Effective Problem Solving and Root Cause Identification

CAP 1760

Shainin (Red X)

Six Sigma

8D

Kepner-Tregoe TQM

BowTie

Fault Tree Analysis

Ishikawa Fish Bone

3 Concerns

5 Whys

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Effective Problem Solving and Root Cause Identification - A guide to compliance

Introduction

This document has been produced as a guide for airworthiness approved organisations to assist in the process of identifying a root cause of an occurrence/non-conformance and the subsequent corrective and preventive action planning required to satisfy the requirements of ICAO, EASA, the EU and the UK CAA.

Current Part M, Part 21, Part 145 and Part 147 regulations require organisations to ‘identify the root cause’ and ensure ‘corrective action to the satisfaction of the competent authority’ for both NAA audit non-conformances and occurrence reports. However, from a CAA perspective the quality of responses detailing root cause, corrective and preventive actions varies considerably and is believed to contribute, at least in part, to repeat or similar non-conformances that can affect both safety and compliance.

With the advent of Regulation (EU) No 376/2014 on ‘the reporting, analysis and follow-up of occurrences in civil aviation’, the Authority is required to assess all submitted Mandatory Occurrence Reports (MORs) / Voluntary Occurrence Reports (VORs) with respect to root cause and corrective actions to enable closure in ECCAIRS. Poor organisational, root cause analysis and corrective action response plans could lead to organisations exceeding the reporting/closure times mandated by the regulation or a repeat of the occurrence internally due to inadequate identification of the true root cause.

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1 M.A. 403. AMC M.A.403(b)
2 M.A.619(c) M.A.716(c) M.A.905(c) 145.A.95(c) 147.A.160(c) 21.A.125B(c) 21.A.158(c) 21.A.258(c)
4 European Co-Ordination Centre for Accident and Incident Reporting System
The future adoption of Safety Management Systems (SMS) under EASA NPA 2013-01(A) into Part M regulation (NPA 2013-01(B) (see EASA Opinion 06/2016) and Part 145 regulation (NPA 2013 -01(C) will require the root cause analysis and corrective action plan procedures which are currently part of the organisations Maintenance Error Management System (MEMS) to be absorbed into a new SMS. EASA is also looking at the introduction of safety management principles to Part 21 organisations through Opinion 07/2016\(^5\) (pending) under a separate rule making task (RMT.0262).

In addition, Annex II - EU 2018/1139\(^6\) ‘Essential requirements for airworthiness’ now requires:

3. ORGANISATIONS (INCLUDING NATURAL PERSONS UNDERTAKING DESIGN, PRODUCTION, CONTINUED AIRWORTHINESS MANAGEMENT OR MAINTENANCE)

3.1.(b) as appropriate for the type of activity undertaken and the size of the organisation, the organisation must implement and maintain a management system to ensure compliance with the essential requirements set out in this Annex, manage safety risks and aim for continuous improvement of that system

Many aviation organisations operate under Quality systems certified to standards such as ISO 9001, AS9100, AS13000 or participate in accreditation programmes such as PRI Nadcap or UKAS. These standards offer additional guidance on root cause and corrective action methodology to ensure compliance with their requirements. This document is intended to build on their documentation and offer some additional airworthiness guidance, as such there should be little or no additional burden to organisations as they should seek to follow one consistent internal approach to root cause.

Effective root cause analysis and appropriate corrective/preventive action plans have been proven to benefit organisations by reducing costs, increasing efficiencies and contributing to continuous improvement.

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\(^5\) EASA Opinion No 07/2016 - Embodiment of level of involvement requirements into Part-21. Related NPA/CRD 2015-03. RMT.0262 (MDM.060) - 23/05/2016

Small non-complex organisations may wish to consider this guidance alongside CAP 1059 - Safety Management Systems: Guidance for small, non-complex organisations.

The format used in the document is for illustrative purposes to allow a worked example to be demonstrated. The style and format of individual approved organisational occurrence documentation is an organisational matter. Completing the stages detailed in this document will ensure the level of detail supplied is sufficient to enable closure of both NAA non-conformances and MOR/VORs by the regulator.

Whilst some organisations already operate a software driven occurrence reporting system which can generate automatic outputs, the level of detail required does not always meet the requirements. This document should be used as guidance to the level of detail required by the regulator to complete both the NAA and ECCAIRS databases.

For further detail please contact:

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Definitions

For consistency the following definitions are used in the guidance:

EVENT - this is ‘what actually happened’, what was reported includes the following: accident, incident, occurrence report, audit finding, product failure etc.

PROBLEM STATEMENT - describes the effects and potential risks of the event on the entire organisation.

CONTAINMENT ACTIONS - actions taken to return the initial event back to a desired state.

DIRECT CAUSE - the immediate or physical cause that led directly to the problem

ROOT CAUSE ANALYSIS - methodology used to determine how and why the problem statement developed.

CAUSAL FACTORS - factors (human errors and component or organisational failures) that, if eliminated, would have prevented the occurrence.

CONTRIBUTING FACTORS - issues identified during the investigation that could not have independently caused the event, but may have influenced the outcome.

ROOT CAUSE STATEMENT - explains the underlying reason that caused the problem statement.

CORRECTIVE ACTIONS - actions taken that directly link to the root cause statement, that return the problem statement back to a desired state.

PREVENTIVE ACTIONS - actions taken to prevent the root cause statement from recurring.

NOTE: Text identified with this style of bullet point should be considered ‘Useful Hints’

The definitions should be used in conjunction with the following route map and flow diagram:
A route map to effective problem solving and root cause identification

Develop a Problem Statement:
Describe the effects and potential risks of the event on the entire organisation. Make sure the problem statement reflects the generic problem.

Investigation:
Carry out an investigation into the event to the extent determined by the risk assessment process.

Risk Assessment (if required):
Carry out a risk assessment to determine the extent the problem statement has on the organisation. Determine the level of investigation required.

Root Cause Analysis:
Use the organisation's chosen method(s) of root cause analysis to determine how and why the problem statement developed.

Corrective Actions:
Develop corrective actions that directly link to the root cause statement that will return the problem statement back to a desired state.

Containment Actions:
Develop containment actions that bring the event back to a desired state. If containment of the event is not possible consider suspending or stopping operations/production.

Organisations often close reports at this point! Don't STOP here... the root cause has NOT been established.

Root Cause Statement:
Develop a root cause statement that explains the underlying reason for the problem statement.

Monitor the Outcome:
To ensure the root cause of the problem statement is correctly identified and addressed to prevent similar events occurring within the organisation. Ensure all corrective and preventive actions are effective by monitoring subsequent performance.

Record the Outcome:
Use the recorded information from each step to update the database. Use key information to develop an organisational risk register. Ensure the reporter of the event is kept informed.
- What Actually Happened
- Details of actual incident, accident, finding etc

- Triage the EVENT, is the event allocated to the correct area? Has it happened before? Review any historic data.
- Is the event the symptom of a larger problem?

- Develop a PROBLEM STATEMENT (PS) that describes the effects and potential risks of the EVENT on the entire organisation

- Carry out a RISK ASSESSMENT (RA) to determine what effect the PS has on your organisation
- Determine the level of investigation required

- Determine and implement CONTAINMENT ACTIONS (Cont A) to bring the EVENT back to a desired state
- If you cannot contain the EVENT you may need to STOP or SUSPEND operations/production

- Carry out an INVESTIGATION into the EVENT as determined by your RA

- Carry out your ROOT CAUSE ANALYSIS (RCA) to determine how and why the PS developed

- Develop and document a ROOT CAUSE STATEMENT (RCS) that explains the underlying reason for the PS

- Develop CORRECTIVE ACTIONS (Corr A) that are directly linked to the RCS that will return the PS back to a desired state

- Develop PREVENTIVE ACTIONS (PA) to prevent the recurrence of the RCS

- Review all Corr A and PA to ensure they were effective. Monitor through Quality/Safety Audits
- If Actions are shown to be ineffective, review Actions taken and RCA to ensure the PS correctly described the effects and potential risks of the EVENT on the entire organisation.
Root Cause Analysis

WHAT DOES IT MEAN FOR YOUR ORGANISATION?

The objective of root cause analysis is to identify the cause of a breakdown in your organisational system, which has resulted in an undesired event, to ensure that repeat occurrences/ findings are minimised.

In undertaking root cause analysis you should seek to investigate all aspects of the process, procedures, environment, performance and any extenuating circumstances surrounding an event to identify what caused the underlying problem (root cause). This will provide you with a framework to develop suitable corrective and preventive actions that when implemented should help limit the opportunity for a recurrence of the event.

A few basic points to consider as you perform root cause analysis:

• This is a methodology which should be applied in a structured and systematic way to get the best outcome.

• The initial reported event may only be a symptom of a deeper underlying problem, very rarely is the reported event the whole story.

• Be prepared to make additional lines of enquiry during your investigation, each event tends to be subtly different and may require different levels of investigation and understanding.

