Certification Regulation

ADDRESS

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1. PURPOSE

This document describes the relationship between ISALAB Srl and the Client, as well as the methods by which ISALAB performs certification activities.
ISALAB Srl (hereinafter referred to as ISALAB) is an independent certification body that provides certification services for products, processes, and services in conformity with the applicable regulatory requirements in the railway sector.

2. SCOPE OF APPLICATION

This regulation applies to the following activities of ISALAB:

- Certification as a Notified Body (in accordance with European Union Directive 797/2016/EU);
- Certification as a Designated Body (in accordance with Legislative Decree 57/2019).

3. REFERENCES

The assessment activities shall be carried out in accordance with the following national and international reference standards and regulations:

- UNI CEI EN ISO/IEC 17065 Conformity assessment — Requirements for bodies certifying products, processes and services
- MNB - Assessment scheme 000MRA1044 Requirements for conformity assessment bodies seeking notification ver.2.0
- DIRETTIVA (UE) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union
- DIRETTIVA (UE) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety
- DECRETO LEGISLATIVO 50 del 14/05/2019 Decreto di recepimento direttiva (UE) 2016/798
- DECRETO LEGISLATIVO 57 del 14/05/2019 Decreto di recepimento direttiva (UE) 2016/797
- Decisioni della commissione europea – Specifiche tecniche di interoperabilità (STI) applicabili del sistema ferroviario ad alta velocità e convenzionale
- Raccolta norme decreti e direttive dell'Agenzia Nazionale per la Sicurezza Ferroviaria (ANSFISA)
- Accredia RG-01 Regolamento per l'accreditamento degli Organismi di Certificazione e Ispezione - Parte Generale
- Accredia RG-01-03 Regolamento per l'accreditamento degli Organismi di Certificazione del Prodotto
- Accredia RG-09 Regolamento per l'utilizzo del marchio ACCREDIA
- Decreto Direttoriale del Ministero delle Infrastrutture e dei Trasporti n°37 del 28/06/2019 sulle modalità di qualifica degli Organismi di Valutazione della conformità

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e degli Organismi di valutazione del procedimento dell'analisi dei rischi in ambito ferroviario a seguito dell'entrata in vigore del Decreto legislativo 14 maggio 2019, n. 57 di Attuazione della Direttiva (UE) 2016/797 e del Decreto legislativo 14 maggio 2019, n. 50 di Attuazione della Direttiva (UE) 2016/798;

- Decreto-legge 10 settembre 2021, n. 121, convertito con modificazioni dalla legge 9 novembre 2021, n. 156, recante "Disposizioni urgenti in materia di investimenti e sicurezza delle infrastrutture, dei trasporti e della circolazione stradale, per la funzionalità del Ministero delle infrastrutture e della mobilità sostenibili, del Consiglio superiore dei lavori pubblici e dell'Agenzia nazionale per la sicurezza delle ferrovie e delle infrastrutture stradali e autostradali";
- Decisione di esecuzione (UE) 2018/1614 della Commissione, del 25 ottobre 2018, che stabilisce le specifiche per i registri dei veicoli di cui all'articolo 47 della direttiva (UE) 2016/797 del Parlamento europeo e del Consiglio e che modifica e abroga la decisione 2007/756/CE della Commissione;
- Decisione della Commissione 2010/713/UE concernente i moduli per le procedure di valutazione della conformità, dell'idoneità all'impiego e della verifica CE da utilizzare per le specifiche tecniche di interoperabilità adottate nell'ambito della direttiva 2008/57/CE del Parlamento europeo e del Consiglio;
- Decisione della Commissione 2012/757/UE del 14 novembre 2012 che modifica la decisione 2007/756/CE che adotta una specifica comune per il registro di immatricolazione nazionale;
- Decisione di esecuzione (UE) 2015/2299 della Commissione del 17 novembre 2015 che modifica la decisione 2009/965/CE per quanto riguarda un elenco di parametri aggiornato da applicare per classificare le norme nazionali;
- Decisione di esecuzione (UE) 2018/1614 della Commissione del 25 ottobre 2018 che stabilisce le specifiche per i registri dei veicoli di cui all'art. 47 della direttiva (UE) 2016/797 del Parlamento europeo e del Consiglio e che modifica e abroga la decisione 2007/756/CE della Commissione;
- Regulation (EU) n. 519/2013 of 21 February 2013 amending Decision 2007/756/EC adopting a common specification for the national vehicle register;
- Commission Regulation (EU) n. 402/2013 f 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009;
- Commission Implementing Regulation (EU) n. 2015/1136 of 13 July 2015 amending Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment;
- Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004;

