



ISO 9001: 2000

QUALITY MANUAL

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## QUALITY MANUAL

### TABLE OF CONTENTS

SECTION	TOPIC	ISO9001:2000 REFERENCE	PAGE NO.
	Revision and Approval Log		3
	Quality Policy		4
	Organization Chart		5
0	Introduction	0	6
1	Scope	1	8
1.1	General	1.1	8
1.2	Application	1.2	8
2	Normative Reference Documents	2	9
3	Terms and Definitions	3	9
4	Quality Management System	4	10
4.1	General Requirements	4.1	10
4.2	Documentation Requirements	4.2	10
5	Management Responsibility	5	12
5.1	Management Commitment	5.1	12
5.2	Customer Focus	5.2	12
5.3	Quality Policy	5.3	12
5.4	Planning	5.4	12
5.5	Responsibility, Authority & Communication	5.5	13
5.6	Management Review	5.6	14
6	Resource Management	6	15
6.1	Provision of Resources	6.1	15
6.2	Human Resources	6.2	15
6.3	Infrastructure	6.3	15
6.4	Work Environment	6.4	15
7	Product Realization	7	16
7.1	Planning of Product Realization	7.1	16
7.2	Customer-related Processes	7.2	16
7.3	Design and Development	7.3	17
7.4	Purchasing	7.4	17
7.5	Production and Service Provision	7.5	18
7.6	Control of Monitoring & Measuring Devices	7.6	19
8	Measurement, Analysis and Improvement	8	20
8.1	General	8.1	20
8.2	Monitoring and Measuring	8.2	20
8.3	Control of Non-conforming Product	8.3	21
8.4	Analysis of Data	8.4	21
8.5	Improvement	8.5	21

QUALITY MANUAL

**(A) Revision and Approval Log**

<u>Revision Level</u>	<u>Changes</u>
B	See marked up original
C	See marked up original
D	See marked up original
E	See marked up original
F	See marked up original

**APPROVALS:**

President: JS 12/19/07

Management Representative: IS 12/19/07

**Date:** December 19, 2007

QUALITY MANUAL

**QUALITY POLICY**

**Our Quality Policy is:**

**“To provide high quality, on time services to satisfy customer needs and satisfaction. We use an ISO/IEC 17025:2005 and ISO 9001:2000 systems, including quality objectives, to continually improve.”**

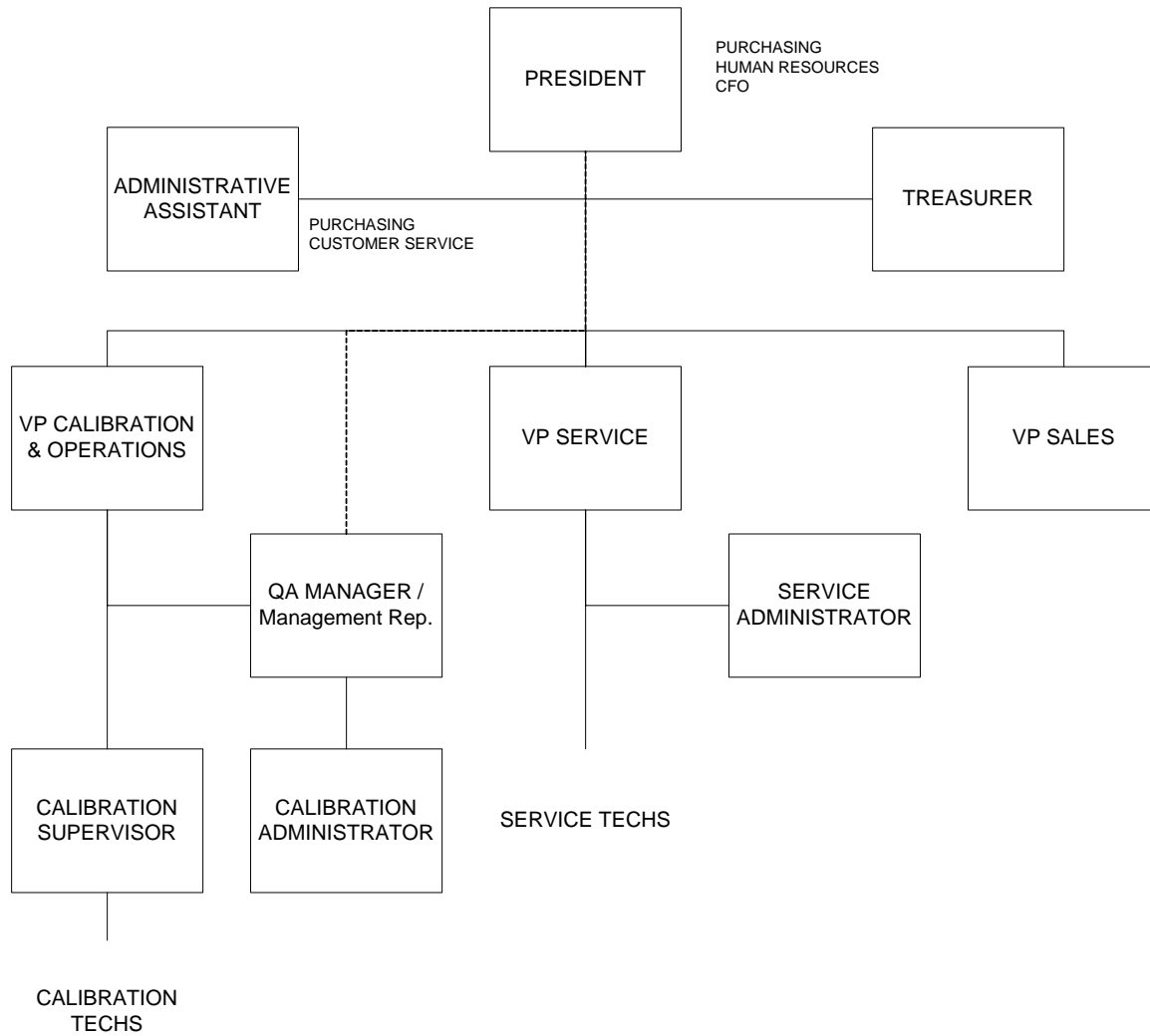
We achieve this by communicating exhaustively with our customers, and internally with our employees, to continually improve our services, products, processes, Quality Management System, methods, and work environment to ensure each customer is receiving the highest quality service or product at the committed cost and on time.