• The corrective and preventive actions should map to the identified underlying root cause.

• Correcting the root cause, as opposed to the event, should normally minimise the possibility of a similar event from occurring.

   **Once the root cause has been correctly identified the combined containment, corrective and preventive actions should ensure both the event and problem statement are addressed.**

   To demonstrate a simplified root cause process this guidance follows an event through from notification to closure.
The first action is to record the event in the internal reporting/occurrence system or quality system documented and operated in accordance with the procedure approved in the appropriate organisation exposition.

If the internal reporting system is in its infancy you could opt to produce a basic table like the Event Record Table (ERT 1) shown overleaf.

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7 See Handouts Section of guidance material for templates
The ERT example has two phases:

Phase 1) for recording the immediate information and actions when the event was discovered.

Phase 2) to be completed at the end of the investigation process.

If the event is deemed to be an MOR or VOR (see EU IR 2015/1018) ensure enough initial detail is recorded to satisfy the requirements of EU 376/2014, Annex 1 which lists the data fields that must be completed when reporting to the NAA. See Appendix 1.

The reporting of MOR/VORs to the NAA is actioned using the ECCAIR system via the CAA website.

If the organisation uses several different databases ie. for Flight Ops, Engineering, Health and Safety, Ground Handling ensure the event is allocated to the correct database.

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Having recorded the event, the organisation needs to start the process of identifying the problem that the event represents.

It is not uncommon for the reported event to be a symptom of a larger underlying problem.

Review your organisational database. Has the organisation experienced this before? What were the organisation's previous actions?

Use any known data to help understand the event at this early stage, but remember the organisation is unlikely to experience two identical events.

Using the worked example:

**STAGE 1a: Triage the Event**

1. Triage the EVENT, is the event allocated to the correct area? Has it happened before? Review any historic data.
2. Is the event the symptom of a larger problem?

Whilst carrying out a Part 21 G audit, the auditor (a CAA Surveyor) noticed a Go-NoGo gauge being used by an operative was out of calibration.

The resulting non-conformance was raised against the appropriate regulation.
The initial non-conformance closure response from the organisation was as follows:

Gauge Part No. X Serial No. Y was immediately removed from the shop floor and re-calibrated in accordance with company procedure (abc) before being put back into service. All the xyz parts in the batch were re-checked using the re-calibrated gauge.

The immediate problem was fixed by re-calibrating the gauge and putting it back into service. However, this did not take into account any other associated risks the event may have uncovered.

Had the organisation taken more time with the analysis, they should have realised that their initial response was not sufficient to ensure that the failure in production could not produce a similar event on other lines of manufacture that used calibrated tools.

The organisation’s response only addressed the immediate issues (containment actions), not final corrective or preventive actions addressing the true root cause of the event.

Do not allow your organisation to stop at the quick fix solution.

In order to carry out effective root cause analysis you should adopt a structured approach that takes into account not only the individual but the working environment including process, procedures, equipment and importantly external factors. Only then will you be able to determine all the factors that influenced the performance of the task on that ‘unique’ occasion. Generally, the tasks would have been carried out many times before without incident, but on this occasion something changed.

As part of the initial event recording/review the organisation should have tried to determine whether the use of a gauge that was out of calibration was likely, a ‘one-off’ or perhaps the ‘symptom’ of a larger systemic issue.
Reviewing previous internal and external quality/safety related audit findings and events that feed into the occurrence and quality systems can help determine previous event similarities. Use this information to ‘help’ identify previous strategies and mitigations but do not allow historic data to drive a fix. Use this only as additional ‘useful’ information to avoid any possibility of hindsight bias.

Returning to the worked example, even at this early stage with limited knowledge of the event the organisation should have realised that the event consisted as a minimum of three additional issues:

1. Why were components being inspected with a gauge that was out of calibration?
2. Why was the gauge out of calibration?
3. How many components had been inspected using the gauge that was out of calibration?

It can be seen that none of these associated issues were addressed in the first response to the audit non-conformance.

It is not uncommon to identify more than one issue when an event is reviewed.

You may find that the problems are linked during the subsequent investigation in which case you may be able to address several issues under one problem statement.

If a link cannot be established you will need to address each problem independently by raising another occurrence in your MEMS/Quality/SMS and if necessary in the ECCAIRS database.

In order to correctly define the problem associated with the event the organisation will need to produce a problem statement.
An effective **Problem Statement** encompasses the following questions:

- **What**
- **When**
- **Where**
- **Who**
- **How**

At this early stage in the organisation’s understanding of the **event**, the answers are unlikely to represent the actual cause of the **event**.
The *What* has already been documented in the system.

The *How* at this stage relates to how the *event* was discovered, **not** how it happened.

*Record the initial findings to these questions in the Phase 1 section of the ERT.*

*(See Event Record Table 2)*

Documenting this information should enable you to produce a *problem statement* which describes the effects and potential risks of the event on the entire organisation. Use this as the basis of the *event* investigation.

The *problem statement* should be generic enough to ensure that all aspects associated with the original *event* are captured.

The *problem statement* should be an expansion of the recorded *event*.

During Phase 1 of the process it should be noted that the recorded information does not imply what caused the *event*. It is purely a statement of *fact* using the information known when the *event* was discovered and reported.

◊ A common error is to use the auditors’ non-conformance description as the *problem statement*. Do **NOT** be tempted to do this without close scrutiny as most non-conformances only represent symptoms of an underlying problem.

*It is for you and your organisation to identify the problem state, **NOT** the auditor.*
Record the evidence and detail you have collected to substantiate the **problem statement** on the Event Record Table (ERT 2).

<table>
<thead>
<tr>
<th>Event (What Happened)</th>
<th>Go-NoGo gauge Part No. X Serial No. Y found out of calibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase</td>
<td>1) Initial event information</td>
</tr>
<tr>
<td>When</td>
<td>On 2nd Jan 2016 @13:23 (dayshift)</td>
</tr>
<tr>
<td>Where</td>
<td>Production line A. Used in the manufacture of Part No. xyz</td>
</tr>
<tr>
<td>Who</td>
<td>CAA surveyor accompanied by QM</td>
</tr>
<tr>
<td>How</td>
<td>During a routine Pt 21G audit</td>
</tr>
<tr>
<td>Problem Statement (Potential effects/risks)</td>
<td>Part(s) on a production line were being inspected (by personnel) using a tool that was out of calibration</td>
</tr>
<tr>
<td>Risk Assessment</td>
<td>Initial Risk Score</td>
</tr>
<tr>
<td></td>
<td>Investigation Low Medium High</td>
</tr>
<tr>
<td>Operation</td>
<td>Production Review Continue STOP</td>
</tr>
<tr>
<td></td>
<td>Sales Review Continue STOP</td>
</tr>
<tr>
<td>Containment</td>
<td></td>
</tr>
<tr>
<td>Evidence</td>
<td>Photos of expired gauge attached. Copy of CAA surveyors non-conformance report.</td>
</tr>
<tr>
<td>Human Factors</td>
<td>Evidence:</td>
</tr>
</tbody>
</table>

**NOTE:** The **problem statement** captures any calibrated tooling being used on any production line, as opposed to a single uncalibrated tool on one production line.

Do not include a specific ‘who’ in the **problem statement** as this often results in actual causes being overlooked.
Having recorded the effects and potential risks of the event on the entire organisation ie. the **problem statement**, you may need to risk assess the **event** with respect to the impact it may have on the organisation and/or customers. The requirement to carry out such a **Risk Assessment** will depend on the type of event recorded. Under regulation EU 376/2014 for the reporting of MORs and VORs your organisation is required to supply a risk assessment as part of your submission. This requirement is not mandatory if the event is an internal or NAA audit finding, although many organisations choose to risk assess all findings as part of their MEMS / SMS process.

Use trained staff to carry out an initial risk assessment or classification of the **event** using a suitable risk assessment/classification tool.

Not all events warrant a detailed investigation. In order to determine whether you wish to investigate or just record the event for tracking/trending you need to develop a standardised approach for classifying events.

This classification of the risk can also be used to determine what immediate actions your organisation should take with regard to production/operations/sales/continuing airworthiness/maintenance etc, in order to contain the impact of the **event**.

These actions are referred to as **containment actions**. (See Stage 4)
A risk assessment tool that uses a scoring system enables your organisation to determine which events require:

- No further action other than recording for trending and future analysis,
- A desktop review,
- An investigation,
- An immediate suspension of operations/production/sales or a product recall.

The same scoring system is often used to determine what level of investigation should be carried out.

Many mid/complex organisations utilise software such as QPulse\(^9\), AQD\(^{10}\), SafetyNet\(^{11}\), Centrik\(^{12}\) for logging and recording events as part of their MEMS or SMS.

These software systems often contain a standardised methodology for the ‘risk rating’ of an event.

If your organisation uses one of these systems we suggest you continue to do so as you have already invested time and money in both the system and training for personnel to use it. You may however wish to talk to your software provider about customising the ‘risk rating’ tool to suit your individual organisational needs.

