SCHEME DOCUMENT FOR SAFETY CERTIFICATION OF SAFETY RELATED ELECTRONIC SYSTEM FOR SIGNALLING

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0.1 Approval and Issue

Prepared and Reviewed by: _____

Management Representative

Approved by: _____

Chief Executive Officer/ GM Technical

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0.3 Amendment Record

Revision No.	Date of Revision	Nature of Revision	Page Ref	Remarks
Issue 02, Rev 00	12.05.2025	Equipment's scope added		

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1.0 CERTIFICATION OF SAFETY RELATED ELECTRONIC SYSTEM FOR SIGNALLING

1.1 Purpose

This scheme provides Third Party Product Safety Certification to SAFETY RELATED ELECTRONIC PRODUCTS / SYSTEM FOR SIGNALLING for Railways on the basis Independent Safety Assessment as per EN Standards.

1.2 Definitions:

Definitions of terms given in Quality Management System, Full Certification Scheme documents of the Product Certification Body and those given in EN Standards at 1.2 above apply.

In addition, following terms are explained for better understanding of this document

VERIFIER

Engineering Person / Team verifying Phase wise RAMS Performance of the documentation/ product with a view to bring about design changes for meeting compliance standards.

VALIDATOR

Engineering Person / Team validating the design, processes and documentation for the RAMS Performance of the product against the compliance standards.

Independent Safety Assessor (ISA)

Engineering Person / Team assigned by the Certification Body independent of the applicant / manufacturer with a view to independently assess the Safety Related Electronic System for Signaling base on records presented including those of verification done by the VERIFIER, validation done by the VALIDATOR, Design Information, Manufacturing Process Inspection and assessment / witness of work / testing, as may be need for the case

ISA is responsible for making recommendations about Safety acceptance and Certification of Safety Related Electronic System for Signaling.

ISA could be assigned right at design conceptualization stage till compliance for the new products and may get engaged otherwise at any stage based on the work stage and the request of the applicant to meet the goal of assessing compliance/fitness of the product / systems to take up independent safety function .

1.3 How the scheme operates:

The Steps involved in this Safety Certifications Scheme are:

a. To arrive at its recommendations, ISA shall identify

i) A list of documents / records to be verified
ii) A list of activities to be witnessed
iii) The need for Assessment of manufacturing facilities
iv) Need to associate any expert at any activity during the certification process

1.4 Who can apply:

This scheme is open to Manufacturers / Brand Owners (Controlling Design and Production), in India or overseas location. The Applicant should be a legal entity, who would be required to execute the Certification Agreement, and shall be responsible for all legal obligations related to certification. Certification is granted individually for product at designated manufacturing unit.

CIIPL reserves the right to verify the antecedents of the applicant, and to reject the application in case the same are not found to be fit for certification.

2.0 Certification Scope:

2.1 Safety Related Electronic System for Signalling

Specific coverage of products is done based on details (type, grade, class, size ranges etc) that are evaluated during the Certification process.

2.2 Applicable Compliance Standards

Following Standards apply for Safety certification of Safety Related Electronic System for Signalling. Other requirements / as specified by any Regulator for a product may also be complied to, when requested.

EN50126-1:2017	Railway Applications- The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Generic RAMS Process
EN50129:2018	Railway Applications -Communication Signaling and Processing System- Safety Related Electronic System for Signaling
EN50128:2011 +A1+A2:2020	Railway Applications -Communication Signaling and Processing System

2.3 Technical Areas presently covered:

- Track Side Equipment
- Rolling Stock Mounted Equipment
- Generic Equipment

2.4 Equipment's used under this scope:

- Onboard Equipment:

KAVACH (Indian Railways Automatic Train Protection System)
GOA2,
Safety Certification Standards.
EN 501216-1: 2017, EN 50128-: :2011-A1-A2-2020, EN 50129-2018, and India Rail specification RDSO/SPN/196/2020 Ver. 4.0

- Wayside Equipment:

