

QUALITY MANUAL

CONTENTS and notes on edition and revision	Rev. 05 of 02 April 2015	
	Verified by:	QM
	Approved by:	GM

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- Note to this edition

This edition of the Quality Manual derives from assumption of the [UNI EN ISO 9001:2008](#) standard as reference model in place of the UNI EN ISO 9001:2000 standard. Any variation of the reference model in fact leads to drafting of a new edition.

- Contents of the current revision

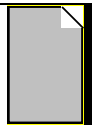
*Considering this edition, the manual is in revision 5 status.
Rev 5, compared to rev 4, has a new three-year Company Programme.*

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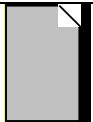
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0 INTRODUCTION

0.1 The company STILMAS S.p.A.

0.1.1 Its history

- 1912:** The Company is founded.
- 1940:** The company takes on the name of: Ing. Giovanni Mascarini S.r.l..
- 1949:** Mascarini supplies Fiat the largest steam production plant comprising 3 x 3000V/50Hz, 30 atm boilers for a total of 22,500 kW, equal to 31,500 kg of steam per hour.
- 1951:** Automatic control systems and “circulation systems” are patented for the distillation of dense and frothy solutions, particularly for sea or brackish water. Autonomous versions for arid areas mounted on a trailer and driven by “total energy recovery” diesel engines, are exported, with success, to North Africa.
- 1956:** At the request of the Nav, Mascarini Srl creates new thermocompression distillers of limited size and weight, also of the non-magnetic type, fitted with antishock equipment for minesweepers, frigates, support ships and submarines.
- 1960:** In collaboration with the C.N.R. and the Politecnico di Milano, Mascarini designs 3 to 20 m³/h turbochargers to be applied to distillers and evaporators.
- 1969:** STILMAS S.p.A. is founded, obtaining from the closed down Mascarini S.r.l. patents, know-how and trademark.
- 1996:** DOC s.r.l., connected to Stilmas via the MASCO group, is founded
- 2005:** STILMAS founds Stilmas Shanghai Co.
- 2007:** STILMAS USA starts up operations.
- 2010:** A representative office is established in Russia.
Sebinox S.r.l. activities are imported into Settala.

The Company is on its way to becoming a global leader in the manufacture of water treatment plants, specialising in the pharmaceutical industry.

Stilmas S.p.A. acquires important qualifications in the international arena and executes important Italian and foreign orders, also as part of applied research. Exports exceed, on average, 90 % of total annual turnover.

0.2 The products

Stilmas designs, manufactures and installs (Turn Key) plant and equipment for

- Filtration, clarification, chlorination
- Softening and demineralisation using resins
- Reverse osmosis and electro dialysis desalination
- Production of drinking water from polluted, brackish and sea water
- Special plant for civil and military and stationary and emergency use
- Concentration of industrial waste
- Production of ultra-pure steam

1 SYSTEM PURPOSE and APPLICATION SCOPE

STILMAS has defined its quality management system as a means:

- to meet the quality policy expressed by the General Manager,
- to achieve the specified quality objectives
- to guarantee its customers that products comply with their expectations
- to indicate how to continually improve performance

The System applies to all activities of those having influence over the products listed in 0.2, both at the Settala (MI) site as well as places where plant is installed

2 REFERENCE STANDARDS

2.1 Reference model

STILMAS has defined its quality management system according to the model UNI EN [ISO 9001:2008](#) - Quality Management Systems – Requirements

2 Exclusions (provisions not applicable)

All requirements are applicable, there are no exclusions

TERMS and DEFINITIONS

3.1 General definitions

All definitions provided by ISO 9000:2005 - Quality Management Systems - Fundamentals and vocabulary are used. The terms below, specific to company activities, are associated with the definitions provided:

KERS ON	<i>Company Program describing Values, Commitments and Development guidelines, as well as KPIs and the relevant measure and collection into a BSC .</i> KERS ON in fact describes the continuous improvement process
BSC	Registration document, updated on a monthly basis, containing the values achieved by each process performance index compared with target values.
YAD	(Yearly Appraisal Document) Methodology for focussing, for each person, on the skills expressed, in relation to those required, and for the definition of programs and resources for professional development
Order No.	Alphanumeric index to which all documents and recordings pertaining to the same Customer order refer
ARDIS Program	Internal communication and repository SW tool, conveys information via the local area network, presenting it to interested parties and simplifying its recovery and archiving.
Contractual requirements	Set of documents with specifications, rules, data, information and project specifications specifying the product and service characteristics covered by the supply contract (order)
Quality plan	Set of documents specifying how STILMAS obtains the utmost confidence that the contractual requirements of a specific order\plant will be satisfied. (and records that testify the results achieved)
FAT	Factory Acceptance Test Verification and control operation via which Stilmas Personnel present the product to the Customer on Stilmas premises and obtain customer acceptance.
SAT	Side Acceptance Test Verification and control operation via which the Customer, in collaboration with Stilmas Personnel, analyses the product under conditions of use and decides on acceptance.

3.2 Abbreviations

In the text the following abbreviations recur:

QMS, QS	Quality Management System
QMan	Quality Manual
PRO	Quality Procedure
ISO 9001	UNI EN ISO 9001: 2008
PEW	Pressure Equipment Workshop
ATW	Assembly Workshop

The diagram below shows the abbreviations used to indicate organisational roles.

The scheme, in addition to the official terminology (in English) provides the alternative terminology, in Italian, often currently used internally

GM	General Manager	Direttore Generale
R&D	R&D Director	Direttore Ricerca e Sviluppo
TM	Technical Manager	Responsabile Tecnico
CM&SD	Commercial Method & System Director	Metodi e Sistemi Commerciali
SCM	Supply Chain Manager	
PR	Procurement	Acquisti
FM	Flow Material	Flusso Materiale
S&SP	Service & Spare Parts Manager	Service
MD	Manufacturing Director	Direttore Produzione
CM	Commercial Director	Direttore Commerciale
AD	Administration Director	Direttore Amministrativo
QM	Quality Manager	Responsabile Qualità
FM	Facility Manager	
IT Dept	Information Technology Dept	
S Dept	Sales Department	Vendite
Doc	Documentation	Documentazione
PM	Project Manager	Capo Progetto
RSPP		Responsabile del servizio prevenzione e protezione
RdF		Responsabile di Funzione

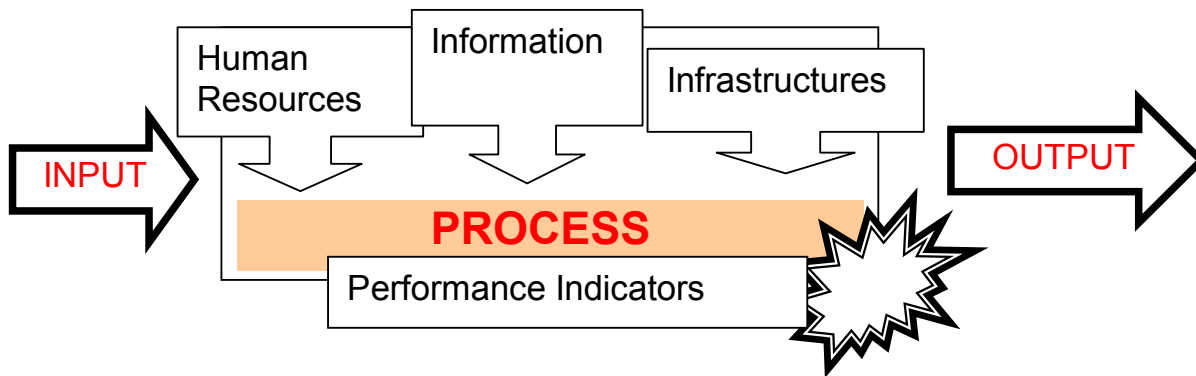
4 QUALITY MANAGEMENT SYSTEM

4.1 Foreword

STILMAS establishes, documents, implements and maintains the quality management system, continuously improving its effectiveness, in compliance with the requirements of the international standard of reference and this manual.

