METROLINX

Metrolinx RCA (Root Cause Analysis) Process

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Metrolinx RCA (Root Cause Analysis) Process
MX-ALM-STD-005

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Metrolinx,

an Agency of the Government of Ontario

Preface

This is the third edition of the *Metrolinx RCA (Root Cause Analysis) Process*. This standard is now part of the Reliability Engineering Standards, a function of the Asset Lifecycle Management office. The Document Number has been changed from MX-SEA-STD-004, Rev 01 to MX-ALM-STD-005, Rev 02. Document content has been updated to align templates and processes developed with best practices.

The purpose of the Reliability Engineering Standards is to formalize the framework to adequately manage RAM (Reliability, Availability, Maintainability) performance of all Metrolinx assets for the entire life cycle. Metrolinx Reliability Engineering standards are built as an adaptation of European Standard EN 50126-1:2017 and modified to suit all asset classes and internal Metrolinx processes. They provide internal Metrolinx staff and external stakeholders involved in the design, construction, operation, and maintenance of Metrolinx assets with a common understanding and a systematic process for Reliability Engineering management. It is intended for suitably qualified professionals that are familiar with the subject matter. These documents are not substitutes for all applicable local codes, standards, and manuals.

The *Metrolinx RCA (Root Cause Analysis) Process* is maintained by the Reliability Engineering team, Asset Lifecycle Management Office, Asset Management and Maintenance Division, Metrolinx.

Suggestions for revision or improvements, including a description of the proposed change along with information on the background of the application and any other useful rationale or justification, can be sent to the Metrolinx Asset Lifecycle Management Office, Attention: Director Asset Lifecycle Management. The Director of Asset Lifecycle Management ultimately authorizes the changes. Proposals for revisions or improvements to include your name, company affiliation (if applicable), e-mail address, and phone number.

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Table 0-1 Supporting Documents

Document Number	Document Title	Relation
BS EN 50126-1:2017	Railway Applications – The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) (PHASE 1: Adoption of European Standard EN 50126-1:2017)	Parent Standard
CPG-QAT-FRM-106	CPG Terms Glossary	Reference
MX-ALM-STD-002	Metrolinx FRACAS (Failure Reporting, Analysis and Corrective Action System) Process	Reference
MX-ALM-STD-003	Metrolinx FMECA (Failure Modes, Effects and Criticality Analysis) Process	Reference

Acronyms and Abbreviations

Table 0-2 Acronyms and Abbreviations

Acronym	Full Name
ALOS	Asset Level of Service
AC	Asset Class team
BU	Business Unit
CAPA	Corrective Action Preventive Action
CAPEX	Capital Expenditure
CLOS	Customer Level of Service
CPG	Capital Projects Group
CSAT	Customer Satisfaction
FMECA	Failure Modes, Effects, and Criticality Analysis
FRACAS	Failure Reporting, Analysis, and Corrective Action System
FRB	Failure Review Board
KPI	Key Performance Indicator
MMS	Maintenance Management System/Software
MTBF *	Mean time between failures
MTTR	Mean time to repair
OPEX	Operational Expenditure
OTP	On-Time Performance
PM	Preventive Maintenance
RAM	Reliability Availability Maintainability
RAMS	Reliability, Availability, Maintainability, and Safety
RCA	Root Cause Analysis
SME	Subject Matter Expert
SOP	Standard operating procedure
WO	Work Order

***Note:** "T" and "Time" may be substituted for other utilization measures as appropriate (i.e., Mean distance between failures as MDBF, etc.).

Definitions

Table 0-3 Table of Definitions

Term	Definition	Source
Asset	Any physical or tangible item that has potential or actual value to Metrolinx (excluding intellectual property, inventory to be sold, human resources, and financial instruments), as well as IT systems and software.	CKH-ASMT-PRC-001 Asset Data and Information Standards Note: refer to CKH-ASMT-PRC-001 Asset Data and Information Standards for additional asset-related definitions.
Asset Class Teams	Metrolinx business units that have been designated as being accountable for the ownership and management of a given class of assets, and for the completeness and accuracy of information for the same class of assets.	CKH-ASMT-PRC-001 Asset Data and Information Standards
Cause	Circumstance or set of circumstances that leads to failure or success.	*CPG-QAT-FRM-106*, *CPG Terms Glossary*
Causal Chain	The path of influence running from a root cause to problem symptoms.	Metrolinx Reliability Engineering
Corrective Action	A documented design, process, procedure, or materials change implemented and validated to correct the cause of failure or design deficiency.	MIL-STD-721
Defects	Something that has failed to meet specification.	*CPG-QAT-FRM-106*, *CPG Terms Glossary*
Failure	[1] Loss of ability to perform as required. [2] The event, or inoperable state, in which any item or part of an item does not, or would not, perform as previously specified.	[1] BS EN 50126-1:2017 [2] MIL-STD-721
Incident	An unwanted or unintended event with a potential of causing harm to people, property and/or environment. Events where harm to people, property and/or environment has occurred, are referred to as “accidents.”	Metrolinx Reliability Engineering

