

Network Certification Body

Scheme rules for assessment of railway projects to requirements of the Railways Interoperability Regulations as a Notified and Designated Body

Introduction and Purpose of Document

This document describes the general rules for the client and for NCB to follow to allow compliance by both parties with the relevant processes mandated by the Railway Interoperability Regulations and in BS-EN-ISO-17065. These rules will be enforced through contract, as required under BS-EN-ISO-17065.

This document sets out a minimum framework: NCB adopts a flexible approach to client requirements, and is able to agree a scope of certification appropriate to client needs provided that the rules specified by this document are adhered to. Please speak to your NCB contact, or email us via our website, to enable us to tailor our services to your needs.

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1 Normative references

1.1 EU and National legislation, accreditation and certification standards

- EU Directive 2008/57/EC on the interoperability of the rail system within the Community
- The Railway (Interoperability) Regulations (as amended)
- BS-EN-ISO-17065 Conformity assessment - requirements for bodies certifying products, processes and services
- ISO 9001 Quality management systems — Requirements

1.2 Technical Specifications for Interoperability

- Energy
- Infrastructure
- Persons with Reduced Mobility
- Safety in Railway Tunnels
- Rolling Stock (Locomotives and Passenger Carriages)
- Rolling Stock (Noise)
- Rolling Stock (Wagons)
- Control, Command and Signalling

1.3 Notified national technical rules

The Department for Transport maintains a list of notified national technical rules. At the time of publication, these are listed [here](#), and form the basis of the designated body assessment carried out by NCB.

1.4 Assessment modules for interoperability constituents

- Module CB. EC-type examination
- Module CD. Conformity to type based on quality management system of the production process
- Module CF. Conformity to type based on product verification
- Module CH. Conformity based on full quality management system
- Module CH1. Conformity based on full quality management system plus design examination
- Module CV. Type validation by in-service experience (suitability for use)

1.5 Assessment modules for sub-systems

- Module SB. EC-type examination
- Module SD. EC verification based on quality management system of the production process
- Module SF. EC verification based on product verification
- Module SG. EC verification based on unit verification
- Module SH1. EC verification based on full quality management system plus design examination

Note: All normative references are the latest editions unless otherwise specified. In the event of changes to directives, regulations or standards these scheme rules will be reviewed and updated. Changes will be notified to scheme participants as outlined in section 10.

2 Terms and definitions

Assessor

An NCB resource who has been identified as having relevant competence in order to evaluate the supplied evidence against the required assessment standard.

Certifier

An NCB resource who has been identified as having relevant competence in order to review the Assessor's work and authorise the appropriate certification.

Customer

The term 'customer' is used throughout this document as equivalent to: applicant; contracting entity; project entity; and manufacturer, all terms used in EU Directives and UK regulations.

Project

Scheme for construction, upgrading or renewal of whole or part of a subsystem of the rail system. For the purpose of this scheme a project includes an interoperability constituent that will be included in a larger project.

Nonconformity

A deficiency where the project does not conform to requirements or where there is doubt about the ability of the customer's management system to consistently produce product that conforms to requirements.

Requirements

Conditions with which the project must conform, including any applicable:

- (a) Technical Specifications for Interoperability
- (b) Notified national technical rules
- (c) Condition applied by the UK Competent Authority to a dispensation from notified national technical rules
- (d) European standards referenced in the Technical Specifications for Interoperability

Site

A construction or manufacturing facility that operates to a management system.

3 General requirements

3.1 Certification agreement

NCB agrees a contract with each customer outlining project requirements and referencing these scheme rules. The contract defines project scope and is the certification agreement between NCB and the customer. The contract and these scheme rules outline expectations on both parties to enable product certification on an individual or series production basis. Project liability is as agreed in the contract and may not be varied subsequently without further negotiation.

3.2 Management of impartiality

As an independent, impartial provider of conformity assessment services, NCB undertakes to advise prospective customers of any potential impartiality issues affecting the project. If a customer perceives any threats to impartiality they should notify NCB as they occur. Failure to manage risks to impartiality has the potential to invalidate any certification or at least require additional assessment and mitigation activities with potential cost implications for one or both parties.

