HELLINOTECHNIKI S.A.

Contents

1. OBJECT

1.1 The object of this Manual is to depict the Quality Management System implemented in the Company **Hellinotechniki** (hereinafter the **"Organization**"), so as to ensure the conformity with the requirements of the international standard ISO 9001:2015 – Quality Management System.

1.2 This Manual specifies the responsibilities/competencies/authorities of the parties involved as well as the actions implemented and the acts undertaken during the implementation of the activities and/or reference is made to individual Processes of the Management System which may have been draw up in particular for the better depiction of specific activities. The manual is implemented by the entire staff of the company, whose activities include actions/acts/authorities directly or indirectly associated with the quality of the services offered by the Organization.

1.3 In order to facilitate the verification that all requirements of the ISO 9001 are met, the numbering and the content of the paragraphs of this Manual are in line with the paragraphs of the said standard.

2. REFERENCES

2.1 EN ISO 9001:2015 Standard.

3. DEFINITIONS

For the needs of this document, the definitions and respective clarifications set out in par. 3 of the reference standard EN ISO 9001:2015 are used.

4. CONTEXT OF THE ORGANISATION

Hellinotechniki determines the limits and the applicability of the Quality Assurance System by reviewing the external and internal parameters and the requirements of the relevant interested parties mentioned above, as well as the services it renders, specifying in this manner its scope of application.
The field of application of the Quality Assurance System of the company is available, constantly updated and retained as documented information.
As in **Form E.E.04.00.03 Scope of Application.**

4.1 Understanding the Organization and its Context

The objective of the Organization is to implement a Quality Assurance System that will lead to the achievement of the output pursued from its operation and its conformity with legislative, regulatory and other requirements.

Hellinotechniki has specified the external and internal parameters of its operation and activity which relate to the Quality Policy and the ability to achieve objects and objectives for constant improvement.

External Parameters:

- The legislative and regulatory context that relates to the operation, products and/or services rendered
- The requirements of interested parties
- The requirements of the Organization from the interested parties

Internal parameters:

- The vision of shareholders and of the Management and the Organization's mission
- Culture and values established by the shareholders and the Administration for the setting of objectives in order to achieve the company's business object
- The shareholding composition, the organizational structure and the allocation of competences and authorities among officers and the members of the Organization's personnel
- Policies applied for the achievement of the objective of the Organization and values on which such polices have been founded
- Staffing of the Organization with respect to the human resources availability and the level of scientific/ technical training, education and working experience
- Level of personnel's awareness towards quality issues during the implementation of activities
- Interpersonal relations among the members of the personnel and of the personnel and the Management
- Equipment used (hardware and software), infrastructure and premises
- Procedures of operation and method statements
- Flow of information and decision-making process
- Nature/object and form of contractual obligations and rights governing the operation of the Organization
- Information related to the above parameters or reference thereto is recorded on the document “Operational Context” which is evaluated during the system's review and updated, if required.

Retained File

E.E.04.00.01 Organization and Operational Context.

4.2 Understanding of the needs and expectations of interested parties

Interested parties in terms of the Organization's performance in relation to the quality of its products and/or services are:

- The Organization's shareholders
- The personnel/external associates (outsourcers) engaged under any employment regime on behalf of the Organization
- The Organization's customers
- The Organization's suppliers

- The society
- The neighbors
- Audit – Regulatory Authorities related to the activities and products and/or services offered by the Organization
- Citizen Protection Services and Authorities dealing with malicious acts or accidents (Police and Prosecution Authorities, Financial and Electronic Crime Combatting Units, Fire Department).

The requirements of each category of interested parties for the measurement of the Organization's performance in relation to the quality objectives are recorded on the relevant document “INTERESTED PARTIES” on which it is also noted if the requirement constitutes an obligation of the Organization under legislative, regulatory and contractual requirements.

A review of the above elements is also performed during the annual review of the system and if required, the document “INTERESTED PARTIES” and/or this document, are updated.

Retained File

EE.04.00.02 Interested parties

4.3 Scope of application of the Management System

Hellinotechniki determines the limits and applicability of the Quality System, examining the external and internal parameters and the requirements of the relevant interested parties mentioned above, as well as the services it offers, specifying in this manner the scope of application of the system.

The scope of application of the Quality Management System of the company is available, constantly updated and retained as documented information.

Scope of Application of **Hellinotechniki**, as in **Form E.E.04.00.03 Scope of Application**

4.4 Documentation of the Quality Management System

The Organization has developed and applies a documented Management System which contains provisions for quality management (ISO 9001) in the facilities and scope of activities mentioned in the above paragraph. The system is documented with this Manual and the supporting documents and files referred to herein. This Manual describes the manner the requirements of each paragraph of the said standard are met and in case a requirement is met by another document, process, method statement, form or file of the Management System, then this document contains the relevant reference.

Processes, method statements and forms draw up in the context of the documentation requirements (apart from this Manual) are cumulatively mentioned in a special form of the system which sets out a complete list of the system's documents being reviewed.

