

QUALITY MANAGEMENT MANUAL

Elaborated	Approved	Date	Revision
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1 PRESENTATION

This Management Manual was developed, approved and published with the aim of demonstrating the compliance of the Management System with the requirements of the reference standards NP EN ISO/IEC 17025 and NP EN ISO/IEC 17065, and presenting the Management System to external entities, whenever necessary.

2 SCOPE

The Management System implemented at QualityLab aims to accredit the tests described in the Technical Accreditation Annex no. L0500 issued by IPAC and the list of tests under a flexible accreditation regime, which can be consulted at http://www.ipac.pt/research/ficha_lae.asp?id=L0500 product certification will be accredited by IPAC and will follow modules B and C2 described in Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016, and will also include the conformity assessment of textile materials and accessories for protective clothing.

3 MAIN REFERENCE DOCUMENTS

Reference documents	Content
NP EN ISO/IEC 17025	General competence requirements for testing and calibration laboratories
NP EN ISO/IEC 17065	Requirements for product, process and service certification bodies
NP EN ISO/IEC 17067	Conformity Assessment – Fundamental aspects of product certification and guidelines for certification schemes.
Regulation (EU) 2016/425	Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.
EC Regulation 765/2008	Regulation (EC) No 765/2008 setting out the accreditation requirements relating to the marketing of products
OGC001	Interpretative Guide NP EN ISO/IEC 17025
OGC002	Guide to accreditation of chemical laboratories
DRC001	General Accreditation Regulations
DRC002	Regulation of accreditation symbols
DRC005	Procedures for laboratory accreditation
DRC006	Procedure for accreditation of certification bodies
OEC025	Specific accreditation requirements - notification
EA 2/17	EA Document on Accreditation for Notification Purposes
EA-6/02	<i>EA Guidelines on the Use of ISO/IEC 17065 and ISO/IEC 17021-1 for Certification to EN ISO 3834</i>
IAF MD 4	<i>Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes</i>
IAF MD 7	<i>Harmonization of Sanctions and Dealing with Fraudulent Behavior</i>
IAF MD 25	<i>Criteria for Evaluation of Conformity Assessment Schemes</i>
RfU's	Horizontal and vertical recommendations for use
Blue guide	Implementation of EU product rules
---	Notification Procedure for Bodies (2019-03-25)

4 GENERAL REQUIREMENTS

4.1 IMPARTIALITY MANAGEMENT

4.1.1 Impartiality

QualityLab's activities are conducted impartially to avoid conflicts of interest. The tests and technical evaluations performed by the team on the samples submitted are free from any internal or external pressure or undue influence, whether commercial, financial, or otherwise, that could negatively affect the quality of the work. The same applies to the analysis of certification applications and the decision-making process (granting, renewal, suspension, or withdrawal).

To minimize impartiality risks, all Commission staff and members sign the Impartiality and Confidentiality Pledge (Form 27). This demonstrates confidence in the competence, impartiality, and operational integrity of all staff.

Risks to impartiality are identified on an ongoing basis, including risks arising from your activities, QualityLab's relationships, or the relationships of your personnel.

Whenever a risk to impartiality is identified, PAP.01.09 – Risks and Opportunities is immediately followed, which defines the methodology for identifying and treating risks, with their analysis/monitoring carried out in the Risk and Opportunity Matrix (Mod. 83).

4.1.2 Mechanism to safeguard impartiality

The mechanism for safeguarding impartiality is described in the Ethics Committee procedure (PCM.01.05). Thus, this Committee is responsible for monitoring the implementation of actions that ensure impartiality in product certification activities.

4.2 CONFIDENTIALITY

QualityLab is responsible for managing the information obtained or created during the execution of its activities. If necessary, QualityLab informs the client in advance about the information that it intends to place in the public domain, with the exception of that

which the client already makes publicly available; all other information is the property of the client and, as such, is treated as confidential.

QualityLab is required that makes confidential information available by legal or contractual provision, the customer will be notified of the information provided, unless prohibited by law.

Client information obtained from sources other than the client itself is treated as confidential between the client and QualityLab. The source of this information is also treated as confidential and is not shared with the client unless agreed upon with the source.

QualityLab personnel, including any committee members, suppliers, external agency personnel, or individuals acting on QualityLab 's behalf , maintain the confidentiality of all information obtained or generated during the execution of QualityLab's activities, except when required by law. Therefore, all employees and committee members sign the Impartiality and Confidentiality Commitment (Mod. 27).

Whenever a risk to confidentiality is identified, PAP.01.09 – Risks and Opportunities is immediately followed, which defines the methodology for identifying and treating risks, with their analysis/monitoring carried out in the Risk and Opportunity Matrix (Mod. 83).

4.3 RESPONSIBILITY AND FINANCING

QualityLab has insurance to cover the liabilities arising from its activities.

QualityLab has the necessary resources to carry out its activities and prepares an annual budget approved by the Director/shareholders. The accounts are audited by an auditor (*TOC*) . Whenever appropriate, QualityLab utilizes projects funded by the European Union or other incentives provided by the Portuguese government.

Any non-compliant situation will be studied as a risk.

4.4 NON-DISCRIMINATORY CONDITIONS

QualityLab's quality management system policies and procedures are written in a non-discriminatory manner.

QualityLab services are available to any interested party upon request, for example via the website (<https://www.qualitylab.pt/>)

The Certification scheme is provided upon request to any interested party.

Each request is processed chronologically in the order it is received. Some more complex certification requests may require a longer review of the documentation before a quote or response is issued.

Therefore, access to the QualityLab process is not conditioned by the size of the client's company or its membership in an association or group, nor by the number of certifications already issued.

QualityLab applies current regulations without exceeding its prerogatives and processes customer orders without any abusive conditions, financial or otherwise.

QualityLab limits its activities to its area of expertise, its scope (see point 2 of this manual) and its responsibilities in terms of requirements, review, decision and monitoring.

4.5 PUBLICLY AVAILABLE INFORMATION

QualityLab keeps all the elements required for product certification up to date and provides the following elements upon request:

- ✓ information about the certification scheme: assessment procedure and procedure for issuing, maintaining, extending or reducing the scope, suspending, withdrawing or refusing certification (defined by the certification scheme);
- ✓ general conditions for the provision of product certification services;
- ✓ information on certification costs (preparation of a quote)
- ✓ description of the rights and duties of customers, including any requirements, restrictions or limitations on the use of the QualityLab name and certification mark, as well as the ways in which the certification issued can be referenced;
- ✓ QualityLab's obligations and rights;
- ✓ information regarding complaints and appeals handling procedures;
- ✓ information regarding the directory of products certified, suspended or withdrawn by QualityLab.
- ✓ other information that may be considered relevant.

5 STRUCTURE REQUIREMENTS

5.1 LEGAL AND CONTRACTUAL ASPECTS

5.1.1 Legal liability

QualityLab is located at Rua Frei Leão de Santo Tomás, 468 B – Ervosa, 4785-154 Trofa. The company's NIF is 510 735 827, the CAE is 71200 R3 and the Director is Joaquim José Meireles da Conceição Moreira.

5.1.2 Certification /Conformity Assessment Contract

When applying for certification - EU Type Examination (Module B) and/or Conformity based on internal production control and supervised product checks at random intervals (Modules C2) or a conformity assessment of textile materials and accessories for protective clothing - a contract is drawn up between QualityLab and the customer (Mod.50.03, Mod.50.16, Mod.50.31 respectively).

A quote (Mod. 50.02) is sent to the customer with the general terms and conditions for providing product certification services. If accepted, it is signed and stamped by the customer. If there are any changes that impact the contract and/or quote, an update will be sent, and the update(s) must be signed and stamped again by the customer to demonstrate acceptance.