President: JS

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QUALITY MANUAL

**ORGANIZATION CHART**



QUALITY MANUAL

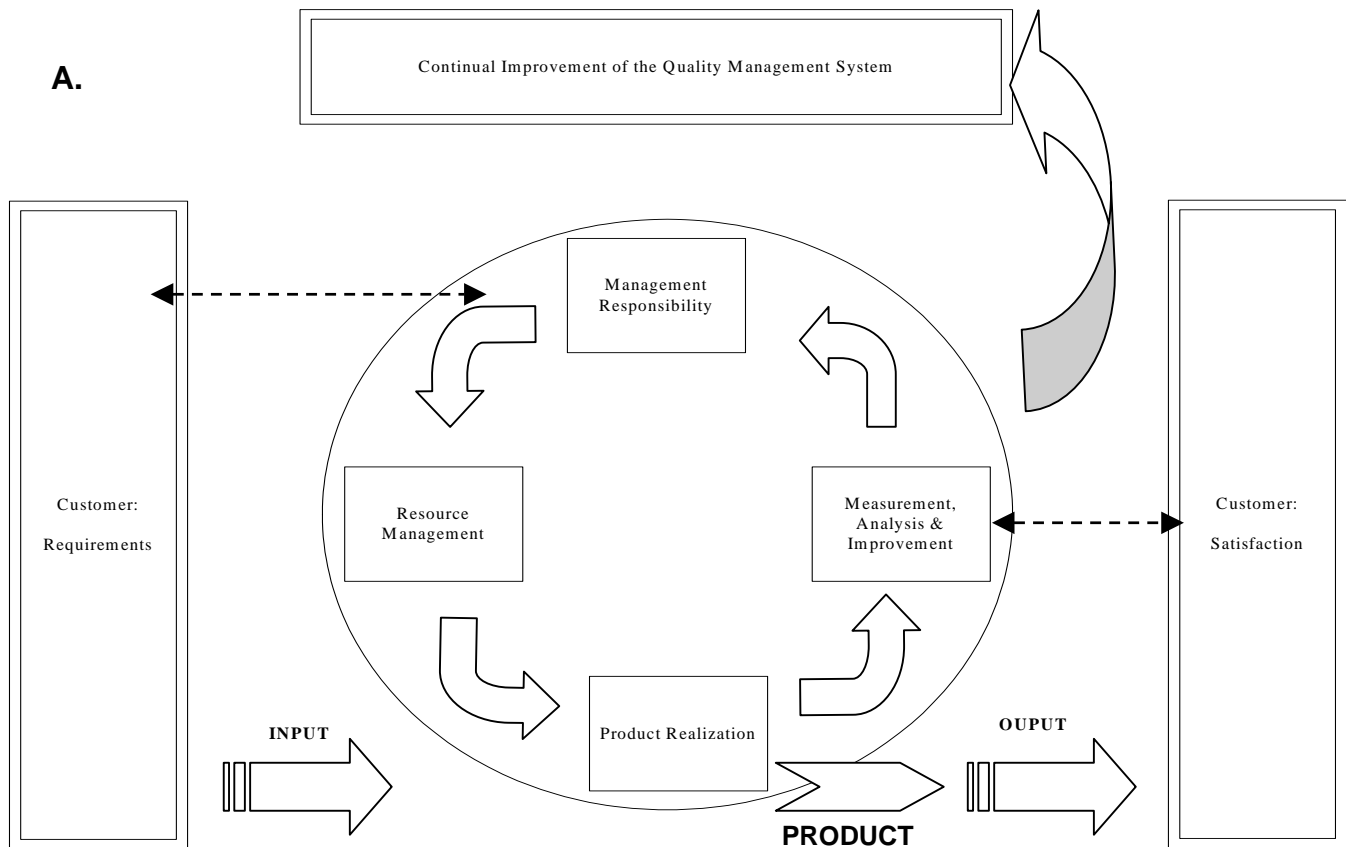
**0) INTRODUCTION**

**0.1 General**

This Quality Manual specifies requirements and policy for IN-CAL used to address customer satisfaction, to meet customer and applicable regulatory requirements and to meet ISO 9001 requirements.