In order to develop the management system the PCDA (*Plan-Do-Check-Act*) approach was applied, as follows:

“Plan”

1. Understanding of the operational context and of the needs and expectations of the interested parties (see paragraph 4)
2. Determination of the scope of application (see paragraph 4.3) and of the development context of the quality management system (present paragraph)
3. Ensure that the senior Management assumes responsibility and commits to the task (see paragraph 5.1)
4. Establishment of the quality policy (see paragraph 5.2)
5. Assignment of competencies, duties and authorities to the personnel (see paragraph 5.3)
6. Acknowledgement of legislative, regulatory and other conformity requirements (see paragraph 8.2.2)
7. Acknowledgement of risks and opportunities based on the operational context and the expectations of the interested parties (see paragraph 8.1.1)
8. Planning of actions for risk management and exploitation of opportunities as they emerge and evaluation of the effectiveness of such actions (see paragraphs 9.1.1 & 9.1.2)
9. Setting of quality objectives (see paragraph 6.2) and indicators and planning of actions for their achievement (see paragraph 6.2)

“Do”

1. Identification of resources required for the implementation and maintenance of the Quality Management System (see paragraph 7.1)
2. Specification of qualifications of the personnel and ensuring that the personnel has the sufficiency (see paragraph 7.2) and awareness (see paragraph 7.3) required
3. Establishment and implementation of procedures or arrangements for internal and external communication (see paragraph 7.4)
4. Creation of the suitable method for the creation, updating (see paragraph 7.5.2) and inspection (see paragraph 7.5.3) of documented information
5. Depiction of processes according to the figure presented below and specification of points and controls in order to ensure the operational controls, so that the operation of the company meets the requirements of the quality management system (see paragraph 8.1)
6. Specification of possible emergencies and necessary response (see paragraphs 6.1.1 and 8.2)

“Check”

1. Monitoring, analysis and assessment of performance (see paragraphs 9.1.1 & 9.1.2)
2. Assessment of satisfaction of conformity obligations (see paragraph 9.1.2)
3. Implementation of periodical internal controls (see paragraph 9.2)
4. Review of the quality management system so as to ensure constant suitability, sufficiency and efficiency thereof (see paragraph 9.3)

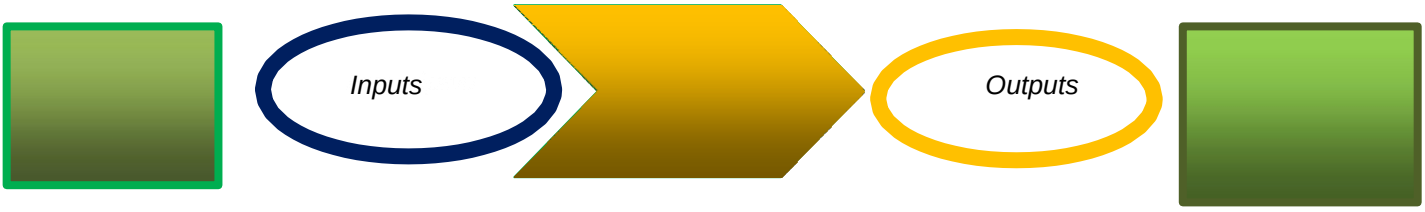
“Act”

1. Planning of actions in order to deal with non-conformity incidents (see paragraph 10.2)
2. Planning of actions for constant improvement, suitability, sufficiency and efficiency of the quality management system for the purposes of improving quality performance (see paragraph 10. 3).

In order to recognize the quality aspects and to establish control mechanisms that will ensure control of the company's operation, the quality features have been recognized through each stage of the lifecycle of products/activities/processes and the overall operation of the Organization, taking into account the legislative, regulatory and other requirements as well as the operational context and the requirements and expectations of the interested parties.

For each process, the inputs and outputs of the process have been taken into consideration, which are affected by the nature of activities, the personnel and equipment used and the quality indicators and measurements that must be performed in order to certify conformity with the requirements and the achievement of the objectives of the Management are specified.

The relevant processes are analyzed based on the following figure:



Advanced processes	Raw materials, Products, Energy, Information, Data HR, Equipment	Implementation of processes, method statements, works, methodologies	Products, Services, procedures, methodologies, assessments	Interested parties or next process

Control points for performance assessment

This analysis is reviewed and evaluated every year along with the assessment of performance, updating of objectives in order to reach the targeted performance. The result of the assessment is documented in the relevant Minutes of the System's review.