5.1.3 Use of licenses, certificates and compliance marks

QualityLab provides CE Marking certification services for textile products used as Personal Protective Equipment (PPE) to validate their compliance with European Union health and safety standards. If compliance is confirmed, the CE Marking is affixed to each PPE, in accordance with the design set out in Regulation EC 765/2008 of July 9, 2008.

QualityLab exercises control over the ownership, use and display of licenses, certificates, conformity marks and any other mechanisms to indicate that a product is certified, as specified by the certification scheme.

The use of incorrect references to the certification scheme or misleading use of licenses, certificates, marks or any other mechanism to indicate that a product is certified found in documentation or other advertising shall be subject to appropriate action (PAP.01.04).

Procedure PCM.01.06 - Management of the conformity mark and conformity certificates describes the methodology to ensure that certified products meet regulatory requirements and are correctly identified in the market.

5.2 HISTORICAL NOTE

As part of Tetribérica's structure, the Textile Quality Control Laboratory began taking its first steps at the end of 2008. In November 2009, the Laboratory underwent a concession audit carried out by IPAC, for accreditation of textile quality control tests (NP EN ISO/IEC 17025:2005 standard).

In 2012, the Laboratory carried out the renewal audit and simultaneously extended the accreditation to new tests.

To increase the Laboratory's growth and competitiveness, it was decided to separate the Laboratory from Tetribérica SA and create an independent company. Thus, in the last quarter of 2013, Tetribérica SA's accreditation was transferred to QualityLab – Laboratório Têxtil Lda.

In 2019, the transition process to the NP EN ISO/IEC 17025:2018 standard begins.

In early 2020, the laboratory moved its space to another area of the facilities, thus having a larger area and being physically more independent from the parent company.

In May 2023, two Belgian shareholders acquired 60% of the laboratory.

In 2024, an NP EN ISO/IEC 17065 accreditation project was started based on modules B and C2 of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and conformity assessment of textile materials and accessories for protective clothing.

5.3 FUNCTIONAL ORGANIZATIONAL CHART



The nominative organizational chart is described in Mod.44. Certification and laboratory activities are structured and managed to ensure impartiality (see 4.1 of this manual) .

5.4 MINIMUM PROFESSIONAL REQUIREMENTS

Function	Minimum academic qualifications	Minimum professional experience
Director	12th grade	2 years in similar roles;
Technical Manager	Bachelor's Degree in Textile Engineering	6 years in similar roles; Training NP EN ISO/IEC 17025 and NP EN ISO/IEC 17065
Quality Manager	12th grade	2 years in similar roles; Training NP EN ISO/IEC 17025 and NP EN ISO/IEC 17065
Laboratory Coordinator	12th grade	Preferably with knowledge/experience in Textile Laboratories; NP EN ISO/IEC 17025 Training

Function	Minimum academic qualifications	Minimum professional experience
Certification Manager	Bachelor's Degree in Textile Engineering	3 years in textile quality control laboratory activities, and preferably also in the textile production process; NP EN ISO/IEC 17065 and EU Regulation 2016/425 Training
Evaluator	12th grade	Preferably with knowledge/experience in Textile Laboratories; NP EN ISO/IEC 17065 and EU Regulation 2016/425 Training
Auditor	12th grade	Preferably with knowledge/experience in modules C2 Internal production control and supervised product controls at random intervals), preferably in the textile area and/or in the desired area; Training in EU Regulation 2016/425 and preferably also in NP EN ISO/IEC 17065
Laboratory technician	12th grade	Quality control laboratory activities preferably in the textile area and/or in the desired area.
Laboratory assistant	12th grade	If possible, with knowledge and experience in textile quality control laboratory activities.

Laboratory and Certification staff must complete a minimum two-hour training course provided by the Technical Manager or Certification Manager upon admission and whenever necessary. This training will cover NP EN ISO/IEC 17025 or NP EN ISO/IEC 17065.

In Human Resources, a registry of employees is maintained, with information on qualifications and training completed.

If there is a need to hire new employees, the Technical Manager/Certification Manager ensures that the competency requirements for the role to be performed will be defined in good time and that these will be verified when selecting candidates.

In the event of a prolonged absence of an employee, the need to retrain him/her will be assessed (PAP.04.03).

5.5 RESPONSIBILITY AND AUTHORITY

The authority and responsibility of the Director and all employees who manage, execute and verify activities relevant to the implemented Quality Management System are defined and documented together with the description of functions, responsibilities and the minimum requirements for their performance in the Competency Profile (Mod.43), in the Competency Matrix (Mod.11) and in the competency matrix for certification (Mod.50.22).

THE Director is responsible for QualityLab's Quality Management System, which delegates to the Quality Manager the responsibility and authority to ensure the establishment, implementation and maintenance of the processes necessary for the Quality Management System and to report its performance and any opportunities for improvement.

The Director appointed Liliana Maia as Technical Manager and Quality Manager, whose competency profile for each role is defined in Mod.43

whose main responsibilities are as follows:

- ✓ carry out maintenance and improvement of the Management System;
- ✓ Collaborate in defining QualityLab's objectives and implement, monitor, and track them;
- ✓ present to the Director the results of the Management System's performance;
- ✓ Responsibility and authority to identify Nonconforming Work and determine appropriate actions (including, if necessary, stopping work and suspending the issuance of test reports). Responsible for authorizing the resumption of work;
- ✓ define plans for the methods developed by the Laboratory and ensure effective communication between all personnel involved;
- ✓ validate the developed method before it is used;
- ✓ validate the skills matrix for carrying out tests;
- ✓ define and maintain the List of tests under flexible accreditation, within the framework of competence given by the Technical Annex;
- ✓ subcontract external calibration services and analyze the compliance of reports;
- ✓ Define procedures for internal inspections of measuring and monitoring equipment. Analyze the conformity of the results obtained;
- ✓ implement safety rules and verify their compliance;
- ✓ ensure the proper functioning of the Laboratory equipment;
- ✓ continuously identify risks and reduce/mitigate their impact on QualityLab;
- ✓ continually identify opportunities and act to improve the effectiveness of the system.

In the absence of the Technical Manager or the Quality Manager, it will be necessary to wait for their arrival or, if it is not possible to wait, this situation will be communicated to the accrediting entity (IPAC).

In the absence of the Laboratory Technician or Assistant, their functions are performed by another employee whose profile matches what is stipulated in the profile/competency matrix, and it is the responsibility of the Technical Manager and/or Laboratory Coordinator to designate the same.

The Director appointed Alexandra Ribeiro as Laboratory Coordinator, [whose skills profile is defined in Mod.43](#)

~~whose main responsibilities are as follows:~~

- ~~✓ manage test report deadlines, controlling deadlines for the Chemical and Physical Laboratory and partners;~~
- ~~✓ validate test reports and send them to Customers;~~
- ~~✓ issue opinions/interpretations on test results;~~
- ~~✓ communicate with Customers (clarifications, information, others);~~
- ~~✓ communicate with partner laboratories;~~
- ~~✓ analyze consultations, proposals and contracts for carrying out tests;~~
- ~~✓ responsibility and authority to identify nonconforming work.~~

In the absence of the Laboratory Coordinator, the function will be performed by the Technical Manager.