If your organisation does not have access to such software systems you will need to add a risk assessment/classification tool to your current MEMS/SMS. There is a vast amount of information available in the public domain referencing risk assessment/classification tools including CAP 1059 the CAA Safety Management Systems: Guidance for small, non-complex organisations which contains an example Risk Tolerability Matrix and information on how to build this into your future SMS.

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\(^9\) Q-Pulse: Ideagen Aviation Compliance and Safety Management Solutions

\(^{10}\) AQD: Rolls Royce Visium Safety, Quality and Risk Management Software

\(^{11}\) SafetyNet: Vistair Safety and Compliance Management Software

\(^{12}\) Centrik: Safety, Risk, Compliance and Documentation Management Software
In addition you should refer to the latest edition of the *International Civil Aviation Organisation (ICAO) doc 9859 - Safety Management Manual* with regard to implementing all aspects of SMS. The adoption of a risk assessment/classification methodology to aid in your event management process will make the future implementation of SMS much easier.

If your organisation does not currently operate an SMS you may wish to produce a simple matrix like the one shown in Appendix 2 of this document for determining what level of risk the *event* poses to the organisation.

The matrix shown is the standard matrix developed by Airline Risk Management Solutions (ARMS)\(^\text{13}\) and is known as the Event Risk Classification (ERC) matrix.

As already stated, not every event warrants further investigation.

For example, depending on your organisation’s risk assessment criteria, you could choose not to investigate events that do not result in the release of a non-conforming product to the customer.

*Using the worked example:*

**Whilst carrying out a Part 21 G audit, the auditor (a CAA Surveyor) noticed a Go-NoGo gauge being used by an operative was out of calibration.**

*The resulting non-conformance was raised against the appropriate regulation.*

**Gauge Part No. X Serial No.Y was immediately removed from the shop floor and re-calibrated in accordance with company procedure (abc) before being put back into service. All the xyz parts in the batch were re-checked using the re-calibrated gauge.**

Using the ERC matrix shown in Appendix 2 the organisation risk assessed the ‘out of calibration gauge’ with an ERC score of 100.

This equated to the event having the following impact on the organisation:

A Medium Impact x Minimal Remaining Barriers

Why an ERC score of 100?

The CAA surveyor identified the issue on the production line which meant there was a disruption to the production line. However, the gauge was immediately removed, re-calibrated and production continued. There was no long term disruption to the production line (Medium Impact).

x

Although part xyz had been inspected using an ‘out of calibration’ gauge 100% of the manufactured parts were inspected prior to certification and supply to the customer. The remaining inspection barrier was deemed by the organisation to be robust enough to have captured any parts that were non-compliant before certification and shipment. However, as the certification process was the last barrier prior to supply, the effectiveness of remaining barriers was deemed minimal.

This was the organisation’s initial Event Risk Classification (ERC) which determined the organisation could continue production but needed to carry out a standard investigation.

Record the initial risk score on the Event Record Table as it is the formal record of the decision made by your organisation with regard to how they wished to proceed with the specific event.
You may find that the event needs re-scoring further into the process as you begin to build a picture of what happened.

This may result in an escalation or de-escalation of the type of investigation required.

If a change in investigation type is required ensure you record your organisation’s actions and the rationale for the change.

If you are investigating an event as the result of a CAA non-conformance or a MOR/VOR your organisational response will require a root cause analysis, corrective and preventive actions to enable closure within the ECCAIRS and NAA databases. To produce the required output your organisation will need to carry out some form of investigation.

The detail behind each level of investigation should be documented in the organisation’s MEMS or SMS so that personnel know what to expect when an investigation takes place.

This document does not go into the depth and types of investigation your organisation should carry out. However, regulation\textsuperscript{14} does require that all personnel employed to carry out such investigative work have been suitably trained.

There is a vast amount of information on risk analysis freely available in the public domain see the reading list on page 61.

\textsuperscript{14} M.A.202 Occurrence reporting AMC.M.A.202(a)  CAP 562 Leaflet 11-50 (AWN 7) MEMS
Having recorded the *event* and documented the perceived risk to your organisation you need to act to contain any consequences from the *event*.

Develop, implement and record your organisation’s decision regarding initial *Containment Action(s)*.

Do this by discussion with others identified as stakeholders in the *event*.

Does your organisation need to **STOP/SUSPEND** operations, production or call back a product/aircraft, in order to contain the risk?

Your organisation needs to ensure that the containment action(s) bring the *event* back to a desired state.

*There will always be a containment action of some description. Record it!*
At this early stage in the process you are unlikely to possess enough information to determine what actually led to the event so concentrate on …

Think of this as a containment ring around the event.

Using the worked example from the CAA database:

**Event** - Go-NoGo gauge Part No. X Serial No. Y found out of calibration

**Action(s)** - Gauge Part No. X Serial No. Y was immediately removed from the shop floor and re-calibrated iaw company procedure (abc) before being put back into service. All the xyz parts in the batch were re-checked using the re-calibrated gauge.

The recorded actions shown were implemented by the organisation when they were informed of the event as an attempt to minimise the risk to production.
These actions were, as already shown in the example, considered by the organisation as the ‘final fix’ or corrective actions in their initial closure response.

The difference between containment actions, sometimes referred to as ‘immediate’ corrective actions and the final corrective action plan expected by the NAA lies in the substance.

The containment actions shown above do not address why the event occurred, undoubtably they address the immediate issue (symptom), but at this early stage the organisation had not determined why the gauge was out of calibration.

If you are a production organisation is the time to determine whether you need to contact customers and/or recall products. If you are an MRO or CAMO you may need to contact the operator and ground aircraft.

Ensure the organisation records the ‘Continue/STOP’ decision and the rationale behind that decision.

Now STOP and take stock.

Be sure that the containment actions you take do not have a severe adverse effect on other parts of your organisation.

Speak to all the stakeholders that were affected by the event and are likely to be effected by the containment actions.

Identify and record any initial Human Factor aspects related to the event.
A documented, factual statement of the reported event, showing a problem statement that describes the effects and potential risks the event could have on your entire organisation.

Determined both the level of risk the problem poses to your organisation and the type of investigation required.

Documented your organisation’s decision and rationale to stop or continue production/sales.

Documented your organisation’s initial containment actions designed to bring the event back to a desired state.

Documented any initial evidence of the Human Factors aspects associated with the event.
Ensure the document makes sense, not only to you but also to your colleagues. It is common at the early stages of an event to start drawing on previous event knowledge and suffer from hindsight bias. As a result the documented information may reflect the biased perception of the event rather than the actual evidence.

*During Phase 1 the documented information should only be a statement of facts and should not imply what caused the event.*
This document has not been written to explain the methodology of the *Investigation Process*. That is a different topic for which you will need to seek separate advice from specialist training organisations.

If the *risk assessment* has identified the need to carry out an investigation of the *event* your organisation should now begin the investigation process. Use Phase 2 of the Event Record Table to document the key factors determined during the investigation.

In order to get to the root cause of an event which has been risk assessed and requires investigation, you will need effective investigator(s). Without a complete and thorough investigation of the *event* your organisation will be unable to identify all the causal and contributing factors. Without these you will not be able to determine the root cause.

As far as the author is aware there are no recognised qualifications for being an investigator in the aviation industry. Fortunately, there are several investigation courses available to enable your organisation to train individuals in the skills required to effectively produce the information needed for effective root cause analysis.

*Ensure staff get the right training to be effective investigators and ensure they remain competent in the use of those skills.*
A primary step in any investigation is to plan how your organisation will document the information/evidence discovered during that stage. There are many ways of doing this and if your organisation already has a method/procedure for this continue to use it.

Ensure that the investigation determines and records all Human Factor aspects that contributed to the event. These should be reviewed and if required re-classified once the investigation is completed and the root cause determined.

**Returning to the worked example:** the organisation in question carried out an internal investigation in line with the ERC score to determine why:

> 'part xyz was manufactured using an 'out of calibration’ Go-NoGo gauge'.

An extract from the full investigation is shown below:

*The CAA conducted an audit and found a Go-NoGo gauge on production Line A outside its calibration date. The gauge had been issued from stores at 08:45 on the 21/01/2016 with the complete task setup to produce a batch of part xyz. but the operative had failed to notice that the gauge was outside of its calibration date. On discovery by the CAA surveyor the tool was immediately removed from the production line. The gauge was sent to the Production Manager for a calibration check against a master slip gauge in accordance with company procedure abc. Unfortunately when the Production Manager went to calibrate the gauge he could find no record of the gauge in the company's calibration records. The spreadsheet used to control all calibrated tooling had recently been updated after a software upgrade to the latest software version 4 and this particular gauge was now missing from the list. A review of an old list revealed that the gauge had previously been in the system with an expiry date of 01/01/2016. The Production Manager spoke to the Quality Manager who told him to treat it like a new tool and add it to the list giving it a new serial number. The Production Manager carried out the Quality Managers instructions, checked its calibration against the master slip gauge and then gave it a new serial number before adding it to the new calibration list. It was noted that the Go-NoGo gauge met the requirements of the check calibration without any adjustment. The gauge was then handed back to the operative on production line A. The operative checked all the xyz parts that had been produced as part of that production batch and found them all to be satisfactory. The batch was then completed before it was sent to the inspection office for certification. All parts from that batch were found in compliance at final inspection and released to the customer on EASA Form 1 - T12345.*
**Problem Statement**

Part(s) on a production line were being inspected (by personnel) using a tool that was out of calibration.