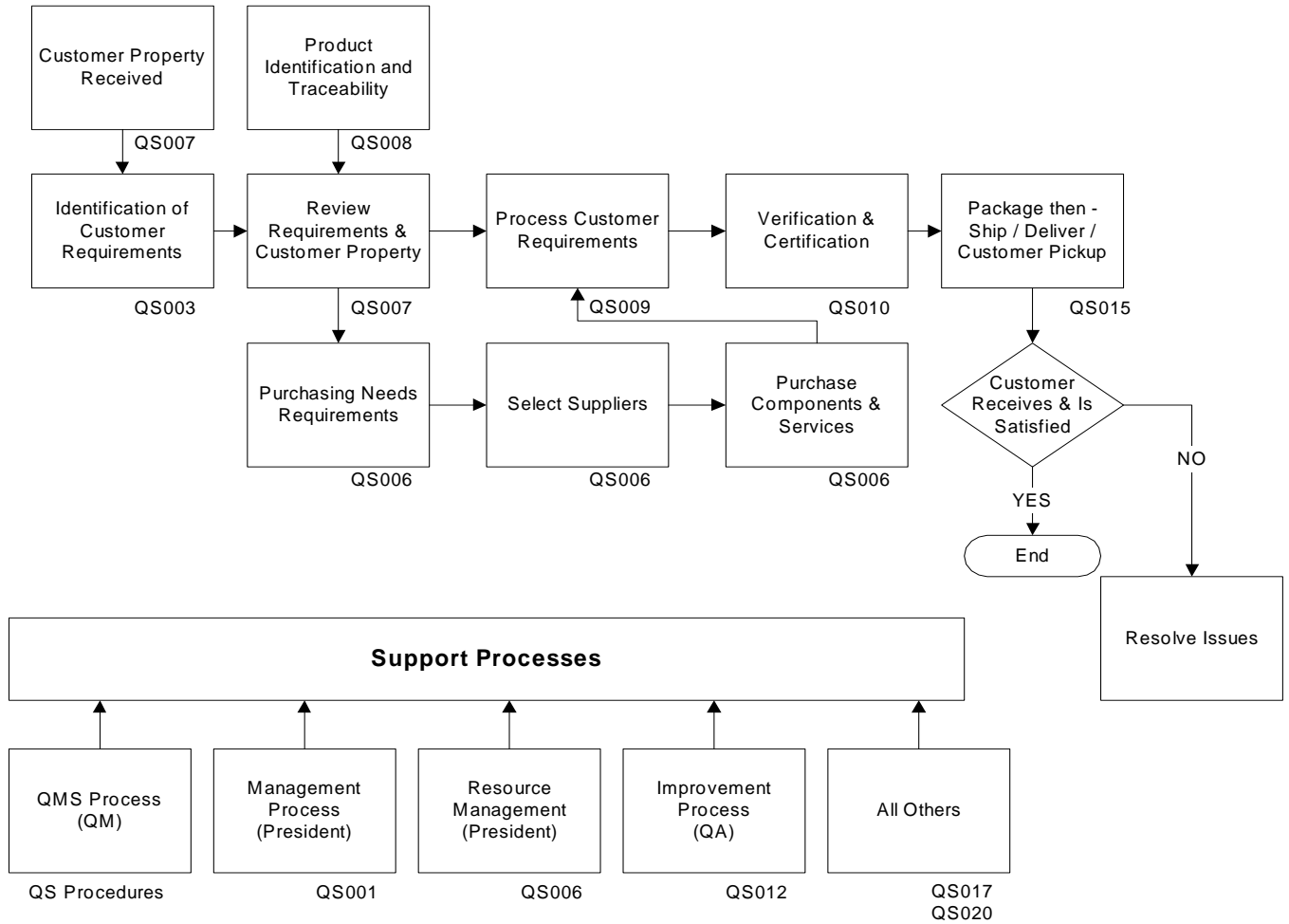
**0.2 Process Approach**

IN-CAL has adopted the process approach to quality management, as described in this manual. Figure A is a conceptual illustration of the process approach at IN-CAL.



QUALITY MANUAL

Major General Processes



Note: Specific IN-CAL processes are described in level II and level III documentation.

**QUALITY MANUAL**

**(1) SCOPE**

**1.1 General**

This document specifies requirements for a quality management system where IN-CAL :

- a) demonstrates its ability to provide consistent product that meets customer and applicable regulatory requirements.
- b) addresses customer satisfaction enhancement through the effective application of the system, including processes for continual improvement and the assurance of conformity to customer and applicable regulatory requirements.

**1.2 Application**

IN-CAL calibrates, services, repairs, and upgrades instrumentation and process equipment, primarily within, but not limited to, the electronic circuit board industry. The company has no exclusions.

Clause or Sub-clause	Exclusion	Justification

## QUALITY MANUAL

**(2) NORMATIVE REFERENCE DOCUMENTS**

## Reference Standards

ISO 9000:2000  
 ISO 9001:2000  
 ISO 9004:2000

NOTE: Documents related to this manual include all procedures with the prefix “QS”, work instructions of QMS and forms used in the organization.

**(3) TERMS AND DEFINITIONS**

NOTE: The terms used in this Manual describe the supply-chain are as follows:

SUPPLIER  ORGANIZATION  CUSTOMER

PRODUCT: Result of services

SERVICE/PRODUCT: Same as Product, above.

PRODUCTION: Act of producing a service or product whether on IN-CAL premises or on a customer site.

OPERATIONS: Act of providing direction and support services to Production (see above). May also include Production, in certain contexts.

## QUALITY MANUAL

**(4) QUALITY MANAGEMENT SYSTEM****4.1 General Requirements**

IN-CAL establishes, documents, implements, maintains and continually improves a quality management system in accordance with the requirements of ISO 9001:2000.

To implement the quality management system, IN-CAL:

- a) identifies the processes needed for the quality management system and their application throughout the organization;
- b) determines the sequence and interaction of these processes;
- c) determines criteria and methods required to ensure the effective operation and control of these processes;
