

Network Certification Body

Schemes Rules for Assessment of Railway Projects (NoBo/DeBo, ECM, PAB)

Introduction and Purpose of Document

This document describes the general scheme rules for the customer and for NCB to follow to allow compliance by both parties with the relevant processes mandated by the applicable regulations, legislation, standards, 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 as NCB adopts a flexible approach to customer requirements and is able to agree a scope of certification appropriate to customer needs, provided that the rules specified by this document are adhered to.

Contents

1	Normative References.....	5
1.1	EU and National Legislation, Accreditation and Certification Standards.....	5
1.2	Technical Specifications for Interoperability	6
1.3	Notified National Technical Rules (DeBo)	6
1.4	Assessment Modules for Interoperability Constituents (NoBo).....	6
1.5	Assessment Modules for Sub-Systems (NoBo).....	7
2	Terms and Definitions.....	7
3	General Requirements	9
3.1	Certification Agreement	9
3.2	Management of Impartiality	9
3.3	Liability and Financing	9
3.4	Fees Charged to Applicants and Customers	10
3.5	Non-Discriminatory Conditions	10
3.6	Confidentiality	10
4	Initial Application.....	10
4.1	General Information.....	10
4.2	Acknowledgement of Receipt of Application.....	11
4.3	Application Review	11
5	Assessment and Evaluation	12
5.1	Planning	12
5.2	Assessment Team Members.....	13
5.3	Pre-Assessment	13
5.4	Initial Assessment.....	14
5.5	Evidence of Compliance	14
5.6	Quality Management System	15
5.7	Inspection and testing.....	16
5.8	Assessment process	16
5.9	Progressive feedback.....	17
5.10	Reporting.....	18
5.11	Assessment findings level:	18
5.12	Surveillance.....	19
5.13	Production samples.....	20

6	Certification	20
6.1	Records	20
6.2	Review by the Certifier	20
6.3	Certification Decision.....	20
6.3.1	Decision to award certification	21
6.3.2	Non-issue of a certificate.....	21
6.4	Certification Documentation	21
6.5	Directory of Certified Products.....	22
6.6	Conditional Certification.....	22
6.6.1	Dealing with completed conditions	22
7	Claims for Certification	22
7.1	Use of Certification Marks	23
8	Nonconformity, complaints and appeals.....	23
8.1	Nonconformity	23
8.2	Appeals	24
8.3	Complaints	24
9	Change Management.....	24
9.1	Changes Affecting Certification	24
9.2	Additions or Alterations.....	25
10	Termination, Reduction, Suspension or Withdrawal of Certification	26
10.1	Suspension of Approval	26
10.2	Implications of suspension	26
10.3	Failure to maintain your audited Management System	26
10.4	Reduction of Scope.....	26
10.5	Requests to Suspend Approval.....	27
10.5.1	Failure to Agree to a Scheduled Visit.....	27
10.5.2	Special Circumstances	27
10.5.3	Notification of Suspension.....	27
10.5.4	Response to Suspension	27
10.6	Withdrawal of Approval - Request to Terminate Approval.....	28
10.7	Termination by NCB.....	28
10.8	Notification of Withdrawal.....	28

1 Normative References

1.1 EU and National Legislation, Accreditation and Certification Standards

- RIS-1702-PLT Rail Industry Standard for the Design of On-Track Machines in Working and Travelling Modes
- RIS-1530-PLT Rail Industry Standard for Technical Requirements for On-Track Plant and Their Associated Equipment and Trolleys
- RIS-1710-PLT Engineering Certification of Railborne Plant and the Assessment of Non - Railborne Plant
- ECM Regulation 445/2011 of 10 May 2011 on a system of certification of the entity in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 (ECM regulation). **Note: Regulation (EU) No 445/2011 is repealed with effect from 16 June 2020 and replaced by Regulation (EU) 2019/779**
- Directive 2004/49/EC of the European Parliament and of the Council on safety on the Community's railways (**to be replaced by Directive (EU) 2016/797 on 16 June 2020**) and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification as amended by:
 - Directive 2008/110/EC of the European Parliament and of the Council
 - Commission Directive 2009/149/EC as regards Common Safety Indicators and common methods to calculate accident costs; and
 - Commission Directive 2014/88/EU as regards common safety indicators and common methods of calculating accident costs
- Regulation 765/2008 of the European Parliament and of the Council of 09 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
- Commission Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment
- EU Directive 2008/57/EC on the interoperability of the rail system within the Community (**to be replaced by Directive (EU) 2016/797 on 16 June 2020**)
- 2010/713/EU: Commission Decision of 09 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council
- The Railways (Interoperability) Regulations (issue 2011)
- ISO/IEC 17065 Conformity assessment - requirements for bodies certifying products, processes and services
- ISO/IEC 17020 Conformity assessment - Requirements for the operation of various types of bodies performing inspection
- ISO/IEC 17007 Conformity assessment -- Guidance for drafting normative documents suitable for use for conformity assessment
- ISO/IEC 17021 - 1 Conformity assessment -- Requirements for bodies providing audit and certification of management systems
- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- ISO 9001 Quality management systems — Requirements

