

# ITTC-Sample

## Quality Manual

(based on the International Standard ISO 9001:2000)

### Company

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no

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Company

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## To the Proceedings of the QSG to the 23<sup>rd</sup> ITTC

### ITTC Sample Quality Manual

In order to support the member organisations of the ITTC in introducing a quality control system according to ISO 9000:2000 or in changing from standard ISO 9000:1994 to ISO 9000:2000, the QSG of the 23<sup>rd</sup> ITTC assembled a updated Sample Quality Manual. This Sample Quality Manual provides guidance for quality management and models for quality assurance.

Compared to ISO 9001/9002:1994 the structure of ISO 9001:2000 was changed completely, including the name from Quality

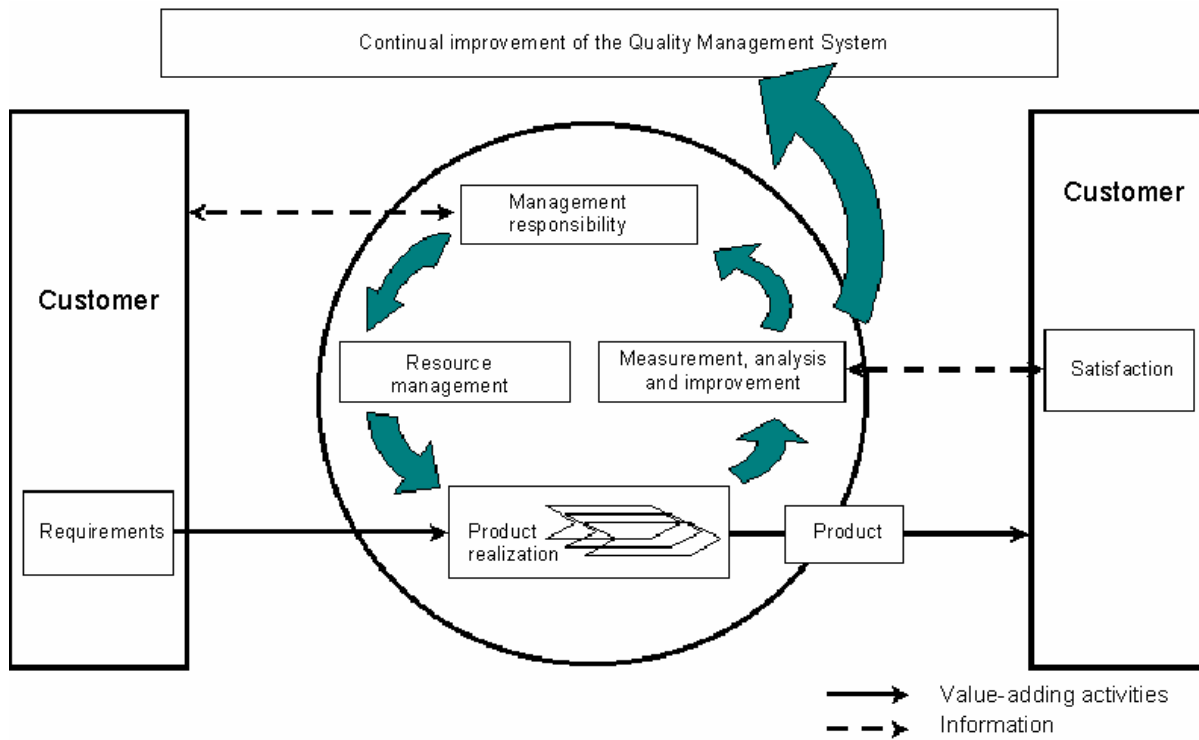
System was changed to Quality Management System. The requirements seem to be more general and provide improved flexibility. ISO 9001:2000 is aimed equally at manufacturing as well as service organizations, with a strong focus on customer satisfaction. The major reasons for the year 2000 revisions of the standard include emphasizing the need to measure customer satisfaction, meeting the need for more user-friendly documents, assuring consistency between quality management system requirements and guidelines, and incorporating generic quality management principles into organizations.

1	Scope
2	Normative reference
3	Terms and definitions
4	Quality management system
5	Management responsibility
6	Resource management
7	Product realization
8	Measurement, analysis and improvement

The 8 sections of the Quality Manual obligatory by the standard ISO 9000:2000

The QSG hopes by submitting this sample to simplify and support the implementation of quality control systems or the adaptation to the

updated standard ISO 9000:2000 in the community of the ITTC.



Model of a process-based quality management system

	<b>ITTC-Sample Quality Manual</b>	Page 1 of 1
	<b>Foreword</b>	

## **FOREWORD**

This Sample Quality Manual provides guidance for quality management and models for quality assurance. Because needs of organizations vary, it is not the purpose of this Sample Quality Manual to enforce uniformity of quality systems. The design and implementation of a quality management system necessarily is influenced by the particular organisation's objectives, products, processes and individual practices.

The selection of appropriate elements and the extent to which these elements are adopted and applied by an organization depends upon several factors such as market being served, nature of product, production processes, clientele, and customer needs.

References in this Sample Quality Manual to a 'product' should be interpreted also as applicable to the generic product categories of service (such as model tests, calculations, etc.), hardware, software or process materials.

Prepared, verified and approved
<b>Quality Systems Group of the 23<sup>rd</sup> ITTC</b>
Date: 09/2002

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 0</b> Page 1 of 1	
	<b>Register</b>	Effective Date 09/2002	Revision 01

## REGISTER

Section	Contents	Effective Date	Revision	Pages
-	Foreword	09/2002	-	1
0	Register	09/2002	01	1
1	Scope	09/2002	01	3
2	Application and ITTC-Recommended Procedures as normative reference	09/2002	01	2
3	Glossary of terms	09/2002	01	5
4	Quality management system	09/2002	01	8
5	Management responsibility	09/2002	01	9
6	Resource management	09/2002	01	4
7	Product realization	09/2002	01	16
8	Measurement, analysis and improvement	09/2002	01	8

Prepared	Verified	Approved
Name	Name	Name
Date	Date	Date

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 1</b> Page 1 of 2	
	<b>Scope</b>	Effective Date 09/2002	Revision 01

## 1. SCOPE

Compared to ISO 9001/9002:1994 the structure of ISO 9001:2000 was changed completely, including the name from Quality System was changed to Quality Management System. The requirements seem to be more general and provide improved flexibility. ISO 9001:2000 is aimed equally at manufacturing as well as service organizations, with a strong focus on customer satisfaction. The major reasons for the year 2000 revisions of the standard include emphasizing the need to measure customer satisfaction, meeting the need for more user-friendly documents, assuring consistency between quality management system requirements and guidelines, and incorporating generic quality management principles into organizations.

A quality-management system brings together people, processes, methods and tools with the aim of constantly improving both the system and the company's products. All of these efforts are geared to the customer and customer satisfaction.

This Sample Quality Manual of ITTC, on the basis of the Standard EN ISO 9001:2000, provide guidance on quality management and quality system elements. The quality system elements are suitable for use in the development and implementation of a comprehensive and effective in-house quality system, with a view to ensuring customer satisfaction.

A primary concern of any organisation should be the quality of its products and services. In order to be successful, an organisation should offer products and services that:

- Meet a well defined need, use, or purpose
- Satisfy customer's expectations
- Comply with applicable standards and specifications
- Comply with requirements of society
- Have an awareness of environmental needs
- Are made available at competitive prices
- Are provided economically

In order to meet its objectives, the organisation should ensure that the technical, administrative and human factors affecting the quality of its products or services will be under control, whether hardware, software or processed materials. All such control should be oriented towards the reduction, elimination and, most importantly, prevention of quality nonconformities.

A quality system should be developed and implemented for the purpose of accomplishing the objectives set out in the organisation's quality policy.

Each element (or requirement) in a quality system varies in importance from one type of

Prepared	Verified	Approved
Name	Name	Name
Date	Date	Date

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 1</b> Page 2 of 2	
	<b>Scope</b>	Effective Date 09/2002	Revision 01

activity to another and from one product to another. In order to achieve maximum effectiveness and to satisfy customer expectations, it is essential that the quality system be appropriate to the type of activity and to the product being offered.

A quality management system has two interrelated aspects:

1. The customer's needs and expectations  
For the customer, there is a need for confidence in the ability of the organisation to deliver the desired quality as well as the consistent maintenance of that quality.
2. The organisation's needs and interests.  
For the organisation, there is a business need to attain and to maintain the desired quality at an optimum cost;

the fulfilment of this aspect is related to the planned and efficient utilization of the technological, human and material resources available to the organisation.

Benefit, cost and risk considerations have great importance for both organisation and customer.

An effective quality management system should be designed to satisfy customer needs and expectations while serving to protect the organisation's interests. A well-structured quality management system is a valuable management resource in the optimisation and control of quality in relation to benefit, cost and risk considerations.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 2</b> Page 1 of 2	
	<b>Application and ITTC-Recommended Procedures as Normative Reference</b>	Effective Date 09/2002	Revision 01

## 2.1 QUALITY

In supplying products or services there are three fundamental parameters which determine their saleability. They are price, quality, and delivery time. Customers require products and services of a given quality to be delivered or be available in a given time and to be of a price which reflects value for money. An organization will survive only if it creates and retains satisfied customers and this will only be achieved if it offers products or services which respond to customers' needs and expectations. While price is a function of cost, profit margin, and market forces, and delivery a function of the organization's efficiency and effectiveness, quality is determined by the extent to which a product or service successfully serves the purposes of the user during usage. Price and delivery are both transient features whereas the impact of quality is sustained long after the attraction or the pain of price and delivery has subsided.

## 2.2 WHAT IS ISO 9001

The standard ISO 9001:2000 has the title "Quality management systems - Requirements". It contains specific requirements and recommendations for the development of a quality management system. ISO 9001 is not a product standard. The requirements and recommendations apply to the organizations that supply the product or

service, and hence affect the manner in which the products and services are designed, manufactured, installed, delivered etc. They are standards which apply to the management of the organization and only the management can and should decide how it will respond to these requirements and recommendations.

## 2.3 APPLICATION AND ITTC-RECOMMENDED PROCEDURES AS NORMATIVE REFERENCE

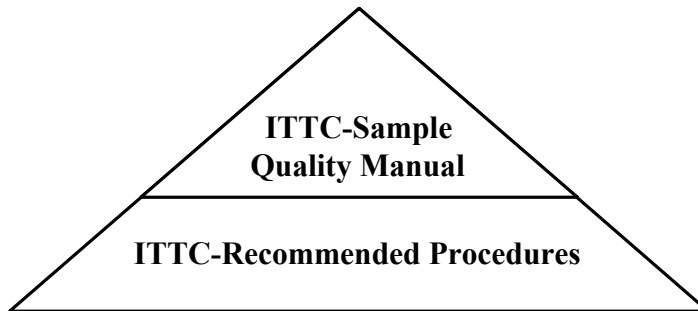
From the very beginning the ITTC aimed to recommend procedures for general use in carrying out physical model experiments. Quality Management Systems in accordance to ISO 9001 only deal with the management of quality management and not with quality requirements. To fix the quality standards for products or services is the responsibility of each individual company. Thus ITTC for years has been acting beyond the scope of quality management systems as the recommendations refer to the quality of the product or service itself. As quality management systems become more and more obligatory for model basins it was decided to assemble a manual called "ITTC-Recommended Procedures" containing all recommendations which have been adopted by the ITTC up to now.

