**INTRODUCTION:**

This Attachment is intended to provide basic knowledge on the Root Cause Analysis (RCA) tools used during investigation of Quality or system issues for example, but not limited to Deviations/Incidents, Market complaints, Product failures. This Attachment is not intended to define detailed procedure for each RCA tool and does not restrict the user to establish other scientific approaches available for implementation of RCA tools. This Attachment provides a basic knowledge of various RCA tools. For any further details, it is recommended to refer to the “INTERNATIONAL STANDARD” published by the “INTERNATIONAL ELECTROTECHNICAL COMMISSION” or equivalent standardized organizations.

**RCA TOOLS:**

Some of the simple techniques that can be used for RCA are as follows:

1. **BRAIN STORMING:**

Brainstorming is a group or individual creativity technique by which efforts are made to find a conclusion for a specific problem by gathering a list of ideas spontaneously contributed by its member(s). Brainstorming technique is considered to be more effective than individuals working alone in generating ideas.

There are two principles that contribute to "ideation efficacy," these being:

* Defer judgment and
* Reach for quantity

Following these two principles, four general rules of brainstorming were established with intention to reduce social inhibitions among group members, stimulate idea generation and Increase overall creativity of the group.

* Focus on quantity: This rule is a means of enhancing divergent production, aiming to facilitate problem solving through the maxim quantity breeds quality. The assumption is that the greater the number of ideas generated, the greater the chance of producing a radical and effective solution.
* Withhold criticism: In brainstorming, criticism of ideas generated should be put on hold, instead, participants should focus on extending or adding to ideas, reserving criticism for a later “critical stage” of the process. By suspending judgment, participants will feel free to generate unusual ideas. Welcome unusual ideas: To get a good and long list of ideas, unusual ideas are welcomed. They can be generated by looking from new perspectives and suspending assumptions. These new ways of thinking may provide better solutions.
* Combine and improve ideas: Good ideas may be combined to form a single better good idea, as suggested by the slogan "1+1=3". It is believed to stimulate the building of ideas by a process of association.
1. **AFFINITY DIAGRAM:**

The affinity diagram is a tool used to organize ideas and data. The tool allows large numbers of ideas stemming from brainstorming to be sorted into groups, based on their natural relationships, for review and analysis. The process involves the following steps:

* Record each idea on cards or notes
* Look for ideas that seem to be related
* Sort cards into groups until all cards have been used.

Once the cards have been sorted into groups, the team may sort large clusters into subgroups for easier management and analysis. Once completed, the affinity diagram may be used to create a cause and effect diagram. In many cases, the best results tend to be achieved when the activity is completed by a cross-functional team, including key stakeholders. The process requires becoming deeply immersed in the data, which has benefits beyond the tangible deliverables.

1. **CHECK SHEET:**

The check sheet is a **form (document)** used to collect data in real time at the location where the data is generated. The data it captures can be quantitative or qualitative. When the information is quantitative, the check sheet is sometimes called a tally sheet. The defining characteristic of a check sheet is that data are recorded by making marks ("checks") on it. A typical check sheet is divided into regions, and marks made in different regions have different significance. Data are read by observing the location and number of marks on the sheet.

**Check sheets typically employ a heading that answers the Five W’s:**

* Who filled out the check sheet?
* What was collected (what each check represents, an identifying batch or lot number)?
* Where the collection took place (facility, room, and apparatus)?
* When the collection took place (hour, shift, day of the week)?
* Why the data were collected?

**Identify five uses for check sheets as:**

* To check the shape of the probability distribution of a process.
* To quantify defects by type.
* To quantify defects by location.
* To quantify defects by cause (machine, worker).
* To keep track of the completion of steps in a multistep procedure (in other words, as a checklist).
1. **ISHIKAWA DIAGRAM:**

Ishikawa diagrams are also called as fishbone diagrams, herringbone diagrams, causeand- effect diagrams, or Ishikawa. Ishikawa diagrams are causal diagrams created that show the causes of a specific event. Common uses of the Ishikawa diagram are product design and quality defect prevention, to identify potential factors causing an overall effect. Each cause or reason for imperfection is a source of variation. Causes are usually grouped into major categories to identify these sources of variation. The categories typically include:

* Man: Anyone 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, paper, 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 process operates.