- EN ISO/IEC 17050-1 Conformity assessment -- Supplier's declaration of conformity -
- Part 1: General requirements
- ISO/IEC 17050-2 Conformity assessment -- Supplier's declaration of conformity --
Part 2: Supporting documentation
- IAF MD 1 Mandatory Document for the Audit and Certification of a Management
System Operated by a Multi-Site Organization
- IAF MD 2 Transfer of Accredited Certification of Management Systems
- IAF MD 4 IAF Mandatory Document for the Use of Information and Communication
Technology (ICT) for Auditing/Assessment Purposes
- IAF MD 5 Determination of Audit Time of Quality, Environmental, and Occupational
Health & Safety Management Systems
- IAF ID 3 Management of Extraordinary Events or Circumstances Affecting ABs,
CABs and Certified Organizations
- ERA ECM guide version 2 (ERA-GUI-100) and associated application guide
- RID 2017– Regulations concerning the carriage of dangerous goods

Note: All normative references are the latest editions and amendments, unless otherwise specified in this document.

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 9.

Referenced standards in NCB electronic records:

All referenced standards imply the latest available issue. If an earlier issue is agreed with the customer this is reported clearly in the related report and/or the issued certificate.

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 (DeBo)

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 (NoBo)

- 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 (NoBo)

- 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

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; manufacturer; contracting entity; project entity; as applicable.

Certification committee

The committee established by the NCB for delivering a decision on certification. NCB also refers to this as the Certification Decision Panel (CDP).

Maintenance workshop or workshop

A mobile or fixed entity composed of staff, including those with management responsibility, tools and facilities organised to deliver maintenance on vehicles, parts, components or sub-assemblies of vehicles.

Nonconformity

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

Separate maintenance function

Refers to entities performing a limited scope of maintenance activities as considered in the ECM regulation article 8, annex I.

Site

A maintenance or construction or manufacturing facility that operates to a management system. This can also include a HQ office function for ECM functions I, II & III. For maintenance workshops (ECM function IV), it may also include a mobile maintenance unit i.e. "man in a van" facility.

Requirements

Conditions with which the applicant ECM or applicant ECM workshop must conform, or
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

Asset Manager

The entity that controls the use of an item of rail-borne or on-track asset.

NoBo Certificate

A certificate issued by a notified body following a conformity assessment of products and subsystems against the relevant requirements of the European Directive on the Interoperability of the Rail System (2008/57/EC and amendment 2016/797/EC).

ECM Certificate

A certificate confirming that Entity in Charge of Maintenance (ECM) functions are conforming to specified requirements. It is issued to entities which manage freight or passenger wagons: railway traffic enterprises, wagon owners and infrastructure operators, following an assessment of the ECM responsibility to meet legal requirements, to apply them consistently and to supervise and ensure continuing compliance over time.

Engineering Conformance Certificate

A certificate issued by a plant assessment body confirming conformance of the design and construction of rail-borne plant and associated equipment, and its maintenance plan, with all relevant mandatory requirements of the standards set out in RIS-1710-PLT.

Engineering change

A change to a rail vehicle or other assets, including control software, in the area of design, construction or maintenance which affects, or potentially affects, conformity to applicable requirements.

On-track Machine (OTM)

Any rail mounted machine meeting the requirements of GM/RT2400 and permitted to be moved, either self-propelled or in train formation, outside of possession.

On-track Plant (OTP)

Collective term for RRVs, demountable machines and their trailers.

