

1. GENERAL INFORMATION.

This information on the conduct of product safety integrity level assessment has been developed and presented to the public to ensure non-discriminatory conditions for all applicants and in order to comply with items 4.4 and 4.6 of BDS EN ISO/IEC 17065:2012.

Definitions:

MS	Management System
PCB	Product Certification Body
SIL	Safety Integrity Level
Applicant	A legal entity that has completed and submitted an Application for Assessment and whose product will subsequently be assessed
Employer	Legal entity with which an assessment contract is concluded
Manufacturer	Legal entity that produces the product to be assessed
Product/ Application	A collection of interconnected elements forming a system/subsystem/equipment in a way that meets certain requirements. In this document, the term 'Product' should also be considered as 'Application' in the context of the applicable standards.
TD	Technical Director
CDC	Certification Decision Committee
EA BAS	Executive Agency 'Bulgarian Accreditation Service'
BIS	Bulgarian Institute for Standardization
Day	Calendar day

1.1 Capabilities of TINSA EOOD.

TINSA EOOD includes in its structure a Product Certification Body (PCB), which holds a Certificate of Accreditation No 9 PCB (9 OCP), issued by EA BAS and published on the website of TINSA EOOD.

The scope of accreditation includes activities on 'Assessment of Products from the Rail System for Safety Integration Levels (SIL)'.

1.2 Information for correspondence with TINSA EOOD.

TINSA EOOD
 3A Nikolay Haytov Str., Floor 4, 1113 Sofia
 Tel.: +359 2 400 33 91, 93; Fax +359 2 952 25 38
 E-mail: office@tinsabg.com; www.tinsabg.com

2. CONFIDENTIALITY AND IMPARTIALITY IN THE PERFORMANCE OF SERVICES.

2.1. A description of the means by which the PCB with TINSA EOOD is financially supported.

The management of the PCB with TINSA EOOD shall declare that it or its staff shall not carry out, propose or recommend consultancy activities, as well as activities related to the development, implementation, manufacture, assembly, distribution and maintenance of the certified products and related processes and organizations, development and implementation of management systems, internal audits of its clients and other consultancy and operational activities related to the Applicants, Customers, Manufacturers and products under assessment. The PCB with TINSA EOOD shall not receive any financial support (sponsorship). Financial stability shall be ensured solely by the contracts signed with the Clients and the strategic decisions of the Management of the PCB and TINSA EOOD.

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2.2. Impartiality of the PCB towards TINSA EOOD in the performance of the services.

The independence and impartiality of the PCB with TINSA EOOD shall be the responsibility of both the Manager of TINSA EOOD and the Technical Director, as well as of all PCB employees (external and internal). This commitment shall be documented by the Management of the PCB with TINSA EOOD in the 'Management Statement on Notified Body, Designated Body and Independent Safety Level Assessor Policy and Objectives' published on the website of TINSA EOOD.

Compliance with impartiality shall also be a condition set out in the contract for the safety level assessment service. All employees of the PCB with TINSA EOOD (internal and external) shall sign declarations of impartiality when concluding an employment or civil contract.

The PCB with TINSA EOOD has established and implemented an impartiality assurance mechanism that includes the involvement of external independent participants.

The Applicant/Client shall have the right to lodge an appeal with the PCB in the event of a breach of the principles of impartiality. The procedure for lodging appeals concerning compliance with impartiality is described in item 9.

2.3. Confidentiality of the PCB with TINSA EOOD in the performance of the services.

The maintenance of confidentiality by the PCB with TINSA EOOD shall be the responsibility of both the Manager of TINSA EOOD and the Technical Director, as well as of all PCB employees (external and internal). This commitment shall be documented by the Management of the PCB with TINSA EOOD in the 'Management Statement on Notified Body, Designated Body and Independent Safety Level Assessor Policy and Objectives' published on the website of TINSA EOOD.

Confidentiality shall also be a condition set out in the contract for the safety level assessment service. All employees of the PCB with TINSA EOOD (internal and external) shall sign declarations of confidentiality when concluding an employment or civil contract.