Term	Definition	Source
Probable Cause	Suspected or likely factor preceding a root cause.	Metrolinx Reliability Engineering
Problem	Multiple related, repeating, or critical incidents or failures that likely exhibit the same symptoms.	Metrolinx Reliability Engineering
Root Cause	The initiating cause in a causal chain that leads to an undesirable situation or condition; the point in the causal chain where corrective action could reasonably be implemented and expected to correct and prevent recurrence of the undesirable situation or condition.	Metrolinx Reliability Engineering
Root Cause Analysis (RCA)	Systematic process to identify the root causes of a problem.	Metrolinx Reliability Engineering
Validation	Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Note 1 to entry: The term "validated" is used to designate the corresponding status. Note 2 to entry: The use conditions for validation can be real or simulated. Note 3 to entry: In design and development, validation concerns the process of examining an item to determine conformity with user needs. Note 4 to entry: Validation is normally performed during the final stage of development, under defined operating conditions, although it can also be performed in earlier stages. Note 5 to entry: Multiple validations can be carried out if there are different intended uses.	BS EN 50126-1:2017 Section 3
Verification	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. Note 1 to entry: The term "verified" is used to designate the corresponding status. Note 2 to entry: Design verification is the application of tests and appraisals to assess conformity of a design to the specified requirement.	BS EN 50126-1:2017 Section 3

1. Overview

1.1 Purpose

1.1.1 The purpose of the Root Cause Analysis (RCA) process is to introduce a systematic approach for identifying and addressing the root cause of asset failures and non-compliance with Reliability, Availability, Maintainability, and Safety (RAMS) targets, Asset Level of Service (ALOS) targets, and/or Customer Level of Service (CLOS) targets.

1.1.2 The intended audience groups for this process are:

a) Asset Class (AC) teams (operations, maintenance, and engineering and asset management departments); and

b) RCA Sponsor (can be an attendee from Failure Reporting, Analysis, and Corrective Action System [FRACAS] review meetings, Failure Modes, Effects, and Criticality Analysis [FMECA] review meetings, Failure Review Board [FRB] meetings, On-Time Performance [OTP] meetings, Customer Satisfaction [CSAT] meetings, asset class team leads, management, trades, supervisors, contractors etc. who wish to request the root cause of a problem).

1.2 Scope

1.2.1 RCA is a step-by-step problem-solving process that identifies the factors contributing to a problem. An RCA is performed with the understanding that problems are addressed, corrected, and prevented by identifying the root causes, rather than the immediate obvious symptoms.

1.2.2 The RCA process focuses on revealing the root cause. Often, an immediate symptom of a problem is mistakenly identified as a root cause. The immediate cause is simply the closest contributory symptom, which itself may have deeper roots that can be revealed through RCA.

1.2.3 The RCA applies to Metrolinx assets in the operation, maintenance, and performance monitoring lifecycle phase. It is a process for analyzing and correcting root causes of actual asset or system-related problems and does not apply to theoretical or potential incidents or failures.

1.2.4 AC teams shall initiate the RCA process during the operation, maintenance, and performance monitoring lifecycle phase for all Metrolinx assets. To ensure that priority problems are addressed with an RCA, incidents and failures should be analyzed according to trend patterns, safety and reliability for varying levels of severity/criticality (e.g., severe accident, catastrophic incidents, recurring failures on a single asset, similar failures within an asset class, service-interrupting, non-service interrupting, etc.) as described in the FRACAS Process (MX-ALM-STD-002).

1.2.5 Using the analyzed incidents and failures, the RCA process elicits a problem statement to act as the focal point of problem-solving. The problem statement outlines the gap that the problem creates between the current state and the ideal state of the asset, asset class, or system in the current lifecycle phase.

1.2.6 There are two outcomes in RCAs when analyzing failures:

a) Outcome 1 – Corrective Action (CA): measures taken to eliminate and/or minimize and/or reduce the effects of the problem on the affected asset, asset class, or system; and

b) Outcome 2 – Preventive Action (PA): measures taken to prevent the problem from recurring on any asset, asset class, or system, or determining mitigation of the problem if prevention is not possible.

Note: CA and PA are collectively known as CAPA.

1.2.7 The RCA process is a valuable tool for organizations; however, it takes time and resources to conduct an RCA properly. Consequently, it is important to know when to use an RCA. Not all incidents, failures, or problems require a full root-cause analysis.

1.2.8 An RCA is to be initiated if:

a) A problem exists where:

i. The root cause is unknown; and

ii. One or both outcomes (CA, PA) are not known.