Project

Scheme for constructing, upgrading, modifying or renewing of whole or part of a rail product, service or structure. A project may include an interoperability constituent that will be included in a larger project.

Plant Assessment Body (PAB)

A body with authority to issue engineering conformance certificates for rail-borne plant and associated equipment.

Rail-borne Plant

On-track machines, on-track plant and manually propelled trolleys.

Railway Undertaking

Any public or private undertaking, the activity of which is to provide transport of goods and/or passengers by rail on the basis that the undertaking must ensure traction; this also includes undertakings which provide traction only (Article 3(c) of Directive 2004/49/EC).

Road-Rail vehicle (RRV)

A road-rail vehicle is one that can travel on the ground and also travel on rail by virtue of a rail wheel guidance system under its own power. Such vehicles are not allowed to run, work, travel or operate on rail outside of possession.

Rolling stock library

The national central database of rail vehicle design and operational data, which is maintained by the Network Rail's authorised agent.

Trailers

A non-self-propelled, rail-mounted rail-borne plant capable of being towed or propelled by a machine (this includes attachments with two or more rail wheels).

Trolleys

A manually propelled, rail-mounted device supported simultaneously on both running rails, as shown in RIS-1530-PLT.

3 General Requirements

3.1 Certification Agreement

NCB agrees a contract with each customer outlining applicable requirements and referencing these scheme rules. The contract defines the project or assessment 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
- ECM or workshop certification on an individual basis

Project liability is as agreed in the contract and may not be varied subsequently without further negotiation.

NCB does not accept any consequential liability arising from delays on the part of the customer to respond to the contract proposed by NCB to the customer.

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 service provided by NCB or a third-party provider contracted by NCB. 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 Customers

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 hours required and the charge out rates applicable to the expertise and competence of staff involved. Fees include administration time and issue of certificates and reports. 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 or 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, associates and sub-contractors being 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 appropriate websites (e.g. ERADIS, NB-RAIL) as required under the regulations or accreditation requirements.

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 or by the applicable standards. Customers should consult the relevant assessment modules or relevant standards 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 conformity assessment body that the project wishes to be considered
- Details of any previous applications for conformity assessment 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 customer intends to comply with requirements for the project scope
- Details to demonstrate conformance of the design, construction and maintenance instructions of the item of plant or engineering change with the requirements
- Maintenance files, maintenance records, annual safety management system reports, applicable national incident reporting of relevance to the ECM maintained vehicles and sites, audit reports and information about vehicles maintained at each site.

For plant, it should be clear from the information supplied whether the certification being requested is for an individual item of plant or a group of identical items, and whether the reason for the request is in relation to a new item, a change of the asset manager, a change of engineering state or maintenance plans, or due to expiry of a previous certificate.

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's responsibility to identify requirements for the scope of certification.

It is recommended that the customer applications/enquiries are submitted to NCB at least six weeks in advance of the required assessment date, to allow for organisation and co-ordination of the assessment activity.

4.2 Acknowledgement of Receipt of Application

Upon receipt of an enquiry for services, NCB enters the details of the request into its IT system. The enquiry is followed up through the E2O process.

An acknowledgement of receipt will be provided to the customer together with details of the requisite standard application forms to be completed by the customer (if not already submitted). Alternatively, if the completed application has been received, then NCB will check the application to ensure correctness and commence treatment of the enquiry in accordance with standard NCB procedures.

4.3 Application Review

Review of the application is undertaken without prejudice to the customer. Applications and expressions of interest will be treated equally for all customers.

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 the application review can be completed. In the event the review of information provided by the customer is acceptable, NCB provides feedback regarding preparation and scheduling for the assessment and retains responsibility for any subsequent certification awarded.

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

Upon receipt of a request from an applicant, an assessment shall be undertaken of factors such as:

- a) the information about the customer and the product is sufficient for the conduct of the certification process
- b) any known difference in understanding between the certification body and the customer is resolved, including agreement regarding standards or other normative documents
- c) the scope of certification sought is defined
- d) the means are available to perform all evaluation activities
- e) the certification body has the competence and capability to perform the certification activity

and depending on the scope, factors such as: the applicant's size of planned operations, the number of maintenance sites, scale of operations, geographical locations, maturity of the project available information, diversity and size of proposed fleets to be maintained, etc.

