



IRIS Guideline 6: SPECIAL PROCESSES

2020 / rev. 01

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1 Introduction

The aim of this guideline is to define the specificities for compliance with the requirements of the IRIS Certification® rev. 03 system regarding special processes. It guides and supports the user in preparatory work for the implementation of the ISO/TS 22163 requirements related to special processes.

Furthermore, it defines and describes the special processes that are relevant to the rail sector and supports the management of those processes in accordance with the ISO/TS 22163 and IRIS Certification® Conformity assessment.

The details on

- the technical requirements can be found in the ISO/TS 22163 “Railway applications – Quality management system – Business management system requirements for rail organizations: ISO 9001:2015 and particular requirements for application in the rail sector”.
- the certification process and the assessment methodology can be found in the IRIS Certification® Conformity assessment.

Compared to other processes, special processes require special attention as the conformity of the output is not readily, technically or economically validated. See definition in clause 3. The following processes are generally considered special processes.

- bonding and sealing,
- casting,
- crimping,
- force fitting or shrink fitting,
- forging,
- heat treatment,
- laminating (composites,...),
- moulding,
- potting (e.g. electronics),
- riveting,
- stress relief treatment,
- surface treatment (painting, coating, chemical and electro-chemical treatment),
- torque tightening/bolt tensioning (for preload application),
- welding (including soldering and brazing),
- 3D printing.

Other processes may be considered.

For the use of this guideline the following three aspects should be considered:

- 1) Is the process a special process? See clause 3,
- 2) What is the criticality level of the process output in terms of safety and quality? See clause 4,
- 3) Is the process carried out internally or externally (external providers)? For external providers see clause 5.1.12.

The guideline content is a recommendation based on good practices from the rail sector experts and methods and is not subject to be audited by any third-party audit as a mandatory requirement.

2 Normative references

ISO/TS 22163	“Railway applications – Quality management system – Business management system requirements for rail organizations: ISO 9001:2015 and particular requirements for application in the rail sector”
IRIS Certification® Conformity assessment	Rules for achieving and maintaining IRIS Certification® recognition

3 Terms and definitions

3.1 Terms and definitions for the rail sector

Special process	A process used in manufacturing, construction of infrastructure or maintenance where the conformity of the resulting product cannot be readily, technically or economically determined without destructive analysis prior to use is referred to as a “Special Process”. NOTE According to ISO 9000:2015, “a process where the conformity of the resulting output cannot be readily or economically validated is frequently referred to as a “special process”.
Special process coordinator	The person who coordinates the special process, see clauses 5.1.1 and 5.2.1.
Special process operator	The person who executes the special process, see clause 5.2.2.
Special process instruction	A procedure for use in the workstation that describes how to carry out the special process.

3.2 Abbreviations

The abbreviations given in ISO/TS 22163 apply for the purpose of this document

FAI	First Article Inspection
FAT	Factory Acceptance Test
FMEA	Failure Mode and Effects Analysis
HSE	Health, Safety and Environment
IRIS	International Railway Industry Standard

IRQB	The International Rail Quality Board
Mock-up	A scale or full-size model of a design
RACI	Responsibility assignment matrix, which contemplates the following participation roles Responsible, Accountable, Consulted/Contribute, be Informed.
REACH	Regulation for registration, Evaluation, Authorization and restriction of Chemicals
RoHS	Restriction of Hazardous Substances in electrical and electronic equipment
TPM	Total Productive Maintenance

4 Criticality level of the output

In special processes the following six input elements (**6M**) need to be rigorously managed to achieve a consistent output:

- **M**anagement,
- **M**anpower,
- **M**achines,
- **M**ethods,
- **M**aterials,
- **M**other nature (Environment).

Process input elements and output can be represented using an Ishikawa diagram [1]. Ishikawa diagrams are causal diagrams that show the potential causes resulting in a specific event.

