PRODUCT CERTIFICATION BODY

by

CSIR - NAL

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3	13, 16, 29, 32, 33, 36, 38, 40, 53-77	Following sections updated based on the NABCB review feedback Section 5, 7, 14, 15, 16, 20, 19 & 25, 26.1, 26.8 to 26.14	17-03-2026
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1. Scope

The **Product Certification Scheme** outlines a comprehensive framework for evaluating and certifying products to meet internationally recognized quality, safety, and performance standards. It ensures that certified products are reliable, safe, and meet both regulatory and market demands across industries.

The scheme specifically applies to the following standards and their related activities:

1. **ISO/IEC 17065 (Design Qualification and Type Approval)**:
   - Ensures the competence, impartiality, and consistency of organizations providing certification services.
   - Certifies that a product's design meets applicable regulatory and industry standards.
   - Covers the **Type Approval** process, which validates prototypes or product models before mass production to ensure compliance with safety and performance criteria.
2. **ISO/IEC 17067 (Guidelines for Product Certification Schemes)**:
   - Establishes the structure and principles of product certification schemes.
   - Details the roles of the certification body, including:
     - Defining the certification process steps (e.g., selection, determination, review, decision, attestation, and surveillance).
     - Ensuring that products maintain conformity with standards throughout their lifecycle.
3. **CENELEC Standards** (Specific Reference: EN 50126-1&2, EN 50128, EN 50129):
   - Addresses **safety, reliability, availability, and maintainability (RAMS)** requirements for safety-critical systems.
   - Guides the risk assessment and hazard identification process for railway applications, safety-critical software, and control systems.

1.1 EN 50126 Standard

EN 50126, titled **"Railway Applications – The Specification and Demonstration of Reliability, Availability, Maintainability, and Safety (RAMS)"**, provides a structured framework for managing the lifecycle of railway systems with a focus on safety and reliability. It is part of the CENELEC standards specifically tailored for the railway industry.

Key Features:

1. **Lifecycle Coverage:**
   EN 50126 addresses all phases of a system's lifecycle, including concept, design, development, operation, maintenance, and decommissioning.
2. **RAMS Principles**:
   - **Reliability**: Ensuring systems perform their intended functions consistently.
   - **Availability**: Maximizing system readiness and uptime.

- **Maintainability**: Ensuring systems are easy to repair and maintain.
- **Safety**: Managing risks to minimize hazards and ensure operational safety.

3. **Risk Management**:
   The standard emphasizes identifying, assessing, and mitigating risks to ensure safety and compliance.
4. **Systematic Approach**:
   It uses a systematic and iterative process to verify and validate that RAMS requirement are met through design, testing, and operational monitoring.

Applications:

EN 50126 is widely used in the railway industry to certify the safety and reliability of:

- Rolling stock (trains, wagons, locomotives).
- Railway signalling and control systems.
- Infrastructure like tracks and stations.

Benefits:

- Ensures passenger and operational safety.
- Promotes reliability and efficiency in railway systems.
- Helps comply with regulatory requirements for railway safety.

1.2 EN 50128 Standard

EN 50128, titled **"Railway Applications – Communication, Signaling, and Processing Systems – Software for Railway Control and Protection Systems,"** specifies requirements for developing and maintaining software used in safety-critical railway applications. It is part of the CENELEC standards for ensuring software safety in railway systems.

Key Features:

1. **Safety Integrity Levels (SILs)**:
   - Defines **Safety Integrity Levels (SIL 0 to SIL 4)** to classify the criticality of software, with SIL 4 being the most critical.
   - The rigor of the development process increases with the SIL level.
2. **Development Lifecycle**:
   - Outlines a structured software development process, including specification, design, implementation, testing, validation, and maintenance.
   - Requires traceability throughout the lifecycle to ensure all safety requirements are met.
3. **Risk Management**:
   - Emphasizes hazard identification and risk mitigation for software failures.
   - Includes measures like fail-safe design and robust error handling.
4. **Verification and Validation (V&V)**:

- Mandates thorough testing and review at each development stage to ensure compliance with safety requirements.
- Independent assessment is required for higher SIL levels.

Applications:

- Control systems for trains (e.g., Automatic Train Control).
- Signalling systems and interlockings.
- Embedded software in safety-critical railway components.

Benefits:

- Ensures the reliability and safety of software in railway systems.
- Minimizes risks of software failures that could lead to accidents or disruptions.
- Promotes compliance with international railway safety regulations.

1.3 EN 50129 Standard

EN 50129, titled **"Railway Applications – Communication, Signaling, and Processing Systems – Safety-Related Electronic Systems for Signaling,"** specifies the safety requirements for electronic systems used in railway signaling. It is part of the CENELEC standards designed for safety-critical railway systems.

Key Features:

1. **Safety Integrity Levels (SILs)**:
   - Defines **SIL levels (SIL 0 to SIL 4)** to classify the safety-criticality of electronic systems, with SIL 4 being the highest.
   - Higher SIL levels require more rigorous safety assessments and validations.
2. **Safety Case Development**:
   - Requires the creation of a **Safety Case**, a structured document providing evidence that the system meets safety requirements.
   - The Safety Case includes:
     - Risk assessments.
     - System architecture and design.
     - Validation and verification results.
     - Maintenance and operational procedures.
3. **Hazard Management**:
   - Focuses on identifying, analyzing, and mitigating hazards throughout the system's lifecycle.
   - Ensures that residual risks are acceptable.
4. **Lifecycle Focus**:
   - Addresses safety at all stages, from concept and design to operation and decommissioning.
5. **Independent Assessment**:

- Requires external safety audits to validate compliance, particularly for higher SIL levels.

Applications:

- Railway signalling systems (e.g., interlocking systems, level crossings).
- Control systems for train movements.
- Safety-critical electronic systems used in railways.

Benefits:

- Ensures the safety and reliability of electronic signalling systems.
- Reduces risks of accidents caused by system failures.
- Promotes compliance with railway safety regulations and standards.

2. Scheme Owner

The **Product Certification Scheme** is owned and managed by the **CSIR-National Aerospace Laboratories (CSIR-NAL)**, a premier research and development (R&D) institution located in Bengaluru, Karnataka, India. The organization plays a pivotal role in overseeing, implementing, and maintaining the certification scheme.

About CSIR-NAL

- **Full Name**: Council of Scientific and Industrial Research - National Aerospace Laboratories (CSIR-NAL).
- **Location**:
  HAL Old Airport Road, Kodihalli, Bengaluru, Karnataka 560017, India.
- **Type of Institution**:
  A constituent laboratory of CSIR, dedicated to cutting-edge R&D in the field of aerospace engineering and allied technologies.
- **Reputation and Expertise**:
  - Recognized globally for its contributions to aerospace engineering and certification frameworks.
  - Known for developing standards and protocols for safety-critical industries like aerospace, railways, and defence.

3. Objectives

The **Product Certification Scheme** is designed to achieve several key objectives that ensure product safety, reliability, quality, and market acceptance as per the CENELEC standards. By providing a structured framework for conformity assessment, the scheme supports manufacturers, regulators, and consumers.

To define the Certification process for ISO/IEC 17065: 2012- Independent Safety Assessment of Railway System.

Primary Objectives

1. **Compliance with ISO/IEC 17065 Requirements**
   - Ensure that the Product Certification Body adheres to the principles outlined in ISO/IEC 17065, which defines the general requirements for bodies certifying products, processes, and services.
   - Guarantee impartiality, transparency, and consistency in certification activities.
   - Promote uniformity in the certification process to avoid conflicts of interest and ensure trust in the certification system.
2. **Building Consumer Trust**
   - Provide independent third-party verification of product quality, enabling consumers to trust certified products.
   - Assure end-users that certified products meet rigorous safety, reliability, and performance standards.
   - Enhance confidence in the brand and reputation of manufacturers that comply with certification requirements.
3. **Facilitating Market Acceptance and Regulatory Compliance**
   - Ensure that products comply with relevant national and international regulations, including safety, environmental, and quality requirements.
   - Help manufacturers achieve smooth entry into global markets by aligning products with widely recognized standards such as CENELEC (e.g., EN50126, EN50128, EN50129).
   - Support adherence to regional directives, such as European Railway Directives, enabling products to meet the demands of competitive and regulated markets.
4. **Promoting Safety and Risk Mitigation**
   - Identify and address potential hazards during the design, manufacturing, and operational phases of the product lifecycle.
   - Enhance public safety by ensuring that certified products undergo thorough risk assessments and meet established safety standards.
   - Reduce the likelihood of accidents, failures, and recalls by mandating compliance with safety-critical system requirements.
   -
   - Establish consistent benchmarks for product performance, reliability, and maintainability.
   - Certify that products can function as intended under various operational and environmental conditions.
   - Increase operational efficiency and reduce downtime by promoting robust product designs and manufacturing practices.

