IRIS
International Railway Industry Standard

GUIDELINE 6 : 2014
SPECIAL PROCESSES

English

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THE EUROPEAN RAIL INDUSTRY

IRIS
Certification

We would like to thank the following people for the excellent cooperation and contribution, without which this Guideline would not have been possible:

Special Processes SWG members

Laurent Dastas
Alstom Transport
Marco Vannucchi
AnsaldoBreda
Dr.-Ing. Gerald Holst
Bombardier Transportation
Nicole Harlan
CAF
Francis Alliot
Faiveley Transport
Wolfgang Emgen
Gutehoffnungshütte Radsatz GmbH
Andreas Glastetter
Knorr-Bremse
Ekaterina Bochkareva
Russian Register
Angela de Heymer
UNIFE
Bernard Kaufmann
UNIFE

Technical Forum for Improvement representatives

Angela de Heymer (Leader)
UNIFE
David Martinez
AENOR
Anne Pouyanne
AFNOR
Jean-Christophe Coulaud
Alstom Transport
Dario Montefusco
AnsaldoBreda
Giuseppe Greco
Bombardier Transportation
Mikael Lindstrom
Bureau Veritas
Wolfgang Domke
DEKRA
Hans Jahn
DQS
Thomas Beck
DNV GL
Benoit Guillon
Faiveley
Rüdiger Mesterheide
Hanning & Kahl
Oliver Stein
Knorr-Bremse
Hans van Mulekom
Nedtrain
Andrea Anfosso
RINA
Ekaterina Bochkareva
Russian Register
Susanne Schaub
SBB/CFF/FFS
Bernd Diekmann
Siemens Transportation & Logistics
Ludivine Francart
SNCF
Kay Jürgensen
TÜV NORD
Riccardo Lasagna
TÜV Rheinland
Alexander Rathiens
TÜV SÜD
Bernard Kaufmann
UNIFE
Marcus Schmid
VOITH TURBO

IRIS Management Centre

Bernard Kaufmann
IRIS General Manager
Angela de Heymer
IRIS Senior Manager
Kujtesa Hajredini
IRIS Manager
Maxime Schaub-Crouan
IRIS Technical Coordinator
Marcos Mendez
UNIFE Operations Manager

Guideline 6 : 2014
SPECIAL PROCESSES

1 INTRODUCTION

The aim of this guideline is to achieve a common understanding and support the management of special processes in our sector. It explains the specificities of special processes required to comply with the IRIS requirements.

2 PURPOSE

The purpose of this guideline is to give guidance and examples for the implementation of IRIS requirements and recommendations concerning special processes.

Special processes play a key role in the rail sector regarding e.g. safety, quality. Therefore their appropriate management through all projects phases and the whole value chain is necessary.

The following processes are identified as special processes relevant for the rail sector. However further processes may be considered depending on the rail products:

- Bonding and sealing
- Casting/Moulding
- Crimping
- Force fitting or shrink fitting
- Forging
- Heat treatment
- Laminating (composites,...)
- Riveting
- Surface treatment (painting, shot peening, coating, corrosion protection)
- Torque tightening
- Welding (including soldering and brazing)

If there are special requirements regulated by international or national standards or legal regulations, these requirements need to be fulfilled.

This guideline focusses on the fundamentals of all special processes. Annexes for specific special processes will amend this guideline.

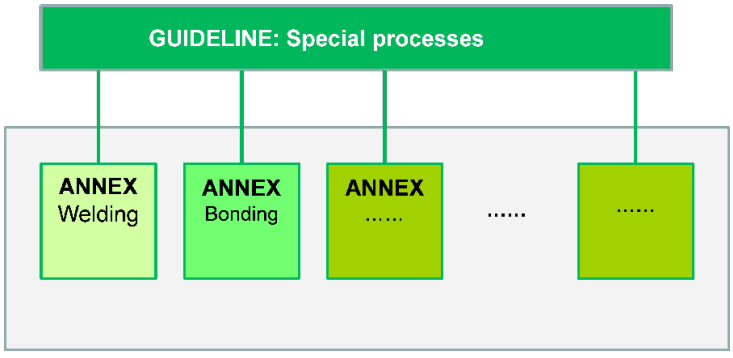

Fig. 1: Structure of special process guideline

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3 TERMS, DEFINITIONS, ABBREVIATIONS

For the purposes of this guideline in general, the terms, definitions and abbreviations given in ISO 9000 and IRIS apply.
Terms in this guideline beginning with capital letters are listed and defined in ANNEX 5 of the IRIS booklet.