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- Commission Implementing Regulation (EU) 2019/772 of 16 May 2019 amending Regulation (EU) No 1300/2014 as regards inventory of assets with a view to identifying barriers to accessibility, providing information to users and monitoring and evaluating progress on accessibility;
- Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 amending Commission Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1303/2014 and (EU) 2016/919 and Commission Implementing Decision 2011/665/EU as regards the alignment with Directive (EU) 2016/797 of the European Parliament and of the Council and the implementation of specific objectives set out in Commission Delegated Decision (EU) 2017/1474;
- Commission Implementing Regulation (EU) 2019/777 16 May 2019 on the common specifications for the register of railway infrastructure and repealing Implementing Decision 2014/880/EU;
- Commission Implementing Regulation (EU) 2020/424 of 19 March 2020 on submitting information to the Commission as regards non-application of technical specifications for interoperability in accordance with Directive (EU) 2016/797;
- Decreto dell'Agenzia n. 5/2011 del 31 marzo 2011 – "Determinazione degli importi dei proventi derivanti dall'esercizio delle attività dirette di servizio con riferimento alla autorizzazione alla messa in servizio dei rotabili di cui all'art.6 del D.Lgs. n. 162/2007";
- Decreto dell'Agenzia n. 2/2012 del 11 luglio 2012 – "Determinazione degli importi dei proventi derivanti dall'esercizio delle attività dirette di servizio con riferimento alla autorizzazione alla messa in servizio dei veicoli conformi ad un tipo autorizzato o riconosciuto";
- Decreto dell'Agenzia n. 4/2012 del 9 agosto 2012 – Emanazione delle "Attribuzioni in materia di sicurezza della circolazione ferroviaria", del "Regolamento per la circolazione ferroviaria" e delle "Norme per la qualificazione del personale impiegato in attività di sicurezza della circolazione ferroviaria" e s.m.i.;
- Decreto dell'Agenzia n. 1/2015 del 28 gennaio 2015 – Emanazione del "Riordino normativo, standard tecnico, sottosistema materiale rotabile. Locomotive da manovra il cui impiego è limitato nell'ambito delle località di servizio del Sistema Ferroviario Italiano" e s.m.i.;
- Decreto dell'Agenzia n. 01/2016 del 13/12/2016 – Emanazione del "Riordino normativo, standard tecnico, sottosistemi materiale rotabile e controllo-comando e segnalamento di bordo. Norme tecniche nazionali in materia di sottosistemi costituenti i veicoli ferroviari relative alla autorizzazione di messa in servizio dei veicoli" e s.m.i.;
- Decreto direttoriale per la determinazione degli importi dei proventi derivanti dall'esercizio delle attività dirette di servizio con riferimento al rilascio dei certificati di sicurezza unici di cui all'art. 9 del D.Lgs. 50/2019 e dell'autorizzazione di immissione

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sul mercato dei veicoli e dell'autorizzazione di tipi di veicolo di cui all'art. 21 e art.24 del D.Lgs. 57/2019 - Prot. ANSF 0009102 del 15/06/2020;

- Linee Guida ANSF per il riconoscimento degli organismi indipendenti ferroviari, rev. 1 del 28/09/2020;
- Linee Guida ANSF per l'applicazione del regolamento (UE) N. 402/2013 della Commissione del 30 aprile 2013 alle modifiche ai sottosistemi strutturali di terra (impianti fissi), rev. B del 27/04/2020;
- Nota ANSF 009372/2013 del 23/12/2013 – Raccomandazione in materia di sicurezza al Gestore dell'Infrastruttura RFI S.p.A. inerente alla conformità ai principi del Regolamento per la Circolazione Ferroviaria;
- Nota ANSF 001076/2014 del 14/02/2014 – Procedura di verifica dei sottosistemi strutturali di terra. Fase di "prove finali";
- Nota ANSF 004457/2014 del 27/06/2014 – Raccomandazione in materia di sicurezza al Gestore dell'Infrastruttura RFI S.p.A. inerente ai procedimenti di autorizzazione di messa in servizio di sottosistemi strutturali Infrastruttura, Energia, Controllo-comando e Segnalamento a terra e di applicazioni generiche/prime specifiche e prodotti generici o componenti per il segnalamento ferroviario;
- Nota ANSF 005157/2015 del 29/06/2015 – Emanazione linee guida inerenti la documentazione relativa alla manutenzione dei veicoli – Rev. A del 23/06/2015;
- Nota ANSF 0016142 del 09/08/2019Integrazione alle Linee Guida ANSF n. 1/2019 rev. 0 del 27/06/2019;
- Nota ANSF 0000978 del 18/01/2019 – "Messa in servizio dei sottosistemi strutturali a terra. Collaudo delle strutture";
- Nota ANSF 0015307/2019 del 02/08/2019 – "Messa in Servizio del sottosistema Infrastruttura. Accessibilità delle persone a mobilità ridotta - STI PMR. Servizi igienici nelle stazioni e nelle fermate";
- Nota ANSF 0008664/2020 del 05/06/2020 – "Messa in Servizio del sottosistema Infrastruttura. Accessibilità delle persone a mobilità ridotta – STI PMR. Dispositivi per l'ausilio della salita a bordo";
- Nota ANSFISA 0018010/2021 "«Sistema ferroviario esistente» (art. 3 comma 1, lettera q, del D.Lgs. n.57/2019) e «Ponti e opere in terra esistenti» (punto 4.2.7.4 della STI Infrastruttura – regolamento (UE) 1299/2014)";
- Norma UNI 11748:2019 "Modalità per la gestione ed effettuazione delle prove dei veicoli sull'infrastruttura ferroviaria" del 18/04/2019;
- Disposizione RFI n. 51/2007 del 12/1/2007 "Modifiche alla Disposizione del Gestore dell'Infrastruttura n. 13 del 26 giugno 2001 e successive modifiche;
- Norma ISO 19011:2018 "Linee guida per audit di sistemi di gestino