4. Abbreviations

Table 1: Abbreviation

SL. NO.	ABBREVIATIONS	EXPANDED FORM
1.	ALD	Aerospace Electronics & Systems Division
2.	BEL	Bharat Electronics Limited
3.	BHEL	Bharat Heavy Electronics Limited
4.	CAB	Conformity Assessment Body
5.	CEL	Central Electronics Limited
6.	CEMILAC	Centre for Military Airworthiness and Certification
7.	CENELEC	European Committee for Electro technical Standardization
8.	CSIR	Council of Scientific and Industrial Research
9.	DMRC	Delhi Metro Rail Corporation
10.	FMEA	Failure Mode and Effect Analysis
11.	FTA	Fault Tree Analysis
12.	GTRE	Gas Turbine Research Establishment
13.	GST	Goods and Services Tax
14.	IEC	International Electro technical Commission
15.	IIT	Indian Institute of Technology
16.	ISA	Independent Safety Assessment
17.	ISO	International Organisation for Standardization
18.	NABCB	National Accreditation Board for Certification Bodies
19.	NAL	National Aerospace Laboratories
20.	OEM	Original Equipment Manufacturer
21.	PAN	Permanent Account Number
22.	QA	Quality Assurance
23.	QMS	Quality Management System

24.	R&D	Research and Development
25.	RAMS	Reliability Availability Maintainability and Safety
26.	RCMA	Regional Centre for Military Airworthiness
27.	RDSO	Research Design and Standards Organization
28.	SIL	Safety Integrity Level
29.	SOP	Standard Operating Procedures
30.	TAN	Tax Deduction and Collection Account Number
31.	V&V	Verification and Validation

5. Application and Quotation Process

The applicant must specify the certification for which the product or system is being submitted. The prospective stakeholder is required to provide complete and accurate information in the application form to enable preparation of a quotation.

CSIR-NAL will review the application to determine whether it meets the defined eligibility criteria. Only applications that are fully completed and include all necessary supporting documents will be considered. If the criteria are met, CSIR-NAL will prepare and send a proposal to the stakeholder for the requested certification. If the criteria are not fulfilled, or if CSIR-NAL lacks prior experience with the stakeholder 's specific requirements, the stakeholder will be informed, and the request will be declined for further evaluation.

The proposal will be formulated based on the information provided by the stakeholder, in accordance with CSIR-NAL's procedures and applicable regulations.

CSIR-NAL reserves the right to modify the proposal if discrepancies are found between the submitted and actual information.

The proposal will be accompanied by the applicable terms and conditions and a draft contract. Upon acceptance of the proposal, a formal contract shall be signed by both parties—CSIR-NAL and the stakeholder. The contract will define the terms and conditions for the use of the certification logo and the certificate. After completion of the evaluation process, the Independent Safety Assessment (ISA) body issues the assessment report along with the certification to Research Designs and Standards Organisation (RDSO). The certificate carries the ISA logo; however, the ISA does not permit the use of its logo by any certified client. The use of the ISA logo is strictly restricted to the issuance of the report and certificate by the product certification body to RDSO.

The certification body to ensure that it has the necessary competence and capability before accepting certification requests involving unfamiliar product types, standards, or certification schemes. This verification is carried out during application review to confirm availability of competent personnel, resources, and evaluation capability. The decision to undertake such certification activities is supported by documented justification and maintained as part of certification records. The certification agreement has been provided in section 26.12.

The Certification Body shall provide information, upon request, regarding the validity and status of any certificate issued. Any interested party may request verification of certification validity by submitting a request through the official email address of the ISA Certification Cell. Upon receipt of such request, the Certification Body shall verify the certification details and provide information limited to publicly releasable data, including client name, certification scope, certificate number, validity period, and certification status. Confidential information related to evaluation results, technical documentation, or proprietary data shall not be disclosed.

6. ISA Assessment Process

For Independent Safety Assessment and Certification, the following steps shall be undertaken:

- Step 1: Early Design Assessment CSIR-NAL shall review the safety-related elements within the planning documents at the onset of the design phase to ensure foundational safety requirements are being addressed from the beginning.
- Step 2: Design Assessment CSIR-NAL shall evaluate the safety analyses and methodologies adopted during the design phase to verify compliance with applicable standards and best practices.
- Step 3: Manufacturing & Installation Assessment CSIR-NAL shall assess the implementation of the system and subsystems through a review of test plans, test specifications, and other relevant documentation to ensure alignment with safety objectives.
- Step 4: Integration, Testing & Commissioning CSIR-NAL shall conduct a Safety Validation to confirm, through examination and objective evidence, that all functional requirements related to safe system performance—including the successful implementation of hazard mitigation strategies identified during earlier phases—have been satisfied.
- Step 5: Operation & Maintenance Assessment CSIR-NAL shall validate the preparedness for operations and maintenance by reviewing the operation manual, maintenance manual, and maintenance management system. This ensures the procedures adequately safeguard personnel, passengers, and third parties throughout the system's operational lifecycle.
- Step 6: Trial Run Evaluation CSIR-NAL shall assess the effectiveness and completeness of routine and emergency procedures during trial operations of the system or section under review.

- Step 7: Final Certification and Evaluation Report Upon completion of all assessment stages and its independent review, CSIR-NAL will issue a Certificate of Acceptance or Rejection, accompanied by a detailed Safety Assessment Report documenting findings and conclusions.

6.1 Major Activities

- Requirement and design review and provide feedback
- Review the V&V activities and provide feedback
- Review the QA activities and provide feedback
- Review the CM activities and provide feedback
- Software validation and report generation
- Hardware validation and report generation
- System validation and report generation
- Audit of End-to-End field testing
- Generation of Evaluation report
- Independent evaluation of the report
- Issue an ISA certificate

The client has to address the feedback provided by the ISA/Certification body.

7. Certification Activities (Conformity Assessment Functions)

This section provides a structured process for certifying products according to established standards like CENELEC and ISO/IEC. The process ensures that every stage of certification is thorough and addresses all necessary quality and safety requirements.

- **Step 1: Selection**

Purpose: Identify the product to be certified and establish the assessment framework.

- **Evaluation Criteria**:
  - Products are chosen based on customer specifications (e.g., RDSO, DMRC, or specific client requirements).
  - Compliance is assessed against relevant CENELEC standards, specifically EN50126-1&2 (RAMS), EN50128 (software safety), and EN50129 (safety-critical systems).
- **Safety Assessment Proposal**:
  - A detailed ISA (Independent Safety Assessment) project proposal is created.

- This proposal includes a **Safety Assessment Plan**, outlining the scope of evaluation and identifying safety-critical functions and potential risks.

➢ **Step 2: Determination**

Purpose: Perform detailed assessments to collect evidence of conformity.

- **Key Activities**:
  - **Reviews**: Examination of documents, such as safety plans, design blueprints, verification reports, test results, and inspection records, ensuring compliance with both design and regulatory standards.
  - **Logic Analysis**: Evaluate design and operational logic for consistency and error minimization.
  - **Testing**:
    - Laboratory tests to validate performance, durability, and safety under simulated conditions.
    - Field tests under real-world conditions to ensure operational reliability.
  - **Inspection**: On-site inspection of manufacturing facilities and production processes to confirm compliance with quality management standards.
  - **Design Evaluation**: Comprehensive review of the technical specifications and blueprints to identify flaws or deviations.
  - **Process Audits**: Examination of production processes to ensure that best practices are followed, and product consistency is maintained.
  - **Additional Methods**:
    - Simulations to predict system performance under abnormal conditions.
    - Failure mode analysis to identify and mitigate potential risks.

➢ **Step 3: Review**

Purpose: Assess and consolidate evidence collected in the determination phase.

- Certification experts conduct a detailed evaluation of:
  - Design specifications.
  - Testing and inspection reports.
  - Process audit findings.
  - Any identified risks or non-conformities.
- Compliance with CENELEC standards and SIL (Safety Integrity Levels) requirements is verified.

➢ **Step 4: Decision**

Purpose: Make a formal judgment on whether the product meets the certification requirements.

- **Decision-Making Process**:
  - Certification body evaluates all findings and determines conformity with CENELEC and customer-specified requirements.
  - If the product meets the standards, a **Certificate of Conformity** is issued.
  - If the product does not meet the requirements. The decision is made not to grant certificate and reasons are documented.
  - If non-conformities are found and the client expresses in continuing the certification, corrective actions are outlined, and re-assessment is conducted after implementation as per PCS and the client must fulfil all additional requirement documents to continue the certification process.

➢ **Step 5: Attestation**

Purpose: Officially certify the product's conformity with safety and performance standards.

- **Certificate of Conformity**:
  - This document acts as proof of compliance and is granted only after a successful safety assessment based on the CENELEC guidelines.

➢ **Step 6: Surveillance**

Not Applicable

Note: The ISA activity is done for the product one time.

8. Certification Scheme Types

The certification scheme offers several structured approaches tailored to different product categories, industries, and risk levels. Each type is designed to ensure products meet rigorous safety, reliability, and quality standards while providing flexibility for manufacturers to align with the most suitable certification process.

8.1 Process-Based Certification

This type of scheme is focused on evaluating and certifying the entire manufacturing and production process to ensure consistent quality and compliance.