**Risk Assessment**

<table>
<thead>
<tr>
<th>Operation</th>
<th>Production</th>
<th>Review</th>
<th>Continue</th>
<th>STOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>Review</td>
<td>Continue</td>
<td>STOP</td>
<td></td>
</tr>
</tbody>
</table>

**Containment**

Go-NoGo gauge Part No. X Serial No. Y removed from production line A and re-calibrated. All xyz parts in the batch on bench were rechecked using the recalibrated gauge.

**Evidence**

- Photos of expired gauge attached.
- Copy of CAA surveyors non-conformance report.

**Human Factors**

Evidence: System allowed Storeman to issue tool. Operator failed to notice expired calibration date.

**Conclusion:**

Copy of calibration list prior to software upgrade showing tool Pt No.X Ser No. Y expiry date 01/01/2016.

Copy of updated sheet at time of event showing **NO** record of Pt No.X Ser No. Y.

Copy of new calibration sheet showing addition of Pt No.X as Ser No. YA

Copy of task sheets completed by operative.

Copy of EASA Form 1

---

Begin to populate Phase 2 of the Event Record Table (ERT 4).

Note: At this stage the ‘How’ is yet to be determined.
Having completed the initial investigation it is time to begin the analysis of the data.

Without completing the previous stages you may not have enough information to carry out this task effectively.

There are many techniques available for carrying out Root Cause Analysis, some are freely available and widely used such as the 5 Whys, The Ishikawa Fish Bone and others require additional tailored training such as the 8D method.

The type of technique used in the analysis is usually determined by the complexity of the event.

It is not uncommon for organisations to document the use of several different techniques, the one chosen being determined by the risk assessment process. Whichever technique your organisation chooses you must ensure that your staff have had suitable training to become not only competent but also retain recency in its use.

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15 Developed by Sakichi Toyoda (founder of Toyota Industries Co.Ltd) 1958

16 Ishikawa diagrams - Developed by Kaoru Ishikawa for Kawasaki shipyards in 1960s

17 Eight Disciplines Problem Solving - Developed by the Ford Motor Co.
Examples of these techniques are readily available on the internet.
J.J. Rooney and L.N. Vanden Heuvel define Root Cause Analysis ‘In 50 Words or Less’ in their paper ‘Quality Basics. Root Cause Analysis For Beginners’\textsuperscript{18} as the following:

- **Root cause analysis** helps identify what, how and why something happened, thus preventing recurrence.
- **Root causes** are underlying, are reasonably identifiable, can be controlled by management and allow for generation of recommendations.
- The process involves data collection, cause charting, root cause identification and recommendation generation and implementation.

In addition the paper also defines causal factors as:

- **Causal Factors** are those factors (human errors and component or organisational failures) that, if eliminated, would have prevented the occurrence.

Contributing factors are issues identified during the investigation that could not have independently caused the event, but may have influenced the outcome.

**A SIMPLIFIED TECHNIQUE FOR ROOT CAUSE ANALYSIS**

Having already identified many common techniques for root cause analysis, a further review of papers, journals and reference books uncovered a different and what appeared to be a simplified technique to get started in **root cause analysis**. The technique chosen to explain the worked example **event** goes back to basics and returns the investigator to the use of fundamental school grammar.

In a paper titled ‘The Root Cause Myth’\textsuperscript{19} by T. Finlow-Bates an event was broken down into its basic grammatical parts, ‘subject’ and ‘state’ in order to carry out an analysis.


For clarity in this document the examples have been altered to represent an aviation context.

<table>
<thead>
<tr>
<th>Subject</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aircraft</td>
<td>parked in the hangar</td>
</tr>
<tr>
<td>Tool</td>
<td>is on the bench</td>
</tr>
<tr>
<td>Part</td>
<td>is on specification</td>
</tr>
</tbody>
</table>

If an event influences the subject and results in the state becoming undesirable we can say the event has produced an undesirable state or problem.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Undesired State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aircraft</td>
<td>catches fire in the hangar</td>
</tr>
<tr>
<td>Tool</td>
<td>snaps when used</td>
</tr>
<tr>
<td>Part</td>
<td>is made of the wrong material</td>
</tr>
</tbody>
</table>

Using this technique you can use the following steps to help you begin your root cause analysis.

Applying this logic to the Go-NoGo gauge worked example:

What was the undesirable state? Refer to your *problem statement*
What was the direct cause? This is sometimes referred to as an immediate or physical cause that led directly to the problem:

<table>
<thead>
<tr>
<th>Step 2</th>
<th>What was the direct cause of the problem expressed in the terms of a subject and state?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gauge(tool) out of calibration</td>
</tr>
</tbody>
</table>

Produce a line of causal factors from your investigation data. Perhaps the easiest way to do this is to take a copy of your investigation report and underline the identified causal factors. Alternatively, producing an investigation time-line may aid in identifying all factors of the investigation and enable the organisation to plot the causal factors in the correct time sequence, see Appendix 3

<table>
<thead>
<tr>
<th>Step 3</th>
<th>Produce a line of causal factors expressed in the terms of a subject and state</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tool calibration not checked prior to use</td>
</tr>
<tr>
<td></td>
<td>Tool issued to task in un-calibrated state</td>
</tr>
<tr>
<td></td>
<td>Tool not set up in company calibration records</td>
</tr>
<tr>
<td></td>
<td>Calibration records incomplete upgrade</td>
</tr>
<tr>
<td></td>
<td>Software package upgraded</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 4</th>
<th>Determine who owns each causal factor?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Operative Storeman</td>
</tr>
<tr>
<td></td>
<td>Production Manager</td>
</tr>
<tr>
<td></td>
<td>Organisation</td>
</tr>
<tr>
<td></td>
<td>Software company</td>
</tr>
<tr>
<td></td>
<td>Tool calibration not checked prior to use</td>
</tr>
<tr>
<td></td>
<td>Tool issued to task in un-calibrated state</td>
</tr>
<tr>
<td></td>
<td>Tool not set up in company calibration records</td>
</tr>
<tr>
<td></td>
<td>Calibration records incomplete upgrade</td>
</tr>
<tr>
<td></td>
<td>Software package upgraded</td>
</tr>
</tbody>
</table>

Determine who owns each of the causal factors. The root cause is the last cause in the chain but, by definition, the root cause needs to be ‘controlled by management’. If you identify the owner to be outside your organisation you need to look at a cause further up the chain.

*You cannot be responsible for fixing other organisation’s issues!*

However, if they are one of your suppliers you may wish to notify them of what you have found.
Now determine which causal factors could be directly influenced by your organisation.

List these causal factors:

| Step 5 | What causal factors can be directly influenced by the organisation. | Operative Storeman Project Manager Organisation | Tool calibration not checked prior to use Tool issued to task in un-calibrated state Tool not set up in company calibration records Calibration records incomplete upgrade |

The last causal factor in the list over which your organisation has direct control is:

| Step 6 | Which of the above causal factors would solve the underlying organisational problem. | Calibration records incomplete upgrade |

As this is the last cause in the chain it should by definition be the root cause.

Calibration records incomplete upgrade

Ask the question … of the stakeholders

If the calibration records had been correctly upgraded would the event have occurred?
Because the investigation had identified that the gauge was on the previous calibration record, it would be a fair assumption that if the calibration procedure adopted by the organisation had been followed that the event would not have taken place.

By definition:  *Causal Factors are those factors that, if eliminated, would have prevented the occurrence.*

Therefore by removing this root cause (causal factor) or link in the chain the event would not have been able to escalate to the undesired state described as the problem statement in Step1.

Part(s) inspected using a tool that was out of calibration.

Had it ever happened before?

The company couldn't tell because up to this point their MEMS only consisted of a spreadsheet with minimal detail.

The QM remembered a similar event a few years earlier when some serialised tools with expired calibration decals were found in the store. These seldom used items were not on the calibration record. The QM assumed that the administration clerk had just failed to input them into the system so they were manually added. The event was never logged as an occurrence, it was just an ‘admin error’ and therefore didn't find its way into their MEMS. The organisation had no official record of the event and so could not be sure what and when it actually happened. Had they upgraded their software then too?