For certification activities, authority and responsibility are defined as follows:

a) development of policies related to the operation of the certification body;	Certification Manager
b) supervision of the implementation of policies and procedures;	Certification Manager
c) supervision of the certification body's finances;	Director
d) development of certification activities;	Certification Manager
e) development of certification requirements;	Certification Manager
f) evaluation (see 7.4);	Evaluator/Auditor
g) review (see 7.5);	Certification Manager
h) certification decisions (see 7.6);	Certification Manager
i) delegation of authority to Committees or staff, as necessary, to carry out defined activities on its behalf;	Director/Certification Manager
j) contractual arrangements;	Certification Manager
k) provision of adequate resources for certification activities;	Director
l) ability to respond to complaints and appeals;	Director
m) personnel competence requirements;	Director/Certification Manager
n) certification body management system	Quality Manager

In the absence of the Assessor or Auditor, the Certification Manager will perform the role. However, the Certification Manager will not be able to perform the review or make the decision. In this situation, the review and decision must be made by the Assessor (if already present) or the review and decision will be made by external resources (outsourcing).

QualityLab has formal rules for the appointment and operation of the Ethics Committee. (PCM.01.05).

5.6 COMMUNICATION AND CHANGE MANAGEMENT

Internal communication is carried out through the means available for disseminating relevant information, the main ones being:

- ✓ Printed documents and their registration;
- ✓ Meeting minutes;
- ✓ Awareness raising actions;
- ✓ E-mail;
- ✓ PHC,

This communication occurs in both hierarchical directions (top-down and/or bottom-up) and whenever possible QualityLab favors means of communication that can be recorded.

External communication with clients, suppliers, audit teams, and other stakeholders is conducted via email, PHC, reports, and verbally. This communication can occur from within and/or from outside.

QualityLab values maintaining a good relationship with its clients. As such, the Laboratory Coordinator is available upon request to assist clients with technical clarification, result interpretation, or monitoring QualityLab's performance. In all cases, QualityLab guarantees confidentiality with respect to other clients.

Every year, a survey is requested to be completed to assess Customer satisfaction regarding the Laboratory's activity and Certification (Mod.49 and Mod.50.21, respectively).

In change management and whenever necessary, planning is done in accordance with PAP.01.07.

The description of the procedure for Communication and Change Management is supplemented in PAP.01.10.

6 RESOURCE REQUIREMENT

6.1 GENERALITIES

QualityLab has the personnel, facilities, equipment, systems and support services necessary to manage and carry out its activities.

QualityLab takes into account the factors that may determine the accuracy and reliability of the tests, namely:

- ✓ skills of its human resources;
- ✓ facilities and environmental conditions;
- ✓ test methods and equipment used;
- ✓ traceability of measurements;
- ✓ sampling;
- ✓ maintenance of test samples.

6.2 STAFF

The staff and members of the Ethics Committee maintain confidentiality and, as such, sign a Commitment to Confidentiality and Impartiality (Mod.27).

This commitment commits to:

- ✓ comply with the rules established by QualityLab, in particular the rules of confidentiality and independence from commercial or other interests;
- ✓ Declare any past and/or current association/partnership of the employee or their employer with the supplier, designer, manufacturer, purchaser, owner, user, or person responsible for maintaining the PPE to be evaluated, nor the representative of any of these individuals, in the evaluation and certification of which they are involved. Disclose any situation of which they are aware that may expose them or QualityLab to a conflict of interest.

This data is used to complete and expand the risk analysis matrix, particularly with regard to personnel impartiality.

QualityLab ensures that when external personnel are employed (e.g., a module C2 auditor), they maintain the confidentiality of all information obtained or generated during certification activities. Outsourced resources are managed in accordance with the assessment plan.

Personnel who influence laboratory or certification activities act impartially and confidentially, are competent and work in accordance with the Management System.

Procedure PAP.04.03 (Personnel) ensures the competence of all those who influence the results of Qualitylab's activities. This procedure considers training, technical knowledge, skills, and experience. This ensures that personnel are competent to perform the laboratory and certification activities for which they are responsible, which are summarized in the competency matrix (Mod. 11 and Mod. 50.22, respectively).

This qualification/demonstration of competence to conduct tests is maintained through supervision by the Technical Manager and through periodic participation in interlaboratory and comparative tests (with other laboratories and among technicians). Personnel assigned to the certification service are subject to a performance evaluation process that includes a behavioral and technical competency analysis, the procedure for which is described in PAP.04.03 (Personnel).

Whenever a new test is introduced within the scope of services, it is implemented and validated by the Technical Manager. The employee's initial qualification to perform a new test is achieved through practical training and then validated by the Technical Manager. Subsequently, these tests are also evaluated through interlaboratory and/or comparative tests with other laboratories and/or technicians.

QualityLab also ensures that responsibilities related to equipment handling, results supervision and validation of test reports are assigned to Human Resources with appropriate skills.

In the employee registry, you will find individual information on education, training, know-how and experience relating to technical qualifications.

If necessary, the Curriculum Vitae is updated at least once a year, whether for new roles assigned or training received.

The Technical Manager and the Certification Manager have a permanent individual employment contract, ensuring a relationship of continuity and trust between QualityLab and IPAC.

QualityLab ensures that when hiring new technical employees and when the team is retrained after a period of absence, the competency requirements defined for technical roles are verified and guaranteed.

Whenever possible training needs are identified, they are formalized for approval and inclusion in the Training Plan.

The management of the Training Plan is the responsibility of the Technical Manager and, whenever applicable, the effectiveness of the Training actions carried out is evaluated. The Director communicates his functions, responsibilities and authorities to his employees through the Competency Profile (Mod.43).

Assessment activities are performed by resources that meet the applicable requirements of EN ISO/IEC 17025 and EN ISO/IEC 17065.

During the management review, QualityLab analyzes the management system to ensure it has the necessary resources to adequately perform the technical and administrative tasks associated with conformity assessment activities and has access to all necessary equipment and facilities. The annual internal audit is used in the management review to also ensure the necessary resources are available.

6.3 FACILITIES AND ENVIRONMENTAL CONDITIONS

Laboratory facilities ensure that environmental conditions do not invalidate results or negatively affect the required validity of any measurement.

The Laboratory is not subject to extreme conditions of dust, noise, vibrations, electromagnetic interference, steam, humidity and temperature, ensuring adequate environmental and lighting conditions for the correct execution of tests.

Environmental conditions (temperature and humidity) are monitored, controlled, and recorded using a thermohygrometer (calibrated equipment). Measures to control the facilities are reviewed whenever necessary.

Suspension of work, in the event of environmental conditions that compromise test results, will be based on a risk assessment.

Laboratory cleaning is provided by a service provider. The Laboratory Coordinator ensures daily cleaning of the laboratory and equipment.

The Laboratory facilities guarantee the necessary safety conditions, among others:

- ✓ Extinguisher,
- ✓ Alarms,

- ✓ Smoke and fire detectors,
- ✓ Emergency exit and,
- ✓ Adequate signage.

To ensure the safety of those performing the tests, the Laboratory has hoods, an emergency shower, blankets and personal protective equipment.

The Quality Manager ensures the maintenance of the Laboratory's safety equipment, as well as ensuring the operation of the equipment's emergency buttons.

The Laboratory also has first aid kits.

Environmental concerns are a priority for the Laboratory, and to this end, it separates its waste. The main waste produced at the Laboratory is textiles, which are collected by a licensed recycling organization. Chemical waste is sent for treatment by licensed organizations.

6.4 EQUIPMENT

The Laboratory has the necessary equipment (including, but not limited to, measuring instruments, software, measurement standards, reagents, consumables or auxiliary devices) for the correct execution of accredited tests that may influence the result.

The Laboratory also guarantees that all equipment is used by qualified personnel and that it does not use faulty equipment or equipment that presents unreliable results.