- **Key Activities**:
  - **Initial Type Testing**:
    - Testing the product prototype or initial design to verify its compliance with applicable standards.
    - Includes performance testing, durability checks, and safety assessments under simulated conditions.
  - **Factory Audits**:

- Periodic audits of manufacturing facilities to ensure processes remain compliant with certification requirements.
- Evaluates production workflows, quality management systems, and adherence to best practices.

- **Market Surveillance Testing**:
  - Conducting random testing of products from the market to ensure continued compliance post-certification.
  - Identifies any deviations caused by production changes or inconsistencies.
- **Continuous Quality System Audits**:
  - Regular evaluations of the manufacturer's quality management system (e.g., ISO 9001 compliance).
  - Ensures that quality standards are integrated into the overall organizational processes.

- **Suitability**:
  - Ideal for high-risk or safety-critical products where process consistency is essential.
  - Commonly applied in industries like aerospace, automotive, railways, and medical devices.
- **Advantages**:
  - Provides robust assurance of product quality and safety.
  - Ensures long-term compliance through ongoing monitoring and audits.
- **Challenges**:
  - Resource-intensive and costly due to the need for frequent audits and surveillance.

9. Documentation Requirements

Documentation is a critical component of the Product Certification Scheme. It ensures that all processes, requirements, and compliance efforts are well-documented, verifiable, and traceable. This section outlines the essential documentation required for both the certification scheme and manufacturers.

9.1 Scheme Documentation

The Scheme Owner must maintain comprehensive documentation to define, regulate, and facilitate the certification process.

1. **Specifications, Standards, and Procedures**:
   - **Purpose**: Establish clear rules, criteria, and workflows for certification activities.
   - **Examples**:
     - Certification procedures outlining the steps for selection, determination, review, and decision-making.
     - Testing standards and performance benchmarks.

- Guidelines for audits, inspections, and surveillance activities.

2. **List of Applicable Standards**:
   - **Purpose**: Specify the standards against which the product will be evaluated.
   - **Examples**:
     - EN50126-1&2 (RAMS lifecycle processes), EN50128 (safety-critical software), EN50129 (safety-related systems).
     - ISO/IEC 17065 and ISO/IEC 17067 for general certification body requirements.
3. **Application Forms and Checklists**:
   - **Purpose**: Facilitate a systematic approach to the certification process.
   - **Examples**:
     - Application forms for manufacturers to initiate the certification process.
     - Checklists for conformity assessment, covering aspects like design evaluation, safety testing, and process audits.
4. **Records Management Procedures**:
   - **Purpose**: Ensure proper storage, retrieval, and updating of certification records for accountability and traceability.
   - **Examples**:
     - Document retention policies.
     - Guidelines for updating records after surveillance audits or re-certification.

9.2 Management System Documentation

In accordance with ISO/IEC 17065, The Certification Body has established, documented, implemented, and maintained a management system capable of supporting and demonstrating consistent conformity of its certification activities.

The management system documentation includes:

- A documented Division Quality Manual describing the scope of certification activities
- Documented Product Certification Scheme, Describing policies and objectives, impartiality, procedures and work instructions, certification schemes, certification processes, and decision-making arrangements and control of the management system

All management system documents are controlled as per documented procedures for control of documents and control of records. The documentation is reviewed periodically and updated to reflect changes in certification schemes, regulatory requirements, and accreditation criteria.

The Certification Body ensures that relevant management system documentation is available to authorized personnel and that obsolete documents are prevented from unintended use. Any changes/modification in certification scheme is duly updated and uploaded in "https://www.nal.res.in/en/isa" and current clients will be informed about this via e-mail. Documented evidence is maintained and made available to NABCB during assessments.

9.3 Manufacturer Documentation

Manufacturers seeking certification must provide detailed documentation about their products, processes, and compliance efforts.

1. **Product/System Lifecycle Data**:
   - **Purpose**: Demonstrate how the product has been developed, tested, and maintained throughout its lifecycle.
   - **Examples**:
     - Development milestones, including concept, design, and testing phases.
     - Risk assessments, hazard logs, and mitigation plans.
     - Maintenance schedules and decommissioning plans.
2. **Product Specifications and Test Reports**:
   - **Purpose**: Provide evidence that the product meets specified performance and safety criteria.
   - **Examples**:
     - Technical specifications and blueprints.
     - Test results from performance, durability, and safety testing.
     - Reports on environmental testing, such as resistance to temperature, humidity, and vibration.
3. **Quality Management System (QMS) Documentation**:
   - **Purpose**: Demonstrate that the manufacturer adheres to consistent and controlled quality processes.
   - **Examples**:
     - ISO 9001 certification and QMS policies.
     - Documentation of manufacturing workflows, standard operating procedures (SOPs), and quality control checklists.
     - Records of supplier audits to ensure input material quality.
4. **Records of Corrective Actions**:
   - **Purpose**: Show that the manufacturer has addressed non-conformities and implemented improvements.
   - **Examples**:
     - Root cause analysis reports for identified defects.
     - Action plans and evidence of corrective measures, such as process adjustments or design modifications.
     - Logs of recurring issues and measures taken to prevent them in the future.
5. **Safety Assessment Reports**:
   - **Purpose**: Provide detailed evaluation of safety-critical components and systems.
   - **Examples**:
     - Safety Integrity Level (SIL) assessment reports.
     - Validation of compliance with EN50126, EN50128, and EN50129.

- Results of Failure Mode and Effect Analysis (FMEA) or Fault Tree Analysis (FTA).

10. Maintenance and Improvement

The **Product Certification Scheme** is not static; it requires continuous review, enhancement, and adaptation to remain relevant and effective. Maintenance and improvement activities ensure that the scheme evolves alongside technological advancements, regulatory updates, and stakeholder needs.

10.1 Annual Review of the Certification Scheme

A systematic review of the certification scheme is conducted annually to identify areas of improvement and incorporate necessary updates.

- **Key Activities**:
  - **Standards Updates**:
    - Regularly monitor changes to international standards such as ISO/IEC 17065, ISO/IEC 17067, EN50126, EN50128, and EN50129.
    - Update the scheme to reflect new requirements, methodologies, or benchmarks introduced in these standards.
  - **Regulatory Changes**:
    - Align the scheme with updated regulations or directives, such as European Railway Directives, aviation safety requirements, or environmental compliance mandates.
  - **Technology Integration**:
    - Identify advancements in testing technologies, safety assessments, or production methods that can enhance certification processes.
- **Examples of Improvements**:
  - Incorporating automated testing technologies for quicker and more accurate safety assessments.
  - Adding new guidelines for evaluating emerging technologies such as autonomous systems or AI-powered control systems.

10.2 Feedback Collection from Stakeholders

Stakeholders play a critical role in identifying gaps and providing suggestions to improve the certification scheme.

- **Stakeholders Involved**:
  - **Manufacturers**: Provide insights into challenges faced during the certification process or areas where clarity is needed.
  - **Consumers**: Offer feedback on product quality, reliability, and safety based on real-world usage.
  - **Regulators**: Share updates on compliance trends and enforcement challenges.

- **Certification Bodies**: Report on common issues encountered during assessments or audits.

- **Feedback Mechanisms**:
  - Conduct surveys, workshops, or forums to gather input from stakeholders.
  - Analyse customer complaints or incident reports to identify recurring issues.

10.3 Documentation Updates

To ensure clarity and accuracy, the documentation supporting the scheme is regularly updated.

- **Key Updates**:
  - Revise certification procedures, checklists, and templates to reflect the latest standards and requirements.
  - Add detailed explanations or case studies to improve understanding of specific processes.
  - Maintain a log of all updates to provide a clear history of changes.
- **Example Updates**:
  - Modifying test report formats to include additional safety metrics or risk factors.
  - Expanding application forms to collect more comprehensive product information.

11. Benefits of Certification

The Product Certification Scheme offers a range of tangible and intangible benefits that contribute to the success of manufacturers, ensure public safety, and promote trust in certified products. These benefits extend across the entire product lifecycle, impacting design, production, market acceptance, and end-user satisfaction.

11.1 Confidence in Product Quality and Safety

Certification assures stakeholders that products meet established quality, safety, and performance benchmarks.

- **For Consumers**:
  - Reduces the risk of purchasing unsafe or substandard products.
  - Provides reassurance that the product has undergone independent third-party verification.
  - Enhances confidence in the durability, reliability, and overall performance of the product.
- **For Regulators**:
  - Demonstrates compliance with safety and environmental standards, reducing the need for additional oversight.
  - Simplifies enforcement by relying on verified certification processes.

- **For Manufacturers**:
  - Acts as a mark of excellence, showcasing adherence to international standards and best practices.

11.2 Promotes Market Access and Competitiveness

Certification opens doors to both domestic and international markets by ensuring compliance with globally recognized standards.

- **Facilitates Export**:
  - Aligning products with international standards (e.g., ISO/IEC, CENELEC) ensures acceptance in global markets.
  - Reduces trade barriers by meeting the regulatory requirements of different countries or regions.
- **Improves Marketability**:
  - Certified products stand out in competitive markets, giving manufacturers an edge over uncertified competitors.
  - Certification logos or marks enhance brand reputation and consumer trust.
- **Enables Entry into Regulated Markets**:
  - Mandatory in industries like railways, aerospace, medical devices, and automotive, where safety and reliability are critical.