Had they missed ‘a learning’ opportunity to prevent the current event from occurring? Perhaps, had they correctly defined the problem of a seemingly trivial issue years earlier the CAA surveyor would never have encountered the non-conformance. The truth is the organisation will never know ….
Producing a Root Cause Analysis table can bring all these steps together and provide clear documentation of the root cause analysis process and outcome.

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Problem Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>What was the problem expressed in terms of a subject and undesired state?</td>
<td>Part(s) inspected using a tool that was out of calibration.</td>
</tr>
<tr>
<td>2</td>
<td>What was the direct cause of the problem expressed in the terms of a subject and state?</td>
<td>Gauge(tool) out of calibration</td>
</tr>
<tr>
<td>3</td>
<td>Produce a line of causal factors expressed in the terms of a subject and state. Think of these causes as links of a chain.</td>
<td>Tool calibration not checked prior to use, Tool issued to task in un-calibrated state, Tool not set up in company calibration records, Calibration records incomplete upgrade, Software package upgraded</td>
</tr>
<tr>
<td>4</td>
<td>Determine who owns each causal factor? Operative: Storeman, Production Manager, Organisation, Software company</td>
<td>Tool calibration not checked prior to use, Tool issued to task in un-calibrated state, Tool not set up in company calibration records, Calibration records incomplete upgrade, Software package upgraded</td>
</tr>
<tr>
<td>5</td>
<td>What causal factors can be directly influenced by the organisation? Operative: Storeman, Project Manager, Organisation</td>
<td>Tool calibration not checked prior to use, Tool issued to task in un-calibrated state, Tool not set up in company calibration records, Calibration records incomplete upgrade</td>
</tr>
<tr>
<td>6</td>
<td>Which of the causal factors would solve the underlying organisational problem.</td>
<td>Calibration records incomplete upgrade</td>
</tr>
</tbody>
</table>
STAGE 7: Develop and Document a Root Cause Statement

Develop and document a ROOT CAUSE STATEMENT (RCS) that explains the underlying reason for the problem statement.

Produce a **Root Cause Statement** from Step 6 that explains the underlying reason for the **problem statement**. If you have identified the correct root cause, addressing the **root cause statement** will prevent both the **problem statement** and event from recurring.

| Root Cause Statement | The calibration records did not fully transfer when the software package was upgraded resulting in a calibrated tool not being recalled for a calibration check prior to its expiry date. |

**The root cause has now been identified and documented in a manner that allows it to be used to implement change.**

Add this to the Event Record Table (ERT 5).

Many of the mentioned software systems have a drop-down list taxonomy for ‘root cause’ and do not allow ‘free text’.

Do not be forced to classify your identified root cause by this taxonomy as it is often too vague.

Speak to your software provider to see if you have the functionality to add additional text to the list of ‘root causes’, this will enable the ability for better root cause trending.
<table>
<thead>
<tr>
<th>Event (What Happened)</th>
<th>Go-NoGo gauge Part No. X Serial No. Y found out of calibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1) Initial event information</td>
<td>2) Subsequent investigation</td>
</tr>
<tr>
<td>When</td>
<td>On 22nd Jan 2016 @13:23 (dayshift)</td>
</tr>
<tr>
<td>Where</td>
<td>Production line A. Used in the manufacture of Part No. xyz</td>
</tr>
<tr>
<td>Who</td>
<td>CAA surveyor accompanied by QM</td>
</tr>
<tr>
<td>How</td>
<td>During a routine Pt 21G audit</td>
</tr>
<tr>
<td>Problem Statement (Potential effects/risks)</td>
<td>Part(s) on a production line were being inspected (by personnel) using a tool that was out of calibration</td>
</tr>
<tr>
<td>Risk Assessment</td>
<td>Initial Risk Score 100</td>
</tr>
<tr>
<td>Investigation</td>
<td>Low</td>
</tr>
<tr>
<td>Operation</td>
<td>Production</td>
</tr>
<tr>
<td>Sales</td>
<td>Review</td>
</tr>
<tr>
<td>Containment</td>
<td>Go-NoGo gauge Part No. X Serial No. Y removed from production line A and recalibrated. All xyz parts in the batch on bench were rechecked using the recalibrated gauge.</td>
</tr>
<tr>
<td>Evidence</td>
<td>Photos of expired gauge attached. Copy of CAA surveyors non-conformance report.</td>
</tr>
<tr>
<td>Human Factors</td>
<td>Evidence: System allowed Storeman to issue tool. Operator failed to notice expired calibration date.</td>
</tr>
<tr>
<td>Root Cause Statement</td>
<td>The calibration records did not fully transfer when the software package was upgraded resulting in a calibrated tool not being recalled for a calibration check prior to its expiry date.</td>
</tr>
</tbody>
</table>
Having completed your root cause analysis it is now time to address the root cause statement and come up with Corrective Action(s) to return the problem statement and by default the event (a symptom of the PS) back to a desired state.

Note: The initial containment actions only addressed the immediate undesired effect caused by the event.

In his book ‘Root Cause Analysis, The core of problem solving and Corrective action’ Duke Okes defines ‘corrective action’ as:

‘the overall process involved with taking an identified problem and seeing that appropriate action is taken to resolve it. Within the corrective action process is a problem-solving process that finds and corrects the cause(s). The problem-solving process includes both a diagnostic phase and a solution phase, and it is the former that involves root cause analysis’.
The **corrective action(s)** need to address the ‘failure(s) in the system’ as identified by the **root cause analysis**. Determining these actions should be a joint effort between the investigator and the stakeholders to ensure no adverse effects are introduced into other areas of the business.

Ensure, that each **corrective action**:

1. **Links directly to the root cause statement** through the analysis.
2. **Takes into account (where applicable) previous events that may have resulted in similar outcomes.**
3. **Is achievable by your organisation, in a timely manner.**
4. **Allocated to the person(s) within your organisation that can best effect change in that area/department.**

It is important to get the **corrective action(s)** right the first time. This may take longer than expected but will benefit your organisation in the long term. Getting it right the first time will ensure there is no repeat of the **problem statement** or **event** in the future.

- There are time limits imposed by regulation\(^{20}\) for responses to MOR/VORs and NAA non-conformances. However, keeping your airworthiness surveyor informed of progress enables them to keep the ECCAIRS database updated. There is the ability to extend MOR time scales if the reason for delay can be justified i.e. awaiting a component strip report from the manufacturer.

- Extensions to NAA non-conformances would need to be discussed as a separate issue with your airworthiness surveyor.

- Your airworthiness surveyor would expect your first **corrective actions** to be the **containment actions** that were put in place when the event occurred. Although these did not address the **root cause**, which at the time had not been determined they were your organisations initial attempt at bringing the event back to a desired state. These actions need to be added to either the ECCAIRS or NAA databases as part of the closure process.

---

**By addressing the Root Cause Statement you will prevent recurrence of both the problem statement and the event.**

Reverting back to the worked example, let us develop some effective **corrective actions** that would address the **root cause statement** and allocate them to the area stakeholder for action.

It is important to ensure that the root cause has not had a wider impact on the organisation. To ensure the organisation is not using any other out of calibration tooling the first corrective action might be:

<table>
<thead>
<tr>
<th>Corrective Action(s)</th>
<th>Notes:</th>
<th>Stakeholder/Action owner</th>
<th>Due Date</th>
<th>Actioned</th>
<th>Additional detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Carry out a comparison check between the new calibration list and the list prior to software upgrade.</td>
<td>Identify any additional mis-matches</td>
<td>Production manager</td>
<td>3 D</td>
<td>Y N</td>
<td>2 additional tools found missing from list. Pt No. 12 Ser No. z Pt No. ab2 Ser No. c1</td>
</tr>
</tbody>
</table>

The corrective action is directly linked to the root cause statement because the records did not fully transfer when the software package was upgraded. The action was allocated to the Production Manager (PM) who controls the calibration list. If no further issues had been found this single **corrective action** would have been enough to bring the **event** and the **problem statement** back into compliance.

Remember the original uncalibrated tool Pt No. X Ser No. Y identified by the airworthiness surveyor was removed and re-calibrated at the time of the **event** as a **containment action**.

The PM identified two additional tools missing from the list, therefore the first corrective action was not enough to bring the **problem statement** back to a desired state and additional corrective actions were required.
The second corrective action was allocated to the PM but was carried out by the Stores Supervisor (SS) as he owned the responsibility for controlling all tooling via the Production Organisation Exposition (POE) procedure. Although no additional items of tooling were discovered to be missing from the new calibration list, one of the items previously identified by the PM as not being on the list **Pt No.12 Ser No. z** was found to have gone out of calibration on 01/12/2015.

Additional measures needed to be put in place to ensure the *root cause* had not resulted in another event for a different product.

