

IRIS Guideline 7: Problem solving

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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 ISO/TS 22163:2017 requirements.

The overall goal of problem solving is to increase customer satisfaction. Only a satisfied customer is likely to buy products and services from an organization again. In this way, an effective problem solving process will directly contribute to an organization's economic success. A problem can be any deviation between a desired state and an actual state of something worth to the customer or the organization, directly or indirectly (e.g., product, service or process related).

This guideline will provide advice on problem solving methodologies with a strong focus on analysing the root causes of problems. The main benefit of RCA is that it identifies the fundamental errors in the process, enabling teams to enact right measures to fix the problems and stop them from recurring ahead. Hence, there is lesser rework and fewer defects in the final product, driving performance to the next level while reducing cost at the same time.

Every problem is an indication that there is still potential for improvement in the organization's products and/or processes and as such problem solving is driving continuous improvement.

Problem solving methodologies can be used to deal with any kind of problem and therefore it is also an integral part of risk management. In the sense of the risk management cycle a problem can be an uncertainty or an event that has occurred outside the requirements management horizon.

In most cases, the solution to a problem will be within the organisation. However, if the problem is complex, the solution will often not be provided satisfactorily by a single person. This is why different perspectives on a problem are needed.

It is proven that collective intelligence will bring the best solutions to complex problems, hence networking with a multidisciplinary approach to form a team (product management, engineering, quality management, suppliers, customers, and all major stakeholders) is crucial to the success of all problem solving activities.

The purpose of this guideline is to give guidance and examples for implementation of ISO TS 22163:2017 and thereby facilitate a better application of the requirements and a common understanding of problem solving in the rail sector.

2. Terms and definitions, Abbreviations

2.1 Terms and definitions

Customer For the purpose of the guideline, the term customer will apply to external

and internal customers.

Customer complaint Reported written or verbal allegation made by a customer that concerns

the identity, quality, durability, safety, security, conformity or

performance of any equipment or protective system or component as

defined in the certificate

Customer ISO 9000:2015: customer's (3.2.4) perception of the degree to which the

satisfaction customer's expectations have been fulfilled Customer perception See IRQB Guideline 9: Customer Perception



Problem A problem is a gap between a desired state and the actual state. Problems

can be product, process or service related.

Problem statement Clear factual description of the problem.

Possible tool to be used:

5W2H: Who, what, where, when, why, how, and how many

5 Why The 5 Whys strategy is a simple, effective tool for uncovering the root

cause of a problem. It can be used in troubleshooting, problem-solving,

and quality-improvement initiatives.

Factor tree analysis Factor tree analysis (or sometimes called Causal Factor Analysis) is a visual

technique displaying causal factors in a tree-structure such that cause-effect dependencies and cause to cause relations using a logic approach. The same term FTA also exists covering fault tree analysis, which is used in

reliability studies as a preventive tool.

2.2 Abbreviations

FTA Factor tree analysis RCA Root cause analysis

6M Cause categories according to ISO/TS 22163:

management

manpower

machine (equipment, technology)

methods (process)

material (includes raw material, consumables, and

information)

mother nature (environmental conditions)



3. Process steps of problem solving

Problem solving should be part of the organization's way of working. The organisation should make sure that people of all professional levels are trained, empowered, and competent to properly apply basic problem solving tools.

This guideline focuses on the already established problem solving methods depending on problem complexity and problem severity (stakeholder impact). Examples for problem solving approaches can be found in Annex 1.

| | | | roblem Severit keholder Impa | - |
|--------------------|--------|----------------------|---------------------------------|----------------------|
| | | Low | Medium | High |
| exity | Low | Basic approach | Advanced approach | Systemic approach |
| Problem Complexity | Medium | Advanced approach | Advanced approach | Systemic approach |
| Probl | High | Systemic approach | Systemic approach | Systemic approach |

| | Problem Severity (Stakeholder Impacts) |
|--------|---|
| Low | Single case problem not affecting operations |
| Medium | Single case problem with limited effect on operations |
| High | Safety Related problem Recurrent problem on stakeholder side Problem is inducing a serious operation disruption |

| | Problem Complexity |
|--------|---|
| Low | One factor creating one effect |
| Medium | Multiple factors creating one effect |
| High | Multiple factors with interaction creating mutliple effects |

