

## ADDRESS

Via Domenico Fiasella 16,  
16121 - Genova (GE) - Italy  
P. IVA: 02567870221  
Capitale Sociale: € 700.000 i.v.  
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## CONTRACT

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## 1 SCOPE

The main purpose of this Regulation is to describe the relations between ISALAB S.r.l. (hereinafter ISALAB) and the Client and the procedures by which ISALAB performs the assessment/inspection activities.

ISALAB S.r.l. is an independent assessment body that provides conformity assessment services against the applicable sector-specific reference regulations for projects and/or products in the railway transport sector.

## 2 SCOPE OF APPLICATION

It applies to the following activities of ISALAB:

- Risk management process assessments in accordance with Regulation (EU) 402/2013 and subsequent amendments and supplements (AsBo)
- Assessments of compliance with European regulations concerning the conformity and safety of railway and wire-guided tramway systems (ISA)
- Assessments of the compliance of products with specifications (of Italian and foreign railway operators and non-railway operators)

## 3 REFERENCES

The assessment activities shall be performed in accordance with the following applicable national and international standards and regulations:

- ISO/IEC 17020 Conformity assessment - Requirements for the operation of various types of bodies performing inspection
- Directive (EU) 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
- Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 and as amended
- Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety
- LEGISLATIVE DECREE No. 50 of 14 May 2019 – Decree transposing Directive (EU) 2016/798
- LEGISLATIVE DECREE No. 57 of 14 May 2019 – Decree transposing Directive (EU) 2016/797
- European Commission Decisions – Applicable Technical Specifications for Interoperability (TSIs)

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for the high-speed and conventional rail system

- Collection of regulations, decrees and directives of the National Railway Safety Agency (ANSFISA)
- Modifications to structural subsystems on the ground (fixed installations). Guidelines for the application of Commission Regulation (EU) No. 402/2013 of 30 April 2013 – Rev. B of 27/04/2020
- EN 50126 The specification and demonstration of reliability, availability, maintainability and safety (RAMS)
- EN 50129 Railway applications - Communication, signalling and processing systems - Safety related electronic systems for signalling
- EN 50716 - Railway Applications - Requirements for software development
- ACCREDIA RG-01 – Regulation for the Accreditation of Certification and Inspection Bodies – General Part
- ACCREDIA RG-01-03 – Regulation for the Accreditation of Product Certification Bodies
- ACCREDIA RG-09 – Regulation for the Use of the ACCREDIA Mark
- ACCREDIA RG-01-04 – Regulation for the Accreditation of Inspection Bodies

## 4 TERMINI E DEFINIZIONI

The definitions provided in the following standard shall apply:

- EN 45020 – Standardization and related activities – General vocabulary
- ISO/IEC 17000 – Conformity assessment – Vocabulary and general principles
- ISO 9000:2015 – Quality management systems – Fundamentals and vocabulary

and the following terms used throughout this document:

**Client:** Organization requesting the Inspection / assessment activity.

**Assessor:** Personnel appointed and qualified by the organization to perform the Inspection / assessment activity.

**Body:** Company performing the assessment activities.

**Inspection:** (§ ISO 17020): Examination of a product, process, service or installation, or their design, and determination of its conformity with specific requirements or, based on professional judgement, with general requirements.

**Assessment** (Source ANSFISA): Investigation undertaken for the purpose of reaching a judgement, based on evidence, regarding the conformity of a project, product, service, process or installation with specific

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requirements.

## 5 GENERAL CONDITIONS

Regulation defines the requirements governing the relationship between the Certification Body and the Client. This Regulation may be supplemented by additional requirements, which shall be specifically included in the contract between the Certification 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, drawn up in accordance with this Certification Regulation. The subject matter and scope of the certification activity shall be defined within the contract.

ISALAB and all personnel involved in the certification activities shall not be involved in the design, manufacture, supply, installation, acquisition, ownership, use or maintenance of the inspected objects, or of objects similar to or competing with those inspected, subject to the applicable two-year time limitation.

ISALAB remains responsible for the certification activities, even when the inspection activities are carried out by appropriately qualified independent contractors acting on behalf of ISALAB.