Or:

b) There is a request to do a deeper investigation into a critical or severe incident or failure (e.g., safety incident, major delay, executive request, etc.).

1.2.9 Efficacy of the RCA process relies on a creating a centralized repository where completed RCA documents are stored for future reference. Before initiating a new RCA, AC teams should review the repository to examine RCA outcomes for similar assets, asset classes, or systems, where previous outcomes may be leveraged and/or iterated upon.

1.2.10 Outputs from the RCA process may be used by the AC team to support or supplement different methods or formats of the problem-solving process, including the Metrolinx Lean A3 template.

1.3 Key Responsibilities

1.3.1 The **RCA Sponsor** is responsible for the following tasks:

a) Requesting the AC team to conduct an RCA following the indication of a problem via a trigger as specified in Section 2.2.1;

b) Defining the scope and creating a clear definition of the observed problem ('RCA Request') and sharing with the Asset Class Team along with all relevant data and information (if available);

c) Tracking due dates for submitting RCA findings and CAPA outcomes by each AC team; and

d) Tracking due dates for implementing CAPA.

1.3.2 The **Asset Class Team** is responsible for the following tasks:

a) Assigning an RCA Leader following the receipt of an RCA Request;

b) Ensuring continuous and adequate communication of information relevant to the RCA to the RCA Sponsor and RCA Leader;

c) Following up on the CAPA implementation plan(s) with the **RCA Leader**;

d) Following up on the CAPA completion with the **RCA Leader**;

e) Following up on the RCA and CAPA outcome(s) with the **RCA Leader**; and

f) Initiating the RCA for BU-related problems.

1.3.3 The **RCA Leader** is responsible for the following tasks:

a) Forming an **RCA Team** with relevant experience to the problem in question and initiating the process of filling the **RCA Template**;

b) Conducting root cause analysis with the **RCA Team** using sound data analysis techniques;

c) Facilitating the RCA process through **RCA Team** meeting sessions and site visits where required;

d) Reporting the CAPA implementation plan(s) to the **RCA Sponsor**;

e) Reporting the CAPA completion to the **RCA Sponsor**;

f) Reporting the RCA and CAPA outcome(s) to the **RCA Sponsor**; and

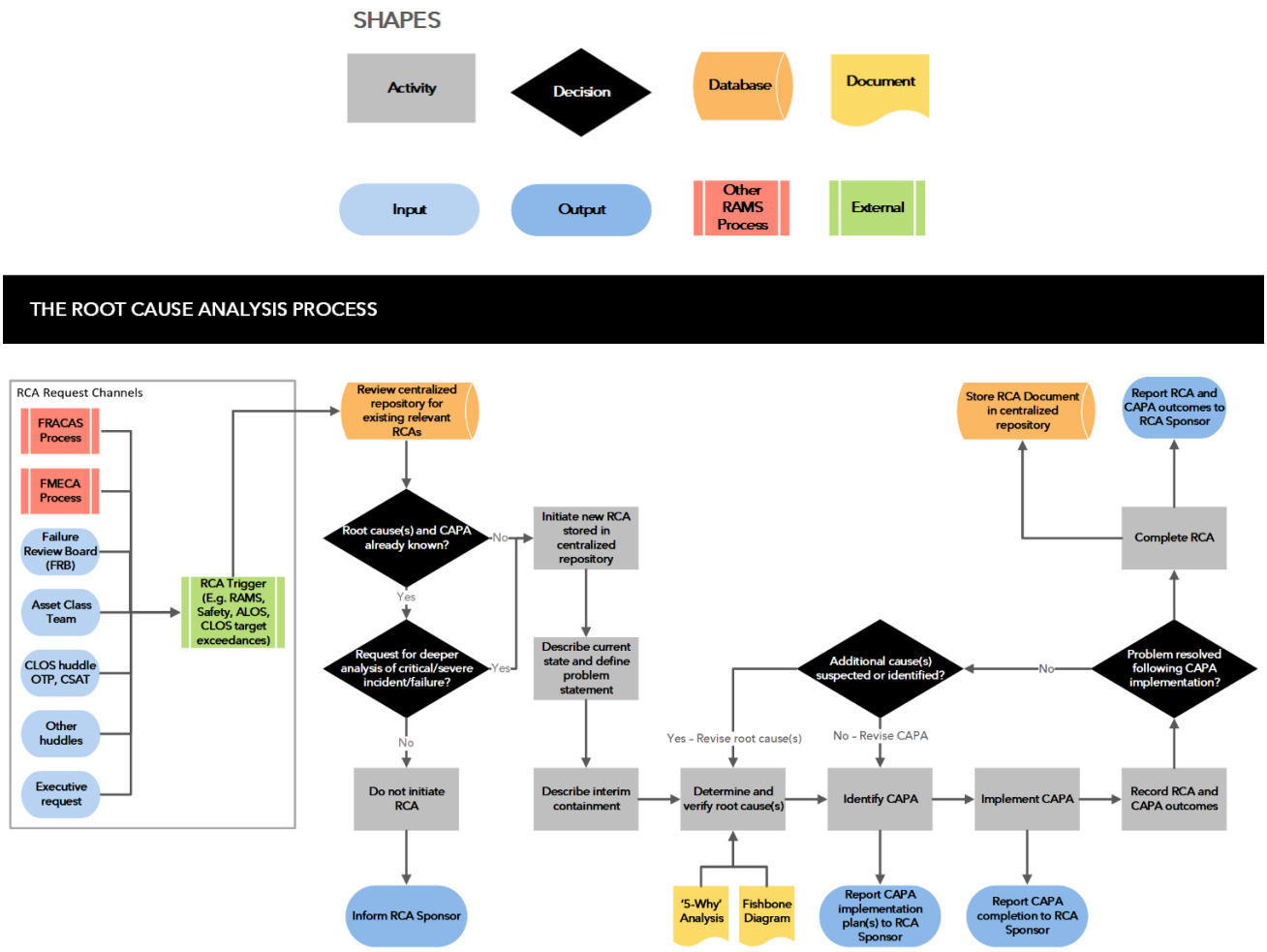
g) Storing the completed **RCA Template** in a centralized repository for future reference.