This will provide an understanding of resource requirements to deliver the certification service in accordance with customer's expectations and requirements of the certification scheme. An understanding of the customer's timescale expectations will also be taken into account.

A proposal shall be submitted to the customer together with the estimated timescale for delivery.

If the customer is in agreement with the proposal, NCB starts co-ordinating and organising internal or external supplier resources. Customer agreement may be in any type of written form.

The estimated cost is subject to changes if:

- a) the timescale for delivery is exceeded due to late submission of required evidence
- b) other customer related delays
- c) the application scope of work requires revision during the evaluation process

In such cases an additional variation estimate may be issued.

5 Assessment and Evaluation

5.1 Planning

NCB produces an assessment plan. The contents and level of detail will be commensurate with the scope of the project, but it includes part or all of the following:

- The assessment activities necessary to determine conformance with the applicable standards. For plant, the level of assessment for each item will depend on whether it is first in class or a subsequent identical piece of plant
- 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 assessment or 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

- For ECM, the primary assessment criteria as outlined in Annex 3 of the ECM regulations.
- Definition of the applicable standards (e.g. ENs) against which compliance is being assessed, together with the assessment activities necessary
- Details on what on site assessments will be undertaken
- Details on what is required at each stage; for example, at maintenance sites and workshops

Criteria against which customers' products are evaluated are selected from relevant requirements, regulations and applicable standards. These are limited to relevant criteria directly concerned with certification scope as provided by the customer (see section 4).

In the event of any conflict or inconsistency with applicable EN or other standards, the appropriate regulation shall prevail.

5.2 Assessment Team Members

NCB allocates assessors to evaluate the evidence against the requirements of the applicable standards and regulations, 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 and reports.

NCB operates competence management and resource allocation systems, ensuring that all staff allocated to projects have sufficient and relevant competence to undertake the necessary assessments for delivering product conforming to normative and regulatory requirements.

Where applicable, at least one person in the team has competence in:

- Quality management systems assessment
- Interpretation of test results directly relevant to project scope
- Witnessing of test and inspection activities including application of ISO/IEC 17025 or ISO/IEC 17020
- Specific requirements of the appropriate regulation or legislation

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 or regulations.

5.3 Pre-Assessment

Pre-assessment is optional and may be proposed to the customer as a tool for improving their understanding of the project requirements and as means of reducing future resources and cost.

When it is agreed with the customer it may include:

- a) a review of the customer's collected evidence and other documented information
- b) evaluation of the customer's site-specific conditions and discussions with the customer's personnel to determine the preparedness level for the assessment
- c) a review of the customer's status and understanding regarding requirements of the standards, with respect to the identification of key performance or significant aspects, processes, objectives and operations
- d) obtaining or verifying necessary information regarding the scope of the project, including:

- The customer's site(s)
 - Processes and equipment used
 - Use of subcontractors
 - Levels of controls established (particularly in case of multisite customers)
 - Applicable requirements
- e) a review of the allocation and availability of resources for the assessment and agreement of the details with the customer
- f) provision of a focus for planning the technical and QMS audits by gaining a sufficient understanding of the customer's preparedness and site operations in the context of the standard or other normative document
- g) evaluation of the level to which preparation and existing evidence substantiates that the customer is ready for the assessment

It may also include a voluntary pre-assessment of the available technical documentation.

5.4 Initial Assessment

Initial assessment, which can take the form of a start-up meeting or a desktop review, is intended to ensure that the submitted application and documentary evidence provided fulfil, in principle, the relevant requirements and also provide sufficient confidence for the certification assessment plan to be prepared in the next stage of the process.

Start-up meetings may include the discussion of the applicable milestones, the preparedness of the customer or even the re-definition of the actual assessment scope and may lead to a revision of the initial planning and estimate or the assigned assessment team.

5.5 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, construction, installation and operation of the subsystem or product. 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.

Information 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. All records submitted, 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 any test samples are representative of production and traceable to manufacture.

The customer information provided shall address the following stages if 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 5.7.

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.

Condition (where applicable to plant)

Visual inspection of OTP/OTM to ensure all aspects meet the technical requirements of the appropriate standard.

Series manufacture (where applicable)

Periodic or manufacturing stage assurance activities to 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 or sub-system.

