

QAM 12050: Root Cause Analysis

Revision History

Author	Description of Change	Revision Date
Kathy Zappia	Initial release of QAM 12050 replaces Root Cause Analysis Procedure 1004.1002 rev. 002.2, issued by the former OQBP, and cancels the OQBP procedure upon publication.	December 2013

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1.0 INTRODUCTION

This chapter describes the activities required to properly perform Root Cause Analysis (RCA). This chapter applies to all Fermilab employees, contractors, subcontractors, and users performing root cause analysis and is intended to provide terminology and basic structure for problem investigations. It is applied to non-ES&H root cause investigations and to ES&H root cause investigations of reported incidents, events, or accidents as defined in FESHM 3020, Incident Investigation and Analysis, findings assigned risk assessment code of 1 or 2, or repetitive events in conjunction with QAM 12030 iTrack Procedures and Risk Assignment.

2.0 DEFINITIONS

2.1 Contributing causes

The causes which did not initiate the problem, but had they not existed the problem could not have occurred or would have been less severe. They raise the probability of a problem.

2.2 Corrective Action

Action to eliminate the cause of a detected nonconformity or other undesirable situation.

Note: There can be more than one cause for nonconformity. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

2.3 Direct cause

The cause which immediately resulted in the problem. This is also known as the physical or proximate cause.

2.4 Extent of condition (EOC)

Determination of the degree to which a problem or cause may exist in other portions of the system or similar systems.

2.5 Incident, non-ES&H

An occurrence which deviates from planned requirements (activities or results), or expected outcomes which may range from a simple procedural noncompliance with minimal risk to an accident/event having substantial risk to personnel. For ES&H incidents refer to FESHM 3020.

2.6 Nonconformity

Non-fulfillment of a requirement.

Note: A nonconformity can be any deviation from work standards, practices, procedures, legal requirements, or applicable code of federal regulations.

2.7 Preventive Action

Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.

Note: There can be more than one cause for a potential nonconformity. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

2.8 Remedial Action

An action taken to alleviate the symptoms of existing nonconformities or any other undesirable situation. Also known as correction or compensatory action, remedial action is used to minimize the effects before the root cause and best solution may be identified. It is a reactive, short term action to stop immediate effects of the problem.

2.9 Root Cause

An identified reason for the presence of a defect or problem. The most basic reason, which if eliminated, would prevent recurrence. The source or origin of an event. Root cause is also known as the system cause.

2.10 Root Cause Analysis (RCA)

A logical thinking process using deductive and inductive searches to collect evidence to support or deny actual causes of a problem.

3.0 RESPONSIBILITIES

3.1 Division/Section Heads and Project Managers

- Ensure compliance with this procedure including flow down of requirements and awareness
- Provide the necessary resources to implement this procedure
- Ensure individuals are trained in root cause analysis where required

3.2 Quality Assurance Manager

- Manages the Fermilab Integrated Quality Assurance Program and this procedure
- Provides support to management
- Determines training requirements for root cause analysis
- Maintains materials and works with ESH&Q and WDRS to provide training

3.3 Employees, Contractors, Subcontractors, and Users

- Complete training in root cause analysis as determined by Fermilab line management
- Notify the immediate supervisor when issues or incidents require investigation, corrective action and potential root cause analysis

3.4 Supervisors

- Notify line management when issues or incidents require investigation, corrective action and potential root cause analysis
- Identify in the Individual Training Needs Assessment those employees who by the nature of their assignments require root cause analysis training.

3.5 Division Safety Officers and Quality Assurance Representatives

- Assist personnel with the application of root cause analysis to unexpected or negative outcomes, incidents, or events brought to their attention

4.0 PROGRAM DESCRIPTION

4.1 Output

The output of the root cause process is an understanding of the events leading to the problem in terms of root, direct, and contributing causes.

4.2 Training/Experience

Personnel should receive root cause analysis training where appropriate. Where required for specific positions, training is indicated on the Individual Training Needs Assessment (ITNA) and tracked in the TRAIN database. Root cause analysis training is required for Quality Assurance Engineers (QAEs), Quality Assurance Representatives (QARs) and Division Safety Officers (DSO's).

Assignment of personnel to an investigation should consider training/experience with RCA as well as with the technology and processes to be investigated. Assignment of someone independent of the area being evaluated but with RCA experience may be useful in providing an objective assessment.

4.3 Containment

Containment and remedial actions to put the affected process in a safe condition and to preclude recurrence shall be taken prior to beginning a root cause investigation. Where safety is not a concern, containment and remedial actions may or may not need to be taken depending on the type of problem encountered. These actions shall be reviewed during the conduct of the root cause analysis to gain clarity of the problem symptoms, scope and evidence.

4.4 Graded Approach

A graded approach should be used when determining the applicability of this procedure to problem solving at Fermilab. This requires considering severity, frequency, cost, and impact on operations or safety issues associated with the problem being addressed. A graded approach includes determining the type of root cause method to be used – varying from an individual performing a simple, informal review of the problem to the establishment of a team and the use of structured, detailed processes to review a problem. The Technical Appendix provides information on some of the root cause methods and tools that may be used at Fermilab.

5.0 PERFORMING THE INVESTIGATION

The order in which the steps described below occur may vary depending on urgency of the problem, degree of problem understanding at the beginning of the investigation, and the need to protect/preserve evidence. Variations in problem resolution methodology such as those described in CDdoc-3248, “*IT Core Services Problem Management and Procedures*” may be employed depending on the nature of the problem or local requirements.

