INTERNATIONAL RAIL QUALITY BOARD

IRIS Guideline 8: Configuration & Change Management

2022

English

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1. Introduction

The aim of this guideline is to help organisations to have a common understanding of configuration management (CM) and to implement and maintain CM processes as part of an IRIS certified Business Management System. It only gives support in understanding the requirements of ISO/TS 22163 and ISO 22163 and does not contain any further requirements.
ISO/TS 22163 describes requirements for configuration and change management in the two chapters 8.1.4 and 8.1.5.
The close relation between those two topics is reflected in the evolutions of ISO 22163 which covers these requirements in chapter 8.1.4 dedicated to configuration management.

Configuration management supports to identify and manage elements of relevance within a product (configuration item) and their relations, so that both the internal and external customer can have a control evolution of these items with contractual agreed methods and their defined parameters at any point in the product life cycle.

Within the Railway Industry, a proper configuration and change management enables organisations to:

- Ensure that the correct products are procured or manufactured and delivered to the correct customer, internal or external, for production, testing & maintenance
- Provide accurate information of the product at all times to be able to handover the information at any moment in the product lifecycle (design to production, production to test, etc.)
- Easily identify documentation that demonstrates the integrity of the design, manufacturing and maintenance e.g. in case of a reliability, safety or accident investigation
- Know all the products where a part or assembly is used, to support reliability or safety impact analysis and obsolescence management
- Administer warranties and determine liabilities
- Easily find product data to avoid duplication of work and maximise opportunities to learn from previous work

Regarding ISO/TS 22163 configuration management is applicable to hardware and software.

The investment in resources necessary to perform effective configuration management throughout the product's lifecycle is returned in long term cost avoidance.

For implementing a configuration management process within an organization, it is highly recommended to use ISO 10007 for guidance as this standard includes detailed information regarding configuration management.

2. Terms and definitions, Abbreviations

2.1. Terms and definitions

Configuration	Interrelated functional and physical characteristics of a product or service defined in configuration information [SOURCE: ISO 10007:2017, 3.1]
Configuration baseline	Approved configuration information that establishes the characteristics of a product or a service at a point in time that serves as reference for activities throughout the life cycle of the product or service [SOURCE: ISO 10007:2017, 3.2]
Configuration information	Requirements for product or service design, realization, verification, operation and support [SOURCE: ISO 10007:2017, 3.5]
Configuration Item	An aggregation of hardware, software, firmware or any discrete portion thereof that contributes an end use function and is designated for separate configuration management (i.e., it has specified requirements and is an item to which the effectivity of changes is addressed).
Configuration status accounting	Formalized recording and reporting of configuration information, the status of proposed changes and the status of the implementation of approved changes [SOURCE: ISO 10007:2017, 3.4]
Part number	A combination of numbers, letters and symbols assigned by a designer, a manufacturer or external provider to identify a specific part or item.
Serial Number	A sequentially-issued character string (alphanumeric identifier) used to designate a specific part or item.

2.2. Abbreviation

CM	Configuration management

3. Process and responsibilities

3.1. CM Planning

Configuration management planning is applied by an organization considering a range of similar products and/or similar business areas (new design, production, maintenance, etc.).

Configuration and change management involves the whole project organization and related external parties.

When defining the CM activities that are appropriate the organization may consider:

- Identification of the immediate CM stakeholders external to the organisation (one step upstream and one step downstream) and the handover points between them
- Identification of the CM stakeholders within the organisation, their roles & responsibilities and the handover points between them
- The defined review points within the product lifecycle and how the configuration at those points will be defined & recorded

The configuration management activities to be undertaken are defined by the organization and define what is done by whom and how (including the IT tools to be used). This provides clarity including both the organisation and the external provider or customers.

The description may be defined in a variety of procedures and plans within the quality management system or in a separate Configuration Management Plan (CMP). This CMP can include or refer to Software Configuration Management Plan as per EN50128 and both plans need to be aligned. The CMP is not a schedule but may refer to project milestones and dates.

To have a clear awareness and overview regarding the configuration and change management, these topics may be covered by the internal audit plan of the organization.

3.2. Identification

3.2.1. General – Configuration Items and their Information

It is important that configuration management is already performed during the design and development phase. It can have for example an influence on purchase orders at external providers if customer requirements demand a special way of identification. If this is not considered it can lead to project delays or claims raised be the customer.