The Applicant shall have the right to lodge an appeal with the PCB with TINSA EOOD in the event of a breach of the principles of confidentiality. The procedure for lodging appeals concerning compliance with confidentiality is described in item 9.

Where the PCB with TINSA EOOD shall be required by law or contractually mandated to disclose information that constitutes a confidential secret, the Applicant/Client will be notified unless prohibited by law.

3. BIDDING AND NEGOTIATION

3.1. Send a letter of intent to PCB with TINSA EOOD.

The Applicant may send a letter to the PCB with TINSA EOOD expressing his/her wish to have a safety level assessment conducted. The letter may be in free text and the Applicant should indicate thereto a description of the product, the activities they wish to be carried out by the PCB with TINSA EOOD and the standards against which the assessment is to be carried out.

A completed (in whole or in part) and submitted ΦOC-09.01.01 'Integrated Safety Level Assessment Request' shall also be accepted as a letter of intent. This form is published on the website of TINSA EOOD.

3.2. Clarification of requirements.

After registering the letter, a meeting or further communication will be arranged to clarify the following issues:

- scope of the assessment;
- the applicable standards against which the assessment will be made;
- a way to communicate and receive/send documents;
- the contact persons on both sides;
- working language and language for issuing PCB documents;
- the time schedule for the assessment;
- specific product information;

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- use of subcontractors in the design, manufacture, testing and installation of the product;
- other clarifying questions.

If the Letter of Intent and the subsequent discussions and/or meetings conducted refer to the performance of activities that are outside the scope of accreditation of the PCB with TINSA EOOD, the Applicant may be offered another accredited body whose scope of notification includes these activities and which is willing to perform them on its own behalf or in partnership with the PCB with TINSA EOOD. In the event of the Applicant's disagreement to form a partnership, these activities shall be excluded from the scope of the future contract.

After the communication, the Applicant shall submit a completed Application to the PCB with TINSA EOOD according to the ΦOC-09.01.01 template (the form is published on the website of TINSA EOOD).

3.3. Application review

The PCB team shall review the Application received and make a final decision on the feasibility of conducting the assessment activities.

The purpose of the review is to establish the availability of sufficient information about the Applicant and the product, to determine the ability to meet the criteria set forth in the Application, and to resolve any existing differences between the Applicant and the PCB with TINSA EOOD.

Additional data shall be collected during the review, and the Applicant shall cooperate with this.

Through the review shall be specified:

3.3.1. External resources used (subcontractors).

In the event of use of a subcontractor by the PCB, TINSA EOOD shall undertake full responsibility for the subcontractor's performance. By selecting the subcontractor, TINSA EOOD shall guarantee its competence, impartiality and confidentiality.

The Applicant shall be notified of the selection and participation of the subcontractor(s) and written consent shall be required from the Applicant. The refusal to use a subcontractor shall be duly justified in writing. If an objection is accepted, a new subcontractor selection and reconciliation shall be carried out.

Subcontractors to the PCB shall be assessed and selected in a manner that shall ensure the accuracy and fairness of their performance, respect for confidentiality and assurance of impartiality.

A representative of the PCB with TINSA EOOD must be present when subcontractors are conducting activities in order to monitor and control the activity.

3.3.2. Possibility of skipping separate activities in the assessment process.

Product/Application Safety Level Assessment activities shall be performed in full and no separate activities or steps may be skipped.

3.3.3. Determining the capability to perform the assessment.

Based on the conducted review of the Application, the PCB with TINSA EOOD shall assess its capabilities to conduct the assessment. The capabilities are:

- human resources — qualifications, competence, workload;
- technical resources;
- time resources;
- other contingencies specific to the product under assessment.

The PCB with TINSA EOOD shall refuse to carry out an assessment when:

- lack of competence and capability to carry out the assessment;

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- clear evidence that the Applicant cannot provide the necessary documentation to complete the assessment;
- where the Applicant is proven to be involved in illegal activities.

Review of the Application shall be completed within 10 (ten) days. Exceptionally and if necessary to clarify additional issues, this period may be extended up to 20 (twenty) days.