- d) ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- e) monitors, measures and analyzes these processes, and
- f) takes action necessary to achieve planned results and continual improvement.

IN-CAL manages all processes in accordance with the requirements of ISO 9001:2000.

**4.2 Documentation Requirements****4.2.1 General**

The Quality Management System includes:

- a) documented quality policy and objectives
- b) quality manual
- c) documented Level II procedures as required by ISO 9001:2000
- d) documents (Level II & Level III) needed to ensure the effective planning, operation, and control of the processes
- e) records as required per QS016

The extent of documentation is in accordance with our size of organization, types of activities, complexity of processes and their interaction as well as the competence of personnel.

## QUALITY MANUAL

### 4.2.2 Quality Manual

This quality manual has been established and maintained to include:

- a) the scope of the quality management system, including details and justification for any exclusions, are identified in section 1.2 of this document;
- b) reference to documented procedures made in this manual, at the end of each section;
- c) a description of the interaction between the processes of the quality management system

This manual is maintained as a controlled document.

### 4.2.3 Control of Documents

Documents required for the quality management system are controlled per QS005. Records are a special type of document and are controlled per section 4.2.4. Documented procedure QS002 has been established:

- a) to approve documents for adequacy prior to issue;
- b) to review, update as necessary and re-approve documents;
- c) to ensure that the changes and the current revision status of documents are identified;
- d) to ensure that relevant versions of applicable documents are available at points of use;
- e) to ensure that documents remain legible and readily identifiable;
- f) to ensure that documents of external origin are identified and their distribution controlled;
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose;
- h) documents in the system prior to 1/14/2002 are grandfathered as approved. Where not otherwise specified, the document effective date may be considered as five (5) days after the approval date shown on the document.

