SLOVENSKI STANDARD
SIST EN 9136:2018

01-julij-2018

Aeronavtika - Analiza izvornih vzrokov in reševanje težav (metodologija 9S)

Aerospace series - Root cause analysis and problem solving (9S Methodology)

Luft- und Raumfahrt - Ursachenanalyse und Problemlösung (9S Methodik)

Série aérospatiale - Analyse de cause racine et résolution de problème (9S méthodologie)

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Ta slovenski standard je istoveten z: **EN 9136:2018**

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ICS:

03.120.01	Kakovost na splošno	Quality in general
49.020	Letala in vesoljska vozila na splošno	Aircraft and space vehicles in general

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2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 9136

May 2018

ICS 03.120.10; 49.020

English Version

Aerospace series - Root cause analysis and problem solving (9S Methodology)

Série aérospatiale - Analyse de cause racine et résolution de problème (9S méthodologie)

Luft- und Raumfahrt - Ursachenanalyse und Problemlösung (9S Methodik)

This European Standard was approved by CEN on 20 November 2017.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European foreword

This document (EN 9136:2018) has been prepared by the Aerospace and Defence Industries Association of Europe - Standardization (ASD-STAN).

After enquiries and votes carried out in accordance with the rules of this Association, this Standard has received the approval of the National Associations and the Official Services of the member countries of ASD, prior to its presentation to CEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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Rationale

The objective of root cause analysis and problem solving is to not only reduce the number of issues (i.e. undesirable conditions, defects, failures), but to minimize their impact on quality, delivery performance, costs, and ultimately on the customer. Often big issues originate with small problems that were discovered too late or were discovered, but were never resolved due to a lack of understanding the actual issue(s), incorrect analysis of the root cause, and/or ineffective actions being taken.

This guidance document was created to provide a methodology for performing root cause analysis to resolve a significant or recurrent issue [e.g. quality, On-Time Delivery (OTD), process, documentation), as guidance within the aviation, space, and defence industry and/or when contractually invoked at any level of the supply chain.

Foreword

In December 1998, the aviation, space, and defence industry established the International Aerospace Quality Group (IAQG) with the purpose of achieving significant improvements in quality and reductions in cost throughout the value stream. This organization, with representation from aviation, space, and defence companies in the Americas, Asia-Pacific, and Europe and sponsored by SAE International, Society of Japanese Aerospace Companies (SJAC), and AeroSpace and Defence Industries Association of Europe -Standardization (ASD-STAN), has agreed to take responsibility for the technical content of this document to promote best practices that would satisfy associated requirements of Aerospace Quality Management System (AQMS) standards (i.e. 9100, 9110, 9120).

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To assure customer satisfaction, aviation, space, and defence industry organizations must produce and continually improve safe, reliable products that meet or exceed customer and regulatory authority requirements. This includes having processes in place to detect and eradicate significant and recurrent issues. This document standardizes methodology to perform root cause analysis and problem solving to support these efforts. The establishment of a common methodology, for use by organizations at all levels of the supply-chain should result in improved action plans and a standardized way of exchanging information between organizations and external stakeholders (e.g. suppliers, partners, customers, regulatory agencies).

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Introduction

This document has been developed by the IAQG. In accordance with the continual improvement requirements defined in the 9100-series standards (see Clause 8, “Measurement, Analysis, and Improvement”), it was deemed useful to promote those industry recognized best practices for identifying the root causes of nonconformities or undesirable conditions (including potential issues and conditions) and implementing correction(s) and associated corrective/preventive actions. The process described in this document was created by comparing and mixing root cause analysis and problem solving methodologies [e.g. 7 Steps, 8D, Root Cause Corrective Action (RCCA)] used by main actors of aviation, space, and defence industry.

Unless contractually specified, other root cause analysis processes with slightly different sequencing of activities and/or different names of process steps may be acceptable, provided that these activities meet the intent of this document and deliver the same outcomes (i.e. immediate protection, temporary fix, durable solution, systemic improvement) and provides the same level of information.

Throughout this document, the words “should” and “required” indicate strong recommendations to apply and correspond to actions that the authors of this document consider important in order to deliver robust root cause analysis. When strict application of this document is decided by an organization or is mandated by a customer, they shall be interpreted as an obligation to be complied with (i.e. interpreted as “shall” and “must”).

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1 Scope

1.1 General

The objective of any organization, as part of continual improvement, is to reduce the number of issues (i.e. undesirable conditions, defects, failures) and to minimize their impact on quality, delivery performance, and cost.

This includes having processes in place to detect and eradicate significant and recurrent issues, which implies having well identified problems, a common understanding of their impact and associated root causes, and having defined and implemented adequate actions so that these problems, including similar issues will not happen again.