In the event of a positive decision, the preparation and drafting of an offer and its submission to the Applicant shall proceed. In the event of a negative decision, the Applicant shall be notified in writing, stating the reasons for the refusal.

3.4. Preparation and submission of an offer.

After a positive review of the Application, an offer shall be prepared and sent to the Applicant within 30 (thirty) days.

3.5. Signing a contract.

Upon acceptance of the offer by the Applicant, TINSA EOOD shall prepare a contract. The Applicant, the Client and the Manufacturer may be either different legal entities or one and the same legal entity.

The signed Annex No 1 to the Contract shall be deemed the last and final version of the Application.

If changes occur during the period between the submission of the offer and the conclusion of the contract, the PCB team with TINSA EOOD shall review the changes to ensure that it has the competence to carry out the assessment in accordance with those changes. Where additional resources are involved, renegotiation shall proceed.

The conclusion of a contract for the assessment of the safety level of a product shall be without prejudice to the obligations of the Applicant to comply with other applicable European Union legislation, including with regard to any checks required to be carried out by the assessment bodies under other rules.

4. CONDUCTING THE ASSESSMENT.

The PCB with TINSA EOOD shall conduct the safety level assessment against the requirements of EN 50126-1, EN 50126-2, EN 50128, EN 50129 and EN 50159, and their equivalents approved by BIS.

During the assessment, the requirements of the procedures and instructions of the approved and accredited quality management system implemented in the PCB with TINSA EOOD shall be followed.

4.1. Team for conducting the assessment.

The assessment shall be conducted by a team designated by the TD. Team members may be expert assessors, auditors and technical experts where appropriate. The PCB with TINSA EOOD may use external collaborators or subcontractors in conducting the assessment activities. The Applicant/Client shall be formally notified of the team members as well as the use of subcontractors.

The Applicant/Client may object to the participation of members of the assessment team only on the grounds of their competence and/or where it has evidence that the individual is an employee or has been employed to perform services for a competing organisation, resulting in a risk to their impartiality. The objection should be accompanied by documented reasons.

In case there is a reasoned and accepted objection, a new team selection and re-coordination with the Applicant/Client shall be carried out.

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4.2. Planning the assessment

The assessment activities shall be carried out in accordance with an assessment plan, which shall include information on the scope of the assessment process, a list of the assessment team, a list of the documents expected from the Applicant (according to the requested standards), a description of the activities to be carried out and a timeframe for completion.

In the event of the need to conduct on-site assessments at the product manufacturing site or at a site where assembly activities are being carried out, further coordination and scheduling of these assessments shall take place.

4.3. Documentation required for conducting the assessment

Within the agreed deadlines, the Applicant shall submit documentation necessary to carry out the assessment in full and to demonstrate compliance for the assessed safety level. The documentation should include, but not be limited to:

- specification of product requirements;
- specification of safety requirements;
- specification of software and software/hardware integrity requirements;
- a safety file including:
 - Part 1: Product definition;
 - Part 2: Quality Management Report/Statement (evidence of quality management);
 - Part 3: Safety Management Report/Statement (evidence of safety management);
 - Part 4: Technical Safety Report/Statement (evidence of functional/technical safety);
 - Part 5: Related safety files (if applicable);
 - Part 6: Conclusion.

The documentation shall be sent in electronic form, duly approved in the organization of the Applicant/Manufacturer. Dispatch of the documentation shall be via the channels of correspondence specified in the contract.

The PCB with TINSA may request additional documents and/or evidence that are necessary to conduct the assessment.

4.4. Product assessment.

The product assessment for safety level is carried out by:

- *review of the documentation provided by the Applicant* — the aim shall be to assess the documents provided and their Application in managing the quality and safety of the product during its life cycle;
- *Specific inspections and tests* — where necessary and in order to increase confidence in the assessment carried out, the PCB with TINSA EOOD may request and/or participate in specific on-site inspections and/or tests. When conducting specific on-site inspections and/or tests, the Applicant/Manufacturer must ensure:
 - accompanying persons;
 - access to its sites, equipment, personnel and/or those of its subcontractors (where the inspection and/or testing is conducted on the territory of a subcontractor);
 - safe conditions for conducting the inspection/test, including the provision of personal protective equipment where applicable;

The organisation of the inspection/test is the responsibility of the Applicant, unless otherwise specified in the contract.