### 4.2.4 Control of Records

All records are kept per Control of Records procedure QS016 to provide evidence of conformity to the requirements and the effective operation of the quality management system. Records are to be legible, readily identifiable and retrievable. QS016 defines controls needed for the identification, storage, protection, retrieval, retention and disposition.

Reference Documents:

QS001	Management Responsibility
QS002	Quality Management System
QS005	Control of Documents
QS014	Corrective and Preventive Actions
QS016	Control of Records
QSM	Quality Manual

## QUALITY MANUAL

**(5) MANAGEMENT RESPONSIBILITY****5.1 Management Commitment**

The President provides evidence of commitment to the development and implementation of the quality management system by:

- a) communicating to every associate at IN-CAL the importance of meeting customer as well as statutory and regulatory requirements. Several channels of communication will be used including training, employee meetings, postings on bulletin boards, etc.;
- b) establishing our quality policy and quality objectives; (sections 5.3 & 5.4.1)
- c) conducting management reviews; (section 5.6)
- d) ensuring the availability of necessary resources by reviewing the workload (per .QS018).

**5.2 Customer Focus**

The President ensures that the customer needs and expectations are determined per procedure QS003, converted into requirements, and met with the aim of achieving customer satisfaction, per section 7.2.1 and 8.2.1 of this manual.

**5.3 Quality Policy**

The President has defined and approved the Company's quality policy as shown in this manual. This policy has considered the following:

- a) the need to be appropriate to the purpose of IN-CAL;
- b) the need to include a commitment to meeting requirements and to continual improvement of QMS;
- c) the need to provide a framework for establishing and reviewing quality objectives;
- d) the need to be communicated and understood within the company by training and posting on bulletin boards;
- e) the need to be reviewed annually for continuing suitability.

The quality policy is a controlled document and is displayed on employee bulletin boards and other appropriate locations in the organization.

Note: This policy statement is also referred as QS200 (ISOIEC17025: 2005 Quality Management System)

**5.4 Planning****5.4.1 Quality Objectives**

Before the start of each calendar year, the President reviews and approves the quality objectives to ensure they are measurable and consistent with the quality policy and that they include the commitment to continual improvement. These quality objectives are established with input from employees and managers.

Quality objectives are reviewed at Management Review meetings and updated if required.

## QUALITY MANUAL

### 5.4.2 Quality Management System Planning

The QMS Plan includes QMS Documentation, and Records. The Management Representative ensures that change is conducted in a controlled manner and that the integrity of the quality management system and its objectives are maintained during this change.

### 5.5 Responsibility, Authority, and Communication.

#### 5.5.1 Responsibility and Authority

Our Organization Chart is described on page 5 of this manual. It identifies functions (and cross-functions) within IN-CAL. The responsibility chart is posted within the organization to communicate and facilitate effective quality management. The Quality Manager is the Management Representative. IN-CAL has defined the detailed responsibilities in the form of job descriptions, which are maintained by the Human Resources Manager.

#### 5.5.2 Management Representative

The President has appointed the Quality Manager as the management representative who, irrespective of other responsibilities, has the responsibility and authority for:

- a) ensuring that processes of the quality management system are established, implemented and maintained;
- b) reporting to top management on the performance of the quality management system, including needs for improvement;
- c) ensuring the promotion of customer requirements throughout IN-CAL.
- d) acting as liaison with external parties on matters relating to the quality management system.

#### 5.5.3 Internal Communication

The President has identified communication processes (e.g., memos, e-mail, fixed and cell phones, other oral communication, and employee meetings) to ensure communication is taking place regarding the effectiveness of the quality management system. Urgent communications are handled through oral communication, cell phones, and e-mail. Management Review minutes, audit report summary, and performance information are posted on bulletin boards. Monthly employee communication meetings cover the QMS and customer operating issues as well as improvement opportunities.

## QUALITY MANUAL

### 5.6 Management Review

#### 5.6.1 General

The President and staff managers review the quality management system approximately every six months to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement and the need for changes to the quality management system. The reviews are recorded and maintained for three years, including quality policy and quality objectives.

