

IRIS
International Railway
Industry Standard

GUIDELINE 7 : 2014
PROBLEM SOLVING

English

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Sub-working Group Problem Solving

Fabien Thibault
Alstom Transport
Martin Redhardt
Bombardier Transportation
Gorden Falk
DB AG
Sebastian Bartels
DB AG
Marie-Laurence Lescure
Faiveley Transport
Wolfgang Emgen
GHH – Radsatz GmbH
Ekaterina Bochkareva
Russian Register
Hubertus Illmer
Siemens
Bernard Kaufmann
UNIFE
Angela de Heymer
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
Michael Lindstrom
Bureau Veritas
Wolfgang Domke
DEKRA
Hans Jahn
DQS
Thomas Beck
DNV GL Business Assurance
Zertifizierung & Umweltgutachter GmbH
Benoit Guillon
Faiveley
Rüdiger Mesterheide
Hanning & Kahl

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

Oliver Stein
Knorr-Bremse
Hans van Mulekom
Nedtrain
Andrea Alfonso
RINA
Ekaterina Bochkareva
Russian Register
Susanne Schaub
SBB CFF FFS
Bernd Diekmann
Siemens
Ludivine Francart
SNCF
Kay Jürgensen
TÜV NORD
Riccardo Lasagna
TÜV Rheinland
Alexander Rathien
TÜV SÜD
Bernard Kaufmann
UNIFE
Marcus Schmid
VOITH TURBO

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1 INTRODUCTION

The aim of this guideline is to define problem solving activities and methods required to facilitate the application of respective IRIS requirements.

2 PURPOSE

The purpose of this guideline is to give guidance and examples for implementation of IRIS requirements and ensure through that a better application of the requirements and a common understanding in the rail sector.

This guideline focuses on the widely known 8D method for problem solving. Depending on the individual situation of the company and the kind/impact of the problem, alternative methods may be used. In case of the involvement of several organizations the use of this 8D method facilitates collaboration.

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.

<S>: Tag to identify items related to safety.

5W2H: Who, What, Where, When, Why, How, and How many (method based on seven questions to characterize

an issue).

8D: Eight disciplines to follow and to secure accurate solving of technical problems.

FMECA: Failure Mode, Effect and Criticality Analysis (preventive method for identifying potential issues).

FTA: Factor Tree Analysis (method for analyzing potential factors).

VDA QMC: German Automotive Industry Association (VDA) Quality Management Center (QMC).

Containment/Remedial action: Action taken to limit the extent of a problem and to protect customer and people. Normally these actions are only interim actions. The final solution is the so called "corrective and preventive action".

Material in transit: Material that has left its initial location and has not yet arrived at its destination.

Poka Yoke: Japanese term that means „mistake-proofing“. It stands for any mechanism that helps to avoid mistakes.

Problem: A difference between actual conditions of a component, system or vehicle and those that are required or desired for operation. Another term is nonconformity.

Root cause: Initiating cause of a causal chain which leads to a problem. To prevent the occurrence of the problem in the future the root cause of the problem needs to be determined and eliminated.

Safety relevant problem: Problem that may have

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influence on a safe operation of a component, system or vehicle.

San Gen Shugi: Japanese words meaning the “3 Real Principle”, attitude expected in front of a problem.

4 IRIS REQUIREMENTS

IRIS refers to problems and nonconformities, and requirements how to deal with them, in:

- Analysis of data Chapter 3, clause 8.4,
- Corrective Actions Chapter 3, clause 8.5.2,
- Preventive Actions Chapter 3, clause 8.5.3,
- Commissioning and Customer Services Chapter 3, clause 7.10 (KO question ANNEX 4 and IRIS Questionnaire #7.10-1).

5 RESPONSIBILITIES

All employees and stakeholders: To report problems once they are detected.

Management:

- Ensure that a company is able to do proper and structured problem solving and to provide qualified resources for problem solving,
- Ensure that company follows the defined problem solving process understanding the process as one important means for continuous improvement,
- Management should be careful when defining problem solving teams to avoid that resource gaps are created which could be the origin for new problems,
- Define and document the processes to (a) detect and report problems and (b) initiate, execute and conclude the problem solving,
- Prioritize problems and problem solving activities by using prioritization approaches, e.g. decision/impact matrix,
- Congratulate the team after successful problem solving process.