5.1 Define the problem

Define the problem by developing a clear, complete and concise statement which includes what the problem is, who was involved (not attributing blame), where it occurred or was identified, when it occurred or was identified and the magnitude (e.g., frequency, impact). Operating conditions or precursor information which may provide additional details for consideration might also be required. This problem statement will become more refined and detailed as the analysis is conducted.

5.2 Understand the Process

Identify initial boundaries of the system to be analyzed. Gain a high-level understanding of the normal sequence of operation of the system which failed by using a Process Analysis Tool from Appendix A to create a process flowchart and timeline showing the activities involved.

5.3 Grade the Process & Identify RCA Method

Determine the severity, frequency, cost, and impact on operations or safety issues. Based on these factors determine the type of root cause method to be used – varying from an individual performing a simple, informal review for simple problems – to the establishment of a team and the use of structured, detailed processes for complex problems.

The Technical Appendix provides tools which may be used when performing root cause analysis. There are methods and tools in addition to those listed in the appendix. Fermilab is not limited to the methods contained in this procedure; however, the chosen method should be recorded and its process followed to provide the best opportunity for reaching a successful conclusion. Human Performance Improvement (HPI) provides tools for understanding human error and how to cope with it and is not part of this procedure. However it could be one of the approaches employed when investigating unexpected or negative outcomes involving human performance or "error proofing" procedures and communications in the context of tools, tasks, and operating environment. RCA and HPI may be complementary and are not mutually exclusive.

5.4 Identify Possible Causes

Develop hypotheses regarding the most logical possible causes of the problem under investigation or at least which steps of the process contributed to the problem. When identifying possible causes it is advisable to consult standards, professional literature, DOE databases, and so on to understand how other organizations may have identified and solved similar problems. This may help avoid over reliance on preconceived conclusions.

- Identify which steps in the flowchart most likely could and could not cause the problem.
- Use Cause Analysis Tools from the Technical Appendix to identify failure modes, cause categories, or other groupings of causes.
- Identify barriers in the system which may have failed by using Cause Analysis Tools from the Technical Appendix. Note that such barriers could include those items intended to prevent the problem and/or intended to detect the problem.
- Assess whether there have been any changes made in the system prior to the time of the problem which may have led to the occurrence.
- Use an Idea Creation Tool from the Technical Appendix to determine a list of possible causes.

5.5 Collect Data

Using the tools described or referenced in the Technical Appendix collect data to refute or support hypotheses regarding the causes that had the greatest impact on problem initiation. In addition to conventional data collection, evidence gathering should include interviews of personnel involved with designing, operating and/or maintaining the system which failed; observation of the processes in action when possible (e.g., in real-time or video/computer recording); scientific analysis of failed system components; and reviews of relevant organizational records related to planning, and maintaining the system.

5.6 Analyze the Data

Use Analysis Tools from the Technical Appendix to evaluate data for evidence that allows determination of which of the possible causes had the greatest impact on problem initiation.

5.7 Refine Problem & Root Cause

Refine the problem definition based on current conclusions, and then repeat the system understanding, possible cause, and evidence gathering & analysis sequence until the level of cause is deemed sufficient for the significance of the problem. For low risk or impact problems finding the direct cause(s) may be sufficient, while for more significant problems the root cause(s) (also known as system causes) should also be found.

5.8 Corrective and Preventive Actions (CAPA)

Identify and implement corrective and preventive actions to ensure the problem has been eliminated and prevented from occurring again. See QAM 12040, “*Corrective & Preventive Actions.*”

5.9 Communicate Lessons Learned

Once the root cause has been determined results should be communicated within the organization to share lessons learned about both root causes for the problem as well as how to perform effective investigations. For ES&H incidents being investigated, [FESHM 3020](#) specifies lessons learned steps.

5.10 Document RCA

A report of the investigation should be created which includes, at a minimum, the original problem definition, actual causes found and supporting discussion/evidence. In most cases where electronic tools retain pertinent records such as iTrack or the Information Technology Service Management (ITSM) are employed, a separate report may not be necessary.

6.0 RELATED DOCUMENTS

CDdoc-3248 IT, “*Core Services Problem Management and Procedures*”

7.0 TECHNICAL APPENDIX - Tools for RCA Problem Solving, Data Collection, & Analysis

The following Appendix describes tools that may be used during root cause analysis. There are many more tools than those illustrated in this procedure including specialized software. Experience and training will guide users in determining the best tools to use in any given situation and in any given step of the RCA process.

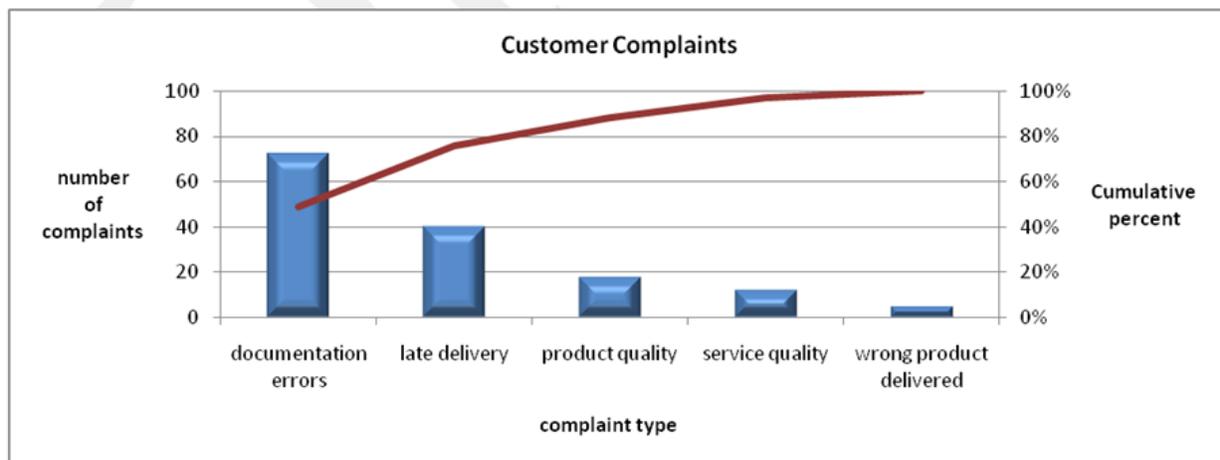
Tools illustrated in one RCA step may apply to other steps as well. These steps may be iterative. For example, as more information is obtained, it may be beneficial to refine the problem statement.