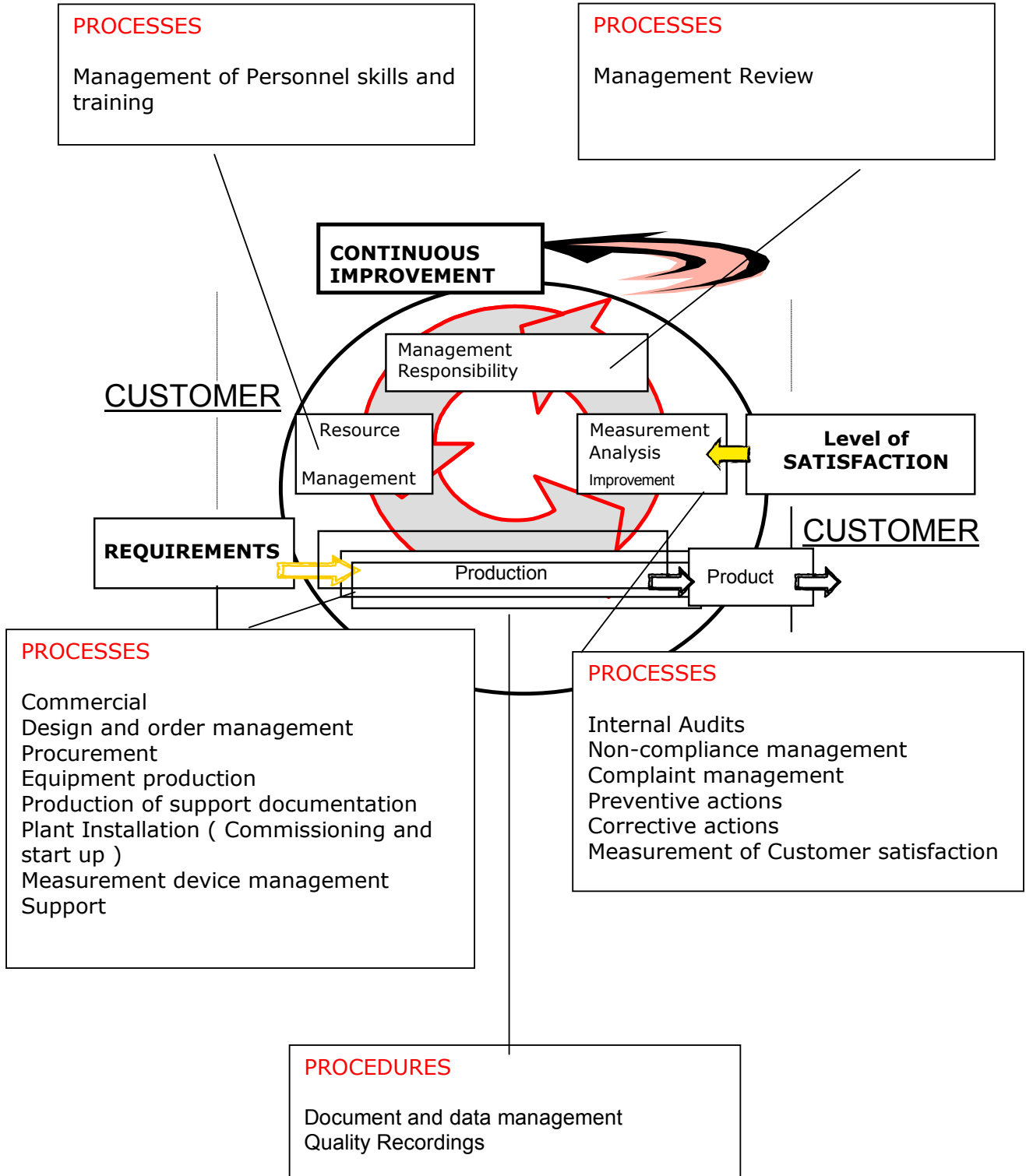
It is considered essential to identify the processes needed for the quality management system and to manage their implementation within the entire organisation.