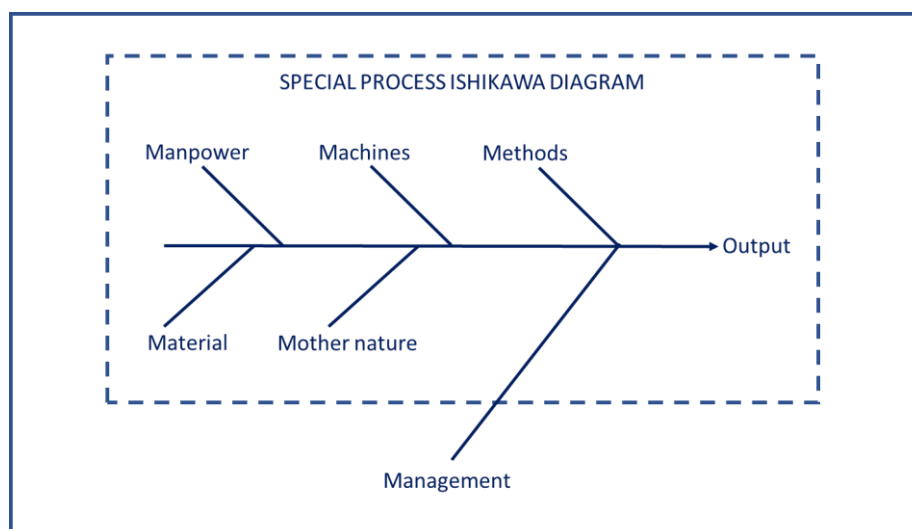


Fig.1: Special process Ishikawa diagram

The criticality of the output of the special process should be determined considering the impact on safety and quality (see clause 5.1.2). The criticality level obtained should be considered to determine the extent of application of this guideline (see Table 1).

Table 1: Special process implementation matrix according to the criticality level of the special process output

Item	Criticality level of the special process output			6M	Clause
	HIGH	MEDIUM	LOW		
Requirements review (contractual and internal)	Review required			Management	5.1.1
Design review	Review required			Management	5.1.1
	Coordinator involvement required	Coordinator involvement may be required	Coordinator involvement not required		
Production planning	Required			Management	5.1.1
Inspection planning	Required		Recommended	Management	5.1.1
Identification & traceability	Required	Recommended	No specific requirement	Management	5.1.1
Quality records	Required	Recommended	No specific requirement	Management	5.1.1
FMEA	Required	Recommended	No specific requirement	Management	5.1.2
Qualification & validation of special process	Required		Recommended	Management	5.1.3
Process control & monitoring	Required		Recommended	Management	5.1.5
Nonconformity and corrective action management	Required			Management	5.1.6
	Procedures for rework required		Recommended		

Item	Criticality level of the special process output			6M	Clause
	HIGH	MEDIUM	LOW		
Special process external provider	Approval of special process required by the organization or its customer	Approval of special process required by the organization or its customer	Approval of special process may be required by the organization or its customer	Management	5.1.12
	Communication of requirements related to special process required	Communication of requirements related to special process required	Communication of requirements related to special process may be required		
Special process coordinator(s)	Required			Manpower	5.2.1
Special process operator(s)	Qualification is required			Manpower	5.2.2
	Skill matrix required	Skill matrix recommended			
Production and testing equipment	Required			Machines	5.3
Equipment maintenance	Preventive (Predictive recommended)	Preventive	Corrective	Machines	5.3
Special process instruction(s)	Required		Recommended	Method	5.4
Inspection of base materials and consumables	Control plan required in accordance with risk analysis			Materials	5.5.1
Materials and consumables storage and handling conditions	In accordance with manufacturer recommendations			Materials	5.5.2
Environmental conditions of the workstation	Control plan required in accordance with risk analysis			Mother nature	5.6

5 Operating method

The management of the special process is key to the output and is therefore described in detail before the other 5M input elements: Manpower, Machine, Methods, Material and Mother nature.

5.1 Management

The management of the special process influences all of the input elements (see Fig. 1) as well as the output. Special process management encompasses:

- roles and responsibilities in special process management,
- risk management,

- process qualification,
- process validation,
- process control and monitoring (indicators),
- nonconformity management,
- change management,
- transfer management,
- supply chain management,
- special process audits/inspections,
- knowledge management,
- special processes performed by external providers.

If there are special requirements regulated by international or national standards or legal regulations, these requirements should be fulfilled, when applicable.

5.1.1 Roles and responsibilities in special process management

Within the organization, roles and responsibilities for managing special processes should be defined.

The organization should designate a special process coordinator and this designation should be communicated to the organization. If the special process coordinator is external (subcontracted), an internal deputy should also be included to the designation.

NOTE In the rest of the guideline where coordinator is mentioned, the activity may be carried out by the coordinator's deputy.

The relationship between the special process coordinator and the organization should be defined and communicated.

The special process coordinator should be integrated into the organization in a way that allows the execution of the tasks in the areas of responsibility without any restrictions; the coordinator should have the required authority to instruct and make decisions, independent from production.