If problem solving is reduced to its functional core, the following universal steps need to be taken:

- 1. Problem definition
- 2. Set up a problem solving team
- 3. Problem containment plan
- 4. Root cause analysis (RCA)
- 5. Corrective actions
- 6. Monitoring of corrective action
- 7. Lessons learned

In large organisations the entire problem solving process can be facilitated by a software solution that provides a searchable database of all problems and the affected population together with the root cause analysis, corrective actions and lessons learnt. In this database every problem should be given a unique identifier.



The checklist provided in the Annex 2 lists these process steps and proposes items to be addressed in each of the process steps.

3.1 Problem definition

Before starting the problem solving process, it is important to get a clear picture about the issue. For this step, the most important activity is to collect all available data. To ensure an efficient process, it is recommended to use a structured approach, e.g., 5W2H. Usually it is very valuable to start with the voice of the customer (internal/external customer), which often consists of a mixture of facts, opinions, and emotions. In a next step the facts from the customer complaint may be extracted in a descriptive way. A way to proceed can be to use a table collecting all stakeholder (e.g., internal/external customer) perspectives e.g., "Voice of customer Analysis". Possible sources of data or information can be e.g.: photos, videos, measurement reports, test reports.

As a next step the problem is described as closely as possible with facts and data in all dimensions of the 5W2H (see Annex 3). Detect and determine the extent of the problem (place, time, quantity, number of affected components, versions, projects, vehicles, customer sites, etc.).

During the problem definition it is also important to check whether the problem is safety relevant and if relevant parties need to be informed.

3.2 Problem solving team

Based on the problem description a team which covers the potentially affected disciplines needs to be assigned to the problem. The team may be extended or adapted whenever new skills or additional resources are required. The management should assure that the team has the appropriate resources (e.g., time, skills, tools) to handle the described problem.

3.3 Problem containment plan

The intent of this important step is to protect the involved stakeholder. (e.g., customer, people, or the environment).

It is also a prominent source of information (affected population, manufacturing time frame etc) that may help the organization having a better understanding of the problem and its potential causes.

The organization should trigger immediate actions to safeguard the customer in the various steps of the process and to prevent contamination. A containment action may be stopping production of a known source of a problem and not shipping any parts or assemblies until the root cause is identified.

When the problem is affecting physical parts, and while planning the sorting operations, the organization should consider all the supply chain:

- Finished products mounted on the Customer application.
- Finished products stored at the customer premises.
- Finished products stored in consignment stores.
- Finished products in transit.
- Finished products in the organization's warehouses.
- Work in process within the organization's premises.
- Components stored within the provider's premises.
- Replacement parts potentially delivered to final Customer depots.



During these sorting operations, the organization should pay a particular attention in terms of traceability of the bad parts as well as the good ones. This also offers the chance to identify and inform the affected customers.

The organization should define a clear identification system for the parts sorted (e.g., green label, specific marking).

The organization should prepare a summary table giving the exhaustive overview of the sorting results regarding the quantity of good and bad parts per date of production.

Matching this sorting information with the production information (traceability of the assembly, e.g., equipment used, specific teams/shift, provider source) should give the organization valuable information to confirm/infirm hypothesis during the root cause analysis.

3.4 Root cause analysis (RCA)

RCA is concerned with the accurate determination of root cause(s) to problems, using reliable approaches and data.

All problems have at least two root causes categories:

- 1. Cause of occurrence: Reasons for the problem to occur
- 2. Cause of non-detection: Reason for the problem to be not detected while generated

3.4.1 RCA tools

The RCA is a questioning technique going where the problem started and focussing on facts and data. It is a technique that explores the hidden causes of the specific problem using descriptive techniques (e.g.: 5W2H for both occurrence and non-detection).