In reviewing the documentation, it is possible that questions may arise from the assessment team initiated by a lack of information or insufficiently accurate and clear evidence. The questions shall be documented in an 'Open Questions List' and sent to the Applicant for response. To complete the assessment, answers and/or evidence must be provided for all open questions.

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4.5. Documentation of the assessment conducted.

The results of the assessment conducted shall be documented in a form from the PCB management system of TINSA EOOD and provided to the Applicant.

In case of deviations/non-compliance or lack of evidence of compliance, the PCB with TINSA EOOD shall formally notify the Applicant. The time limits for response shall be specified in the contract. With regard to the identified non-conformities, the Applicant shall conduct a root cause analysis and identify corrective actions, deadlines and responsibilities for their implementation.

5. MAKING A DECISION ON CERTIFICATION AND ISSUING A CERTIFICATE.

The decision on the safety level certification is made by the Certification Decision Committee (CDC) of the PCB with TINSA EOOD.

In case of a positive decision of the CDC, the process of issuing the Certificate will proceed. All certificates shall be issued in the name of the Applicant. Certificates are perpetual.

In the event of a negative decision of the CDC, the report documenting the decision to deny and the report of the assessment shall be sent to the Applicant. The latter has the right to object to the decision within 10 (ten) days of its receipt (see item 9).

5.1. Additional terms and conditions.

If during the term of the contract or within the validity of a certificate already issued, changes occur in the configuration of the product, the Applicant must notify the PCB with TINSA EOOD. PCB shall review changes to ensure that the product continues to meet the safety level for which it is being assessed and certified. Where this involves additional resources, renegotiation shall take place, which may be by means of an Annex or a separate contract.

6. COMMUNICATION.

The Applicant/Client must:

- inform the PCB with TINSA EOOD of any irregularities detected by inspection bodies, suspension, freezing or revocation of permits, licenses, and the like directly or indirectly related to the subject matter of the contract with TINSA EOOD;
- inform the PCB with TINSA EOOD of any procedural actions concerning the subject matter of the contract with TINSA EOOD, except in cases of restrictions established by law;
- inform the PCB with TINSA EOOD of any changes in the configuration and in the process of manufacturing/installation of the product and after issuance of the certificate.

In the cases mentioned in this item, the PCB with TINSA EOOD may appoint additional and extraordinary inspections, as well as suspend or revoke the issued certificate, if necessary.

7. TERMINATION, LIMITATION, SUSPENSION OR REVOCATION OF CERTIFICATION.

The certificates issued by PCB with TINSA EOOD indicate the safety level of the product under assessment at the date of issue of the certificate.

Where, in the course of examinations, tests, assessments or otherwise, the product is found and proven not to comply with the requirements of the applicable standards, or a change in the manufacturing or installation technology is found, which change is not disclosed by the Applicant recorded in the certificate issued by the PCB, the following actions may be taken:

- termination of certification;
- limiting the scope of certification;
- suspension of certification;
- withdrawal of certification.

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7.1. Termination of certification.

Termination of certification shall take place in one of the following cases:

- at the request of the Applicant;
- in the event of the Applicant's bankruptcy and/or dissolution.

In these cases of termination of certification, the Applicant shall:

- notify the PCB with TINSA EOOD of its intentions;
- return the certificate issued by the PCB with TINSA EOOD;
- duly notify all interested parties of the terminated certification.

The PCB with TINSA EOOD shall:

- examine the validity of the reasons for termination;
- notify the Applicant of the termination decision by a formal letter.

7.2. Limiting the scope of certification.

The decision to restrict coverage shall be made at a meeting of the CDC, reviewing and assessing records and evidence of declared product changes. In this case, it may be found that the originally certified safety level in the intended use cannot be achieved and the certificate should be reissued for the corresponding safety level or use.