3.3 Liability and financing

NCB operates as a financially viable business on a cost recovery basis with the aim to operate at a small operating profit and meet strategic shareholder objectives, NCB business plans and legal and accreditation requirements.

3.4 Fees charged to applicants and clients

Applicants requesting certification services from NCB will be offered a proposal and associated cost estimate. The fees will be based on an assessment of the man-days required and the charge out rates applicable to the expertise and competence of staff involved. Charge out rates are set as consistent with section 3.3.

3.5 Non-discriminatory conditions

NCB operates its policies and procedures in order to not discriminate, impede or inhibit access by customers / suppliers for assessment verification and certification services. NCB accepts contract work from all appropriate parties, without prejudice.

3.6 Confidentiality

Except as required by law or these certification scheme rules, information gained in the course of certification activities about a particular product or customer is not disclosed to any other party without the customer's written consent. Where the law requires information to be disclosed to another party, the customer is informed of information provided as permitted by law. Customer confidentiality is achieved through:

- NCB employees and sub-contractors are required to sign a confidentiality agreement prior to undertaking any assessment, verification or certification activity
- Inclusion of a confidentiality clause within the contract between the NCB and the customer
- Inclusion of a confidentiality clause within the contract between the NCB and any sub-contractor that it employs .

Information about certification issued by NCB is made available on the CIRCABC website as required under the regulations.

4 Initial application

4.1 General Information

The customer shall supply the information required by the EC assessment module(s) (Section 1) being specified for the assessment. Customers should consult the relevant assessment modules for a definitive list of the required information, but it typically includes:

- A list of all sites at which the customer produces product to the requirements for which certification is sought
- Details of requirements that apply to the project for the scope of certification
- Details of any current certification issued by NCB or another Notified / Designated Body that the project wishes to be considered
- Details of any previous applications for Notified / Designated Body approval for the project including any refused or withdrawn
- Any testing carried out prior to application that the customer believes supports product certification
- Details of EC assessment module(s) to be applied to the project
- A plan to establish how the project intends to comply with requirements for the project scope.

Where the customer does not have all of the required information at the time of application NCB will identify any information required to progress the application and work with the customer to ensure these gaps are filled. It remains the customer responsibility to identify requirements for the scope of certification.

4.2 Evidence of Compliance

Technical documentation provided by the customer in the course of the project shall cover, as far as relevant for the project scope, the design, manufacture, installation/construction and operation of the subsystem. This documentation constitutes the evidence assessed by NCB as the basis for any certification decision and forms the basis of the technical file used for project authorisation

This may be presented to NCB in a format of the customer's choosing but shall be legible and able to be understood by NCB assessors. Records shall be produced under the customer's quality management system.

Activities outsourced by the customer may include measuring, inspection and test reports issued by an accredited body. Any such evidence shall be presented to NCB for evaluation. The customer shall maintain evidence to demonstrate that test samples are representative of production and traceable to manufacture.

4.3 Quality management system

For each project where the customer requires NCB to assess a quality management system as supporting product certification in accordance with EC modules for conformity assessment, they shall provide evidence of having implemented a quality system including the following:

- Details of any accredited third party quality certification including a copy of certificate and scope statement
- Uncontrolled copy of relevant quality manual(s)
- A copy of the most recent third party audit for each site relevant to the intended product certification

Where the customer is intending to rely on certification for outsourced activity including design, manufacture / construction or commissioning they shall provide a copy of any relevant evidence of having implemented a quality management system as above.

Where the customer intends to produce multiple projects or parts of projects they shall in addition provide information necessary for series manufacture, including:

- A copy of the control plan (or equivalent document) describing the planned inspections and measurements and basis for any sampling
- Identification of projects included in the series, and any product marking
- Estimated production quantities for each item covered by the project

NCB works to NB-Rail document RFU-STR-065 when assessing quality management systems under this scheme.