An Equipment Calibration/Verification Plan (Mod. 30) is prepared annually. According to this, the following are carried out:

- ✓ external calibrations, in laboratories accredited for this purpose;
- ✓ checks to confirm the condition of the equipment and/or technical specifications defined in test methods. Where applicable, metrological test procedures (PEM) are described.

At the same time, an intermediate maintenance and verification plan (Mod.31) is also defined for the equipment.

For all Equipment there is an Equipment Sheet (Mod.12), and the Equipment Control procedure is defined in PAP.01.03.

6.5 METROLOGICAL TRACEABILITY

The traceability of test results performed in the Laboratory is ensured by calibrations performed in accredited external laboratories. This ensures that the equipment involved in measurements and tests provides results traceable to national or international standards.

6.6 PRODUCTS AND SERVICES FROM EXTERNAL SUPPLIERS

QualityLab defined, in PAP.03.04 – Selection and purchase of products and services, the process for selecting and acquiring products and services that affect the quality of laboratory activities.

QualityLab guarantees that:

- Orders are placed with qualified suppliers, who are periodically evaluated according to the criteria defined in PAP.01.08 - Supplier Qualification and Evaluation;
- The selection of new potential suppliers and/or existing suppliers is carried out in accordance with PAP.01.08 (Supplier Qualification and Evaluation).

The use of external suppliers to carry out tests is carried out when QualityLab does not have the necessary resources to carry out the test requested by the Customer.

QualityLab may also resort to the use of temporary external suppliers to carry out tests within the scope of accreditation, for unforeseen reasons, such as equipment failure, work overload or lack of staff.

If external suppliers are used, QualityLab informs the Client to obtain their approval. If the results are transposed into the report, they will be identified as such.

QualityLab guarantees that it uses competent laboratories, that is, laboratories that operate in accordance with the requirements of the ISO/IEC 17025 standard. The Laboratory is responsible to the Client for the work performed by the external supplier. QualityLab takes on external testing suppliers as a service acquisition and, as such, selects, evaluates and qualifies subcontracted laboratories.

QualityLab considers that the main requirements for selecting a Testing Supplier are the following:

- ✓ test ;
- ✓ Means and technical competence;
- ✓ Impartiality;
- ✓ Professional secrecy and confidentiality;
- ✓ Availability and reliability of information;
- ✓ Delivery times;
- ✓ Price.

As a certification body, QualityLab subcontracts:

- ✓ laboratory activities to bodies that meet the applicable requirements of EN ISO/IEC 17025

~~✓ audit activities of bodies that comply with the applicable requirements of EN ISO/IEC 17065~~

QualityLab draws up a legally binding commitment/contract with the entity providing the subcontracted service, including provisions for confidentiality and conflicts of interest.

7 PROCESS REQUIREMENTS

7.1 LABORATORY PROCESSES

7.1.1 Analysis of queries, proposals and contracts

The Customer may request a quote and this will be sent with all the necessary information.

Receipt of the sample for analysis demonstrates that the Client has accepted the conditions of the consultation and the assignment of the analysis request number confirms that the Laboratory has also accepted it.

Any discrepancies between the consultation or proposal and the contract must be resolved before any work begins. Each contract must be acceptable to both the Laboratory and the Client, and both may request changes.

If the Client's request is in writing (e.g., letter, email, etc.), the test order number is included in that document. Otherwise, the Laboratory transfers the information provided by the Client to the internal form (Test Order – Form 05). If there are any changes, these are noted in the email /test order and signed/dated by the person who submitted the request.

If there is a need to change the contract after the work has begun (any internal change to the Test Request or the established contract, requested by the Client or the Laboratory – example: equipment failure, involuntary destruction of the sample, work overload, need to use an external supplier, etc.) and which jeopardizes the response time and/or the impossibility of fulfilling the Test Request or the contract entered into, the Laboratory Coordinator must inform the issuer of the Order/Contract.

Changes or amendments to contracts must be authorized by the Laboratory Coordinator. These changes or amendments will be communicated to all involved personnel.

This description is supplemented in PAP.02.01 - Analysis of queries, proposals and contracts.

The Laboratory values a good relationship with its Clients. Therefore, upon request, the Laboratory Coordinator is available to assist Clients with technical clarification, result interpretation, or monitoring the Laboratory's performance. In all cases, the Laboratory guarantees confidentiality with other Clients.

Every year, a survey (Mod. 49) is requested to be completed to assess customer satisfaction regarding laboratory activities.

7.1.2 Selection, verification and validation of methods

The tests performed in the Laboratory are conducted according to standardized methods described in Portuguese and/or international standards. Certain tests have been partially transcribed into Work Instructions; however, the standards are available for consultation at the Laboratory.

The Laboratory also uses test methods developed internally.

All standardized methods are verified and all non-standardized methods are validated before use (i.e., they are always confirmed whether all conditions for their execution are met and whether the field of application is suitable).

Subsequently, the methods are periodically verified/validated through intermediate and functional checks carried out on measuring equipment, repeatability/blind tests, comparative tests and by participating in interlaboratory tests.

The tests for which the estimated measurement uncertainty can be calculated are calculated according to:

- ✓ *EA – 4/ 16: EA Guidelines on the expression of uncertainty in quantitative testing;*
- ✓ Analytical measurements: measurement uncertainty and statistics.
- ✓ Relacre No. 31: Quantification of measurement uncertainty in chemical and physical-chemical tests.

This description is complemented in PAP.03.02 – Selection, verification and validation of methods.

7.1.3 Sampling

Requirement not applicable. The Laboratory does not perform sampling.

Sampling is safeguarded in the test report by indicating that the results obtained refer exclusively to the sample tested.

Tested samples will not be returned to the Customer unless specified in the contract.

7.1.4 Handling of test items

The Laboratory considers textile samples to be items to be tested. These samples may be raw materials, yarn, fabric/knit, finished item, etc.

The reception, identification, handling, protection, storage, retention, and/or removal of test items are carried out in a manner that ensures the integrity and confidentiality of the samples. This description is provided in PAP.03.01 – General Laboratory Operation.

The Laboratory reserves the right to refuse samples for testing if they are found to be in abnormal conditions upon receipt: insufficient sample size, poor appearance of the sample and/or without any identification.

7.1.5 Technical records

The Laboratory ensures that the technical records of laboratory activities contain sufficient results and information to facilitate, where possible, the identification of factors affecting the measurement result and the associated measurement uncertainty.

Record control is described in PAP.01.02

7.1.6 Assessment of measurement uncertainty

The Laboratory has a work instruction for calculating uncertainties (IT10), which specifies how the measurement uncertainty of laboratory activities is calculated. Significant contributions are assessed, and critical influencing factors identified are ensured to be under control.

7.1.7 Ensure the validity of the results

Maintenance of validated tests is referred to in PAP.03.02 – Selection, verification and validation of methods.

The internal quality control used is based on the use of statistical tools, the performance of replicated (blind) tests and intermediate/functional checks on the measuring equipment.

External quality control is achieved through periodic participation in suitability tests (interlaboratory tests at international level and intralaboratory tests through comparative tests with other Accredited Laboratories). Suitability testing is planned in accordance with Mod.77 and is reviewed if a risk is identified.

Carrying out external quality controls associated with internal controls allows the Laboratory to periodically monitor its performance.

7.1.8 Presentation of results

The test specimens are filed in the form - Test Record (Mod.04) as well as the results obtained in the tests.

Test reports are issued in Form 03 – Test Report . Reports will be sent by email in PDF format (data control) and in paper format (if the Customer so requests).

The reports present the results, as well as all information considered relevant for the identification and traceability of the test, in a clear and concise, objective, accurate, easy-to-read manner and in accordance with the standards and test conditions required by the Clients.