Processes are designed in accordance with the following scheme

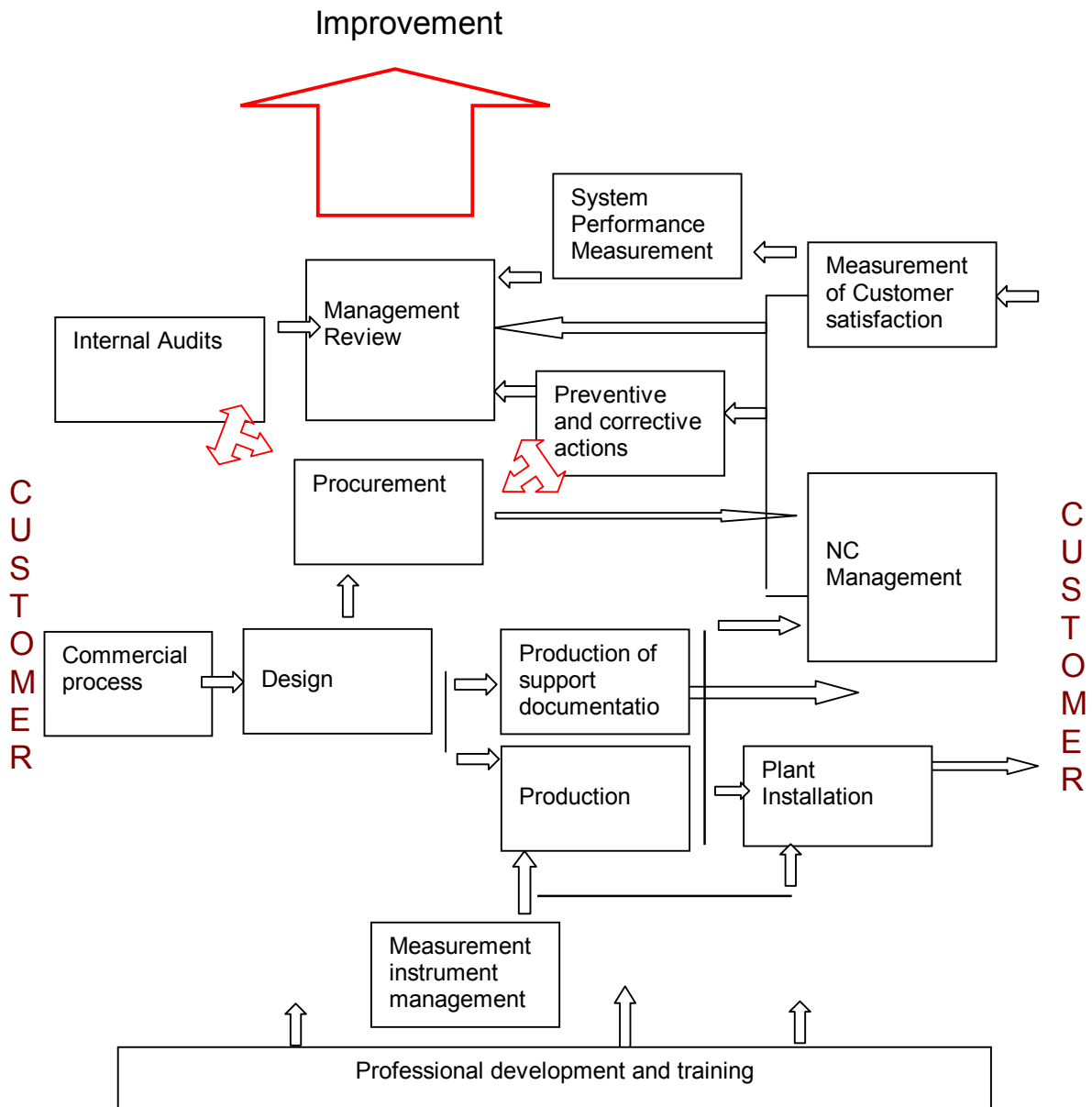


Below, the fundamental processes and their general interrelation is shown

The diagram shows the 4 fundamental macro processes (Management Responsibility, Resource Management, Product Implementation, Measurements, analysis and improvement)
For each of the four macro processes the significant constituting processes are specified.



The correlations between processes are graphically described in the following scheme



Responsibilities	GM identifies the relevant processes, i.e. processes that are closely related to implementation of his policy and development program, according to the four fundamental macro processes.
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With regard to these processes, the company is committed to:

- establishing criteria and methods needed to ensure the efficient operation and effective control of these processes,
- ensuring availability of resources and information necessary to support operation and monitoring of these processes,
- monitoring, measuring and analysing these processes,
- implementing the necessary actions to achieve the planned results and continuous improvement of these processes.

These processes are managed by our organization in compliance with the requirements of the ISO 9001 standard.

Appropriate procedures for each of the processes shown are prepared and maintained when the information contained in this manual does not appear to be sufficient

If it is decided to outsource process, or any part thereof, which are necessary for the Quality Management System or which affect product compliance, control of the same is ensured.

In particular, recourse is often made to machining suppliers for the construction of part of STILMAS equipment.

The procedures for maintaining control over these processes provides for supplier audits, incoming inspection of machined parts, as well as the requirement for all checks carried out by suppliers to be recorded. Control of machining suppliers is facilitated by the fact that these suppliers have in common with Stilmas ownership, value system and policies.


Site management often makes use of local companies for installation of services and plant parts.

The activity of these companies is always supervised by Stilmas personnel. These suppliers are in any case subject to the provisions specified in 7.4

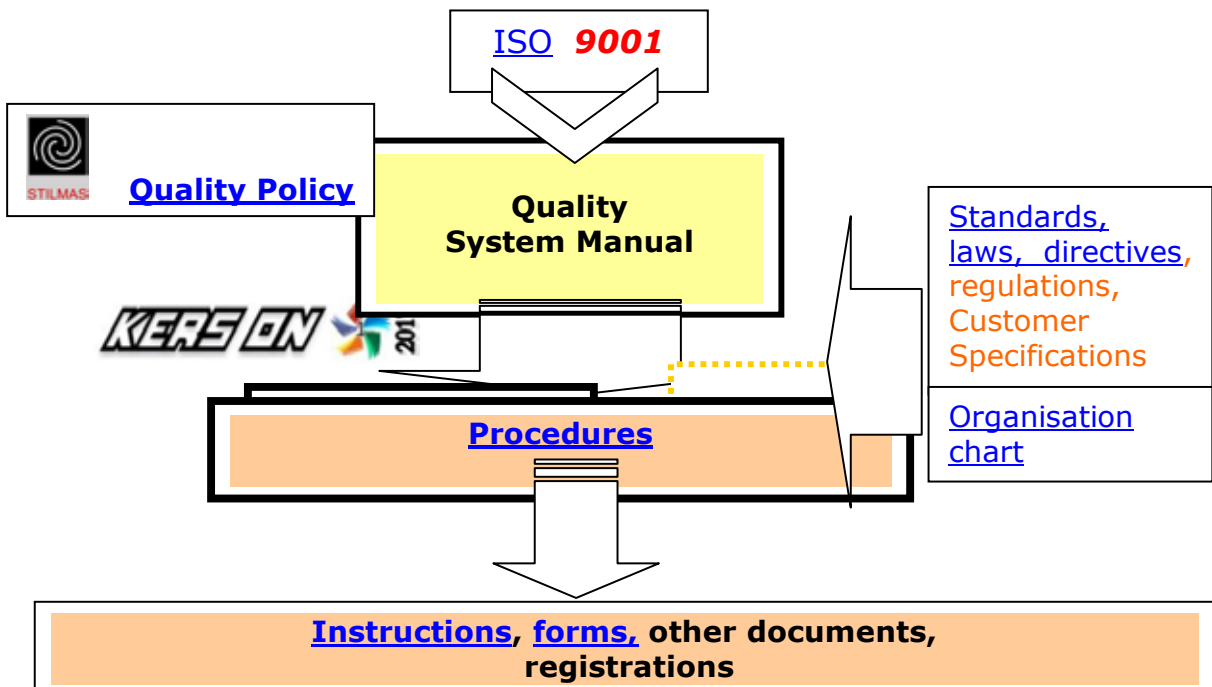
4.2 Documentation management

4.2.1 Foreword

The quality management system documentation includes:

- statements on the quality policy and quality objectives,
-  2017
- This quality manual,
- documented procedures required by the international standard and the manual itself,
- documents needed by the organisation to ensure the effective planning, operation and control of its processes, including documents constituting obligatory references for correct product construction (Standards, laws, directives, regulations, etc.)
- required records (see 4.2.4).

The following diagram shows the system documentation structure



4.2.2 Quality Manual

STILMAS prepares and maintains this quality manual which includes:

- a) the scope of application of the quality management system, as well as details of any exclusions and corresponding justifications
- b) Reference to the quality procedures prepared for the quality management system
- c) The general procedures for application of the requirements expressed by the reference standard and corresponding responsibilities
- d) a description of the interactions among quality management system processes.