1. AXLE Counter, EN 501216-1: 2017, EN 50128-: :2011-A1-A2-2020, EN 50129-2018, and India Rail specification RDSO/SPN/176/2013 Ver 3.0 an RDSO/SPN/177/2012 Ver 3.0
2. Electronic Interlocking (IXL), EN 501216-1: 2017, EN 50128-: :2011-A1-A2-2020, EN 50129-2018, and India Rail specification RDSO/SPN/203/2011 Ver1.0 and RDSO-SPN-192-2019 Ver 2.0
3. Solid state Block proving BY Axle Counter (digital), EN 501216-1: 2017, EN 50128-: :2011-A1-A2-2020, EN 50129-2018, and India Rail specification RDSO/SPN/175/2005 Ver 1.0
4. Block Proving by Axle Counter using UFSBI (BPAC), EN 501216-1: 2017, EN 50128-: :2011-A1-A2-2020, EN 50129-2018, and India Rail specification RS:S: 105/2012 Ver. 0
5. Failsafe Network Multiplexer (FNmux), EN 501216-1: 2017, EN 50128-: :2011-A1-A2-2020, EN 50129-2018, and India Rail specification RDSO/SPN/211/2022 Ver 1.0
6. LED Signal Lamps for Main Colour Light Signals for Railway Signalling, EN 501216-1: 2017, EN 50128-: :2011-A1-A2-2020, EN 50129-2018, and India Rail specification RDSO/SPN/199/2010 Rev. 1.1
7. LED Signal Lighting Units for Subsidiary Colour Light Signals (Route, Shunt, Calling On and Tunnel Signals) For Railway Signalling, EN 501216-1: 2017, EN 50128-: :2011-A1-A2-2020, EN 50129-2018, and India Rail specification RDSO/SPN/153/2023 Rev. 5.0
8. Universal Fail-safe Block Interface (UFSBI), EN 501216-1: 2017, EN 50128-: :2011-A1-A2-2020, EN 50129-2018, and India Rail specification IRS:S:104/2012 Ver. 0

2.5 Certification Marks:

CIIPL allows the use of its Safety Mark for Electronic System for Signaling. The terms of use of the mark are governed by the Certification Agreement.

The agreement clearly defines that it is the responsibility of the applicant to report to the certification body about any changes in aspects of design, manufacturing, installation, trainings etc. that have bearing on the Safety. Any adverse filed reports, end user observations and regulator pointed issues during the Certification period must be reported upon by the applicant to the Certification Body promptly.

3.0 Certification Process:

3.1 Application:

Applicants / an authorized representative of the applicant is required to sign a duly completed application form **(CCS/F 08)** which contains the requisite information;

a) The scope of the desired certification:
   I. Product Nomenclature
   II. Product Standard
   III. Product Description / Declared Performance Ratings
   IV. Model Number

b) Corporate entity, name, address and legal status.

c) Undertaking that the applicant agrees to comply with the requirements for certification and to supply any information needed for evaluation of products to be certified.

d) Manufacturing locations address.

e) Since Scheme of Product Certification operated by Conformity India International is Voluntary Certification, the applicant must specify if any additional regulatory requirements are to be addressed for the Certification to make it acceptable to the end users.

f) Current Stage of evolution of Safety Related Electronic System for Signaling and stage at which involvement of ISA is sought for independent Review

g) List of Records / Documents of Verification, Validation etc. to be made available for demonstration of compliance to requirement of V diagram given in Figure-4 of EN50129:2018, the following documents are mandatory

1) Quality Assurance Plan for the Product
2) Risk Analysis Document
3) Safety Plan
4) RAM Plan
5) Hazard Log
6) Software Quality Assurance Plan
7) Hardware and Software Configuration Management Plan
8) Verification Plan
9) Validation Plan
10) System Requirement Specification which includes Safety Requirement Specification
11) Hardware Requirement specification
12) Software Requirement Specification
13) Hardware Architecture and Design (should be accessible at applicant's premises)
14) Software Architecture and Design (should be accessible at applicant's premises)
15) FMEA Report
16) FMECA Report and Fail Safety Test Report
17) Hardware Module Test specification and Report
18) Software Module Test specification and Report
19) RAM Validation Report
20) Product Life Cycle Phase Verification report up to Manufacturing and Installation Phase documentation
21) Product Life Cycle Validation report up to Manufacturing and Installation documentation
22) Quality Management Report
23) Safety Management Report
24) System Functional Test Report (Integration Test Report) as per Acceptance Protocol approved by RDSO (Railway Authority)
25) Technical Safety Case for the Product including Type Test Report as specified by Railway Product Standards

3.2 Application review:

The request received for grant of certification is submitted to the Project Coordinator.