#### 5.6.2 Review Input

The following input is reviewed:

- a) audits results (third party, customer audits, regulatory audits, internal audits, special process & other audits);
- b) feedback from customers (complaints, survey results, meeting minutes, issues resulting from customer communications);
- c) process performance and service/product conformity;
- d) status of preventive and corrective actions;
- e) follow-up actions from previous management reviews;
- f) changes that could affect the quality management system;
- g) any other recommendations for improvement;
- h) input from employees;
- i) other inputs/comments from attendees

#### 5.6.3 Review Output

5.6.3.1 The output from the management review is meeting minutes, which will include decisions and actions related to the:

- (a) improvement of the effectiveness of the quality management system and its processes;
- (b) improvement of service/product related to customer requirements; and
- (c) resource needs.

5.6.3.2 The President will follow up on past due action items

#### Reference Documents:

- QS001 Management Responsibility
- QS002 Quality Management System
- QS003 Customer Related Processes
- QS014 Corrective and Preventive Actions
- QS016 Control of Records
- QSM Quality Manual

## QUALITY MANUAL

**(6) RESOURCE MANAGEMENT****6.1 Provision of Resources**

President reviews resource needs regularly depending on operation/manufacturing workload. The organizational resources needed are provided to implement and maintain QMS and its effectiveness and also to enhance customer satisfaction.

**6.2 Human Resources****6.2.1 General**

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

**6.2.2 Competence, Awareness and Training (Ref.: QS018)**

The Department Managers at IN-CAL:

- a) identify competency needs for personnel performing activities affecting quality using job descriptions;
- b) provide training or taking other actions (e.g., coaching, communication, reading) to satisfy these needs when training is required;
- c) evaluate the effectiveness of the actions taken;
- d) ensure that its employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;
- e) maintain appropriate records of education, training, skills and experience.

**6.3 Infrastructure**

The President & VP Operations determines, provides and maintains the infrastructure needed to achieve the conformity of service/product to requirements, including, as applicable:

- a) buildings, workspace and associated utilities;
- b) process equipment, (both hardware and software);
- c) supporting services (such as transport and communication).
- d) work environment

**6.4 Work Environment**

The VP of Calibration determines and manages the work environment (e.g., facilities and supporting items/services) and conducts a yearly audit to achieve service/product conformity to requirements. This audit includes: (a) infrastructure, (b) health & safety, (c) housekeeping, and (d) work ethics

**Reference Documents:**

QS001	Management Responsibility
QS014	Corrective and Preventive Actions
QS016	Control of Records
QS018	Resource Management

## QUALITY MANUAL

**(7) PRODUCT REALIZATION****7.1 Planning for Product Realization**

IN-CAL plans and develops the processes needed for service/product realization. Planning of these realization processes is consistent with the other requirements of the IN-CAL Quality Management System. In planning the processes for realization of service/product, IN-CAL has determined the following, as appropriate:

- a) quality objectives and requirements for the service/product, section 5.4.1;
- b) the need to establish processes and documentation, and provide resources specific to the service/product, section 6.1;
- c) verification, validation, monitoring, inspection and test activities, specific to the service/product and the criteria for service/product acceptance;
- d) the records necessary to provide that the realization of the processes and resulting service/product meets requirements.

**Note:** Documentation that describes how the processes and resources of the quality management system are applied for a specific service/product are referred to as a Service Report or a Cal Lab List.

**7.2 Customer-Related Processes****7.2.1 Determination of Requirements Related to the Service/Product**

IN-CAL determines:

- a) service/product requirements specified by the customer, including the requirements for delivery
- b) service/product requirements not specified by the customer but necessary for specified or intended use where known and;
- c) statutory and regulatory requirements related to the service/product;
- d) any additional requirements determined by the organization.

**7.2.2 Review of Requirements Related to the Service/Product**

IN-CAL reviews the customer requirements per QS003 – Customer Related Processes. This review is conducted prior to the commitment to supply a service/product to the customer (e.g. submission of a quotation or acceptance of a job) and ensures that:

- a) service/product requirements are defined;
- b) order requirements differing from those previously expressed (e.g. in a tender or quotation) are resolved;
- c) IN-CAL has the ability to meet defined requirements.

The results of the review and subsequent follow-up actions are recorded (section 4.2.4). Where service/product requirements are changed, IN-CAL ensures that relevant documentation is amended,

## QUALITY MANUAL

and communicates any changes to relevant personnel to ensure they are made aware of the changed requirements.

### 7.2.3 Customer Communication

IN-CAL determines and implements effective arrangements for communicating with customers in relation to:

- a) Service/Product
- b) Inquiries, contracts or order handling, including amendments by Sales or Customer Service;
- c) Customer feedback, including customer complaints to Customer Service following QS014 and QS003.