The identification of configuration items and the scope of the configuration management activity that the organisation applies to a specific configuration item is depending on the importance and potential risk of the item.

Typical considerations may include:

Area	Example considerations
Customer requirements	Do the customer requirements contain dedicated configuration information?
Contractual performance	Is the item on the critical path to achieve successful delivery? Is the item of high value or does it require high cost processes and /or tools to produce?
Safety criticality	Is the item safety critical in performance? Does the item need special production measures to ensure compliance with requirements?
Complexity and novelty	Does the item consist of complex integrated systems? Is the item novel or being used in a novel application?
Reliability	Is the reliability of the item critical to product performance?
Maintainability	What level of planned maintenance (if any) does the item require? What level of unplanned maintenance (e.g. damage & vandalism) is expected?
Regulated Maintenance	Is there any maintenance activity compulsory/driven by an existing law?
Legal	Are there any requirements regarding fourth railway package and/or ECM?

Table 1: Examples of criterion for determination of the level of configuration control required

3.2.2. Configuration information

All configuration items should be described by a configuration information. Configuration information can differ depending on which kind of products or systems they are describing. It is expected that the amount of configuration information associated with a product will grow through its lifecycle.

The table below gives examples of the different configuration information that may be appropriate for various characteristics of configuration items.

	Complex product	**Sub-system**	**Sub-assemblies**	**Simple fabrications**	**Standard Components**	**Raw materials**
Examples	Vehicle, signalling installation	Bogie, converter, control system	Wiring Harness, coupler head	Brackets, luggage rack, window	Screws, resistors, cable	Sections (extruded or rolled)
Serial number	X	X	X			
Batch number					(X)	X
Technical specification	X	X	X		X	
Declaration of conformity (1)	X	X				X
Test protocols and reports	X	X	X			
Operating manuals	X	X				
Data sheet					X	
Component Drawing				X		
(1) Declaration of Conformity should include the configuration of the specification it conforms to						

Table 2: Example of configuration information

Every relevant item of configuration information should be managed such that it is linked and traceable to the relevant configuration items(s). Every item of configuration information should be subject to a formal release procedure before it is used.

Duplicate numbering should be avoided. This typically happens when a part or document number comprises a combination of part code and project code or projects create new number sets even if re-using existing items. If a serialised item is to carry an additional identification label (e.g. pre-defined wheelset numbers), no additional serial number should be applied.

For software, the requirements from EN 50126, EN 50127, EN 50128 and EN 50657 should be followed regarding the inclusion of release notes on new versions.

The extend of configuration information can be defined by the organization. Possible ways the define the needed configuration information can be found in the table with examples below:

Criterion	Explanation	Example & Reason
Critical to a) Safety or b) "Mission" Performance	a) Items for which failure could lead directly to fatality or major injury b) Items for which failure could directly incur performance related penalties from the customer	a) Door mechanism - passenger falls from train due to doors opening whilst train is moving b) Horn – train is not allowed to enter service unless working (service provision contract)
Customer, statutory or regulatory requirement	Items that are specified by an external body, even though they may not meet other criteria	Wheelset – defined in a standard
Interchangeable and replaceable	Items of operational equipment that may be removed from a vehicle and re-used if they continue to meet their required function	Damper - may be inspected, tested and re-used if fit. If not fit for use, it would not be repaired.
Repairable	Items of operational equipment that may be repaired or overhauled in accordance with a predetermined method to return to originally required function	Brake Actuator - may be taken apart (e.g. to fit new seals), re-assembled and re-installed
Operational interface with other CI's (hardware or software)	Items that directly impact the operational performance of another CI	Software - a control unit cannot operate correctly without the correct software version installed

Table 3: Examples for configuration information

An organization should define rules for serialization and the following criteria might be used when setting up the rules.

Configuration information:

- Preferably be of a consistent format within an organization, i.e., number of Latin characters and pattern (if a mix of alpha- & numeric- characters)
- Not use leading ‘0’ (zero)
- Not use letters ‘I’ or ‘O’
- Not include spaces or ‘special’ characters - #, @, etc.