Tools for Defining the Problem

Pareto Chart

The purpose of the **Pareto chart** is to highlight the most important of a set of factors. It often represents the most common source of defects, the highest occurring type of defect, or the most frequent reason for service interruptions, customer complaints and so on. In the example below, it is immediately evident that “documentation errors” is the major cause of customer complaints, accounting for approximately 50% of all complaints.

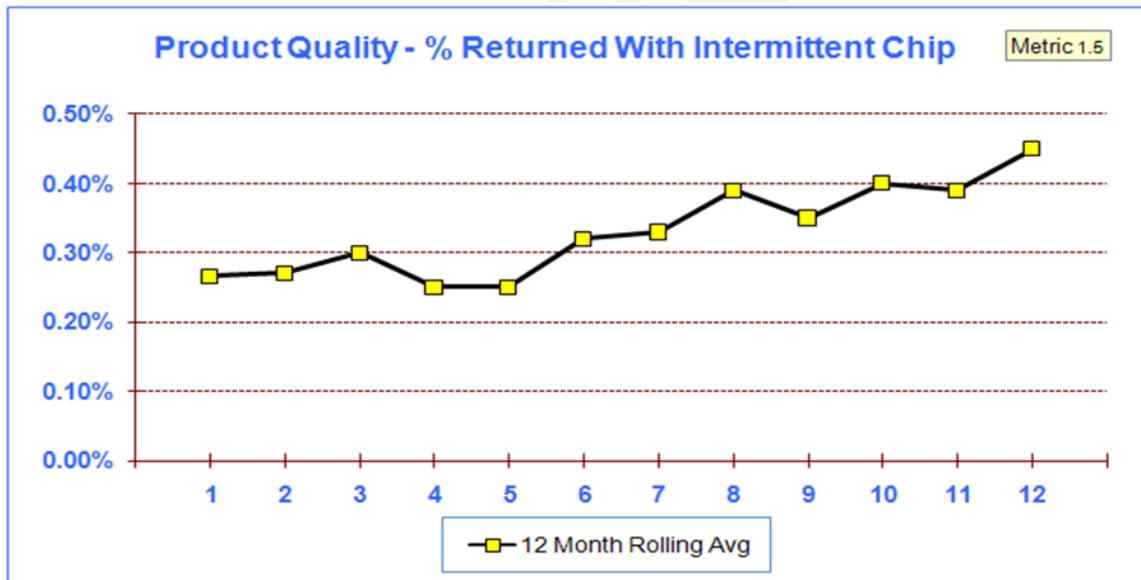
During root cause analysis this tool is useful for determining, categorizing, and displaying information that may help better define the problem. For instance, the chart below further defines the problem “customers are complaining” into the reasons for complaints and identifies that 50% of complaints are for documentation errors. When multiple causes are identified later in the RCA, it may also be useful in determining the most important cause or causes to resolve in order to reduce or eliminate the problem.



Run Chart

The **run chart** is used to analyze data to detect trends, shifts or patterns over time. It allows the comparison of process performance before and after a process or activity has changed. In the example below a team is investigating system performance problems. They analyze data for the percent of returns with a malfunction over a period of twelve months. When defining the problem this chart helps refine a problem statement like “error rates were high this year” to “chip performance error rates have increased from 0.25% in month 5 to 4.5% in month 12”. The cause of the marked increase in chip errors could be a contributing cause of system performance problems like the one under investigation.

During root cause analysis this tool is useful for displaying and analyzing process behavior over time. It is particularly useful in detecting changes in process behavior.



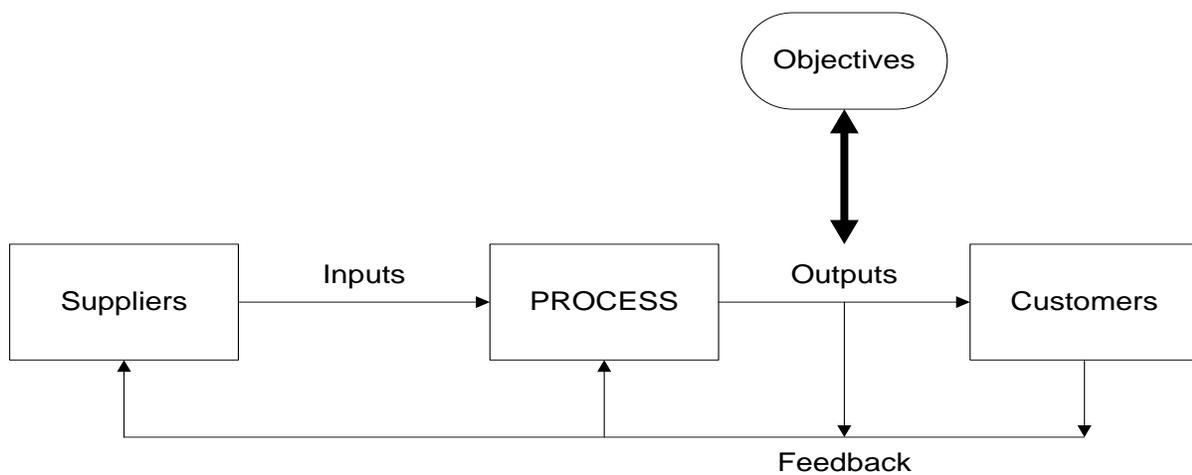
Like the Pareto chart, the run chart is often useful during the data analysis step.