Responsibilities	The QM compiles the QMan and conducts verification in terms of compliance with ISO 9001: 2008. The GM approves the document
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4.2.3

"Kers On" is the Company Program describing values, targets and the relevant action plans. KPIs are collected and measured via a specific BSC. The Program foresees three years activity and represents the continuity and the improvement to the previous Company Programs (S-10 and ACE) which took place in the period 2008-2014. The new one is based not anymore on three axes rather than on five axes:



The Focal Points of the program are:

Growth

>grow existing markets, develop new markets, conceive and develop new businesses

Efficiency

>develop listening to the Customer, improve internal processes, measure performance, support the image

People

>increase the value of employees, create stimulation in work, build trust and affection, ensure health and safety in the workplace

Innovation

>thinking outside the box, daring to be different

Customer

>delivering the promise, and seeking for a Customer, not a sell only

Kers On defines the procedures to achieve new company targets and deploy organisational matters for continuous improvement.

4.2.4 Standards, laws, directives, regulations, Customer specifications

The external origin codes which constrain the design and construction of the product are part of the system.

Customer specifications, if any, fall into this category.

The Community Directives on pressure vessels (ASME, PED, etc.) and those governing electromagnetic compatibility also apply to products.

4.2.5 Instructions

The procedures, when necessary, refer to instructions.

Instructions are descriptions on how to conduct specific activities. They refer to a specific process. Assessment of the need for instructions and their subsequent drafting is the responsibility of the Process Manager (matrix on page 22).

In some cases, instructions are reduced to a list of actions needed to accomplish a given activity. In this case the instructions are called OP (Operating Procedures)

4.2.6 Keeping documents under control

Documents required by the quality management system are kept under control. The documents include this manual, the procedures referred to therein, the operating instructions and documents referred to in the manual, procedures and instructions. The documents also include the standards, laws, regulatory provisions, Community directives applicable to the organisation and products, as well as the Quality Management Standard taken as a reference. Records are a special type of document and are kept under control in compliance with the provisions of section 4.2.4.

[PRO 4.1 - Quality Document Management](#) is prepared which defines the procedures necessary for:

- a) approving documents, in terms of adequacy, prior to their release,
- b) reviewing, updating (when necessary) and re-approving the documents themselves,
- c) ensuring that changes and the current revision status of documents are identified,
- d) ensuring that the relevant versions of applicable documents are available at the sites of utilisation,
- e) ensuring that documents are and remain legible and readily identifiable,
- f) ensuring that documents of external origin are identified and their distribution controlled,
- g) preventing the unintended use of obsolete documents and adopting adequate identification of the same should they need to be retained for any reason.
- h) Ensuring that the management of personal data takes place in compliance with confidentiality, personal identity and right of the interested parties to protection of their data

Since the distribution of the Manual and procedures takes place in electronic form, the necessary precautions to prevent inadvertent and/or unwanted changes have been installed.

Responsibilities	<p>All Personnel is responsible for management of pertinent documents, in compliance with the general provisions</p> <p>The data controller of personal data is the legal representative of the Company who monitors compliance with the requirements expressed in current legislation</p> <p>Instructions are issued by managers of the processes which the instructions are intended to support.</p> <p>The applicable technical standards, Community directives, laws and regulatory provisions are identified by the TM</p> <p>Updating of this category of documents is ensured through regular contact with persons called upon to certify compliance with the said standards, periodic access to specific Web sites, to documentation periodically transmitted by AIMA of which Stilmas is a member.</p>
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4.2.7 Keeping records under control

Records are prepared and retained to provide evidence of compliance with the requirements and of the effective operation of the Quality Management System.

Records are legible, readily identifiable and traceable. [PRO 4.2 – Quality Record Management i](#) is prepared to establish the procedures necessary for identification, storage, protection, retrieval, definition of retainment period and record disposal procedures.

Responsibilities	<p>The QM determines the list of necessary records and outlines the management profile (collection, archiving, storage responsibilities) Ensures that the list meets the requirements of the reference model.</p> <p>All Personnel is responsible for management of pertinent record documents, in compliance with the valid provisions</p>
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5 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

STILMAS Management is committed to the development and implementation of the quality management system and continuous improvement of its effectiveness.

This is accomplished by:

- a) communicating the organisation the importance of meeting customer and applicable regulatory requirements,
- b) establishing the quality policy,
- c) ensuring that quality objectives are established,
- d) conducting management reviews,
- e) ensuring the availability of resources.

5.2 Customer focus

STILMAS intends to ensure that customer requirements are defined and satisfied in order to increase customer satisfaction. The Quality Policy reiterates this approach.

5.3 [Quality policy](#)


The quality policy is defined in order to:

- a) be appropriate for the purposes of the organisation and consistent with its development programs,
- b) include the commitment to satisfy the requirements and the continuous improvement of effectiveness of the quality management system,
- c) provide a structural framework for establishing and reviewing quality objectives,
- d) be communicated and understood within the organisation,
- e) be reviewed to ascertain its appropriateness over time

Responsibilities	<p>The GM defines the Policy in accordance with the specified requirements and periodically reviews its adequacy.</p> <p>The declaration is made known to all Personnel by permanent posting on the Noticeboard</p>
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5.4 Planning

5.4.1 Quality objectives

For the relevant levels and functions of the organisation, the  program sets quality targets, including those necessary to comply with product requirements. The quality objectives are measurable and consistent with the quality policy.

Responsibilities	<p>The GM, in collaboration with Directors and Managers, establishes the overall objectives of the Company and ensures their distribution to the various functions, each for the pertinent aspects.</p> <p>The GM, in line with the intentions and mandate of the CEO, explains, in the management review, the definition of strategic and period objectives</p>
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5.4.2 Quality Management System Planning

- Overall planning
 Overall planning of the quality management system is conducted in a manner consistent with that specified in 4.1 and such as to facilitate achievement of quality objectives
 The Manual, the PRO and other categories of documents serve this purpose
- Planning of improvement activities
 Improvement activities are planned, i.e. content is defined, implementation responsibilities are assigned, implementation timing is defined and actual implementation is monitored
- Planning of preservation of the integrity of the system during changes
 Predictable changes (of people, production sites, layout) are addressed that could, if not addressed in time, constitute critical issues for the Quality System.