2. The Root Cause Analysis (RCA) Process

2.1 The Root Cause Analysis (RCA) Flow Chart

2.1.1 Figure 0-1 illustrates the Root Cause Analysis Process.

Figure 0-1 Root Cause Analysis Process



2.2 The Root Cause Analysis (RCA) Process Narrative

2.2.1 The following steps describe the RCA Process:

a) An RCA may be triggered by a problem related to the performance or underperformance of an asset in comparison to defined RAMS targets, ALOS targets, and CLOS targets, or a specific critical incident or failure; the RCA should be requested through specified channels:

i. RCA request channels:

1) FRACAS reviews [ref. FRACAS Process MX-ALM-STD-002];

2) FMECA reviews [ref. FMECA Process MX-ALM-STD-003];

3) FRB meetings;

4) AC team lead (i.e., Manager, supervisor, lead within the business unit);

5) Executive request;

6) OTP huddle;

7) CSAT huddle; and

8) Other huddles.

ii. RCA triggers include, but are not limited to:

1) RAMS metric target exceedances:

i) Reliability parameters such as Mean Time Between Failures (MTBF);

ii) Maintainability parameters such as Mean Time to Restore (MTTR);

iii) Availability parameters such as Asset Availability; and

iv) Other RAMS targets

iii. Safety triggers: Injury, effluent exceedances, spills, etc.;

iv. OTP triggers: Service-interrupting failures, on-time fleet performance, etc.;

v. CSAT triggers: Comfort-related complaints, PRESTO ease of payment complaints, etc.; and

vi. Other ALOS or CLOS target triggers

b) The affected AC team shall assign an RCA Leader with relevant experience and influence on the asset in question to conduct an RCA;

c) The RCA Leader shall review the centralized, accessible repository to review any existing RCA documents that contain similar, applicable analyses related to the problem triggering the request for an RCA. Two outcomes are possible:

i. Root cause(s) of the problem is fully known, and CAPA measures are currently in place to remediate the problem. An RCA shall not be initiated by the affected AC team, and the RCA Leader shall

inform the RCA Sponsor of this outcome. Evidence documenting the existing understanding of the root cause(s) and the application of CAPA measures must be provided by the RCA Leader to the RCA Sponsor; and

ii. Root cause(s) of the problem is not fully known, and CAPA measures are not currently in place to remediate the problem, or a request exists to initiate an RCA for a critical or severe incident or failure. An RCA shall be initiated by the affected AC team, and the RCA Leader continue the RCA process.

d) The RCA Leader shall initiate an RCA by using the Metrolinx Reliability Engineering RCA Template or another problem-solving method. In-work or completed RCA documents shall be stored in a centralized, accessible repository;

e) The RCA Leader shall form an RCA team; the team members should be selected based on the specific expertise needed to analyze the problem and implement the outcome(s) (CAPA);

Note: An effective RCA Team should include members with diverse experience and insights. A team with a diversified background reduces individual bias and minimizes the number and scope of assumptions made during the development of root cause(s).

f) The RCA Leader shall then lead the RCA team through the analysis following the general steps:

i. Prepare for the analysis by forming a team, defining the current state, setting goals for the outcome(s) of the RCA, and recording important details related to the problem;

ii. Define the problem statement;

iii. Describe interim containment actions taken immediately following the occurrence of the problem, if applicable;

iv. Organize and perform a site visit to the location where the problem occurred, if applicable;

v. Use RCA tools (Appendix A) to analyze the causes of the problem:

1) Fishbone diagram to identify the probable cause(s) of the failure, if not already known or identified.