The areas of responsibility of the special process coordinator within the organization should be documented. These areas of responsibility may include:

- internal guidelines, specifications, procedures and instructions,
- requirement review and feasibility confirmation in tender management,
- validation of special processes content/items in design review phase (if applicable),
- material specifications (including base and consumables materials),
- supply chain management,
- external providers of special processes,
- equipment and tools, including inspection/testing,
- qualification of personnel,
- production planning and start up, especially for new products,
- inspection planning,
- process qualification and validation,
- process and product audits,
- non conformities and corrective actions,
- identification and traceability,
- quality records,
- knowledge management.

These areas of responsibility may be managed in different ways, for example, via specification, participation, inspection, approval, control, act of presence, etc. and may be documented using a responsibility assignment matrix, e.g. RACI.

Complementary roles and responsibilities can be defined according to the relevant applicable special process standards (e.g. EN 15085, DIN 6701, etc.)

The relationship among locations within the same organization that share the same special processes should be defined.

5.1.2 Risk Management

When no guidance or standard on the special process is available (e.g. EN 15085, DIN 6701, etc.), the organization should consider how the input elements (see Fig. 2) and changes in these input elements impact the output of the special process. The criticality of the input elements should be determined in this analysis and approved by the special process coordinator.

A typical sequence for a process FMEA analysis is shown in the figure below:

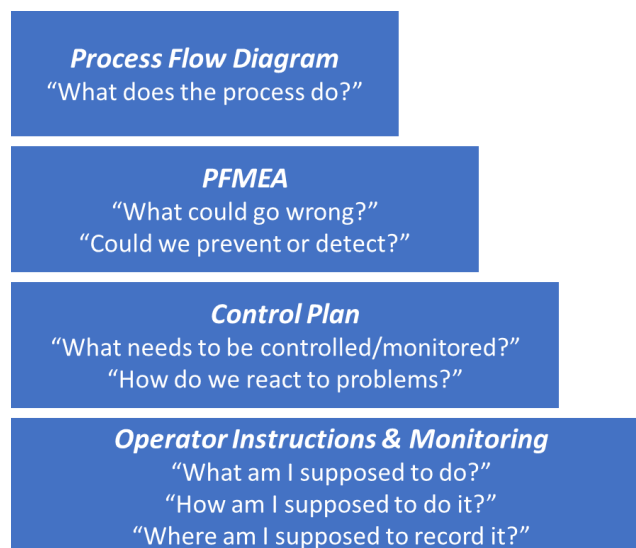


Fig. 2: Sequence for a process FMEA analysis

5.1.3 Process qualification

A special process instruction should be established and include the definition of the input elements required (5M in Fig.1) to produce a specific output.

Process qualification should fulfil the requirements established in the relevant national/ international special process standard and contract. If such standard does not exist, the special process coordinator defines the qualification process and criteria.

The organization should issue a process qualification plan, approved by the special process coordinator, which describes how to qualify a special process.

The qualification is carried out, as a general rule, on a mock-up and/or test pieces and under industrial conditions to represent the performance of the product/process couple.

The qualification plan should include:

- required qualification documents (e.g. preliminary special process instruction, evaluation sheet, qualification record),

- relevant standards (if applicable),
- identification and storage of mock-ups/test pieces and test records,
- inspection, non-destructive and/or destructive testing methods, including acceptability criteria,
- range of validity (input elements) of the qualification,
- renewal criteria.

A standard qualification record form should be established. If a standard qualification form exists, for example, in international or national standards, that form may be used directly.

Qualification tests are to be supervised by the special process coordinator. Qualification approval needs to be given by the special process coordinator or by an external accredited examination body, if applicable.

To assist in the determination of range of validity (if none exists), the risk management tools specified in clause 5.1.2 should be used.

5.1.4 Process validation

The process validation is carried out when the first representative product is manufactured, installed or maintained, before or as a part of the FAI. Depending on the results of the risk management (see clause 5.1.2.) further process validations during series production, construction or maintenance may be required.

During this validation the correct application of the qualified special process(es) should be checked, as well as the ability to produce the expected results. These checks are performed throughout the entire process (before, during and after).

5.1.5 Process control and monitoring (Indicators)

The organization should establish appropriate controls of the input elements and special process considering the output of the risk analysis (see clause 5.1.2), e.g. control sheets, inspection plans, ...