11.3 Enhances Brand Reputation and Trust

Certification strengthens the manufacturer's reputation and fosters trust among customers, stakeholders, and partners.

- **Proof of Excellence**:
  - Certification demonstrates a commitment to quality, safety, and innovation.
  - Helps build long-term relationships with customers and partners by establishing trust.
- **Risk Mitigation for Consumers**:
  - Consumers view certified products as safer, more reliable, and better quality compared to uncertified alternatives.

11.4 Reduces Risk of Failures, Recalls, and Liabilities

Certification processes include thorough testing, audits, and risk assessments, minimizing the likelihood of failures or safety incidents.

- **For Manufacturers**:
  - Reduces costs associated with product recalls, warranty claims, and redesigns.

- Identifies potential risks early in the product lifecycle, preventing costly downstream issues.

- **For Regulators and Insurers**:
  - Certification reduces liability risks, as certified products are less likely to cause accidents or harm.
  - Easier to ensure products that meet stringent safety and quality standards.

11.5 Strengthens Stakeholder Relationships

Certification promotes transparency and accountability, strengthening relationships with stakeholders, including suppliers, partners, regulators, and consumers.

- **For Suppliers**:
  - Encourages a quality-focused supply chain, as components and materials must meet certification requirements.
- **For Partners and Investors**:
  - Increases confidence in the company's ability to produce high-quality, compliant products.
- **For Regulators**:
  - Simplifies oversight and ensures public safety through rigorous, standardized certification processes.

11.5.1 Stakeholder Details

Table 2: Stakeholder Details

Sl. No	Stakeholder	Roles
1.	Gas Turbine Research Establishment (GTRE)	Customer
2.	Central Electronics Limited (CEL)	Customer
3.	Bharat Heavy Electricals Limited (BHEL)	Customer
4.	Bharat Electricals Limited (BEL)	Customer
5.	Indian Institute of Technology, Madras	Customer
6.	South Western Railway	Customer
7.	TUV	CENELEC certification training academy
8.	Punyam Academy	IEC/ISO certification training academy
9.	Research Design and Standard Organization (RDSO)	Regulatory Body
10.	Delhi Metro Rail Corporation (DMRC)	Regulatory Body
11.	RCMA-CEMILAC	Regulatory Body
12.	IIT, Delhi	Sub-Contractor
13.	Humming Bird	Sub-Contractor

14.	Hewlett-Packed Global Soft Limited	Sub-Contractor

Table 3: Project Details

Sl. No	Project Name	OEM	Customer	V&V	ISA	Approving Authority
1.	MSDAC	CEL	Indian Railways	Hewlett-Packed Global Soft Limited	CSIR-NAL	RDSO
2.	DMI	BEL, Kotdwara	DMRC	BEL, Ghaziabad	CSIR-NAL	DMRC
3.	ngSSDAC	CEL	Indian Railways	IIT-Delhi	CSIR-NAL	RDSO
4.	ngHASSDAC	CEL	Indian Railways	IIT-Delhi	CSIR-NAL	RDSO
5	nMSDAC	CEL	Indian Railways	IIT-Delhi	CSIR-NAL	RDSO
6	MSDAC with S002 Field unit software	CEL	Indian Railways	Humming Bird	CSIR-NAL	RDSO
7	Multi Section Digital Axle Counter (MSDAC) with CCC-DFSK card and S001 field unit software	CEL	Indian Railways	IIT-Delhi	CSIR-NAL	RDSO
8	Multi Section Digital Axle Counter (MSDAC) with CCC-DFSK card and S002 field unit software	CEL	Indian Railways	IIT-Delhi	CSIR-NAL	RDSO

12. ISA Activities mapped with CENELEC Standards

Table 4: ISA Activities

Phase	Stages	ISA Activities
Step-1 **Planning phase (It's mapping with CENELEC EN50126 standard)**	**Initial contractor plan** • Software Quality Assurance Plan • Software Configuration Management Plan • Software Verification Plan • Software Validation Plan • Software Maintenance Plan • System Safety Plan • Organization Chart • SIL Competence Development and Training Plan • SIL Allocation Approach paper • Application Preparation Plan • RAM Plan • RAM Validation Plan	1.Assessment of the initial plans 2.Plan assessment report
Step-2 **Development Phase (It's mapping with CENELEC EN50128**	**Design Assessment** • Software Design Specification • Application Requirements Specification • Software Requirements Specification • Software Integration Test Specification • Software Component Test Specification • Software Design Specification • Interface Design Document	1.This assessment report shall be based on assessment activities on completion of detailed design phase for each stage of the project compiled in Detailed Design Specific Application Safety case 2.Design Assessment Report

standard)	• System Architecture and Requirement Allocation	
Step-3 **Testing Phase (It's mapping with CENELEC EN50128 standard)**	**Test Assessment** • Software/Hardware Integration Test Report • Software Maintenance Verification Records/Record • Deployment Verification Report • Software Integration Test Report • Software Component Test Report • System Acceptance Test Report • Application Test Report • Software Deployment Manual • Application Preparation Verification Report • Software Quality Assurance Verification Report • Software Requirements Verification Report • Software Architecture Design Verification Report • Overall Software Test Report • Software Validation Report • Tools Validation Report • SRD Verification Report • Safety Case	1.ISA shall perform Audit as well as Testing at site location and supply audit report based on the findings. 2.Testing and Hazards closeout process report
Step-4 **Safety Case & Certificate Phase**	Progress Report, Evaluation Report, Independent checking of the evaluation report, & ISA Certificate	1.Assessment of Client identified hazards and its mitigation. 2.Physical implementation safety case assessment report for each stage. 3.Preparation of Evaluation report. 4. Independent checking of the evaluation report. 5.ISA Certificate with Evaluation Report.

13. Management Review

The Management Review is conducted by Top Management twice in a year to review management system and covers all elements of the certification activities, including compliance with applicable standards, certification scheme requirements, and regulatory obligations. Inputs to the review include results of internal and external audits, feedback from clients and interested parties, complaints and appeals, effectiveness of corrective actions, review of impartiality risks, performance of outsourced activities, adequacy of resources, and changes affecting the management system.

Outputs of the Management Review include decisions and actions related to improvement of the management system, enhancement of certification processes, mitigation of risks to impartiality, resource requirements, and opportunities for continual improvement (Refer section 26.8). Documented records of the Management Review are maintained and retained as objective evidence and are made available for accreditation body assessment.

Plan Management Review

(Schedule at planned intervals – Twice in a year)

↓

Identify Participants

(Top Management, Quality Manager, relevant personnel)

↓

Collect Inputs

- Previous MR actions
- Internal & external audit results
- Complaints / appeals
- Impartiality risks
- Outsourced activities
- Resources & competence
- Changes & risks

Conduct Management Review Meeting

(Evaluate suitability, adequacy, effectiveness & impartiality)

Decisions & Actions Defined

- System improvements
- Certification process improvements
- Impartiality safeguards
- Resource needs
- Policy/procedure changes

Document Management Review Minutes (ISA Team)

(Responsibilities & timelines assigned)

Approve by Top Management (ISA Head)

Implement Actions

Monitor & Verify Effectiveness

Maintain Records

14. Internal Audit

It is a management system audit in which organization plans, establishes implements and maintains audit program, including its frequency, methods, and responsibilities, planning requirements and reporting. Internal audit takes into consideration:

- Importance of the activities concerned
- Changes affecting the organization
- The results of previous audits.

Internal audit ensures to the management that the system is implemented. It is also known as a self-audit, as this is done by internal trained personnel (Internal Auditor). Internal Auditor, operating under an ISO/IEC 17065-accredited certification framework, shall conduct systematic and impartial reviews of each ISA project to verify compliance with the applicable standards, including EN 50126-1 & 2 (RAMS), EN 50128 (software safety), and EN 50129 (safety-critical systems). Any deviation or non-compliant identified during the course of the audit shall be subjected to a structured verification process to establish its authenticity and significance. Where such findings are validated, the responsible entity shall be formally required to provide justification, implement appropriate corrective actions within a defined timeframe, and, where applicable, introduce preventive measures to mitigate recurrence. In cases of non-resolution or inadequate response, the matter shall be escalated in accordance with established procedures. The auditors will not review their own work

All findings, justifications, corrective and preventive actions shall be documented, retained, and monitored to ensure effective closure, complete traceability, and sustained compliance with the prescribed standards, thereby maintaining the integrity and credibility of the certification framework. For every audit ensure that the previous audit quires are closed. The audit will be performed for every single project/once in every six months. Based on the predefined checklist the QA audit will be performed and audit records will be generated.

The internal auditor work shall be reviewed by ISA head on project basis to ensure the quality of internal audit is effective.