4. TERMINI E DEFINIZIONI

Si considerano valide le definizioni citate nelle norme:

- CEI UNI EN 45020 Standardization and related activities - General vocabulary

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- UNI CEI EN ISO/IEC 17000 Conformity assessment — Vocabulary and general principles
- UNI ISO EN 9000: 2015 Quality management systems — Fundamentals and vocabulary

and the following terms used in the text:

- Client: Organization that requests the certification activity.
- Evaluator: Personnel appointed and qualified by the organization to perform inspection and assessment activities.
- Body: Organization that carries out the assessment activities.

5. GENERAL CONDITIONS

This Regulation contains the provisions governing the relationship between the Body and the Client. The Regulation may be supplemented by additional provisions that must be specifically included in the contract between the Body and the Client.
The contractual relationship between ISALAB and its Client shall be governed exclusively by the order/contract concluded between the parties, including the general conditions, drafted in accordance with this Certification Regulation. The subject of the certification activity shall be defined within the contract.
ISALAB and all personnel involved in the certification activity are not engaged in any activities related to the design, manufacture, supply, installation, acquisition, ownership, use, or maintenance of the inspected items, or of similar competing items.
ISALAB shall remain responsible for the certifications even when the inspection activity is carried out by adequately qualified independent collaborators performing such activities on behalf of ISALAB.

Depending on the agreements made, the inspection activity may be performed, according to the type of assessment activity, on site, at the Client's premises, or at ISALAB's premises.

Note: For order/contract it is understood the document that describes and governs the mutual obligations of the Parties; it may consist either of a dedicated document specifically prepared by the Client or of the formal acceptance of the offer submitted by ISALAB. In cases where the order has been specifically prepared by the Client, it shall comply with this Regulation and shall include the acceptance of the general purchasing conditions (Md-COM-06).

6. CERTIFICATION PROCESS

Certification activities may be requested by all companies operating in the railway and guided transport sectors.

6.1. Certification Application and Review

To initiate the certification activity, the Client shall submit to ISALAB a request for quotation containing the information necessary to identify the object of certification and the

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specifications/standards against which the assessment is to be performed, in accordance with the form (Md-COM-07).
In order to facilitate the collection of information, ISALAB may send the Client requests for additional information, to be completed, signed by the Client, and sent to ISALAB's email address.

Furthermore, when required by the applicable regulation, the offer shall include a declaration in which the Client specifically declares that no similar request for assessment has been submitted, or alternatively, that an assessment by another Conformity Assessment Body (CAB) has already been performed, and that the corresponding assessment reports with findings and open issues will be provided.

The contractual relationship between ISALAB and the Client shall be governed exclusively by the terms specified in the order/contract signed between the parties and by this Regulation.

By signing the certification order/contract, the Client undertakes to:

- Always comply with the certification requirements. Should such requirements be modified, the Client undertakes to implement the necessary changes to maintain the certification within the timeframes and according to the methods agreed with ISALAB or established by the certification requirements.
- Ensure the continued fulfilment of the requirements for the product/service/process.
- Provide access to its sites and the documentation necessary for certification and subsequent surveillances, when applicable.
- Maintain records of complaints related to the certified product/service/process, make them available to ISALAB, take appropriate actions to restore conformity, and document their management.
- Promptly inform ISALAB of any changes affecting the certification requirements (changes related to the product/service/process, organizational changes, ownership, legal status, operational site, etc.).
- Use the certificate within its scope of application and, in any case, in compliance with what is described in Chapter 7 of this document.