Team leader:

- Manage the problem solving team,
- Ensure the required communication and documented output of the problem solving process within the required timeframe,
- Escalate any issues as required,

- Ensure that the 8D process as documented in this guideline is respected and fulfilled.

Team: To actively participate in the problem solving process.

6 PROCESS

6.1 General

The 8D method, as documented in the VDA QMC volume 4 (German Version 2009), can be used where the cause of a problem is unknown. It fulfills three tasks complementing each other.

It is:

- a problem solving process,
- a standard method,
- a report form.

As a problem solving process, it is a sequence of steps that should be run through as soon as a problem appears. If handled correctly, it helps to identify early enough a complete solution of the problem.

The 8D methodology is also a standard method, which is based in particular on the following areas:

- Fact-oriented system: System in which problem solving, decision making and planning are based on real data and are monitored by collecting real data.
- Termination of the root cause: It is characteristic for the problem solution that it focuses on the eliminating of the root cause of the problem and not just covers the occurred effects.

The 8D methodology is also a report form for progress tracking. Individual steps of the process can only be completed when the respective information on their execution is available. As long as only some of the eight steps are executed, the 8D report also serves as an action plan which shows the outstanding actions.

Note: It is the intention of this guideline to describe the 8D process steps but not to recommend any template for an 8D report.

6.2 Process steps of 8D

The original 8D method is based on eight process steps (or disciplines). The checklist provided in the ANNEX 1 lists these eight process steps and proposes items to be addressed in each of the process steps. Some items consider specific aspects and requirements of the rail sector.

In addition, a step 0 is added to address preparation and initial clarification – effectively resulting in nine process steps:

- 0 Preparation and initial clarification,
- 1 Establish a problem solving team,
- 2 Describe the Problem,
- 3 Implement and verify interim containment/remedial actions,
- 4 Identify root causes and verify them,
- 5 Define corrective actions and proof their effectiveness,
- 6 Introduce the corrective actions and validate their effectiveness,
- 7 Take actions to prevent recurrence of the problem,
- 8 Conclude problem solving and congratulate team.

6.3 Management attention

Make sure that the management team is informed and involved into the resolution of the problems, starting by step 0. Additionally it needs to have the opportunity to escalate the issue further if necessary.

Benefit for the problem team to have management attention:

- Alignment and sharing of goals and objectives,
- Escalation for management decision when necessary,
- Get additional support and means (resources, time, budget) when necessary,
- Further sharing and cascade of "lessons learned".

Benefit for the management to focus their attention on problem solving:

- Proper understanding and evaluation of risk exposure

- regarding problem encountered,
- Keep the team motivated through management attention and support,
- Forecast and evaluation of workload and resources needed for problem solving activity,
- Ensure proper sense of urgency on problem solving.

In order to control the process, management should set up and monitor KPIs regarding e.g.:

- Criticality of backlog of problems,
- Quantity of problems,
- Resolution time.

6.4 Problems with the suspicion that they may be safety relevant

This application guide also covers recommendations regarding the solving of problems with the suspicion that they may be safety relevant, i.e. that they may influence the safe operation of the component, system or vehicle. For such cases, the checklist below provides special process steps marked with "<S>". In addition, the following recommendations should be followed:

- **Reporting:** Define and communicate processes, tools and communication channels which make it easy for all involved parties to report problems with the suspicion that they may be safety relevant.
- **Documentation:** Make sure that all data, decisions and communications are documented according to the relevant laws or regulations and could (in worst case) stand up in court.
- **Information:** Define clear internal communication channels for all information regarding problems that may be safety relevant and their status. These channels should include the relevant management functions and the person in charge of product safety within the organization.