In short, the reports contain all the information required by the NP EN ISO/IEC 17025 standard.

Whenever the Client requests opinions/interpretations on test results, the Laboratory Coordinator is responsible for analyzing and issuing a response.

For the conformity assessment, the laboratory has established the decision rule in which the uncertainty associated with the test is not taken into account in this assessment, unless otherwise indicated by the Client.

The validation of the Test Report is carried out by the Laboratory Coordinator, or by the Technical Manager, who are responsible for the final technical content.

The original Test Report remains at the Laboratory and is considered a controlled copy. All other copies are considered uncontrolled, and the Laboratory is not responsible for their updating or destruction. If Clients request the original report, it will be sent to the Client, and the copy will remain at the Laboratory.

The placement of the Accreditation mark on test reports complies with the provisions of DRC002 "Regulation of Accreditation Symbols".

All results are traceable.

At the Customer's request, additions may be made to the test reports. These are identified in the report by the word "Addendum/ *To complete*".

The final report will include the sentence: "This report completes and supersedes the previous one with the same number dated dd-mm-yyyy. "

Amendments to previously issued test reports are made by issuing new test reports. New test reports have the same number as the previous ones, but are identified with "A" (Amended), state the changes made, and include the following sentence:

«This report replaces and supersedes the previous one with the same number dated dd-mm-yyyy»/ *«This report replaces and supersedes the previous one with the same number dated dd-mm-yyyy».*

If there is a new change, it will be A1 and so on.

Once a modified test report exists, all previous ones are considered obsolete, but remain traceable in the computer system (PHC).

7.1.9 Complaints

See §7.2.13

7.1.10 Non-conforming work

The Technical Manager has the responsibility and authority to identify Nonconforming Work during the execution of tests and/or during the analysis of suitability tests in which the Laboratory participates, among other things. It is also their responsibility to define and take action (including, if necessary, interruption of the work and suspension of the issuance of the test report, based on the risk levels established by the laboratory).

Management of Non-Conforming Work includes recording (Mod.08 – Action Bulletin), assessing the importance and carrying out an immediate correction, as well as any decision regarding the acceptance of non-conforming work (resumption of work or derogation).

If there is a possibility of non-conforming work occurring again, corrective actions will be defined in accordance with PAP.01.04 and/or the Risk and Opportunity Matrix will be reviewed in accordance with PAP.01.09.

Whenever non-conforming work involves reports already issued, an impact analysis is carried out and, if necessary, Clients are notified of this occurrence, its treatment and the test report is re-evaluated.

This description is supplemented in PAP.03.03 – Non-conforming work.

7.1.11 Data control and information management

QualityLab ensures that data control and information management related to laboratory and certification activities are verified and validated, thus maintaining data integrity.

7.2 CERTIFICATION PROCESSES

7.2.1 Generalities

QualityLab has a certification scheme that covers the following areas:

- ✓ PPE intended for general body protection (clothing)
- ✓ PPE designed for protection against the cold ($> -50\text{ }^{\circ}\text{C}$)
- ✓ PPE intended for protection against heat ($< 100\text{ }^{\circ}\text{C}$)
- ✓ PPE intended for protection against heat ($> 100\text{ }^{\circ}\text{C}$ and fire and flames)
- ✓ PPE intended for protection against electric shock
- ✓ PPE for high visibility clothing

A PPE (Personal Protective Equipment) certification scheme consists of a set of processes and procedures designed to ensure that PPE meets certain standards of quality, safety and effectiveness to protect workers from workplace hazards.

The certification scheme begins with a request for evaluation by the manufacturer and ends with an evaluation report. If approved, a certificate of conformity is issued. PPE are assessed in accordance with the requirements of the harmonized standards, giving presumption of conformity with EU Regulation 2016/425 .

When applicable, QualityLab uses the following documents in order of priority:

- ✓ Harmonized "product" standards,
- ✓ RfU's validated by the PPE Working Group (vertical and horizontal),
- ✓ Non-harmonized product standards published by CEN,
- ✓ RfU's validated by the Horizontal Commission HC
- ✓ RfUs validated by vertical groups (VG5)
- ✓ or where there are no standards, draw up a specific assessment protocol in agreement with the manufacturer, based on existing standards or draft standards in the field and its experience as a notified body.

Where explanations are required regarding the application of these documents, they must be provided by the Certification Manager.

QualityLab also assesses the compliance of textile materials and accessories for protective clothing with specific standards and/or technical requirements, according to the Type 1a certification scheme (NP EN ISO/IEC 17067), in which one or more product samples are subjected to testing. A conformity assessment certificate (Mod. 50.28) is issued, which does not cover subsequent production items.

7.2.2 Application

The customer sends the completed and signed EU type examination application (Mod.50.01 – [Module B](#)) and, where possible, the technical documentation for the product(s).

Analysis of the request must allow determining:

- whether the subject matter falls within the scope of the regulation;
- if the object is composed of elements that, in turn, comply with the regulation;
- if an importer or distributor intends to place PPE on the market under its brand or if it modifies the PPE (Article 12 of the Regulation);
- if the object declares conformity based on several technical references, in particular multi-risk PPE;
- if it is a re-examination

In the case of module C2, the manufacturer initiates the order by sending the completed and signed Mod.50.24 form.

If Module B was not performed by QualityLab, the manufacturer must submit the following:

- Technical documentation referred to in Annex III of the Regulation;
- Copy of the EU Type Examination Certificate

The manufacturer informs the expected date and place of the inspection.

In the case of a conformity assessment of textile materials and accessories for protective clothing, the process begins with completing the application - Mod.50.29

A more detailed description of this task is referred to in PCM.01.02 (Conformity assessment – Module B), PCM.01.04 (Conformity assessment – Module C2) and PCM.01.07 (Conformity assessment of textile materials and accessories for protective clothing).

7.2.3 Analysis of the application

QualityLab analyzes the customer's request to ensure that:

- a) the information about the customer and the product is sufficient to conduct the certification process;
- b) any known difference of understanding between the client and QualityLab is resolved, including agreement on standards or other normative documents;
- c) the intended scope of certification is defined;

- d) the means to carry out all assessment activities are available;
- e) the certification body has the competence and capacity to carry out the certification activity.

QualityLab will refuse specific certifications for which it does not have the competence or capacity to carry out them.

If QualityLab relies on certifications that it has already granted to the client, or that it has already granted to other clients to omit any activity, then QualityLab does reference to the certification(s) existing in its records. If requested by the client, QualityLab provides justification for the omission of activities.

QualityLab prepares and sends the quote (Mod. 50.02) to the customer. At the same time, it sends the Procedure: QualityLab Certification Scheme – Module B (PCM.01.01). For module C2, it sends PCM.01.03 (Certification Scheme – Module C2) or PCM.01.07 for the conformity assessment of textile materials and accessories for protective clothing. If the customer wishes to proceed with the certification process, QualityLab sends the "Product Technical Data Sheet" form - Mod. 50.07 (for module B) and electronically signs and sends the contract (Mod. 50.03 for module B; Mod. 50.16 for module C2 and Mod. 50.31 for the conformity assessment), which must be returned signed and stamped by the customer (or electronically signed). This ensures both parties' commitment to compliance.

Along with the signed contract, the client will have to send the documentation requested by QualityLab.

A more detailed description of this task is referred to in PCM.01.02 (Conformity assessment – Module B), PCM.01.04 (Conformity assessment – Module C2) and PCM.01.07 (Conformity assessment of textile materials and accessories for protective clothing).

7.2.4 Assessment

QualityLab ensures that all necessary information and/or documentation is available for carrying out the assessment activities. The assessor plans the assessment activities, and they are responsible for meeting deadlines.

