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International Railway Industry Standard

UNDER REVISION

GUIDELINE 8 : 2016
CONFIGURATION AND CHANGE MANAGEMENT

English

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Certification

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Guideline 8 : 2016 CONFIGURATION AND CHANGE MANAGEMENT

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.

Configuration Management comprises not only identification and traceability of elements but additionally:

- Configuration Management Planning
- Configuration Identification: items and Baselines
- Change Management
- Configuration Status Accounting
- Configuration audits

2 PURPOSE

Configuration Management provides means to identify and manage elements of relevance within a Product (Configuration Items), and their relations, so that both the Internal and external customer is able to trace these elements and their defined parameters at any point in the product life cycle.

Within the rail sector, it enables organisations to:

- Ensure that the correct parts 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, manufacture 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

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

3 TERMS, DEFINITIONS, ABBREVIATIONS

The following definitions are additional to those in the IRIS standard.

Configuration: (1) The product attributes of an existing or planned product, or a combination of products; (2) one of a series of sequentially created variations of a product.

CM: Configuration Management

CMP: Configuration Management Plan

Configuration Audit: Review of processes, product definition information, documented verification of compliance with requirements, and an inspection of products, to confirm that products have achieved their required attributes and conform to released product configuration definition information.

Functional Configuration Audit: An audit conducted to verify that the development of a configuration item has been completed satisfactorily, that the item has achieved the performance and functional characteristics specified in the functional or allocated configuration identification, and that it is operational and support documents are complete and satisfactory.

Physical Configuration Audit: An audit conducted to verify that a configuration item, as built, conforms to the technical documentation that defines it.

Configuration Baseline: Configuration of a product, at a specific point in time, which serves as a basis for defining change, for conducting verifications, and for other management activities. For a software product, the build baseline includes the actual product.

Configuration Identification: The CM function which (1) establishes a structure for products and product configuration information; (2) selects, defines, documents, and baselines product attributes; (3) assigns unique identifiers to each product and product configuration information.

Configuration Item (CI): An aggregation of hardware, software, firmware or any discrete portion thereof that satisfies 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 Management: A technical and management process for establishing and maintaining consistency of a product's functional and physical attributes with its requirements, design and operational information throughout its life.

Configuration Status Accounting: Activity that formalises the recording and reporting of the established product configuration information, the status of requested changes, and the implementation of approved changes including changes occurring to product units during operation and maintenance.

(Product) Configuration Information: Information about a product consisting of product definition information and product operational information.

Duplicate Number: Two (or more) identification numbers exist within an organisation for items that are fully interchangeable. Note – there may be two or more different supplier or customer part numbers may exist that an organisation may map to its identity number. These are not duplicate numbers.

Serial Number: A sequentially-issued character string (alphanumeric identifier) used to designate a specific unit of a product.

4 RESPONSIBILITIES

The responsibility for different CM activities is spread around an organization, and will be dependent on the nature, activity and products of the organization. Section 5.1 guides the organization to document the responsibilities for the various CM activities.

However, the below responsibilities may be ensured by the organization

- Configuration Manager/Coordinator >> able to decide over production stops, if necessary, to comply with configuration agreements.
- Change Disposal Team/manager >> able to approve/ reject change proposals.

5 PROCESS

5.1 CONFIGURATION MANAGEMENT (CM) PLANNING

It is expected that the approach taken to Configuration Management in an organisation would usually be consistent across, as minimum, a range of similar products and/or similar business areas (new design, production, maintenance, etc.).

When defining the CM activities that are appropriate, the organisation should consider the specific guidance given in sections 5.2 to 5.2.6 with respect to:

- Identification of the immediate CM stakeholders external to the organisation (1 step upstream and 1 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 and recorded

The organisation should describe the Configuration Management activities to be undertaken, by whom, and how (including the IT tools to be used). This provides clarity both within the organisation and to suppliers/customers.

The description may be defined in a variety of procedures and plans within the business management system or in a separate Configuration Management Plan CMP (including a Software Configuration Management Plan as per EN50128). The CMP is not a schedule, but may refer to project milestones and dates.

5.2 IDENTIFICATION

5.2.1 GENERAL – CONFIGURATION ITEMS AND THEIR INFORMATION

Configuration items should include every item from the top level product to the lowest level component that will be designed and/or produced and/or maintained by your organisation.