5. LEADERSHIP

5.1 Leadership and commitment

The Management of **Hellinotechniki** plays the primary role in the development and improvement of the Quality Management System and renders its commitment clear by:

a. Assuming responsibility, via the Policy for the efficiency of the Quality System and the specification of quality objectives
b. Ensuring that the quality policy and the quality objectives are compatible with the expectations of the interested parties, as these are documented on the relevant documents of the system, “Policy”, “Organization and Operational Context” and “Interested Parties”.
c. Ensuring that the requirements of the Quality Management System are incorporated in the main processes for implementing the relevant activities.
d. Ensuring the resources required for the implementation of the system.
e. Identifying the importance of the efficient implementation of the system.
f. Ensuring that the Quality Management System produces the planned output with the regular monitoring of the achievement of objectives, as described in the relevant documents setting out the objectives.
g. Motivating, guiding and supporting the Organization's personnel so as to contribute to the effective implementation of the system with systematic update and training of the personnel and contribution of resources for the implementation of the system.
h. Promoting improvement, via the specification of objectives that verify improvement
i. Supporting the leadership institution in any case possible, endorsing the members of the personnel to whom roles and competences have been assigned.

The above are proven via the establishment and implementation of the corporate Quality Policy.

5.2 Quality Policy

Policy for the Quality of services and products constitutes proof of the Organization's commitment to the conformity with the requirements of the standard, the legislative, regulatory and other requirements and the constant improvement, as well as with other relevant commitments and obligations in the context of its operation.

The policy for the quality of services is the suitable and relevant to the Organization's activities and creates the context for the establishment of performance indicators and the respective objectives for quality, which is endorsed by the Management, constitutes a document of the system that will be checked and communicated to the interested internal and external parties (employees, customers, suppliers etc.) by means of posting it at transparent locations within the Organization's premises or at its website and/or sent to the interested parties, if requested.

Quality Policy of the Organization, as in **Document Π.05.01 Quality Policy**

Retained File

Π.05.01 Quality Policy

5.3 Organizational roles, responsibilities, and authorities

5.3.1 The Organization's Management ensures that responsibilities and authorities of its officer are clearly described and communicated to its personnel. This is managed on one hand, by depicting the organizational structure on the Organizational Chart of the Organization where hierarchy and reference line among the operational structural units are described and on the other, by means of the preparation of Method Statements where duties, obligations and authorities of each job position are illustrated.

5.3.2 The Management Systems Supervising Officer is responsible for the constant monitoring of the Quality Management System so that it always focuses on the customer and it is in conformity with the requirements of the Standard, for ensuring effectiveness and efficiency of processes and achieve the planned output, for preserving its integrity when changes occur and informing the Management for the performance of the system and the improvement opportunities.

Retained File

Ε.Ε.05.00.01 Organizational Chart

Δ.05.01 HR Management

Ε.Δ.05.01.01 Employees List

6. Planning

6.1 Actions to address risks and opportunities

6.1.1 General

The Management makes sure that during the planning of the Quality Management System the "Operational Context" and the "Interested Parties" documents are taken into account and detects risks and opportunities that must be addressed and exploited respectively, so as to ensure the effectiveness of the system, the elimination or mitigation of adverse effects and constant improvement via the planning, implementation and assessment of the effectiveness of the suitable actions that will be incorporated in the Management System.

In order to plan the system, the external and internal features of the Organization that affect the Management System have been taken into consideration, as well as the requirements of the interested parties, the lifecycle of products/activities/processes and the scope of application of the system. The relevant affected processes and the elements affecting those processes have been documented on the **forms E.E.04.00.01 Organization and Operational Context** and **EE.04.00.02 Interested Parties**, while the stages of the lifecycle of products/activities/processes are documented on the relevant lifecycle table/diagram where the ability to intervene on the impact on the conformity of products and services based on the following data:

- The lifecycle stage of the product or service
- The degree of control at the lifecycle stages e.g. a products designer may be responsible for selecting raw materials, while a manufacturer can be responsible only for the reduction of the use of raw materials for the use and disposal of the product
- The degree at which the specific stage affects the entire lifecycle e.g. the designer may only affect the production methods, while the producer can also affect the design and the manner the product will be used
- The lifetime of the product
- The Organization's effect on the supply chain
- The extent of the supply chain
- The technological complexity of the product.

Data included in the said table is taken into account for the identification and assessment of impact.

6.1.2 Risks, impact and opportunities/ Risk Assessment for Quality

6.1.2.1 Identification of risks and impact assessment

At each stage or process, risks that may be related to the quality features of the processes are identified. Each risk/threat is assessed as to its impact with the use of a tool that is integrated in the **Form Έντυπο Ε.Δ.06.01.03 Risk Assessment.**

6.1.2.2 Assessment of risks and opportunities

In order to specify and classify **risks** each impact is assessed based on the following parameters and the severity of each parameter as follows:

a. The department /process with which it relates
b. Possible consequences

c. Non-performance of conformity obligations, a fact that may incur fines, expenditures for corrective actions and possible loss of the operation permit
d. Increase of customer demand which requires an unscheduled increase in productivity without the corresponding increase in specialized employees, which may lead to mistakes that can cause service delays
e. Views of the interested parties in relation to the quality performance of the Organization, a fact that may raise contradictions
f. Measures adopted for addressing risks and opportunities without taking into account any unintended consequence of such measures
g. Other.

Relevant documents/files

Δ.06.01 Risk Assessment

Ε.Δ.06.01.03 Risk Assessment

6.1.3 Conformity obligations

Conformity obligations are dictated by the legislative and regulatory framework of operation and the requirements of the external interested parties.