2) '5 Why' analysis to develop the probable cause(s) into root cause(s).

vi. Validate root cause(s) with evidence and knowledge from the RCA team, AC team, and SMEs;

vii. Develop CAPA measures to remediate the root cause(s), identifying the expected outcome(s), owners, and implementation

timelines. Testing/piloting of proposed CAPA measures may be undertaken where appropriate;

viii. Follow up on the CAPA measure implementation until closure, updating the RCA document to ensure all relevant details are captured as CAPA work progresses;

ix. Guide the RCA Team in validating CAPA measure actual outcome(s) against the expected outcome(s) to determine whether:

1) CAPA measure actual outcome that achieves an expected outcome;

2) CAPA measure actual outcomes do not achieve an expected outcome, and additional root cause(s) are suspected and/or identified, requiring additional root cause development. The RCA Leader then guides the RCA team through additional root cause identification and validation; and

3) CAPA measures actual outcomes do not achieve an expected outcome, and additional root cause(s) are not suspected and/or identified, requiring additional CAPA development. The RCA Leader then guides the RCA team through additional CAPA measure development, piloting (as needed), implementation, and validation.

x. Verify that CAPA measures are completed and closed out and the RCA goals are met.

g) The RCA Sponsor shall record the RCA completion due date and CAPA implementation plans and due date(s) and follow up with the RCA Leader when the action items reach the due date. This follow-up continues until all actions are completed and recorded in the RCA document;

h) The RCA Leader shall report the outcome of the RCA in terms of findings and CAPA implementation plans and due date(s) to the RCA Sponsor, respectively, and to any applicable RCA request channels as specified in Section 2.2.1 a) i);

i) The RCA Leader shall verify completeness and close-out the RCA document when root cause(s) and CAPA actual results are validated;

j) The RCA Leader shall store/save the completed RCA template in the centralized repository (e.g., EDMRS, specific software tool, or the BU shared drive as applicable);

k) The RCA Leader or RCA Team may use results of the RCA process and output documentation to supplement or support another problem-solving method, including the Metrolinx Lean A3 template.

Appendix A. Root Cause Analysis (RCA) Tools

A.1 Fishbone Diagram

A.1.1. The fishbone diagram, created by Kaoru Ishikawa, is an idea-eliciting tool that depicts the cause-and-effect relationship that exists between a problem and its probable causes.

A.1.2. Probable causes typically stem from one or more process deviations that function as contributing factors to the occurrence of incidents/failures and, in turn, problems.

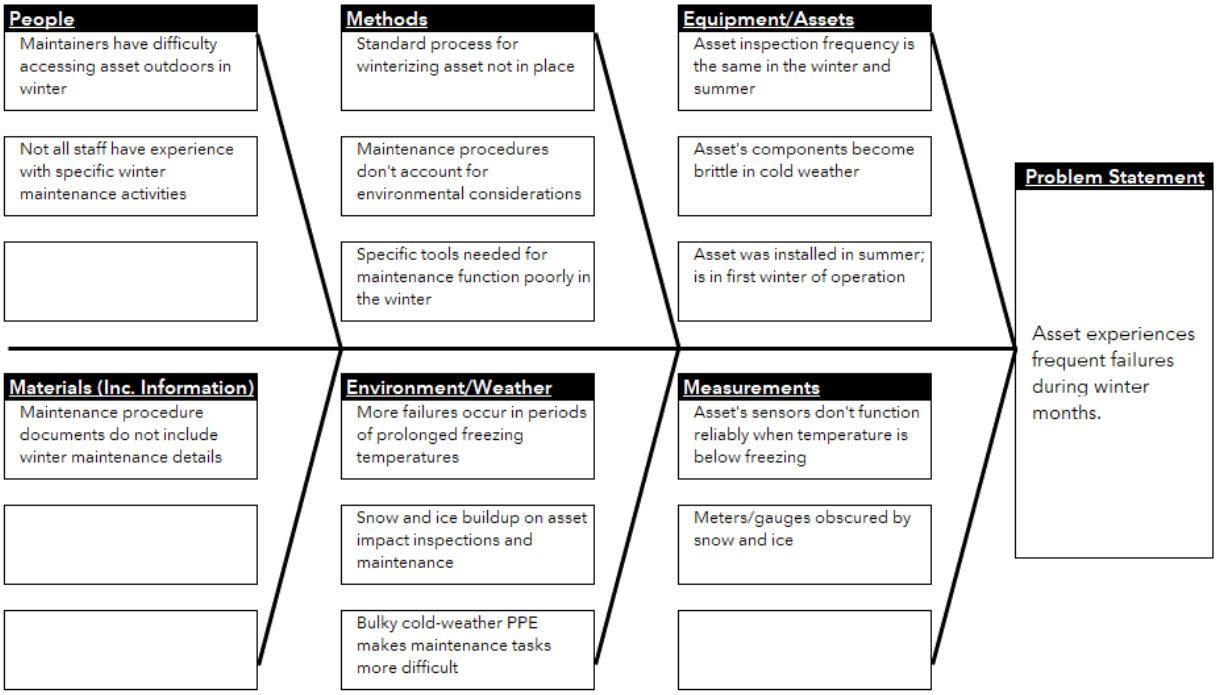
A.1.3. To facilitate the RCA process, the sources of variation are placed into six categories: people, methods, equipment/assets, materials (including information), environment/weather, and measurements.