According to the rail sector's understanding of special processes, the following definition applies:

BMS: Business Management System.
EQF: European Qualifications Framework (http://ec.europa.eu/eqf/home_en.htm).
FMEA: Failure Mode and Effect Analysis.
HSE: Health; Safety and Environment.
K.O.: Knock Out
PFMEA: Process Failure Mode and Effect Analysis.
RACI: Responsibility assignment matrix, which contemplates the following participation roles: **R**esponsible, **A**ccountable, **C**onsulted, **I**nformed
TPM: Total Productive Maintenance
VDA 6.3: German Automotive Industry Association (VDA) – Process audit

Mockup: a scale or full-size model of a design.
Special process: A Process **used in manufacturing or maintenance** where the conformity of the resulting Product cannot be readily **determined without destructive analysis prior to use** is referred to as a "Special Process".
Special process operator: the person who executes the special process, see clause 6.2.1.
Special process coordinator: the person with special responsibilities described in clause 6.1.1. and 6.2.2.
Special process instruction/standard: specification of the input elements to produce a specific output

4 IRIS REQUIREMENTS

IRIS requirements on special processes are covered in the IRIS booklet in several clauses.

The management of special processes including its identification, related work instruction, skills and qualification and the related records are assessed through the verification of a K.O. question (IRIS, ANNEX 4 and IRIS Questionnaire #7.5.2-3).

In addition, IRIS requires a Process (IRIS Questionnaire #7.5.2-4) to be established within the Organization's BMS in order to control special processes, including qualification, approval prior to use and any subsequent changes to ensure proper outcome of the process.

Furthermore IRIS requires that
- all personnel performing special processes are identified, trained and authorized (IRIS chapter 3, clause 7.5.2 and 6.2.2.3).
- requirements are cascaded and approved special processes are used in the supply chain (IRIS chapter 3, clause 7.4.1)

An organization performing special processes should have as a minimum an internal standard or apply an external standard or customer requirements:
- The effectiveness of these standards to deliver the desired output should be demonstrated.
- Compliance with customer requirements should be demonstrated.

5 RESPONSIBILITIES

The responsibilities within the process are described in clause 6.1.1.

6 PROCESS

Special processes differ from other manufacturing or maintenance processes, because the following input elements of these processes need to be rigorously managed to guarantee a consistent output:

- Management
- Manpower
- Machine
- Methods
- Material
- Mother nature (Environment)

Process input elements and output can be represented

using an Ishikawa diagram. (Ishikawa, Kaoru (1956). Guide to Quality Control. Tokyo: JUSE). Ishikawa diagrams are causal diagrams that show the potential causes resulting in a specific event.

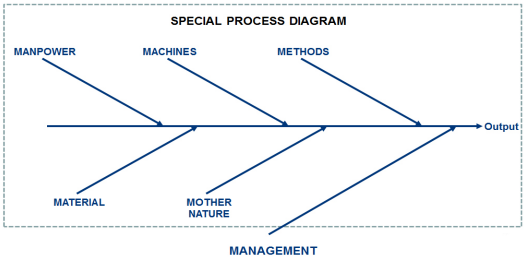

Fig. 2: Special process Diagram

The management of the special process is key to the output and to all other input elements. Therefore it is described in detail first.

6.1 MANAGEMENT

The management of the special process influences all of the input elements (see Fig. 2) 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
- Nonconformity management
- Change management
- Transfer management
- Supply chain management
- Special process audits
- Knowledge management

6.1.1 ROLES AND RESPONSIBILITIES IN SPECIAL PROCESS MANAGEMENT

Within the organization, roles and responsibilities for managing special processes are to 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 in the designation.

The relationship between the special process coordinator and the management representative (IRIS chapter 3, clause 5.5.2) should be defined and communicated. The relationship among locations within the same organization that may share the same special processes should be defined.

The special process coordinator should be integrated in the organization in a way that allows 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 and the deputies within the organization are to be specified in writing. These areas of responsibility should include:

- Internal guidelines, specifications, procedures and work instructions
- Requirement review and feasibility confirmation in tender management
- Design review (if applicable)
- Material specifications (including base and auxiliary materials)
- Special process suppliers
- Equipment and tools including 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 responsibilities may be managed in different ways, e.g.: via specification, participation, inspection, approval, control, act of presence, etc. and may be represented using a responsibility assignment matrix, e.g. RACI.