Prepared	Verified	Approved
Name	Name	Name
Date	Date	Date



Company	<b>ITTC-Sample Quality Manual</b>		<b>Section 2</b> Page 2 of 2	
	<b>Application and ITTC-Recommended Procedures as Normative Reference</b>		Effective Date 09/2002	Revision 01

**ITTC  
QUALITY SYSTEMS MANUAL**



The scope of the ITTC-Recommended Procedures is to give the member organizations the possibility to make reference in the work

instructions of their own Quality Manual to the ITTC-Recommended Procedures.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 3</b> Page 1 of 5	
	<b>Glossary of Terms</b>	Effective Date 09/2002	Revision 01

### 3 GLOSSARY OF TERMS

This glossary has been prepared to provide a definition of some of the terms used in the field of quality assurance.

- Assurance** Evidence (verbal or written) that gives confidence that something will or will not happen or has not happened.
- Audit** Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. The comparison of the practices and systems with the precisely defined methods, procedures and instructions it has stated it works to. An examination of records or activities to verify their accuracy, usually by someone other than the person responsible for them.
- Benchmarking** A technique for measuring an organisation's products, services, and operations against those of its competitors, resulting in search for best practice that will lead to superior performance.
- Calibration** All the operations are engaged in for the purpose of determining the values of errors of a measuring instrument and, if necessary, of determining other measurement properties.
- Capability** Ability of an organization, system or process to realize a product that will fulfil the requirements for that product.
- Certification** The authoritative act of documenting compliance with agreed requirements.
- Competence** Demonstrated ability to apply knowledge and skills.
- Computer software** Software covers all instructions and data which are input to a computer to cause it to function in any mode; it includes operating systems, compilers and test routines as well as applications programs. The definition embraces the documents used to define and describe the program (including flowcharts, network diagrams and program

Prepared	Verified	Approved
Name	Name	Name
Date	Date	Date

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 3</b> Page 2 of 5	
	<b>Glossary of Terms</b>	Effective Date 09/2002	Revision 01

listings) and also covers any associated specifications, inspection plans, inspection data, inspection results and other instructions.

<b>Contract</b>	An agreement formally executed by both customer and organisation (enforceable by law) which requires performance of services or delivery of products at a cost to the customer in accordance with stated terms and conditions.
<b>Conformity</b>	The fulfilment of a specified requirement by quality characteristic of an item or service.
<b>Corrective action</b>	Action to eliminate the cause of a detected nonconformity or other undesirable situation.
<b>Customer</b>	Organisation or person that receives a product.
<b>Customer satisfaction</b>	Customer's perception of the degree to which the customer's requirements have been fulfilled.
<b>Define and document</b>	To state in written form, the precise meaning, nature, or characteristics of something.
<b>Design</b>	A process of originating a conceptual solution to a requirement and expressing it in a form from which a product may be produced or a service delivered (e.g. design of a test procedure).
<b>Design and development</b>	Set of processes that transforms requirements into specified characteristics or into the specification of a product, process or system. Design creates the conceptual solution and development transforms the solution into a fully working model.
<b>Design approval procedure</b>	The definitive procedure through which a product design is tested and reviewed against specification.
<b>Design review</b>	A formal documented comprehensive and systematic examination of a design to evaluate the design requirements and the capability of the design to meet those requirements and to identify problems and propose solutions.
<b>Evaluation</b>	To ascertain the relative goodness, quality, or usefulness of an entity with respect to a specific purpose.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 3</b> Page 3 of 5	
	<b>Glossary of Terms</b>	Effective Date 09/2002	Revision 01

<b>Evidence of conformance</b>	Documents which testify that an entity conforms with certain prescribed requirements.
<b>Inspection</b>	The inspection of an entity to determine whether it conforms to prescribed requirements.
<b>Instruction</b>	The written and/or spoken direction given in regard to what is to be done, including the information given in training.
<b>ISO</b>	The International Standard Organisation. It is the specialised international agency for the making of standards. It has a membership of over 90 countries.
<b>Management representative</b>	The person the management appoints to act on their behalf to manage the quality system.
<b>Management system</b>	System to establish policy and objectives and to achieve those objectives.
<b>Measuring equipment</b>	Measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a measurement process.
<b>Objective evidence</b>	Data supporting the existence or verity of something.
<b>Organisation</b>	Group of people and facilities with an arrangement of responsibilities, authorities and relationships.
<b>Preventive action</b>	Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.
<b>Procedure</b>	Specified way to carry out an activity or a process. A sequence of steps to execute a activity.
<b>Process</b>	Set of interrelated or interacting activities which transforms inputs into outputs.
<b>Process capability</b>	The ability of a process to maintain product characteristics within present limits.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 3</b> Page 4 of 5	
	<b>Glossary of Terms</b>	Effective Date 09/2002	Revision 01

<b>Product</b>	Result of a process.
<b>Quality</b>	Degree to which a set of inherent characteristics fulfils requirements. The totality of features and characteristics of a product or service that bear on its ability to satisfy a given need.
<b>Quality assurance</b>	All activities and functions concerned with the attainment of quality.
<b>Quality control</b>	The operational techniques and activities that sustain the product or service quality to specified requirements. It is also the use of such techniques.
<b>Quality manual</b>	Document specifying the quality management system of an organisation.
<b>Quality management system</b>	Management system to direct and control an organization with regard to quality.
<b>Quality plan</b>	Document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract.
<b>Quality policy</b>	The overall quality intentions and direction of an organisation as regards quality as formally expressed by top management.
<b>Quality records</b>	Objective evidence of the achieved features and characteristics of a product or service and the processes applied to its development, design, production, installation, maintenance, and disposal as well as records of assessments, audits, and other examinations of an organization to determine its capability to achieve given quality requirements.
<b>Quality system</b>	The organisation structure, responsibilities, activities, resources and events that together provide organised procedures and methods of implementation to ensure the organisation can meet quality requirements.
<b>Requirement</b>	A need or expectation that is stated, generally implied or obligatory.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 3</b> Page 5 of 5	
	<b>Glossary of Terms</b>	Effective Date 09/2002	Revision 01

<b>Review</b>	Activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives.
<b>Rework</b>	Action on a nonconforming product to make it conform to the requirements.
<b>Specification</b>	The document that describes in detail the requirements with which a product or service has to comply.
<b>System</b>	Set of interrelated or interacting elements.
<b>System audit</b>	An audit carried out to establish whether the quality system conforms to a prescribed standard in both its design and its implementation.
<b>Traceability</b>	Ability to trace the history, application or location of that which is under consideration.
<b>Validation</b>	Confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.
<b>Verification</b>	Confirmation, through the provision of objective evidence that specified requirements have been fulfilled.
<b>Work instructions</b>	Instructions which describe work to be executed, who is to do it, when it is to start and be completed, and how, if necessary, it is to be carried out.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 4</b> Page 1 of 8	
	<b>Quality Management System</b>	Effective Date 09/2002	Revision 01

## 4 QUALITY MANAGEMENT SYSTEM

### CONTENTS

#### 4.0 INTRODUCTION

#### 4.1 GENERAL REQUIREMENTS

#### 4.2 DOCUMENTATION REQUIREMENTS

##### 4.2.1 General

##### 4.2.2 Quality Manual

The structure of the Quality Manual

Quality system procedures

Work instructions

##### 4.2.3 Control of Documents

##### 4.2.4 Control of Records

#### 4.3 RESPONSIBILITY IN GENERAL

Prepared	Verified	Approved
Name	Name	Name
Date	Date	Date

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 4</b> Page 2 of 8	
	<b>Quality Management System</b>	Effective Date 09/2002	Revision 01

#### 4.0 INTRODUCTION

Leading and operating an organization successfully requires managing it in a systematic and visible manner. Success should result from implementing and maintaining a management system that is designed to continually improve the effectiveness and efficiency of the organisation's performance by considering the needs of the interested parties. Top management should establish a customer-oriented organization.

Reasons for creating a documented quality management system:

- to ensure products and services satisfy customer requirements
- maintain the standards which have been successful in achieving
- to improve standards in those areas where performance is wanting
- to harmonize policies and practices across all departments
- improvement of efficiency
- creating stability and minimizing variance
- eliminating complexity and reducing processing time
- benchmarking current performance
- focus on attention on quality
- to ensure products and services are delivered on time
- reduction of operating costs.

#### 4.1 GENERAL REQUIREMENTS

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of the International Standard ISO 9001.

The organization shall:

- identify the processes needed for the quality management system and their application throughout the organization
- determine the sequence and interaction of these processes
- determine criteria and methods needed to ensure that both the operation and control of these processes are effective
- ensure the availability of resources and information necessary to support the operation and monitoring of these processes
- monitor, measure and analyse these processes
- implement actions necessary to achieve planned results and continual improvement of these processes.



Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 4</b> Page 3 of 8	
	<b>Quality Management System</b>	Effective Date 09/2002	Revision 01

## 4.2 DOCUMENTATION REQUIREMENTS

### 4.2.1 General

The quality management system documentation shall include:

- documented statements of a quality policy and quality objectives
- a quality manual
- documented procedures required by the ISO 9001
- documents needed by the organization to ensure the effective planning, operation and control of its processes
- records required by the International Standard ISO 9001.

### 4.2.2 Quality Manual

The organization shall prepare a Quality Manual covering the requirements of the ISO 9000 series and also requires the Quality

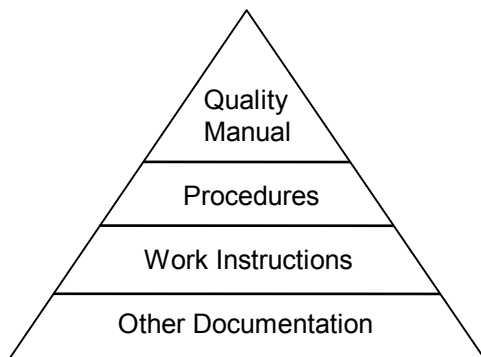
Manual to include or make reference to the quality management system procedures and outline the structure of the documentation used in the system.

The Quality Manual includes:

- the scope of the quality management system, including details of and justification for any exclusions
- the documented procedures established for the quality management system, or reference to them
- a description of the interaction between the processes of the quality management system.

The Quality Manual defines the company quality policy in relation to each clause of the standard ISO 9001. It states the quality policy to meet the requirements of certification bodies and clients.