A.1.4. The structure of the fishbone diagram graphically relates the categorized probable causes to the problem statement and provides a medium for an RCA Team to develop the probable causes into root causes through summarization and iteration.

A.1.5. Sharing a diverse and inclusive set of ideas is encouraged during the fishbone diagram exercise; the process is meant to elicit various probable causes of the problem. Care should be taken to record or summarize any information shared during the process.

A.1.6. A fishbone diagram may be completed using the RCA Template or an external tool, though the results/outcomes from the process must be recorded in the same document/tool that houses the main RCA.

Figure A-1 Fishbone Diagram Example



Notes:

a) Not all spaces provided in the fishbone need to be filled in.

b) Similar probable causes may exist under distinct categories and may be grouped for further analysis in the 5-Why.

A.2 5-WHY

A.2.1. 5-Why is a simplistic approach which exhausts the question "Why?" to help determine the root cause of a failure. The 5-Why tool was created by Japanese inventor Sakichi Toyoda. The effectiveness of the model became apparent in the Japanese automotive industry. Toyota became a proponent of the 5-Why model, which became a critical component of the company's problem-solving training.

A.2.2. The 5-Why tool elicits a problem's root cause(s) by examining probable or suspected causes and iterating through the question "Why?" to form a causal chain.

A.2.3. Answers to the question "Why?" can be considered as a root cause when the output can be actioned via implementation of CAPA measures, and the output cannot be further devolved.

A.2.4. A probable or suspected cause may branch during the 5-Why process into two or more streams, and each stream should be fully developed into a root cause as applicable.

A.2.5. The 5-Why analysis may be initiated in two primary ways depending on the method used to develop probable cause(s):

a) If developed during the RCA process, the 5-Why will begin with the individual or summarized results from the fishbone diagram; and

b) If already known or identified prior to beginning the RCA process, the 5-Why will begin with the RCA Team's suspected probable cause(s).

A.2.6. A 5-Why may be completed using the RCA Template or an external tool, though the results/outcomes from the process must be recorded in the same document/tool that houses the main RCA.

Figure A-2 5-Why Example

RC No.	Probable Cause	1st 'Why'	2nd 'Why'	3rd 'Why'	4th 'Why'	5th 'Why'
RC1	Maintainers have difficulty accessing asset outdoors in winter	Route to access asset isn't frequently cleared of snow and ice	No work plan to clear snow and ice around asset following snowfall events	Work order schedulling not fully completed during asset commissioning		
RC2	Asset's sensors don't function reliably when temperature is below freezing	Sensitive monitoring equipment is exposed the elements	Sensor system not designed to withstand cold environment	Manufacturer was not aware of enivronmental requirements during design	Asset class team did not communicate changes to asset operating environment	
RC3	Asset's sensors don't function reliably when temperature is below freezing	Sensitive monitoring equipment is exposed the elements	Sensor system not designed to withstand cold environment	Manufacturer was not aware of enivronmental requirements during design	No design standard exists to prescribe adequate shielding for equipment	Design standards were not modified to reflect new asset
RC4	Snow and ice buildup on asset impact inspections and maintenance	No work plan to clear snow and ice around asset following snowfall events	Work order schedulling not fully completed during asset commissioning			
RC5						

Notes:

a) Root Causes 2 and 3 share the same probable cause but branch into two different root causes;

b) Root Cause 1 and 4 begin with two different probable causes but resolve to the same root cause;

c) It may take a different number of "whys" to reach the root cause of each probable cause (i.e., five distinct "whys" are not required for each probable cause); and

d) The final "why" should be actionable as a root cause of the problem.

Appendix B. Minimum Requirements of a RCA Template

The following details are the minimum requirements for an RCA template:

B.1 Preparation – D0.0

B.1.1. Each RCA template shall contain the following information to ensure the document can be tracked:

a) An RCA name or title;

b) A unique RCA number used to identify the document;

c) The date of RCA initiation; and

d) The name of the RCA author, which can be the name of the RCA Leader.

B.2 RCA Trigger(s) – D0.1

B.2.1. The RCA trigger(s) shall identify what prompts the problem to be analyzed.