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 some or all of project sites, equipment, customer personnel, documents, records and samples of projects. The customer shall make all necessary arrangements to enable this access to be provided.

5.6 Quality Management System

For each project where the customer or the applicable regulation requires NCB to assess a quality management system to support product certification, the customer 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) and, where required, titles of available procedures
- 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.

If an accredited quality management system certificate is not available and is required for

the specific certification product, NCB will audit the full documentation and implementation of the quality management system, without issuing a QMS certificate to the customer.

5.7 Inspection and testing

As an accredited notified and designated body, NCB checks 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 NCB, based on evidence provided. Typical evidence of equivalence to accredited inspection body or testing laboratory status may include:

- Documents demonstrating certification or 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

NCB may decide to assess them using competent resources and/or witness tests to satisfy applicable requirements.

5.8 Assessment process

The assessment process follows the requirements or modules specified for the project or product in line with the plan produced. Depending on the requirements and the stage of assessment, the assessment may take the form of document review, site inspections, process audits, witnessed testing, meetings and other activities. Related records are kept in NCB's IT system.

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.

The assessor reviews the populated checklist and any associated documented evidence against the appropriate standard, regulation or technical document and queries or identified nonconformities will be raised with the customer through the technical query or non-conformance notification (NCN) process.

For PAB only:

Having identified whether the OTP/OTM is first in class or a subsequent identical

machine, the level of assessment is determined. A first in class machine will require a more rigorous level of assessment.

Where applicable, the assessor will conduct a physical examination of the OTP/OTM to visually assess the machine including areas which may have been an issue on previous machines. The aspects considered are based on the experience, knowledge and professional judgment of the assessor. The customer is responsible for ensuring the OTP/OTM is suitably tested under operational conditions in running, working and travelling modes, dynamically and statically (where appropriate), in accordance with the appropriate standard. NCB will witness these tests and review the test reports to understand whether the outcome conforms to the requirements of the appropriate standard.

In order to conduct its evaluation, NCB needs access to project sites, equipment, customer personnel, documents and records of projects. To comply with requirements, NCB may also require access for observers from relevant interested parties including accreditation bodies, contracted testing, 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.

In the event that, on the day or dates of assessment, restrictions arise such that access to either documentation, facilities, staff or vehicles within the allocated time for the assessment is not possible and this is due to factors attributable to the customer, NCB reserves the right to inform the applicant of the need for an extension of the current visit or a revisit in order to complete the assessment process in its entirety.

5.9 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. Stages where this might occur include:

- Review of requirements listings
- Review of documents, including but not limited to:
 - derogations
 - drawings
 - specifications
 - test reports
 - inspection reports
 - audit and assessment reports
 - certificates

All technical queries are managed using the non-conformity process (NCN).

During all on-site assessments, the team holds opening and closing meetings with the customer's management. At the closing meeting, the assessment team:

- Explains the assessment findings
- Provides documented evidence of findings allowing opportunity for questions
- Summarises any assessment follow-up activities
- Explains any certification process requirements and follow up activities

In the event that a non-conformity 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.

5.10 Reporting

During the assessment, NCB may provide the customer with progress reports that may include parts of the final assessment report.

Following completion of the assessment, 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
- The list of the assessment team members with their scope of activity
- The scope of the certification
- Details and results of evaluation activities carried out
- Details of 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 non-conformity prior to or following authorisation by UK or EU regulatory body.
- The assessment programme
- The assessment synthesis – list of requirements examined for each site and non-conformities
- Details of timescales agreed with the applicant to respond to any identified non-conformances or to provide additional evidence
- The assessment conclusions (justification on certification decision)
- Date proposed to the applicant for any surveillance or reassessment (if applicable)
- Recommendation proposed to the certification panel

Any non-conformity raised during the evaluation, needs to be formally closed before the issue of the final report or certificate.

5.11 Assessment findings level:

Assessment findings may be classified in the report(s) as follows:

Non-compliant

- Evidence provided is clearly at variance with a mandatory requirement in applicable legislation or standards.
- No evidence has been provided against a mandatory requirement in applicable legislation or standards.
- Part of a mandatory process has been omitted or is substantially incomplete.

Recommendation

- Evidence provided against a mandatory requirement in applicable legislation or standards is limited, incomplete or questionable (but not clearly at variance).