Understanding the Process

SIPOC

Supplier, Input, Process, Output, Customer (SIPOC) describes the high level structure for a flow chart. Suppliers deliver inputs which are then processed to produce outputs. The outputs are delivered to customers. The outputs need to meet the objectives in order to satisfy customers. These objectives may include product features, quality levels, on-time delivery, etc. Finally, feedback from customers, the outputs, and the process are used to improve suppliers, the process and ultimately outputs in order to improve customer satisfaction.

During RCA evaluations this chart may be helpful in identifying high level process boundaries which is useful when defining the scope of the RCA.

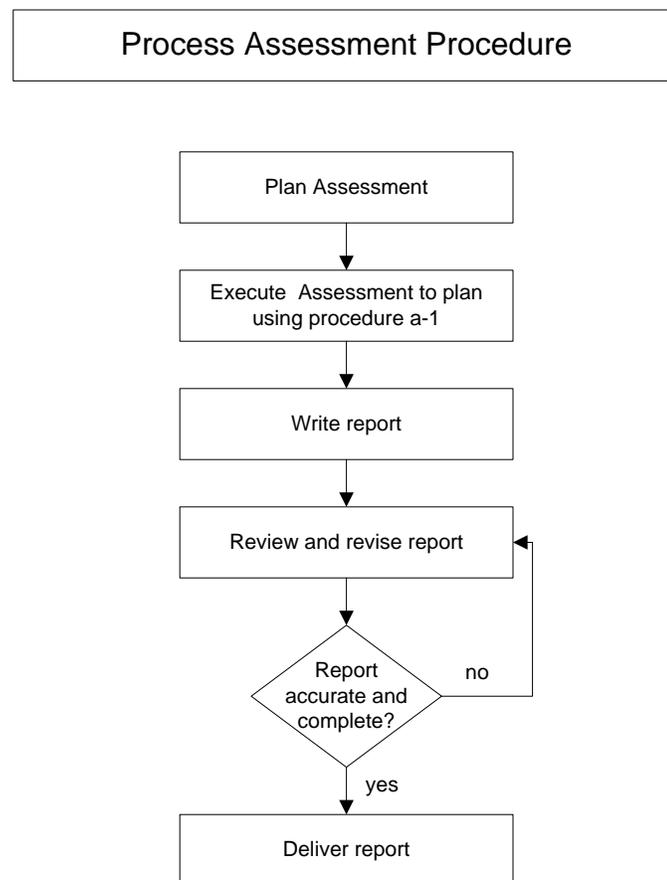


Process Flowchart

Flowcharts are used to analyze, design, document, or manage a process or program. More sophisticated flowcharts may employ other specialized shapes, symbols and graphics to represent the steps and events in a process.

In the example below the order in which each task of the assessment process is completed is clearly identified. In addition, there is a feedback loop for reviewing and revising the assessment report and the process output is the report.

During root cause analysis this tool is useful for defining the process in order to identify possible areas where problems or defects may be encountered.



Identify Possible Causes

5 Whys

The **5 Whys** is a question asking methodology used to determine the cause/effect relationships underlying a particular problem. The purpose of applying the 5 whys is to determine the root cause of a problem.

The process begins with a problem statement. The question why is then asked to determine why the problem exists. When the answer to the first question has been determined, the question why is asked again relative to the answer. The question why is asked and answered a total of 5 times (more or less if necessary) in order to determine the root cause of the problem. In the example below, using the problem statement “the product does not meet customer needs”, successive whys are asked until the root cause of the problem is determined:

- Why does the product not meet customer needs?
 - Because of one or more issues with delivery, features, or defects
- Why did we miss the delivery deadline?
 - Because requirements changes caused development delays
- Why?
 - Because engineering changed the drawing
- Why?
 - Because the customer requested new features

During root cause analysis this tool is useful for determining, categorizing, and displaying effects and potential causes.