B.2.2. RCA triggers may be represented by the list in Section 2.2.1 a) 2), or another trigger may be specified and described as needed.

B.2.3. If the RCA trigger does not sufficiently outline the reason an RCA is to be conducted, additional detail must be provided.

B.3 Emergency Response Action- RCA Template Section 0 Interim Containment Plan – D3.0

B.3.1. If any action is taken to contain the problem immediately following its occurrence, details shall be included in the RCA template.

B.3.2. Interim containment details shall contain the following:

a) The date, time, and/or timeline corresponding to the completion of the action(s);

b) The names and/or credentials of the person(s) who completed the action(s); and

c) The status of the action(s) carried out (e.g., planned, in progress, completed, cancelled, etc.).

B.4 Current Condition Analysis – D4.0, D4.1

B.4.1. Analysis of the current condition shall be carried out to identify common candidate areas or categories of fault/failure that lead to problem occurrence.

B.4.2. Results of the current condition analysis may feed directly into the fishbone diagram or 5-Why.

B.4.3. The following current condition analysis questions are recommended for review:

a) Is the difference between the normal state and the abnormal state clear to all people involved in containing/resolving the abnormal state?

b) Are relevant standard operating procedures (SOP) or specifications/standards available and complete?

c) Are people consistently following the relevant SOPs or specifications/standards?

d) Is there preventive maintenance (PM) in place to test for or reduce the likelihood of this failure mode at an acceptable frequency?

e) Is PM work performed in a timely manner? (Tip: review the compliance time on at least the last 3 PM work orders);

f) Has the operating environment remained unchanged? (Changes include service changes, construction projects, significant weather events, etc.); and

g) Is the area organized and easy to access information, tools, and materials?

B.4.4. A negative response to any of the questions in B.7.3 should be treated as an indication that further analysis should be undertaken in the corresponding area or category.

B.5 Analyze the Root Cause(s) of the Problem – D4.2, D4.3

B.5.1. Analysis of a problem's root cause(s) is often a two-step process involving:

a) Development of probable causes from common areas or categories of fault/failure; and

b) Refinement of the probable cause(s) into the root cause(s) through iteration across the causal chain.

B.5.2. The completed RCA template may include:

a) A **Fishbone Diagram** to narrow down the most likely areas or categories of incident/failure of the problem into probable cause(s), if not known at the time the RCA is being conducted.

i) Probable causes used in the fishbone must relate to the problem statement;

ii) Appropriate detail must be included for each probable cause (i.e., one-word entries are discouraged);

iii) To ensure all RCA Team members' experiences are valued and heard, all contributions to the discussion shall be summarized and recorded in the fishbone diagram where possible; and

iv) The following categories shall be examined in the fishbone diagram:

1) **People** – Related to the people associated with the problem being analyzed (e.g., operators, maintainers, system specialists, etc.);

2) **Methods** – Related to process documents and instructions (e.g., maintenance task plans, installation instructions, etc.);

3) **Equipment/Assets** – Related to all assets and equipment related to the problem being analyzed (e.g., asset or part of the asset that failed, tools used to maintain the asset, etc.);

4) **Materials (Including Information)** – Related to any materials needed or added when the problem occurs, generally: raw materials, inspection/maintenance materials, or documentation (e.g., hardware, fuel, lubricant, design drawings, communication records, etc.);

5) **Environment/Weather** – Related to relevant external and natural factors (e.g., location, temperature, humidity, precipitation, wind, etc.); and

6) **Measurements** – Related to techniques used to measure whether a part or process meets the desired quality standards (e.g., data tracking, measurement devices, deviations in measurement, availability of results, etc.).

b) A **5-Why Analysis** to develop the problem's root cause(s) by iterating over the probable cause(s) developed via the fishbone diagram or previously known prior to the initiation of the RCA. When conducting a 5-Why analysis, the following shall be considered:

i) Each individual probable cause or summary of probable causes shall be used as the basis for an individual "Why;"

ii) Each "Why" must further build upon and develop the previous entry related to the initial probable cause;

iii) It may take greater or fewer than 5 "Whys" to arrive at a root cause;

iv) "Whys" may branch to form different root causes or converge at a single root cause; and

v) The final "Why" may be considered as a root cause, given the "Why" is:

1) Actionable with CAPA measures; and

2) Linear, arriving at a unique root cause and not re-stating the initial probable cause.

B.6 Target State Description – D4.4

B.6.1. Following determination of the problem's root cause(s), a description of the target state shall be formulated by the RCA Team.

B.6.2. The target state shall describe the condition attained following implementation of CAPA measures to achieve the goal statement.

B.6.3. The RCA Team may find benefit in considering the gap between the current state (described following section B.4.2) and the desired condition to be attained that is caused by the problem that exists due to the existence of the root cause(s).