The scope of the Configuration Management activity that the organisation applies to a specific configuration item will be dependent on the importance and potential risk of the item. Typical considerations may include:

Area	Example considerations
Safety criticality	Is the item safety critical in performance? Does the item need special production control measures to ensure consistency?
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?
Contractual performance	Is the item on the critical path to achieving successful delivery? Is the item of high value or does it require high cost processes and /or tools to produce?
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?

5.2.2 PART / DOCUMENT NUMBERING

All configuration items may have a unique identity number.

Identity numbers may:

- Preferably be of a consistent format within an organization, i.e. number of 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.

Parts carrying the same identity 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 identity number or should be allocated a new identity number.

An example set of rules is shown in Figure 1

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.

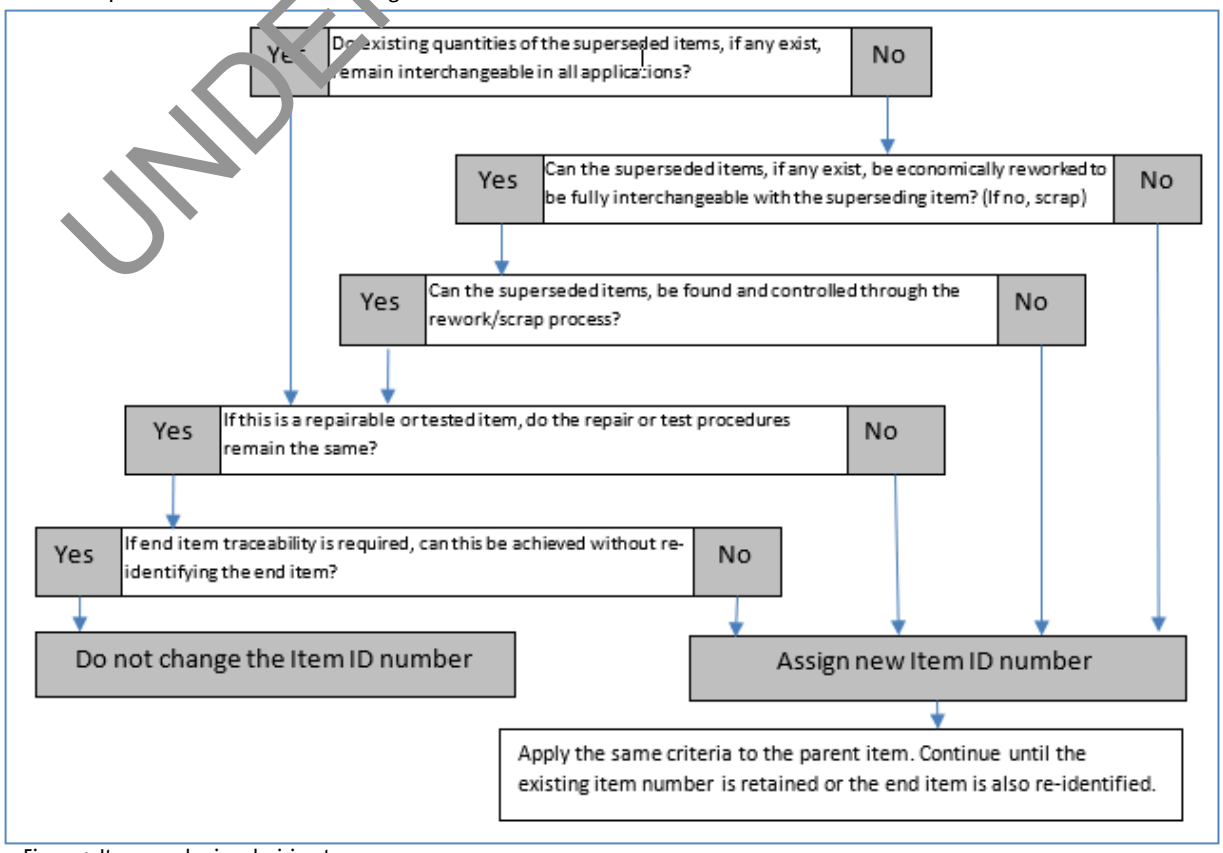


Figure 1–Item numbering decision tree

5.2.3 REVISION LEVELS, MODIFICATION LEVELS & SOFTWARE VERSIONS

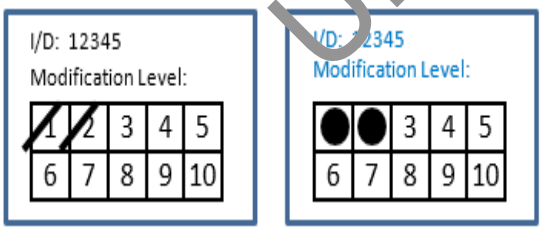
Revision levels are applied to documents and product data to designate a controlled change to their content. This should be according to ISO 7200 or an equivalent.

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 2-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. In such cases one variant must be re-numbered according to 5.2.2.

The method and interpretation should be used as shown. The first two numbers are crossed off or blocked out; the item is at Modification level 2



Software should be controlled using versions. It is recommended that this is done in accordance with IEEE 828.

It should be possible to identify the software installed in a device. This should be through a Human Machine Interface (HMI) device for externally updatable software and by product identification for embedded software.

5.2.4 CONFIGURATION INFORMATION

In the rail environment, configuration information should cover all information that describes what the product is, how it is produced, how it is operated and how it is maintained or repaired. This will principally be produced as documents: specifications (customer, design, test, etc.), schemes, drawings, spare parts lists, operating manuals, etc.

An organisation defines what configuration information is applicable to their product(s) and / or activities through the lifecycle. It is expected that the amount of configuration information associated with a product will grow through the lifecycle.
Every relevant item of configuration information may be managed such that it is linked and traceable to the relevant configuration items(s).