The application shall be reviewed by Project Coordinator to make a decision if it could be accepted. The case shall be discussed with GM (Tech) or above and if needed a provisional decision to identify an ISA for the job may be made. Views of the ISA may be sought before accepting the application.

On confirmation about acceptance of the job, NDAs and other contractual documents may be signed as needed, and ISA may be formally assigned

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The ISA shall study all the information given in the application for its adequacy to complete the certification process.

Before proceeding with the evaluation by ISA, a review of the application is conducted by Project Coordinator using 'APPLICATION REVIEW FORM' as provided in **CCS/F 11.** ISA is nominated for the duties of Project Assessor as well as Factory Inspection ASSESSOR for RAMS Products. In case there is any deficiency in the application documents, the applicant shall be requested to provide the required information.

3.3 Assessment Process

3.3.1 Initial Assessment:

After acceptance of the application, the ISA shall draw a plan for his engagement with the applicant at appropriate stages. Review of any specific work / activity like Product Design Stage etc. requested before Initial Assessment, shall be taken up by the ISA for respective stage only with a view to assess if the Design / Documents have been verified and validated by the VERIFIER and VALIDATOR respectively to meet the requirements of the applicable standards.

Once overall System is ready for initial Assessment, with a view to evaluate the Quality Management Report generated by Validator, ISA draws the assessment plan, in consultation with the applicant for the initial assessment.

Initial Assessment includes the following activities performed on site:

a) Opening / closing meetings with Applicant's management
b) Credentials/ Competence of the Validator (role defined in Fig 5 of EN50129:2018)
c) Survey of process lines
d) Survey of laboratories / testing arrangements with calibration control
e) Assessment of test equipment functionality through factory tests
f) Survey of storage areas
g) Survey of handling systems
h) Verification of company records relating to incoming materials, process controls, in-process checks, process validation (where applicable), final inspection, Complaints / feedback
i) Verification of competence of company's personnel
j) Evaluation of Applicant's Quality Assurance Plan in relation to product quality levels (in-company and customer end)

Factory Assessment shall be carried out by ISA in accordance with Factory assessment Guidelines document - CIS/OP 11

The ISA shall inform the applicant the results of the initial assessment. Deficiencies observed if any, as well as proposed changes to QAP shall be communicated to applicant in writing and explained during closing meeting. The period for corrective actions for removing the deficiencies shall be agreed with the Applicant.

A follow up inspection may be conducted in case the corrective actions require physical verification. In case the applicant does not remove the deficiencies within a period of one year from date of initial assessment, CIIPL may take a decision to close the application. An applicant is free to apply afresh.

3.3.2 Second Assessment:

a) Based on Successful Initial Assessment, Witness Testing for Safety and Performance is taken up by the ISA. Such evaluation is also feasible to be done by review of documentation for a Technical Safety Case.
b) The ISA has the liberty to seek Witness testing when so needed.

3.3.3 Field Performance Assessment:

After successful Initial Assessment and Second Assessment, product may be released for Field Trails. Normally, filed trials shall be conducted in 2 stages, as follows:

a) Parallel Trial without taking Safety Role for 45 days
b) Stand Alone / Independent Safety Function Trial for 45 Days

Trial at 3.3.3 (b) shall only be undertaken after satisfactory performance of the product in trial at 3.3.3 (a)

Arrangement for Filed trials shall be the responsibility of the applicant. ISA must be involved during such assessment. It shall be the responsibility of the Applicant to fetch a Positive Performance Certificate from authorities under whose jurisdiction the trial has been performed.

3.4 Review:

The Independent Safety Assessment Work of ISA shall be reviewed by Another ISA / Quality Manager who shall be designated as **Project Reviewer** for the purpose

Review shall be for completeness as well as for conformance with requirements mentioned in the Product standard.