The evaluator works in conjunction with accredited laboratories, promoting cooperation that aims to guarantee rigor, impartiality, confidentiality and conflicts of interest in carrying out the requested tests.

In the case of module C2, QualityLab will carry out a product control at least once a year.

Assessment activities are carried out by the evaluator (module B/C2 and conformity assessment of textile materials and accessories for protective clothing) or by the auditor (module C2). Records are kept to identify those involved in the assessment.

The assessor carries out the assessment of the PPE using the applicable documents (EU Regulation 2016/425, harmonized standards, ...) and documentation requested from the client (Test reports, Product technical data sheet, ...).

QualityLab only relies on certification-related assessment results completed prior to the certification application, where it assumes responsibility for the results and confirms that the body that carried out the assessment meets the requirements contained in 6.2.2 of NP EN ISO/IEC 17065 (External resources – subcontracting) and those specified by the certification scheme.

The client is informed when a nonconformity is detected. If the client wishes to continue the certification process, they are informed of the assessment tasks that must be repeated to verify that the nonconformities have been corrected. If the client agrees, the additional assessment tasks are repeated, and the assessment process is repeated. If the Evaluator considers that the PPE meets the requirements, he/she prepares and signs the Evaluation Report, prepares the Certificate and forwards the complete file to the Certification Manager for review and certification decision.

A more detailed description of this Assessment task is referred to in PCM.01.02 (Conformity assessment – Module B), PCM.01.04 (Conformity assessment – Module C2) and PCM.01.07 (Conformity assessment of textile materials and accessories for protective clothing).

7.2.5 Revision

The review of all information and results related to the evaluation is carried out by a person who was not involved in the evaluation activities.

The review and/or certification decision is carried out by the Certification Manager and recorded in the respective reports.

7.2.6 Certification decision

The person designated to make a certification decision must be employed and have an employment contract with QualityLab as well as be qualified and authorized.

QualityLab has designated the Certification Manager responsible for the review and certification decision, when the latter is not involved in the assessment activities.

The certification decision is taken on the basis of all information relating to the assessment, its review and any other relevant information (assessment report, test reports, technical data sheet, etc.) and is recorded in the respective reports.

QualityLab informs the client of any decision not to grant certification, specifying the reasons.

In the event of granting Certification, QualityLab issues an EU Type Examination Certificate or a Module C2 Conformity Certificate.

A more detailed description of this task is referred to in PCM.01.02 (Conformity assessment – Module B), PCM.01.04 (Conformity assessment – Module C2) and PCM.01.07 (Conformity assessment of textile materials and accessories for protective clothing).

7.2.7 Certification documentation

At the end of the certification process, QualityLab issues a formal document to the client in accordance with the certification decision. QualityLab issues an EU Type Examination Certificate, or a revision/extension/refusal/withdrawal of a certificate, or a certificate of conformity (module C2) in accordance with RfU PPE/R/00.008.

The certificate must contain at least the following information:

- ✓ Name and address of QualityLab;
- ✓ date on which certification is granted (this date is after the date of the certification decision);
- ✓ customer name and address;
- ✓ scope of certification (product name, applicable standards and regulations);
- ✓ Certification expiration date
- ✓ any other information required by the Certification scheme.

In the case of a certificate of Conformity Assessment of Textile Materials and Accessories for Protective Clothing, it contains the information previously described, except for the expiry date.

All formal documents must be digitally signed by the Certification Manager.

Documents shall only be issued after or at the same time as the decision to grant or extend the scope of certification, the fulfillment of the certification requirements or the completion/signature of the Certification agreement (contract).

7.2.8 Directory of certified products

QualityLab maintains an updated list of issued certifications (Mod.50.09).

This list contains at least the following information:

- ✓ product identification,
- ✓ the harmonized standard(s) and other normative document(s) against which conformity was assessed,
- ✓ customer identification,
- ✓ the validity of said certification

This information can be provided upon request.

By signing the contract, the customer accepts the publication of his/her identification, the identification of his/her product, harmonized standards used, other data associated with the certificate and current certification status in the directory of certified products.

DIC017 (Certification Activity Record) is sent to IPAC annually.

The Annual Report (Mod-DAESPQ-01-20) is sent annually to IPQ regarding the activity carried out in assessing the conformity of the products and modules for which they were notified.

7.2.9 Follow-up

Internal production control and supervised controls at random intervals (module C2) is carried out only in the case of category III Personal Protective Equipment, as specified in the certification scheme.

QualityLab proposes a contract to the client (Mod. 50.16) that defines the terms and conditions for the implementation of this module. Module C2 involves assessment, review, and the Certification decision, and as such, the procedures described for these activities must be followed.

The contract is drawn up for a period of 5 years.

Assessment activities are defined and scheduled over a 5-year cycle. Each year, PPEs and different audit locations (if applicable) are randomly selected to ensure a more representative sample of production homogeneity.

Sampling intervals are defined by QualityLab and must not exceed 12 months after the date of issue of the EU-type examination certificate.

The random nature of sampling, in accordance with EU PPE Regulation 2016/425 and RfU PPE/R/00.007, is ensured by the fact that the auditor himself chooses the location and products to be sampled. The number of products sampled depends on the annual production quantities and the critical tests performed, which may be destructive.

The tested requirements are distributed over a maximum period of 5 years in accordance with RfU PPE-R/00.012, supplemented by VG5 No. 30-009. During the first audit of module C2, the requirements that will be checked as a priority will be those that are most critical for protection, i.e., those that obtained values at the compliance limit during the initial assessment.

The procedure for sampling is defined in PCM.01.04

QualityLab carries out the checks (visual and physical) and tests that it considers particularly critical to the PPE certification scheme.

QualityLab issues a module C2 compliance report (Mod.50.19).

If the report indicates that production is not homogeneous or that the tested PPE does not conform to the model described in the EU type-examination certificate, QualityLab informs the manufacturer and the horizontal recommendation for use (Rfu) 00.009 applies.

The manufacturer must analyze the causes of the identified nonconformities and inform QualityLab of the corrective actions implemented. The manufacturer may request that QualityLab conduct a new sampling to validate the effectiveness of the implemented actions. This procedure may be performed only once after the audit.

If product conformity or production homogeneity cannot be validated, QualityLab issues the Conformity Report - Module C2 with the results obtained and does not issue the Conformity Certificate - Module C2.

QualityLab does not grant authorization for permanent use of a certification mark, as the certifications issued are valid for 5 years (EU Regulation 2016/425).

QualityLab does not certify a process or service, but only products covered by its scope. As part of its surveillance activities, QualityLab checks at least annually whether the certification marks ("CE" mark followed by the notified body number, where applicable) are still in use to ensure the continued validity of the demonstration of compliance with product requirements.

A more detailed description of this procedure is referred to in PCM.01.02 (Conformity assessment – Module B) and PCM.01.04 (Conformity assessment – Module C2).

7.2.10 Changes affecting certification

When the certification scheme introduces new requirements or requirement revisions that impact the customer and the product (for example, when a standard is removed from the list of harmonized standards in the OJEU, or when a standard on which the certification scheme is based is revised), or if the PCM sent to the customer is changed, QualityLab informs its customers of these changes and its analysis of the impact on compliance with the requirements of EU Regulation 2016/425. QualityLab ensures that customers implement the appropriate changes and take the actions required by the certification scheme. QualityLab uses the directory of certified products (Mod. 50.09) to identify affected customers.

When QualityLab detects changes that have consequences for certification, including changes initiated by the client, the Evaluator and the Certification Manager meet to consider the actions to be taken and should include, if necessary, the following:

- ✓ assessment,
- ✓ review/decision,
- ✓ issuance of revised formal certification documents to extend or reduce the scope of certification,
- ✓ issuance of certification documents for revised monitoring activities, where applicable.