Every item of configuration information may be subject to a formal release before it is used, in accordance with IRIS requirements for the production documentation.

For software, the requirements from EN50128 should be followed regarding the inclusion of release notes on new versions.

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

Configuration Info (y) / Item (x)	**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			X	
Data sheet					X	
Component Drawing	X	X	X	X		

Table 1 – Example of configuration information

(1) Declaration of conformity should include the configuration of the specification it conforms to

As part of the assessment to determine the level of configuration control required, the assessment criteria below may be applied. Some items may meet several criteria.

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 provided that 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 Configuration Items (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 2 – Examples of criterion for determinination of the level of configuration control required

5.2.5 SERIALIZATION AND BATCH NUMBERING

For items that are identified according to section 5.2.1 as requiring specific controls, serial or batch numbering should be used.

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 time limited parts.

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.

Examples of when batch numbers may be applied are:

- When raw material must be traceable back to sample test records
- When an item must be traceable back to sampled performance testing or screening

If a serialised item is to carry an additional identification label (e.g. customer part number), no additional serial number should be applied.

If it can be reasonably foreseen that an item could be converted into another similar item (e.g. by changing colour) during its service life, then the serial number series for both must be unique.

5.2.6 EFFECTIVITY, EFFECTIVE DATES & RELEASE DATES

The release date of a document or item is the point at which it receives its approval and is made available for a specific purpose.

The effective date represents when a newly released document or item is to be used.

For the initial version of a document or item, the release and effective dates are normally the same. For revisions, the release date of each document should ideally be left as late as possible (just-in-time) compared to its effective date in order to ensure the correct sequencing of changes. The need to balance a department's workload will determine the actual release date.

Effectivity is the point from which a specific configuration applies to a product (highest level), i.e. it is the effective date for the controlling or highest level document(s) in the configuration.

Whilst effectivity is often expressed in terms of serial numbers, block numbers, batch numbers, lot numbers or an event, the simplest definition is time-based. A time-based effectivity can be cross-referenced to serial numbers, etc. by means of the production schedule.