In order to monitor these obligations, a list of documents is created from which the obligations result, and the obligation and monitoring method are recorded on the said list and the conformity is documented.

Obligations resulting from the granting of the operation permit are inspected and systematically monitored with the assessment of the satisfaction of all terms and conditions of permits and approvals granted.

The above are documented with the use of the **Document Ε.Δ.08.09.01 Non-Conformity Reporting – Corrective Actions** which is constantly updated and its contents are taken into account during identification and assessment, while it constitutes inputs for the System's Review.

Relevant document/file

Ε.Δ.08.09.01 Non-Conformity Reporting – Corrective Actions

6.2 Quality objectives and performance indicators and planning to achieve them

In order to monitor the Organization's performance in relation to Quality, the Management specifies performance indicators and sets objectives based on the assessment of threats/risks and opportunities as described in the preceding paragraph.

Suitability/sufficiency of the performance indicators and objectives is reassessed in each System Review by the Management, with regard to the Organization's Activities, as well as the output from the investigation of any incidents.

At the care of the System Supervisor, a n Achievement Plan is prepared for each OBJECTIVE, which is approved by the Management and sets out:

a. The objective measurement indicator and the objective
b. The necessary resources

c. The actions that must be implemented
d. The persons in charge for implementing the actions
e. The actions implementation/completion time schedule
f. The person in charge for the achievement of the objective.

The assessment of the achievement of the OBJECTIVES in performed in the context of the Review by the Management (see par. 9.3 below)

6.2.1 At the care of the Quality System Supervisor, the objectives are communicated to the members of the personnel involved which is in turn responsible for achieving them, to the extent permissible based on the duties each of them is vested with.

Relevant document/file

E.Δ.09.03.01 List of Objects and Objectives

6.3 Planning of Changes

In case the Organization's Management identifies the need to effect changes in the Management System with respect to the Quality of Services, then at the care of the Internal Control Officer, a Changes Plan is prepared which contains:

a. An accurate description of all changes that will be implemented and the purpose of these changes (e.g. changes in the scope of application, the Policy, Processes, Procedures, infrastructure, personnel and working relationships etc.)
b. Provisions and actions that must be performed in order to ensure the integrity of the Management System during the implementation of changes and thereafter
c. The resources required during the implementation of changes and thereafter
d. The assignment or reallocation of competencies and responsibilities during the implementation of changes and thereafter.

Relevant document /file

E.E.06.00.01 List of Changes and Planning

7. Support

7.1 Resources

7.1.1 General

The Organization's management specifies, makes available and maintain the infrastructure required for the operation and implementation of processes. The nature of infrastructure required for the operation and achievement of conformity of products and services has been specified. The main infrastructure categories are:

- Buildings
- Equipment

- Software
- Means of transportation
- Information and communication technologies
- Monitoring and measurement instruments

In order to check the sufficiency of infrastructure, a List of Equipment and Maintenance Schedule is deployed, which sets out data that relates to the traceability of assets and acquisition time thereof. In parallel, the head of each activity creates a check and maintenance mechanism for the infrastructure and a record is retained for the said check, preventive and corrective maintenance; where required, special guidelines are issued.

At regular intervals (at least once a year in the context of the System Review by the Management) the Organization's Management examines the resources required for the implementation of activities and the development and implementation of the Management System as well as for the constant improvement thereof. In order to satisfy the needs for resources, a specification is performed in relation to the actions that will be implemented by the Organization's own resources or if external resources need to be obtained. The nature of resources originating from external sources are analytically described in the Review Minutes and/ro if necessary, documents are drawn up which clearly specify the characteristics of such resources and the manner their sufficiency is verified. In case that during a year the need for resources emerges which were not foreseen or resulted from particular or additional requirements, the Management specifies those needs and decides for the allocation of resources by assigning the relevant duties for the preparation of the relevant documents.

A file is retained on which the available resources – by the Organization or from external sources – are recorded, as well as a file of documents describing the terms and conditions of supply.

7.1.2 People

The Organization's Management determines and provides the persons necessary for the effective implementation of the Quality Management System. In order to satisfy the requirements of the relevant paragraph of the Standard, the Organization has prepared an Organizational Chart that depicts the staff and specifies authorities and responsibilities for each organic position.

7.1.3 Infrastructure

The Organization's Management specifies, makes available and maintains the infrastructure required for the implementation of the activities and the application of processes required for the effective implementation of the System. In order to satisfy those requirements, the necessary Guidelines have been issued.

Relevant document /file

O.07.01 Guidelines for Disposal – Use – Maintenance – Recall of Equipment

E.O.07.01.01 List of Equipment

E.O.07.01.02 Maintenance of Equipment

E.O.07.01.03 List of Vehicles

E.O.07.01.04 List of Security Keys

7.1.4 Environment for the operation of processes

The Organization's Management ensures the suitable working environment for the implementation of activities and the application of processes.