Responsibilities	<p>Everyone, coordinated by the GM, identifies actions needed to overcome the problems resulting from predictable changes</p>
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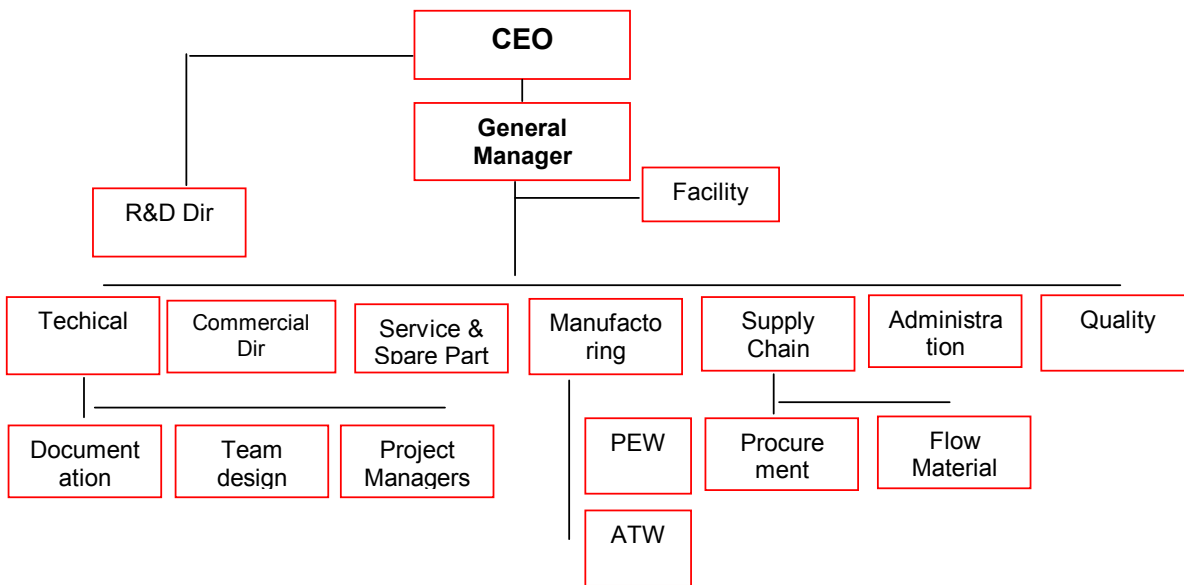
5.4.3 Product Quality Planning

Market requirements and the resulting product requirements are defined, for each order\plant in the order documents

5.5 Responsibilities, authorisations and communication

5.5.1 Responsibilities and authorisations

Responsibilities and authorisations are defined and made known within the company. The key organisational positions are shown in the diagram below. (Organisation chart)



They are also appointed , in accordance with current legislation , organisational positions relating to health and safety in the workplace (**RSPP** , **RLS**) and to data protection (**Data Processor** ,) are defined In the text and in the procedures, the R&D director, CM&S director and all those reporting to the GM are conventionally called “First Levels”

Responsibilities	<p>The GM defines and distributes the corresponding <u>organisation chart with names</u>.</p> <p>The organisation chart with names, in the valid version, is permanently posted on the noticeboard</p>
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Those who hold the Organisational positions indicated participate in processes according to the following matrix.

The matrix also identifies the Process Manager, i.e. the organisational position

responsible for managing the resources dedicated to the process and who works to ensure Management that process results are as expected.

Organisational Positions	Management Review	Non-compliance Management	Corrective and preventive actions	Management of Personnel skills and training	Commercial	Support	Procurement	Order design and management	Production	Plant Installation	Production of support documentation	Measurement device management	Measurement of Customer satisfaction	Internal Audits	Complaint management	Corrective actions for product improvement
	General Manager	G		P	G									G	P	
R&D Director	P		P					G			P			P		P
CM&S Director	P		P		P								P	P	P	P
Commercial Director	P		P	P	G								P	P		
Sales Dept					P			P					P			
Quality Manager	P	G	G									P	P	G	P	
Projects & Tech Mng		P	P		P		P	G			P			P		
Supply Chain		P	P				G					P		P		
S&SP Manager		P	P			G				P			P	P	G	G
Manufacturing Dir		P	P						G			G		P		
Administration Dir						P	P									
Documentation		P	P						P		G					
Team Design							P	P								
Project Manager		P				P		P		G			P	P		
Facility Manager						P		P								
IT		P						P			P		P		P	

P	= Participates in process
G	= Manages the process

Everyone creates, updates, processes or files documents under their responsibility, in accordance with current procedures

5.5.2 Management representative

In STILMAS a member of the management team (the Quality Manager) is designated who, irrespective of other responsibilities, also has the responsibility and authority to:

- a) ensure that processes required for the quality management system are prepared, implemented and maintained,
- b) report on performance of the quality management system and any need for improvement,
- c) ensure promotion of awareness of customer requirements.

5.5.3 Internal communication

Management ensures that appropriate communication processes are activated within the organisation and that communications regarding the effectiveness of the quality management system are also provided.

In particular

- A SW system is used to manage internal communication. The ARDI system organises, transmits and files information within the company, recording acknowledgement by interested parties

Responsibilities	IT ensures efficiency of the ARDIS program, taking care of its continuous improvement, according to communication needs
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- Regular meetings are held to inform all personnel of company actions carried out and planned, of the objectives such actions aim to achieve and of actual results.
- The BSC is periodically analysed and discussed by Personnel concerned

5.6 Management review

5.6.1 Foreword

At least once a year, Management reviews the Quality Management System of the organisation to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the Quality Management System, Quality policy and objectives included.

Records of management reviews are kept (see 4.2.4).

[PRO 5.1 Management Reviews](#) provides further details

5.6.2 Review input

Management review input includes information concerning

- a) The results of internal and external Audits,
- b) customer feedback,
- c) process performance and product compliance,
- d) the status of corrective and preventive actions,
- e) The results of periodic evaluations of suppliers
- f) The status of follow-up actions from previous management reviews,
- g) the changes\innovations\planned changes that could affect quality management
- h) any recommendations for improvement.

5.6.3 Review output

Review output is therefore the Quality Development Plan, a planning document containing decisions and corresponding actions concerning:

- a) improvement of the effectiveness of the quality management system and its processes, product improvement according to customer requirements and resource requirements.
- b) objectives and their allocation to the various functions

Responsibilities	The GM plans, organises and conducts the review. QM coordinates the preparation of necessary review documents and data.
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6 RESOURCE MANAGEMENT

6.1 Provision of resources

Management identifies and makes available the resources needed to:

- a) implement and maintain the quality management system and continually improve its effectiveness,
- b) increase customer satisfaction, complying with customer requirements.

6.2 Human resources

6.2.1 Foreword

The company pursues continued growth of professionalism, skills and abilities of those engaged in activities affecting product quality.

People are motivated and competent if they possess appropriate education, training, abilities and experience.

The process aimed at this result is presented in [PRO 6.1 – Professional Development and Training. \(Yearly Appraisal Document\)](#)

Responsibilities	<p>The GM verifies the presence of the necessary skills in the Company to perform the activities necessary to conduct processes, clarifying, as a consequence, the responsibilities assigned to people.</p> <p>Every person with responsibility for managing others assesses the necessary skills and growth requirements\opportunities. (YAD)</p>
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6.2.1a Personnel motivation and involvement

In order to achieve the objectives and stimulate innovation, involvement of personnel is encouraged, facilitating participation of Personnel in setting goals and taking decisions, encouraging awards and incentives, facilitating dialogue in both directions.

Responsibilities	All Directors and Managers take care of this aspect
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6.2.1b Competence, awareness and training

Process managers:

- a) define the necessary skills for personnel performing activities affecting product quality,
- b) provide training or undertake other actions to satisfy these requirements,
- c) evaluate the effectiveness of actions taken,
- d) ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives,
- e) maintain appropriate records on the level of education, training, ability and experience of personnel (see 4.2.4) .

Responsibilities	The GM plans personnel training Managers , for the area of responsibility, organise the implementation of training sessions, The QM evaluates the result, also based on participant assessments
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6.3 Infrastructures

In Stilmas we define, prepare and maintain in good order infrastructures necessary to achieve compliance with product requirements.