7 ANNEXES

ANNEX 1: Checklist process steps of 8D

ANNEX 2: Do's and Don'ts

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ANNEX 1: Checklist process steps of 8D

Step	What	Completed
0	Preparation and initial clarification	
	Get a clear picture of what the problem is (based on the data currently available - from internal/external sources - incl. photos and videos). Define the goals/ target situation which need to be achieved (as a resolution).	<input type="checkbox"/>
	Check whether the problems have been confirmed by measurements and test.	<input type="checkbox"/>
	Check whether additional data is needed to get a clear picture (and request additional data if and as needed).	<input type="checkbox"/>
	Do a first assessment whether the problem may be safety relevant. If yes “tag” the problem respectively.	<input type="checkbox"/>
	<S> Inform the relevant parties within the organization and assign the required internal priorities.	<input type="checkbox"/>
	Check whether the use of the 8D method is appropriate (not every problem requires 8D).	<input type="checkbox"/>
1	Establish a problem solving team	
	Establish a small team of people who have appropriate process / production skills, time, willingness to cooperate, expertise and knowledge in the techniques necessary to solve the problem and to introduce corrective actions. The team leader should be appointed by the organization or selected by the team members.	<input type="checkbox"/>
	Decide whether external team members are beneficial for a best possible problem solving process. Depending on the problem and its impact these may be experts from suppliers or customers. (Note: If needed external support can be called in at a later stage.).	<input type="checkbox"/>
	Start to maintain an action plan or list of open points.	<input type="checkbox"/>
2	Describe the Problem	
	<p>Define the problem of the internal/external customer(s) as closely as possible. Work out the core of the problem and quantify it. Collect and analyze statistical data. Detect and determine the extent of the problem (number of affected components, versions, projects, vehicles, customer sites, etc.). Review the goals /target situation which need to be achieved as a resolution (see Step 0).</p> <p>When determining the number of affected parts the following process steps should be considered:</p> <ul style="list-style-type: none"> - Half-finished products, - Products in own production process, - Material in own stock, - Material in transit, - Material in customer or consignment stock. <p><i>Note 1:</i> Same process steps should be considered for containment /remedial and corrective action.</p> <p><i>Note 2:</i> Issue can be described with the following questions: what, why, when, where, who, how, how many (5W2H methodology) and information can be categorized with Pareto principle.</p>	<input type="checkbox"/>

Step	What	Completed
	Classify the problem (or review previous classification) and decide whether there is the suspicion that the problem may be safety relevant.	<input type="checkbox"/>
	<S> Perform an (ad-hoc) risk assessment. Based on the assessment results deadlines should be given for the execution of (temporary) containment /remedial actions and final corrective actions.	<input type="checkbox"/>
	Define the goals which need to be achieved by the team (and get them confirmed by the management).	<input type="checkbox"/>
	Decide whether it makes sense to review the problem description with the internal/external customer(s). If yes, do so.	<input type="checkbox"/>
3	Implement and verify interim containment/remedial actions	
	Initiate measures that keep the impact of the problem for the internal/external customers at an acceptable level, until a permanent solution is found.	<input type="checkbox"/>
	Document measures clearly and communicate them (and their status) to all stakeholders.	<input type="checkbox"/>
	Constantly review the effectiveness of these temporary measures, and initiate additional measures if necessary. Make sure that containment/remedial actions do not introduce new problems.	<input type="checkbox"/>
	If defective parts/systems have already reached the "end customers", appropriate after sales service measures must be taken. The 8D report shall relate to potential service measures	<input type="checkbox"/>
4	Identify root causes and verify them	
	Search for all possible causes that could explain the occurrence of the problem (and why it has not been detected by the defined quality assurance measures). Determine the probable cause(s) and evaluate, through comparisons with the problem description and the available data, whether the most probable cause is the root cause. Consider the involvement of additional expert(s) in the root cause analysis process or at least an independent review for completeness. For analysis, recommended methodologies are the following: a) for identification of potential impacting factors: Ishikawa(fishbone diagram), b) for characterization of the factors and their influence: Factor Tree Analysis (FTA) for occurrence AND non-detection of the issue c) for identifying real root causes: 5 Whys for occurrence and non-detection	<input type="checkbox"/>
	Prove the assumption (usually testing and/or experiments).	<input type="checkbox"/>
	Communicate status information (results of root cause analysis, ...) to relevant stakeholders. <i>Note: Communication should be done latest after successful completion of step 5.</i>	<input type="checkbox"/>
5	Define permanent corrective actions and proof their effectiveness.	
	Search for possible actions which could eliminate the root cause and thus solve the problem. Select the optimal permanent corrective action(s).	<input type="checkbox"/>
	Check (with reasonable efforts) whether the standard measurements and tests are appropriate for a sufficient proof of effectiveness. Modify process if/as required.	<input type="checkbox"/>