**Fishbone Diagram Example**

**Measurements**

In-process controls, Monitoring frequency, observations, Test Results, Experiment’s results, Statistical evaluation of Analytical results, Compliance with specification, Critical Control points and Critical control parameters, Validation, Calibration- Qualification data

**Men**

Education + Training Factors:

Competence

Supervision,

Training evidence,

Appropriateness of training

methodology, doer level training

evidence, and effectiveness.

**Environment**

Working condition factors**:** Administrative / supervisory structure, Design of physical environment- working space, orderliness of Activities, Quality of Environmental condition: Trend of observation –Temp/ %RH, EM trend, any unusual

appropriateness of Staffing Workload and working hours (times)

**Material**

Input material’s Quality,

Correctness and controls of input,

Specifications,

Grades - Pharmacopoeial;

Critical Quality Attribute, Trend

analysis, History of failure of Quality

**Method**

Procedures/

Protocols,

Decision aids,

Task design,

Instructions, SOPs,

Display- guidance for operations,

User guide-Recommendations

**Machine**

Equipment condition,

Maintenance,

Controls,

Integrity,

Positioning,

Usability, Equipment Ancillary

component relationships,

Calibration/Qualification status

**Problem or**

**issue**

1. **SCATTER DIAGRAM:**

Also called: scatter plot, X–Y graph. The scatter diagram graphs pairs of numerical data, with one variable on each axis, to look for a relationship between them. If the variables are correlated, the points will fall along a line or curve. The better the correlation, the tighter the points will hug the line.

1. When to use a Scatter Diagram:
* When there is a paired numerical data.
* When dependent variable may have multiple values for each value of independent variable.
* When trying to determine whether the two variables are related, such as:
* When trying to identify potential root causes of problems.
* After brainstorming causes and effects using a fishbone diagram, to determine objectively whether a particular cause and effect are related.
* When determining whether two effects that appear to be related, both occur with the same cause.
* When testing for autocorrelation before constructing a control chart.
1. Scatter Diagram Procedure:
2. Collect pairs of data where a relationship is suspected.
3. Draw a graph with the independent variable on the horizontal axis and the dependent variable on the vertical axis. For each pair of data, put a dot or a symbol where the x-axis value intersects the y-axis value. (If two dots fall together, put them side-by-side, touching, so that you can see both.)
4. Look at the pattern of points to see if a relationship is obvious. If the data clearly form a line or a curve, you may stop. The variables are correlated. Regression or correlation analysis can be used now. Otherwise, complete Steps 4 through 7.
5. Divide points on the graph into four quadrants. If there are X points on the graph:
* Count X/2 points from top to bottom and draw a horizontal line.
* Count X/2 points from left to right and draw a vertical line.
* If number of points is odd, draw the line through the middle point.
1. Count the points in each quadrant. Do not count points on a line.
2. Add the diagonally opposite quadrants. Find the smaller sum and the total of points in all quadrants.

A = points in upper left + points in lower right

B = points in upper right + points in lower left

Q = the smaller of A and B

N = A + B

1. Look up the limit for N on the trend test table (Table 1).
* If Q is less than the limit, the two variables are related.
* If Q is greater than or equal to the limit, the pattern could have occurred from random chance.

Table 1



1. **CONTROL CHART:**

The control chart is a graph used to study how a process changes overtime. Data are plotted in time order. A control chart always has a central line for the average, an upper line for the upper control limit, and a lower line for the lower control limit. These lines are determined from historical data. By comparing current data to these lines, conclusions can be drawn about whether the process variation is consistent (in control) or is unpredictable (out of control, affected by special causes of variation).Control charts for variable data are used in pairs. The top chart monitors the average, or the centering of the distribution of data from the process. The bottom chart monitors the range, or the width of the distribution. If the data were shots in target practice, the average is where the shots are clustering, and the range is how tightly they are clustered. Control charts for attribute data are used singly.