- Evidence provided is at variance with published good practice (e.g. by RSSB or ORR).
- Evidence provided is in a format that makes it difficult to assess and/or difficult for the project to use effectively.
- Part of a mandatory process is partially incomplete.

Observation

Observations may be improvement based or positive (complimentary).

- An aspect of the project under assessment could have been performed more effectively (improvement).
- Evidence could have been presented more clearly (improvement).
- An aspect of the project under assessment was performed notable above average (positive).

5.12 Surveillance

Where there is series manufacture in the scope of the project or where QMS conformance is involved in the related NoBo module/requirements, NCB agrees a surveillance programme with the customer 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 may include:

- Witnessing of product inspection and testing
- Use of marks or any other reference to certification
- Assessment of control plan activities (sample)
- 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
- Review of specific requirements of ISO 9001 standard, as detailed in the assessment plan.

All QMS related assessment time is calculated using the IAF MD 5.

Extraordinary surveillance measures may also be implemented as a result of identified major non-conformances that require further investigation or monitoring as described in section 8.

For ECM only:

Surveillance audits are required and will be undertaken annually to include:

- Review of SMS annual reporting
- Review of NIRs
- Review of applicable NIRs relating to the fleets being maintained

5.13 Production samples

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

- Taken in accordance with the applicable 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.

6 Certification

6.1 Records

NCB gathers evidence of compliance as the basis for the certification decision. Records are managed in accordance with NCB's management system procedures. Certification decisions are based on records of evidence of conformance with requirements in accordance with the applicable legislation and standards, in section 1.

6.2 Review by the Certifier

Certification review and 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 6.3.2). If limitations on the subsystem's or machine's operation may be considered to address any nonconformities, these will be identified on the issued certificate.

NCB assigns a "certifier" that is independent from the evaluation process to review the available records. 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.

6.3 Certification Decision

The certification decision is usually taken by a "Certification Decision Panel" (CDP). For some, typically smaller projects, the "Certification Decision" is concurrent with the "Review" and is undertaken by the certifier when signing the certificate.

The persons conducting the CDP (and the certifier for smaller projects) 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
- Non-conformity significance and impact
- Significance and impact of conditions and limitations (see also section 6.6).

The certifier recommends to the CDP whether certification should be awarded and, if so,

any conditions required by the appropriate standards are detailed on the certification. The CDP makes the decision on whether to issue the certificates and, if not, advises what further work is required before certification can be re-considered. Minutes are kept as records.

6.3.1 Decision to award certification

Following completion of the assessment, production of the final report and upon final agreement of the CDP to award a certificate, NCB undertakes the following:

- Issues the new certificate to the customer/applicant
- Informs the appropriate authority as required
- Registers the new certificate details on the appropriate website
- Notifies the customer of the final decision

6.3.2 Non-issue of a certificate

Following completion of the assessment and the decision taken not to issue a certificate to the applicant, NCB undertakes the following:

- Formally records any open non-conformances on the assessment report
- Informs the appropriate authority as required
- Notifies the customer of the final decision

An estimate for an additional assessment or a variation may also be provided.

6.4 Certification Documentation

When the provided service requires the issue of a certificate, NCB issues a certificate to the customer that conforms to specific requirements. Templates of the certificates are available in NCB's IMS.

If so required, the certificates are copied to the appropriate authority in both UK and EU. All issued certificates are recorded in NCB registers.

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

NCB PAB certificates are created in accordance with Appendix A of RIS-1710-PLT. Three copies are issued as follows:

- Rail-borne plant asset manager
- Network Rail Asset Information
- NCB internal records

NCB's ECM certificates comply with requirements of the ECM certification scheme in the ECM Regulation Annex 5 and 6.

- For new ECMs, who have not undertaken ECM activity previously, the period of validity of new certificates will be for a maximum duration of one year
- For existing ECMs the period of validity of new certificates may be up to a maximum period of five years. A programme of at least one surveillance per year, and subjects to be audited, may also be issued
- For existing ECMs who have demonstrated need for significant improvement at audit, the validity period of the new certificate may be reduced to one year and subject to an audit at the end of that period

6.5 Directory of Certified Products

NCB maintains records of projects certified under these scheme rules. This directory is maintained internally but may be (if so required) replicated to the appropriate authority in both UK and EU.