3.5 Preparation of Case file:

The ISA shall prepare the Case file for Review. This shall include the following:
a) Application
b) Application Review Record
c) Quality Management Report generated by Validator
d) Factory Inspection Report issued by ISA
e) Evaluation Report generated by ISA
f) Relevant correspondence with applicant evidencing corrective actions taken
g) Recommendations for certification

In case all actions are found to be complete, Project reviewer shall compile the information in the Format recommending grant of Certification **CCS/F 02b.** He shall record a clear recommendation for grant of certification without condition. In case any aspect merits specific attention of the Decision maker, these shall be highlighted.

3.6 Case Review and Decision on certification:

The entire documentation submitted for recommending grant of Certification **CCS/F 02b** shall be reviewed independently by the Project Reviewer. The following shall form the basis for review:

a) The product being recommended is within the scope of certification of CIIPL.
b) Project Assessment has been carried out by person(s) who are authorized as competent.
c) Clear evidence is recorded that no conflict of interest exists between CIIPL and the applicant and the certification personnel involved.
d) The Quality Management Report generated by Validator brings out all relevant aspects that would provide evidence that the applicant has the capability to produce conforming products in the long term.
e) All deficiencies have been appropriately addressed by the applicant and verified by the ISA.
f) The scope recommended is in line with CIIPL's policies.

In case of any doubts or observed short-coming, Project reviewer shall record his observations for clarifications by the ISA.

Project reviewer shall recommend the case for certification decision based on his assessment after reviewing all available evidence. The recommendation may be positive or negative.

Certification decisions shall be made by the General Manager / CEO based on the information and recommendation of the Reviewer. Where necessary, expert's opinion to determine the technical basis for the decision may also be sought.

3.7 Issue of Certificate of Conformity and Mark of CIIPL:

On successful completion of Initial Assessment, the Product may be issued a Provisional Certificate of Conformity with condition that all other phases of Assessment must be completed in a stipulated time as recommended by the ISA. In case of genuine reasons like non-availability of sites for filed trails etc., the Provisional certification may be extended for up to 6 months each time. Provisional Certification would not entitle the applicant to use CIIPL Safety Mark on the Provisionally Certified Products.

The Provisional Certification is issued to enable applicants to make a convincing case for filed trials with appropriate authorities and should not in any way be construed as evidence of full compliance to the Standards.

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On successful completion of all phases of the Assessment, the applicant is issued a Certificate of Conformity, with CII Safety Mark, the related Standard, and the declared type, grade, class, size and any special declarations,) and a restriction of the period for which the certification shall remain valid. This information can be provided in supplements to the Certificate.

The customer is informed the manner in which he is authorized to use the statement of conformity given in the certificate, through a Certification Agreement forwarded along with the Certificate, highlighting the following:

- Validity of Certification. The validity of certification is normally 3 years however the same can be extended based on request of the applicant and continued compliance of the products with the certification requirements.
- The stipulation that the applicant shall implement the agreed QAP
- The stipulation that the Mark of CII shall not be used on any other class of product, than those certified
- The stipulation that the applicant shall keep record of all production on which the Mark of CII shall be applied and to make available such information to CIIPL when requested
- The stipulation that the applicant keeps a record of all complaints relating to compliance with certification requirements and ensures the availability of resolution of complaints to CIIPL at the time of factory inspection.
- To permit entry of CIIPL's assessors to its factory premises and ware-houses for conducting inspection and for taking samples, whether pre-informed or without intimation.
- The consent that CIIPL shall publish information relating to the certification in its certification directory and to make available such information to any person on request
- The stipulation that the applicant shall inform CIIPL of any changes in its legal status, administrative set-up, technical process changes, changes in product, etc
- The stipulation that applicant shall implement any changes in the scheme as and when notified by CIIPL
- The manner in which the Applicant can claim certification of the products for supplying to any customer or in the market place, and where applicable to demonstrate compliance to regulations
- The stipulation that the Applicant shall not issue any misleading statement in respect of the type of certification and the scope
- Conditions under which Certification will be Suspended, withdrawn, cancelled, reduced in scope
- The conditions under which certification shall be renewed
- The conditions for timely payment of certification fees and costs

A copy of the Assessment Report of ISA is also issued to the Applicant. The Certificate is listed in the Certified Applicants Register.