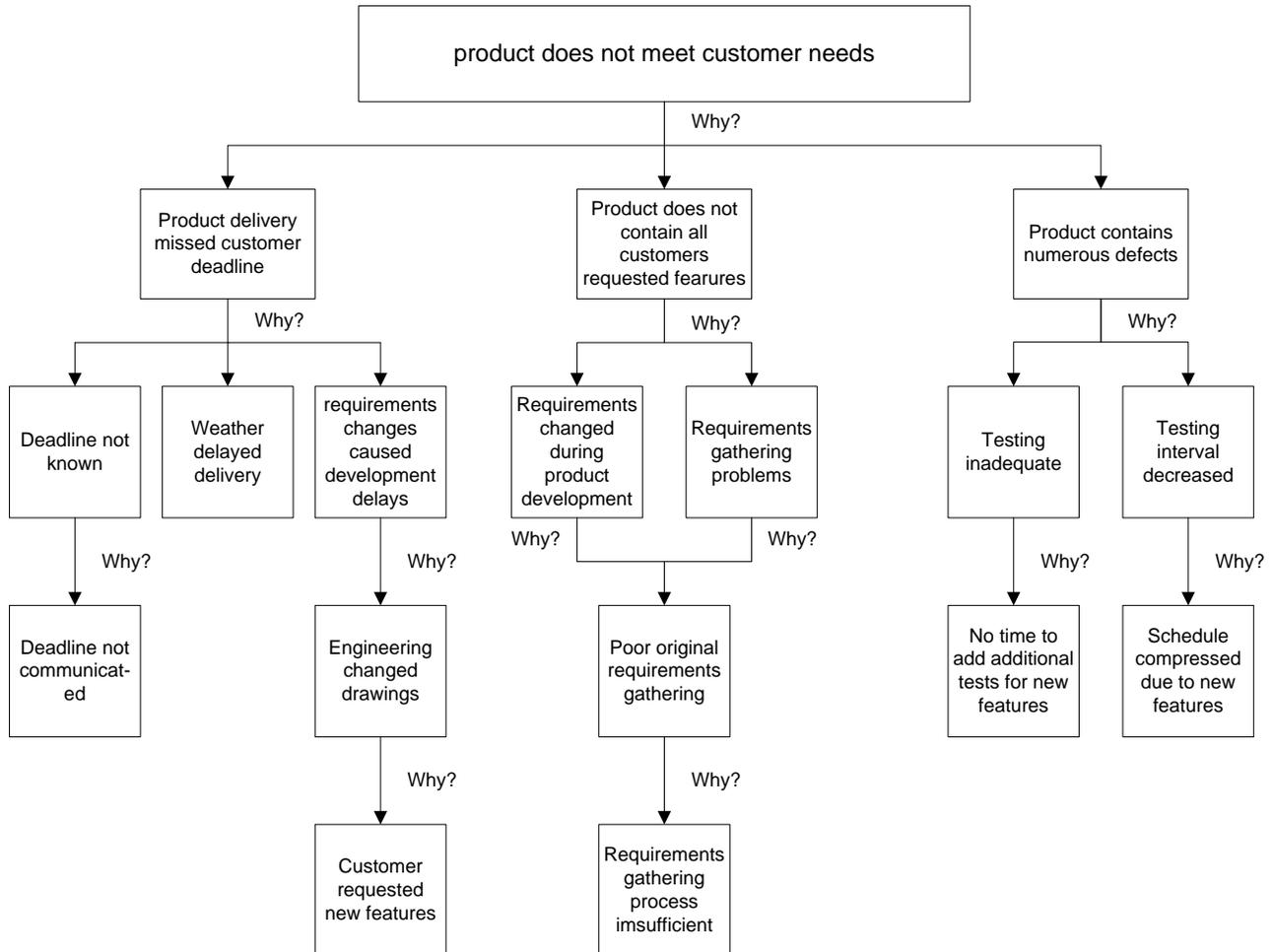
The logic tree (see below) provides a graphical representation of the application of the 5 Whys. The tree grows as more branches are added to it as a result of asking the 5 “whys”

Logic Tree

A **Logic Tree** is a diagram that shows the causes of events and the relationship among events. It is used to identify potential factors causing an overall effect. Each cause or reason for imperfection is a source of variation.

The Logic Tree can be constructed with the help of the 5 Whys Tool (see above). After defining the initial problem or event, use the 5 Whys tool to find the causes of each succeeding branch of the tree, until arriving at the root causes. In the example below “why?” is asked of the problem statement and again for each answer until the root causes are reached for each major branch.

During root cause analysis this tool is useful for determining, categorizing, and displaying root causes.



Logic Trees may also be constructed using AND or OR operators which are not illustrated here. AND is used to indicate when multiple lower level causes can only result in the problem when each of them is in a specified state at the same time. OR is used to indicate when any one or more lower level causes can result in the problem independently.

Brainstorming

Brainstorming is a method for generating a large number of ideas about the potential causes or sources of the problem quickly. Typically, the problem description is recorded on a flip chart so the entire group can see it. Using the flip chart, one person acts as the recorder and writes down ideas about the possible causes or sources of the problem as participants offer them. Participants are encouraged to generate as many possible causes or sources as possible with no evaluation or judgment made. Once the team has stopped generating potential causes or sources, they are clarified and duplicates eliminated. This leaves the team with a large list of possible causes or sources of the problem. These may be reduced through the use of quality tools such as Nominal Group Technique or Multi-voting.

During root cause analysis this tool is useful for generating a list of potential problems to be resolved or for generating a list of potential causes for an identified problem.