During RCA it might be necessary to work with assumptions first, but these assumptions need to be proven. There are several techniques available to determine potential causes (e.g.: 5-Why, Fishbone Analysis (Ishikawa), Factor Tree Analysis).

The organization may select the appropriate methodology based on problem complexity (see Annex 1). It may not hesitate to switch or to extend methodologies in case it realises it is not getting down to the root cause.

3.4.2 Verifying root causes

While verifying root causes the organization should use a structured methodology. One possibility could be to use the 5 Why analysis.

This is a popular technique that explores the hidden causes of the specific problem by repeatedly asking Whys, the number 5 is not fixed, but usually the root cause is identified around it.

The way to formulate the Why shall drive to go more in depth. Testing the logic of the 5 whys from the first one to the last "Why", and then using a reverse approach to validate the logic using the "Therefore" from last Why to first one (see Annex 3).

Starting with a problem and asking why it is occurring. Assuring the answer is grounded in fact, and then asking the question again. This process can be continued until the root cause of the problem is reached, and identification of counter-measure that will prevent it from reoccurring.



Be aware that root causes can also be related to each other and sometimes a failure or problem only arises if two or more root causes appear at the same time. In such case a failure tree analysis might be used.

A simple example for multiple root causes: A person on the street got wet during a rain shower.

The problem (wet person) has two root causes:

- 1. The occurrence of rain (not manageable root cause)
- 2. The fact that the person did not use an umbrella or outdoor clothing (manageable root cause).

3.5 Corrective actions

At this stage the root cause of the problem should be clearly identified and validated. Permanent corrective actions need to address both Occurrence and Non-Detection root causes. It might be necessary to validate the solution in one or more steps e.g., workshop validation and field validation.

Set up an action plan with clear responsibilities and target dates.

Note: In the case there are non-manageable root causes identified, it is useful to develop risk mitigating actions (e.g., early warning system, monitoring of pre-indicators).

3.6 Monitoring of corrective actions

The monitoring of corrective actions can be done by an action plan defining the actions and related action holders and needs to be communicated to all relevant stakeholders of the problem solving process. Ongoing checks can be defined to ensure that the cause of the problem is really fixed. Monitor both the status of implementation of corrective actions as well as their effectiveness, including internal and external stakeholders. The effectiveness of corrective actions may be checked by appropriate tests. It might be useful to define at least one specific KPI per action to measure the effect of each action.

Depending on the criticality of the problem solving, governance needs to be defined with regular reviews: e.g., daily quick meetings can be held to update each other on the progress, including top management when needed.

3.7 Return of experience and lessons learned

Return of experience can be fed by lessons learned from various sources of information of the organizational knowledge (see ISO/TS 22163:2017, chapter 7.1.6.1).

Once the problem is properly characterized, contained, analysed, and corrected, the organization should gather key information inside a lesson learned record for knowledge sharing inside its organization.

The organization should consider the following information for the edition of a Lesson Learned record:

- Identification of the Lesson Learned (e.g., reference and/or link with the problem identification number);
- Description of the problem using a 5W2H approach.
- Description of the cause of the problem.
- Description of the learning out of this problem (e.g., output of a 5 Why analysis).



- Identification of the organization's functions and locations potentially affected by the learning.
- Keywords to ease the search of Lessons Learned record covering specific topics (e.g., problem typology, product family, key processes).

The organization should share and use these Lessons Learned:

- While designing product or launching new project
- During new people induction for knowledge acquisition.
- During Process Review, to make the process more robust and avoid having the same (or similar) problem
 - e.g., in another process/ product subject to the same/ similar preconditions for an occurrence of this (type of) problem.

By considering not only the recent problem, but where similar types of problem potentially occur, this can lead to better / more comprehensive prevention of recurrence of problems (see ISO/TS 22163:2017, chapter 10.2).

The organization can use an application software to ease the search and sharing of these Lessons Learned record.

3.8 Leadership attention

Make sure that the Leadership team is informed and involved into the resolution of the problems. The organization should define an escalation process based on problem criticality (From Safety related down to single case problem not affecting operation)

Benefit for the problem solving team to have leadership 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.