Infrastructures include:

- a) buildings, workspace and associated services,

Responsibilities	The FM ensures availability of the necessary infrastructures
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- b) process machinery and equipment (both hardware and software), in compliance with [PRO 7.18 Maintenance](#)

Responsibilities	The MD plans and provides for execution of maintenance taking into account the fundamental need to maintain machine components which have an impact on worker safety efficient
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- c) communication services.

Responsibilities	IT maintains HW and SW structures efficient and directly takes care of user training
------------------	---

6.4 Work environment

The work environment needed to safeguard the health and safety of workers and ensure compliance of products with requirements is defined and managed. The corresponding physical and environmental factors are taken into consideration

Responsibilities	DG appointment the health and safety manager RSPP (HSM) analyses and evaluates the risks associated with work activities, identifies and implements the necessary measures for their reduction The MD manages the state of repair of the factory, ensuring the presence of handling and storage means suitable to protect product\component characteristics
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7 PRODUCT IMPLEMENTATION

7.1 Product implementation planning

STILMAS plans and develops the processes needed for product implementation. Product implementation planning is consistent with the requirements of other quality management system processes (see 4.1).

In planning product implementation, the following are defined:

- a) product quality objectives and requirements,
- b) the need to define processes and documents and provide resources specific for the product,
- c) product specific verification, validation, monitoring, inspection and test activities and corresponding acceptance criteria,
- d) necessary records to provide evidence that implementation processes and resulting products meet requirements (see 4.2.4).

7.2 Customer processes

7.2.1 Determination of products requirements

The following are determined:

- a) requirements specified by the customer, including those relating to delivery and after sales support,
- b) requirements not specified by the customer but necessary for the specified or expected use, where known,
- c) mandatory requirements related to products ,
- d) payment procedure requirements
- e) shipping/transport procedure requirements

Responsibilities	CD coordinates Sales Dept activities for collection and review of requirements.
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7.2.2 Review of products requirements

The review takes place before there is commitment to supply a product to the customer to ensure that:

- a) product requirements are defined (this part of the review is not required when ordering standard equipment).
- b) Agreement has been reached on all aspects of the supply.
- c) the defined requirements can be met.

The result of the review is formalised by an order confirmation.
 Records of review results and consequent actions are kept (see 4.2.4).
 Should product requirements be changed, it is ensured that the corresponding documents are amended and that personnel involved are made aware of changes to requirements.

In any case, the confirmation of sale contains the detailed descriptions of all agreements.

The subject is dealt with in [PRO 7.2 – Contract review](#)

7.2.3 Communication with the customer

Our company defines and activates effective procedures for communicating with customers in relation to:

a) product information,

Responsibilities	TM (in collaboration with PMs) verifies the correctness of information and data in brochures, folders, data sheets, etc., both in paper and electronic form, possibly made available via the website
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b) questions, management contracts or orders and corresponding amendments,

Responsibilities	CD and those managing business relations with Customers maintain relationships with the Customer with regard to offers, orders and contracts
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c) customer feedback, including complaints.

Responsibilities	Everyone having contact with Customers collects, records and forwards information from the Customer, in particular with regard to complaints and comments.
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7.3 Design and development

Based on Customer specifications, requirements expressed, on similar previous projects and consistent with applicable mandatory standards, plant and equipment are designed

Details can be found in [PRO 7.3 General order design and development](#)

7.3.1 Design and development planning

During design and development planning the following are established:

- a) design and development phases,
- b) review, verification and validation activities
- c) responsibilities for the various phases.

Responsibilities	The TM plans design and development activities
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The interfaces between the various people involved in the design and development are managed to ensure effective communication and clear assignment of responsibilities. Outputs from planning are updated, as appropriate, as design and development progresses.

7.3.2 Design and development input

Input, relating to product requirements, is defined and the corresponding records kept (see 4.2.4).

Such input includes:

- a) functional and performance requirements,
- b) requirements of mandatory standards,
- c) information from previous similar designs, where applicable ,
- d) other constraints and information provided by the customer as essential requirements for design and development.

This input is reviewed to verify its adequacy. Requirements are described in a complete, unambiguous manner, without any mutual conflict.

Responsibilities	The TM gathers requirements, including specifically applicable laws or regulations, contacting the Customer, if need be, for this latter information
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7.3.3 Design and development output

Design output is provided in a form that enables verification against the input and is approved prior to release.

Design and development output:

- a) satisfy design and development input,
- b) provides adequate information for procurement, production and installation

- c) contains or refers to product acceptance criteria,
- d) specifies the product characteristics that are essential for their safe and proper use.

7.3.4 Design and development review

At appropriate stages systematic reviews of design and development are carried out, in accordance with the plan (see 7.3.1), in order to:

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

Such reviews are attended by representatives of functions involved in the design and development under review. Records of review results and any necessary actions are kept (see 4.2.4).

7.3.5 Design and development verification

Verifications are carried out, in accordance with the plan (see 7.3.1), to ensure that design and development output is compatible with input requirements. Records of verification results and any necessary actions are kept (see 4.2.4).

Responsibilities	The TM defines and implements review and verification sessions
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7.3.6 Design and development validation

Validation of design and development is carried out in accordance with the plan (see 7.3.1) to ensure that the product resulting from design and development meets the requirements for the specified application or, where known, that foreseen.

Validation includes functional product testing (FAT). Records of validation results and any necessary actions are kept (see 4.2.4).

Responsibilities	The MD plans validation (testing) activities and supervises implementation
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7.3.7 Keeping changes under control

Design and development changes are identified and records kept. The effects of design changes on equipment already delivered, in particular with regard to spare parts, is analysed. Records of change results and any necessary actions are kept (see 4.2.4).

7.4 Procurement

7.4.1 Procurement process

The process aims to ensure that products procured comply with the requirements specified by STILMAS

[PRO 7.4 Purchase Order management](#) and [PRO7.5 Supplier evaluations](#)

specify the operating procedures required for the purpose. The type and extent of control performed on the supplier and the product purchased is related to the effect that the product purchased might have on subsequent product implementation or on the final product.

This category comprises

- catalogue products
- STILMAS specification products
- Services
- Transport

Suppliers of products listed are evaluated and selected based on their ability to provide products that comply with our requirements. Supplier selection, evaluation and re-evaluation criteria are established.

Records of evaluation results and of all necessary actions resulting from evaluation are kept (see 4.2.4).

Responsibilities	SM evaluates potential suppliers SM periodically evaluates suppliers, based on the records of each supplier SM defines incoming and storage inspection procedures for goods
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7.4.2 Procurement information (Purchase Orders)

Orders describe the products to be purchased, including, where appropriate

- a) requirements for product, procedure, process and equipment approval,
- b) requirements for qualification of personnel,
- c) quality management system requirements.

The adequacy of specified procurement requirements is ensured prior to their communication to the supplier.

Responsibilities	PC reviews the order prior to issue
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7.4.3 Verification of products purchased

Our organisation establishes and carries out the necessary controls to ensure that products purchased comply with procurement requirements.

[PQ 7.22 Receipt of products purchased](#) specifies the procedures for receipt, registration of arrivals, controls and allocation of incoming goods

7.5 Production

7.5.1 Keeping production activities under control

STILMAS plans and carries out production under controlled conditions.