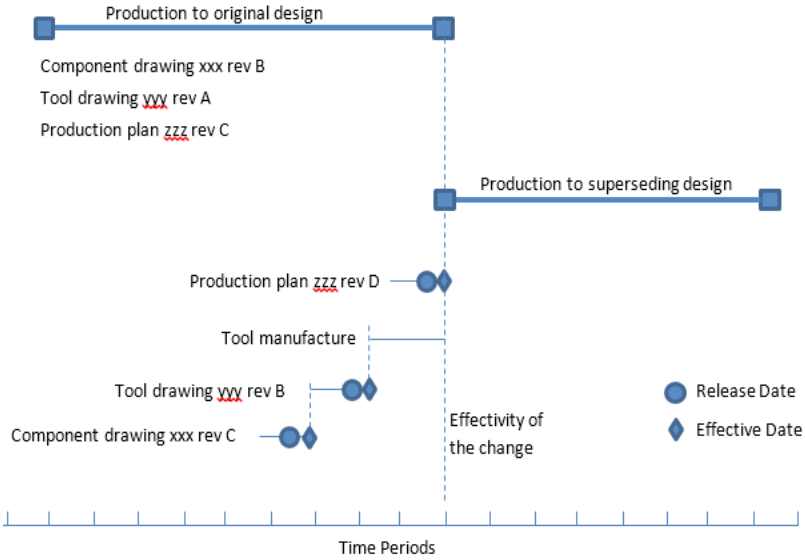


Figure 3- Example of effective dates and effectivity

In the example in Figure 3, the revised component drawing (xxx rev. C) is to be used in order to create the tool drawing (yyy rev. B). There is then a lead time for that tool before it can be used. The effective date for the component drawing is therefore set by the lead times for the subsequent activities.

5.3 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.

- To monitor the effectiveness and efficiency of the configuration processes
- To compile information that is needed as a deliverable for handover between stakeholders and / or to provide benchmarks (baselines)

Some example status accounting reports and their input sources are given in:

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	• 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 • 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

5.4 CHANGE MANAGEMENT

It is recommended to define a set of criteria that are used to decide whether a change proposal1 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.)
- The cost, schedule and resource impact for each department and aggregated for the business

Based on the assessment, the change proposal is then approved or rejected.

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.

The person or group of people who are responsible for approving a change proposal should be defined (defined as the 'dispositioning authority' in ISO 10007). Note – the dispositioning authority may change through the product lifecycle – e.g. in design, production, service, etc.

Note 1 – Change Proposal is also commonly known as a Change Request

5.5 AUDIT

Configuration audits determine to what extent the actual CI reflects the required physical and functional characteristics.

Configuration management supports the FAI process (IRIS Guideline No2) by ensuring that all the documentation required for that activity is released and structured.

Note – The IRIS FAI process encompasses ISO 10007 for a Functional Configuration Audit.

Configuration management supports the Control of production and service provision by ensuring that all the documentation required for that activity is released and structured.

Note – The IRIS Control of production and service provision process encompasses ISO 10007 for a Physical Configuration Audit.

Configuration Management processes shall be subject to audit according to the IRIS requirements for internal audits.

6 ANNEXES

Annex 1: Explanation of current approved configuration and Baselines.

ANNEX 1: EXPLANATION OF CURRENT APPROVED CONFIGURATION AND BASELINES

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 per section 5.3. of this guideline.

A) Current Approved Configuration

There are two basic approaches to achieving a current approved configuration for serial production, installation or maintenance activities. These are described below as 'Approach 1' and 'Approach 2'.

It is recommended to use 'Approach 2'.

One-off activities, such as a signalling system installation, repair of crash damage, or constructing a single bespoke item of complex equipment are beyond the scope of this annex. However, they should similarly commence work based on an approved configuration (e.g. a set of released and approved procedures), agree and document variations from those procedures as work proceeds, then ensure that a final clear and concise record of the final configuration is created.