4.4 Inspection and testing

As an accredited Notified and Designated body NCB ensures that any inspection and testing is carried out under controlled conditions equivalent to those operated by NCB. The following controls need to be exercised by the customer:

- Test laboratories used shall hold accreditation to ISO / IEC 17025 with a scope covering the testing activity
- Inspection bodies used shall hold accreditation to ISO/IEC 17020 with a scope covering the inspection activity

In the event that a customer is proposing to use in house facilities or other ways of providing inspection and test evidence to support their application then this shall be agreed in advance by the NCB based on evidence provided. Typical evidence of equivalence to accredited inspection / testing laboratory status may include:

- Documents demonstrating certification / accreditation status of organisations involved in the project scope including for inspection(s) and test(s) referenced in this scheme and requirements
- Method of verification of results for inspection(s) and test(s) referenced in this scheme and in requirements
- Documented procedure(s) to be followed when inspection and test results do not meet requirements
- Documented procedure(s) for repeating invalid inspections and tests
- Evidence of competence of the staff conducting the tests
- Evidence of appropriate independence of the personnel conducting the tests from the design, manufacturing and maintenance of the equipment under test.

5 Application review

NCB assesses information provided by the customer and provides feedback on adequacy of information provided. In the event that the information provided does not satisfy requirements in the project scope NCB will formally raise this as an issue requiring resolution before certification can be completed. In the event the review of information provided by the client is acceptable NCB retains responsibility for any subsequent certification awarded.

NCB may choose to continue assessing the application while the customer obtains additional information. No certification will be provided until all required information has been provided and evaluated in accordance with these scheme rules.

6 Assessment and evaluation

6.1 Planning

NCB produces an assessment plan detailing the activities required in accordance with the applicable assessment modules. This includes:

- Definition of the applicable standards (TSIs, ENs, NNTRs) against which compliance is being assessed, together with the assessment activities necessary
- Details on when the expected compliance evidence is expected from the customer
- Details on any testing that is to be witnessed or undertaken
- Details on what audits will be undertaken
- Details on what is required at each stage, for example, at design and at manufacture
- Resources who will undertake the assessment and certification
- The milestones by when various activities need to have been satisfactorily completed in order for certification to be successfully issued.

Criteria against which a customer's project is evaluated are selected from relevant requirements and applicable assessment modules. These are limited to relevant criteria directly concerned with certification scope and provided by the customer (Section 4).

6.2 Assessment Team Members

NCB allocates assessors to evaluate the evidence against the requirements of the applicable standards, and to produce the certificate and any checklists or reports that may be required. NCB allocates a certifier to separately review the work of the assessors, and to sign the certificates.

NCB operates a competence management and resource allocation system, ensuring that all staff allocated to projects have sufficient and relevant competence to undertake the necessary assessments for delivering product conforming to normative (Section 1) and project (Section 4) requirements. Where applicable, at least one person in the team has competence in:

- quality management systems assessment (where applicable)
- interpretation of test results directly relevant to project scope
- witnessing of test and inspection activities including application of ISO/IEC 17025 and / or ISO / IEC 17020

In all cases the assessment team contains members who have technical expertise in the field being assessed, including detailed understanding of the applicable Technical Specifications for Interoperability.

6.3 Assessment

The customer shall demonstrate full compliance with this scheme and project scope requirements before certification can be completed. In order to conduct its evaluation NCB needs access to project sites, equipment, customer personnel, documents, records and samples of projects. To comply with requirements NCB may also require access to observers from relevant interested parties including accreditation bodies, contract testing and inspection personnel and regulators. NCB will inform the customer in advance if this access is required. The customer shall make all necessary arrangements to enable this access to be provided.

The customer information provided shall address the following stages as applicable:

Design

Planned activities to ensure design verification before release for manufacture. Planned validation activities at stages of manufacture, installation and commissioning to demonstrate the

design is capable of meeting intended outcomes.

Manufacture

Assurance checks at stages of initial manufacture to demonstrate the project meets requirements as built.

Testing

See section 4.4.

Installation

Where the project forms part of a larger system those checks planned to demonstrate interfaces with existing sub-systems are operating as planned.

Commissioning (and testing where applicable)

Assurance activities during commissioning to demonstrate the project delivers intended outcomes.

Series manufacture (where applicable)

Periodic or manufacturing stage assurance activities demonstrate series manufactured projects perform as for the first of type and the project is able to deliver intended outcomes when incorporated in the system / sub-system.

6.4 Assessment process

The assessment process follows the assessment module(s) specified for the project in line with the plan produced in accordance with Section 6.1. Depending on the module requirements and the stage of assessment, the assessment may take the form of document review, site inspections, process audits and other activities.