Cause and Effect Diagram

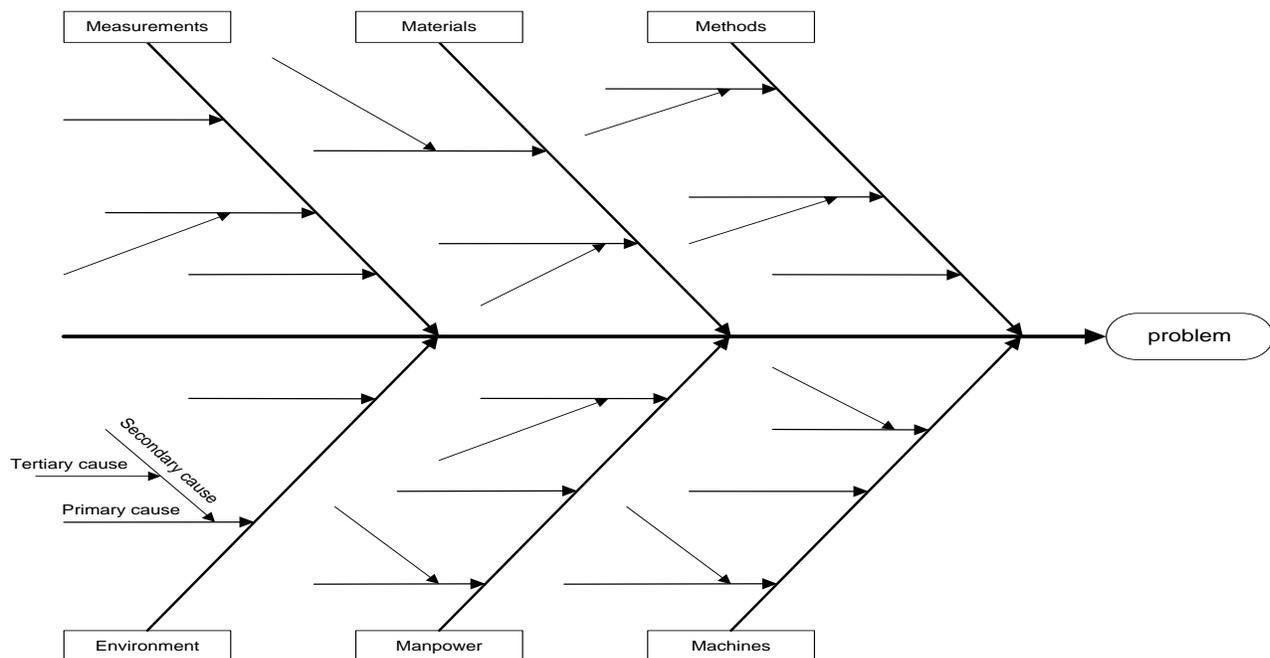
A **Cause and Effect Diagram** is a diagram that shows the causes of an event. The cause and effect diagram (also called **fishbone diagram** or **Ishikawa diagram**) is used to identify potential factors causing an overall effect. Each cause or reason for imperfection is a source of variation. Note: this definition of cause and effect diagram is different than that used by the DOE in *Root Cause Analysis Guidance Document, DOE-NE-STD-1004-92*.

The effect or problem is stated on the right side of the chart and the major influences or causes are listed on the left. Causes are grouped into major categories to identify the sources of variation. The categories typically include:

- Manpower: people involved with the process
- Methods: How the process is performed and the specific requirements for doing it, such as policies, procedures, rules, regulations, and laws.
- Machines: Any equipment, computers, tools, etc. required to accomplish the job
- Materials: Raw materials, parts, pens, papers, etc. used to produce the final product
- Measurements: Data generated from the process that are used to evaluate its quality
- Environment: the conditions such as location, time, temperature and culture in which the process operates.

In the example below, it can be seen that the major causes of the problem are broken down further into primary, secondary, and tertiary causes which fill in the “bones” of the fish

During root cause analysis this tool is useful for determining, categorizing, and displaying root causes.