Depending on the agreements established between the Parties, the inspection activity may be carried out, according to the type of assessment activity, at the site, at the Client's premises, or at ISALAB's premises.

### **Applicant Different from the Client**

Where the Client, as the signatory to the contract, wishes the assessment documents to be issued in the name of a different entity (e.g. a subsidiary or another entity designated by the Client), ISALAB shall require a written declaration from the Client specifying the name and details of the entity in whose name the documents are to be issued.

For this purpose, ISALAB shall use the Declaration Form for the Issuance of the Assessment Report, provided in Annex 1 to this procedure. The form shall be completed and returned only where the Md-COM-07 Request Form indicates that the applicant is different from the Client, and in any case before the offer is issued or the activities are commenced.

In the absence of such formalized authorization, ISALAB shall not proceed with the issuance of the offer or the conclusion of the contract.

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*Note: For the purposes of this Regulation, the term order/contract refers to the document describing and governing 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. If the order has been specifically prepared by the Client, it shall comply with this Regulation and shall include acceptance of the General Conditions of Purchase (MD-COM-06).*

## 6 ASSESSMENT PROCESS

Assessment activities may be requested by all companies operating in the railway and wire-guided tramway transport sector.

### 6.1 Assessment Application

To initiate the assessment activity, the Client shall submit to ISALAB a request for quotation containing the information necessary to identify the subject of the assessment and the specifications/standards against which the assessment is to be carried out, in accordance with the provisions set out in form (Md-COM-07).

ISALAB may request any additional information where the documentation is not sufficient.

Furthermore, where required by the applicable regulations, the quotation shall require a declaration in which the Client specifically declares that no similar application for assessment has been submitted to another body for the same subject of assessment or, alternatively, that an assessment has already been carried out by another body and the assessment reports, including findings and open points, shall be provided.

ISALAB may require the signature of the section of the order/contract requiring the declaration regarding the uniqueness of the assignment.

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

Following the signing of the order/contract, ISALAB personnel shall communicate to the Client the names of the appointed inspectors/assessors (following a Start-up meeting with the parties concerned).

Should ISALAB decide not to submit an offer, it shall inform the Client of the reasons.

In cases where ISALAB operates as a subcontractor for another Notified/Accredited Body, the management of the interface between the parties shall be governed by this procedure.

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Before the activities commence, the following shall be defined and formalized with the other Body:

- the scope of the assessment activities;
- the applicable parts of the TSIs, the relevant versions and any elements excluded;
- the applicable national rules (NNTR);
- the configuration of the Technical File subject to assessment;
- the common processes and the allocation of responsibilities, including import/export of activities;
- the measures to prevent duplication of the assessment of the same requirements.

This information shall be documented in the Assessment Plan and in the offer scope, completed and shared before the start of the activities.

Any changes to the assessment boundaries assigned to ISALAB during the assessment process shall be communicated by the Project Manager to the personnel involved through Md-TEC-03 MoM, properly recorded through Md-TEC-04 List of Open Points (LOP), and shall result in the corresponding update of the Assessment Plan (Md-TEC-09, Md-TEC-14, Md-TEC-23 or Md-TEC-45).

## 6.2 Method for Submission of Documentation

For the performance of the assessment activities, the Client shall send or make available to the ISALAB appointed personnel, by granting access to a shared area, the documentation in electronic format and, where not available, in hard-copy format. ISALAB and its personnel shall comply with the confidentiality agreements concerning the information required by the aforementioned regulations.

## 6.3 Performance of the Assessment

ISALAB shall communicate to the Client the names of the assigned assessors and the Team Leader, who constitutes the primary interface for the Client. The Client shall have 10 calendar days from receipt of the communication to reject one or more assessors, if necessary. The Client shall provide documented reasons, which shall be verified by the Team Leader. If the Client's requests are deemed justified, DT shall replace the assessor(s).

The same approval process shall also apply to the selection by ISALAB of external laboratories, where these are required for the performance of the commissioned activity.

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ISALAB shall also inform the Client of the possible presence of Accredia inspectors as observers. The Client is obliged to accept the presence of such Inspectors.

The Client is obliged to inform the assessors of the safety regulations and risks concerning the site where the assessment takes place.