6.6 Conditional Certification

In some instances, it may be necessary for NCB to issue certification with conditions or limitations. 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 sound 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.

The expiry date for issued certificates may vary as NCB follows specific (e.g. NB Rail, RFU STR 060) requirements.

For PAB:

in addition, initial OTP certification is issued with a maximum life of seven years from the date of the first assessment in accordance with the requirement detailed in RIS-1710-PLT: this does not apply to OTM and trolleys.

OTP may be re-assessed during certification life (as a result of modification) and the expiry date shall remain the same as the previously accepted OTP unless the whole vehicle has been fully reassessed. Following a whole vehicle reassessment, the OTP shall be certificated for a maximum of seven years irrespective of the age of the machine constituent parts.

6.6.1 Dealing with completed conditions

Once the conditions are fulfilled by the customer, NCB will:

- Assess the information against the requirements
- Report on findings, and send this to the customer for them to add to the technical file

NB: The customer may specifically request NCB to update the technical file on their behalf to incorporate their new compliance state.

In instances where the conditions are not completed within the given timeframe, NCB will notify the customer 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 10 of these scheme rules and notify the ORR.

7 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 certification is complete and accurate. All information included on the certificate for a 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.

Certificate conditions or limitations 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. Sections 9 and 10 refer.

7.1 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 10 of these scheme rules.

The UKAS accreditation logo and symbols are not used on NCB issued certificates. When they are used (by any customer or NCB) the latest version of “The National Accreditation Logo and Symbols: Conditions for Use by UKAS and UKAS Accredited Organisations” issued by BEIS, is followed.

8 Nonconformity, complaints and appeals

8.1 Nonconformity

Before any assessment, NCB provides the names of the assessment team to the customer 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 notification process. At 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 allow 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.

If a non-conformity is not resolved within an agreed timetable (usually less than six months from the date it was raised), then:

- The audit process may be repeated and additional cost may be incurred for the customer
- If it affects confidence that an applicant satisfies requirements, the certification decision will normally be not to certify (section 7.3) or to withdraw/terminate certification (section 10)

8.2 Appeals

Where a customer believes a nonconformity has been incorrectly raised, the behaviour of the assessment team was not appropriate, 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 Head of Business Development (HoBD) 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.

8.3 Complaints

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 HoBD 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.

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.

9 Change Management

9.1 Changes Affecting Certification

NCB's certification is 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) 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 may include new designs, modifications to existing designs, additional audits, extended audit surveillance, expiry of certification previously issued by NCB, etc.

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 10 of these rules. However, NCB reserves the right to recover any costs committed until the actual withdrawal or during the preparation for the transition.

9.2 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.

For a project manufactured in series or a group of identical items (e.g. plant), the customer shall include in the management system a process for identifying and immediately reporting any proposed additions or alterations to certified products.

Change types that may require re-certification include:

Change type	Description
Design	Any change to design
Material	Any change to approved engineering material
Manufacturing method	Any change to approved manufacturing process
Work flow arrangements	Major changes or deviations to approved safety procedures and processes
New maintainers	Introduction of additional maintainers/suppliers
Personnel with safety responsibility	Organisational changes to key personnel responsible for Safety

Significant organisational change or a location change can impact some of the above variables, and so could be considered significant change in this context.

Failure to assess and implement appropriate measures in response to significant change may invalidate existing NCB certification. Such changes may be reviewed during surveillance activities.

10 Termination, Reduction, Suspension or Withdrawal of Certification

10.1 Suspension of Approval

Suspension of customer's approval may be:

- At customer's request
- Due to identified nonconformity of major safety significance or complaint from external parties, or
- Due to failure to comply with the contractual requirements in place, including terms & conditions related to payment

10.2 Implications of suspension

When approval is suspended, NCB customers:

- May no longer claim to be approved by NCB
- May no longer accept orders in which approval is a condition of contract
- May no longer promote approval by NCB
- Must notify any customer with whom they have contracts for which approval is a contractual requirement, that approval has been suspended

10.3 Failure to maintain your audited Management System

If a major nonconformity is raised at a routine surveillance or a certificate renewal visit, customers will be required to implement all corrective actions necessary to bring the system back into conformity with the assessment standard to maintain MS acceptance.

The NCB assessor will discuss and agree arrangements and timescales for NCB to verify the corrective action that was taken. The method of follow up and timescales will depend on the nature and severity of the nonconformity.