The client is informed of the decisions taken and must provide QualityLab with an action plan that they undertake to comply with.

The actions taken by QualityLab are carried out in accordance with the provisions of applicable points 7.2.4, 7.2.5, 7.2.6, 7.2.7 and 7.2.8 of this manual.

QualityLab maintains a record that includes the justification for the exclusion of any of the above activities (for example, when changing a certification requirement that is not a product requirement, and no assessment, review or decision activities are necessary).

7.2.11 Cancellation, reduction, suspension or withdrawal of certification

When a non-conformity with certification requirements is identified, whether as a result of monitoring or by any other means (e.g., information provided by the client, etc.), the Certification Manager analyzes the non-conformity and decides on appropriate measures. Appropriate measures may include:

- ✓ Maintenance of certification under the conditions specified by QualityLab, for example with more rigorous monitoring (reduced monitoring period, more extensive assessment, etc.);
- ✓ reduction of the scope of certification to eliminate non-conforming product variants;
- ✓ suspension of certification pending implementation of the client's corrective action;
- ✓ withdrawal of certification.

When the appropriate action involves evaluation, review, or certification decision, the requirements of 7.2.4, 7.2.5, 7.2.6, and 7.2.9 of this manual shall be followed.

If certification is revoked at the customer's request, suspended or withdrawn, QualityLab takes the appropriate actions specified in the certification scheme and makes the necessary changes to the formal Certification documents, information intended for the public (Member States, competent authority), authorizations for use of the marks, etc., to ensure that there is no indication that the product is still certified.

In the event of a reduction in the certification scope, QualityLab performs the actions specified in the certification scheme and makes the necessary changes to the formal certification documents, information intended for the public (Member States, competent authority), authorizations for use of trademarks, etc., to ensure that the client has received clear information about the reduction in the certification scope. This reduction in scope must be clearly described in the certification documents and information intended for the public.

When certification is suspended, the Certification Manager informs the client and communicates:

- ✓ the actions necessary to terminate the suspension and reinstate the certification of the product(s) in accordance with the certification scheme;
- ✓ any other action required by the certification scheme.

Any assessments, reviews or decisions necessary to resolve the suspension or that are required by the certification scheme are completed in accordance with the applicable parts of 7.2.4, 7.2.5, 7.2.6, 7.2.7, 7.2.9 and 7.2.11 of this manual.

If certification is reinstated after suspension, QualityLab must make all necessary modifications to the formal certification documents, public information, trademark authorizations, etc., to ensure that all appropriate indications exist that the product continues to be certified. If a decision to reduce the scope of certification is made as a condition of reinstatement, QualityLab must make all necessary modifications to the formal certification documents, public information, trademark authorizations, etc., to ensure that the reduced certification scope is clearly communicated to the client and clearly specified in the certification documentation and public information.

7.2.12 Records

QualityLab maintains records to demonstrate that all certification process requirements have been effectively met. Records control is described in PAP.01.02. The retention period for QualityLab records is defined in the Records control table (Mod. 48). It is important to note that EU Regulation 2016/425 defines a five-year validity period for certificates; therefore, the retention period covers at least the current and previous cycles. QualityLab maintains the confidentiality of its records. Records are transported, transmitted, and transferred in a manner that ensures confidentiality (see section 4.2).

7.2.13 Complaints and appeals

There are two types of dissatisfaction:

- ✓ Appeals against certification decisions: written request by an applicant to reconsider any decision taken by QualityLab regarding the certification in question.

- ✓ Complaints: A written expression of dissatisfaction, other than an appeal, made by a person or organization to QualityLab regarding its activities, to which a response is expected.

QualityLab views its complaints and appeals process as impartial and transparent for its customers and stakeholders. However, appeals must be filed within 60 days of receiving the decision.

Therefore, upon receiving a complaint or appeal, the Quality Manager confirms receipt and confirms whether the complaint or appeal is related to Certification or testing activities. The Quality Manager collects and verifies all necessary information to subsequently make a decision. The causes are investigated to determine the actions to be taken to resolve the complaint or appeal. Once the actions are defined, they are monitored to subsequently evaluate their effectiveness.

The conclusions of the investigation will be drawn up by the Director.

Whenever possible, QualityLab formally informs the complainant of the outcome and the end of the complaint handling process and the appellant of the appeal process.

The procedure for handling complaints is described in PAP.02.02 – Complaints and appeals, and always guarantees the confidentiality of this processing.

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1 OPTIONS

QualityLab has established, implemented, and maintained a management system capable of supporting and demonstrating consistent compliance with the requirements of NP EN ISO/IEC 17025 and NP EN ISO/IEC 17065 and ensuring the quality of its outputs and services. This management system complies with Option A.

8.2 MANAGEMENT SYSTEM DOCUMENTATION

This Quality Management Manual is supported by a set of relevant documentation, namely that which describes existing procedures.

The main objective of this Manual focuses on defining and disseminating the basic characteristics of the elements of the Quality Management System, the Quality Policy, the organization and the means at its disposal.

This Manual constitutes part of the documentary support for the implementation, maintenance and development of the Quality Management System and aims to objectively translate to Customers, Suppliers, Employees and third parties, the reality of the structure and activity of QualityLab.

The Quality Management Manual is prepared by the Quality Manager and approved by the Director.

Employees can consult the Quality Management Manual and other relevant documentation in the shared folder on the computer system. It is the Quality Manager's responsibility to update it and disseminate a new edition to employees. Whenever a physical copy of the Quality Management Manual is requested, the Quality Manager will identify it as an uncontrolled copy.

The adequacy of the Quality Management Manual, Policy and Procedures is reviewed at least once a year, when the management system is reviewed.

The Quality Manager has the responsibility and authority for the following:

- ✓ ensure that the processes and procedures necessary for the management system are established, implemented and maintained;

- ✓ report to the Director on the performance of the management system and any need for improvement.

8.2.1 Quality objectives

The objectives defined for QualityLab are monitored by the established indicators and targets and, whenever necessary, actions are established to correct any deviations and the inherent risks and opportunities are analyzed.

In the system review, these are reviewed and, if applicable, new objectives/indicators are established.

8.2.2 QualityLab Policy Statement

The QualityLab Policy Statement was defined by the Director and assumes a philosophy that aims to satisfy the Client's requirements, as well as comply with legal and regulatory requirements.

The Director considers that the implementation of a Management System in accordance with the NP EN ISO/IEC 17025 and NP EN ISO/IEC 17065 standards is fundamental in pursuing an image of excellence, particularly with regard to the high quality of the services provided.

In this sense and in order to comply with the established Policy, QualityLab declares that:

- performs tests in accordance with established methods/standards, Customer requirements and legal requirements;
- assesses tests and certification processes in an impartial, objective, rigorous, independent and impartial manner, complying with the requirements of standards NP EN ISO/IEC 17025, NP EN ISO/IEC 17065 and the Portuguese Accreditation Institute (IPAC);
- respects the principles of confidentiality and professional secrecy regarding all information to which he/she has access in the performance of his/her duties;
- identifies, avoids, mitigates and manages conflicts of interest and mitigates pressures;
- applies the guidelines established in the management system documentation in harmony with the requirements of the NP EN ISO/IEC 17025 and NP EN ISO/IEC 17065 standards, contributing to the consistent functioning of QualityLab's activities;
- uses human resources with adequate competence and training;
- maintains a privileged relationship with customers based on satisfaction and loyalty;

- promotes transparent communication with Customers, Suppliers, employees and stakeholders;
- contributes to the continuous improvement of the effectiveness of the Management System.