6.1.2 RISK MANAGEMENT

The organization should consider how the input elements (see Fig. 2) impact the outcome of the special process. This analysis should be handled and documented using risk management tools, such as FMEA.

The criticality of the input elements should be determined in this analysis and approved by the special process coordinator. In consequence the appropriate qualification, validation and control plans for the individual input elements and for the complete special process should be established.

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

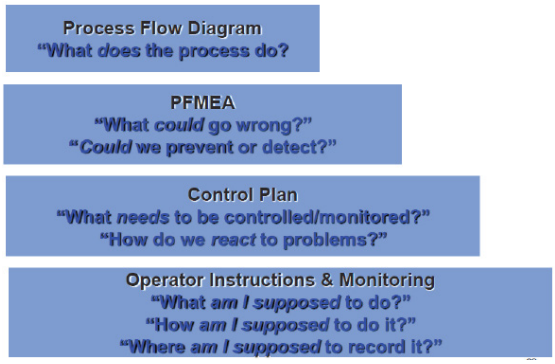

Fig. 3: Sequence for a PFMEA analysis

The impact of changes in the input elements should be part of the risk analysis.

6.1.3 PROCESS QUALIFICATION

A special process instruction is to be established and should include the definition of the input elements required (Manpower, Machine, Methods, Material, Mother nature (Environment)) to produce a specific output.

Process 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 process and criteria (see clause 6.1.1 for the roles and responsibilities for special process coordinator).

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 representative mockup or test specimen and under industrial conditions to justify the performance of the product/process couple.

The qualification plan should include:

- Requirements for personnel skills.
- Required qualification documents (e.g. preliminary special process instruction/standard, evaluation sheet, qualification record)
- Relevant standards (if applicable)
- Identification and storage of test pieces and test records
- Inspection method and acceptability criteria (if relevant)
- Determination of the range of validity of the 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 to be supervised or approved against a recognized standard by the special process coordinator or authorized deputy. Qualification approval has 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 6.1.2 are to be used.

6.1.4 PROCESS VALIDATION

The process validation is carried out when the first representative product is manufactured or maintained, before series production is released. Depending on

the results of the risk management further process validations during series production 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).

If the product is considered critical (see risk management) during the process, destructive test may be necessary to complete validation.

6.1.5 PROCESS CONTROL AND MONITORING

The organization should ensure constant monitoring of the input elements and the special process, considering the outcome of the risk analysis (see clause 6.1.2), e.g. control sheets, inspection plans...

In addition to the outcome of the process (product characteristics) the organization should choose key process indicators for the monitoring of a stable process. If there are significant deviations in these key process indicators the organization should analyze the reasons, even if product characteristics are in the limits. The results of this investigation may be used for continuous improvement purposes.

6.1.6 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, ...), product criticality and contract requirements.

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

6.1.7 CHANGE MANAGEMENT

This clause describes 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 clause 6) mandates a new or revised qualification (see clause 6.1.3) and process validation (see clause 6.1.4).

A revised qualification may include complete or partial testing that justifies the change. If no further testing is carried out, the justification for no testing should be recorded.

When a qualified special process is substituted by another in the manufacturing or maintenance of a product, a new process validation (see clause 6.1.4) needs to be carried out.

6.1.8 TRANSFER MANAGEMENT

This clause 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 6.1.4) needs to be carried out at the new location.

6.1.9 SUPPLY CHAIN MANAGEMENT

The organization should ensure that the requirements for material and services used in special processes (includes base and auxiliary materials) are fully

described in the purchase order or associated specification. The organization should ensure that these requirements are reconfirmed by the supplier.

Special processes requirements should be communicated and verified through the supply chain.

6.1.10 SPECIAL PROCESS AUDITS

Special process audits should be performed internally and may also be carried out on suppliers.

6.1.10.1 Audit content

The questionnaire should cover the following key aspects:

- **Design process**
  - Project management
  - Product design planning
  - Process design planning
  - Product design realization
  - Process design realization
- **Serial production process**
  - Supplier management
  - Process input
  - Process content/process flow
  - Process support
  - Material resources
  - Process efficiency
  - Process output

VDA 6.3 is an example for a process audit questionnaire covering the above mentioned key aspects.

6.1.10.2 Auditor qualification

The special process coordinator should ensure that the auditor is qualified to evaluate the special process and can recognize what kind of deviations and failures may occur. If no person with this qualification in the organization is available an external auditor should be contracted.

6.1.10.3 Audit frequency

The special process audit should be done periodically considering the risk management (see clause 6.1.2).