### The structure of the Quality Manual



Level 1: Defines Approach and Responsibility

Level 2: Defines Who, What, When

Level 3: Answers How

Level 4: Results - shows that the system is operating

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 4</b> Page 4 of 8	
	<b>Quality Management System</b>	Effective Date 09/2002	Revision 01

The Quality Manual should describe, in broad terms, the overall adaptation of ISO 9001 to the working environment of the company. It needs to describe how each applicable section of the standard is to be implemented. It should also establish the structure, authority and responsibility for the maintenance of the company's Quality Management System.

Contents of the Quality Manual:

- introduction, covering purpose, scope, applicability, and definitions
- business, overview describing the nature of the business
- corporate policy, covering the mission, vision, values, objectives, and quality policy
- operational management, covering planning, organization, and management control including quality system management, audits, reviews, and improvement
- operational policies, structured to align with the sequence of key processes from receipt of customer enquiry through to delivery and customer support, referencing to implementing control procedures
- cross reference matrix between manual and ISO 9001 (in this manual the numbering system also is the cross reference as it corresponds to the standard).

**Quality system procedures**

These prescribe the actual detail of how the company operates. They are written in simple, straightforward language appropriate to meet the needs of internal staff. The listed operating procedures prescribe in detail how the requirements of the Documented Quality Management System and the customer contract requirements will be met. The procedures should be numbered so that they relate to the section of the Quality Manual that has been implemented. The Operating Procedures in particular are strictly commercial - in confidence. Quality Procedures should contain clear, detailed descriptions of those processes which are related to the application of ISO 9001. These would include such functions as quality auditing, documentation and its control, customer-complaint handling, Quality Management System reviews, etc.

Contents of procedures

An effective procedure would contain some or all of the following elements:

- a flowchart of the process that depicts the sequence of actions and decisions, inputs, outputs, and interfaces with other procedures
- paragraphs describing the actions and decisions required, indicating the role responsible by matching the flowchart in the sequence in which they occur
- the minimum information and equipment needed to perform each activity or make each decision

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 4</b> Page 5 of 8	
	<b>Quality Management System</b>	Effective Date 09/2002	Revision 01

- the criteria for decisions as a list of aspects to be considered or a statement of requirement which the decision should satisfy
- the criteria for choosing optional routes and the sequence of steps to be taken
- the entry conditions for starting the process, in terms of the minimum inputs and approvals to be satisfied before the procedure may commence
- the exit conditions for ending the process or task, in terms of the minimum outputs and approvals to be satisfied for successful completion of the process
- the source of information or product needed, in terms of from what process, what procedure, what person (role) or organization it comes
- the routing instructions for information or product emerging from the procedure
- any precautions needed to prevent incident, accident, error, problems etc.
- any recording requirements to provide evidence of actions or decisions or to enable traceability in the event of subsequent problems
- any rules that have to be followed in order to ensure that the task is carried out in a uniform manner and satisfies statutory obligations
- controls needed to verify the quality of any products with feedback loops
- controls needed to verify that the process or task achieves its purpose and to verify that critical activities and decisions occur when required
- any forms to be completed, together with form-filling instructions and responsibilities, the numbering system to

be used, and the registers to be maintained

- cross reference to other documents in which essential supplementary information can be found.

### **Work instructions**

Work Instructions may be prepared according to the needs of individual tasks, jobs or contracts. Any instructions need to be written simply and in plain language. They may incorporate diagrams or photos if appropriate. The Quality Policy Manual and associated Operating Procedures contain Mandatory requirements on all of the staff. They are 'living' documents and will be continually amended and updated as required. Work Instructions provide a means by which a manager can describe exactly how some function within his authority should be carried out. Any work instruction needs to be constantly reviewed to ensure it is accurate and describes the optimum way to carry out the task.

### **4.2.3 Control of Documents**

A document is an information and its supporting medium. Examples are record, specification, procedure document, drawing, report, standard etc.

The standard ISO 9001 requires that the organization establish and maintain documented procedures to control all documents and data that relate to the requirements of the standard. There are three types of controlled documents:

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 4</b> Page 6 of 8	
	<b>Quality Management System</b>	Effective Date 09/2002	Revision 01

- policies and practices (these include control procedures, guides, operating procedures, and internal standards)
- documents derived from these policies and practices, such as drawings, specifications, plans, work instructions, technical procedures, and reports
- external documents referenced in either of the above.
- A documented procedure shall be established to define the controls needed:
  - to approve documents for adequacy prior to issue
  - to review and update as necessary and re-approve documents
  - to ensure that changes and the current revision status of documents are identified
- to ensure that relevant versions of applicable documents are available at points of use
- to ensure that documents remain legible readily identifiable
- to ensure that documents of external origin are identified and their distribution controlled
- to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Relationship between documents, data and records:



#### 4.2.4 Control of Records

A record is a document stating results achieved or providing evidence of activities performed. Records shall be 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.

All quality records have one thing in common: they describe the results of activities, the results of inspections, tests, reviews, audits, assessments, calculations etc. These are a number of records to be created and maintained:

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 4</b> Page 7 of 8	
	<b>Quality Management System</b>	Effective Date 09/2002	Revision 01

- management review records
- contract review records
- design review records
- design verification measures
- process/product change implementation records
- records of acceptable subcontractors
- records of unsuitable customer supplied products
- product identification records
- qualified process records
- qualified equipment records
- qualified personnel records
- positive recall records
- inspection and test records
- verification records for test hardware and test software

- calibration records
- non - conformance records
- non - conformance investigation records
- subcontract quality records
- audit result records
- follow-up audit records
- training records.

In addition the following records should be maintained:

- calibration status records
- procedure change records
- customer complaints
- failure analysis reports
- subcontractor assessments
- contract change records.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 4</b> Page 8 of 8	
	<b>Quality Management System</b>	Effective Date 09/2002	Revision 01

**(possible completion:)**

#### **4.3 RESPONSIBILITY IN GENERAL**

Quality Tasks	Responsibility			
	①	②	③	④
Implementation of the quality management system	D	A	A	A
Documentation of the quality management system	D	A	E	A
Establishment of the Quality Manual	D	I	E	I
Control of documents	D	E	E	E
Control of records	D	E	E	E
etc.	...	...	...	...

- |  |
|--|
| ① Management<br>② Commercial department<br>③ Management representative<br>④ Engineering department |
|--|

- |   |
|---|
| D → decide<br>E → execute<br>A → advise<br>I → inform |
|---|

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 5</b> Page 1 of 9	
	<b>Management Responsibility</b>	Effective Date 09/2002	Revision 01

## **5. MANAGEMENT RESPONSIBILITY**

### **CONTENTS**

#### **5.1 MANAGEMENT COMMITMENT**

#### **5.2 CUSTOMER FOCUS**

#### **5.3 QUALITY POLICY**

#### **5.4 PLANNING**

##### **5.4.1 Quality Objectives**

##### **5.4.2 Quality Management System Planning**

#### **5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION**

##### **5.5.1 Responsibility and Authority**

##### **5.5.2 Management Representative**

##### **5.5.3 Internal Communication**

#### **5.6 MANAGEMENT REVIEW**

##### **5.6.1 General**

##### **5.6.2 Review Input**

##### **5.6.3 Review Output**

#### **5.7 RESPONSIBILITY IN GENERAL**

Prepared	Verified	Approved
Name	Name	Name
Date	Date	Date

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 5</b> Page 2 of 9	
	<b>Management Responsibility</b>	Effective Date 09/2002	Revision 01

## 5.1 MANAGEMENT COMMITMENT

The top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements
- establishing the quality policy
- ensuring that quality objectives are established
- conducting management reviews
- ensuring the availability of resources.

The quality management system, introduced by the organization, is monitored concerning its development, its implementation and the constant improvement of its effectiveness by the top management in the form of internal audits.

## 5.2 CUSTOMER FOCUS

The top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction. Customers need confidence that the organization produces under controlled conditions. Customer-related processes are described in section 7.2 and monitoring and measurement of customer satisfaction in section 8.2.1.

## 5.3 QUALITY POLICY

The top management shall ensure that the quality policy:

- is appropriate to the purpose of the organization
- includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system
- provides a framework for establishing and reviewing quality objectives
- is communicated and understood within the organization
- is reviewed for continuing suitability.

It is the policy of the company to always supply to the customers products and services which conform exactly to stated or agreed specifications, and also meet the needs and expectations of those customers. It is essential that the company and all the staff do this in order that they meet the goal to survive and prosper in a competitive market place.

Types of quality policy:

- government policy, which applies to any commercial enterprise
- corporate policy, which applies to the business as a whole and may cover, for example:
  - \* environmental policy - our intentions with respect to the conservation of the natural environment
  - \* financial policy - how the business is to be financed
  - \* marketing policy - to what markets the business is to supply is products
  - \* investment policy - how to secure the future



Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 5</b> Page 3 of 9	
	<b>Management Responsibility</b>	Effective Date 09/2002	Revision 01

- \* expansion policy - the way in which to grow, both nationally and internationally
- \* personnel policy - how to treat the employees and the labour unions
- \* safety policy - intentions with respect to hazards in the work place and use of the products
- \* social policy - how to interface with society
- \* quality policy - intentions with respect to meeting customer requirements
- operational policy, which applies to the operations of the business, such as design, procurement, manufacture, servicing, quality assurance etc. And may cover, for example:
  - \* pricing policy - how the pricing of products is to be determined
  - \* procurement policy - how to obtain the components and services needed
  - \* product policy - what range of products the business is to produce
  - \* inventory policy - how to maintain economic order quantities to meet the production schedules
  - \* production policy - how to determine what to make or buy and how the production resources are to be organised
  - \* servicing policy - how to service the products the customers have purchased
- department policy, which applies to one department, such as the particular rules a department manager may impose to allocate work, review output, monitor progress etc.
- industry policy, which applies to a particular industry, such as the codes of practice set by trade associations for a certain trade.

The following are some typical quality policy statements:

- \* *We will perform exactly like the requirement or cause the requirement to be officially changed.*
- \* *We will satisfy our customers' requirements on time, every time, and within budget.*
- \* *Our aim is to give customer satisfaction in everything we do.*

In order to consistently achieve its objectives the company is wholly committed to the operation of a management system, with the full co-operation of adequately trained staff which satisfies the requirements of ISO 9001.

The system and policy are regularly reviewed by the Managing Director or by the Executive responsible for Quality, to ensure their ongoing effectiveness and efficiency in meeting the company objectives. It is also regularly reviewed to ensure the organisation's systems and policy continue to meet the current needs and expectations of the customers.