These conditions include, as applicable:

- a) availability of information describing product characteristics,
- b) availability of processing instructions, where necessary,
- c) use of appropriate equipment,
- d) availability and use of monitoring and measurement devices,
- e) implementation of monitoring and measurement activities
- f) preparation of accompanying technical documentation
- g) implementation of activities for the release and delivery of products and for after sales service.

Details can be found in

[PRO 7.6 Process control](#)

[PRO 7.21 Technical manual issue](#)

[PRO 7.19 After sales service and spare parts management](#)

[PRO 7.20 Management of plant installation at Customer site](#)

7.5.2 Production process validation

Our organisation carries out welding, a production processes whose final result cannot, in general, be verified by subsequent monitoring or measurement.

Validation demonstrates the ability of this process to achieve the planned results. For these processes we provide provisions, where applicable, concerning:

- a) criteria defined for process review and approval,
- b) approval of equipment and personnel qualification,
- c) use of defined methods and procedures,
- d) recording requirements (see 4.2.4),

Specific instructions keep the welding process under control

Responsibilities	MD validates special processes
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7.5.3 Identification and Traceability

We identify products with appropriate means in order to avoid confusion.

The progress of products is identified in relation to monitoring and measurement requirements.

Each piece of equipment can be correlated with the corresponding registration documents via the order number (serial number).

Details can be found in [PRO 7.14 Identification and Traceability](#)

7.5.4 Customer property

In certain cases, contract requirements may provide for installation of materials or components supplied by the Customer as contract work on the equipment supplied to the Customer. In these cases the offer specifies the essential technical characteristics of products supplied by the customer in order for the same to be used, as well as essential documentation associated with materials\components for preparation of accompanying documentation. The material\component is inspected on receipt to verify the presence of the required characteristics.

The material\component is identified, as well as in the standard manner, with a label with the name of the Customer.

Information on materials/components which cannot be used (also in the event of accidental damage in the manufacturing process) is transmitted to the customer

Intellectual property and personal data are also considered to be Customer property.

Information provided by the customer on its products, its sites, its production facilities and its processes is considered confidential.

Responsibilities	<p>The PM informs the Customer of the inability to use (for any reason) the material supplied as contract work by the same and determines the appropriate arrangements in order to overcome the problem.</p> <p>The system implemented by Stilmas, managed by the Data processor, ensures confidentiality of customer data</p>
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Details can be found in [PRO 7.15 Customer property](#)

7.5.5 Product preservation

We maintain product compliance unchanged throughout internal processing and delivery to the final destination. This preservation includes identification, handling, packaging, storage and protection during transport.

Responsibilities	<p>The SM establishes identification, handling, storage and packaging procedures in order to prevent accidental product non-compliance</p>
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7.6 Keeping monitoring and measuring devices under control
 STILMAS identifies monitoring and measurement to be carried as well as monitoring and measuring devices needed to provide evidence of product compliance with specified requirements (see 7.2.1).
 Uncertainty associated with measuring equipment is compatible with the acceptable tolerances of the characteristics to be measured

Measurement equipment is:

- a) calibrated or verified at specified intervals or prior to its use with respect to international or national standards; where such standards do not exist, the criteria used for calibration or verification are recorded;
- b) adjusted or readjusted, if necessary;
- c) identified in order to ascertain their calibration status;
- d) protected against adjustments that would invalidate measurement results;
- e) protected against damage and deterioration during handling, maintenance and storage.

Responsibilities	The MD is responsible for measuring equipment management
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In addition, we evaluate and record the validity of previous measurement results when it is found that the equipment does not comply with requirements and take appropriate actions for equipment and products involved.

Responsibilities	The QM estimates the extent of errors as a result of measurements carried out with inappropriate instruments and determines any action required
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Recording of calibration results and of Verifications are kept. Where software is used for monitoring and measuring specific requirements, its suitability to operate for the intended applications is confirmed.

This confirmation precedes initial use and, when necessary, must be repeated. [PRO 7.17 Measurement and control instrument management](#) provides additional provisions in this regard

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 Foreword

STILMAS plans and implements processes for monitoring, measurement, analysis and improvement required to

- a) demonstrate product compliance,
- b) ensure compliance with the quality management system,
- c) continuously improve the effectiveness of the quality management system.

This includes identification of applicable methods, including any statistical techniques, and their use.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

STILMAS analyses information relating to customer perception of the extent to which their requirements were met, this monitoring being one of the performance measurements of the quality management system. The methods for obtaining and using such information include

- a) Customer complaints and comments regarding the product\service
[PRO 8.1 Customer Complaint Management](#)
- b) the answers provided by customers themselves concerning their perception of the quality of the STILMAS product\service, at the various stages of the contractual relationship

[PRO 8.5 Customer satisfaction measurement](#) illustrates the operating procedures

Responsibilities	QM, in synergy with the GM and the CD, prepares the means for measuring customer satisfaction.
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8.2.2 Internal Audits

Our organisation performs Internal Audits at scheduled intervals to determine whether the quality management system:

- a) conforms to plans, to the requirements of the international reference standard and to the requirements of the quality management system established by us,
- b) has been effectively implemented and maintained updated.

The Audit program takes into account the status and importance of the processes subject to Audit , as well as the results of previous audits. The criteria, scope, frequency and assessment method are established. The choice of Assessors and the audit procedure ensure objectivity and impartiality of the audit process. The Assessors do not make evaluations on their own work.

Responsibilities	The QM plans the Audits in accordance with requirements. QM conducts said audits. Audits of process in which the QM has the role of Manager are carried out for the Management Review
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The requirements for planning and conducting Audits, for documenting the results and storage of records (see 4.2.4) are specified in [PRO 8.2 Internal Audits](#)

Managers of processes subject to audit ensure that the necessary actions to eliminate non-compliances detected and the related causes are adopted without undue delay. Subsequent actions include verifying implementation of actions defined and notification of the results of this verification (see 8.5.2).

8.2.3 Process monitoring and measurement

Measurement of process performance is according to the BSC as outlined in the table below

Process	KPIs			
	Influence			
Commercial	Specific orders Turn over	Claims (global & critical) Company turn over	Customer credit	Delivery late
People management	Number of Days Lost (Safety)	Training (Hours) Numbers of people trained	Numbers of organisational proposal	
Order design and management	Delivery late	New business Company Turn Over	Internal NC	
Purchasing	NC on Purchasing	Quality Service 5dd Saving		
Production	Delivery late	Internal NC	Number of Days Lost (Safety)	
Installation	Delivery late	Claims (global & critical)	Number of Days Lost (Safety)	Internal NC
Service	Service & Spare parts Turn Over	Spare Parts delivery late	Claims (global & critical)	
Technical documentation	Delivery late	Claims (global & critical)		
Data analysis and performance measurement	IS Frequency BSC Frequency	Flash letter		

Should the expected process results not be achieved, corrections are adopted and the necessary actions taken.

8.2.4 Product monitoring and measurement

STILMAS monitors and measures product characteristics to verify that the corresponding requirements have been met.

This is carried out in the appropriate product implementation processes, in accordance with plans (see 7.1).