Following the signing of the order/contract, ISALAB shall communicate to the Client the names of the appointed inspectors/evaluators (after a start-up meeting with the involved parties). In the event that ISALAB decides not to issue an offer, it shall inform the Client of the reasons.

6.2. Method of Submission of Documentation

For the performance of the assessment activities, the Client shall send the documentation to ISALAB in electronic format and, where not available, in paper format.

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6.3. Initial Certification

Following the completion of the review of the certification application and the signing of the contract, ISALAB appoints the project team, updates the program prepared in the previous phase if necessary, and initiates the assessment activities.

6.4 Conduct of Assessment Activities

Under the coordination of a Project Manager or the Technical Director (DT), the following main activities for the management and execution of the assessment are carried out:

- Appointment of the evaluators and obtaining their acceptance of the assignment with a commitment to confidentiality and impartiality.
- Possible signing of contracts with external evaluators/inspectors.
- Possible signing of contracts with laboratories.
- Updating of the assessment program.
- Execution of the assessment (documentary or on-site) in accordance with what is described in the Assessment Program.
- Review of the report by the Technical Manager and submission to the Client.

ISALAB shall communicate to the Client the names of the assigned evaluators and the Technical Director, who acts as the primary contact person for the Client. The Client has 10 calendar days from receipt of the communication to object to one or more evaluators. The Client must provide documented reasons, which will be verified by the Technical Director (DT). If the Client's requests are found to be justified, the DT (or, if appointed, the Project Manager) will proceed with the replacement of the evaluator.

This approval process also applies to the selection of external laboratories by ISALAB, when such laboratories are necessary for the performance of the commissioned activity.

ISALAB shall also inform the Client of the possible presence of ANSFISA or Accredia inspectors as observers. The Client is required to accept the presence of such inspectors.

The Client is required to inform the evaluators/inspectors of the safety regulations and risks associated with the site where the assessment takes place.

In the event of the prolonged absence of an evaluator/inspector, in order to ensure service continuity, ISALAB shall replace them with an evaluator/inspector possessing equivalent professional competence, whose name shall be promptly communicated to the Client.

The assessment, depending on the procedural requirements, may be conducted by a single evaluator/inspector or by an assessment team. In the case of an assessment team, ISALAB shall appoint a team leader.

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The Client is required to provide all documentation necessary for the inspections deemed necessary by ISALAB.

The Technical Director (DT) is responsible for the technical coordination of all assessment processes. In the event of the unavailability of the DT, or when the DT performs assessment activities directly as an Evaluator, this responsibility is assumed by the Deputy Technical Director (SDT); if the SDT is unavailable, the activity shall be suspended.

Where a Subsystem Coordinator is appointed, they are responsible for the technical coordination of all assessment processes relating to the subsystem.

Where applicable, the Client shall submit a Test Plan to ISALAB for approval. Once approved, the Client may conduct the tests at laboratories whose acceptability must again be approved by ISALAB. If provided for in the contract, ISALAB itself may organize the tests at laboratories selected and approved by ISALAB in agreement with the Client. The test results, when performed at an independent external laboratory, shall be transmitted to the ISALAB coordinator. If, during testing, "Non-Conformities" with the applicable requirements arise, the assessment coordinator shall evaluate whether to interrupt the test.

6.5 Subcontracting

ISALAB does not subcontract assessment activities.

Should it become necessary for ISALAB to request laboratory testing, ISALAB shall ensure and demonstrate that the selected subcontractor is competent to provide the service in question and, where applicable, is capable of meeting the criteria specified in standard ISO/IEC 17025.

In the event of subcontracting of laboratory tests, ISALAB shall inform the Client, and the subcontractor shall be submitted to the Client for acceptance.

6.6 Assessment / Inspection / Audit Reports

At the conclusion of each assessment activity, ISALAB issues a final report that describes, as detailed below, the outcome of the assessment.

The reports issued by ISALAB include all the results and conclusions of the assessment activities performed.

In the event that corrections or modifications are made to an Assessment Report after its issuance, ISALAB shall issue a new document that cancels and replaces the previous one. Within the new document, the changes that led to the new issuance shall be indicated and justified.

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6.7 Findings, Non-Conformities, and Corrective Actions

During assessment activities, non-conformities may be identified, observations may be made, or comments may be raised:

Non-conformities: are issued when a requirement concerning the product, design, or management system under assessment is not met. They are also issued in the presence of a deficiency in the Client's management system such that product conformity cannot be ensured.

Observations: are issued when a deficiency in the Client's product, process, or management system is detected, although not such as to jeopardize the conformity of the product.