The Quality Assurance Manager or Management Representative has the authority and is responsible for implementing, managing and maintaining the Quality Policy Manual and Operating Procedures. S/he also has the authority and organisational freedom to identify and investigate problems affecting the quality of the product, services and Documented Management System.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 5</b> Page 4 of 9	
	<b>Management Responsibility</b>	Effective Date 09/2002	Revision 01

## 5.4 PLANNING

### 5.4.1 Quality Objectives

The top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

The basis for a long-term development of the organization is the securing of a high degree of performance of the quality requirements and the reaching of the given quality objectives.

Important priorities are:

- permanent promotion of quality consciousness by the management
- optimally trained and motivated staff
- controlled product and service realization within all areas
- cooperation with customers and supplier
- control and monitoring of implementation and maintenance of the quality objectives in planned intervals.

### 5.4.2 Quality Management System Planning

The top management shall ensure that:

- the planning of the quality management system is carried out in order to meet the requirements given in section 4.1, as well as the quality objectives
- the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

The standard requires that quality planning which is in accordance with all other requirements of the quality management planning is implemented into all standard operating procedures. This is achieved by initially carrying out an appropriate, formal and recorded review before tendering for, and on receipt of, each contract. Also the regular management review considers performance and future plans for quality. The documented quality system is designed to build in quality at the appropriate stage by:

- adequate specification of work and inspection requirements
- use of trained or qualified personnel
- careful and recorded review of every individual contract.

## 5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

### 5.5.1 Responsibility and Authority

The top management shall ensure that the responsibilities and authorities are defined and communicated within the organization.

There are four principle ways in which responsibilities and authority can be documented:

- in an organization structure diagram, or organigram
- in job descriptions
- in terms of reference
- in procedures.

The Directors and all managers and supervisors ensure that all the requirements of the Quality Policy Manual and the Operating

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 5</b> Page 5 of 9	
	<b>Management Responsibility</b>	Effective Date 09/2002	Revision 01

Procedures have been fully implemented and are maintained. They also ensure all staff understand the requirements of the Operating Procedures and Work Instructions affecting their tasks and the requirements of each contract. The Directors, managers and supervisors also ensure that their staff have the necessary, procedures, work instructions, training, specifications, drawings, tools and equipment to effectively carry out the work.

Each employee of the company is responsible for maintaining the specified standards of work for every contract, at all times. Other staff's responsibilities are adequately covered by the Operating Procedures and Work Instructions.

### 5.5.2 Management Representative

The top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

- ensuring that processes needed for the quality management system are established, implemented and maintained
- reporting to top management on the performance of the quality management system and any need for improvement
- ensuring the promotion of awareness of customer requirements throughout the organization.

The management representative is the system designer for the quality management system. This person may not produce the policies and procedures but operate as a system designer. This person lays down the requirements needed to implement the corporate quality policy and verifies that they

are being achieved. It is also necessary to have someone who can liaise with customers on quality issues, who can co-ordinate the assessment and subsequent surveillance visits, who can keep abreast of the state of the art in quality management. The person should be an advisor to the top management who can measure the overall performance of the company with respect to quality.

To meet this requirement the management representative needs the right to:

- manage the design, development, implementation, and evaluation of the quality management system including the necessary resources
- determine whether proposed policies and practices meet the requirements of the standard ISO 9001, are suitable for meeting the business needs, are being properly implemented, and cause non-conformity to be corrected
- determine the effectiveness of the quality management system
- report on the quality performance of the organization
- identify and manage programs for improvement in the quality system
- liaise with external bodies on quality matters.

The management representative has specific responsibility for:

- administration, control, day to day running and maintenance of the documented quality management system
- updating, issuing and controlling the quality policy manual, operating procedures and work instruction
- formal recording, investigating and reporting on customer complaints

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 5</b> Page 6 of 9	
	<b>Management Responsibility</b>	Effective Date 09/2002	Revision 01

- liaison with the customer and certification body on Quality topics
- approving and monitoring the performance of suppliers
- responsibility for verification and recording of goods inward material
- ensuring the requirements of ISO 9001 are fully addressed and the system completely and effectively implemented, maintained and reviewed
- ensuring the quality requirements of customers are met and that the necessary inspection, tests or verification are carried out. If required by the contract to prepare or approve a formal Quality Plan
- providing and managing a system of internal audits using adequately trained staff who are independent of the activity being audited
- initiating and controlling projects to prevent recurrence or occurrence of nonconforming product or service. Or initiating and controlling projects to give improvements to the grade of product, service or lowering the scrap/rework rate. Such projects may extend to the management of the processes and quality management systems.

### 5.5.3 Internal Communication

The 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.

The organization shall establish suitably conditions, by which internal communication

between their different functional areas is guaranteed. This is concerning especially the effectiveness of the processes of the quality management system. Internal communication is for example:

- periodical consultation in work groups
- periodical meetings of the entire staff
- internal audit.

Additional communication processes can be executed within the organization for special reasons too.

## 5.6 MANAGEMENT REVIEW

### 5.6.1 General

The standard ISO 9001 requires that the top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained.

The management review should do several things:

- establish whether the system is being used properly; determine this by providing the results of all quality audits of the system, of processes and of products
- establish whether the audit program is effective; by providing the evidence of previous audit results and problems reported by other means

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 5</b> Page 7 of 9	
	<b>Management Responsibility</b>	Effective Date 09/2002	Revision 01

- establish whether customer needs are being satisfied; by providing the evidence of customer complaints, market share statistics, competitor statistics, warranty claims etc.
- establish whether the defined quality objectives are being met
- analysis of the date the system generates should reveal whether the targets are being achieved
- establish whether there is conflict between the state quality policy, the quality objectives and the organisational goals and expectations and needs of your customers
- establish whether the quality philosophy is being honored
- an analysis of managerial decisions should reveal whether there is constancy of purpose or lip service being given to the policy
- establish whether the system requires any change to match changing business needs; by assessing the proposed changes in business against the known capability of the system
- establish whether the system provides useful data with which to manage the business; by providing evidence showing how business decisions have been made. Those made without using available data from the quality system show either that poor data is being produced or management is unaware of its value.

### **5.6.2 Review Input**

The input to management review shall include information on:

- results of audits
- customer feedback
- process performance and product conformity
- status of preventive and corrective actions
- follow-up actions from previous management reviews
- changes that could affect the quality management system
- recommendations for improvement.

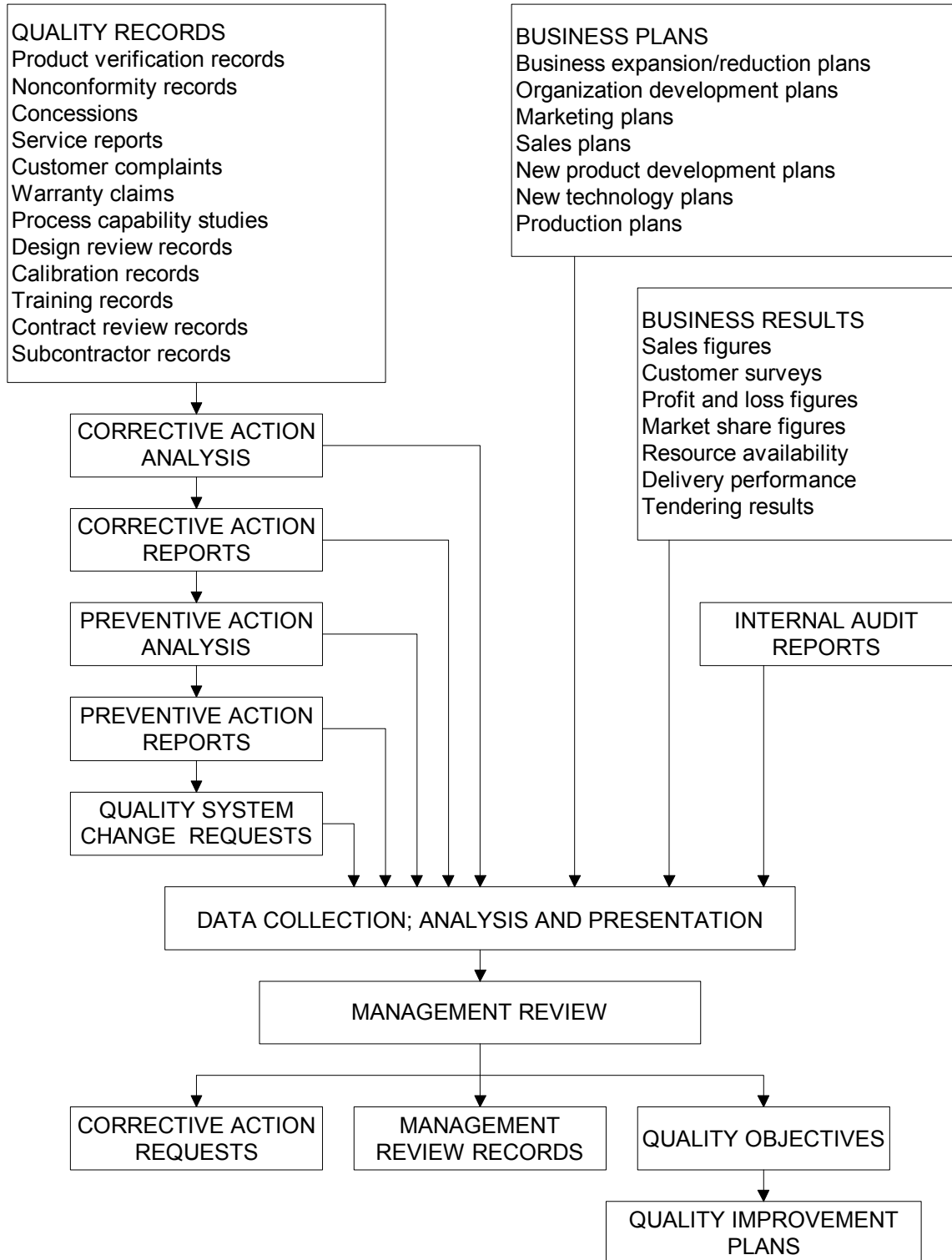
### **5.6.3 Review Output**

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

- improvement to the effectiveness of the quality management system and its processes
- improvement of product related to customer requirements
- resource needs.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 5</b> Page 8 of 9	
	<b>Management Responsibility</b>	Effective Date 09/2002	Revision 01

Management review process



Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 5</b> Page 9 of 9	
	<b>Management Responsibility</b>	Effective Date 09/2002	Revision 01

(possible completion:)

### 5.7 RESPONSIBILITY IN GENERAL

Quality Tasks	Responsibility			
	①	②	③	④
Definition of the quality policy	D	A	A	A
Definition of the quality objectives	D	A	A	A
Quality management system planning	D	A	E	A
Definition of responsibility and authority	D	I	I	I
Ensuring of the internal communication	D	A	A	A
Conducting of management review	E	A	E	A
Ensuring of resources	D	A	I	A
etc.	...	...	...	...