Compliance evidence is captured against clause numbers of the applicable standard being assessed: this is often completed in checklists, and summarised in a report, which forms the overview of the technical file.

6.5 Progressive feedback

If at any point in the assessment process NCB identifies a nonconformity with requirements that will lead to a delay in certification being made then it will raise the issue with the customer at the earliest possible time using the technical query system. Stages where this might occur include:

- review of requirements listings
- review of documents, including:
 - derogations
 - drawings
 - specifications
 - test reports
 - inspection reports
 - audit and assessment reports
 - certificates

All technical queries are managed using the nonconformity process in Section 9. At all on-site assessments the team holds opening and closing meetings with the customer's management. At the closing meeting, the assessment team:

- explains assessment findings and providing opportunity for questions
- documented evidence of findings
- summarises any assessment follow-up activities

- explains any certification process requirements and follow up activities

In the event that a nonconformity has been addressed by the customer obtaining a deviation from the standard, the details of the deviation are to be supplied to NCB so that they can be detailed on the issued certificate.

6.6 Reporting

NCB provides an assessment report to the customer including:

- a brief description of the customer and project
- a statement of the requirements to which conformity has been assessed
- an executive summary of the overall findings (conclusions) of the assessment, including comments on the effectiveness of the customer's production process controls and management system associated with production of the product, and a summary of findings identified during the assessment
- details and results of evaluation activities carried out
- details of personnel and equipment used in assessment
- Information on fulfilment of requirements
- Identification of any inspection and testing activity including witness
- Any requirement for surveillance or follow-up assessment including close out of any nonconformity prior to or following authorisation by UK or EU regulatory body.

6.7 Surveillance

For series manufacture in the scope of the project NCB agrees a surveillance programme with the customer annually to demonstrate conformance with scheme requirements for certified products manufactured in accordance with the control plan in the period, as follows:

- Confirmation that relevant ISO 9001 certification is current
- Submission of test and inspection results and test data

Surveillance audits include:

- Witnessing of product inspection and testing
- Use of marks and/or any other reference to certification
- Sample assessment of control plan activities;
- Review of:
 - Any changes to services, organisational structure or personnel
 - Cumulative inspection and test results
 - Effectiveness of responses to nonconformities identified during internal and external audits.

6.8 Production samples

Where, in the course of surveillance NCB selects samples for inspection and testing. The samples shall be:

- taken in accordance with the standard
- representative of production
- identifiable to allow for product traceability .

Where possible additional samples may be taken by the customer and independently tested or retained in the event of a disputed test report.

7 Certification

7.1 Records

NCB gathers evidence of product conformity to prepare a technical file as evidence of the basis for the decision. Records are managed in accordance with NCB's management system procedures.

7.2 Review by the Certifier

Certification decisions are based on records of evidence of conformance with requirements in accordance with the standards identified in Section 1. Where records indicate nonconformity with requirements, NCB may decide not to award certification and will notify the customer of this at the earliest possible stage (Section 6.5). If limitations on the subsystem's operation may be considered to address any nonconformities, these will be identified on the issued certificate.

Once the certifier is clear that all aspects of the assessment have been completed satisfactorily and that all aspects of the relevant standards have been met, including being in receipt of any required deviations and accepted certification limitations, the certificate can be generated, including any appropriate limitations and details of the deviations gained.

7.3 Certification Decision

The Certification Decision is usually taken by an "Internal Technical Review" (ITR). For some, typically smaller, projects, the Certification Decision is concurrent with the Review, and is undertaken by the Certifier when signing the certificate.

The person(s) conducting the ITR (and the certifier) must have sufficient knowledge and experience to understand:

- any report(s) and findings
- any additional risk arising from multiple findings
- scheme requirements
- test requirements, methods and data
- nonconformity significance and impact
- conditions significance and impact (see also section 7.6).

The NCB assessment team makes recommendation to the ITR whether certification should be awarded and, if so, any conditions required by the appropriate standards are detailed on the certification. The ITR makes the decision on whether to issue the certification, and if not, advise what further work is required before certification can be re-considered.

7.4 Certification documentation

NCB's NoBo and DeBo certificates comply with NB-Rail document RFU-STR-001. Technical Files comply with RFU-STR-011.