Criteria for Internal Auditors

- Auditors should act independently
- Expertise in safety critical and similar standards
- Certified auditor with knowledge in ISO/IEC 17065
- Meets the criteria for NABCB Accreditation Body requirements for Internal auditor
- Internal auditor shall have knowledge of PCB standard
- Internal auditor shall have auditing experience

Internal Audit Procedure

Prepare Annual Audit Schedule

↓

During scheduling, two things should be taken care of:

- Period of Audit (At least once in six months)
- Status and importance of the activity

↓

Prepare Audit Plan, at least one week in advance. Consider:

Department, Date and Time, Scope of Audit, Name of Auditee, Name of Auditor

↓

During selection of auditor, followings care should be taken:

- He/she should have undergone training on Internal Management system audit
- He/she should be independent from the activity being audited.

↓

Audit plan is circulated amongst the Auditor and Auditee

↓

Actual audit is executed by the auditor as per the date and time of audit. Auditor is given clause-wise and document-wise audit checklist by ensuring auditing of all applicable clauses during the audit.

↓

Auditor conducts audit and verifies all obligations with respect to documented management system.

↓

Auditor notes down his findings in Audit Report and identifies non- compliances, if any

↓

Internal Audit Nonconformity Report (NCR) is prepared by Auditor and nonconformity is got acknowledged by auditee

↓

Auditor submits audit non conformity to management system coordinator along with clause - wise document-wise audit checklist

↓

Management system coordinator reviews the following:

- Auditing of all applicable clause
- Details of nonconformity

↓

Management system coordinator communicates with the auditee and decides planned date for actions and sends copy of NCR.

Auditee takes appropriate time to take actions and informs auditor to close the NCR

Auditor verifies the action taken by auditee and based on satisfactory compliance NCR is closed.

Auditor submits the closed NCR to management system coordinator.

Management system coordinator files the copy in audit file and gives copy of closed NCR to the auditee for his/her reference.

Audit findings are discussed in the management review meeting

Assessment Checklist

Table 5: Checklist for Internal Audit

Check	Check for	Department Area
Management System Manual, Procedures, Forms (Documented Information)	Availability, Current copy in use, Approving Authority, Amendments carried out, approval for amendments.	ISA Certification
Specification issued by standard	Availability, Current copy in use, Understanding	ISA Certification

15. Control of Documents

Control of documents is the process by which the Certification Body ensures that all documents forming part of the management system are approved, reviewed, updated, and made available at points of use to ensure consistent and effective implementation of certification activities in accordance with ISO/IEC 17065 and applicable certification scheme requirements.

All management system documents, including policies, procedures, manuals, formats, and external documents, are reviewed and approved for adequacy by authorized personnel prior to issue. Documents are identified with a unique document number, revision status, issue date, and approval authority. A master list or document control system is maintained to ensure that only current versions are available for use. The control of documents ae track in the form of issue numbers and revision numbers whereas the change of issue numbers due to major releases which affects scope, intent and requirements of systems. The Minor changes are caused due to minor changes such as typographical errors, clarifications which does not affect the intent of process, scope and requirements.

The Certification Body ensures that all information required to be publicly available in accordance with ISO/IEC 17065 Clause 4.6 is formally controlled through documented procedures, published "https://www.nal.res.in/en/isa", and periodically reviewed for accuracy.

Identify Document

(Policy / Procedure / Format / External Document)

↓

Prepare Document

(Authorized Personnel)

↓

Review Document

(Adequacy & Compliance Check)

↓

Approve Document

(Designated Authority)

↓

Issue & Distribute Document

(Controlled Distribution)

↓

Update Master Document List

(Version / Revision Status)

↓

Make Document Available

(Latest Version at Point of Use)

↓

Control of External Documents

↓

Document Change Control

↓

Control Obsolete Documents

(Remove / Mark "OBSOLETE")

↓

Access and Availability in Public domain

↓

Maintain Document Control Records

16. Control of Records

Control of records is the process by which the Certification Body ensures that all records related to certification activities and the management system are identified, maintained, protected, retrievable, and retained in a controlled manner to provide objective evidence of conformity with ISO/IEC 17065 and applicable certification scheme requirements.
Records are generated during the performance of certification activities and shall be legible, accurate, complete, and traceable. The Certification Body defines responsibilities for the creation, storage, and protection of records to ensure confidentiality, integrity, and prevention of unauthorized access and time line of retention of documents shall be 10 years from the date of issue of certificate. After retention time elapses, the artefacts are destroyed by shredding the documents and deleting the released software.

Identify Records

↓

Generate Records

↓

Review & Approval

(if applicable)

↓

Store Records

(Physical / Electronic)

↓

Protect Records

(Confidentiality & Integrity)

↓

Retrieve Records

↓

Retain Records

(As per retention policy for 10 Years)

↓

Dispose Records Securely (by shredding)

(After retention period)

17. Certificate Validity and Retention:

The validity of the issued certificate shall remain in force for the entire lifetime of the product or system, or until such time that any modification in scope is implemented. All associated documentation shall be maintained in strict compliance with applicable regulatory requirements and shall be retained for a minimum period of 10 years to ensure complete traceability and accountability. When reference document is made out of certificate it should not deviate from requirement. When existing certifications are relied upon to omit any certification activities, the certification body must clearly reference those certifications and document the technical justification for omission. This ensures transparency, consistency, and technical validity of the certification process. The documented justification is retained in records and provided to the client upon request.

The defined retention period is established to provide adequate evidence for regulatory reviews, audits, and safety investigations that may arise during or subsequent to the operational life of the product or system. The client shall ensure that such records are readily accessible, securely archived, and safeguarded against loss, damage, or unauthorized alteration for the entirety of the prescribed retention period. RDSO reserves the authority to suspend or withdraw the certificate. When a certification is suspended, withdrawn, or terminated, the client must immediately stop using all advertising or promotional materials that mention the certification. Misuse of the certificate will lead to withdrawal of the certificate. The scope extension is applicable if the product undergoes requirement changes with impact analysis. There is no repetition of a project with the same client; however, the same project may be carried out for a different client. suspension, reduction, or termination of certification are not applicable to ISA activities.

In case of requirement changes of certified product/ suspension, the client will re-approach the ISA with impact analysis. The impact analysis shall be verified with reference to the following

1. List of changes
2. Impact on safety aspects of the product

3.Assessment and evaluation will be performed as per PCS section 6.3, 6.4 and 6.5.
4. Records will be maintained as per section 16.

17.1 Reproduction of Certificate

Reproduction of Certificate is not applicable.

18. Retention of client Artefacts

The client shall keep records of the product lifecycle (EN-50126,50128) in their configuration as mentioned in both Configuration Management (both software and hardware), Quality Assurance (both software and hardware).

19. Impartiality

The certification body ensures that all certification activities are conducted impartially and remains fully responsible for safeguarding impartiality in every stage of its operations. The certification body shall establish an Impartiality Committee to ensure objectivity and prevent any conflicts of interest in certification activities. The committee comprises of balanced representation of relevant stakeholders

- ISA Head
- Research Designs and Standards Organisation (RDSO)
- Delhi Metro Rail Corporation (DMRC)
- Central Electronics Limited (CEL)
- Bharat Electronics Limited (BEL)

The committee is responsible for reviewing policies, processes, and certification decisions to safeguard impartiality. The committee shall meet at planned intervals, typically once in six months, or earlier if required due to any identified risk, complaint, or appeal related to impartiality. During these meetings, risks to impartiality are identified, analyzed, and mitigated, and any undue commercial, financial, or other pressures are evaluated. The committee may also review specific cases such as complaints or appeals impacting impartiality. All findings and recommendations are documented, and necessary actions are implemented within defined timelines, ensuring continuous monitoring, transparency, and compliance with ISO/IEC 17065 requirements.

The certification body actively identifies and invites significantly interested parties, including clients, regulators, users, industry associations, and consumer representatives, to participate in the mechanism.

Define Scope of Certification Activities

↓

Identify Stakeholders & Interested Parties

↓

Assess Risks to Impartiality

↓

Implement Controls to Prevent Conflicts of Interest

↓

Establish Organizational Structure to Ensure Independence

↓

Assign Responsibilities Clearly

↓

Monitor and Review Impartiality Measures Regularly

↓

Corrective Actions if Impartiality is Compromised

If the top management of the Certification Body does not act on or rejects the recommendations of the Impartiality Committee, the Head of the Impartiality Committee is authorized to take independent action. This may include notifying the Accreditation Body (NABCB), relevant regulatory authorities, or other appropriate stakeholders ensuring confidentiality is maintained. The organization shall formally document such decisions with clear technical or regulatory justification. The issue shall be recorded in the risk assessment system and reviewed during management review to promote transparency, ensure accountability, and prevent recurrence.