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Step	What	Completed
	Prove by appropriate means that the chosen permanent corrective action(s) solve the problem from a customer perspective and have no adverse side effects. <i>Note: Steps 4 and 5 are repeated until proven effectiveness.</i>	<input type="checkbox"/>
	Communicate status information (effective corrective actions ...) to relevant stakeholders (including internal and external customers).	<input type="checkbox"/>
6	Implement the permanent corrective actions and validate their effectiveness.	
	Generate an action plan to implement the selected corrective actions and define supporting actions to secure their effectiveness as needed. Define ongoing checks to ensure that the cause of the problem is really fixed. Consider the applicable requirements for change management (specified quality assurance actions incl. FAI, customer approval, documentation changes, homologation and modification of existing stock).	<input type="checkbox"/>
	Communicate the corrective actions and the action plan to relevant stakeholders (including internal and external customers). Obtain necessary approvals (e.g. for tests on customer property).	<input type="checkbox"/>
	Execute the action plan, observe the effects and take the supporting actions as required.	<input type="checkbox"/>
	Check the effectiveness of corrective actions at the end user/customer (by verification).	<input type="checkbox"/>
	Check whether some or all actions also relevant for other components or systems with similar risks (and take actions as required).	<input type="checkbox"/>
7	Take action to prevent recurrence of the problem.	
	Change the management and control systems, instructions and/or processes (as applicable), to prevent the same or similar problems occur again. The following should be considered: <ul style="list-style-type: none"> - Work instructions and procedures, - Introduction of Poka Yoka measures, - Process descriptions, - Training and instructions plans and documents, - Quality control plans, instructions and records, - Design and process guidelines (incl. FMECA). 	<input type="checkbox"/>
	Document problem and its root cause(s) and solution as a "lessons learned" in a knowledge management system to ensure that similar mistakes will not be repeated in new developments or design revisions.	<input type="checkbox"/>
8	Conclude problem solving and congratulate team	
	<S> Relevant management functions and the person in charge of product safety within the organization to formally close the problem.	<input type="checkbox"/>
	<S> Archive the complete documentation of the problem solving process (data, decisions and communications).	<input type="checkbox"/>
	Complete team work, recognize the combined efforts and experience and rejoice over the success.	<input type="checkbox"/>
	Reflection by the team on the problem solving process (lessons learned) and if necessary feedback to the relevant person(s).	<input type="checkbox"/>

ANNEXE 2: DO'S AND DON'T

Following examples of good and bad practices may help to apply problem solving effectively.

Do's :

- Speak with data. The recommended attitude to face the problem is based on San Gen Shugi, "three real principle":
 - a) Go on the real place where the problem occurred,
 - b) Compare regular and problem situation,
 - c) Obtain objectives characteristics/data.
- Take necessary time at the beginning to ensure that team members know each other to ease collaboration,
- Define clear goals that the team needs to achieve,
- Set-up proper and clear ways of working (frequency of periodic meeting at team level/with management/with external parties),
- Problem solving process is an action driven process and require to set-up a clear and shared action plan,
- When confirming root cause and defining solution, it is important to ensure proper validation
- Take time to share the lessons learned and perform the necessary changes to prevent recurrence of problem,
- Have fun: problem solving is exciting, challenging and rewarding.

Don'ts :

- Use the problem solving approach with the main objective to identify who is responsible of the problem,
- "Finger pointing",
- Jump prematurely to conclusion without proper analysis and validation,
- Hesitate to ask for help and external support,
- Underestimate the time and energy that will be needed to perform problem solving,
- Twist facts to suit theories (instead of theories to suit facts).

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