4.0 Surveillance:

Under the Certification Scheme, CIIPL shall undertake the following surveillance activities:

a) At least one surveillance assessment shall be conducted at the applicant site once in a year during which:

i. The factory arrangements including plant, machinery, test set-ups, storage conditions shall be re-verified for continued suitability and for any changes.

ii.The QAP is being fully implemented by the applicant and records are available to evidence the same.
iii.The plant's personnel are competent.
iv.Review of Records maintained by Reviewer and Validator.
v.The correct application of Certification Mark as per CIIPL's guidelines.
vi.Specific Actions of feedbacks received form field installations.
vii.Any Changes to Certified Products

5.0 Renewal of Certification:

The validity of certification is normally 3 years however the same can be renewed based on request of the applicant and continued compliance of the products with the certification requirements. The Third surveillance audit prior to the expiry of the certificate can be treated as assessment for renewal. On the basis of renewal audit, the earlier surveillance audits and the product continued compliance. This is adjudged if applicant has continued to maintain the conformity and effectiveness of the applicant's production and quality system as a whole and its continued relevance and applicability for the scope and duration of certification. Operational and Maintenance reports of the product for the certification period form a crucial basis for renewal of the Certification. **(CCS / F19)** to be used for renewal decision. Normally a renewed certificate is valid for additional 3 years unless the certification body decides otherwise based on some reasons.

6.0 Re-Certification:

In case of cancellation of certification due to any reasons as given under cl. 5.3 or lapse of more than six months for not getting the renewal, re-certification will be desired. Re-certification can be granted only on request from the applicant with a fresh application **CCS/F08** and follow full process of certification as late down in cl. 3.0 of **CCS/D 03**.

The purpose of re-certification audit is to confirm the continued conformity and effectiveness of the applicant's production and quality system as a whole and its continued relevance and applicability for the scope of certification. The Re-Certification audit shall include site audit and shall consider the performance of production and quality system over the period of certification and shall also include a review of previous surveillance audit reports.

7.0 Extension of the scope of certification:

Any extension to the scope of certification to additional types or models of products etc. shall be treated as a fresh application and handled accordingly.

8.0 Conditions for Suspension/ Cancellation/ Reduction in Scope/ Withdrawal of the Certification: CII/EP 11

8.1 Suspension:

A Certification may be suspended if it has been established that:

a) Any deficiencies / deviations observed by the regulator, end users, Certification Body, by virtue of Customer Complaint or otherwise, or by the applicant need to be acted upon by the applicant promptly. The Certification may be suspended till Impact Analysis and Design Modification is implemented.
b) The Applicant has failed to take suitable improvement actions within 30 days, after CIIPL has served show cause notice following failure in respect of deficiencies observed in Applicant's quality control system, or non-adherence to the provisions of QAP, during factory surveillance operations.
c) In case, a repeat failure is observed in respect of a requirement for which the Applicant has already taken corrective action, CIIPL shall suspend the certification without any show cause notice.
d) The Applicant has used the mark in respect of a type or grade, or brand which is not covered in the Certification, as observed during factory or market surveillance operations. CIIPL reserves the right to issue suspension directly or issue a show cause notice depending on the facts of the case.
e) The Applicant has failed to submit proper justification within 7 days, after CIIPL has served show cause notice following a factory surveillance inspection where the Applicant has failed to provide reasonable facilities for completing the factory surveillance.
f) The Applicant has failed to comply with any other conditions of the Certification, within 30 days of show cause notice period;
g) Any critical problem reported from any of the field installations would need the applicant to report the same to the Certification Body and submit a plan to redress the same in a prompt manner. Failure to do so may lead to suspension of Certification without any Show-cause notice.
h) Certification Body may disagree with the plan / timeline proposed by the applicant for the remedial measure to be taken in case of problems reported from operations / installations. In such cases of disagreement, the Certification may be suspended till remedial actions are taken.