As regards the social and psychological dimension of the working environment (absence of discriminations, peace, absence of conflicts, limitation of stress etc.) the Organization has drafted Policies for the behavior and conduct which are binding for each employee being in its service, under any employment regime.

As regards physical/natural factors (working schedule, ergonomy of premises and job positions (work stations), temperature, humidity, lights, noise), as provided for by the Law on Health and Safety at Work (Law 3850/2010) the Organization's Management has vested the duties of the Safety Technician to an suitably trained officer and has prepared and always updates a Written Professional Risk Assessment where measures that must be adopted are specified.

7.1.5 Monitoring and Measuring Resources

The Organization's activity and the application of processes **do not** include measurements (this paragraph is reserved for the purposes of corresponding the paragraphs of this Manual with those of the reference standards).

In case of subcontracting which includes the use of measurement equipment, the subcontractor will be bound in the subcontract agreement to use verified and approved measurement equipment.

7.1.6 Organizational Knowledge

The Organization's Management specifies the necessary knowledge for the application of processes and the effective implementation of activities which are depicted for each organic position in the Job Positions Description. The analytical Job Positions Description mention the minimum education required for covering the respective job post.

7.2 Staff Competence

The Organization's Management specifies and makes available the persons necessary for the effective implementation of the Management System. The organizational structure and hierarchy are depicted on an Organizational Chart where the core structure of the Management and the staffing thereof are illustrated, as well as in analytical Job Positions Descriptions where the authorities and responsibilities for each organic position are specified, as well as any outsourcing (see also paragraph 5.3).

In case of outsourcing of activities, the relevant agreements are concluded where the object of outsourcing is described, together with the obligations of the contracting parties.

The necessary staff qualifications (education, training, experience) to whom duties and authorities have been assigned, are described in the relevant **Process Δ.05.01 HR Management**.

The **Form Ε.Δ.07.01.03 Status of Education Monitoring** records the necessary training offered by the Organization for each employee, in the context of the system's implementation.

During the System Review by the Management, the staff performance is assessed, which is documented on the same document and the staff training activities are decided.

The qualifications and training of external associates are monitored in the same manner, unless the relevant information is included and constitutes an integral part of the outsourcing agreement.

Relevant document/file

Ε.Δ.07.01.03 Training Monitoring Report

Ε.Δ.07.01.05 Personal Training Sheet

7.3 Awareness

In the context of a special training session which is held at the onset of the implementation of the system when new employees are recruited and in case of any changes, the System Supervisor informs employees and outsources for

- The Quality Policy
- The important processes and the relevant actual or potation impact related to each task
- Their contribution to the effectiveness of the Quality Management System
- The effect of non-conformity with the requirements of the management system, including the non-performance of the conformity obligations of the Organization with legislative and other requirements.

7.4 Communication

7.4.1 General

The System Supervisor documents the system's information which is sent or received, as the case may be, to and from the interested parties on a special form titled “Communication Details”. The contents of this document are approved by the Management usually during the System Review. The form “Communication Details” records:

- The object of the communication
- The time of communication
- The person or organization (interested party) to whom the communication is addressed
- The manner of communication
- The file retained or the manner documenting that the communication took place
- The person in charge for securing the accuracy of information.

The object of the communication which is included in the form is the obligation to file reports to the authorities in relation to the system elements such as quantity of waste or records-keeping which must be available to the authorities during various audits and inspections.

The “Correspondence Protocol” is retained, which lists the incoming and outgoing documents from and to the external interested parties.

Relevant document/file Δ.07.02 Communication of Information
Ε.Δ.07.02.01 Communication Details

7.5 Documented Information

7.5.1 General

The management system includes:

a. Documented information required under the Standard and more specifically:
   - The scope of application of the Quality Management System (see par. 4.3)
   - The Quality Policy (see par. 5.2)
   - The identified risks and opportunities that must be addressed (see par. 6.1.1)
   - The procedures required for identifying and assessing the effects, the specification of the conformity obligations and the control and monitoring thereof based on the conformity requirements (see par. 6.1.1-6.1.4)
   - Description of effects, criteria applied for the specification of essential aspects of the system and important parameters (see par. 6.1.2)
   - The conformity obligations (see par. 6.1.3)
   - Information regarding objectives (see par. 6.2.1)
   - Information regarding the documentation of the operation control (See par. 8.1)
   - Procedures required for preparation and response to contingencies and emergencies as identified in par. 6.1.1, to the extent required in order to reassure that processes are applied in accordance with the provisions formed (see par. 8.2).
   - Files that contain:
     - ✓ Personnel sufficiency information (see par. 7. 2)
     - ✓ Communication details (see par. 7. 4. 1)
     - ✓ Details of monitoring, measurement, analysis and evaluation of ouput (see par. 9.1.1)
     - ✓ Output of the conformity assessment (see par. 9.1.2)
     - ✓ Application of the internal inspection schedule, and the output of internal inspections (see par. 9.2)
     - ✓ Management's Review Output (see par. 9.3)
     - ✓ Information from the non-conformity incidence detected and any subsequent actions, as well as the output of any corrective measures and actions (see par. 10.2)

b. Documented information specified as necessary for the effectiveness of the management system which derive from the process analysis, as documented in the lists described below.