In the event of the prolonged absence of an assessor, in order to maintain continuity of the service, ISALAB may replace the assessor with an assessor of equivalent professional competence, whose name shall be promptly communicated to the Client.

The assessment may, depending on the requirements of the procedure, be conducted by a single assessor or by an assessment team. In the case of an assessment team, ISALAB shall appoint a person responsible for the team.

The Client shall make available all documentation necessary for the inspections that ISALAB deems necessary.

The Team Leader is responsible for the technical coordination of all assessment processes. In the event of the unavailability of the Team Leader or in the event of directly performing assessment activities as an Assessor, responsibility shall be assigned to the Technical Director or his/her deputy; in the event of the unavailability of both the Technical Director and his/her deputy, the activity shall be suspended.

In the event of supplementary tests, the Client shall submit the Test Plan to ISALAB, which shall be subject to approval.

The testing phase includes products, installations and associated documentation and provides fundamental inputs for the assessment and certification decision.

Assessment activities relating to tests shall be performed in accordance with ISO/IEC 17025.

ISALAB ensures that the tests used in its assessment activities have been performed according to the following acceptance criteria:

- ✓ In a competent, independent and reproducible manner in accordance with the requirements of ISO/IEC 17025 and
- ✓ in compliance with the applicable requirements of the normative documents for the products and their manufacturing process.

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ISALAB has documented methods to ensure compliance with the above criteria according to the following possibilities:

➤ *accredited test;*

The assessment provides the necessary assurance regarding the test reports prepared as part of such assessment. An accredited test is ISALAB's preferred means of demonstrating both acceptance criteria. An accredited test is accepted only if:

- the test report includes a valid assessment rating and/or assessment ID number, and
- ISALAB has received a copy of the assessment certificate of the laboratory performing the test, including its annex. The test performed shall have been carried out within the scope and subject to the rules of this assessment.

➤ *non-accredited test;*

ISALAB shall have a documented process for assessing the technical competence of the non-accredited testing laboratory prior to the performance of the tests. This process documented by ISALAB shall ensure that:

- ISALAB personnel assessing testing laboratories have the appropriate competence;
- ISALAB retains records to demonstrate the assessment performed on the laboratory for compliance with the requirements of ISO/IEC 17025 as follows:
  - ✓ Clause 5 Structural requirements
  - ✓ Clause 6.6 Subcontracting of testing and calibration
  - ✓ Clause 7.6 Evaluation of measurement uncertainty
  - ✓ Clause 7.10 Control of nonconforming testing and/or calibration work
  - ✓ Clause 6.2 Personnel
  - ✓ Clause 6.3 Facilities and environmental conditions
  - ✓ Clause 7.2 Selection, verification and validation of methods
  - ✓ Clause 6.4 Equipment
  - ✓ Clause 6.5 Metrological traceability
  - ✓ Clause 7.3 Sampling

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- ✓ Clause 7.4 Handling of test or calibration items
- ✓ Clause 7.7 Ensuring the validity of results
- ✓ Clause 7.8 Reporting of results
- ✓ the testing laboratory shall provide all records of a specific test upon request by ISALAB;
- ✓ the competence and independence of laboratory personnel shall be assessed and recorded (Clause 4.1 - 6.2);
- ✓ participation in interlaboratory comparison or proficiency testing programmes shall be recorded (in accordance with UNI CEI EN ISO/IEC 17043 - Clause 7.7 of ISO/IEC 17025);
- ✓ ISALAB shall periodically assess the laboratory, at least every 24 months, to demonstrate that its competence is maintained, as required for certification purposes.

If “Non-Conformities” with the applicable requirements arise during the tests, the assessment coordinator shall assess whether the test should be discontinued.

## 6.4 Subcontracting

ISALAB does not subcontract the assessment activities.

Should ISALAB need to request laboratory tests, ISALAB shall ensure and demonstrate that the selected subcontractor is competent to provide the relevant service and, where applicable, is able to meet the criteria specified in ISO/IEC 17025.

If ISALAB requests laboratory tests for assessments, the subcontractor shall be accredited according to ISO/IEC 17025 and compliant with ERA standards.