In some cases, corrective actions will be verified by conducting a follow-up or special visit within three months of the major nonconformity being raised. If circumstances allow, it may be appropriate for the assessor to conduct a review of corrective action remotely without the need for a site visit. In extreme circumstances, such as the unlikely event that the entire management system has broken down (as evidenced by the raising of multiple major nonconformities), NCB may elect to suspend the customer's approval with immediate effect.

If the special visit (or other review) confirms that effective corrective action has been taken so that the major nonconformity can be downgraded or closed, NCB will confirm this in writing and the related approval will be resumed in line with the existing surveillance programme.

If the special visit (or other review) finds that customer has failed to take the corrective action required, approval will be suspended.

10.4 Reduction of Scope

Any identified nonconformity of major safety significance or complaint from external parties, or failure to comply with the contractual requirements in place, may result in a reduction of the existing certificate scope if not actioned to the satisfaction of NCB.

At any time, a customer may request the reduction of the existing scope (where applicable).

NCB will review and authorise the request in writing, providing a new estimate for the issue of new documentation and any required assessment or administration work.

10.5 Requests to Suspend Approval

Such a request shall be submitted to NCB in writing, giving reasons for the request. If, after review and authorisation by NCB, such a request for suspension is granted, suspension will remain in force until:

- A request for reinstatement of approval is received and NCB has conducted a satisfactory special audit, or
- Until the expiry of the related certificate - when approval automatically ceases.

10.5.1 Failure to Agree to a Scheduled Visit

If NCB has been unable to agree to a scheduled visit taking place within a reasonable timescale, such that NCB has been denied the opportunity to verify the continued implementation and conformity of your certificate, approval will be suspended.

10.5.2 Special Circumstances

If continuing conformity can not be demonstrated due to unusual circumstances (for example, a temporary lack of business or other “force majeure”) a decision may be made to temporarily suspend any approval.

10.5.3 Notification of Suspension

In all cases, we will notify customers in writing that their approval has been suspended. This notification will include:

- The timescale by which the customer must respond. (Note: for cases of failure to maintain the management system, or nonconformity of major safety significance or complaint from external parties, customers will be required to respond within 14 days from the date of notification)
- Where appropriate, the duration of the suspension period. (Note: suspension normally remains in force until the satisfactory completion of a special visit, or the certificate expiry date)
- The implications of suspension

10.5.4 Response to Suspension

If a customer’s approval has been suspended because of failure to maintain the existing certification, the customer may:

- Claim to have taken appropriate corrective action and request NCB to verify its effectiveness and then reinstate approval (for example, a special visit)
- Invoke the NCB appeals process if it does not agree with NCB’s justification for suspending approval
- Decide to make no response or take no further action. If so, NCB will initiate the withdrawal process

If a special visit is requested, this will only be undertaken if the timescale for the visit is acceptable to NCB (that is, normally within one month of the first special visit).

10.6 Withdrawal of Approval - Request to Terminate Approval

Approvals may be terminated upon request and may be withdrawn at any time in line with the "Termination" terms defined by the NCB agreement or NCB terms and conditions.

10.7 Termination by NCB

NCB will terminate a contract and withdraw a certificate of approval if any of the following circumstances occur:

- Failure to respond to a suspension letter resulting from a failure to maintain an approved system or service
- Customer's decision to opt for withdrawal of approval as an alternative to implementing corrective action
- If we find corrective action not to be acceptable after a second special surveillance visit, or other contract reasons (for example, financial obligations)

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 with an opportunity to provide additional information for NCB's consideration, before taking the action determined.

10.8 Notification of Withdrawal

In all cases customers will be notified in writing by NCB that their approval has been (or will be) withdrawn, stating the date from which the withdrawal is (or becomes) effective.

If so, the following actions may apply and the customer should:

- Destroy all copies of relevant NCB certificates of approval
- Make no further claims to be approved by NCB
- Withdraw from circulation any documents (including reports) bearing the NCB logo
- Review current tenders and contracts to find out if approval is a condition of contract and notify any customers imposing such requirements that approval has been withdrawn

NCB will notify the withdrawal of approval to any interested parties by whatever means is considered by NCB to be most effective. This will normally include notification to any approved company directory that was notified of the original approval.

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.