Examples of when batch numbers are used:

- Where it is necessary to correlate items to a process, date, event or test but it is unnecessary or impractical to identify individual units e.g.:
    - When raw material must be traceable back to sample test records
    - When an item must be traceable back to sampled performance testing or screening

Examples of when serial numbers may be applied are:

- When products have warranties, the serial number is used to correlate information concerning dates of manufacture and sale and the warranty period for each individual unit.
- Whenever each unit must be subject to individual functional and performance testing or screening, such as acceptance testing, serialization provides the means to correlate each unit to its test records.
- When units of the product require operational and maintenance reporting
- When traceability of a part is desired or required to track safety critical or timely limited parts.

3.2.3. Configuration baselines

A configuration baseline is a set of approved and consistent configuration information at a point in time and is specific to an area of responsibility – e.g. functional design, test, production, etc. Baselines will typically be required at the defined review points within the product lifecycle.

Regarding configuration baselines and statuses, the following configurations "as designed", "as build" and "as maintained" are commonly used:

"as-designed"- Result from the As-Specified configuration and all the approved design of the configuration items of the system, including its sub-systems. It is a structured description of the designed items, to be delivered / installed, embedding the bill of material of any hardware and software involved.

Fix the configuration baseline at a certain point of time (e.g. at type test); use BOM and record drawing and drawing revision).

"as-built" – The "as-built" configuration is reflecting the "as-designed" configuration and all changes applied until the production of the product.

Configuration Status of an individual Product/Service corresponding to the product upon fabrication/installation, resulting from the agreed configuration with the next customer and including any deviations compared to the Target Configuration.

Capture data of each serialized part (incl. software) and document (e.g. in a Bogie History Book)

"as-maintained" – The "as-maintained" configuration is reflecting the "as-build" configuration and all changes applied until the maintenance activities performed.

Configuration status of an individual product/service as operated/maintained and its associated maintenance tasks strategy. It is constantly updated following the maintenance and repair operations during the Product Service lifetime.

Update data of each serialized part (incl. software) after service or maintenance and update the documentation

A revised baseline at a review point of the product/service life cycle includes a list of implemented changes into the released configuration items.

More detailed examples for configuration baselines can be found in Appendix 1.

3.2.4. Revision levels, modification Levels and software versions

Revision levels are applied to documents and product data to identify a controlled change to their content. This should be according to ISO 7200 or an equivalent.

Created by Jane Smith	Approved by David Brown	
Document type Sub-assembly drawing	Document status Released	
Title, Supplementary title Apparatus plate Complete with brackets	**AB123 456-7**	
	Rev. A / Date of Issue 2002-05-14 / Lang. en / Sheet 1/5	

Figure 1: Example of revision status in a document header

Modification levels are applied to physical items to designate that they have been built or converted to a defined condition. Modification levels should not be used to designate two variants of an item that are non-interchangeable and used in different applications.

The method and interpretation should be used as shown below.

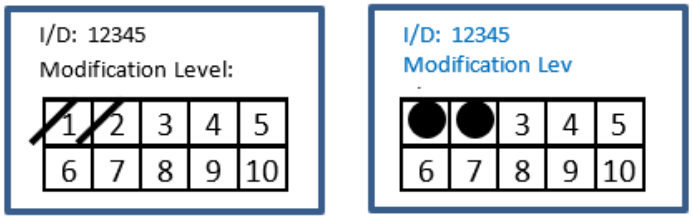


Figure 2: Two examples for the modification levels for a physical item in revision 2

. Software commonly use versions with multi digits, depending on the impact of the new version. It should be possible to identify the software installed in a device.

It is recommended that this is done in accordance with IEEE 828.

3.3. Status Accounting

The status of configuration information at defined points in a product's lifecycle must be known and able to be reported in a variety of different ways as required by different stakeholders.

Reports based on configuration data are produced for two main purposes:

- To monitor the completeness of products, effectiveness and efficiency of the configuration processes
- To compile information that is needed as a deliverable for handover between stakeholders for baselines.

Some examples for status accounting reports and their input sources are given in the table below.