### 7.3 Design and Development

Design & Development does not apply to calibration services. Usually, IN-CAL does not design product for services. If service business needs to design product, Design & Development procedure QS004 will be followed.

### 7.4 Purchasing

#### 7.4.1 Purchasing Process

IN-CAL has established purchasing processes to ensure purchased product or service conforms to requirements. IN-CAL:

- a) Evaluates and selects its suppliers based on their ability to supply product or service in accordance with our requirements;
- b) Defines the type and extent of control to be exercised depending upon the type of product or service (Major or Minor), the impact of purchased product or service on the quality of final service/product, and previously demonstrated capability and performance of vendors.

The results of evaluations and necessary actions are maintained.

#### 7.4.2 Purchasing Information

Purchase Orders and other documents contain information describing the product to be purchased, including where appropriate:

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

Purchasing ensures the adequacy of specified requirements contained in the purchasing documents prior to their release.

## QUALITY MANUAL

### 7.4.3 Verification of Purchased Products and Services

IN-CAL identifies and implements plans and the activities necessary for verification of purchased product. Where IN-CAL or its customer proposes to perform verification activities at the supplier's premises, we specify the intended verification arrangements and method of product release in the purchasing information.

## 7.5 Production and Service Provision

### 7.5.1 Control of Production and Service Provision

IN-CAL controls production and service provisions per QS009 and QS019 under controlled conditions. Controlled conditions include, as appropriate:

- a) the availability of information that describes the key characteristics of the service/product;
- b) the availability of work instructions, as necessary;
- c) the use of suitable equipment;
- d) the availability and use of monitoring and measurement devices;
- e) the implementation of monitoring and measurement;
- f) the implementation of defined processes for release, delivery and applicable post-delivery activities.

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

IN-CAL validates any production and service processes where the resulting output cannot be verified by subsequent measurement or monitoring. This includes any processes where deficiencies may become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results.

IN-CAL has defined arrangements for these processes that include the following, as applicable:

- a) defined criteria for review and approval of the processes;
- b) approval of equipment and qualification of personnel;
- c) use of specific methods and procedures;
- d) requirements for records;
- e) re-validation.

### 7.5.3 Identification & Traceability

IN-CAL identifies the product by suitable means following QS008 –ID and Traceability. Status is identified with respect to measurement and monitoring requirements per QS008 –ID and Traceability. IN-CAL controls and records the unique identification of the product where traceability is a requirement.

### 7.5.4 Customer Property

Care will be exercised while customer property is under control of or being used by IN-CAL, and is treated the same as purchased material. The management will identify, verify, protect and safeguard customer property (including intellectual property given in confidence) provided for use or

**QUALITY MANUAL**

incorporation into the product. Occurrence of any customer property that is lost, damaged or otherwise found to be unsuitable for use is recorded and reported to the customer.

**7.5.5 Preservation of Product**

IN-CAL follows the appropriate methods/instructions to preserve product conformity to customer requirements during internal processing and delivery to the intended destination. This includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

**7.6 Control of Monitoring and Measurement Devices**

IN-CAL identifies the measurements to be made as well as the monitoring and measurement devices required to assure product conformity to specified requirements (section 7.2.1). Monitoring and measurement devices used are controlled to ensure that measurement capability is consistent with the monitoring and measurement requirements. Where applicable, monitoring and measurement devices are:

- a) calibrated and adjusted periodically or prior to use, against devices traceable to international or national standards; where no such standards exist, the basis used for calibration or verification is recorded;
- b) adjusted or re-adjusted as necessary;
- c) identified to enable calibration status to be determined;
- d) safeguarded from adjustments that would invalidate the measurement result
- e) protected from damage and deterioration during handling, maintenance and storage;
- f) to have the results of their calibration recorded per procedure QS011;
- g) to have the validity of previous results re-assessed if they are subsequently found to be out of calibration, and corrective action taken.

Software used for monitoring and measurement of specified requirements is validated prior to first use and reconfirmed as necessary.

**Reference Documents:**

QS003	Customer Related Processes	QS006	Purchasing
QS008	Identification & Traceability	QS009	Control of Production Provision
QS011	Control of Monitoring & Measuring Devices	QS013	Control of Non Conforming Product
QS015	Preservation of Product	QS016	Control of Records
QS019	Provision for After-Sale Service	QS020	Measurement, Analysis and Improvement
QS007	Customer Property		

## QUALITY MANUAL

**(8) MEASUREMENT, ANALYSIS,  
AND IMPROVEMENT****8.1 General**

IN-CAL defines, plans (section 7.1) and implements the monitoring, measurement, analysis, and improvement processes needed to assure conformity and achieve continual improvement of the service/product and the quality management system. This includes the determination of the need for, and use of, applicable methodologies including statistical techniques.