<table>
<thead>
<tr>
<th>Corrective Action(s)</th>
<th>Notes:</th>
<th>Stakeholder/Action owner</th>
<th>Due Date</th>
<th>Actioned</th>
<th>Additional detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>If additional mis-matches are noted carry out a full physical calibrated tooling check against the new calibration list.</td>
<td>Record all tooling that was out of calibration date</td>
<td>Production manager / (Stores supervisor)</td>
<td>1 Wk</td>
<td>Y N</td>
</tr>
</tbody>
</table>

In order to determine that no other products could have been placed into stock or released to customers that had been inspected using out of calibration tooling, all tasks that used tool **Pt No. 12 Ser No. z** had to be identified. The Planning Manager (PLM) was requested to identify the task(s). The PLM identified only 1 task 234098 that required the use of tool **Pt No. 12 Ser No. z**.
The PM was requested to determine when task 234098 was last accomplished. Production and stores records demonstrated that the task was last carried out in April 2015 and the last stock item issued out in June 2015.

<table>
<thead>
<tr>
<th>Corrective Action(s)</th>
<th>Notes:</th>
<th>Stakeholder/Action owner</th>
<th>Due Date</th>
<th>Actioned</th>
<th>Additional detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Identify all tasks that use tool Pt No.12 Ser No.z</td>
<td>Record all tasks</td>
<td>Planning manager</td>
<td>3 D</td>
<td>Y</td>
<td>N Only one task 234098 utilises this calibrated tool</td>
</tr>
</tbody>
</table>

As tool Pt No. 12 Ser No. z calibration had only recently expired on 01/12/2015 the last step demonstrated that no product had been produced or issued to a customer by the organisation that had been inspected using the out of calibration tool.

For clarity within your organisation’s MEMS and to help your airworthiness surveyor in the completion of the required databases, group the containment and corrective actions together in a manner similar to the one shown in the Event Closure Table (ECT 1) below.
The organisation has now contained and corrected the initial event and subsequent findings that could have been related to the root cause statement. This has returned the organisation to a desired state.

To ensure that there would be no recurrence of the root cause statement the organisation should develop and document suitable preventive actions.
The organisation needed to determine effective measures to prevent the root cause statement from re-occurring. These actions are referred to as the Preventive Actions.

Once again to ensure all stakeholders are engaged, a brainstorming session is probably the best method to collect ideas for preventing recurrence. As previously suggested, get a selection of staff from different areas to ensure that the resulting preventive actions do not result in some other unexpected event.
A **preventive action** for the worked example could be:

When the **event** occurred it would have made sense for the quality department to communicate the issue to all staff.

The **preventive actions** should also, where possible address any identified contributing factors. This ensures that all aspects of the **root cause statement** have been addressed.

‘*Contributing factors are issues identified during the investigation that could not have independently caused the event, but may have influenced the outcome.*’

In the worked example the use/failure to use the calibrated tooling Standard Operating Procedure (SOP) could not have caused the **event**, as it contained **no** information about software upgrades. Therefore the SOP’s influence is identified as a ‘**contributing**’ not a ‘**causal**’ factor.
On completion of the root cause analysis process the organisation should produce a fully completed Event Closure Table (ECT 2) or equivalent document.

The completed Event Closure Table ensures the organisation has a complete record of the actions taken to address both the event and subsequent root cause statement.
Having completed the previous stages your organisation needs to ensure that the Corrective and Preventive Actions you have put in place achieve their objectives.

If the event was identified as a non-conformance the regulator will need to see evidence that both the corrective and preventive actions have been effective in eliminating or at the very least mitigating the root cause of the problem statement developed from the event. If the only option open was to mitigate the impact on your organisation the regulator will need to see the justification for that approach.

Think how you will determine if your organisation’s actions have been effective.

However, only review their effectiveness once they have had sufficient time to become embedded into the system.

You may wish to measure the frequency with which similar event(s) occur, but remember if your organisation correctly identified and subsequently eliminated the true root cause it should have prevented any recurrence. If a similar event appears you will need to go back and re-evaluate the initial root cause analysis as it is likely that it only addressed a symptom of the problem.

You should introduce additional items to the quality and/or safety audit plan to validate the effectiveness of your organisation’s actions. Record this information on both the ERT and ECT as supplied in the ‘Handouts' section of this document or within your chosen system.

STAGE 10: Monitor Outcome - Ensure Corrective and Preventive Actions are Effective

- Review all Corr A and PA to ensure they were effective. Monitor through Quality/Safety Audits
- If Actions are shown to be ineffective, review Actions taken and RCA to ensure the PS correctly described the potential effects/risks of the EVENT on the organisation
From the worked example it can be seen that the **corrective actions** adopted ensured that no other products had been manufactured using the out of calibration tool. The **preventive actions** ensured that a new procedure was adopted that would prevent new software from being uploaded and used by the organisation without checks being put in place to ensure the correct transfer of data.

Now that the organisation has identified and addressed the root cause statement you may consider re-risk scoring the event.

If, as in the worked example, you have correctly identified and addressed the **root cause statement** you should have eliminated the risk. Subject to the actions being confirmed as effective, the risk can be closed. Mark the Final ERC Score on the ERT as 1 the lowest score from the ERC matrix requiring no further investigation.

If, as may be the case in other events you are only able to mitigate the **event** risk you should now re-risk score the **event** taking into consideration the **containment, corrective** and **preventive actions** adopted by the organisation. Mark the ERT with the mitigated Final ERC Score. A mitigated risk should remain as an open risk within your organisation and should be reviewed on a regular basis as determined by the organisational MEMS/SMS policy.

Now is also the time to add a conclusion of the **human factors** aspects determined by the **event** investigation and analysis to the ERT.

In the worked example, the **event** could be attributed to an organisational failure to ensure the calibration records were correctly updated after a software upgrade. If the records had been accurate the operative would not have been issued the Go-NoGo gauge by the store-man and the **event** would not have occurred. Ensure the ERT evidence and conclusion boxes reflect the identified **human factors**.

Having now completed the Event Record Table (ERT) and Event Closure Table (ECT) your organisation has a documented account of the **event**, the derived **problem statement**, a risk score and associated operational actions, **containment actions**, detail of the type and results of the investigation, all identified **human factor** aspects, a **root cause statement** and the **corrective** and **preventive actions** implemented to prevent recurrence.
Well Done ....

But you haven't quite finished.

Regulation (EU) No 376/2014 requires organisations to operate and promote a ‘Just Culture’ to encourage open and honest reporting from within the business. An aspect of this that has not been discussed is ‘culpability,’ how the organisation determines who is culpable. In this example the root cause could be linked back to an ‘organisational failure to effectively control IT system upgrade.’ However, on the rare occasion that the investigation determines an individual is responsible for the event, the organisation’s documented ‘Just Culture’ policy must identify how culpability should be determined. There are several tools freely available to aid in this process including the FAiR 2 and FAiR 3 Systems²¹.

Ensure the process is carried out only after all the facts have been determined by the investigation. Record the outcome of this process and ensure your Human Resources department are made aware of the outcome (when appropriate).

Remember to ensure all staff are made aware of the event and subsequent corrective and preventive actions. Publicise these events internally to add to the ‘learning experience’ for all staff.

The CAA expects the organisation to talk about significant events during Human Factors and Continuation training.

To keep all staff well informed your organisation could also produce regular promotional material such as safety bulletins, safety posters in addition to Quality/Safety Notices with an executive summary of the organisations events and findings. By doing this you fulfil the requirements of the Promotion Pillar of an effective SMS.

In addition, if you start to use these types of safety information (Event, Problem Statement, Risk Assessment & Root Cause Statement) as part of your current MEMS you are already building corporate safety knowledge before SMS becomes a requirement.

²¹ FAiR 2 and FAiR 3 System: A behaviour-based system for supporting and sustaining a Just Culture. © Baines Simmons Limited
Closing down the event - the organisation’s obligation to the regulator

As described in the introduction to this document, your organisation has an obligation to submit ‘root cause’ and ensure ‘corrective action to the satisfaction of the competent authority’ for both NAA audit non-conformances and MOR/VORs.

If the event is classified as an MOR/VOR or was the subject of an NAA audit non-conformance you need to make this information available to the regulator to enable closure within the ECCAIRS or the NAA database.

Having submitted your initial MOR/VOR to ECCAIRS including the data shown in Appendix 1 you will receive a .pdf and an E5Y. file from the portal. In addition to storing the .pdf, your organisation will also need to store the E5Y. file. The E5Y. file will allow you to re-enter the ECCAIRS database when you are ready to update the MOR/VOR with your investigation findings.

If you have used the Event Record Table (ERT) and Event Closure Table (ECT) shown in this document or an alternative method of recording your information, attach it to the information your organisation sends to ECCAIRS via the CAA weblink for MOR/VORs. That way the airworthiness surveyor can open the documents within ECCAIRS and use them as evidence for closure.

If your organisation uses another method of recording the event information such as AQD, Centrik, SafetyNet etc, you may be able to submit the information directly to ECCAIRS for MOR/VORs. Talk to your software provider regarding submission using an E5X. file format.