7.5 Directory of certified products

NCB maintains records of projects certified under these scheme rules. This directory is maintained internally but is replicated through customer's notification of projects to the National Safety Authority.

7.6 Conditional Certification

In some instances it is necessary for NCB to issue certification with conditions. Conditions are time-specific and may form part of the ORR's authorisation for entry into service. Conditions that are placed because assessment is not complete are followed up by NCB to allow the assessment to be completed. Examples of these include – but are not limited to – provision of as-built drawings (where the TSI requires the NoBo to assess the as-built configuration) and PA and lighting tests on stations. Conditions which are placed for other reasons will not be followed up by NCB. These include provision of information that is not assessed by NCB (such as other certificates and information for the RINF), and additional conditions that the ORR may include in their authorisation letter.

7.6.1 Dealing with completed conditions

Once the conditions are fulfilled by the client, NCB will:-

- Assess the information against the requirements
- Report on findings, and send this to the client for them to add to the Technical File
- NB: The client may specifically request NCB to update the Technical File on their behalf to incorporate their new compliance state.
- If the findings are that the project is non-compliant, then NCB reserves the right to withdraw the certificates in line with Section 11 of these scheme rules.

In instances where the conditions are not completed within the given timeframe, NCB will notify the client in writing a minimum of three times recommending completion. If the project does not demonstrate compliance despite these notifications, NCB reserves the right to withdraw certification in line with Section 11 of these scheme rules and notify the ORR.

8 Claims for certification

Customers may make no claims of certification until a certificate has been issued by NCB. Until this time customers should agree acceptable wording with NCB to reflect project approval status.

After a certificate is issued customers should ensure that information about project certification is complete and accurate. Information included on the certificate for the project should be used where its absence could be misleading. In particular where a project forms part of a larger programme great care should be taken to ensure there is no implication that the programme has been certificated.

Any certificate conditions should be referenced in any claims for certification unless they have been resolved following certification. Where post certification activities identify potential nonconformity with requirements the customer shall prevent further active claims to holding certification until the situation is resolved. Section 9, 10 and 11 refer.

8.1 Use of certification marks

All NCB certification documents and marks remain the property of NCB. Where marks may be useful to the customer in claiming and advertising conformance with scheme requirements, customers should agree acceptable wording and use of marks with NCB. In the event marking guidance changes NCB will notify affected customers and these changes will be managed in accordance with Section 11 of these scheme rules.

9 Nonconformity, complaints and appeals

9.1 Nonconformity

For any initial or surveillance assessment NCB informs customers of names of members of the assessment team with sufficient notice to appeal against appointment of any team member.

All technical queries raised during assessment and evaluation (Section 6) are managed using the nonconformity process in this section. At all on-site assessments the team holds opening and closing meetings with the customer's representatives and includes any reports on current state of nonconformity with requirements.

Where a technical query is identified, NCB provides opportunity for the customer to question the nature and content of the technical query. For all technical queries forming part of the assessment report NCB agrees with the customer a plan and timetable for responding to and resolving the technical query. This plan shall ensure the customer takes all necessary steps to prevent provision of nonconforming product and, commensurate with the risks, notify significantly affected parties as soon as practicable.

Where a nonconformity cannot be resolved and it affects confidence that a project satisfies requirements the certification decision will normally be not to certify (Section 7.3) or to withdraw / terminate certification (Section 11).

9.2 Appeals

Where a customer believes a nonconformity has been incorrectly raised or a certification decision is incorrect they are encouraged to use NCB's appeals process. All NCB personnel will be able to provide further information on how to initiate an appeal. Where a customer wishes to raise a confidential appeal they may direct it to the NCB independent Finance and Commercial team using the ncbenquiries@networkrail.co.uk e-mail address or via the 'Contact us' page on NCB's web site www.net-cert.co.uk or using the general enquiries telephone number 01908 784002.

All appeals are handled independently in accordance with NCB's management system up to and including access to NCB's Certification Advisory Committee and the NCB Board. In the event an appeal remains unresolved then NCB will direct a customer to the regulatory appeals process.