20. Complaints and appeals

The certification body has a process for receiving, evaluating, and deciding on complaints and appeals, with all such cases recorded, tracked, and resolved appropriately below. The certification body shall maintain a record of documents to manage complaints and appeals in a timely, impartial, and transparent manner. When a complaint or appeal is received, it is first formally registered and acknowledged to the complainant/appellant within 2–5 working days. The issue is then assigned to competent personnel who were not involved in the original activity or certification decision or employed by a client to ensure impartiality. An investigation is conducted by reviewing relevant records, audit reports, and supporting evidence, typically within 10–15 working days. If required, corrective actions and root cause analysis are initiated. For appeals related to certification decisions, The RDSO, an approving

authority to ISA will conduct reviews the case and evaluates the justification for the appeal. After completing the evaluation, the certification body communicates the final decision to the complainant/appellant generally within 30 days from the date of submission. All records of the complaint or appeal, including investigation results, decisions, and corrective actions, are documented and maintained to ensure transparency, traceability, and compliance. if an appeal is raised against the Head of the ISA, the complaint shall be handled through an independent and impartial process by Head of Organization to avoid any conflict of interest.

21. Non-discriminatory Conditions

The certification body operates its policies and procedures in a non-discriminatory manner, ensuring that no applicant is unfairly restricted from accessing its services. Access to the certification process is open to all organizations whose activities fall within the defined scope of operations, regardless of their size, association, or number of certifications already obtained. The body does not impose undue financial, membership-based, or other restrictive conditions that could limit fair participation. Certification activities are confined strictly to the scope of certification and relevant requirements, without introducing unnecessary barriers. Applications may only be declined for justified reasons such as illegal activities or repeated non-conformances, but otherwise the process remains impartial, transparent, and non-discriminatory.

22. Confidentiality

The certification body ensures that all information obtained or generated during the certification process is managed with strict confidentiality. Through legally enforceable agreements, it safeguards proprietary information of clients and only discloses it when the client has made it publicly available, or when disclosure is required by law or authorized under contractual arrangements. In such cases, unless prohibited by law, the client or concerned party is informed in advance via mail/post about the release of information. Furthermore, any data collected from external sources, such as regulators or complainants, is also treated as confidential. The certification body establishes and maintains secure procedures for handling, storing, transmitting, and protecting this information to ensure that confidentiality is never compromised.

23. Corrective Actions

The certification body has a documented procedure as mentioned in section 6.1, 13, 14 & 19 for identifying and managing nonconformities. Root causes are analysed according to the concerns raised, and corrective measures are taken and implemented in a timely manner. The corrective actions are verified by the originator (Internal Auditor, MRM committee, impartiality committee, report evaluator) the effectiveness of these actions is reviewed to prevent recurrence. Refer 26.8, 26.9 and 26.10 for action taken results.

24. Preventive Actions

The Certification Body has established and implemented documented procedures for identifying potential nonconformities and taking preventive actions to eliminate their causes before they occur. Preventive actions are initiated based on analysis of risks, trends identified from certification activities, internal audits, management reviews, complaints, appeals, and feedback from interested parties. The need for preventive action is evaluated to ensure that actions taken are appropriate to the potential impact on certification integrity and compliance with ISO/IEC 17065 and the applicable certification scheme.

Preventive Action Procedure

1. Identification of Potential Nonconformity

Potential nonconformities shall be identified through:

- Risk assessments
- Impartiality analysis

2. Risk Evaluation

Identified risks shall be evaluated based on:

- Probability
- Impact on impartiality, competence, or consistency

3. Preventive Action Planning

Preventive actions may include:

- Process improvements
- Additional controls
- Training and awareness
- Procedure updates

4. Implementation and Monitoring

Preventive actions shall be implemented and monitored to ensure risk mitigation.

5. Effectiveness Review

Effectiveness shall be reviewed during:

- Internal audits
- Management reviews

25. External Resources (Outsourcing)

External Resource is Not Applicable to the current certification scheme. All evaluation, review, and certification decision activities are performed internally by competent personnel of the certification body. The certification body does not outsource any evaluation activities such as testing, inspection, or management system auditing to external bodies. Therefore, the requirements related to outsourcing to bodies conforming to ISO/IEC 17025, ISO/IEC 17020, or ISO/IEC 17021 do not apply. Notwithstanding the above, the certification body retains full responsibility for ensuring the competence, impartiality, and objectivity of all personnel involved in evaluation activities, and this arrangement is periodically reviewed to ensure continued compliance with ISO/IEC 17065.The Management has been decided that not to outsource any certification activities.

26. Annexure

26.1 ISA Certificate

Independent Safety Assessment Certificate

Reference of the Certificate:

Issued to

Company Name

By

National Aerospace Laboratories, India, CSIR-NAL, Bengaluru

Object of Assessment	**Project Title**
Applicant	**Applicant Name**
Manufacturer	**Manufacturer Name**
Assessment Requirements	Applicable CENELEC Standards
Assessment Results	On the grounds of the evidences reported in the reference documents mentioned in XXX, the Assessor considers that the activities performed by Manufacturer Name have been planned and managed in compliance with the CENELEC standards (Applicable Standards) for the safe revenue operation of Project The detailed assessment results can be found in the ISA Assessment Report (Applicable Assessor documents) that is integral part of this Certificate.
System configuration (Software or Data version)	System and software configuration information
The following conditions and limits of use apply	Applicable conditions and limitations
Annex	As applicable
Documentation accompanying this certificate	As applicable
Date of issue	Issuing Date
Validity of Certificate	For the entire lifetime of the product or system, or until any change in scope is implemented or any revision to the applicable regulatory standards occurs

(Ctrl)

Assessor Signature with Seal

26.2 Client Request Template

Independent Safety Assessment

Client Details

To

National Aerospace Laboratories, India, CSIR-NAL, Bengaluru

Organization Details	
Project Name	
Project Details	
Project Cost	
Applicant Details	
TIN no:	
Assessment Requirements	
SIL Level	
Document List	
Application Date	
Validity Period	

Dr. Manju Nanda
ISA Head
(Generic Signalling Systems)

Client Signature :

Date :

Remarks :

26.3 Competence Requirement

ZERTIFIKAT ◆ CERTIFICADO ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ

TÜV SÜD South Asia

CERTIFICATE

The Academy Division's Certification Body for Persons of

TÜV SÜD South Asia Pvt. Ltd. hereby certifies that

Sachin Chauhan

has successfully completed

Functional Safety Engineer: Certification program on

Railway RAMS & Functional Safety in accordance

(EN 50126-2017, EN 50128-2011, EN 50129- 2018)

Held on: 07th June 2022 to 09th June 2022

Certificate No.:IN/15758/166482

Vishal Nerurkar
Sr. Vice President
TÜV SÜD South Asia Pvt. Ltd.

Dipti Dubal
Course Manager
Functional Safety

Anil Kumar Ammina
Trainer

Date: 12.07.2022
Place: Ahmedabad, India

TÜV SÜD South Asia Pvt. Ltd. • TÜV SÜD Group • Off. Saki Vihar Road • Saki Naka • Andheri (East) • Mumbai - 400 072 • India

TÜV

26.4 Reports Template

26.4.1 Safety Assessment Plan

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26.4.2 Initial Contractor Plan

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26.4.3 Design Assessment

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26.4.4 Test Assessment

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26.4.5 Evaluation Report

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26.5 Master list of Documents

Categories	Document Name
ISO/IEC 17065	Memorandum/Article of Association
	Declaration on Shareholder(s) and directors(s)
	Master List of Documents (with issue and/or revision status)
	Quality Manual
	Procedure Manual/ Procedures including technical documents, formats, checklists etc (Product Certification Scheme)
	Business Liability Insurance
	Letter of authorization from management to act behalf of the CAB
	Latest Audited Financial Statement (P/L Statement)
	PAN card for Legal Entity
	TAN for Legal Entity
	GST certificate
	Sample of the Mark of the applicant and proof of its ownership rights
	Recently issued 'Inspection Reports/ Certificates/ V&V Statement' (few as specimen)
	Sample of the Inspection/ Certificate/ V&V agreement with clients (as specimen)
	Duly filled Cross Reference Matrix [BCBF-010] for ISO/IEC 17065
Independent Safety Assessor	Safety Assessment Plan
	Initial Contractor Plan
	Design Assessment
	Test Assessment
	Evaluation Report
	Evaluation Certificate
Customer documents	Work Order for development, supply and installation of Product/System
	Software Quality Assurance Plan
	Software Configuration Management Plan
	Organization Chart
	SIL Competence Development and Training Plan
	Application Preparation Plan
	Safety Plan
	Software Maintenance Plan
	Software Verification Plan
	RAM Plan
	Documentation QA Plan
	RAM Validation Plan

Quality Process for Development
SIL Allocation Approach paper
Application Requirements Specification
Software Requirements Specification
Software Design Specification
Software Integration Test Specification
Software Component Test Specification
Interface Design Document
System Architecture and Requirement Allocation
Software Deployment Manual
Deployment Verification Report
Software/Hardware Integration Test Report
Software Maintenance Verification Records/Record
Software Integration Test Report
Software Component Test Report
System Acceptance Test Report
Application Test Report
Application Preparation Verification Report
Software Quality Assurance Verification Report
Software Requirements Verification Report
Software Architecture Design Verification Report
Overall Software Test Report
Software Validation Report
Tools Validation Report
SRD Verification Report
Software Integration Verification Report
Safety Case
Software Source Code and supporting documentation Verification Report
Application Data/Algorithms Verification Report
Acceptance Test Procedure
Programming Instructions
Factory Acceptance Test
Part List
General Assembly
System Traceability Matrix
Release Note