## 6.5 Assessment Reports

At the end of each assessment activity, ISALAB shall issue a final assessment report, which describes, in accordance with the provisions set out below, the outcome of the assessment.

The Assessment Report coincides in all cases with the Inspection Report in accordance with UNI CEI EN ISO/IEC 17020.

The Assessment Reports issued by ISALAB contain all the results and conclusions of the assessment

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activities performed, in particular the statement of identified findings.

In the case of an ISA assessment, the Assessment Report shall be prepared by the Lead Assessor based on the assessments required as detailed in EN 50129. If it is a system consisting of several subsystems, each of them shall have its own assessment report prepared by the appointed Assessor. In this case, the Lead Assessor shall compile the final assessment report for the overall system, reporting all findings and any restrictions on use, including those applicable.

In the case of an AsBo assessment according to 17020, all reports prepared are subject to a two-stage approval process. Draft final reports are prepared by the AsBo Safety Integrator / Operation and Organization Change Evaluator.

In the first review stage, these prepared reports are examined by the AsBo Technical Reviewer. If findings are identified in the report, such findings are notified to the AsBo Safety Integrator / Operation and Organization Change Evaluator, who takes action to eliminate them. The results of the actions taken both by the AsBo Safety Integrator / Operation and Organization Change Evaluator and by the applicant are re-evaluated by the AsBo Technical Reviewer and approved after being deemed appropriate.

The second approval process is carried out by the AsBo Technical Reviewer, and the same process is followed with regard to the findings. Subsequently, the prepared reports are delivered to the Client with approval status.

In the event of corrections or amendments to an Assessment Report made after its issuance, ISALAB shall issue a new document that cancels and replaces the previous one. The new document shall indicate and provide the reasons for the amendments that resulted in the new issuance.

## 6.6 Final Assessment Reports

The Final Assessment Report includes all the results of the examinations and the determination of conformity resulting from such results, as well as all information necessary for their understanding and interpretation. In the case of complex assessment activities, in addition to the Final Assessment Report, Intermediate Assessment Reports may be issued, which are incorporated into and/or attached to the final report.

The information is detailed below:

- Title of the document (Intermediate Assessment Report, Final Assessment Report);

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- Unique document code and date of issue for traceability purposes;
- Identification of ISALAB and its mark;
- Identification of the Client;
- Description of the activity performed for the Client;
- Date(s) of the assessments resulting in the issuance of the Report;
- Identification of the object(s) of the assessment (where possible, also of the individual components) and location where the tests performed were carried out;
- Brief description of the assessment methods used (specifying any deviations from the procedures and standard methods);
- Identification of any assessment activities subcontracted to third parties and the related results;
- Identification of the measurement or test equipment used;
- Verification results, the statement of the findings identified;
- Names and signatures of the persons who participated in the preparation, review and approval of the document (internal and external);
- Revision index with the respective Notes / Amendments;
- Assessor's judgement on conformity with the identified requirements and standards, including any relevant observations, open points and conditions of application;
- Where applicable and if not already specified in the description of the methods/procedures used, information relating to the selection criteria for the samples subject to assessment;
- Information on the sites where the assessment activity was carried out and the relevant environmental conditions, where applicable;
- Any omissions of activities planned at the start of the assignment (and the related reasons);
- Statement that the Assessment Report shall not be reproduced except with the full approval of ISALAB and the Client;
- Statement that the Assessment Report refers exclusively to the object(s) identified in the Report itself.

At the end of the assessment activity, the assessor(s) shall prepare the Final Assessment Report, the Technical Manager shall approve it, verifying its consistency with the provisions of the system documents and contractual documents, and the Legal Representative shall sign it for authorization.

For this purpose, the Technical Manager collects all records of conformity with the requirements (intermediate reports, product test reports, etc.) issued by the assessors and/or appointed laboratories and verifies their compliance with internal procedures and applicable

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standards/directives.

At the end of the assessment activity, the final report shall be transmitted to the organization and discussed, where applicable, in a final meeting with the Client's management or its representative.