Final closure within ECCAIRS will require the organisation to enter an ‘analysis’ of the MOR/VOR by entering the results from your chosen root cause analysis methodology. The ‘corrective actions’ field should be populated with your organisation’s containment, corrective and preventive actions. The ‘conclusions’ field should be populated with the root cause statement. In addition ECCAIRS will also require your organisation to add a risk classification from your chosen risk assessment tool.
Closing NAA audit non-conformances must be carried out in a way agreed with the NAA. Sending the completed ERT and ECT with an official non-conformance response letter to the NAA should contain enough information to enable closure of NAA audit non-conformances.

Reverting to the worked example for a final time, had the organisation sent the completed ERT 6 and ECT 2 overleaf, the NAA airworthiness surveyor would have been able to close the non-conformance with a degree of confidence that the true root cause had been identified, suitably contained, corrected and addressed to prevent recurrence.
<table>
<thead>
<tr>
<th>Event (What Happened)</th>
<th>Go-NoGo gauge Part No. X Serial No. Y found out of calibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase</td>
<td>1) Initial event information</td>
</tr>
<tr>
<td>When</td>
<td>On 22nd Jan 2016 @13:23 (dayshift)</td>
</tr>
<tr>
<td>Where</td>
<td>Production line A. Used in the manufacture of Part No. xyz</td>
</tr>
<tr>
<td>Who</td>
<td>CAA surveyor accompanied by QM</td>
</tr>
<tr>
<td>How</td>
<td>During a routine Pt 21G audit</td>
</tr>
</tbody>
</table>

**Problem Statement (Potential effects/risks):** Part(s) on a production line were being inspected (by personnel) using a tool that was out of calibration

**Risk Assessment**

<table>
<thead>
<tr>
<th>Initial Risk Score</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigation</td>
<td>Low</td>
</tr>
<tr>
<td>Operation</td>
<td>Production Review</td>
</tr>
<tr>
<td></td>
<td>Sales Review</td>
</tr>
<tr>
<td>Containment</td>
<td>Go-NoGo gauge Part No. X Serial No. Y removed from production line A and recalibrated. All xyz parts in the batch on bench were rechecked using the recalibrated gauge.</td>
</tr>
<tr>
<td>Evidence</td>
<td>Photos of expired gauge attached. Copy of CAA surveyors non-conformance report.</td>
</tr>
<tr>
<td>Human Factors</td>
<td>Evidence: System allowed Storeman to issue tool. Operator failed to notice expired calibration date.</td>
</tr>
</tbody>
</table>

**Root Cause Statement:** The calibration records did not fully transfer when the software package was upgraded resulting in a calibrated tool not being recalled for a calibration check prior to its expiry date.

Send a copy of the Event Record Table or equivalent document generated by your organisation that details the:

- Event
- Problem Statement
- Root Cause Statement
- Phase 1 info
- Phase 2 info
- Operational impact
- Risk Assessment
- Investigation type
- Human Factors

... to ECCAIRS for MOR/VORs and the NAA for non-conformances.
### Event (What Happened)

Go-NoGo gauge Part No. X Serial No. Y found out of calibration

### Problem Statement (Potential effects/risks)

Part(s) on a production line were being inspected (by personnel) using a tool that was out of calibration.

### Containment Action(s)

<table>
<thead>
<tr>
<th>Action</th>
<th>Notes</th>
<th>Stakeholder/Action owner</th>
<th>Due Date</th>
<th>Actioned</th>
<th>Additional detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Go-NoGo gauge Part No. X Serial No. Y removed from production line A and re-calibrated.</td>
<td>Production manager</td>
<td>N/A</td>
<td>Y N</td>
<td>Gauge not on calibration sheet</td>
</tr>
<tr>
<td>2</td>
<td>Recheck all xyz parts in the production batch using the recalibrated gauge.</td>
<td>Operative</td>
<td>N/A</td>
<td>Y N</td>
<td>All parts found within specification</td>
</tr>
</tbody>
</table>

### Root Cause Statement

The calibration records did not fully transfer when the software package was upgraded resulting in a calibrated tool not being recalled for a calibration check prior to its expiry date.

### Corrective Action(s)

<table>
<thead>
<tr>
<th>Action</th>
<th>Notes</th>
<th>Stakeholder/Action owner</th>
<th>Due Date</th>
<th>Actioned</th>
<th>Additional detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Carry out a comparison check between the new calibration list and the list prior to software upgrade.</td>
<td>Production manager</td>
<td>3 D</td>
<td>Y N</td>
<td>2 additional tools found missing from list. Pt No. 12 Ser No. z Pt No. ab2 Ser No. c1</td>
</tr>
<tr>
<td>2</td>
<td>If additional mis-matches are noted carry out a full physical calibrated tooling check against the new calibration list.</td>
<td>Production manager / (Stores supervisor)</td>
<td>1 Wk</td>
<td>Y N</td>
<td>No additional tooling discovered. Pt No. 12 Ser No. z shown above was found outside calibration date expire 01/12/2015</td>
</tr>
<tr>
<td>3</td>
<td>Identify all tasks that use tool Pt No.12 Ser No. z</td>
<td>Planning manager</td>
<td>3 D</td>
<td>Y N</td>
<td>Only one task 234098 utilises this calibrated tool</td>
</tr>
<tr>
<td>4</td>
<td>Determine when task 234098 was last carried out</td>
<td>Production manager</td>
<td>3 D</td>
<td>Y N</td>
<td>None last batch produced April 2015</td>
</tr>
</tbody>
</table>

### Preventive Action(s)

<table>
<thead>
<tr>
<th>Action</th>
<th>Notes</th>
<th>Stakeholder/Action owner</th>
<th>Due Date</th>
<th>Actioned</th>
<th>Additional detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Implement a document comparison check whenever the tool calibration software is upgraded.</td>
<td>Production manager</td>
<td>10 D</td>
<td>Y N</td>
<td>Update SOP abc</td>
</tr>
<tr>
<td>2</td>
<td>Issue Quality Notice regarding the use of calibrated tooling and associated SOP</td>
<td>Quality manager</td>
<td>10 D</td>
<td>Y N</td>
<td>Confirm Read and Sign completed by staff at end of month.</td>
</tr>
<tr>
<td>3</td>
<td>Ensure tool calibration SOP is up-to-date and reflects current practice</td>
<td>Production manager</td>
<td>10 D</td>
<td>Y N</td>
<td>No reference to software upgrade. To be updated.</td>
</tr>
</tbody>
</table>

Send a copy of the Event Closure Table or equivalent document generated by your organisation that details the:

- **Event**
- **Problem Statement**
- **Containment Actions**
- **Root Cause Statement**
- **Corrective Actions**
- **Preventive Actions**

Send to ECCAIRS for MOR/VORs and the NAA for non-conformances.
Appendix 1

THE MINIMUM RECORDED DATA FIELDS REQUIRED FOR REPORTING AN MOR/VOR TO ECCAIRS

The following is an extract from Annex 1 of EU 376/2014 which lists the data fields that must be completed when reporting to the NAA

I. COMMON MANDATORY DATA FIELDS

When entering, in their respective databases, information on every occurrence mandatorily reported and, to the best extent possible, every occurrence voluntarily reported, organisations, Member States and the Agency must ensure that occurrence reports recorded in their databases contain at least the following information:

(1) Headline  \textbf{(event)}
   - Headline

(2) Filing Information
   - Responsible Entity — File Number
   - Occurrence Status

(3) When — UTC Date

(4) Where — State/Area of Occurrence — Location of Occurrence

(5) Classification — Occurrence Class — Occurrence Category

(6) Narrative — Narrative Language — Narrative

(7) Events — Event Type

(8) Risk classification\textsuperscript{Appendix (x)}

The list of reportable occurrences, previously described in CAP 382 are now shown in EU Commission Implementation Regulation 2015/1018.

2. SPECIFIC MANDATORY DATA FIELDS

2.1. Aircraft-related data fields

When entering, in their respective databases, information on every occurrence mandatorily reported and, to the best extent possible, every occurrence voluntarily reported, organisations, Member States and the Agency must ensure that occurrence reports recorded in their databases contain at least the following information:

(1) Aircraft Identification
   - State of Registry
   - Make/Model/Series
   - Aircraft serial number
   - Aircraft Registration
   - Call sign

(2) Aircraft Operation — Operator — Type of operation

(3) Aircraft Description
   - Aircraft Category
   - Propulsion Type
   - Mass Group

(4) History of Flight — Last Departure Point — Planned Destination — Flight Phase

(5) Weather — Weather relevant

Please note:
CAA reporting forms SRG 1601, 1602 and 1603 are obsolete.
Appendix 2
RISK ASSESSMENT CLASSIFICATION

In the body of the text the risk classification section discussed the use of the Airline Risk Management Solutions (ARMS), Event Risk Classification (ERC) matrix as a method of risk scoring the event. Other matrices can be used, see ICAO for alternative 5x5 matrix.

The matrix shown below is the standard ARMS, ERC matrix.