1.2 Purpose

Propose a methodology to improve the way escapes and issues are managed, including communication between all parties [e.g. engineering, Materials Review Board (MRB), manufacturing, manufacturing engineering, supplier, customer] to reduce their impact, contain them as far upstream as possible, and prevent recurrence (i.e. ensure the right measures are taken at the right location and at the right time).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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EN 9100, *Quality Management Systems — Requirements for Aviation, Space and Defence Organizations*

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EN 9110, *Quality Management Systems — Requirements for Aviation Maintenance Organizations*

EN 9120, *Quality Management Systems — Requirements for Aviation, Space and Defence Distributors*

EN ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary (ISO 9000:2015)*

3 Terms and definitions

Definitions for general terms can be found in EN ISO 9000 and the IAQG Dictionary, which is located on the IAQG website. An acronym log for this document is presented in Annex A.

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
apparent cause
(also referred to as obvious cause, direct cause, or immediate cause)
event or action that immediately results in or precedes the nonconformity

Note 1 to entry: This is generally NOT the root cause.

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3.2
containment
action to control and mitigate the impact of a problem and protect the organization and/or customer (i.e. stop the problem from getting worse), includes correction, immediate corrective action, immediate communication, and verification that problem does not further degrade

3.3
contributing causes
causes that by themselves would not cause the problem, but can increase the risk of the issue to occur. Analysis for these causes generally requires taking a closer look at the existing conditions and associated actions

3.4
correction
(also referred to as Immediate Correction)
action taken to eliminate a detected nonconformity

[SOURCE: EN ISO 9000:2005, 3.6.6, modified]

Note 1 to entry: A correction can be made in conjunction with a corrective action.

Note 2 to entry: For product nonconformity, correction might be understood as reworking the part, accepting the nonconformance through concession process, or scrapping the product.

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Note 3 to entry: For a system issue, it may include correcting the paper work or issuing a new purchase order.

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Note 4 to entry: For a delivery issue, it may include revising to air transportation instead of delivering product by truck or ship, increasing production rate, etc.

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3.5
corrective action
action taken to eliminate the cause of a detected nonconformity or other undesirable situation to prevent recurrence

[SOURCE: EN ISO 9000:2005, 3.6.5, modified]

Note 1 to entry: A correction can be made in conjunction with a corrective action.

Note 2 to entry: Corrective action may address all types of causes (i.e. apparent, contributing, root causes).

3.6
immediate corrective action
action taken to eliminate, prevent, or reduce the probability of any additional nonconformances related to the apparent cause from happening again in the short term

Note 1 to entry: These actions may be temporary and should remain in place until the root cause(s) is identified and permanent RCCA is implemented and verified to be effective.

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3.7
nonconformity
non-fulfilment of a requirement

[SOURCE: EN ISO 9000:2005, 3.6.2]

Note 1 to entry: It may be a nonconforming product, but may also be a late delivery, incorrect paperwork, incorrect process [production or Quality Management System (QMS) related], etc.

3.8
preventive action
action to eliminate the cause of a potential nonconformity or other undesirable potential situation

[SOURCE: EN ISO 9000:2005, 3.6.4, modified]

Note 1 to entry: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

3.9
root cause
original event(s), action(s), and/or condition(s) generating (directly or in cascade) an actual or potential undesirable condition, situation, nonconformity, or failure

Note 1 to entry: There is sometimes more than one root cause associated to a single nonconformity or one root cause with multiple contributing causes.

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3.10
root cause analysis
process of identifying all the causes (root cause and contributing causes) that have or may have generated an undesirable condition, situation, nonconformity, or failure

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3.11
Root Cause Corrective Action
RCCA
(also referred to as Permanent Corrective Action)
action implemented to address the root cause(s) and contributing cause(s) of the undesirable condition, situation, nonconformity, or failure; action taken to prevent recurrence

3.12
Root Cause Corrective Action (RCCA) Effectiveness Verification
action taken to verify that the planned corrective action(s) have prevented recurrence of the identified root cause or contributing causes, and have consequently eradicated the problem

Note 1 to entry: This may include auditing, monitoring of specific metrics, or any other reporting methodologies.

3.13
Root Cause Corrective Action (RCCA) Implementation Verification
action taken to verify that the planned actions were taken as scheduled

Note 1 to entry: This includes specific actions, milestones, completion dates, and responsibilities.