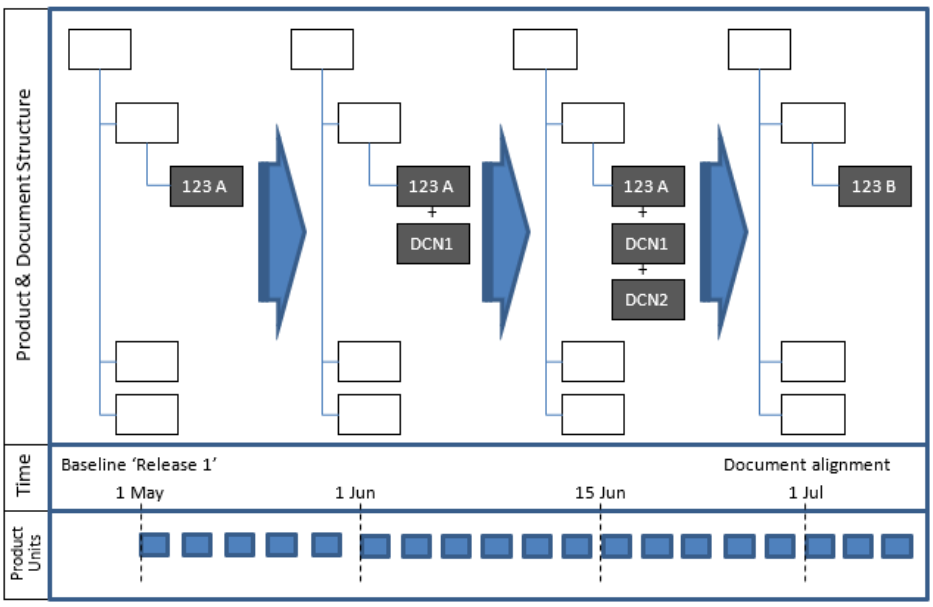
In Approach 1:

- The starting point for the process is a baseline – shown as 'Release 1' in this example.
- When a change is required, Design Change Notices (DCNs) are used to approve information used for production.
- The document(s) to which those DCNs apply are formally revised to include the DCN content at some future date –shown as 'Document alignment' in this example.
- The documentation revision (at 'Document alignment'), does not trigger a change to the actual product build state
- Document alignment may or may not be coincidental with the next baseline, as defined in section B)

Using this approach, there is a risk that what is put into the final document revision is different to the DCN contents. An organisation using this approach should define and implement checks to eliminate this risk. It is also more complicated for production to record 'as-built' configuration as each produced item potentially has many DCN records. As a consequence, simple creation of clear and concise status accounting reports is more difficult.

Approach 1

Current approved configuration = Last baseline + approved changes.

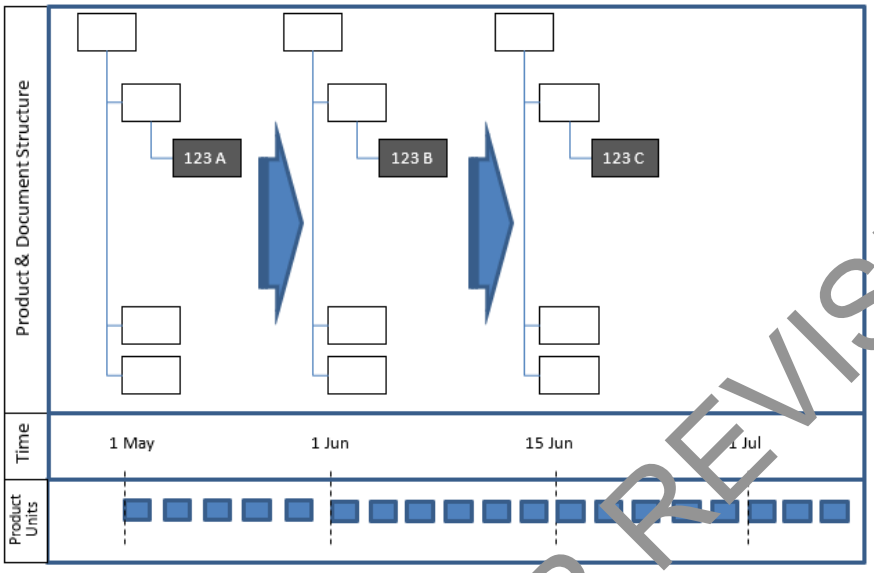


In Approach 2
- Documents are updated for each change
- Production always work to the current effective document revision
- Demands a fast process for updating documents

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'.

Approach 2

Current approved configuration = Last approved document revisions



B) Baselines

A baseline is a set of approved configuration information at a point in time. A baseline 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 (as defined in section 5.1) A baseline should have a unique identity number. If the IT systems that contain the product configuration information enable that information to be linked to a baseline, there is no need to produce a baseline document – unless it is specifically required by a stakeholder (e.g. customer contract requirement).

Some example baselines and their content are illustrated below:

Area	When	Baseline Content	Comments
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.	-
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	-

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