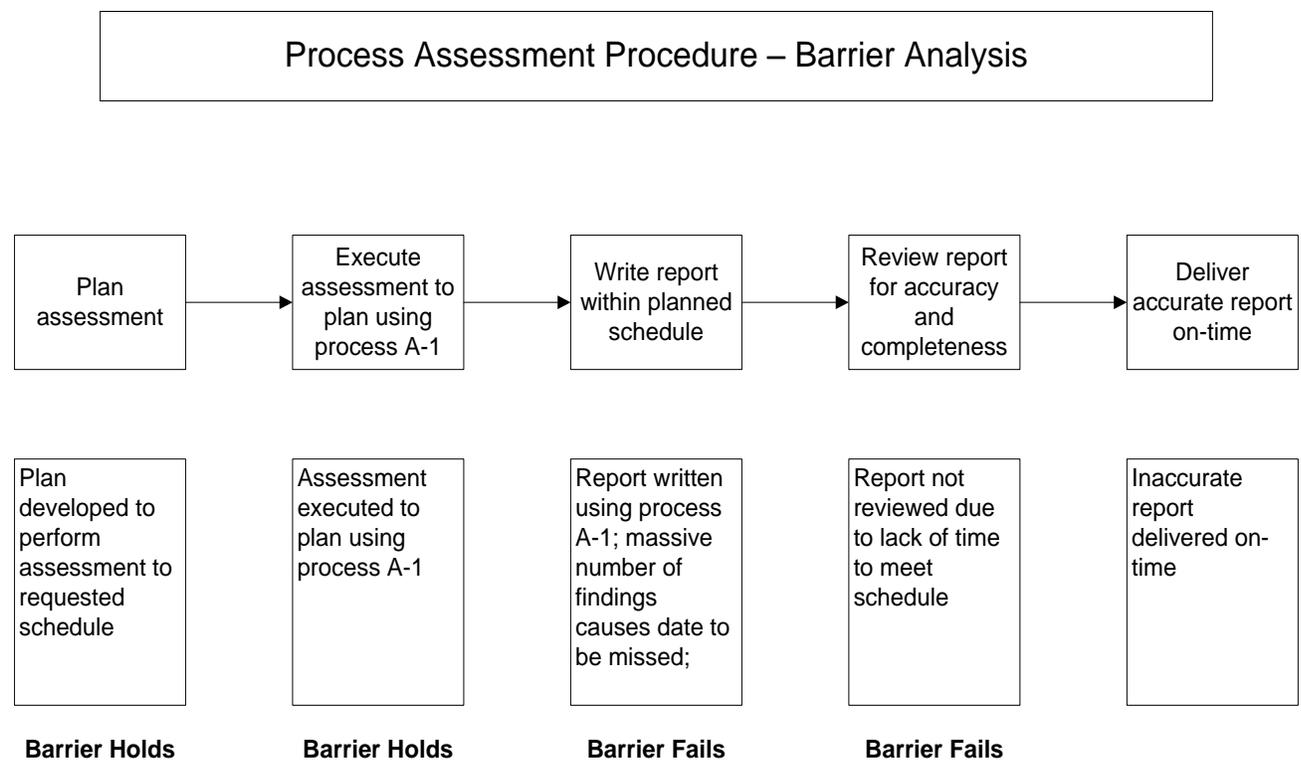


Barrier Analysis

Barrier analysis is a process used to identify failures in processes and systems. It begins by identifying the process failure. Next, the barriers already in place to protect against this failure occurring are identified. Then it is determined which of the barriers were effective and which failed, causing the problem. Next, it is determined what additional barriers need to be developed to ensure the failure does not happen again. Finally, a plan is developed to implement the new barriers and to strengthen existing barriers.

In the example below, the process failure is the delivery of an inaccurate report. Two Barriers held – planning the assessment and executing the assessment using the process, and two barriers failed – writing the report to schedule and reviewing the report. The failed barriers caused the overall process failure.

During root cause analysis this tool is useful for determining, categorizing, and displaying root causes, especially failure of process steps intended to prevent the problem from occurring or intended to detect an occurrence of the problem.



Collect Data

Check Sheet

A **Check Sheet** is a structured form that is used for collecting data in real time at the location where the data is generated. The check sheet is typically a blank form that is designed for the quick, easy, and efficient recording of the desired information, which can be either quantitative or qualitative.

A defining characteristic of a check sheet is that data is recorded by making tally marks ("checks") on it. A typical check sheet is divided into regions, and marks made in different regions have different significance. Data is read by observing the location and number of marks on the sheet. The check sheet is most useful when collecting data on the frequency or patterns of events, problems, defects, defect location, defect causes, etc.

In the example below reasons for product returns are recorded on the check sheet. For each reason, the number of returns is recorded per day. This allows the total returns for each day of the week and the total returns for each reason for the week to be easily calculated.

During root cause analysis this tool is useful for collecting and recording data.

Reason for return	Week 1					
	Monday	Tuesday	Wednesday	Thursday	Friday	Total
scratch	III	IIII II	II	II	IIII III	22
snag	I	IIII	III	II	III	14
Missing piece	II	IIII	III	IIII IIII	II	24
Wrong size	IIII III	III	IIII II	III	IIII IIII II	33
Wrong color	III	IIII	III	IIII IIII II	IIII	26
Total	17	24	18	31	29	119

Other quantitative tools include records of data collected during a multi-vari study or a statistically based sampling activity. Some qualitative data collection tools include interviews, observations, review of records and logs, and pictograms (concentration diagrams) to illustrate spatial orientation (location) of symptoms of the problem. Sometimes specialized laboratory tests may provide useful types of data.

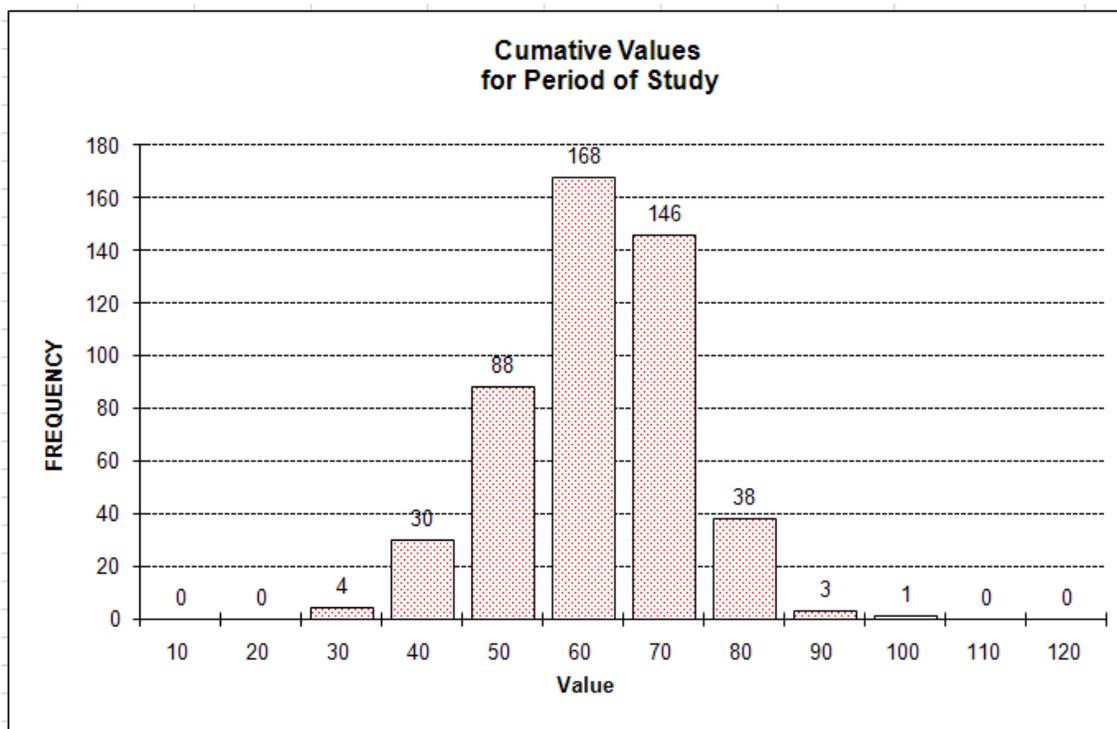
Analyze the Data

Histogram

A **Histogram** is a graphical display of a frequency distribution. It shows how often different values in a set of data occur within predetermined bins. It can be used to summarize data from a process that has been collected over time. It is important to understand the frequency distribution of any data set prior to performing any formal statistical analysis. To construct a histogram individual observations are counted in bins located on the x-axis and the frequency in each bin is plotted on the y-axis. There are a number of rules of thumb and formulas available to determine the optimum number of bins for a given data set.