① Management
② Commercial department
③ Management representative
④ Engineering department

D → decide
E → execute
A → advise
I → inform

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 6</b> Page 1 of 4	
	<b>Resource Management</b>	Effective Date 09/2002	Revision 01

## **6. RESOURCE MANAGEMENT**

### **CONTENTS**

#### **6.1 PROVISION OF RESOURCES**

#### **6.2 HUMAN RESOURCES**

##### **6.2.1 General**

##### **6.2.2 Competence, Awareness and Training**

#### **6.3 INFRASTRUCTURE**

#### **6.4 WORK ENVIRONMENT**

#### **6.5 RESPONSIBILITY IN GENERAL**

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Name	Name	Name
Date	Date	Date



Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 6</b> Page 2 of 4	
	<b>Resource Management</b>	Effective Date 09/2002	Revision 01

## 6.1 PROVISION OF RESOURCES

The organization shall determine and provide the resources needed:

- to implement and maintain the quality management system
- to improve continually its effectiveness
- to enhance customer satisfaction by meeting customer requirements.

## 6.2 HUMAN RESOURCES

### 6.2.1 General

The management of the organization shall provide personnel for performing of activities, which influence the product quality, for the solution of quality management functions as well as for internal quality audits who are particularly suitable due to their appropriate education, training, talents, skills and experiences for leading, executing and checking work. Appropriate members of the staff have the necessary training and expertise to undertake self-checking and checking of others as specified in the operating procedures.

The implementation of the quality policy as well as the compliance with all actions securing quality are a principle task of each employee.

### 6.2.2 Competence, Awareness and Training

In order to secure that all staff are able to fulfill their tasks in accordance with the quality objectives the organization shall:

- determine the necessary competence for personnel performing work affecting product quality
- provide training or take other actions to satisfy these needs
- evaluate the effectiveness of the actions taken
- 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
- maintain appropriate records of education, training, skills and experience.

Particular attention should be given to the qualification, selection and training of newly recruited personnel and personnel transferred to new assignments.

Training should be given which will provide executive management with an understanding of the quality management system together with the tools and techniques needed for full executive management participation in the operation of the system. Executive management should also understand the criteria available to evaluate the effectiveness of the system.

Training should be given to the technical personnel to enhance their contribution to the success of the quality management system. Training should not be restricted to personnel with primary quality assignments, but should also include assignments such as marketing, procurement, and process and product engineering.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 6</b> Page 3 of 4	
	<b>Resource Management</b>	Effective Date 09/2002	Revision 01

Motivation of personnel begins with their understanding of the tasks they are expected to perform and how those tasks support the overall activities. Personnel should be made aware of the advantages of proper job performance at all levels, and of the effects of poor job performance on other people, customer satisfaction, operating costs, and the economic well-being of the organization.

### **6.3 INFRASTRUCTURE**

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity product requirements. Infrastructure includes, as applicable:

- buildings, workspace and associated utilities
- process equipment (both hardware and software)
- supporting services (such as transport or communication).

### **6.4 WORK ENVIRONMENT**

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

The work environment includes:

- work environment in offices
- work environment in workshops
- work environment in test facilities
- work environment in laboratories
- regulations over the access and over the use of work areas.

Process operations under controlled conditions includes suitable production, installation, and servicing equipment, and a suitable working environment.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 6</b> Page 4 of 4	
	<b>Resource Management</b>	Effective Date 09/2002	Revision 01

**(possible completion:)**

### 6.5 RESPONSIBILITY IN GENERAL

Quality Tasks	Responsibility			
	①	②	③	④
Provision of resources	D	A	A	A
Human resources	E	A	A	A
Infrastructure	E	A	I	A
Work environment	E	A	I	A
etc.	...	...	...	...

- |                             |
|-----------------------------|
| ① Management                |
| ② Commercial department     |
| ③ Management representative |
| ④ Engineering department    |

- |             |
|-------------|
| D → decide  |
| E → execute |
| A → advise  |
| I → inform  |

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 1 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

## **7. PRODUCT REALIZATION**

### **CONTENTS**

#### **7.0 INTRODUCTION**

#### **7.1 PLANNING OF PRODUCT REALIZATION**

##### **7.1.1 Process Control Model**

#### **7.2 CUSTOMER-RELATED PROCESSES**

##### **7.2.1 Determination of Requirements Related to the Product**

##### **7.2.2 Review of Requirements Related to the Product**

##### **7.2.3 Customer Communication**

#### **7.3 DESIGN AND DEVELOPMENT**

##### **7.3.1 Design and Development Planning**

##### **7.3.2 Design and Development Inputs**

##### **7.3.3 Design and Development Outputs**

##### **7.3.4 Design and Development Review**

##### **7.3.5 Design and Development Verification**

##### **7.3.6 Design and Development Validation**

##### **7.3.7 Control of Design and Development Changes**

#### **7.4 PURCHASING**

##### **7.4.1 Purchasing Process**

##### **7.4.2 Purchasing Information**

##### **7.4.3 Verification of Purchased Product**

#### **7.5 PRODUCTION AND SERVICE PROVISION**

##### **7.5.1 ITTC Recommended Procedures**

##### **7.5.2 Validation of Processes for Production and Service Provision**

##### **7.5.3 Identification and Traceability**

##### **7.5.4 Customer Property**

##### **7.5.5 Preservation of Product**

#### **7.6 CONTROL OF MONITORING AND MEASURING DEVICES**

##### **7.6.1 Work Instructions in the ITTC-Recommended Procedures**

#### **7.7 RESPONSIBILITY IN GENERAL**

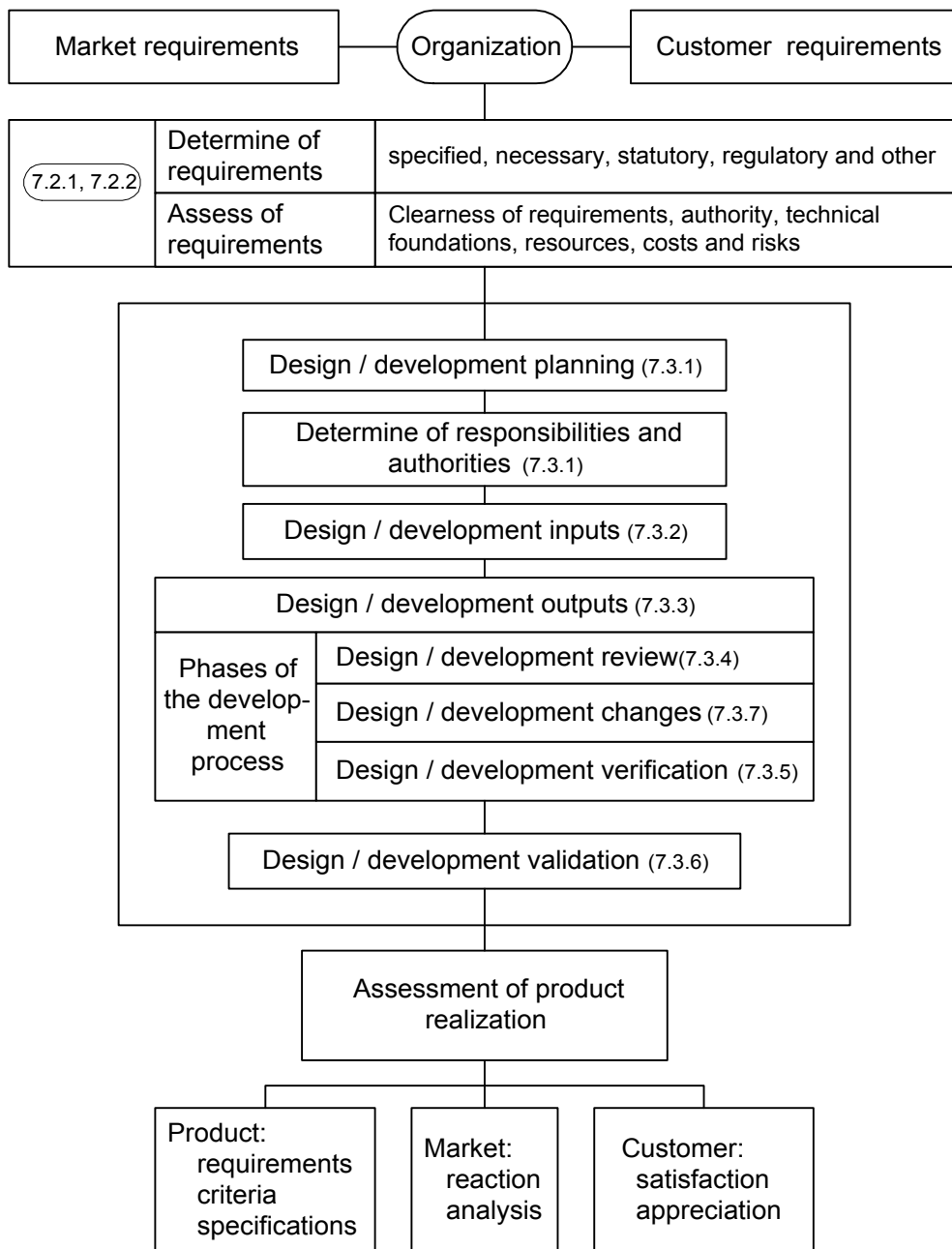
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Date	Date	Date

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 2 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

## 7.0 INTRODUCTION

The top management should ensure the effective and efficient operation of realization and support of processes and the associated

process network so that the organization has the capability of satisfying its interest parties.



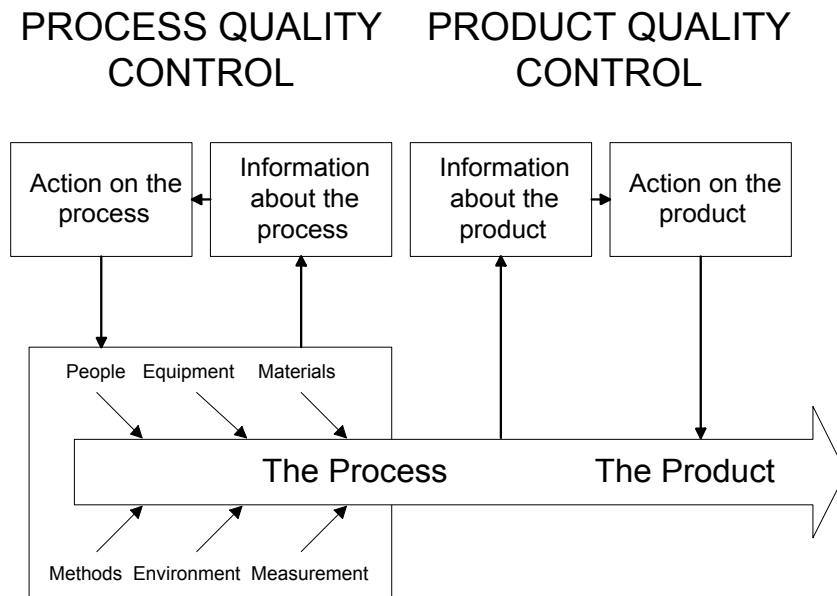
Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 3 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

## 7.1 PLANNING OF PRODUCT REALIZATION

The standard ISO 9001 requires that the organization identifies and plans the production, installation, and servicing processes which directly affect quality. Each step of the production process follows a predetermined plan. It expects that the process,

no matter how many steps are involved, has carefully planned and documented procedures and that adequate check points have been designated throughout the process so as to verify that the end product will be of satisfactory quality.