Lists of documented information are retained:

I. Which are developed by the Organization in the form of a process, method statement, form, diagram, table etc., in the context of developing, maintaining and improving the management system; those lists contain at least the information on the version number and date, author and approval officer and the locations within the Organization's premises where the documented information must be made available

II. Which derive from external sources and affect the management system (equipment operation manuals etc., product specifications, MSDS, materials TDS) which include at least information on the version, origin, frequency and latest inspection date and the job positions which must access that information

III. Of files created in order to prove the implementation of the system, which include the authority for keeping these files, their form, the retention period and the confidentiality obligation as well as the access authorization to the information contained therein.

7.5.2 Creating and Updating

During the creation and updating of documented information the following has been provided for:

a. appropriate identification of documents which is ensured with the:
   - use of a unique title and/or code
   - reference to the version number and/or version date
   - reference to the author and officer in charge for their approval

In case of documents such as forms or documents generated by mechanical processing, the above information such as title and version will be mentioned therein, or are mentioned in the lisdt of controlled documents set out in the preceding paragraph.

b. a standard form with defined font and header and footer contents, as applicable. The list of controlled documents contains information in relation to the nature of the document (printed or electronic) and if the language required, a file of all documents developed by the Organization is available to all parties involved in an non-processable form, while the Documentation Officer is authorized to access a processable form of the file.

c) Review and approval regarding suitability and adequacy.

The authorities for reviewing and approving the documents are mentioned in the relevant list and when provided for, in the document.

Retained Document/File

Δ.07.03 Management of Documents and Files

8. Operation

8.1 Operational planning and control

In order to control operation, methods have established and applied in order to control the processes based on the identified risks and opportunities for the provision of products and services, as well as the implementation of actions specified in par. 6.1 and 6.2.

More specifically, the Organization has established the planning and implementation control as well as qualitative control which are depicted in **Process Δ.08.01 "Project Management"** based on information deriving from:

- Determination of requirements for products and services
- Analysis of flows and process for the acceptance of products and services
- Determination of necessary resources
- Determination of parameters contributing to the control and mitigation of effects
- Determination of the operational criteria with specification of the control parameters values
- Determination of control and monitoring methods.

In case of any change, the relevant information is reviewed and the **"List of Equipment"** is updated if necessary, as well as the **Form E.O.07.01.02 Equipment Maintenance Schedule**. In case external associates are involved in the operation, these associates are informed – trained for the implementation of the operational control plan.

During the annual review of the system, the planning outputs are assessed so as to confirm that the planning of processes is suitable for controlling the effects. A review of planning may also be performed extraordinarily, if required, when malfunctions emerge or deviations from the objectives and systematic non-conformity. The planning review process is activated by the persons in charge, as the case may be, together with the System Supervisor. A file is retained by the System Supervisor which entails the enquiries and management thereof for changes in the design of monitoring effects and processes.

If no outsourcing of the implementation of part or all processes is required to organizations outside the company, the Management appoints the Process Supervisor, who in collaboration with the System Supervisor evaluates the possible risks and prepares the relevant document where the process to be implemented is described, in accordance with the above, which constitutes an integral part of the outsourcing agreement.

Retained Document/File

Δ.08.01 Project Management

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers includes:

a. Provision of information for products and services,
b. Handling of enquires, contracts or orders, including any changes
c. Customers feedback relating to the products and services, including customer complaints,

d. Handling or controlling customer property and
e. Establishment of specific requirements for contingency actions, if likely to occur.

Communication with customers is effected by email and in any case a communication record in retained in a specific file according to the Organization's electronic archiving system.

8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services offered to customers, the Organization will ensure that:

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

8.2.3 Review of the requirements for products and services

8.2.3.1 The Organization ensures that it has the ability to meet the requirements for products and services to be offered to customers. The Organization conducts a review before committing to supply products and services to a customer, which includes:

a. requirements specified by the customer, including the requirements for delivery and post-delivery activities;
b. requirements not stated by the customer, but necessary for the specified or intended use, when known;
c. requirements specified by the Organization,
d. statutory and regulatory requirements that apply to products and services and
e. requirements the contract or order which are different from those previously stipulated.

The Organization ensures that any disputes between the contract or order requirements and those initially stipulated are resolved.

Whenever the customer does not provide a documented statement of requirements, customer's requirements are confirmed prior to their acceptance by the Organization.

8.2.3.2 The Organization retains documented information when required:

a. On the review outputs and
b. On possible new requirements for products and services.

8.2.4 Changes to requirements for products and services

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

Retained document/file

Δ.08.02 Customers Communication

Δ.08.03 Customers Satisfaction Measurement

8.3 Design and development planning

The Organization conducts no activities related to design and development of new products or services (this paragraph is retained for the purposes of correspondence of the paragraphs of this Manual with those of the reference standards).