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4 General Process

4.1 Basic Principles

a) In many instances, organizations and their suppliers do not provide adequate root cause analysis and problem solving results because:

- no clear criterion exists for an acceptable corrective action plan; organizations are satisfied when they no longer receive defective parts;
- the organization continues to accept inadequate corrective action plans as priority is given to schedule versus quality;
- organizations (internal/external) do not have a root cause analysis mind set; people don't know or understand the process and/or have not been effectively trained.

b) A robust root cause analysis and problem solving process should provide visibility of the following information:

- how the issue is managed and communicated between all stakeholders (e.g. engineering, MRB, suppliers, customer);
- how it is ensured that the actual root cause(s) has been identified;
- how it is ensured that the right measures are taken at the right location, at the right time, and by the right individuals;
- how containment actions taken to protect the customer and production efforts are identified and managed.

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c) Problem solving approaches can be summarized as:

- Reactive Mode – solving the abnormality that has occurred; gathering and analysing data aims to provide customer protection and associated countermeasures;
- Proactive Mode – analysing failures and looking for product, process, or system improvements;
- Preventive Mode – putting in place solutions before an undesirable condition, defect, or failure occurs.

4.1.1 Cultural Change

Cultural change is generally required to progress from a "reactive" mode to "proactive" and/or "preventive" modes.

a) Examples of traditional behaviours:

- quick fix;
- not taking adequate time for analysis;
- going from one crisis to another;
- looking for the guilty party – "Who did that?"

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— blaming or transferring responsibility;

— generate laundry list of solutions to firefight the symptoms;

— narrow focus taken to address the immediate problem;

— focus on performance metrics/measures (e.g. sales, profits) with hope that processes will improve by themselves.

b) Expected “systems thinking” behaviour to get “systemic solutions”:

— understanding that many factors contribute to a complex situation;

— fully understanding the actual problem and then addressing the systemic root cause(s);

— permanently fixing and improving performance;

— seeking total understanding of the process – “How did that happen?”

— taking time to understand the big picture; to dialogue and elicit diverse perspectives before applying the solution;

— focusing on improving processes; actually effecting process performance.

4.1.2 Effective Communication

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The behaviour of all process performers and stakeholders are key factors of success in the application of a robust root cause analysis and problem solving process.

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Effective communication is mandatory:

— Within the organization where the problem originated, and between process performers and stakeholders of the supply chain to ensure effective root cause analysis and corrective action implementation.

— Between supplier and customer to immediately stop the problem from getting worse, ensure full understanding of the problem, and verify that implemented solutions are satisfactory.

NOTE The conditions where the customer must be notified should be established and documented. If the conditions cannot be specified with tangible trigger points, then direction should be given for how to evaluate each situation to ensure the customer is kept informed, as appropriate.

4.2 When to Apply a Structured Root Cause Analysis and Problem Solving Process

Launching a formal root cause analysis and problem solving process should always be considered, when an issue (undesirable conditions, defects, and failures) is detected and the cause is unknown or inconclusive (not obvious). The decision to apply or not apply the process should be made at the appropriate level of management within the company based on the level of risk and whether the risk associated is acceptable or not, using a rational decision making process and maintaining records of significant decisions.

The process should always be applied, if one or more of these conditions exist:

— safety impact (product/personal);

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— product strength, performance, and/or reliability issue;

— high impact on production/maintenance operations:

  — stop the production/maintenance line; prevent next operation to occur satisfactorily, etc;

  — regulatory authorities and/or customer dissatisfaction;

  — costs issue (generated to the customer or the organization);

  — disruption of supplier's process or customer's operations.

— repetitive problems to one part or similar activities/processes;

— difficulty to detect;

— customer request;

— significant quality or QMS issue;

— complex problem that cannot be solved without assistance of other people than those located where the problem occurred.

Generally speaking, the impact of an issue and the frequency of its occurrence should always be considered when deciding to launch or not launch a formal root cause analysis (see Figure 1).

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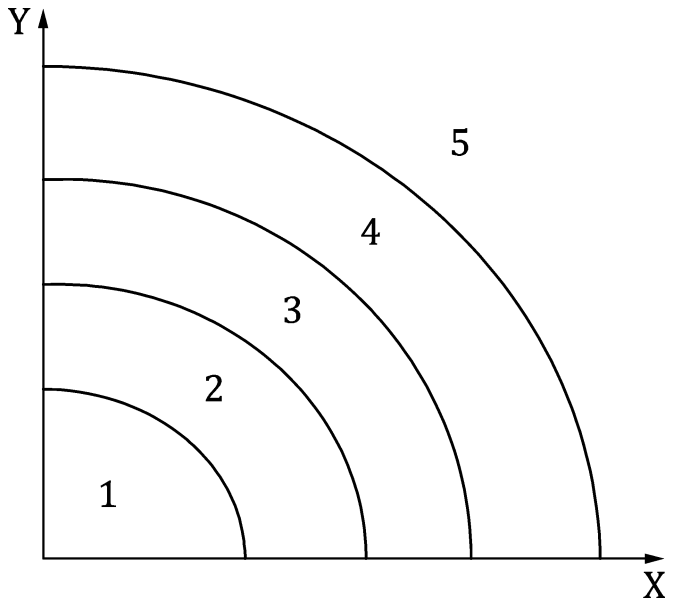

Key

1 Not required
2 Optional
3 Recommended
4 Mandatory
5 Customer request shall always take precedence
X Frequency
Y Impact

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Figure 1 — Applying a structured root cause analysis and problem solving process depending on the impact and frequency of a problem

4.3 Process Step Description

The process is described in nine steps by S0 to S8 (see Figure 2).