Programme Phase	Typical inputs	Typical reports
Concept	• Performance/cost/schedule goals • System requirements documents • Preliminary system performance specifications	• Current revision / version of each document • Approval status for each document
Design & Development	• Inputs from concept phase (e.g. current revision / version of each document; approval status for each document) • System performance specification • Performance specifications • Detailed specifications • Engineering drawings and • associated lists • CAD files • Test plans/procedures& results • Audit plans • Audit reports • Audit certifications • Requests for change • Requests for Variance • Engineering orders, change notices, etc. • Installation and as-built verification • Removal and re-installation instructions	• Approval authority for each document • Release and approval status of each document • Current baselines • Baselines as of any prior date (they are covered by the other bullet points already listed) • As-designed configuration, current and as of any prior date • As-tested configuration, current and as of any prior date • Status of requests for change and variances in process • Effectivity and incorporation status of approved changes and variances, including retrofit effectivity • Test and certification requirements to be completed prior to milestones such as reviews, demonstrations, tests, trials, delivery • Verification and audit status and action items
Manufacture & Assembly	All development phase items plus: • System/Component location by traceable number • Support equipment and software • Trainers • Training Material • Delivery dates and warranty data • Shelf life or Operating limits on components with limited life or limited activations, etc. • Verification/Validation of Retrofit Instructions, Retrofit Kits • Incorporation of Retrofit Kits	All development phase items plus: • As-built configuration, current up to time of delivery and any prior date • As-delivered configuration
Commissioning, Operation & Maintenance	All manufacture & assembly phase items plus: • Spares • Operating and Maintenance Manuals • Operational history data • Installation of spares, replacements by maintenance action • Obsolescence data	All manufacture & assembly phase items plus: • Equipment history • Obsolescence action items

Table 4: Example status accounting reports and their input sources

3.4. Change management

The change management process can be described in the CMP. Changes can be initiated by the organization itself, by external providers or also by customers and are often called change requests or change proposals. The person or group of people who are responsible for approving a change proposal shall be assigned within the organization.

It is recommended to define a set of criteria that are used to decide whether a change proposal is valid before starting a detailed analysis. This analysis should include:

- Defining which departments are impacted (engineering, procurement, field service, project management, etc.)
- Defining which external stakeholders are impacted (customer, maintainer, operator, etc.)
- Define how the product functions and performance are impacted (safety, reliability, maintainability, etc.)
- Identify which configuration items are impacted
- The cost, schedule & resource impact for each department and aggregated for the business

Based on the assessment, the change proposal is then approved or rejected. The implementation plan is agreed based on a rank/date of application and a target configuration. It is recommended that the assessment is managed using an IT system which also supports the change approval and execution in the documentation and the product.

Parts carrying the same part number are considered to be fully interchangeable. The organisation should have a clear set of rules that are used to decide if, after a change, a part can retain its original part number or should be allocated a new part number.

An example for change management application can be found in Appendix 2.

ANNEXES

Annex 1: Examples of project key events to define configuration baselines/record

Area of responsibility	When	Baseline Content	Comments
Product management phase	Reference Library	Bricks of solutions mapping the most common products that can be offered to customers. Reference Library is maintained regularly.	
Tender management phase	As-Proposed	It is the reference to the proposal made to customer at the tender submission, including at least the customer requirements analysis and feedback as well as related documentation.	
	As-Sold	It is the reference to the offer made after discussions and negotiations with the Customer. A gap analysis shall be conducted to compare the As-Proposed and As-Sold Baselines	
Product Design	At end of design phase (e.g. concept, detail, etc)	Product structure (incl. part ID + Document ID & revision): Specifications Drawings Etc.	For an assembly (e.g. door leaf), the baseline may be for the entire product design. For a complex integrated product (e.g. multiple unit) baselines may be by sub-system or specialist engineering area
Product manufacture / assembly	Before commencing production (in a series)	Production documents (work instructions, inspection & control charts, etc.) CNC code, tooling.	

Area of responsibility	When	Baseline Content	Comments
Testing & Commissioning	Before commencing a test or commissioning (cycle)	Approved design configuration, physical product record (incl. serial numbers, software versions), test / commissioning procedures	
Acceptance	Before submission to acceptance body	Testing / Commissioning baseline + test reports + certification declarations	
Warranty	Before close of warranty	Open items status, physical product record (incl. serial numbers, software versions),	
Maintenance or overhaul	Before handover of maintenance or overhaul activities	physical product record (incl. serial numbers, software versions), + repair / maintenance records + manuals & procedures	

Annex 2: Explanation of configuration baseline vs. current approved configuration

ISO 10007 describes baselines with reference to the 'approved configuration information' and 'current approved configuration'. This annex provides an interpretation of the standard and explains the methods that may be used to achieve configuration status accounting as described in ISO 10007.