8.4 Control of externally provided processes, products services

8.4.1 General

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

The Organization determines the controls to be conducted for the processes, products and services externally provided:

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

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

8.4.2 Type and extent of control

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

The Organization:

a) Ensures that externally provided processes remain within the control of its quality management system;

b) Specifies both the controls that it intends to conduct to an external provider and those it intends to conduct to the resulting output;

c) T akes into consideration:

1) The potential impact of the externally provided processes, products and services on the Organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

2) The effectiveness of the controls applied by the external provider;

d) Determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for external providers

The Organization ensures the adequacy of requirements prior to their communication to the external provider.

The Organization communicates to external providers its requirements for:

a) the processes, products and services to be provided;

b) the approval of:

1) products and services;

2) methods, processes and equipment;

3) the release of products and services;

c) competence, including any required qualification of persons;

d) the external providers' interactions with the Organization;

e) control and monitoring of the external providers' performance to be applied by the Organization;

f) verification or validation activities that the Organization, or its customer, intends to perform at the external providers' premises.

Retained Document/file

Δ.08.06 Suppliers Assessment

Δ.08.07 Management of Supplies and Warehouse

8.5 Production and Service provision

8.5.1 Control of production and service provision

The Organization implements production and service provision under controlled conditions. Controlled conditions include, as applicable:

a. the availability of documented information that defines:

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2) the results to be achieved;

b. the availability and use of suitable monitoring and measuring resources;

c. the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

d. the use of suitable infrastructure and environment for the operation of processes;

e. the appointment of competent persons, including any required qualification;

f. the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
g. the implementation of actions to prevent human error;
h. the implementation of release, delivery and post-delivery activities.

8.5.2 Identification and traceability

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

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

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

8.5.3 Property belonging to customers or external providers

The Organization sees to the protection of the property of customers or external providers under the control or used by the Organization.

The Organization identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

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

A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

8.5.4 Preservation

The Organization preserves the outputs during production and service provision, to the extent required to ensure conformity to requirements.

Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection

8.5.5 Post-delivery activities

The Organization meets requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the Organization considers:

a. statutory and regulatory requirements;
b. the potential undesired consequences associated with its products and services;
c. the nature, use and intended lifetime of its products and services;

d. customer requirements;
e. customer feedback.

Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of changes

The Organization reviews and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.
The Organization retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

The Organization implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.
Release of products and services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.
The Organization retains documented information on the release of products and services. Such documented information includes:

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

Retained Document/File
Δ.08.01 Project Management

8.7 Control of non-conforming outputs

8.7.1 The Organization ensures that outputs that do not conform to the requirements are identified and controlled to prevent their unintended use or delivery.
The Organization takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.
The Organization deals with nonconforming outputs in one or more of the following ways:

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

Conformity to the requirements must be verified when nonconforming outputs are corrected.

8.7.2 The Organzation retains documented information that:

a. describes nonconformity,
b. describes the subsequent actions performed,
c. describe any concessions obtained and
d. identifies the person in charge for approving the subsequent actions in respect of non-conformity.

Retained Document/File

Δ.08.08 Control and Measurement Processes and Processes Performance Measurement

Δ.08.09 Management of non-conformity

9. Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

When analyzing the lifetime of products/activities and processes and determining the elements that must be monitored, the Organization determines:

a. what needs to be monitored and measured,
b. the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results,
c. the acceptance criteria
d. when monitoring and measuring is performed
e. when the output of monitoring and measurement are analyzed and evaluated
f. when the measurement output must be analyzed.

The needs for the use of verified equipment are documented on the relevant equipment maintenance and monitoring form **E.O.07.01.02 List of Equipment – Maintenance.**

The overall performance of the management system is assessed by the Management during the review unless otherwise defined for specific monitoring parameters of certain processes, as determined during the setting of objectives and planning of actions for their achievement. Assessment is documented in the relevant Review Minutes.

Relevant document/file

Δ.09.01 System Assessment Procedure

E.Δ.09.01.01 Quality Management System Assessment Form

9.1.2 Conformity Evaluation

Conformity to the requirements is documented at the following points:

- The quality policy which has been issued by the Management, is available to the interested parties and entails commitment to conformity with requirements
- The acknowledgement of legislative, regulatory and other obligations

- The assessment of conformity with the conditions of permits and approvals
- The relevant objectives determined by the Management
- The information from the operation control
- The measurement outputs
- Relevant corrective and preventive actions

The overall assessment on conformity performed during the System reviews.

9.2 Internal audit

9.2.1 Once a year, the System Supervisor performs with the assistance, if required, of other members of the Organization, a series of internal audits in order to provide information as to whether the quality management system:

a. conforms:
   I. with the requirements set by the Management that concerns the Quality Management System
   II. The requirements of the relevant International Standard (ISO 9001)
b. Is effectively implemented and updated.