In particular, the FAT ensures the necessary tests on products awaiting shipment/delivery.

Evidence of compliance with acceptance criteria is documented.
Records indicate the person authorising products release.
Product release and service delivery is not carried out until that planned has been satisfactorily completed

8.3 Keeping non-compliant products under control

Products not compliant with the corresponding requirements are identified and monitored to prevent their inadvertent use or delivery.

[PRO 8.3 Non-compliance management](#) specifies the procedures and related responsibilities and authorities for dealing with non-compliant products.

Our company manages non-compliant products by taking actions to eliminate the detected non-compliances or, as convenient, returning the product to the supplier

Records are kept on the nature of non-compliances and subsequent actions taken, including concessions obtained (see 4.2.4).

Should non-compliant products be corrected, these are re-verified in order to demonstrate their compliance with requirements.

Should a non-compliant product be detected after delivery or after commencement of use, appropriate actions regarding the effects, real or potential, arising from such non-compliance are taken.

8.4 Data analysis

STILMAS identifies, collects and analyses data needed to demonstrate the adequacy and effectiveness of the quality management system and to evaluate where continuous effectiveness improvements to the same can be made.

Included in this context is data resulting from monitoring and measurement activities.

Data analysis provides information on:

- a) customer satisfaction (see 8.2.1),
- b) product requirement compliance (see 7.2.1),
- c) process and product characteristics and performance, including opportunities for preventive actions,
- d) supplier responses

Data are organised in numerical indicators, in accordance with KERS ON

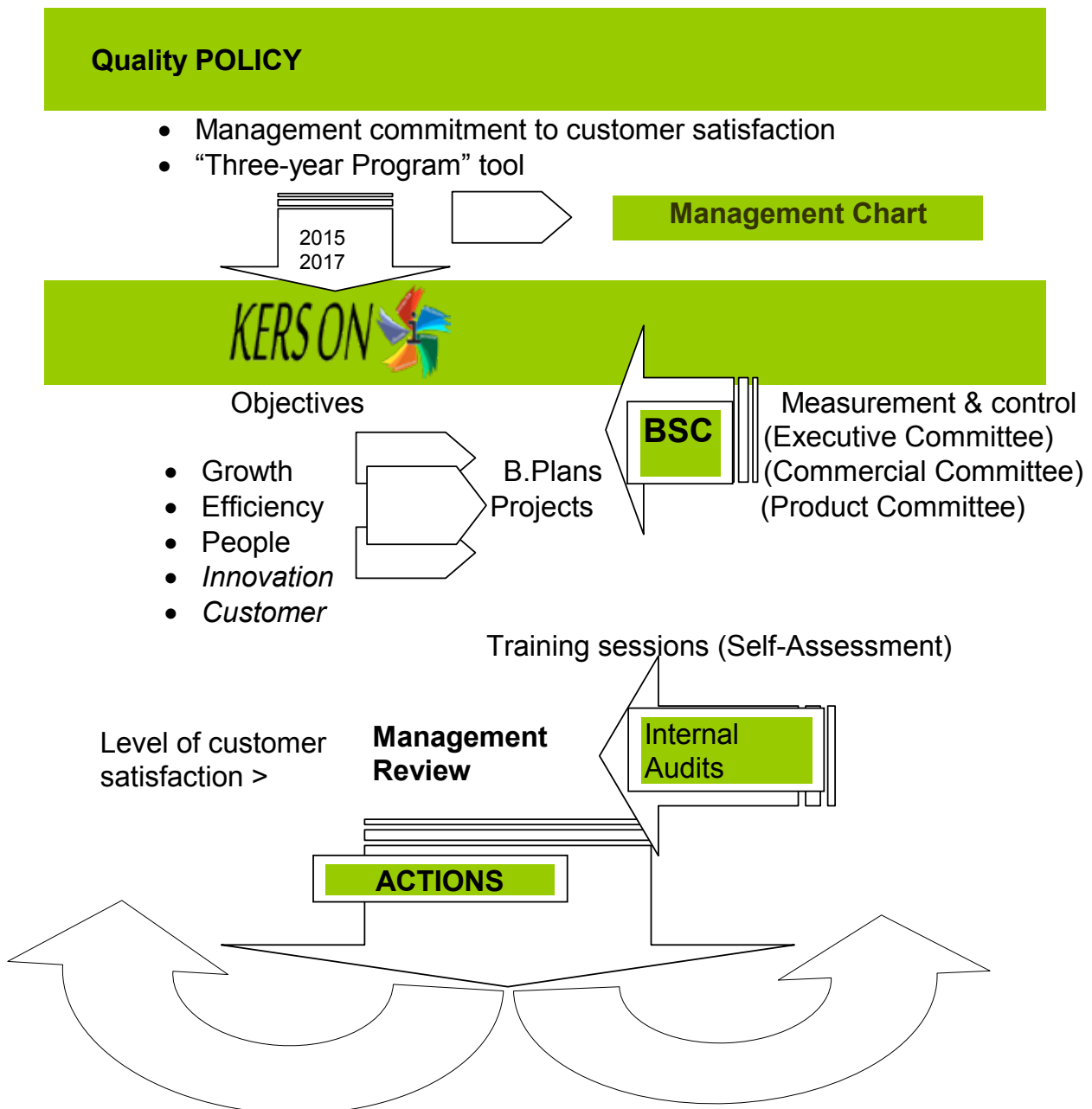
Responsibilities	QM collaborates in drafting the BSC
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8.5 Improvement

8.5.1 Continuous improvement

Our organisation intends to continuously improve the effectiveness of the quality management system using the *KERSON* Company Program, the quality policy, the audit results, data analysis (BSC), preventive and corrective actions and Management Reviews.

The general scheme is given in the following diagram:



8.5.2 Corrective actions

STILMAS implements actions to eliminate the causes of non-compliances in order to prevent their recurrence. Corrective actions are appropriate for the purposes of non-compliances detected.

Responsibilities	<p>The MD evaluates the effects of the production non-compliance and then decides on activation of CA</p> <p>The S&SP Manager, the TM and the MD, based on the evaluation of complaints received and on events occurring during plant start up, decide on the need for activation of CA</p> <p>The QM coordinates, as necessary, appropriate working groups</p>
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[PRO 8.6 Corrective and Preventive Actions for product improvement](#) has been prepared which specifies the requirements for:

- a) reviewing non-compliances (including customer complaints),
- b) identifying the causes of non-compliances,
- c) assessing the need to implement actions to prevent the recurrence of non-compliances,
- d) identifying and implementing the necessary actions,
- e) assessing the effectiveness of actions implemented
- f) recording the results of actions implemented.

8.5.3 Preventive actions

Our company identifies actions to eliminate causes of potential non-compliances in order to prevent their occurrence.

Preventive actions implemented are appropriate for the purposes of the potential problems.

The procedure mentioned specifies actions for:

- a) identifying potential non-compliances and their causes,
- b) assessing the need to implement preventive actions to prevent the occurrence of non-compliances,
- c) identifying and implementing the necessary actions,
- d) assessing the effectiveness of actions implemented
- e) recording the results of actions implemented.