### 7.1.1 Process Control Model



The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management (see section 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

- quality objectives and requirements for the product
- the need to establish processes, documents, and provide resources specific to the product
- required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 4 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

- records needed to provide evidence that the realization processes and resulting product meet requirements ( see section 4.2.4).

All processes that affect the quality of the product or of the service that the organization to meet its contractual obligations (or the implied contractual needs or requirements of its customers) carry out under management control which include:

- formally documented, controlled and authorised operating procedures; also where required appropriate checklists, proformas, record books, etc.;
- where found to be appropriate or necessary, additional work instructions or possibly quality plans; these may include one-off instructions to cater for specific contract conditions, reworks, etc.; all such instructions will be formally documented, identifiable to the process/or contract, be signed for authorisation and dated;
- specifying where necessary experienced or trained staff, appropriate tools, instruments, equipment and also the materials and components required;
- definition of acceptable standard of workmanship; where appropriate or desirable these may include drawings, visual aids, photos, or comparative representative standards of actual product; such visual aids or comparative standards will be carefully labelled, authorised and controlled (or- placed in the controls of the calibration system);
- additional process controls, verification, or restrictions to trained operatives for critical or 'special processes', in particular for those which cannot be easily checked when the process is complete;

- inspection or Quality Assurance checks during and after appropriate steps or key stages in the process.

In general all processes and controls are continually reviewed. It is expected that over a period of time, they will be modified, either to improve the standard of workmanship, to meet new or additional customer requirements, to maintain the lead over competitors or to meet new legislation.

## **7.2 CUSTOMER-RELATED PROCESSES**

### **7.2.1 Determination of Requirements Related to the Product**

The organization must determine the requirements of the customer regarding the product or the service before it bid an offer or accept a contract or an order. The organization shall determine:

- requirements specified by the customer, including the requirements for delivery and post-delivery activities
- requirements not stated by the customer but necessary for specified or intended use, where known
- statutory and regulatory requirements related to the product
- any additional requirements determined by the organization.

### **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

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 5 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

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

- product requirements are defined
- contract or order requirements differing from those previously expressed are resolved
- the organization has the ability to meet the defined requirements.

Customers need confidence that the organization's tender was produced under controlled conditions. In ensuring that the contract requirements are adequately defined one should establish where applicable that:

- there is a clear definition of the purpose of the product or of the service
- the conditions of use are clearly specified
- the requirements are specified in terms of the features that will make the product or of the service fit for its intended purpose
- the quantity and delivery are specified
- the contractual requirements are specified, including: warranty, payment conditions, acceptance conditions, customer supplied material, financial liability, legal matters, penalties, subcontracting, licenses, and design rights
- the management requirements are specified, such as points of contract, program plans, work breakdown structure, progress reporting, meetings, reviews, interfaces
- the quality assurance requirements are specified, such as quality system

standards, quality plans, reports, customer surveillance, and concessions.

Initial enquiries may be received by letter, fax, telephone, e-mail, formal 'invitations to tender', or personal contact. The initial enquiry is logged e.g. into a contract register and reviewed according to documented procedures.

A formal review is carried out before submission of a tender and also on receipt of every contract to ensure that:

- there are no unresolved discrepancies between any tender and proposed contract
- all documents, specifications and drawings stipulated within the contract, or invitation to tender documents, are readily available and are of the correct issue; that any standards stipulated are practically achievable and can be met
- the company is able to meet all the requirements of the proposed contract, or has ensured outside capacity by certified sub-contractors
- any additional requirements are addressed with regards to 'customer supplied material' or 'verification by the customer of purchased material at source'
- if the proposed contract makes a requirement to temporarily amend the Documented Quality Management System, that this is formally addressed and controlled
- all review of tenders and contracts are recorded in the contract register and are signed and dated.

Records of the results of the review and actions arising from the review shall be



Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 6 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

maintained (see 4.2.4). Each order or contract should be signed by a person authorised to accept orders or contracts on behalf of the organisation. A register should be maintained of all contracts or orders and in the register indicate which were accepted and which declined.

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.

### 7.2.3 Customer Communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to:

- product information
- enquiries, contracts or order handling, including amendments
- customer feedback, including customer complaints.

## 7.3 DESIGN AND DEVELOPMENT

Design and development of products will be conducted in a model basin normally as a scientific method, a technical solution or a test design. The result is an optimisation or a new awareness for design or construction of ships, propulsion systems and other. Services will be conducted in the form of surveys, calculations of profitability, help for reasons for decisions, test reports and other topics.

### 7.3.1 Design and Development Planning

During the design and development planning, the organization shall determine:

- the design and development stages
- the review, verification and validation that are appropriate to each design and development stage
- the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

The design and development plannings should identify:

- the design requirements
- the design and development program showing activities against time
- the work packages and names of those who will execute them (work packages are the parcels of work that are to be handed out either internally or to subcontractors)
- the work breakdown structure showing the relationship between all the parcels of work
- the reviews to be held for authorizing work to proceed from stage to stage
- the resources in terms of finance, manpower, and facilities
- the risks to success and the plans to minimize them
- the controls (quality plan or procedures and standards) that will be exercised to keep the design on course.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 7 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

Design and development schedule as an example:

- design requirement review
- conceptual design review
- preliminary design review
- critical design review
- final design review.

### 7.3.2 Design and Development Inputs

The principal aim of design input is to make sure that what the management or the customer want from the product or service has been adequately specified at the outset. The design input should embrace every aspect of the requirement and give consideration to the factors and parameters that the service is to meet, once it becomes part of the business.

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

- functional and performance requirements
- applicable statutory and regulatory requirements
- where applicable, information derived from previous similar designs
- other requirements essential for design and development.

Design input requirements could be:

- the purpose of the product or service
- the conditions under which it will be used
- the skills and category of those who will use and maintain the product or service
- the countries to which it will be sold

- the special features and characteristics which the customer requires the product or service to exhibit
- the constrains in terms of timescale, operating environment, or other factors
- the standards with which the product or service needs to comply
- the products or service with which it will directly and indirectly interface, and their features and characteristics
- the documentation required of the design output necessary to manufacture, procure, inspect, test, install, operate, and maintain a product or a service.

### 7.3.3 Design and Development Outputs

The standard ISO 9001 requires that the outputs of design and development be provided in a form that enables verification against the design and development input and be approved prior to release.

Design and development outputs shall:

- meet the input requirements for design and development
- provide appropriate information for purchasing, production and for service provision
- contain or reference product acceptance criteria
- specify the characteristics of the product that are essential for its safe and proper use.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 8 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

### 7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements like described in section 7.3.1 “Design and Development Planning”

- to evaluate the ability of the results of design and development to meet requirements
- to identify any problems and propose necessary actions.

The standard requires that participants at each design review include representatives of all functions concerned with the design and development stage being reviewed, as well as other specialist personnel as required. Records of the results shall be maintained.

### 7.3.5 Design and Development Verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met **the design and development requirements**. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

At appropriate stages of design, design and development verification shall be performed to ensure that the design stage output meets the design stage input requirements:

- recording design verification measures
- alternative design calculations
- comparing similar designs
- undertaking tests and demonstrations
- reviewing design stage documents before release.

### 7.3.6 Design and Development Validation

Design and development validation be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting **the requirements for the specific application or intended use**. Records of the results of the validation and any necessary actions shall be maintained (see 4.2.4).

Design and development validation be performed to ensure that product conforms to defined user needs and/or requirements:

- design validation follows successful design verification
- validation is normally performed under defined operating conditions
- validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion
- multiple validations may be performed if there are different intended uses.

### 7.3.7 Control of Design and Development Changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4):

- identification of design and development changes
- identification of modifications

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 9 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

- documenting design and development changes
- documenting modifications
- review and approval of design and development changes
- review and approval of modifications.

#### 7.4 PURCHASING

As bought-in materials or services have a direct affect on the output of the company, the selection of suppliers or subcontractors is of obvious importance. Of equal importance is that the staff of the company correctly specify the exact requirements.

The procedures controlling the selection of suppliers and for purchasing are mandatory for the procurement of all products or services that affect the quality of the product or service. The organization shall establish and maintain records of acceptable subcontractors. The records may include:

- details of each order placed
- the performance in supplying against orders
- control records
- information on defects
- corrective actions.

##### 7.4.1 Purchasing Process

The organization shall ensure that purchased product conforms to specified purchase requirements. The organization shall evaluate and select suppliers based on their ability to supply products in accordance with the organization's requirements. Criteria for

selection, evaluation and re-evaluation shall be established. Records shall be maintained.

Evaluation of subcontractors:

- evaluation and selection of subcontractors
- purchasing from approved subcontractors
- control of subcontractors
- defining subcontractor controls
- selecting the degree of control
- records of acceptable subcontractors.

##### 7.4.2 Purchasing Information

Purchasing information shall describe the product to be purchased, including:

- requirements for approval of product, procedures, processes and equipment
- requirements for qualification of personnel
- quality management system requirements.

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

Purchasing data can be:

- product identification
- purchasing specifications
- subcontract quality management system requirements
- review and approval of purchasing documents.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 10 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

### 7.4.3 Verification of Purchased Product

The organization establishes and implements necessary inspection or other activities and scrutinizes the purchased products or the services ensuring that purchased products or the services meet **specified requirements**. Results of verification will be recorded and used for evaluation of the subcontractors.

Possible verification can be too:

- verification of organization at subcontractor's premises
- customer verification of subcontracted product.

## 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:

- the availability of information that describes the characteristics of the product
- the availability of work instructions, as necessary
- the use of suitable equipment
- the availability and use of monitoring and measuring devices
- the implementation of monitoring and measurement
- the implementation of release, delivery and post-delivery activities.