In addition, the organization should define and implement indicators to monitor the special process. Performance indicators (KPIs) are based on quality, time and/or cost performance (IRIS Guideline 1: KPIs). Because the performance cannot be readily or economically measured in a special process during series production, the following KPIs are recommended:

- results of product inspection (partial conformity),
- results of destructive testing on series production witness samples,
- feedback from warranty period.

It may be useful to create additional indicators to measure the correct application of the special process for example:

- results of workstation (5M) inspection,
- results of internal or external audits.

If there are significant deviations in these process indicators the organization should analyze the root causes, even if the product characteristics are within the required limits. The indicators should be used for continuous improvement purposes.

5.1.6 Nonconformity management

The special process coordinator needs to be involved in nonconformity management in the special process. The degree of involvement required should be documented and take into account the severity of the nonconformity (e.g. rework, repair, reject, etc.), product criticality and contract requirements.

Re-qualification, validation and traceability requirements should be defined.

5.1.7 Change management

This chapter describes the aspects of change management of released (qualified and validated) special processes under the following conditions:

- same location (factory),
- same product technical specification.

The special process coordinator will determine when a change in the input elements (see Fig. 1) requires a new or revised qualification (see clause 5.1.3) and process validation (see clause 5.1.4).

A revised qualification may include complete or partial inspection or testing that justifies the change. If no further testing is carried out, the justification for not testing should be recorded.

When a qualified special process is substituted by another one, a new process validation (see clause 5.1.4) needs to be carried out.

5.1.8 Transfer management

This chapter describes aspects of change management of released (qualified and validated) special processes under the following conditions:

- different location (factory),
- same product technical specification.

The special process coordinator at the original location should be informed of the location change. All released documentation corresponding to the qualified special process should be transferred to the new location.

The special process coordinator at the new location should review the documentation to ensure it can be correctly applied at the new location. If not, new special process qualification(s) should be carried out.

A new process validation (see clause 5.1.4) needs to be carried out at the new location.

5.1.9 Supply chain management

The organization should ensure that the requirements for material and services used in special processes (including base materials and consumables) are fully described in the purchase order or associated specification. The organization should ensure that these requirements are acknowledged by the external provider.

These requirements should be communicated and verified through the supply chain.

5.1.10 Special process audits and inspections

Special process audits and/or inspections should be performed internally. Two cases are given in the following table:

Name	Special process quality audit	Special process workstation inspection
Aim	Evaluate whether the special process has been designed, qualified and validated correctly prior to launching series production	Evaluate the correct application of the special process at the workstation
Scope	Special processes as they apply to: <ul style="list-style-type: none"> - product design planning - process design planning - product design - process design - risk analysis for process design - special Process design (5M methodology) - roles and mandates - design reviews - special Process qualification - special process validation - FAI - change management - knowledge management - performance evaluation - continuous improvement 	Special process inputs (5M methodology): <ul style="list-style-type: none"> - input documentation / data - operators competence and qualification - inspection of materials and consumables - machines maintenance - control and measuring resources - storage and handling conditions - environment Special process outputs Quality records
Reference documentation	ISO/TS 22163 IRIS Guideline 6: Special processes Organization Quality Management System	Special process instruction (Manufacturing or Construction or Maintenance)
When	In accordance with risk analysis and/or applicable requirements and/or indicators	Periodic inspection based on risk analysis and/or indicators
Who	One or more persons able to identify what kind of deviations and failures may occur and with the following competences: <ul style="list-style-type: none"> - auditor (ISO 19011) - ISO/TS 22163 - IRIS Guideline 6: Special processes - organization quality management system (related party) 	Special process coordinator
Record	According to the quality management system	Record required

5.1.11 Knowledge management

The knowledge about the special process, its characteristics and the prevention of process and product failures should be documented in an adequate way.

Recommended knowledge management tools are process FMEAs and knowledge data bases. The organization should choose the best way to manage its knowledge.

Special process deviations and internal and external feedback are triggers for review. New knowledge should be incorporated into the knowledge management tools.

Results of knowledge management should be incorporated into special process instructions, control sheets and/or inspection plans, and are the basis for special process training and personnel qualification.

5.1.12 Special processes performed by External providers

In case external providers that carry out special processes, the organization should communicate all the necessary requirements related to the product and the process including, when required, the approval of the special process by the organization or by the customer.