## 7 FINDINGS AND MANAGEMENT OF FINDINGS

With regard to the document review work carried out as part of the AsBo activities, the analysis focuses primarily on the verification of the documents referred to in Commission Implementing Regulation (EU) No 402/2013 concerning the common safety method for risk evaluation and assessment, in particular:

- Description of the change
- FMEA Analysis
- Risk Analysis
- Hazard Log

If the proposed change has an impact on safety, the Proposer shall preliminarily determine the significance of the change. Subsequently, an assessment body shall carry out an independent assessment of the adequacy of the application of the risk management process referred to in Annex I to Regulation (EU) No 402/2013, as well as of the related results.

All comments formalized by ISALAB shall be collected in a Technical Note (LOP – List of Open Points). The comments may have one of the following severities: Blocker, Major, Minor, Formal, Hint, Question.

Each comment shall be associated with the relevant status, among the following:

- Open
- Conditionally Closed (pending documentary evidence)
- Closed
- Transferred Internally
- Transferred Externally

Each comment shall also be associated with the name of the respective author, by indicating the initials.

The process may be concluded only when all comments have been closed and/or conditionally closed, through the preparation of a final report demonstrating compliance with the safety requirements and reporting the conclusions of the independent assessment.

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The assessment body shall satisfy all the requirements of ISO/IEC 17020:2012, as well as subsequent amendments. In carrying out the inspection activities provided for by this standard, the body shall express professional judgement.

Furthermore, the assessment body shall ensure compliance with the general competence and independence requirements provided for by the standard, as well as the following specific competence requirements:

- competence in risk management, with knowledge and experience in standard safety analysis techniques and relevant standards;
- competence in all relevant parts of the railway system subject to the change;
- competence in the correct application of safety and quality management systems, or audit management systems.

## 8 USE OF ASSESSMENT REPORTS, ISALAB LOGO, ACCREDIA MARK

The Client may use the assessment reports as permitted by law, which shall be considered confidential documents and shall not be reproduced except for internal use and official use vis-à-vis the supervisory bodies of the Agencies (European and National) and/or the final Clients (users of the products subject to assessment).

Companies receiving Assessment Reports issued by ISALAB are entitled to use and reproduce such reports, including where they bear the ISALAB logos, exclusively in their entirety and in compliance with the conditions and limitations indicated in the reports themselves, so that the scope and nature of the assessment performed are always evident.

The use of the Assessment Reports and, in general, of the assessment documentation is not permitted and shall be deemed improper in cases where the assessment has been revoked or suspended, in the case of expired documentation, where applicable, or in cases of use outside the scope for which the assessment was performed.

Furthermore, the Client is prohibited from using the Assessment Reports or documentation bearing the ISALAB logos to discredit the ISALAB Assessment Body and/or from making statements regarding the assessment activities performed that may be considered misleading or unauthorized.

The use of the ISALAB logo within their own materials is permitted exclusively where such use is clearly related to the Assessment Reports issued by ISALAB and there is no risk of misleading the user of the documentation regarding the type, nature, scope and limitations of the assessment performed.

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ISALAB uses the ACCREDIA mark in its Assessment Reports for activities/services falling within the Accreditation scheme.

No other use of the ACCREDIA mark by the Client is permitted outside the aforementioned Assessment Reports.

## 9 DIRITTI E DOVERI DEL COMMITTENTE

By accepting these Regulations, the Client undertakes to:

- i. Operate in accordance with the provisions set out in this Regulation.
- ii. Allow access to its premises and make available the resources necessary for carrying out the assessment activities, in particular the personnel responsible for the activities subject to assessment and, where applicable, ANSFISA and/or ACCREDIA inspectors, in compliance with the applicable safety regulations.
- iii. Ensure all the conditions necessary for the effective performance of the assessment, including where the assessment is carried out at third-party premises
- iv. Comply with the payment obligations set out in the contractual documents.

The Client has the right to require ISALAB to enter into a confidentiality agreement prior to receiving any documents.

If the Client identifies any discriminatory or non-impartial conduct on the part of ISALAB, the Client has the right to refer the matter to ISALAB's Impartiality Safeguarding Committee (ISC).