Comments: are issued when a potential improvement in the Client's product, process, or management system is identified, in order to ensure product conformity to the applicable technical standard and aimed at preventing non-conformities and mitigating risks.

All Non-conformities, Observations, and Comments are promptly communicated to the Client after sharing of a written record.

From the moment the record is shared, the Client has 3 working days to submit any objection addressed to ISALAB Management.

After 3 days, with or without an objection, and within 10 days from the execution of the audit, the Management (or another function not involved in the audit) confirms the findings and notifies the Client so that it may prepare a Findings Management Plan.

Following this communication, the Client shall inform ISALAB of the corrective actions to be taken and the timeframes for their implementation (defined according to the specific complexity of the case), which the Client undertakes to respect.

It is specified that corrections related to Non-conformities and Observations must be implemented as soon as possible; the implementation period for corrective actions shall not exceed three months from the planning date, except in justified cases approved by ISALAB, which may authorize extensions not exceeding the established limits.

ISALAB shall evaluate the Findings Management Plan received from the Client and communicate its approval. In case of rejection, ISALAB shall issue new comments to allow the Client to revise the Findings Management Plan, ensuring its subsequent approval and related notification by ISALAB.

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The Client must also communicate to ISALAB any variation to the approved Findings Management Plan (for example, extended timeframes or changes to the corrective treatment/action).

If the Findings Management Plan or the supporting documentary evidence is deemed unsuitable and/or not submitted within the maximum permitted timeframe, ISALAB may proceed with the closure of the assessment procedure or a temporary suspension of the activity until the non-conformity is resolved.

6.8 Management of Findings

All findings formalized by the Conformity Assessment Body (CAB) must be duly reviewed by the Client, who shall submit to the CAB, within 15 working days from receipt of the communication and confirmation of the findings, an appropriate Findings Management Plan including:

For non-conformities: the correction (where applicable), a root cause analysis, and the corrective actions related to the identified causes, with an indication of the implementation timeframe. The closure evidence for this type of finding must be positively evaluated by the CAB prior to the certification decision.

For Observations: the correction, a root cause analysis, and, when determined by the Client in relation to the identified causes, the corrective actions (where applicable), with an indication of the implementation timeframe.

For Comments: the management may be conducted through the initiation of an improvement action, or they may be not adopted.

6.9 Review and Decision

At the conclusion of the assessment process, once all findings have been closed in accordance with what was agreed and approved during the approval phase of the Findings Management Plan, a review of the results is conducted so that ISALAB may make a decision regarding the issuance or non-issuance of the certification.

Upon completion of the review, ISALAB assigns one of the Decision Makers not involved in the project to make the certification decision based on all information relating to the assessment, its review, and any other relevant information.

Depending on the type of certification scheme applied, the decision may be taken by the same person who performed the review or by another Decision Maker not involved in the project. In both cases, the person making the decision shall be someone who has not been involved in the assessment process.

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In particular cases, and depending on the criticality of the findings, the validity of the certificate may be limited, or an additional surveillance may be required, to be performed normally within 6 months from the issuance of the certification/surveillance visit, in order to verify the effectiveness of the actions implemented and agreed with ISALAB.

The Decision Maker makes a positive or negative decision regarding the certification. The Technical Director (DT) communicates the decision to the Client.

6.10 Issuance and Delivery of Certificates

In the case of a positive decision, the certificates are issued and sent to the Client.

6.11 Update of the Certificate List

ISALAB shall maintain an updated list of issued certifications and their respective expiry dates. Such lists shall be promptly updated within 7 days from the issuance of the certificate.

6.12 Communication with Accredia, Ansfisa, and Era

When required, ISALAB shall send a summary list of the attestations/certificates to the supervisory authorities (ANSFISA and/or ACCREDIA). For example, ISALAB shall annually send ANSFISA a summary list of the attestations issued and the surveillance activities carried out, attaching the related assessment reports.

Furthermore, ISALAB shall register in the ERADIS application (European Railway Agency Database of Interoperability and Safety) all certificates issued, in accordance with Directive (EU) 2016/797, Directive (EU) 2016/798, and Regulation (EU) 2016/796. The registration shall be carried out in compliance with the ERADIS Terms of Use V 2.0 and according to the communication protocols established by the European Union Agency for Railways (ERA). The information thus transmitted shall be made publicly accessible by ERA to ensure transparency and traceability of the certificates issued.

6.13 Surveillance, Modification, Suspension, Withdrawal, Reduction, and Cancellation of the Certificate

6.13.1 Surveillance

When required and depending on the type of certificate, a surveillance activity shall be carried out.