26.6 Information Supplied to CAB

Sl. No	Document Name
1	Work Order for development, supply and installation of the Product
2	Software Quality Assurance Plan
3	Software Configuration Management Plan
4	Organization Chart
5	SIL Competence Development and Training Plan
6	Application Preparation Plan
7	Safety Plan
8	Software Maintenance Plan
9	Software Verification Plan
10	RAM Plan
11	Documentation QA Plan
12	RAM Validation Plan
13	Quality Process for Development of Project
14	SIL Allocation Approach paper
15	Application Requirements Specification
16	Software Requirements Specification
17	Software Design Specification
18	Software Integration Test Specification
19	Software Component Test Specification
20	Interface Design Document
21	System Architecture and Requirement Allocation
22	Software Deployment Manual
23	Deployment Verification Report

Sl. No	Document Name
24	Software/Hardware Integration Test Report
25	Software Maintenance Verification Records/Record
26	Software Integration Test Report
27	Software Component Test Report
28	System Acceptance Test Report
29	Application Test Report
30	Application Preparation Verification Report
31	Software Quality Assurance Verification Report
32	Software Requirements Verification Report
33	Software Architecture Design Verification Report
34	Overall Software Test Report
35	Software Validation Report
36	Tools Validation Report
37	SRD Verification Report
38	Software Integration Verification Report
39	Safety Case
40	Software Source Code and supporting documentation Verification Report
41	Application Data/Algorithms Verification Report
42	Acceptance Test Procedure
43	Programming Instructions
44	Factory Acceptance Test
45	Part List
46	General Assembly
47	System Traceability Matrix
48	Release Note

26.7 Description of Scopes (PCB)

IAF Scope	Product/Processes/Services covered under the scope	Normative Documents Standard(s)/Regulation(s), etc.	Description of Scheme
IEC/ISO 17065	PCB, Metro Signalling Projects/System, Generic Signalling Products/Systems	DQM, Stake holders , Projects, Scheme Documents, EN50126-1&2 (RAMS), EN50128 (software safety), and EN50129 (safety-critical systems).	Scheme 5, The Product Certification Scheme is designed to achieve several key objectives that ensure product safety, reliability, quality, and market acceptance as per the CENELEC standards. By providing a structured framework for conformity assessment, the scheme supports manufacturers, regulators, and consumers. To define the Certification process for ISO/IEC 17065: 2012- Independent Safety Assessment of Railway System.

26.8 Management Review Meeting (MRM) template

CSIR-NAL
Management Review Meeting (MRM)

1. General Information

Date	
Time	
Location	

2. Participants

Name	Designation	Role

3. Management Review Inputs

3.1 Follow up actions from previous MRM

Follow up action items:

S. No	Action Item	Status (Addressed / Pending)	Details	Responsible person & Due date

3.2 Internal audit results

Discussion points:

Action Items:

S. No	Action Item	Status (Addressed / Pending)	Details	Responsible person & Due date

3.3 Status of corrective and preventive actions

Discussion points:

Action Items:

S. No	Action Item	Status (Addressed / Pending)	Details	Responsible person & Due date

3.4 Feedback from clients and interested parties

Discussion points:

Action Items:

S. No	Action Item	Status (Addressed / Pending)	Details	Responsible person & Due date

3.5 Complaints and appeals status

Discussion points:

Action Items:

S. No	Action Item	Status (Addressed / Pending)	Details	Responsible person & Due date

3.6 Impartiality Feedback

Discussion points:

Action Items:

S. No	Action Item	Status (Addressed / Pending)	Details	Responsible person & Due date

3.7 Changes affecting management system

Discussion points:

Action Items:

S. No	Action Item	Status (Addressed / Pending)	Details	Responsible person & Due date

4. Management Review Points (Additional to above)

(Improvement to overall effectiveness of system and processes, certification body related to the fulfilment of this International Standard, resource needs discussion)

Action Item Summary

Action Items:

S. No	Action Item	Status (Addressed / Pending)	Details	Responsible person & Due date

5. Next Meeting Schedule

- Date:
- Time:
- Location:

(Name) **(Name)** **(Name)** **(Name)**

(Name) **(Name)** **(Name)** **(Name)**

26.9 Risk Assessment template

As part of the ISO/IEC 17065, risk assessment will be carried out as per the template given below. Based on the risk assessment the mitigation will be planned and executed.

CSIR-NAL

Impartiality Risk Assessment

1. General Information

Prepared by	
Date	

2. Impartiality Risk Register

Sl. No	Impartiality Risk Type	Situation / Scenario in CB	How Risk Can Arise	Impact on Certification Credibility	Existing Controls	L (1–5)	S (1–5)	Risk (L×S)	Additional Control Required	Responsibility	Review Frequency	Status
1	Self-interest											
2	Self-review											

Sl. No	Impartiality Risk Type	Situation / Scenario in CB	How Risk Can Arise	Impact on Certification Credibility	Existing Controls	L (1–5)	S (1–5)	Risk (L×S)	Additional Control Required	Responsibility	Review Frequency	Status
3	Advocacy											
4	Over-familiarity											
5	Intimidation											
6	Competition											

Note: Risk Rating Criteria

Likelihood (L)

Rating	Description
1	Rare
2	Unlikely
3	Possible
4	Likely
5	Almost Certain

Severity (S)

Rating	Description
1	Negligible
2	Minor
3	Moderate
4	Major impact on credibility
5	Severe impact on impartiality / accreditation

Risk Criteria (L*S)

Risk (L*S)	Risk Category
1 – 6	Minor Risk
7 – 14	Moderate Risk
15 – 25	Major Risk

(Name) **(Name)** **(Name)** **(Name)**

(Name) **(Name)** **(Name)** **(Name)**

26.10 Internal Audit plan

Internal Audit Plan

Auditee _____

Type of Audit: Initial Office Assessment, Product Certification

Location: ASDG, ALD, CSIR-NAL

Internal Audit criteria:
- Compliance with defined assessment scheme
- Compliance with ISO/IEC 17065 and applicable standards
- Impartiality and independence of assessment
- Competence of personnel
- Adequacy of assessment planning and execution
- Documentation and record control
- Adherence to agreed scope

Scope of Internal Audit: The internal audit covers all ISA assessment activities and management system processes to ensure compliance with ISO/IEC 17065, applicable standards, and the defined assessment scheme.

Internal Audit Team _____

Internal Audit dates _____

Day 1	Date
Time	**Activity**
	Opening meeting. Review of: • Quality manual • Certification procedures • Impartiality policy
	Check **Impartiality Compliance** • Conflict of interest declarations • Impartiality committee records • Independence of decision-making
	Review **Competence** • Auditor qualifications • Training records • Authorization matrix Verify **Risk Assessment** • Risk register • Impartiality risks included
Day 2	**Date**
Time	**Activity**
	Project Review Select a project file: • Application review • Applicable standards identified • Assessment plan prepared?
	Evaluation & Decision • Assessment report completeness • Findings properly recorded • Non-conformities addressed • Certification decision taken by independent authority

	Compliance Checks • Certification status(valid/suspended) • Directory of certified products • Complaint/appeal records • Record traceability

Notes:

1. The above program is tentative and may be changed based on audit findings & availability of personnel
2. Please keep ready in advance the following information and provide the same to the assessment team during OA.
   - Client List and Number of Certifications issued for the scheme.
   - List of evaluators for scope.
   - List of technical reviewers and certification decision makers.
   - List of ISA staff and position and organization chart showing names.
   - List of Board and/or Committee Members (as applicable) showing names
3. Certification files as well as personnel files may be taken up for review during the assessment at any time. Keep ready list of files and list of personnel sectors wise.
4. All relevant documents & records should be made available during assessment on time. In case there is delay in completing the entire assessment for inordinate delay in providing documents and/or for any other factors, assessment can be extended beyond planned dates and days with mutual consent.
5. All relevant / key personnel should be available during assessment and arrangements to be made for telephonic/ web link discussion with certification personnel on field assignments.