## 10 RIGHTS AND OBLIGATIONS OF ISALAB

ISALAB undertakes to:

- i. Operate in accordance with the provisions set out in these Regulations
- ii. Ensure the availability of the assigned assessment personnel throughout the assessment activities
- iii. Comply with the applicable safety regulations at the Client's premises to which ISALAB personnel have access.
- iv. Comply with the agreed timelines for carrying out the assessment activities and delivering the final documentation
- v. Ensure the confidentiality of the information received from the Client that is useful or necessary for carrying out the assessment activities.

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## 11 RESPONSABILITY

The Client undertakes to ensure the completeness and accuracy of the documents and information made available to ISALAB.

ISALAB shall be expressly exempt from any liability in the event of failure to communicate, or incomplete communication of, data, as well as in the event that such data do not correspond to the actual situation of the company.

ISALAB is responsible for verifying compliance with the provisions agreed at contractual level and assumes no direct responsibility for the adequacy of the technical decisions adopted by the Client's Organization for this purpose, as the Client remains solely responsible for such decisions, nor for verifying compliance with statutory and regulatory requirements.

ISALAB's assessment activities shall not relieve the Client of its statutory obligations arising from the products, processes and services it provides, nor of its contractual obligations towards its customers, and shall not entail any liability or warranty obligation on the part of ISALAB. In particular, it is agreed that ISALAB shall bear no liability for defects in products, processes or services provided by the Client to third parties, in the cases governed by Legislative Decree No. 206 of 6 September 2005, as amended and supplemented (Consumer Code), and by EEC Directive 85/374, as amended and/or supplemented, concerning liability for damage caused by defective products, nor for any systematic or occasional conduct of the Client that is not compliant with applicable laws and/or regulations.

ISALAB shall not be liable for any inadequacies or damages of any kind caused by the Client or by its products, processes or services during the assessment activities.

## 12 COMPLAINTS AND APPEALS

Any interested party, including certificate holders and other relevant stakeholders, may submit a complaint concerning ISALAB's activities.

All complaints relating to ISALAB's activities shall be submitted in writing by registered mail with acknowledgment of receipt or by certified electronic mail (PEC) within three months of the occurrence of the event giving rise to the complaint.

All complaints received in this manner shall be handled by the Quality Manager and reviewed by the organization within seven days of receipt.

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The person responsible for handling the complaint shall have appropriate technical competence and shall be independent and impartial, and shall not have been involved in the activity to which the complaint relates.

The outcome of the review shall be communicated to the Client in writing within thirty days of receipt of the complaint. Where the complaint is found to be justified, ISALAB shall promptly implement the necessary corrective actions and communicate them to the Client.

Appeals may be submitted by the Client to ISALAB no later than three months from the date of delivery of the Final Assessment Report and/or the Certificate. Appeals shall be submitted in writing by registered mail with acknowledgment of receipt or by certified electronic mail (PEC).

The appeal shall be handled by the Quality Manager, who shall appoint an Appeal Officer. The Appeal Officer shall have appropriate technical competence and shall be independent and impartial in reaching a decision, and shall not have been involved in the activity to which the appeal relates. The Client shall be notified in writing of the appointment of the Appeal Officer and shall have five days to object to the appointment, providing written justification for the objection.

The results of the review shall be communicated by ISALAB to the Client in writing by registered mail with acknowledgment of receipt or by certified electronic mail (PEC) within sixty days of submission of the appeal.

ISALAB shall notify the Client of the outcome of the appeal, including the reasons for the decision, and shall also provide any documentation relating to the reviews carried out in connection with the subject matter of the appeal.

A more detailed description of the procedure for handling complaints and appeals may be provided upon request.

## 13 DISPUTES

In the event of any dispute between the Client and ISALAB, the Court of Genoa shall have jurisdiction, unless otherwise specified in the confidentiality agreement signed by the parties.

## 14 CONFIDENTIALITY

All information and documents necessary for carrying out the assessment activities shall be treated as confidential.

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Access to such documents and information shall be restricted to persons involved in the assessment process, the Client and, where necessary, the accreditation body.