A few weeks before the expiry of the surveillance period, the Client shall inform ISALAB of any changes that may impact the certification. If only the surveillance activity (without modifications) is confirmed as necessary, the surveillance shall be performed in accordance with the assessment program.

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In the case of a positive outcome of the assessment activity, the certificate shall retain its validity.

In the case of a not fully positive result (when findings identified during the surveillance activities could jeopardize the attestation/certification), the Decision Maker shall decide on the maintenance, withdrawal, or suspension of the certificate (see subsequent paragraphs).

6.13.2 Modification of the Certificate

In the case of requests for modification of the certificate, such requests must be submitted in writing by the Client. In the case of formal modifications, ISALAB shall assess their impact on the certificate and proceed with the re-issuance of the certificate, the update of the relevant lists, and, when required, the communication of the modification to the interested parties.

In the case of substantial modifications (e.g., change of operational site, extension of the scope of the certificate, etc.), a specific assessment program shall be prepared, including the activities to be carried out in order to verify the feasibility of the certificate modification. In these cases, the Decision Maker shall be required to express their judgment regarding the modification of the certificate. In the event of a positive outcome, the updated certificate shall be reissued, the lists shall be updated, and, when required, the modification shall be communicated to the interested parties.

ISALAB shall communicate the relevant information to ERA via ERADIS within one week.

6.13.3 Suspension of the Certificate

The decision to suspend a certificate may be taken in the following cases:

- The Client's quality management system has constant or serious deficiencies in meeting the certification requirements.
- The Client has not allowed the performance of surveillance audits according to the required frequency.
- The Client voluntarily requests the suspension.
- The presence of nonconformities identified during the surveillance or reassessment activities of the certificates.
- Complaints and appeals that are ongoing or have been closed with an impact on the certificate.
- Non-payment.

The suspension decision is communicated by ISALAB to the Client, together with a justification document indicating the elements necessary for the Client to have the suspension revoked, as well as a maximum timeframe within which to provide them, or alternatively, a maximum timeframe within which ISALAB may carry out a reassessment to

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verify the corrective actions implemented. The Client is also informed through this communication that the certificate must not be used during the suspension period.

The suspension status is updated in the certificate list. When applicable, the interested parties shall be informed.

If the Client fails to provide feedback and the cause of the suspension is not resolved, the procedure for the withdrawal of the certificate shall be initiated.

ISALAB shall communicate the relevant information to ERA via ERADIS within one week.

6.13.4 Revocation of the Certificate

The decision to revoke a certificate may be taken in the following cases:

- If the Client does not provide feedback following a suspension and the cause of the suspension has not been resolved;
- Following the identification of serious nonconformities;
- Following serious violations of the rules regarding the use of the certificate.

In such cases, the Decision Maker is responsible for deciding on the revocation of the certificate. The revocation decision is communicated by the Technical Director (DT) to the Client, together with the related justification documentation. The Client is also informed through this communication that the certificate must not be used.

The revocation status is updated in the certificate list. When applicable, interested parties are notified. ISALAB must communicate the relevant information to ERA via ERADIS within one week.

6.13.5 Reduction of the Scope of the Certificate

The decision to reduce the scope of a certificate may be taken in the following cases:

- Upon voluntary request by the Client;
- If the Client does not provide feedback following a suspension and the cause of the suspension has not been resolved (applicable only to a portion of the certification scope).

The decision on the reduction is communicated by ISALAB to the Client, together with the related justification documentation. The Client is also informed through this communication that the previous version of the certificate must no longer be used.

The certificate list is updated accordingly. When applicable, interested parties are notified. ISALAB must communicate the relevant information to ERA via ERADIS within one week.

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6.13.6 Cancellation of the Certificate

A certificate is cancelled either upon its natural expiry or following a voluntary written request submitted by the Client.

In the case of a voluntary request, ISALAB proceeds to cancel the certificate by updating the certificate records and notifying the relevant interested parties, where applicable. ISALAB must communicate the related information to ERA via ERADIS within one week.

6.13.7 Verification of Certificate Use

If ISALAB becomes aware either through its own personnel or from third parties of any breach of the conditions for certificate use as specified in this regulation, it shall take the following actions:

- Remind the certificate holder in writing of the obligation to comply with the conditions of use;
- Request that all necessary measures be taken to restore compliance with these conditions;
- Require that such corrective actions be promptly communicated to ISALAB in writing.

In cases of serious misuse or failure by the Client to present corrective actions, ISALAB shall initiate the procedure for suspension or revocation of the certificate.