9.3 Complaints to NCB

NCB maintains a customer complaint system related to the service provided and independent of the appeals process. All NCB personnel will be able to provide further information on how to initiate a complaint. Where a customer wishes to raise a complaint confidentially, they may direct it to the independent NCB Finance and Commercial team using the ncbenquiries@networkrail.co.uk e-mail address or via the 'Contact us' page on NCB's web site www.net-cert.co.uk or using the general enquiries telephone number 01908 784002.

All complaints are handled independently in accordance with NCB's management system up to and including access to NCB's Certification Advisory Committee and the NCB Board. In the event a complaint remains unresolved then customers may complain to UKAS, the accreditation body for this scheme, again NCB personnel will be able to provide further information on how to do this.

9.4 Complaints about the customer

9.4.1 Customer system

As part of its management system, customers are expected to have a process to identify, capture and resolve complaints relating to the project scope and requirements. The customer should keep records of any complaints it is aware of that relate to compliance with scheme requirements including any actions taken to resolve any nonconformity.

9.4.2 NCB system

Where NCB receives a complaint relating to a customer, project scope or requirements, we review the complaint to decide whether the complaint relates to NCB certification activities. If so, we acknowledge receipt of the complaint and investigate by gathering necessary information to enable a decision to be made independently on the complaint validity.

NCB will notify the complainant of the result of their complaint and of any follow up activity (subject to confidentiality requirements). In the event the complainant is not satisfied NCB will advise them of routes to appeal or escalate the complaint and will manage or co-operate with subsequent stages.

In the event the complaint requires action with NCB's customer and / or a project then NCB will manage this process respecting any confidentiality requirements.

10 Change management

10.1 Changes affecting certification

NCB's Notified and Designated Body certification has been based around normative references (Section 1). In the event requirements change, these scheme rules will be reviewed by NCB and, if necessary, updated. Similarly in the event of changes to NCB processes referenced in these scheme rules or (e.g. use of NCB marks) or to scheme rules themselves NCB reviews potential impact on existing customers and notifies affected customers at the time of the change. Any necessary transition arrangements are notified at the same time.

Transition arrangements include new designs, modifications to existing designs, additional audits or extended audit surveillance, expiry of certification previously issued by NCB.

In the event that existing customers are unwilling or unable to meet additional scheme requirements including transition arrangements then NCB will work with the customer to withdraw certification in accordance with Section 11 of these rules.

10.2 Additions or alterations

Certified products shall not deviate from that approved by NCB from the time of assessment to certification and authorisation by the UK authority without NCB's prior consent. Where after NCB assessment, part of a project requires a change before certification, that part of the project is subject to additional assessment and evaluation in accordance with section 6 of these rules. The customer shall advise NCB of planned changes and controls to be implemented to manage the change and agree a plan of evaluation for the change.

For a project manufactured in series, the customer shall include in its management system a process for identifying and immediately reporting any proposed additions or alterations to certified products.

11 Revoking certification

11.1 Termination, reduction, suspension or withdrawal of certification

Where an identified nonconformity or complaint from external parties indicates an inability to consistently produce a product conforming to requirements, NCB will take appropriate action, including but not limited to:

- Extraordinary surveillance assessment (in accordance with Section 6)
- Additional product testing (in accordance with Section 6)
- Re-evaluation of the certification decision (Section 7)

The findings from the above actions are handled in accordance with section 9 above. In addition, in the event that NCB decides that amendment, suspension or withdrawal of certification is appropriate, if this is due to an immediate safety risk, no notice will be given: otherwise NCB will give one month's notice in order to provide the customer an opportunity to provide additional information for NCB's consideration before taking the action determined.

Where a customer terminates certification or if NCB suspends or withdraws certification, all certificates and certification documents shall be returned to NCB. The customer shall cease to make any claims to certification and cease use of NCB marks (Section 8). NCB will contact relevant public and regulatory bodies and withdraw any references to continuing customer certification.

In the event certification is suspended NCB will appoint and communicate to the customer a named NCB employee who will work with the customer during any suspension period. NCB will make clear what is required to:

- end suspension and restore product certification
- manage claims for certification and handle enquiries on product certification

All NCB and customer actions including evaluation and assessment (Section 6) in support of certification reinstatement shall be carried out in compliance with these scheme rules. Reinstatement of product certification requires a further certification decision (Section 7) and NCB will seek cost reimbursement for this activity.