8.2 Removal of suspension:

a) Suspension could be revoked only when evidence of successful filed trial is submitted based on remedial measures taken for safety issues reported in the product.
b) Suspension based on deviations observed in manufacturing QMS could be revoked once satisfactory action has been submitted with evidence and verified by the ISA.

8.3 Cancellation of Certification:

Certification shall be cancelled if the following conditions apply:
a) In cases involving product non-conformance or deficiencies observed during surveillance, serious non-conformities reported during field trails, field applications.
b) if the Applicant does not take action to rectify the deficiencies that led to the suspension, the Certification shall be cancelled after a period of six months from the date of suspension. A show cause notice for a period of 30 days shall be issued to the Applicant before deciding on the cancellation of certification.

c) In cases involving marking of variety which is not covered in the certification, which is determined to be willful, the certification shall be cancelled without any further notice to the Applicant, in case the notice for suspension was given earlier. In case notice was not served before suspension, a show cause notice for a period of 15 days shall be issued to the Applicant before deciding on the cancellation of certification.

d) In cases involving not providing facilities for inspection, or failed to comply with any other conditions of the Certification, if the Applicant does not take action to rectify the deficiencies that led to the suspension, the Certification shall be cancelled after a period of 30 days from the date of suspension.

e) CIIPL reserves the right to cancel a certification in case a certified product is found to be failing in a critical requirement affecting public health and safety without invoking the show cause / suspension process.

f) If more than two suspensions for the same or similar deficiencies occur within a period of two years.

8.4 Withdrawal of certification:

a) On request by the Applicant.

b) When a requirements standard such as the Standard is withdrawn by the Standards body, or reduced in scope, or merged with other standards and CIIPL takes a policy decision to withdraw certifications having such varieties in the scope.

c) Following revisions or amendments.

8.5 Expiry of certification:

In case the validity of issued certification is over without renewal or recertification, the certification would deem to have expired. In such a case the applicant:

a. May request for renewal within six months as per clause 4.1.1.
b. May request for recertification on expiry of six months, giving a fresh application.
c. Shall cease the right to use certification mark and logo or any other claim related to the same on the product or its stationary or on any other marketing material, unless specifically permitted by the Certification body in writing. In such a case the conditions applied by the certification body need to be complied to.

9.0 Use of Certificate or mark of conformity:

The use of certificate or mark of conformity is elaborated in CCS/OP 02.

9.1 Publicity by the applicant:

A certified applicant shall have the right to publish the fact that it has been authorized to issue a mark of conformity for products to which it has received certification.

In every case the applicant shall take sufficient care of its publications and advertising that no

confusion arises between certified and non-certified products.

The applicant shall not make any claim or the like in user information that could lead purchasers to believe that performance of the product or its use is covered by the certification when in fact they are not. For example, a product certified for safety shall not be claimed for compliance to performance standards.

10.0 Confidentiality:

CIIPL is committed for the protection of the proprietary information of the certified product. Adequate arrangements consistent with applicable laws are in place to safeguard confidentiality of the information obtained in the course of the certification activities at all levels of organization, including committees and external bodies or individuals acting on its behalf. If felt necessary to place the part/ complete collected information in public domain, CIIPL will obtain prior approval of the applicant.

CIIPL ensures that where the law requires information to be disclosed to a third-party, the supplier is kept informed of the information provided as permitted by the law. CIIPL also ensures that the information about the applicant, if obtain from other sources, is kept confidential.

CIIPL is responsible for ensuring that confidentiality of information is maintained by its employees and those of its subcontractors concerning all information obtained as a result of their contacts with the licensee.
(Refer CII/F 05)

11.0 Misuse of a certificate or mark of conformity:

CIIPL takes action for unauthorized, incorrect, or misleading use of the certificates or a mark of conformity is found.
Incorrect references to the certification system or misleading use of certificates or the mark found in advertisements, catalogues, etc., shall be dealt with by cancellation of certification and in case of serious misuse followed by legal action.
(Refer CCS/OP 02)

12.0 Liability

The liability analysis is elaborated in CII/F 24.

13.0 Fee Structure of CIIPL:

The Fees structure is detailed in CII/F 10.

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