7. USE OF ASSESSMENT REPORTS, CERTIFICATES, ISALAB LOGO, AND ACCREDIA MARK

Il Committente potrà far l'uso consentito dalla legge e quando applicabile dai regolamenti ANSFISA dei rapporti di valutazione, che dovranno essere ritenuti documenti riservati non riproducibili se non per gli usi interni e ufficiali verso gli organi di controllo di ANSFISA e/o dei suoi Committenti finali (utilizzatori dei prodotti oggetti di valutazione).
Le Aziende che ricevono i Certificati ISALAB hanno diritto di esporre il Certificato e di utilizzare la riproduzione, sulle proprie bacheche e nei propri documenti pubblicitari, solo nella sua interezza, in modo che sia evidente quale sia la conformità dichiarata ed i limiti del certificato stesso.
Non è consentito l'uso e sarà ritenuto scorretto l'uso del Certificato ed in generale della certificazione nei casi di revoca o sospensione del certificato o nel caso di certificato scaduto o nei casi di utilizzo al di fuori dell'ambito per cui la certificazione è stata concessa.
Inoltre, il Committente ha il divieto di utilizzare la certificazione per portare discredito all'Organismo di Certificazione ISALAB e/o di effettuare dichiarazioni riguardo alla propria certificazione che possano essere considerate ingannevoli o non autorizzate.
E' consentito usare il logo ISALAB all'interno dei propri materiali solo se questo è chiaramente riferito alla certificazione conseguita, senza il rischio di trarre in inganno il fruitore della documentazione sul tipo, sulla natura e sui limiti della certificazione stessa.

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ISALAB utilizza il marchio ACCREDIA nei propri certificati per le attività/servizi che rientrano nello schema di Accreditamento:
UNI CEI EN ISO/IEC 17065 – quale Organismo di Certificazione
Per l'ambito di accreditamento indicato nel Certificato di Accreditamento e relativi allegati
Non è concesso altro uso del marchio ACCREDIA al Committente, al di fuori di tali rapporti/certificati.
È espressamente vietato per i clienti l'utilizzo improprio di ON.

The Client may use the assessment reports only within the limits permitted by law and, where applicable, by ANSFISA regulations. These reports must be considered confidential documents, not reproducible except for internal use or for official submission to ANSFISA or to the Client's final customers (end users of the evaluated products).

8. RIGHTS AND DUTIES OF THE CLIENT

By accepting this Regulation, the Client agrees to:

1. Operate in full compliance with the provisions contained herein.
2. Allow access to its premises and provide all resources necessary for the performance of the assessment activities in particular, access to the personnel responsible for the activities under evaluation and, where applicable, to inspectors from ANSFISA and/or ACCREDIA, in full compliance with current safety regulations.
3. Ensure all necessary conditions for the proper and effective execution of the assessment, including when the activity takes place at third-party sites.
4. Fulfill all payments as established in the contractual documents.

The Client has the right to request that ISALAB sign a confidentiality agreement prior to receiving any documentation.

If the Client detects discriminatory or non-impartial behaviour by ISALAB, they have the right to report it to the ISALAB Committee for Safeguarding Impartiality (MSI).

9. RIGHTS AND DUTIES OF ISALAB

ISALAB undertakes to:

1. Operate in full compliance with the provisions of this Regulation.
2. Ensure the presence of qualified inspection personnel assigned to carry out the assessments.
3. Comply with all safety regulations in force at the Client's premises to which ISALAB personnel are granted access.
4. Respect the agreed timelines for performing the assessment activities and for delivering the final documentation.
5. Guarantee the confidentiality of all information received from the Client that is useful or necessary for carrying out the assessment activities.

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10. RESPONSIBILITY

1. The Client undertakes to guarantee the completeness and truthfulness of all documents and information made available to ISALAB.
2. ISALAB is expressly exempt from any liability in cases where data or information are missing, incomplete, or do not reflect the Client's actual situation.
3. ISALAB is responsible solely for verifying compliance with what has been contractually agreed. ISALAB assumes no responsibility for the technical choices made by the Client's organization these remain the sole responsibility of the Client nor for verifying compliance with legal requirements.
4. The assessment activity carried out by ISALAB does not exempt the Client from any legal obligations related to the products, processes, or services it provides, nor from any contractual obligations toward its own customers. ISALAB shall not bear any responsibility or warranty obligation in these matters. In particular, ISALAB shall not be held liable for any product, process, or service defects attributable to the Client, as governed by Legislative Decree 6 September 2005 No. 206 and subsequent amendments (Consumer Code), Directive 85/374/EEC, and subsequent updates concerning product liability and any behaviour systematic or occasional by the Client that is not compliant with applicable laws or regulations.
5. ISALAB shall not be held liable for any inadequacies or damages of any kind caused by the Client or by its products, processes, or services during the performance of the activities.