9.2.2 The System Supervisor files to the Management for approval and next constantly updates, an audit plan which includes the frequency, the methods, responsibilities, planning and reporting requirements I case of any findings. During the preparation of this plan, the importance of the relevant processes, the changes that affect the system and the findings of previous audits are taken into account,

The criteria based on which internal audits are conducted, are the requirements that result from:

- the Standard
- the Policy
- the Installed Management System
- the conformity obligations

Internal auditors do not audit their activity in order to ensure objectivity and impartiality of the inspection.

The audit findings referred to the relevant Management Level, which proceeds with corrections and corrective actions without any unjustified delay.

The audit findings and any corrective actions performed or planned are assessed by the Management during the System Review.

A record of plans and internal audit findings is retained, as well as of the actions implemented in order to address such findings. Reference of the results of the Management's assessment is made in the System Review Minutes.

Retained Document/File

Δ.09.02 internal Audits Procedure Ε.Δ.09.02.01 Audit Scheduling Ε.Δ.09.02.02 Internal Audit Reports Ε.Δ.09.02.03 Deviations – Corrective Actions Recording Form

Δ.08.08 Audit and Processes Performance Measurement Procedures

9.3 Management Review

9.3.1 General

Senior Management reviews the Quality Management System regularly once a year, so as to ensure its continual suitability, sufficiency and compatibility with the strategic orientation of the Organization.

9.3.2 Management review inputs

The Management review is prepared by the System Supervisor and is carried out while taking into consideration:

a. The progress of implementation of actions rom previous Management reviews,
b. Any changes in:
    i. external ad internal parameters which relate to the Quality Management System,
    ii. needs and expectations of interested parties
    iii. risks and opportunities
    iv) the extent to which quality objectives have been achieved
    v) feedback regarding the Organization's performance, including trends resulting from:
        - non-conformity and corrective actions
        - monitoring and measurement outputs
        - performance of the conformity obligations
        - findings of internal audits
        - sufficiency of resources,
        - relevant communication with interested parties, including complaints
        - improvement opportunities.

9.3.3 Management review outputs

The outputs of the Management Review include conclusions, decisions and actions as follows:

i. Conclusions which relate to the continual suitability, sufficiency and effectiveness of the Quality Management System
ii. Decisions related to improvement opportunities
iii. Decisions related to any need for changes to the Quality Management System, including resources
iv. Actions, if required, when quality objectives have not been achieved
v. Actions for the improvement of the integration of the Quality Management System to other business processes, if required
vi. The effects of the system on the strategic orientation of the Organization.

During the review, the fields in which resources will be made available are examined and planned and reference is made to to actions that result from the application of procedures and documents are assessed or approved such as:

- Future internal audits schedule
- Personnel Training Schedule
- Approval of Suppliers
- Objectives and Achievement Plans
- A record of Minutes is retained which documents the Management Review.

Retained Document/File

Δ.09.03 Management Review

Ε.Δ.09.03.02 Review Minutes

10. Improvement

10.1 General

One of the major goals of the Management is to trace and select opportunities for improvement, as well as to implement any actions that are necessary in order to customer requirements and enhance customer satisfaction.

10.2 Non-conformity and corrective actions

In case of non-conformities, including those arising from Complaints or enquires by interested parties, the person coming across the non-conformity, hierarchically informs the head of the process who, if required, in co-operation with the System Supervisor:

a. promptly addresses such non-conformity, and where applicable:
   I. takes action in order to control and correct it,
   II. deals with the consequences via the appropriate actions including mitigation of adverse effects,
b. assesses the need for actions that will eliminate the causes of non-conformity, so as to avoid recurrence or occurrence elsewhere, via:
   I. the review and analysis of the non-conformity,
   II. determination of the non-conformity causes and
   III. determination of whether similar non-conformities are present elsewhere or could potentially arise
c) Implements any action required,
d) reviews the effectiveness of the corrective actions implemented,
e) updates the Quality Management System where required and also updates risks and opportunities if necessary and
f) The relevant file is available at the assigned points under the supervision of the System supervisor for the appropriate archiving and filling in of the relevant database.

The System Supervisor keeps a complete record which documents:

a. The nature of non-conformities and subsequent corrective actions and
b. The result of the corrective actions.

Retained Document/File

Δ.08.09 Management of Non-conformities, Corrective-Preventive Actions

Ε.Δ.08.09.01 Non-Conformity Reporting-Corrective Actions

Δ.09.03 Management Review

Ε.Δ.09.03.02 Review Minutes

10.3 Continual Improvement

The Management's goal is to constantly improve suitability, sufficiency and effectiveness of the Quality Management System and the security of data and information. The System Supervisor examines the outputs of the analysis and assessment, as well as the outputs of the Management Review in order to trace any contingent needs or opportunities that will be implemented as part of the continual improvement, which he/she files to the Management.

Retained Document/File

D.10.01 Development and Application of Improvement Schemes/Plans

LIST OF AMENDMENTS- REVISIONS

S/N	**VERSION/AMENDMENT**	**DATE/ AUTHOR'S NAME – SIGNATURE**	**DATE APPROVAL OFFICER NAME – SIGNATURE**
1	Original Version	3 /5/ 2022	3 /5/ 2022