6.1.11 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 FMEAs and knowledge data bases. The organization should choose the best way to manage its knowledge.

Special process deviations as well as internal and external feedbacks are triggers for review. New knowledge should be incorporated in the knowledge management tools.

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

6.2 MANPOWER

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

6.2.1 SPECIAL PROCESS OPERATOR

6.2.1.1 Operator qualification

Operator qualification is a minimum requirement for every special process. The required number of qualified operators needs to 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 process and criteria (see clause 6.1.1 for the roles and responsibilities for special process coordinator).

The organization should issue an operator qualification plan, approved 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/standard, evaluation sheet, qualification record)
- Relevant standards (if applicable)
- Identification and storage of test pieces and test records, including traceability to operator

- Inspection method and acceptability criteria (if relevant)
- Determination of the range of validity of the 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 or approved against a recognized standard by the special process coordinator or authorized delegate. Qualification approval may 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.

6.2.1.2 Operator skill matrix

Organizations with a more mature level of special process control consider additional criteria when assigning operators to tasks or workstations. These criteria may include:

- Professional experience,
- Participation in coaching and training programs,
- Manual dexterity.

For this purpose, an operator skill matrix is recommended. This matrix may reflect minimum qualification requirements for a given task or work station as well as other criteria considered relevant by the organization.

6.2.2 SPECIAL PROCESS COORDINATOR

6.2.2.1 Coordinator qualification

If there are no requirements from international or national special process standards, the organization should define the minimum academic and professional pre-requisites in writing. These prerequisites should ensure that the special process coordinator is able to fulfill the roles and responsibilities described in clause 6.1.1. As a minimum education Level 4 (EQF) or equivalent is recommended. 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 participate in on-going professional training in the special process, for example: participation in workshops, training sessions, conferences, etc. Evidence of this training should be documented.

These requirements apply for internal and external personnel.

6.3 MACHINES

The input element "Machine" refers to all equipment and tools that affect the special process.

The equipment and tools, which are required to perform the special processes, are to be defined and regularly maintained.

Handling, capability, capacity, ergonomic and HSE aspects, TPM (autonomous and planned preventive maintenance), calibration or verification requirements and cost should be considered when defining equipment and tools in order to ensure a consistent special process output with the expected quality level.

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

Equipment and tools critical to special process output should be traceable, so that affected products can be identified in case of non-conformity.

6.4 METHODS

The input element "Methods" refers to how the special process is performed.

The specific special process parameters and/or instructions which could affect the outcome of the special process should be defined and under control.

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.

Instructions that may be necessary are:

- Deposition dimensions
- Execution or application sequence
- Expected visual aspect
- Final cleaning or protection
- Hold points
- Material preparation and cleaning
- Protection requirements
- etc.

A suitable operational 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.

Parameters and/or instructions critical to special process output should be traceable, so that affected products can be identified in case of nonconformity.

6.5 MATERIALS

The input element "Materials" refers to the materials that go into the product and auxiliary materials: touching the product or consumed by the process.

The material used needs to:

- Fulfill the governmental requirements
- Fulfill the defined technical specifications
- Conform to the specifications in the special process documentation and be available in sufficient quantity and scope
- Be purchased by suppliers approved by the organization (see IRIS clause 7.4)
- Be identified

Material critical to special process output should also be traceable, so that affected products can be identified in case of non-conformity.

6.5.1 CONTROL IN RECEPTION

A reception control plan should be established, taking into account the risk management and configuration management aspects considered in clause 6.1.

The maximum usage period is to be determined, recorded and maintained.

6.5.2 STORAGE AND HANDLING CONDITIONS

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

- Material in stock should be checked for deviations with an adequate frequency
- A stock inventory system e.g. „first-in/first-out" (FIFO) should be used to optimize the warehouse response time and to secure the turnover
- Expired products should be handled in the same way as defective products
- The transport and storage conditions (e.g. temperature and humidity) required by the special process technology should be determined and maintained
- Transport devices (gantry crane, suction crane, etc.) should be specified and used depending on the size, shape and weight of the parts

6.5.3 CHECK BEFORE OR DURING USE

The material should be checked for:

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

Any incidents should be escalated according to the organizations rules.

6.6 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 which could affect the outcome of the special process should be defined and be under control.

Conditions that may be considered are:

- Air currents
- Air quality
- Cleanliness
- Contamination sources
- Humidity
- Lighting
- 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 critical to special process output should be traceable, so that affected products can be identified in case of non-conformity.

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