements,
b) Applicable statutory and regulatory requirements,
c) Where applicable, information derived from previous similar designs, and
d) Other requirements essential for design and development.

These inputs are reviewed for adequacy. It is ensured that the requirements are complete, unambiguous and not in conflict with each other.

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7.3.3 DESIGN AND DEVELOPMENT OUTPUTS

The outputs of design and development are provided in a form that enables verification against the design and development input and this form is approved prior to release.
Design and development outputs shall

a) Meet the input requirements for design and development
b) Provide appropriate information for purchasing, production and for service provision,
c) Contain or reference product acceptance criteria, and
d) Specify the characteristics of the product that are essential for its safe and p roper use.

7.3.4 DESIGN AND DEVELOPMENT REVIEW

At suitable stages, systematic review of design and development is performed in Accordance with planned arrangements

a) To evaluate the ability of the results of design and development to meet requirements, and
b) To identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are maintained.

7.3.5 DESIGN AND DEVELOPMENT VERIFICATION

Verification is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

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7.3.6 DESIGN AND DEVELOPMENT VALIDATION

Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained.

7.3.7 CONTROL OF DESIGN AND DEVELOPMENT CHANGES

Design and development changes are identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained.

7.4 PURCHASING

7.4.1 PURCHASING PROCESS

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection.

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7.4 PURCHASING

7.4.1 PURCHASING PROCESS

The organization ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.
The organization evaluates and selects suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and reevaluation are established. Records of the results of evaluations and any necessary actions arising from the evaluation are be maintained.

7.4.2 PURCHASING INFORMATION

Purchasing information describes the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel, and
c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 VERIFICATION OF PURCHASED PRODUCT

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

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7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) The availability of information that describes the characteristics of the product,
b) The availability of work instructions, as necessary,
c) The use of suitable equipment,
d) The availability and use of monitoring and measuring devices,
e) The implementation of release, delivery and post-delivery activities.

7.5.2 VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION

The organization validates all such processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.
Validation shall demonstrate the ability of these processes to achieve planned results.
The organization shall establish arrangements for these processes including, as applicable

a) Defined criteria for review and approval of the processes,
b) Approval of equipment and qualification of personnel,
c) Use of specific methods and procedures,
d) Requirements for records and
e) Revalidation

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7.5.3 IDENTIFICATION AND TRACEABILITY

Where appropriate, the organization shall identify the product by suitable means throughout product realization.
The organization shall identify the product status with respect to monitoring and Measurement requirements.
Where traceability is a requirement, the organization shall control and record the unique identification of the product.

7.5.4 CUSTOMER PROPERTY

The organization shall exercise care with customer property while it is under the Organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.

7.5.5 PRESERVATION OF PRODUCT

The organization shall preserve the conformity of product during internal processing and delivery to be intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.6 CONTROL OF MONITORING AND MEASURING DEVICES

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.

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The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.
Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used of calibration or verification shall be recorded;
b) be adjusted or re-adjusted as necessary;
c) be identified to enable the calibration status to be determined;
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

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8.1 GENERAL

The organization plans and implements the monitoring, measurement, analysis and improvement processes needed to

a) Demonstrate conformity of the product
b) Ensure conformity of the QMS, and
c) Continually improve the effectiveness of the QMS.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 MONITORING AND MEASUREMENT

8.2.1 CUSTOMER SATISFACTION

As one of the measurements of the performance of the quality management system, the organization monitors information related to customer perception about organization's capabilities in meeting customer requirements. The methods of obtaining and using this information have been determined.

8.2.2 INTERNAL AUDIT

The organization shall conduct internal audits as planned intervals to determine whether the quality management system

a) Conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the organization.
b) Is effectively implemented and maintained.

An audit programmer shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audit shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

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Documented procedure exists which defines the responsibilities and requirements for Planning and conducting audits, and for reporting the results of the audits and maintaining the internal audit records.
EPC management is committed to ensure that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

8.2.3 MONITORING AND MEASUREMENT OF PROCESSES

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

Evidence of conformity with the acceptance criteria shall be maintained. Records indicate the person(s) authorizing release of product.
Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 CONTROL OF NON-CONFORMING PRODUCT

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.
The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

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The organization deals with nonconforming product by one or more of the following ways:

a) By taking action to eliminate the detected non-conformity;
b) By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer,
c) By taking action to preclude its original intended use or application.

Records of the nature of non-conformities and any subsequent actions taken, including concessions obtained, shall be maintained.
When conforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.
When conforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

8.4 ANALYSIS OF DATA

The organization determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made.
This shall include data generated as a result of monitoring and measurement and from other relevant sources.
The analysis of data shall provide information relating to

a) Customer satisfaction
b) Conformity to product requirements
c) Characteristics and trends of processes and products including opportunities for preventive actions and
d) Suppliers.

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8.5 IMPROVEMENT

8.5.1 CONTINUAL IMPROVEMENT

The organization continually improves the effectiveness of the quality management system through the use of the Quality Policy, quality objectives, audit results analysis of data, corrective and preventive actions and management review.

8.5.2 CORRECTIVE ACTION

The organization shall take action to eliminate the cause of non-conformities in order to prevent recurrence. Correction actions shall be appropriate to the effects of the nonconformities encountered.
A documented procedure shall be established to define requirements for

a) Reviewing non-conformities (including customer complaints),
b) Determining the causes of non-conformities,
c) Evaluating the need for action to ensure that non-conformities do not recur,
d) Determining and implementing action needed,
e) Records of the results of action taken and
f) Reviewing corrective action taken.

8.5.3 PREVENTIVE ACTION

The organization shall determine action to eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.
A documented procedure shall be established to define requirements for

a) Determining potential non-conformities and their causes,
b) Evaluating the need for action to prevent occurrence of non-conformities,
c) Determining and implementing action needed,
d) Records of results of action taken and
e) Reviewing preventive action taken.

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