Controlled conditions include too:

- Documented procedures which should define:
  - \* the qualifications required for the person carrying out the procedure, if any special qualifications are required
  - \* the preparatory steps to be taken to prepare the product for processing
  - \* the preparatory steps to be taken to set up any equipment
  - \* the steps to be taken to process the product
  - \* the precautions to observe
  - \* the settings to record.
- Suitable production, installation, and servicing equipment, and a suitable working environment.
  - \* documentation from the standards that are to be maintained
  - \* providing training for staff
  - \* providing procedures for maintaining the equipment to these standards
  - \* maintenance of records of the conditions as a means of demonstrating that the standards are being achieved.
- Compliance with reference standards/codes, quality plans and/or documented procedures
- Monitoring and control of process parameters and product characteristics
- Approval of processes and equipment
- Workmanship criteria, can comprise:
  - \* a list of the equipment upon which process capability depends
  - \* defined maintenance requirements specifying maintenance tasks and their frequency

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 11 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

- \* a maintenance program that schedules each of the maintenance tasks on a calendar
- \* procedures defining how specific maintenance tasks are to be conducted
- \* procedures governing the decommissioning of plant prior to planned maintenance
- \* procedures governing the commissioning of plant following planned maintenance
- \* procedures dealing with the actions required in the event of equipment malfunction
- \* maintenance logs which record both the preventive and corrective maintenance work carried out.

### 7.5.1 ITTC Recommended Procedures

ITTC Recommended Procedures as a rule are descriptions of special processes for towing tanks and hydrodynamic facilities. All the adopted recommended procedures and summary descriptions of bench mark data and test cases since 1955 are contained in the ITTC-Recommended Procedures. Additionally, the respective list of parameters, recommendations of the ITTC for some of the parameters, the corresponding benchmark tests, validation procedures, and uncertainty analyses have been added, if mentioned in the proceedings. The ITTC-Recommended Procedures should be used as reference for basic internal procedures and work instructions.

### 7.5.2 Validation of Processes for Production and Service Provision

Such processes of production and service provision requiring pre-qualification of their process capability are frequently referred to as special processes. The standard defines special processes as processes, the results of which cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use. The standard ISO 9001 requires special processes to be carried out by qualified operators and/or continuous monitoring and control of process parameters to ensure that the specified requirements are met.

Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including:

- defined criteria for review and approval of the processes
- approval of equipment and qualification of personnel
- use of specific methods and procedures
- requirements for records
- revalidation.

Within the quality management system a list should be produced and maintained of all processes that have been qualified and a list of the personnel who are qualified to operate them. The records of qualified personnel using special processes should be governed by the training requirements covered in section 6.2.2.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 12 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

### 7.5.3 Identification and Traceability

Where it is appropriate it should be possible for a company to trace any product back through the manufacturing or testing process to the specifications and drawings. The organization shall establish and maintain documented procedures where appropriate for identifying the product by suitable means from receipt and during all stages of production, delivery, and installation.

Documented procedures are needed where the product identity is not inherently obvious. Procedures for identifying product should start at the design stage when the product is conceived. The design should be given a unique identity, a name or number, and that should be used on all related documents. Apart from the name or number given a product you need to identify the version and the modification state so that you can relate the issues of the drawing and specifications to the products they represent.

The organization shall where, and to the extent that traceability is a specified requirement, establish and maintain documented procedures for unique identification of individual product or batches and goes on to require this identification to be recorded. Traceability to the original subcontractor's material or document is not a common requirement. But traceability is important to control processes. You may need to know which products have been through which processes and on what date, if a problem is found some time later. The same is true of test and measurement equipment.

The organization shall identify the product status with respect to monitoring and

measurement requirements. The requirements for inspection and test status are identification requirements that enable conforming product to be distinguishable from nonconforming product. Inspection and test status is either 'reject' or 'accept'. If not fully conforming the product should be rejected and identified as such. If conforming the product should be accepted and identified as such.

The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product (report, software) that has passed the required inspections and tests is dispatched, used or installed.

- define and document what inspections are to be carried out
- define what constitutes an acceptable item
- list who is authorised to do the inspections
- carry out the inspections and identify who did them
- place the Test Status on the item itself if at all possible
- reject those which failed the test criteria
- keep detailed records of fail or pass to form useful statistics
- review the failures for possible corrective and preventive action.

### 7.5.4 Customer Property

Customer property are materials, services, or intellectual property provided by the client, and are the property of the client. The materials are needed to supply the product or service and

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 13 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

are either built into the product or service, or are needed as a related activity or, in the case of documents to provide information.

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, by:

- receipt inspection to check that the items agree with any information supplied by the customer;
- identification to ensure that the items are not inadvertently used on the wrong contract or work;
- any shortages or damage identified is reported in writing immediately to the customer;
- checks and precautions as required, to protect and prevent deterioration;
- any defective material received, or arising during processing or excess material left over at the end of the contract will be returned to the client, unless formal written authority is received for disposal.

**7.5.5 Preservation of Product**

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection.

The organization shall provide methods of handling product and storage that prevent

damage or deterioration. These are important especially for:

- measuring and test equipment
- products (models)
- customer supplied products.

In order to detect deterioration, the condition of equipment and products shall be assessed at appropriate intervals. If necessary the organization should:

- control packing, packaging and marking processes to the extent necessary to ensure conformance to specified requirements
- apply appropriate methods for preservation and segregation of product when the product is under the organization's control
- arrange for the protection of the quality of product after final inspection and test.

**7.6 CONTROL OF MONITORING AND MEASURING DEVICES**

The integrity of products depend upon the quality of the devices used to create and measure their characteristics. ISO 9001 specifies requirements for ensuring the quality of such devices. If the devices used to create and measure characteristics are inaccurate, unstable, damaged, or in any way defective then the product may not possess the required characteristics.

Devices that one used for product verification at all stages in the quality loop need to be controlled and this includes devices used for inspection and test on receipt of product, in-process, and final acceptance before release to the customer. It also includes



Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 14 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

devices used during design and development for determining product characteristics and for design verification. Some characteristics cannot be determined by calculation and have to be derived by experiment. In such cases the accuracy of the used devices must be controlled.

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. The organization shall establish and maintain documented procedures to control, calibrate, and maintain inspection, measuring, and test equipment including test software.

Procedures for the control, calibration, and maintenance of measuring devices will need to cover the various types of devices employed for measurement purposes, such as:

- electronic measuring equipment
- mechanical measuring devices
- test software
- forming tools and equipment.

Where necessary to ensure valid results, measurement equipment shall:

- 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, the basis used for calibration or verification shall be recorded
- be adjusted or re-adjusted as necessary
- be identified to enable the calibration status to be determined
- be safeguarded from adjustments that would invalidate the measurement result

- be protected from damage and deterioration during handling, maintenance and storage.

Control of monitoring and measuring devices in this instance can mean several things, for example:

- knowing where the equipment is located so that one can recall it for calibration and maintenance
- knowing what condition the equipment is in so that one can prohibit its use if the condition is unsatisfactory; one will need a defect report for this purpose
- knowing when the instrument's accuracy was last checked so that there can be confidence in its results; calibration records and labels fulfil this need
- knowing what checks have been made using the instrument since it was last checked, so that one can repeat them should the instrument be subsequently found out of calibration
- knowing that the measurements made using the instrument are accurate so that one can rely on the results; a valid calibration status label will fulfil this purpose
- knowing that the instrument is only being used for measuring the parameters for which it was designed, so that results are reliable and equipment is not abused.

In addition to calibrating the devices one will need to carry out preventive and corrective maintenance in order to keep them in good condition. Preventive maintenance is maintenance to reduce the probability of failure, such as cleaning, testing, inspecting etc. Corrective maintenance is concerned with restoring a device after a failure has occurred

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 15 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

to a condition in which it can perform its required function.

Calibration operations included:

- calibration against certified equipment
- documenting the basis for calibration
- defining the calibration process
- indicating calibration status
- maintaining calibration records.

Protection of measuring equipment included:

- ensuring that environmental conditions are suitable
- ensuring that accuracy and fitness for use is maintained
- safeguarding inspection, measuring, and test equipment.

Records for control of monitoring and measurement devices are quality documents. The results of calibration and verification shall be maintained like described in section 4.2.4 "Control of Records".

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.

**7.6.1 Work Instructions in the ITTC-Recommended Procedures**

For test laboratories the control of inspection, measuring and test equipment is of vital importance. Therefore several working instructions were prepared by the ITTC Quality Systems Group describing the most important aspects of this task which are contained in the ITTC-Recommended Procedures. The purpose of these working instructions is to ensure that the measuring equipment used in standard tests is efficient and its metrological characteristics ensure test results with the intended accuracy. These working instructions are to be considered as examples.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 7</b> Page 16 of 16	
	<b>Product Realization</b>	Effective Date 09/2002	Revision 01

(possible completion:)

**7.7 RESPONSIBILITY IN GENERAL**

Quality Tasks	Responsibility			
	①	②	③	④
Planning of product realisation	D	A	A	A
Determination and review of requirements related to the product	D	I	I	E
Customer communication	D	E	E	E
Design and development planning and inputs	D	A	A	A
Review, verification and validation of design and development outputs	D	I	I	E
Purchasing of products	E	A	I	A
Control of Production and service provision	D	A	I	E
Identification and traceability	D	E	E	E
Handling and exercise with customer property	D	A	I	E
Control of monitoring and measurement devices	D	I	A	E
etc.	...	...	...	...

① Management
② Commercial department
③ Management representative
④ Engineering department

D → decide
E → execute
A → advise
I → inform

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 8</b> Page 1 of 8	
	<b>Measurement, Analysis and Improvement</b>	Effective Date 09/2002	Revision 01

## **8. MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### **CONTENTS**

#### **8.1 GENERAL**

#### **8.2 MONITORING AND MEASUREMENT**

##### **8.2.1 Customer Satisfaction**

##### **8.2.2 Internal Audit**

##### **8.2.3 Monitoring and Measurement of Processes**

##### **8.2.4 Monitoring and Measurement of Product**

#### **8.3 CONTROL OF NONCONFORMING PRODUCT**

#### **8.4 ANALYSIS OF DATA**

#### **8.5 IMPROVEMENT**

##### **8.5.1 Continual Improvement**

##### **8.5.2 Corrective Action**

##### **8.5.3 Preventive Action**

#### **8. 6 RESPONSIBILITY IN GENERAL**

Prepared	Verified	Approved
Name	Name	Name
Date	Date	Date

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 8</b> Page 2 of 8	
	<b>Measurement, Analysis and Improvement</b>	Effective Date 09/2002	Revision 01

## **8 MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### **8.1 GENERAL**

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

- to demonstrate conformity of the product
- to ensure conformity of the quality management system
- to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extend of their use.

Deviations become promptly detected by planned monitoring, measurement, analysis and improvement before, while and after the service contribution or the product creation. If necessary corrective actions are arranged. The executed checks should be adapted at the sequence in the work areas. The later the check the more costly the rework. But type and scope of activities of the checks must be economically justifiable. The application of statistical methods is possible only in very limited measure for a ship model basin because performance essentially consists of scientific-technical performances and products in one-off production.

## **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 shall monitor information relating to customer perception as to whether the organization has met customer requirements.

The measurement and monitoring of the customer satisfaction are based on the evaluation of customer's information, which can be collected actively or passively. The methods for obtaining and using this information shall be determined.

### **8.2.2 Internal Audit**

In evaluating the effectiveness of a quality management system, audits are an important element. Audits may be conducted by, or on behalf of, the organization itself (internal quality audit), its customers, or independent bodies.