Audits and/or inspections may be necessary to ensure the proper execution and control of the special processes. Two cases are given in the following table:

Name	Special process audit	Process inspection for FAI or non-conforming products
Aim	Evaluate if the external provider is able to correctly manage and execute the special process: <ul style="list-style-type: none"> - first evaluation - periodical assessment 	<ul style="list-style-type: none"> - authorize the launch of the series production - promote corrective action(s) <p>Applicable to specific products</p>
Scope	Special processes as they apply to: <ul style="list-style-type: none"> - product design planning - process design planning - product design - process design - risk analysis for process design - special process design (5M methodology) - roles and mandates - design reviews - special Process qualification - special process validation - FAI - change management - knowledge management - performance evaluation - continuous improvement 	<p>Special process inputs (5M methodology):</p> <ul style="list-style-type: none"> - input documentation / data - operators competence and qualification - inspection of materials and consumables - machines maintenance - control and measuring resources - storage and handling conditions - environment <p>Special process outputs Quality records Special process qualification Special process validation</p>
Reference documentation	ISO/TS 22163 IRIS Guideline 6: Special processes External provider quality management system Customer requirements	External provider quality management system, including special process instructions Customer requirements
Who	One or more persons able to identify what kind of deviations and failures may occur and with the following competences: <ul style="list-style-type: none"> - auditor (ISO 19011) - ISO/TS 22163 - IRIS Guideline 6: Special processes 	Special process coordinator
Record	According to the quality management system	Record required

If the organization designs a product involving an outsourced special process but has no internal expertise in process execution, the external provider should be involved in the design phase.

In case no internal expertise, it is recommended that the audit/inspection is performed by an external expert.

If both the design and manufacturing are outsourced to the same external provider, the organization should provide the complete set of requirements for design, manufacturing and quality/safety.

5.2 Manpower

The input element “Manpower” refers to the personnel involved with the special process.

5.2.1 Special process coordinator

For definition see clause 3 Terms and definitions.

5.2.1.1 Coordinator qualification

If there are no requirements from international or national special process standards, the organization should document the minimum academic and professional pre-requisites. These pre-requisites should ensure that the special process coordinator is able to fulfill the roles and responsibilities described in clause 5.1.1. The coordinator should be an “expert” in the special process: a person with special skill or knowledge derived from training or experience.

The special process coordinator should continuously renew his/her knowledge in the special process, for example by participating in exhibitions, benchmarking, workshops, professional training, technical meetings and conferences, etc. Evidence should be documented.

These requirements apply for internal and external coordinators.

5.2.2 Special process operator

For definition see clause 3 Terms and definitions.

5.2.2.1 Operator qualification

Operator qualification is a minimum requirement for every special process. The required number of qualified operators should be defined by the organization, considering the type of work, production capacity and schedule (minimum two qualified operators).

Qualification should fulfill the requirements established in the relevant national/international special process standard and contract. If such standard does not exist, the special process coordinator defines the qualification procedure and criteria (see clause 5.1.1 for the roles and responsibilities for special process coordinator).

The organization should issue an operator qualification procedure, defined by the special process coordinator, which describes how to qualify an operator. This document should include:

- required qualification documents (e.g. applicable special process instruction, evaluation sheet, qualification record),
- relevant standards (if applicable),
- identification and storage of test pieces and test records, including operator traceability (if relevant),
- inspection method and acceptability criteria (if relevant),
- range of validity of the qualification,
- qualification renewal criteria.

A standard qualification record form should be established by the organization. If a standard qualification form exists, for example, in international or national standards, that form may be used directly.

Qualification tests are supervised by the special process coordinator. Qualification approval should be given by the special process coordinator or by an external accredited examination body, if applicable.

The same requirements apply for internal and external personnel.

5.2.2.2 Operator skill matrix

The special process skill matrix should include all relevant special processes operators. The matrix criteria should include:

- academic qualification,
- professional experience,
- participation in coaching and training programs,
- manual dexterity,
- process or task assessment level.

This matrix should reflect the minimum requirements for a given task or workstation as well as other criteria considered relevant by the organization.

5.2.3 Other special processes personnel

Other personnel involved in the special process such as designers, auditors and inspectors should be trained and their competences should be documented (e.g. skill matrix).

5.3 Machines

The input element “Machines” refers to all equipment and tools that affect the special process.

The equipment and tools that are required to perform the special processes should be qualified according to clause 5.1.3 and regularly maintained (corrective, preventive and predictive maintenance) to ensure the same performance.

Calibration and/or verification requirements should be considered when defining equipment and tools in order to ensure a consistent special process output with the expected quality level.