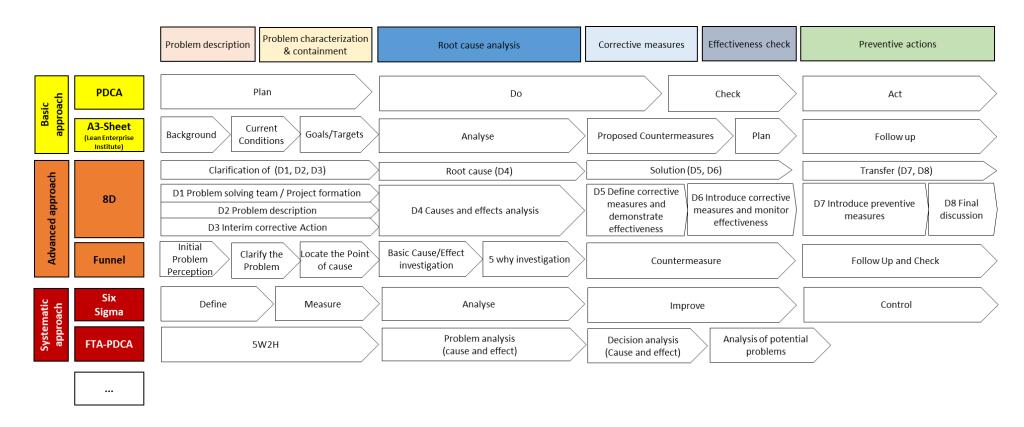
In order to control the process, management should set up and monitor KPIs regarding e.g.: Criticality of backlog of problems, quantity of problems, resolution time.





ANNEXES

ANNEX 1 - Problem solving methods - Matrix



ANNEX 2 - Checklist process steps of problem solving

Items marked with <S> are related to safety related problems.

| Step | What | | Completed |
|------|---|---|-----------|
| 1 | Problem definition | | |
| | from i | clear picture of what the problem is (based on the data currently available - nternal/external sources - incl. photos and videos). Define the goals which o be achieved (as a resolution). | |
| | who, h | ssue can be described with the following questions: what, why, when, where, now, how many (5W2H methodology) and information can be categorize with principle. | |
| | Check | whether the problems have been confirmed by measurements and test? | |
| | | whether additional data is needed to get a clear picture (and request onal data if and as needed). | |
| | | rst assessment whether the problem may be safety relevant. If yes "tag" the m respectively. | |
| | <\$> | Inform the relevant parties within the organization and assign the required internal priorities. | |
| | Check | the use of the most appropriate method (see ANNEX 1) | |
| 2 | Establ | ish a problem solving team | |
| | time, necess stakeh The te | sh a small team of people who have appropriate process / production skills, willingness to cooperate, expertise and knowledge in the techniques cary to solve the problem and to introduce corrective actions including all olders (incl. the customer or customer representative if needed). The customer of customer representative if needed by the team ers based on the problem complexity and severity (see Table XX). | |
| | Depen | whether external team members are beneficial for a best possible process. ding on the problem and its impact these may be experts from suppliers or ners. (Note: If needed external support can be called in at a later stage). | |
| | Start t | o maintain an action plan or list of open points. | |
| 3 | Proble | m containment plan | |
| | Contai | n the problem as described in chapter 3.3. | |
| | Classify the problem (or review previous classification) and decide whether there is the suspicion that the problem may be safety relevant . | | |
| | <\$> | Perform an (ad-hoc) risk assessment. Based on the assessment results deadlines should be given for the execution of (temporary) containment actions and final corrective actions. | |
| | | the goals which need to be achieved by the team (and get them confirmed sponsor). | |