Date:

26.11 Planning Template

CSIR-NAL

Planning Template

1. Planning Information

Item	Details to be Filled
Certification Body Name	
Scheme / Product Category	
Planning Period	

2. Understanding Context of the Organization

Sl. No	Aspect	Description
1.	Internal issues affecting certification activities	
2.	External issues (regulatory, market, accreditation)	
3.	Interested parties (regulators, clients, consumers, accreditation body)	
4.	Scope of certification services	

3. Risks and Opportunities Planning

Sl. No	Risk / Opportunity	Source	Impact	Likelihood	Risk Level	Control / Action Planned	Responsible	Target Date

4. Objectives Planning

Sl. No	Objective	Measurable Target	Method to Achieve	Resources Required	Responsible	Target Date	Monitoring Method

5. Resource Planning

Sl. No	Resource Type	Requirement	Availability	Action Required	Responsible
	Personnel (evaluators, reviewers, decision makers)				
	Infrastructure				
	IT / Software tools				
	External experts / subcontractors				

6. Competence Planning

Sl. No	Role	Required Competence	Existing Competence	Gap	Training / Action Planned	Target Date

7. Impartiality Safeguarding Planning

Sl. No	Identified Threat	How it Can Occur	Existing Control	Additional Control Planned	Responsible

8. Operational Planning for Certification Process

Sl. No	Stage	Activity Planned	Procedure Reference	Responsible	Records to be Maintained
	Application Review				
	Review				
	Evaluation / Testing				
	Certification Decision				
	Recertification				

9. Outsourcing / Subcontracting Planning

Sl. No	Activity Outsourced	Criteria for Selection	Monitoring Method	Records	Responsible

10. Communication Planning

Sl. No	What to Communicate	To Whom	Method	Frequency	Responsible
	Scheme requirements	Clients			
	Changes in requirements	Clients			
	Impartiality mechanism	Stakeholders			
	Complaints & appeals process	Public			

11. Monitoring and Measurement Planning

Sl. No	What to Monitor	Method	Frequency	Responsible	Record

12. Internal Audit Planning

Sl. No	Area to be Audited	Frequency	Auditor	Record

13. Management Review Planning

Sl. No	Input to Management Review	Source	Responsible

14. Change Management Planning

Sl. No	Change Identified	Impact on Certification	Action Planned	Responsible	Completion Date

15. Record Retention Planning

Sl. No	Record Type	Retention Period	Storage Location	Responsible

(Name) **(Name)** **(Name)** **(Name)**

(Name) **(Name)** **(Name)** **(Name)**

26.12 Certification Agreement Template

This Certification Agreement for the project titled '**Solid State Block Proving by Axle Counter (SSBPAC)**' is entered into by and between ISA organisation (CSIR-NAL), and Client for the purpose of providing certification services in accordance with applicable certification schemes, standards, accreditation requirements, and regulatory obligations, as follows:

1. Compliance with Certification Requirements

The Client agrees to comply with all applicable certification requirements, certification scheme rules, standards, policies, and procedures established by the Certification Body. The Client shall implement and maintain all arrangements necessary for evaluation, surveillance, reassessment, and investigation of complaints related to the certified scope.

2. Provision of Information and Access

The Client shall provide the Certification Body with timely access to relevant premises, personnel, processes, products, services, documents, records, and other information necessary for the performance of certification activities, including audits, surveillance, reassessment, and complaint investigations.

3. Changes Affecting Certification

The Client shall promptly notify the Certification Body of any changes that may affect conformity with certification requirements, including but not limited to: legal, commercial, or organizational status; ownership or management; organizational structure; operational processes or systems; key personnel; and scope of certified activities.

4. Suspension, Withdrawal, or Reduction of Scope

The Certification Body reserves the right to suspend, withdraw, or reduce the scope of certification in cases of non-compliance with certification requirements, misuse of certification marks or claims, or failure to meet contractual obligations. Upon suspension, withdrawal, or reduction of certification, the Client shall immediately cease all use of certification claims, certificates, logos, marks, or references related to the affected certification status.

5. Complaints and Appeals

The Client shall have the right to submit complaints and appeals regarding certification decisions or activities of the Certification Body. All complaints and appeals shall be handled in accordance with the Certification Body's documented procedures.

6. Confidentiality and Information Disclosure

The Certification Body shall maintain the confidentiality of all Client information obtained during certification activities, except where disclosure is required by law, regulatory authorities, accreditation bodies, or applicable certification scheme requirements. Where disclosure is required, the Client shall be informed unless prohibited by law.

7. Certification Status and Public Information

The Certification Body may make publicly available information regarding the Client's certification status, scope of certification, validity, suspension, withdrawal, or reduction of certification as required by accreditation or regulatory requirements.

8. Acceptance of Agreement

Certification activities shall commence only upon acceptance and execution of this Agreement by both parties.

For ISA:	**For Client:**
Dr. Manju Nanda	Name
ISA & Chief Scientist, CSIR-NAL	Designation
Signature:	Signature:
Date:	Date:
Official Seal :	Official Seal:

26.13 ISA Performance evaluation

The performance of the ISA team shall be monitored by the parent organization (CSIR-NAL) through its internal assessment mechanism.

Name	
ISA Role	
No of projects handled in last year	
No. of projects completed in time frame	
No. of delayed projects justified & accepted	
No. of complaints/defects received	
Feedback from stakeholder	
• Feedback from client (Very Good / Good/ Fair/ Poor)	
• Feedback from certification body (Very Good / Good/ Fair/ Poor)	
• Feedback from regulatory body (Very Good / Good/ Fair/ Poor)	
Interaction with stake holder	
Interaction with management committee	

26.14 Report Evaluation Template

NATIONAL AEROSPACE LABORATORIES	**Review Report of Evaluation Documents**	**Reference Document:** xx/xxx/xx **Issue: xx Rev.: xx** **Date:**
		Review Report No.:
	Applicant Name:	**Evaluation date:**
		Review date:
		Page xx

Scope of the Review:

1. …..
2. …..
3. …..

Basis of the Review:

BS EN ISO/IEC 17065:2012

Sl. No.	Review Query	Review Result	Observations with evidences
[A] Administrative Completeness of Evaluation			
2.	Are applicant details (name, address, scope) complete and consistent?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
4.	Are Product identification (model, type, version) clearly defined?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
6.	Are applicable certification scheme and standards specified?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
8.	Are evaluation dates and locations recorded?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
10.	Are authorized Field assessor(s) name, designation, and signature	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	

	present in the evaluation reports?		
12.	Is report version control and traceability ensured?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
[B] Scope / Standard covered during Evaluation			
2.	Are applicable regulatory requirements clearly listed?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
4.	Does scope of evaluation matches certification request?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
6.	Are any exclusions or limitations clearly mentioned and justified?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
8.	Has the assessor carried out correct interpretation of requirements during the evaluation?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
[C] Evaluation Methodology			
2.	Are the evaluation methods defined (inspection, testing, audit, sampling)?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
4.	Are sampling plan appropriate and justified?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
6.	Are standards for Test methods recommended appropriately?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
8.	Have the Test conducted as per the recommended standards?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
10.	Has the accreditation of the labs conducting testing verified?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
12.	Have the traceability of measurements ensured?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	

[D] Evaluation Results			
2.	Are all required reports / tests / Inspections furnished and are completed in all aspects?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
4.	Are results recorded clearly and accurately?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
6.	Have the Pass/fail criteria applied correctly?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
8.	Are the results consistent with the standard requirements?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
10.	Have all the deviations explained?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
[E] Non-Conformity (NC) during Evaluation			
2.	Are NCs clearly described with objective evidence?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
4.	Have NC classification (major/minor) appropriately done?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
6.	Has the applicant provided Root cause analysis reports?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
8.	Are all the corrective actions defined and implemented?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
10.	Have the field assessor (s) verified the effectiveness of the corrective actions?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
12.	Are any open NCs clearly highlighted?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
[F] Consistency & Objectivity of Evaluation			
2.	Are findings evidence-based	☐ Satisfactory	

	i.e. no subjective bias is present in the evaluation report?	☐ Unsatisfactory ☐ Not Applicable	
4.	Are the evaluation conclusions aligning with recorded data?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
6.	Are there any contradictions observed within the evaluation reports?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
8.	Has the Field Assessor (s) maintained impartiality?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
[G] Risk assessment during Evaluation			
2.	Have the risks related to product use identified?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
4.	Have the impacts of non-conformities assessed?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
6.	Are Safety, regulatory, and functional risks considered during the evaluation process?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
8.	Are there any critical risks unresolved?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
[H] Certification Scheme Requirements verified during Evaluation			
2.	Have the scheme-specific requirements fulfilled?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
4.	Have the evaluation requirements defined?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
6.	Have the product Marking/labelling requirements verified?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
8.	Are the conditions under which the certification is valid stated clearly?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	

[I] Documentation & Traceability of Evaluation			
2.	Are the supporting documents attached (test reports, photos, records) with the evaluation report?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
4.	Is the traceability from findings → evidence → conclusion clearly established through the evaluation report?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
6.	Are the document retention requirements verified?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
[I] Field Assessor'(s) conclusions			
2.	Is clear conclusions provided by the field assessor based on the end to end evaluation?	☐ Satisfactory ☐ Unsatisfactory ☐ Not Applicable	
4.	Is the justification for recommendation provided by the field assessor adequate?	☐ Satisfactory ☐ Unsatisfactory ☒ Not Applicable	
[J] Report Evaluator's Disclaimers			
2.	Is Independent review conducted?		
4.	Have all checklist items verified?		
6.	Have any gaps or clarifications raised?		
8.	Are review comments documented?		
[H] Report Evaluator's Comments and Recommendations			
2.	Reviewer' comments		
4.	Compliance status of the Evaluation Report by the Field Assessor.	☐ Fully Compliant ☐ Compliant with conditions ☐ Not Compliant ☐ Outstanding risks clearly highlighted	
6.	Recommendation for decision on Certification	☐ Approve Certification ☐ Approve with condition	

		☐ Reject Certification