The Quality Manager undertakes to comply with and enforce the Quality Policy, as well as other procedures/documents of the Management System. It is also their responsibility to contribute to the continuous improvement of the Management System's effectiveness. To ensure that the Quality Policy Statement is understood and implemented within the organization, it is posted at the QualityLab reception desk.

8.3 CONTROL OF MANAGEMENT SYSTEM DOCUMENTS

8.3.1 Document structure

The documentary structure of the Quality Management System consists of three hierarchical levels:

Level 1 – This level includes the Quality Management Manual, which defines the organizational structure, the structure of the Quality Management System and the Quality Policy.

Level 2 - This level includes procedures to support processes, plans, work instructions, documents of external origin and profiles/competency matrix.

Level 3 – This level includes Quality records. These provide evidence of compliance with the requirements, criteria, and methodologies defined in the Quality Management System, and their effectiveness.

In accordance with PAP.01.01 (Document control), whenever necessary and before being issued, documents are reviewed and approved for their suitability and compliance with applicable requirements.

Document management (internal and external) ensures the use of updated, approved documents that are available to all who need them. Updates are placed on physical media or in the computer system. and communicated verbally and/or via email.

8.4 RECORD CONTROL

QualityLab establishes and maintains records to provide evidence of compliance with the requirements of NP EN ISO/IEC 17025, NP EN ISO/IEC 17065 Standards and the effective operation of the Management System.

PAP.01.02 (Records Control) defines the controls necessary for the identification, storage, protection, retention time and disposal of records (Quality and Technical).

Records are legible and, where applicable, confidential.

Internal technical records allow the establishment of an audit trail from the test request to the test report and from the service request to the certificate of conformity.

8.5 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

QualityLab considers the risks and opportunities associated with its activities to achieve the following points:

- ✓ ensure that the management system achieves the intended results;
- ✓ increase opportunities to achieve goals;
- ✓ prevent or reduce undesirable impacts and possible failures in their activities;
- ✓ achieve improvements.

The procedure for analyzing risks and opportunities is described in PAP.01.09

Therefore, the activities QualityLab's data are analyzed to identify potential risks and determine how to mitigate them. The actions described in sections 8.6 and 8.7 also contribute to identifying, analyzing, and preventing risks.

8.6 IMPROVEMENT

QualityLab ensures continuous improvement in the effectiveness of the Management System. To this end, the following inputs stand out:

- ✓ effectiveness of corrective actions and improvements implemented;
- ✓ monitoring of objectives;
- ✓ results of internal and external audits;
- ✓ management review;
- ✓ feedback from employees;
- ✓ feedback from customers/complaints and appeals;
- ✓ feedback of information from suppliers and third parties.

8.7 CORRECTIVE AND PREVENTIVE ACTIONS

A corrective action arises from a Nonconformity, Nonconforming Work, a complaint, or an appeal. It aims to eradicate the cause and prevent its recurrence.

The actions to be followed in the treatment of Corrective Actions are defined in PAP.01.04. Recording and monitoring is carried out in the Action Bulletin (Mod.08)

Carrying out a supplementary audit may be justified, for example, when a specific Corrective Action does not, by itself, guarantee the recurrence of the detected Non-Conformity.

A preventive action arises from a potential Non-Conformity, a potential Non-Conforming Work or another potential undesirable situation and aims to eliminate the cause.

The actions to be followed in the treatment of Preventive Actions are defined in PAP.01.04. Registration and monitoring is carried out in the Action Bulletin (Mod.08).

8.8 INTERNAL AUDIT

QualityLab has established the Audit procedure (PAP.01.05) to plan and execute internal audits.

In all cases, independence from the audited areas is always guaranteed and the correct assessment of the implemented Management System is ensured.

Audit planning in the accreditation cycle is carried out so that all accredited tests and services are audited in the cycle.

The internal audit program must cover all elements of the management system, in order to assess whether it meets the requirements specified in standards NP EN ISO/IEC 17025 and NP EN ISO/IEC 17065, and whether it is implemented and maintained effectively.

After the audits, actions are defined to eliminate detected nonconformities and their causes, as well as actions for improvements. Both are implemented by the Quality Manager.

8.9 MANAGEMENT REVIEW

The QualityLab Management System review is carried out once a year.

Reviews include assessing risks and opportunities, as well as the need for changes to the QualityLab Management System, including the Quality Policy and Quality Objectives.

The inputs for review by QualityLab Management and the resulting outputs are illustrated in the following table:

Entries	Exits
1. Changes to internal and external environments relevant to QualityLab 2. Achievement of objectives 3. Adequacy of policies and procedures 4. Status of actions resulting from previous management reviews 5. Results of recent internal audits 6. Corrective and preventive actions 7. Assessments carried out by external bodies 8. changes in the volume and type of work or in the type of QualityLab activities 9. Feedback from Customers, Employees and interested parties (e.g. Competent Authority) 10. Complaints and appeals 11. Effectiveness of any improvements implemented 12. Adequacy of resources 13. Risk identification results 14. Impartiality safeguard mechanism feedback 15. Conclusions on ensuring the validity of results 16. Other relevant factors, such as monitoring and training activities	- The effectiveness of the management system and its processes; - Improvement of activities related to compliance with standard requirements - Provision of resources - Any need for changes

The outputs of the Management Review are highlighted in the Management Review Report and/or meeting minutes. The Quality Manager oversees the review. Any change involving significant organizational changes outside the scope of the system review requires activity planning as described in PAP.01.07.

9 CORRESPONDENCE TABLE

Quality Management Manual	NP EN ISO/IEC 17025	NP EN ISO/IEC 17065
§4.1.1	§4.1	§4.2
§4.1.2	---	§5.2
§4.2	§4.2	§4.5
§4.3	---	§4.3
§4.4	---	§4.4
§4.5	---	§4.6
§5.1.1	§5.1, 5.2	§4.1.1
§5.1.2	---	§4.1.2
§5.1.3	---	§4.1.3
§5.2	§5.3	---
§5.3	§5.2, 5.5	§5.1.1, 5.1.2
§5.4	§5.5	---
§5.5	§5.5	§5.1.3, 5.1.4
§5.6	§5.6	---
§6.1	§6.1	§6.1
§6.2	§6.2	§6.1, 6.2.1
§6.3	§6.3	---
§6.4	§6.4	---
§6.5	§6.5	---
§6.6	§6.6	§6.2.2
§7.1.1	§7.1	---
§7.1.2	§7.2	---
§7.1.3	§7.3	---
§7.1.4	§7.4	---
§7.1.5	§7.5	---
§7.1.6	§7.6	---
§7.1.7	§7.7	---
§7.1.8	§7.8	---
§7.1.9	§7.9	---
§7.1.10	§7.10	---
§7.1.11	§7.11	---
§7.2.1	---	§7.1
§7.2.2	---	§7.2
§7.2.3	---	§7.3
§7.2.4	---	§7.4
§7.2.5	---	§7.5
§7.2.6	---	§7.6
§7.2.7	---	§7.7
§7.2.8	---	§7.8
§7.2.9	---	§7.9
§7.2.10	---	§7.10
§7.2.11	---	§7.11
§7.2.12	---	§7.12
§7.2.13	---	§7.13
§8.1	§8.1	§8.1
§8.2	§8.2	§8.2
§8.3	§8.3	§8.3
§8.4	§8.4	§8.4
§8.5	§8.5	---
§8.6	§8.6	§8.8
§8.7	§8.7	§8.7
§8.8	§8.8	§8.6
§8.9	§8.9	§8.5