The standard requires that the organization shall conduct internal audits at planned intervals to determine whether the quality management system

- conformed to the planned arrangements, to the requirements of ISO 9001 and to the quality management system requirements established by the organization, and
- is effectively implemented and maintained.

Procedures for both planning and implementing internal audits should exist and these should cover the following:

- preparing an annual audit program
- the selection of auditors and a team leader if necessary
- planning audits of each type
- conducting the audit

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 8</b> Page 3 of 8	
	<b>Measurement, Analysis and Improvement</b>	Effective Date 09/2002	Revision 01

- recording observations
- determining corrective actions
- reporting audit findings
- implementing corrective actions
- confirming the effectiveness of corrective actions
- the forms on which you plan the audits
- the forms on which you record the observations and corrective actions.

The standard requires that the selection of auditors and the conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. To ensure their independence, auditors need not be placed in separate organizations. Although it is quite common for quality auditors to reside in a quality department it is by no means essential. There are several solutions:

- Auditors can be from the same department as the activities being audited, provided they are not responsible for the activities being audited.
- Separate independent quality audit departments could be set up, staffed with trained auditors.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining shall be defined in a document procedure.

The audit report should state the results of the audit, what was found compliant as well as what was found noncompliant. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit. There are

three actions which the responsible manager should take:

- remedial action to correct the particular nonconformity
- research for other examples of nonconformity and to establish how widespread the problem is
- establish the root cause of the nonconformity and prevent its recurrence.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

### **8.2.3 Monitoring and Measurement of Processes**

ISO 9001 requires that the organization apply suitable methods for monitoring and measurement of the quality management processes.

For the evaluation of the effectiveness of the quality management processes may be executed on the internal audit a self-assessment for selected areas of the organization by top management following the standard DIN EN ISO 9004 Appendix A. The evaluation of the requirements and expectations of the interested parties are to be the centre of attention like

- abilities of the organization
- response time to inquiries
- use of technologies
- input-output ratio.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 8</b> Page 4 of 8	
	<b>Measurement, Analysis and Improvement</b>	Effective Date 09/2002	Revision 01

### 8.2.4 Monitoring and Measurement of Product

In agreement with the planned regulations in the quality management manual chapter 7.1 "Planning of Product Realization" in suitable phases of the product realization or service provision checks are executed. Recordings of these checks are created in accordance with quality management manual chapter 4.2.4 "Control of records".

Type and scope of the monitoring and measurement of product as well as the competencies for execution and the evaluation of the results are to be determined.

The product monitoring and measurement plans should:

- identify the product to be inspected and tested
- define the specification and acceptance criteria to be used and the issue status which applies
- define the inspection aids and test equipment to be used; standard measuring equipment would not need to be specified as your inspectors and testers should be trained to select the right tools for the job; any special equipment should be identified
- define the environment for the measurements to be made if critical to measurement accuracy
- identify the organization which is to perform the inspections and tests
- make provision for the results of the inspections and test to be recorded.

Final inspection is the last inspection of the product or service. There are two aspects to final inspection. One is checking what has gone

on before and the other one is accepting the product or service.

Final inspection and test checks should detect whether:

- all previous inspections and checks have been performed
- the product (draft, drawing, program etc.) bears the correct identification, part numbers, serial numbers, modification status etc.
- all recorded non conformances have been resolved and remedial action taken and verified
- all concession applications have been approved
- all inspection and test results have been collected
- all documentation to be delivered with the product or service has been produced and conforms to the prescribed standards.

No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.

### 8.3 CONTROL OF NONCONFORMING PRODUCT

A nonconforming product is one that does not conform to the specified requirements. Specified requirements are either requirements prescribed by the customer and agreed by the organization in a contract for products or services, or are requirements prescribed by the organization which are perceived as satisfying a market need.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 8</b> Page 5 of 8	
	<b>Measurement, Analysis and Improvement</b>	Effective Date 09/2002	Revision 01

The standard ISO 9001 requires that the organization ensures that products which do not conform to product requirements are identified and controlled to prevent their unintended use or delivery.

The top management should empower people in the organization with the authority and responsibility to report nonconformities at any stage of a process in order to ensure timely detection and disposition of nonconformities. Authority for response to nonconformities should be defined to maintain achievement of process and product requirements. The organization should effectively and efficiently control nonconforming product identification, segregation and disposition in order. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a document procedure.

The organization shall deal with nonconforming product by one or more of the following ways

- by taking action to eliminate the detected nonconformity
- by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
- by taking action to preclude its original intended use or application

Nonconforming product shall be reviewed in accordance with documented procedures. It may be:

- reworked to meet the specified requirements, or
- accepted with or without repair by concession, or
- regarded for alternative applications, or
- rejected or scrapped.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

## 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.

The analysis of data shall provide information relating to

- customer satisfaction (see 8.2.1)
- conformity to product requirements and service requirements (see 7.2.1)
- characteristics and trends of processes and products including opportunities for preventive action
- evaluation of suppliers
- market-analysis.

## 8.5 IMPROVEMENT

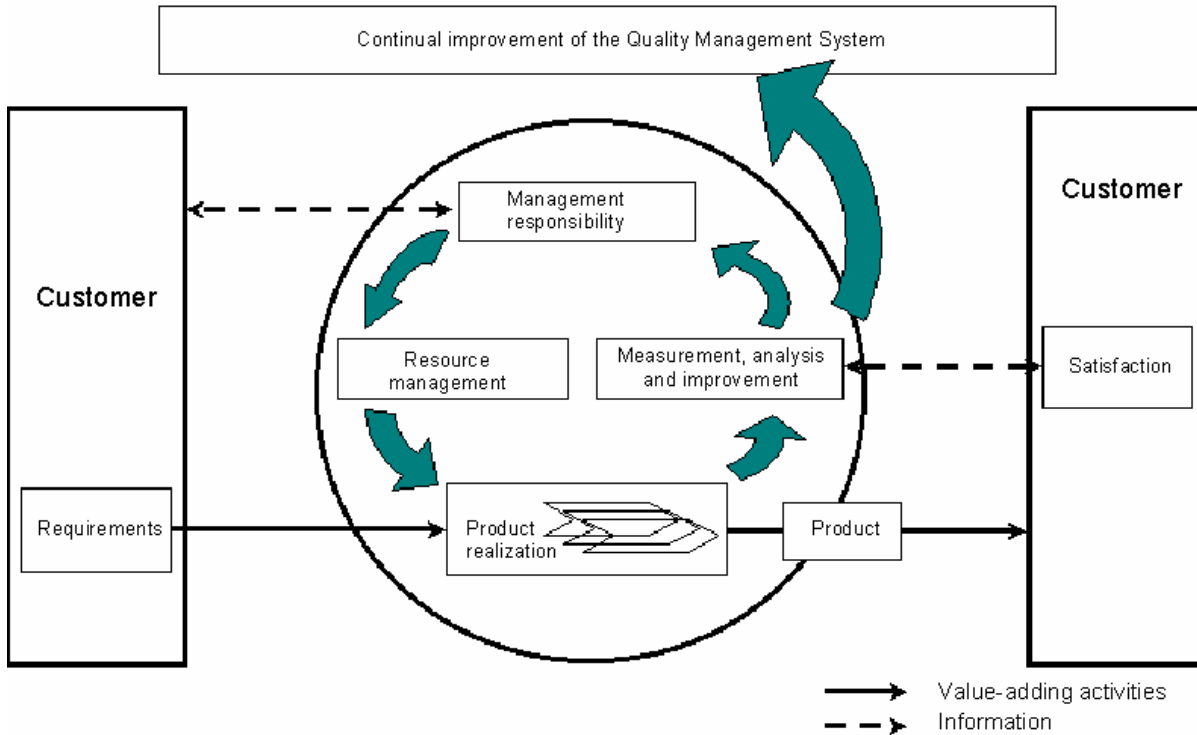
### 8.5.1 Continual Improvement

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.

The requirements for quality improvement can be related to any aspect such as effectiveness, efficiency or traceability.



Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 8</b>	
		Page 6 of 8	
	<b>Measurement, Analysis and Improvement</b>	Effective Date 09/2002	Revision 01



**Model of a process-based quality management system**

**8.5.2 Corrective Action**

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. A documented procedure shall be established to define requirements for

- reviewing nonconformities (including customer complaints)
- determining the causes of nonconformities
- evaluating the need for action to ensure that nonconformities do not recur
- determining and implementing action needed
- records of the results of action taken (see 4.2.4)
- reviewing corrective action taken.

Non-conformities are caused by one or more of the following:

- deficiencies in communication
- deficiencies in documentation
- deficiencies in personnel training and motivation
- deficiencies in materials
- deficiencies in tools and equipment
- deficiencies in the operating environment
- deficiencies in calibration of test equipment.

In pursuing corrective actions, the organization identifies sources of information,

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 8</b> Page 7 of 8	
	<b>Measurement, Analysis and Improvement</b>	Effective Date 09/2002	Revision 01

and collects information to define the necessary corrective actions. The defined corrective actions are focused on eliminating causes of nonconformities in order to avoid recurrence. Examples of sources of information for corrective action consideration include:

- customer complaints
- nonconformity reports
- internal audit reports
- outputs from management review
- outputs from data analysis
- outputs from satisfaction measurements.
- relevant quality management system records
- the organization's people
- process measurements
- results of self-assessment.

### **8.5.3 Preventive Action**

The organization shall determine actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. A documented procedure shall be established to define requirements for

- determining potential nonconformities and their causes
- evaluating the need for action to prevent occurrence of nonconformities
- determining and implementing action needed
- records of results of action taken (see 4.2.4)
- reviewing preventive action taken.

Results of the evaluation of the effectiveness and efficiency of the preventive action should be an output from management review, and should be used as an input for the modification of plans and as an input to the improvement processes.

Company	<b>ITTC-Sample Quality Manual</b>	<b>Section 8</b> Page 8 of 8	
	<b>Measurement, Analysis and Improvement</b>	Effective Date 09/2002	Revision 01

(possible completion:)

**8. 6 RESPONSIBILITY IN GENERAL**

Quality Tasks	Responsibility			
	①	②	③	④
Planning of monitoring and measurement	D	I	A	E
Measurement and monitoring of customer satisfaction	A	A	A	A
Planning and conducting of audits	A	A	E	A
Monitoring and measurement of processes	D	E	I	E
Monitoring and measurement of product	D	I	I	E
Control of nonconforming product	D	E	I	E
Analysis of data	D	E	I	E
Corrective and preventive action	D	E	I	E
etc.	...	...	...	...

- |                             |
|-----------------------------|
| ① Management                |
| ② Commercial department     |
| ③ Management representative |
| ④ Engineering department    |

- |             |
|-------------|
| D → decide  |
| E → execute |
| A → advise  |
| I → inform  |