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| Step | What | Completed |
|------|---|-----------|
| | Decide whether it makes sense to review the problem description with the internal/external customer(s). If yes, do so. | |
| | Initiate measures that keep the impact of the problem for the internal/external customers at an acceptable level, until a permanent solution is found. | |
| | Document measures clearly and communicate them (and their status) to all stakeholders. | |
| | Constantly review the effectiveness of these temporary measures and initiate additional measures if necessary. Make sure that containment actions do not introduce new problems. | |
| | If defective parts/equipment/systems have already reached the "end customers", appropriate after sales service measures must be taken. | |
| 4 | Root cause analysis | |
| | Perform the root cause analysis as described in chapter 3.4 | |
| | 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. | |
| | Verify the root cause using logic according to chapter 3.4.3 | |
| | Check the quality of the root cause analysis by verifying if cause for non detection and reoccurrence is covered | |
| | Communicate status information (results of root cause analysis,) to relevant stakeholders. | |
| | Note: Communication should be done latest after successful completion of step 5. | |
| 5 | Corrective actions | |
| | Search for possible actions which shall eliminate the root cause and thus solve the problem. All defined corrective actions need to be linked to the root causes. | |
| | List the corrective actions and select according to time to resolve and efficiency of implementation. | |
| | Set up an action plan with responsibilities and timeline. | |
| | Check (with reasonable efforts) whether the standard measurements and tests are appropriate for a sufficient proof of effectiveness. Modify process if/as required. | |
| | Prove by appropriate tests that the chosen permanent corrective action(s) solve the problem from a customer perspective and have no adverse side effects. Note: Steps 4 and 5 are repeated until proven effectiveness. | |
| | | |
| | Communicate status information (effective corrective actions) to relevant stakeholders (including internal and external customers). | |

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| Step | What | | Completed |
|------|--|---|-----------|
| 6 | Monit | oring of corrective actions | |
| | suppoi to ensi | ate an action plan to implement the selected corrective actions and define ring actions to secure their effectiveness as needed. Define ongoing checks are that the cause of the problem is really fixed. | |
| | assura | er the applicable requirements for change management (specified quality nce actions incl. FAI, customer approval, documentation changes, ogation and modification of existing stock). | |
| | (includ | unicate the corrective actions and the action plan to relevant stakeholders ling internal and external customers). Obtain necessary approvals (e.g., for n customer property). | |
| | Execut require | e the action plan, observe the effects and take the supporting actions as ed. | |
| | Check verifica | the effectiveness of corrective actions at the end user/customer (by ation). | |
| | | whether some or all actions also relevant for other components or systems milar risks (and take actions as required). | |
| 7 | Lesson | s learned | |
| | applica | e the management and control systems, instructions and/or processes (as able), to prevent the same or similar problems occur again. The following be considered: | |
| | - Work instructions and procedures, | | |
| | - Intr | oduction of Poka Yoka measures, | |
| | - Pro | cess descriptions, | |
| | - Tra | ining and instruction plans and documents, | |
| | - Qua | ality control plans, instructions, and records, | |
| | - Des | sign and process guidelines (incl. FMECA). | |
| | knowle | nent problem and its root cause(s) and solution as a "lessons learned" in a edge management system to ensure that similar mistakes will not be repeated developments or design revisions. | |
| 8 | Conclude problem solving and congratulate team | | |
| | <\$> | Relevant management functions and the person in charge of product safety within the organization to formally close the problem. | |
| | <\$> | Archive the complete documentation of the problem solving process (data, decisions and communications). | |
| | Complete team work, recognize the combined efforts and experience and rejoice over the success. | | |
| | Reflection by the team on the problem solving process and if necessary, feedback the relevant person(s). | | |

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ANNEX 3 – 5W2H

5W2H: To understand the customer concern the 5W2H (5 Why 2 How) method can be used:

- o What?: What is the problem?
- o Why?: Why is it a problem?
- o When?: When did the problem happened?
- o Who?: Who is affected by the problem?
- o Where?: Where is the problem located?
- o How?: How was the problem identified?
- o How Many?: How many parts, places, people, times,...?

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ANNEX 4 - 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":
 - 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 need 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 opinion,
- Underestimate the time and energy that will be needed to perform problem solving,
- Twist facts to suit theories



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