ISALAB and its employees/external collaborators undertake to:

- i. Not disclose or use in any way any information, data or documents related to the assessment activities in which they participate;
- ii. Store and manage the documentation received from the Client in such a manner as to prevent third parties from accessing or making copies of such documentation;
- iii. The assessors shall also undertake to return to ISALAB any hard copies of the documents and to delete any electronic versions upon completion of the assessment.

This commitment is formalized through the signing of confidentiality agreements, whereby employees and external suppliers undertake to avoid conflicts of interest and to remain impartial and free from external influence, whether of an economic or psychological nature.

ISALAB shall in any event operate in full compliance with the requirements of Regulation (EU) 2016/679 ("GDPR") and Legislative Decree No. 196 of 30 June 2003 concerning the processing of personal data, as amended by Legislative Decree No. 101 of 2018.

## 15 FORCE MAJEURE

ISALAB shall not be bound by these Regulations and shall not be held liable in the event of external circumstances constituting "force majeure" over which it has no control or influence. The term "force majeure" shall mean any unforeseeable events or circumstances beyond ISALAB's control that occur after the conclusion of the contract.

## 16 SAFETY OBLIGATIONS

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

Compliance with the legislation on occupational health and safety set out in Legislative Decree No. 81/2008, as amended and supplemented, is hereby declared, with particular regard to the obligations under Article 20 of the aforementioned Decree, as well as to the instructions issued by the person responsible for the Prevention and Protection Service.

The obligations provided for under Article 26 of Legislative Decree No. 81/2008, as well as the provision of personal protective equipment (PPE) in relation to the specific risks present at the host facilities,

**ADDRESS**

Via Domenico Fiasella 16,  
16121 - Genova (GE) - Italy  
P. IVA: 02567870221  
Capitale Sociale: € 700.000 i.v.  
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**CONTRACT**

+39 010 0980270  
info@isalab.it

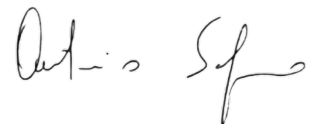
shall be the responsibility of the person in charge of the host facility, pursuant to Article 2 of Legislative Decree No. 363/1998.

In implementation of the requirements of Legislative Decree No. 81/2008:

- Where interference is foreseeable between the activities of the Client and those of ISALAB, the designated personnel of the Client and ISALAB shall cooperate in implementing measures for the prevention and protection against occupational risks affecting the activities covered by the assessment. In particular, in the cases provided for under Article 26(3-ter) of the Consolidated Occupational Health and Safety Act, ISALAB shall prepare the document assessing risks arising from interference (DUVRI), containing an initial assessment of the standard risks associated with the type of service that may potentially arise from the performance of the contract. Before the commencement of the contract, the entity at whose premises the contract is to be performed shall supplement the aforementioned document with reference to the specific interference risks present at the locations where the activities will be carried out. The supplement, signed for acceptance by the contractor, shall form an integral part of the contractual documents.
- Without prejudice to the fact that coordination of measures for the protection and prevention of risks to which workers are exposed shall always remain the responsibility of the Client, the safety officers appointed by the Client and ISALAB shall exchange relevant information, including for the purpose of eliminating risks arising from interference between the activities of the various companies involved in the performance of the activities entrusted to ISALAB.

Management

Eng. Antonio Scofano



## ADDRESS

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## CONTRACT

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### Annex 1. Declaration of Assessment Report Heading

I, the undersigned, \_\_\_\_\_ in my  
capacity as \_\_\_\_\_ of the company \_\_\_\_\_  
holder of Offer No \_\_\_\_\_ Project \_\_\_\_\_

hereby declare that the assessment reports issued by XXXX shall be addressed to:

Company Name \_\_\_\_\_ Registered Office  
\_\_\_\_\_ Street/Square \_\_\_\_\_  
No \_\_\_\_\_ Postcode \_\_\_\_\_ Province \_\_\_\_\_

Data confidentiality:

We hereby inform you that your personal data will be processed in accordance with Regulation (EU) 2016/679 concerning the protection of natural persons with regard to the processing of personal data, including by electronic means, exclusively for the purposes of the procedure for which this declaration is being made.

For Acknowledgement

Company Named in the Offer

Place and Date

Stamp and Signature

Company Named in the Report

Place and Date

Stamp and Signature