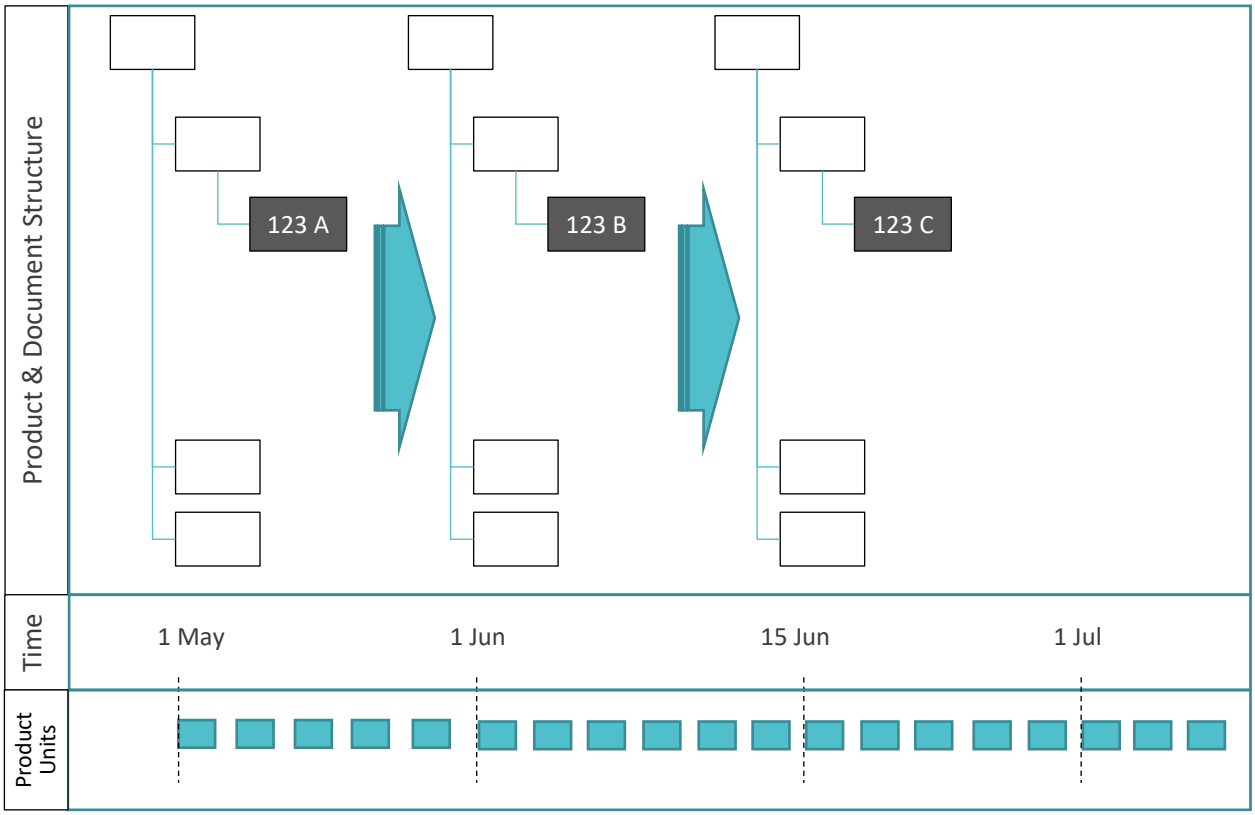
In this approach:

- Documents are updated for each change or batch of changes depending on the impact. For complex products or systems updates can also be made by group/batch of changes.
- Production always works according to the current effective document revision
- Demands a fast process for updating documents

Using this approach, the 'as-built' configuration has only to confirm compliance with the released product structure. This simplifies status accounting reports. This approach is sometimes known as a 'rolling baseline'. To be used only for simple products, whereas complex products need consistency as regard to the approved configuration.

Current approved configuration contains:

- an increment of the previous release
- updated and released list of the agreed and approved changes assigned
- the complete list of configuration items with their revisions



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