In the example below the center of each bin is displayed as 30, 40, 50 and so on. The value 30 represents observations in the range (bin) 26 to 35, the value 40 represents observations between 36 and 45 and so on. The y-axis indicates a frequency of 4 observations in the first bin, 30 observations in the second bin, 88 observations in the third bin and so on.

During root cause analysis this tool is useful for displaying and analyzing the frequency distribution of data.

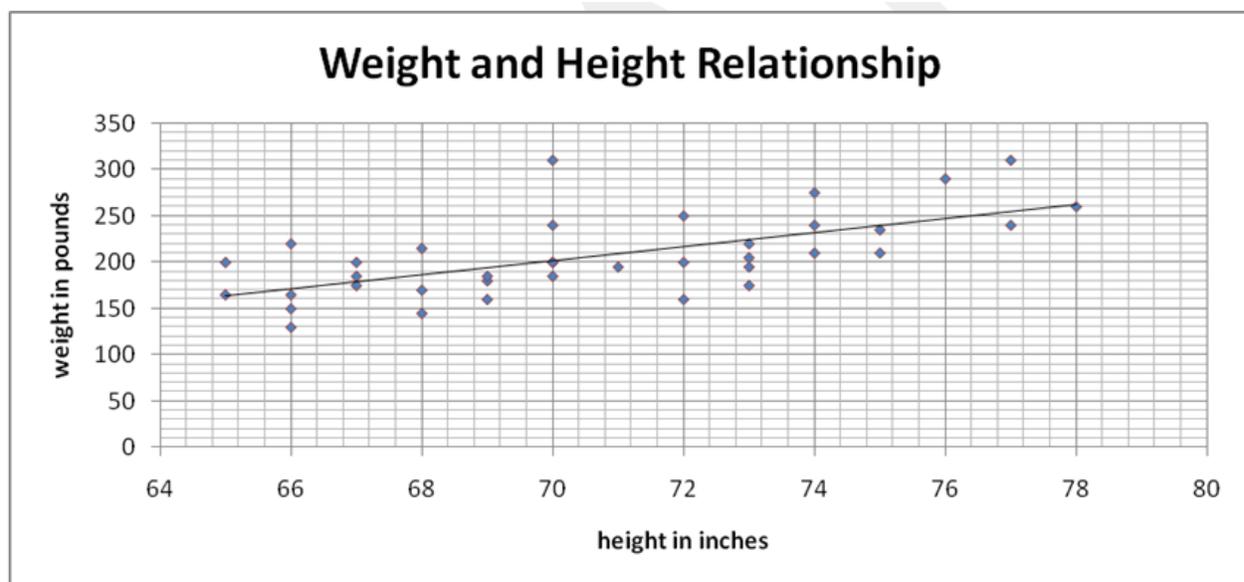


Scatter Diagram

A **Scatter Diagram** is a type of diagram that displays pairs of numerical data, with one variable on each axis, to look for a relationship between them. The data is displayed as a collection of points with each point having the value of one variable determining its position on the horizontal axis and the value of the other variable determining its position on the vertical axis. The points suggest various kinds of correlations between the variables such as positive (rising), negative (falling), or null (uncorrelated). A line of best fit (sometimes called a trend line) can be drawn to study the correlation between the variables.

In the example below weight and height of individuals are the 2 variables plotted on the graph. A trend line has been drawn which shows a positive (rising) correlation between weight and height – that is, as weight increases, height tends to increase as well.

During root cause analysis this tool is useful for displaying and analyzing the relationship or correlation between 2 variables.



Control Chart

A **Control Chart** is a graph used to study how a process changes over time. A control chart is really a run chart that contains statistically determined upper and lower control limits drawn on either side of the process average center line. The control limits indicate the threshold at which the process is considered to be in or out of control. Control charts are often interpreted using additional rules such as the number of consecutive values above or below some value or an upward or downward trend inside the control chart lines.

Variations of the process points within the control limits are due to variation built into the process, also called common causes. Variation of the process points outside the control limits (and other rules violations) are due to causes outside the process, also called special causes. The purpose of

control charts is to monitor, control, and improve process performance over time by detecting variation and its causes.

In the example below the process is considered to be in control, because all points lie between the upper and lower control limits. Variation in individual points is due to variation built into the process, also known as common cause.

During root cause analysis this tool is useful for displaying and analyzing process behavior over time. By investigating conditions leading to out of control situations it is possible to uncover clues as to the underlying causes.



Statistical Techniques

Statistical techniques are formal statistical models, methods and procedures used to analyze results of experiments or to monitor process outcomes as time series. Most of these techniques are beyond the scope of this document. A few types of statistical techniques are process capability analysis, Hypothesis Tests, Design of Experiments, and Regression Analysis.