The PCB with TINSA EOOD shall formally notify the Applicant/Client of the decision taken.

When limiting the scope of certification, the Applicant shall have to:

- return the certificate already issued;
- duly notify all interested parties of the changed scope.

The PCB with TINSA EOOD shall:

- issue a certificate with the updated scope or safety level.

7.3. Suspension of certificate.

The PCB with TINSA EOOD shall have the right to suspend the validity of the issued certificate when there is information that the product no longer complies with the requirements of the applicable standards, as well as in the following cases:

- lack of adaptation to changes in certification rules and/or requirements of the relevant reference standard communicated by the PCB with TINSA EOOD;
- refusal of the Applicant/Manufacturer to have assessments carried out by the PCB with TINSA EOOD in cases of declared or identified product changes;
- in the absence of notification of PCB with TINSA EOOD of changes made to the product;
- withholding information regarding legal actions, claims or lawsuits regarding the Applicant and the product under assessment;
- delays in payments to the PCB with TINSA EOOD compared to the terms of the relevant contract relating to the product under assessment;
- in case of proven misuse of a certificate issued by PCB with TINSA EOOD.

The suspension decision shall be made at a meeting of the CDC, based on a Report from the Assessment Team Leader or as a result of inspections conducted when changes to the product are declared or identified. The Applicant shall be notified of the decision.

In the event of suspension of the certificate, the Applicant shall:

- duly notify all interested parties of the suspension of the certificate.

The PCB with TINSA EOOD shall:

- notify the Applicant of the measures and conditions to be taken for the renewal of the

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certificate.

The period of suspension of a certificate shall not exceed 6 months. Failure to resolve the issues that led to the suspension within the specified timeframe shall result in revocation of the certificate.

The renewal of a suspended certificate shall be by means of a new assessment which shall cover only the implementation of the actions that have resolved the issues for the suspension. A decision on the renewal of the certificate shall be taken at a meeting of the CDC.

During the suspension period, the Applicant shall not use the certificate and/or declare its products certified.

7.4. Certificate revocation.

Reasons for a certificate revocation may be:

- in cases where significant non-conformities have been identified or information received indicating a complete failure to comply with the requirements of the applicable standards or the product documentation already assessed by the PCB;
- failure to take action when a certificate is suspended within the prescribed period;
- preventing scheduled inspections by the Applicant/Manufacturer;
- if the Applicant is convicted for non-compliance with mandatory legal requirements concerning the certified product, including revocation of relevant permits, licenses and the like;
- in case of proven misuse of the certificate;
- in the event of non-fulfilment of contractual obligations.

The decision to revoke a certificate shall be made at a meeting of the CDC, based on the records and evidence of the inspections/audits conducted or additional verifiable information containing justification for the proposal. The TD shall notify the Applicant of the decision in writing.

Upon revocation of the certificate, the Applicant shall:

- to cease communication with third parties regarding the certificate issued;
- return all certificates issued to PCB with TINSA EOOD within 3 (three) working days of receipt of the notice of revocation of certificates by PCB with TINSA EOOD.

The PCB with TINSA EOOD shall:

- notify the Client when it is different from the Applicant.

8. PUBLIC INFORMATION ON CERTIFICATES ISSUED.

The PCB with TINSA EOOD may be statutorily required to disclose or provide information about certificates issued on a periodic basis. In this case, the PCB with TINSA EOOD shall not inform the Applicant/Client of the disclosure of such information. In all other cases, the Applicant/Client shall be informed of the disclosure of information concerning the certificate issued.

9. OBJECTIONS AND APPEALS.

The Applicant may object to and/or appeal decisions of the PCB with TINSA EOOD within 10 (ten) days of receipt of notification of the decision, explaining the reasons for their disagreement in writing. On receipt of his objection/appeal, the PCB with TINSA EOOD sends an acknowledgement of receipt.

Appeals and objections shall be sent to the attention of the PCB with TINSA EOOD at the addresses and contact details indicated (see item 1.2).

All appeals and objections shall be reviewed within 30 (thirty) calendar days by an independent 'Appeals and Objections Committee', the members of which shall be different from those who

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were directly or indirectly involved in the contract service and made the relevant opinion and/or certification decision.