11. COMPLAINTS AND APPEALS

Any interested party, including certificate holders and other stakeholders, may submit a complaint regarding ISALAB's activities. All complaints related to ISALAB's activities must be submitted in writing by registered mail with return receipt or certified email (PEC) within three months from the occurrence of the event giving rise to the complaint.

All complaints received will be managed by the Quality Manager and analyzed by the organization within 7 days of receipt. The Complaint Manager shall have adequate technical competence and shall be independent and impartial, with no involvement in the activity concerned. The outcome of the verification will be communicated in writing to the Client within thirty days of receipt of the complaint. In the case of a justified complaint, corrective actions shall be promptly implemented by ISALAB and communicated to the Client.

Appeals may be submitted by the Client against ISALAB within three months from the delivery of the Final Assessment Report and/or the Certificate. Appeals must be submitted in writing by registered mail with return receipt or certified email (PEC).

The appeal is handled by the Quality Manager, who appoints an Appeal Officer. The Appeal Officer shall have adequate technical competence and shall be independent and impartial,

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with no involvement in the activity concerned. The Client will be informed in writing of the appointed Appeal Officer and will have 5 days to challenge the appointment, providing written justification for their decision.

The results of the appeal review shall be communicated by ISALAB to the Client in writing via registered mail with return receipt or PEC within sixty days of the appeal submission.

ISALAB shall communicate the outcome of the appeal to the Client, including the reasons for the decision, and shall provide any relevant documentation relating to the review of the subject matter of the appeal.

A more detailed description of the complaints and appeals management procedure can be provided upon request.

12. DISPUTES

In the event of disputes between the Client and ISALAB, the Court of Genoa shall have exclusive jurisdiction.

13. CONFIDENTIALITY

All information and documents necessary for the assessment activities shall be considered confidential. Access to such documents/information shall be restricted to those involved in the assessment process, the Client, and, if necessary, the accreditation body.
ISALAB and its employees/external collaborators undertake to:

1. Not disclose or use in any way information, data, or documents related to the assessment activities in which they participate;
2. Store and manage documentation received from the Client in a manner that prevents third parties from accessing or copying it;
3. Assessors shall also return all paper copies of documents to ISALAB and delete any digital versions at the end of the assessment.

This commitment is formalized through confidentiality agreements, in which employees and external suppliers commit to avoiding conflicts of interest and to remain impartial and free from external influences, whether economic or psychological.

ISALAB operates in full compliance with the provisions of European Union Regulation No. 679/2016 (“GDPR”) and Legislative Decree 30 June 2003 No. 196 (personal data processing), as amended by Legislative Decree 101 of 2018.

14. FORCE MAJEURE

ISALAB non risulterà obbligata dal presente regolamento e non sarà ritenuta responsabile nel caso in cui si dovessero presentare degli eventi esterni definiti come “forza maggiore" sulle quali non ha nessuna influenza. Con il termine "forza maggiore" si intendono tutti gli eventi imprevedibili e indipendenti da ISALAB avvenuti dopo la stipula del contratto.

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15. SAFETY OBLIGATIONS

ISALAB undertakes to comply with the Client's Safety Plan, which must be provided to ISALAB in advance.

ISALAB declares compliance with the Italian Workers' Safety legislation (Legislative Decree 81/08 and subsequent amendments and integrations), particularly observing the obligations under Article 20 of the cited Decree, as well as the provisions of the Service Manager for Prevention and Protection.

The obligations established under Article 26 of Legislative Decree 81/08, including the provision of personal protective equipment (PPE) in relation to specific risks present at the hosting facilities, are assigned to the top management of the hosting organization (Article 2, Legislative Decree 363/98).

In implementation of the requirements of Legislative Decree 81/08:

- In the event of interference between the Client's activities and those of ISALAB, the personnel in charge from both the Client and ISALAB shall cooperate to implement prevention and protection measures against occupational risks affecting the work activities under assessment. In particular, in cases provided under Article 3-ter of the Consolidated Law on Occupational Safety, ISALAB prepares a risk assessment document for interferences, containing a survey of standard risks related to the type of service that could potentially arise from contract execution. The entity where the contract is to be performed shall, before starting the activity, integrate this document with the specific interference risks present at the sites where the activity will take place; this integration, signed by the performing party for acceptance, becomes part of the contractual documentation.
- Without prejudice to the fact that coordination of prevention and protection measures for risks affecting workers always remains the responsibility of the Client, the safety managers of both the Client and ISALAB must inform each other to eliminate risks arising from interferences between the activities of different organizations involved in the execution of the contract assigned to ISALAB.

Management of ISALAB
Ing. Antonio Scofano