Handling, capacity, ergonomic and HSE aspects should be considered during validation (see clause 5.1.4).

A capability analysis is recommended to ensure that the equipment and tools can deliver the parameters that are required by the process, in a reproducible and repeatable manner.

Equipment and tools that are critical (see clause 5.1.2) to the special process output should be traceable, so that affected products can be identified in case of nonconformity.

Special process operators should be trained (e.g. user manual) to use the relevant equipment and tools.

5.4 Methods

The input element “Methods” refers to how the special process is performed:

- specification of relevant 4M (Manpower, Machine, Material and Mother nature),
- sequence of operations,
- parameters,

- etc.

The methods used in the special process should be qualified according to clause 5.1.3 and documented. The methods should be revised and maintained as necessary.

Parameters that may be considered are:

- distance,
- energy (current, voltage, method of transfer, arc length),
- flow rate,
- pressure or force,
- position (operator, machine, tooling, workpiece, etc.),
- quantity (weight/volume),
- rate or speed,
- temperature,
- time,
- torque,
- etc.

A suitable range of parameters should be established. Means should be provided to control the parameters within the established range and ensure the proper execution of the instructions.

The method should also describe, when necessary:

- material preparation,
- cleaning (initial, intermediate and final),
- execution sequence,
- inspections (initial, intermediate and final) and/or hold points,
- preservation,
- etc.

Parameters and/or instructions that are critical (see clause 5.1.2) to the special process output should be traceable, so that affected products can be identified in case of nonconformity.

5.5 Materials

The input element “Materials” refers to the materials that go into the product (base materials) and auxiliary materials (consumables).

The materials used in the special process should be qualified according to chapter 4.1.3. The materials should also:

- fulfil the applicable regulations and laws (e.g. REACH, RoHS, etc.),
- fulfil the applicable technical specifications and standards,
- fulfil the requirements defined in the organization’s special process documentation,

Materials that are critical (see clause 5.1.2) to the special process output should also be traceable, so that affected products can be identified in case of nonconformity.

5.5.1 Inspection

A control plan should be established, taking into account the risk management aspects considered in clause 5.1.2. The inspection may be performed at the external provider’s premises (e.g. FAI, FAT) or during reception.

Declaration of Conformity, test reports and inspection certificates should be considered.

Perishable materials should be managed appropriately.

5.5.2 Storage and handling conditions

Material storage and handling conditions for special processes should be defined and managed.

- The transport and storage conditions (e.g. temperature and humidity) required by the special process should be defined and respected,
- A stock inventory system e.g. "first-in/first-out" (FIFO) or "first-expiry/first-out" (FEFO) should be used to optimize the warehouse response time and to secure the turnover,
- Material in stock should be checked for deviations with an adequate frequency,
- Expired products should be handled in the same way as defective products.

5.5.3 Check at the workstation

The material should be checked for:

- Identification, usability and damage,
- Deviations from expected behaviour or characteristics e.g. appearance, smell and consistency.

5.6 Mother nature (Environment)

The input element "Mother nature" refers to the environmental conditions of the workstation where the special process is carried out.

The specific environmental conditions that affect the output of the special process should be qualified according to clause 5.1.3.

Conditions that may be considered are:

- air currents,
- air quality,
- cleanliness,
- contamination sources,
- electrostatic discharge,
- humidity,
- illumination,
- magnetic fields,
- noise,
- radiation,
- temperature and temperature gradients,
- vibration,
- etc.

A suitable operational range should be established for the entire special process (before, during and after execution). Means should be provided to control the environmental conditions within the established range based on risk assessment.

Environmental conditions that are critical (see clause 5.1.2) to the special process output should be traceable, so that affected products can be identified in case of nonconformity.



Bibliography

- [1] Guide to Quality Control, 1972 – Kaoru Ishikawa
- [2] EN 15085 Series Railway applications – Welding of railway vehicles and components
- [3] DIN 6701 Series Adhesive bonding of railway vehicles and parts
- [4] ISO 19011:2018-07 Guidelines for auditing management systems
- [5] IRIS Guideline 1: Key Performance Indicators
- [6] IRIS Guideline 2: First Article Inspection
- [7] IRIS Guideline 3: Maintenance
- [8] IRIS Guideline 4: RAMS/LCC
- [9] IRIS Guideline 5: Obsolescence
- [10] IRIS Guideline 7: Problem solving
- [11] IRIS Guideline 8: Configuration and change management

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