The PCB with TINSA EOOD provides ongoing information to the appellant on the status, progress and outcome of the appeal/objection.

The PCB with TINSA EOOD shall send a formal notification to the appellant of the end of its appeal process and its final opinion.

If the appellant is not satisfied with the response to the appeal or the objection, he/she shall have the right to refer the case to the relevant accreditation body and/or judicial institution.

10. RULES FOR USE OF A CERTIFICATE.

The PCB with TINSA EOOD shall provide the Applicant with a certificate. PCB signs or logos are not provided. The terms and conditions for the use of certificates are published on the website of TINSA EOOD (www.tinsabg.com).

11. FINANCIAL TERMS AND CONDITIONS.

The PCB with TINSA EOOD shall not charge fees for processing an Application.

The financial terms and conditions (prices, method of payment, payment schedule, etc.) shall be set out in a contract or an annex thereto. The prices agreed with the Client shall cover all services requested by the Client, including verification of documents, conducting on-site inspections/audits, preparation of reports, protocols, maps, etc., decision on certification or refusal, issuance of certificates or refusal document.

The prices agreed with the Customer shall cover all costs of the service, unless other terms are specified in the contract.

Charges for additional services shall be made as specified in an annex to the contract.

Unless otherwise agreed, all prices quoted are exclusive of VAT.

TINSA EOOD shall issue a tax invoice for the service rendered after the conclusion of a contract or after the performance of the respective service, unless otherwise agreed.

All payments are made by bank transfer.

The Employer shall not withhold or delay payment of any sums due to PCB with TINSA EOOD by reason of any conflict, counterclaim, objection or appeal.

TINSA EOOD shall be entitled to take all necessary legal and factual actions to collect the unpaid fees before the competent courts.

All agreed amounts shall be paid to TINSA EOOD upon completion of the relevant services, even if the result of the assessment is negative and does not lead to the issue of a certificate, and upon termination of the contract if the service has been previously performed in its entirety.

All certificates shall be provided to the Applicant upon effective payment for the assessment service carried out, unless otherwise agreed in the contract.

12. MANAGEMENT OF FLEXIBLE ACCREDITATION SCOPE

The PCB with TINSA EOOD shall apply a flexible accreditation scope for Safety Assessment Level (SIL) activities.

In this regard, the PCB with TINSA EOOD has fulfilled the requirements of the BSA IA Procedure — BAS QR 32 'Procedure for Flexible Accreditation Scope' by developing and implementing a procedure for managing Flexible Accreditation Scope in its management

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system.

The dated revisions/versions of the standards included in the flexible accreditation scope of the PCB with TINSA EOOD shall be described in the 'List of external documents covered by the PCB accredited scope' published on the website of TINSA EOOD.

In the case of changes in the revisions/versions of the standards referred to as documents against which the assessment is carried out, the PCB with TINSA EOOD will inform the Applicant of these changes as well as of the possible consequences (e.g. change in deadlines for implementation or inability to issue certificates during the transition period to the new revisions/versions).

Within 5 days of identifying the change, the TD of the PCB shall inform the client in writing, via formal correspondence or email, who at the time of identifying the change has submitted a request for assessment against the cancelled/outdated documents/standards.

In the letter, the TD shall specify a reasonable period of time by which to defer implementation of the request depending on the time and resources required to meet the requirements of the updated or superseded standard. The minimum period is 5 working days.

In the event that the client does not agree with the time deferral made, the client shall have the right to refuse the assessment under the relevant standard.

In case the client agrees, he shall undertake to provide the necessary documents, conditions and access to conduct the assessment. In this case, a new certificate will be issued.

13.APPROVAL.

	Name, surname	Position	Revision	Date	Signature
Compiled by	eng. E. Petrov	QM	01	01 August 2023	Signed
Changed by					
Verified by	PhD R. Dimitrov	Expert Assessor	01	01 August 2023	Signed
Approved by	PhD B. Boiadjiev	Technical Director	01	01 August 2023	Signed