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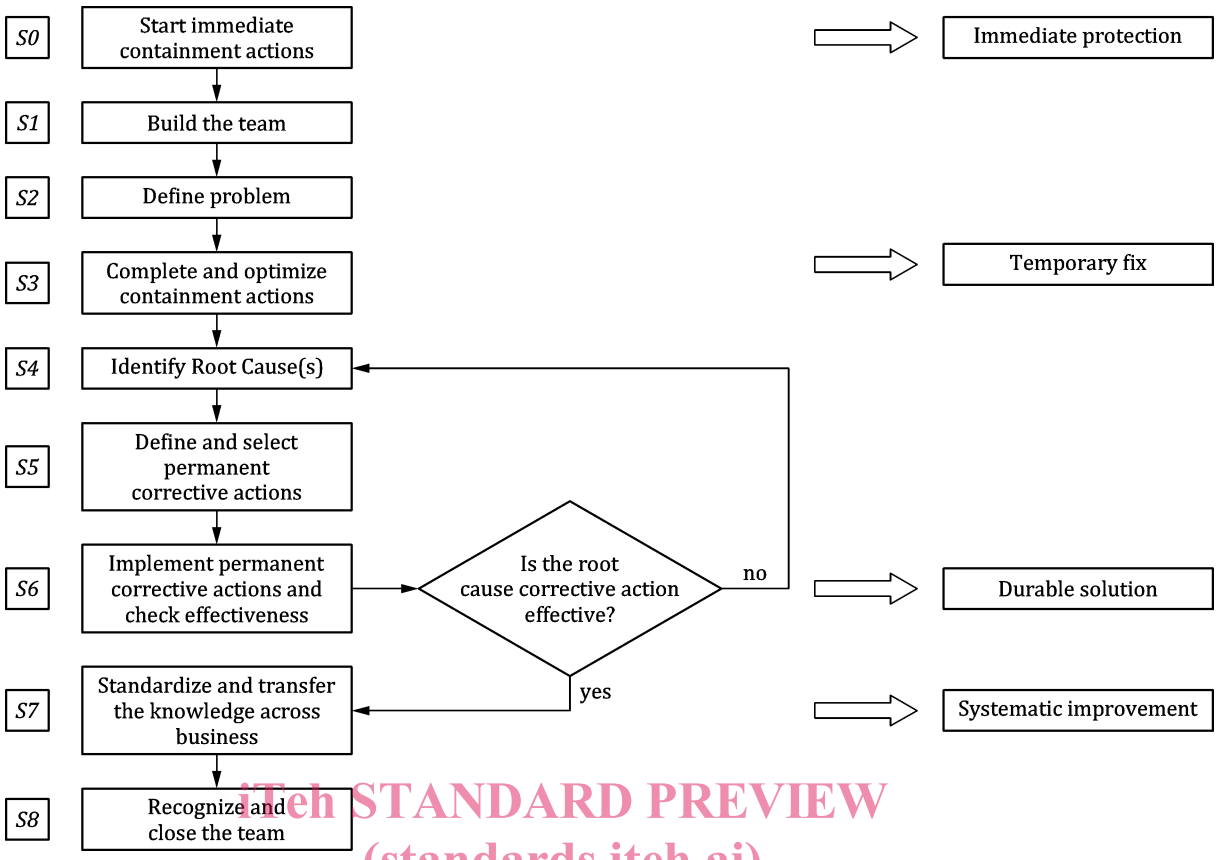

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Figure 2 — Root cause analysis general process mapping

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The criticality of the problem should be determined, based on evaluation of the risk(s) it generates, taking into consideration the following elements: the severity of the issue (i.e. its impact on the business, the product, and/or the customer) its detectability, its probability to occur, etc.

This document defines the elements for each of the nine process steps:

a) ***objective(s)*** of the step;

b) ***output(s)*** of the step;

c) ***what*** are the associated actions for this step;

d) ***why*** this step is necessary and the potential risk if no action is taken;

e) ***when*** does the activity take place;

f) ***who*** are the principle process performers and applicable stakeholders;

g) ***how*** to manage this process step so that it is effective, including providing some proposed tools to be used;

h) ***communication*** aspects to take into consideration;

i) ***specific Items*** to be considered.