<table>
<thead>
<tr>
<th>Question 1</th>
<th>Question 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>What was the effectiveness of the remaining barriers between this event and the most probable accident scenario?</td>
<td>If this event had escalated into an accident, what would have been the most probable accident outcome?</td>
</tr>
<tr>
<td>Effective</td>
<td>Limited</td>
</tr>
<tr>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Negligible</td>
<td>No potential damage or injury could occur</td>
</tr>
</tbody>
</table>

The questions shown were developed for airline operations, however they can and should be adjusted to suit your organisation’s business. ARMS standard matrix:

Before we adjust the matrix to better represent our example a few explanations are required. For a full explanation of ARMS go to https://essi.easa.europa.eu/essi/documents/ARMS.pdf
Question 1 - Refers to the effectiveness of the barriers between the event and most probable accident scenario. This makes sense for a maintenance organisations/airline but it may be less relevant for a production organisation. Perhaps a more useful analogy for the production world would be barriers between the event and releasing the product to customers.

Question 2 - Looks at the most probable outcome if the event escalates into an accident. Although this makes sense for a maintenance organisations/airlines it may be less relevant for a production organisation. That would depend on the type of product being manufactured and its function on an aircraft. If the parts you manufacture are unlikely to cause the loss of an aircraft it would make sense to adjust this statement to look at the impact the event would have on your organisation.

So what are the ‘barriers’? Remember your Human Factors training and James Reason Swiss Cheese model …. These are the lines of defence that can capture an error or failure before it becomes an accident/incident or in this example the release of a non-conforming product to the customer.

As was already stated, not every event warrants further investigation. Notice that the bottom row of the ERC matrix is one block. This is because some events could not result in the release of a non-conforming product to the customer. Had the event used in the example been scored in this area the organisation would not need to determine how many barriers remained for capture.

The use of a scoring system enables the organisation to determine which events require no action (other than recording for future analysis), a detailed review or the immediate suspension of operations/production. In organisations that employ several levels of investigation depending on the complexity of the event, it is common to use the same scoring system to determine what level of investigation should be carried out on the individual event.
ERC matrix amended to represent the example at the production organisation:

Using an amended ERC matrix for the example the organisation risk assessed the ‘out of calibration gauge’ with an ERC score of 100.

Effectivity of Remaining Barriers x Organisational Impact = 100 ERC Score.

The MEMS, SMS and POE / MOE should have a detailed procedure for using the risk assessment process used by your organisation. The procedure should also include detail of the level of investigation required for level of ERC scoring.

Events that score 1 have an insignificant effect on the organisation and cause no disruption to production. As such they do not warrant any further investigation. The event should be recorded for trend analysis.

Events that score 2 -10 have a low or medium effect or on production/operations and as such may not warrant any further detailed investigation. A small local fix may be all that is required to address the event. The resulting actions should be recorded for trend analysis.

<table>
<thead>
<tr>
<th>Effective</th>
<th>Limited</th>
<th>Minimal</th>
<th>Not effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>100</td>
<td>500</td>
<td>2500</td>
</tr>
<tr>
<td>10</td>
<td>20</td>
<td>100</td>
<td>500</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>20</td>
<td>100</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If this event had escalated into the release of a non-conforming product, what would have been the impact the organisation?

- High: Significant disruption to production AND/OR Cost > £10000
- Medium: Disruption to production AND/OR Cost > £1500 < £10000
- Low: Minimal disruption to production AND/OR Cost > £500 < £1500
- Insignificant: No disruption to production AND/OR Cost < £500
Events that score 20 -100 may have varying effects on production/operations causing disruption. Depending on the effectiveness of the remaining barriers the event may or may not require some form of mitigation. The organisation should carry out a standard type investigation to understand the complexities of the event.

Events that score 500 - 2500 require the operation/production to STOP or be Suspended as there will be not only disruption to production but a lack of barriers to capture the event before the product is released to the customer. The event will require an in-depth investigation such as MEDA\textsuperscript{22} and/or suitable event mitigation.

\(\Phi\) Your surveyor may challenge your risk assessment, be prepared to justify your risk score and the level of investigation carried out.

The reason for carrying out your root cause analysis was to determine the underlying cause of the event enabling your organisation to either eradicate the problem or, at the very least put in place mitigations to allow your organisation to continue its operation.

When you risk assess the event at the beginning of the process you do not have all the facts. Therefore the initial risk assessment is at best an educated guess by trained individuals.

As the investigation continues you may determine that the event had greater or lesser consequences on your organisation than originally expected. If this is the case carry out a second risk assessment. You may find you can amend the level of investigation required. Finally, having addressed the root cause you should have eliminated the risk. Subject to the actions being confirmed as effective, the risk should be closed on the risk register. Where risks can only be mitigated they should remain as an open risk on the risk register and should be reviewed on a regular basis in accordance with the organisation’s MEMS/SMS policy.

\textit{Record any change to your risk assessment score on the event record table.}

You may care to read ‘Basic Risk Analysis - A step by step guide to risk consciousness in your organisation’. by Vibeke Myras

\textsuperscript{22} MEDA - Maintenance Error Decision Aid developed by The Boeing Company.
Appendix 3

TIMELINE IDENTIFYING ALL FACTORS ASSOCIATED WITH INVESTIGATION

Highlight all Causal factors to use in the root cause analysis

Highlight any Contributing factors to aid in the development of corrective/preventive actions

Evaluate all identified factors to establish the human factor aspects associated with the root cause
READING LIST


3. *Root Cause Analysis - Simplified Tools and Techniques.* Bjorn Andersen, Tom Fagerhaug

4. *Pre-Accident Investigation - An introduction to organisational safety.* Todd Conklin

5. *Pre-Accident Investigations - Better questions an applied approach to operational learning.* Todd Conklin


9. *A Life in Error - From Little Slips to Big Disasters.* James Reason

10. *Basic Risk Analysis - A step by step guide to risk consciousness in your organisation.* Vibeke Myras
ROOT CAUSE PROCESS FLOW DIAGRAM

- What Actually Happened
  - Details of actual incident, accident, finding etc
- Review
  - Triage the EVENT, is the event allocated to the correct area? Has it happened before? Review any historic data.
  - Is the event the symptom of a larger problem?
- PS
  - Develop a PROBLEM STATEMENT (PS) that describes the effects and potential risks of the EVENT on the entire organisation
- RA
  - Carry out a RISK ASSESSMENT (RA) to determine what effect the PS has on your organisation
  - Determine the level of investigation required
- Cont A
  - Determine and implement CONTAINMENT ACTIONS (Cont A) to bring the EVENT back to a desired state
  - If you cannot contain the EVENT you may need to STOP or SUSPEND operations/production
- INV
  - Carry out an INVESTIGATION into the EVENT as determined by your RA
- RCA
  - Carry out your ROOT CAUSE ANALYSIS (RCA) to determine how and why the PS developed
- RCS
  - Develop and document a ROOT CAUSE STATEMENT (RCS) that explains the underlying reason for the PS
- Corr A
  - Develop CORRECTIVE ACTIONS (Corr A) that are directly linked to the RCS that will return the PS back to a desired state
- PA
  - Develop PREVENTIVE ACTIONS (PA) to prevent the recurrence of the RCS
- Monitor
  - Review all Corr A and PA to ensure they were effective. Monitor through Quality/Safety Audits
  - If Actions are shown to be ineffective, review Actions taken and RCA to ensure the PS correctly described the effects and potential risks of the EVENT on the entire organisation
<table>
<thead>
<tr>
<th>Step 1</th>
<th>What was the problem expressed in terms of a subject and stated?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2</td>
<td>What was the direct cause of the problem expressed in terms of a subject and stated?</td>
</tr>
<tr>
<td>Step 3</td>
<td>Produce a line of casual factors expressed in terms of a subject and stated.</td>
</tr>
<tr>
<td>Step 4</td>
<td>Determine who owns each casual factor?</td>
</tr>
<tr>
<td>Step 5</td>
<td>Which causal factors can be directly influenced by the organization?</td>
</tr>
<tr>
<td>Step 6</td>
<td>Which of the causal factors would solve the underlying organizational problem?</td>
</tr>
</tbody>
</table>
# EVENT RECORD TABLE

<table>
<thead>
<tr>
<th>Phase</th>
<th>1) Initial event information</th>
<th>2) Subsequent Investigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Problem Statement (Potential effects/risks)

<table>
<thead>
<tr>
<th>Risk Assessment</th>
<th>Initial Risk Score</th>
<th>Final Risk Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Investigation</td>
<td>Low</td>
</tr>
</tbody>
</table>

## Operation

<table>
<thead>
<tr>
<th>Operation</th>
<th>Production</th>
<th>Sales</th>
<th>Operations</th>
<th>Review</th>
<th>Continue</th>
<th>STOP</th>
</tr>
</thead>
</table>

## Containment

| Evidence
<table>
<thead>
<tr>
<th>Human Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence:</td>
</tr>
</tbody>
</table>

## Root Cause Statement

## Validation / timescale