B.7 Corrective Action Development, Implementation, and Validation – D5.0, D6.0

B.7.1. Upon determination and validation of the root cause(s) of the problem, the RCA Team shall undertake the development of CAPA measures to directly address each root cause.

B.7.2. If required, the RCA Team may utilize a Plan, Do, Check, Act (PDCA) or a similar, structured piloting tool to test potential CAPA before full-scale implementation. A PDCA pilot may be useful in determining the quality, gathering initial feedback, and experimenting with proposed CAPA solutions. A PDCA plan may include the following sections:

a) **Hypothesis** – Description and proposed result of a possible CAPA measure aimed at remediating the root cause(s);

b) **Change** – Descriptive plan to pilot the proposed action/task;

c) **Measures** – Success criteria for full-scale implementation of the hypothesis into a CAPA measure; and

d) **Results** – Analysis of the success or failure of the piloted hypotheses compared to the stated measures (i.e., Adopt, adapt, or abort the hypothesis as a CAPA measure).

B.7.3. At least one CAPA measure must be recorded and implemented for each root cause identified in the RCA.

B.7.4. A single CAPA measure may address multiple root causes, in which case the root causes being addressed are clearly documented in the RCA template to establish a relationship.

B.7.5. Each CAPA measure must be monitored to ensure the action is effective in relation to its expected outcome.

B.7.6. Each CAPA measure shall be designed to:

a) Reduce the likelihood of the root cause recurring in the future; and/or

b) Reduce the impact or consequence when a root cause does recur; or

c) Eliminate the root cause entirely.

B.7.7. During Corrective Action development and implementation, the RCA Team shall include the following details for each measure upon entry into the RCA Template:

a) Corrective Action Item Description – Details on the action to be conducted;

b) Corrective Action Owner – Name of a single individual (i.e., not the name of a group or team) who is responsible for the completion of the action item;

c) Corrective Action Start Date – Date and time (if applicable) that the action item is scheduled to start;

d) Corrective Action Due Date – Date and time (if applicable) that the action item is scheduled to be completed;

e) Corrective Action Status – Description of the position of the action item at a given point in time (e.g., planned, in progress, completed, cancelled); and

f) Corrective Action Expected Result – Quantitative or qualitative description of the expected outcome of the action item representing the target result, linking the action item to the root cause(s).

B.7.8. To validate that the Corrective Action measures developed and implemented address the root cause(s) of the problem, the RCA Team shall provide the following details for each measure:

a) Corrective Action Actual Results - Actual results measured/observed following implementation of the action item, commenting on whether the outcome meets the expected result; and

b) Corrective Action Close Date – Date and time (if applicable) that the action item is validated and verified by the RCA Leader.

B.7.9. Validation of the Corrective Action measures shall not be considered complete unless the Corrective Action Actual Results and the Corrective Action Close Date are populated, and the Corrective Action Status reflects verification of the measure.

B.7.10. Upon validation of the Corrective Action measures, the RCA Team shall document the acceptance or rejection of the outcomes of each measure and, if required, document the revision of any root cause(s) or corrective action measures.

B.8 Prevent Recurrence – D7.0

B.8.1. To prevent recurrence of the problem, each corrective action measure shall be examined to determine its applicability across a wider scope as a Preventative Action measure. In each case, the following details shall be provided:

a) Preventative Action Item Scope – Description of the extent to which the action item will be applied (i.e., System-level, asset-class level, location, single asset);

b) Preventative Action Implementation Plan – Description of the action(s) taken to implement the measure across the scope indicated, describing how a corrective action item can be modified to prevent the recurrence of the problem in the future (e.g., modifying/creating an SOP, modifying/creating a PM, increasing/decreasing maintenance patterns, creating/modifying standards, etc.);

c) Preventative Action Start Date – Date and time (if applicable) that the action item is scheduled to start;

d) Preventative Action Due Date – Date and time (if applicable) that the action item is scheduled to be completed; and

e) Preventative Action Close Date – Date and time (if applicable) that the action item is validated and verified by the RCA Leader.

B.9 Team Recognition and Close Out – D8.0

B.9.1. To close out the RCA, the RCA Team shall compare and document the following:

a) The overall outcome of the RCA against the goal statement (i.e., the desired outcome;)

b) The actual condition attained following implementation of CAPA against the target state; and

c) The actual result(s) of each corrective action against the expected outcome(s).

B.9.2. If the goal statement has not been achieved or the target state has not been attained, the RCA Team shall propose, and document next steps required to achieve fulfillment.

B.9.3. To close out the RCA, the RCA Leader shall recognize and document the efforts of the RCA Team throughout the process.

B.9.4. The RCA Template shall be completed by documenting the following information:

a) **Sign-off Name** – Name indicating that the RCA Sponsor has approved the outcomes and verification of the RCA Template; and

b) **RCA Close Date** - Date and time (if applicable) that the RCA Template is closed out.

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