**8.2 Monitoring and Measurement****8.2.1 Customer Satisfaction**

IN-CAL monitors information relating to customer perception (as to whether we have met customer requirements) as one of the measurements of performance of the quality management system. The methodologies for obtaining and using this information are described in procedure QS020.

**8.2.2 Internal Audit**

IN-CAL conducts internal audits to determine whether the quality management system conforms to the requirements of ISO 9001: 2000 and has been effectively implemented and maintained.

IN-CAL develops the audit plan annually, taking into consideration the status and importance of the activities and areas to be audited as well as the results of previous audits. The audit plan is revised after each audit and updated if needed. The audit criteria, scope, frequency and methods are defined. Audits are conducted by personnel other than those who perform the activity being audited. Procedure QS017 – Internal Audit identifies the responsibilities and requirements for conducting audits, recording results and reporting to management. Responsible managers take timely corrective action on deficiencies found during the audit. Follow-up actions include the verification of the implementation of corrective action, and the reporting of verification results.

**8.2.3 Monitoring and Measurement of Processes**

**IN-CAL applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods will demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action will be taken, as appropriate, to ensure conformity of the product.**

## QUALITY MANUAL

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

IN-CAL measures and monitors the characteristics of the service/product to verify that requirements for the service/product are met. This is carried out as planned at appropriate stages of the service/product realization process (section 7.1). Evidence of conformity with the acceptance criteria is documented. Records will indicate the authority responsible for release of service/product.

Product release and service delivery will not proceed until all the specified activities have been satisfactorily completed, unless otherwise approved by the customer.

### **8.3 Control of Nonconforming Product**

IN-CAL ensures that service/product which does not conform to requirements is identified and controlled to prevent unintended use or delivery. These activities and responsibilities are defined in documented procedure QS013 – Control of Nonconforming Product. Records of the nonconformities and actions taken are kept per QS016 Control of Records.

Nonconforming service/product is corrected and subject to re-verification after correction to demonstrate conformity. When nonconforming product is detected after delivery or use has started, IN-CAL takes appropriate action regarding the consequences of the nonconformity.

### **8.4 Analysis of Data**

IN-CAL determines, collects and analyzes appropriate data to determine the suitability and effectiveness of the quality management system and to identify improvements that can be made using QS020 - Measurement, Analysis & Improvement. This includes data generated by monitoring and measurement activities and other relevant sources.

IN-CAL analyzes this data to provide information on:

- a) customer satisfaction and/or dissatisfaction (section 8.2.1);
- b) conformity to service/product requirements (section 7.2.1);
- c) characteristics of trends of processes and service/products including opportunities for preventive action, and
- d) suppliers.

### **8.5 Improvement**

#### **8.5.1 Continual Improvement**

IN-CAL improves the effectiveness of the quality management system through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive action and management review using procedure QS020 - Measurement, Analysis & Improvement.

## QUALITY MANUAL

### 8.5.2 Corrective Action

IN-CAL takes corrective action to avoid and eliminate the cause of nonconformities in order to prevent recurrence. Corrective action is to be appropriate to the impact of the nonconformities encountered. The documented procedure for corrective action, QS014 - Corrective & Preventive Actions, defines requirements for:

- a) reviewing nonconformities (including customer complaints);
- b) determining the causes of nonconformities;
- c) evaluating the need for actions to ensure that nonconformities do not recur;
- d) determining and implementing the corrective action needed;
- e) recording results of action taken;
- f) reviewing of corrective action taken.

### 8.5.3 Preventive Action

IN-CAL identifies preventive action to avoid and eliminate the causes of potential nonconformities to prevent occurrence. Preventive actions taken are appropriate to the impact of the potential problems. The documented procedure for preventive action, QS014, defines requirements for:

- a) determining potential nonconformities and their causes;
- b) evaluating the need for action to prevent occurrence of nonconformities;
- c) determining and implementing action needed;
- d) recording results of action taken;
- e) reviewing of preventive action taken.

### Reference Documents:

QS003	Customer Related Processes
QS009	Production Provision
QS010	Monitoring and Measurement of Product
QS012	Continual Improvement
QS013	Control of Nonconforming Product
QS014	Corrective & Preventive Actions
QS017	Internal Audit
QS020	Measurement, Analysis & Improvement