1. When to Use a Control Chart:
* When controlling ongoing processes by finding and correcting problems as they occur.
* When predicting the expected range of outcomes from a process.
* When determining whether a process is stable (in statistical control).
* When analyzing patterns of process variation from special causes (nonroutine events) or common causes (built into the process).
* When determining whether quality improvement project should aim to prevent specific problems or to make fundamental changes to the process.
1. Control Chart Basic Procedure:
* Choose the appropriate control chart for the data.
* Determine the appropriate time period for collecting and plotting data.
* Collect data, construct the chart and analyze the data.
* Look for “out-of-control signals” on the control chart. If identified, mark it on the chart and investigate the cause.
* Document the investigation, learning, the cause and how it was corrected.
* Continue to plot data as they are generated. As each new data point is plotted, check for new out-of-control signals when you start a new control chart, the process may be out of control. If so, the control limits calculated from the first 20 points are conditional limits. When you have at least 20 sequential points from a period when the process is operating in control, recalculate control limits.
1. **HISTOGRAM:**

A frequency distribution shows how often each different value in a set of data occurs. A histogram is the most commonly used graph to show frequency distributions. It looks very much like a bar chart, but there are important differences between them.

1. When to Use a Histogram:
* When the data are numerical.
* When you want to see the shape of the data’s distribution, especially when determining whether the output of a process is distributed approximately normally.
* When analyzing whether a process can meet the customer’s requirements.
* When analyzing what the output from a supplier’s process looks like.
* When seeing whether a process change has occurred from one time period to another.
* When determining whether the outputs of two or more processes are different.
* When you wish to communicate the distribution of data quickly and easily to others.
1. Histogram Construction:
* Collect at least 50 consecutive data points from a process.
* Use an Excel worksheet or equivalent to set up the histogram.
* Do not allow for spaces between bars.
1. Histogram Analysis:
* Before drawing any conclusions from your histogram, ensure that the process was operating normally during the time period being studied. If any unusual events affected the process during the time period of the histogram, the analysis of histogram shape probably cannot be generalized to all time periods.
* Analyze the meaning of your histogram’s shape.
* A frequency distribution shows how often each different value in a set of data occurs. A histogram is the most commonly used graph to show frequency distributions.

**Interpreting Histogram**



**Interpreting process variation**



1. **PARETO CHART:**

Also called: Pareto diagram, Pareto analysis

Variations: Weighted Pareto chart, comparative Pareto charts

A Pareto chart is a bar graph. The lengths of the bars represent frequency or severity and are arranged with longest bars on the left and the shortest to the right. In this way, the chart visually depicts which situations are more significant.

1. When to Use a Pareto Chart:
* When analyzing data about the frequency of problems or causes in a process.
* When there are many problems or causes and to focus on the most significant.
* When analyzing broad causes by looking at their specific components.
* When communicating with others about data.
1. Pareto Chart Procedure:
2. Decide the categories to group items.
3. Decide what measurement is appropriate. Common measurements are frequency, quantity, etc.
4. Decide what period of time the Pareto chart will cover: One work cycle? One full day? A week? Etc.
5. Collect the data, record the category each time. (Or assemble data that already exist.)
6. Subtotal the measurements for each category.
7. Determine the appropriate scale for the measurements collected. The maximum value will be the largest subtotal from Step 5. (If Steps 8 and 9 below are done, the maximum value will be the sum of all subtotals from Step 5). Mark the scale on the left side of the chart.
8. Construct and label bars for each category. Place the tallest at the far left, then the next tallest to its right and so on. If there are many categories with small measurements, they can be grouped as “other.” Steps 8 and 9 are optional, but are useful for analysis and communication.
9. Calculate the percentage for each category: The subtotal for that category divided by the total for all categories. Draw a right vertical axis and label it with percentages. Be sure the two scales match: For example, the left measurement that corresponds to one-half should be exactly opposite 50% on the right scale.
10. Calculate and draw cumulative sums: Add the subtotals for the first and second categories, and place a dot above the second bar indicating that sum. To that sum add the subtotal for the third category, and place a dot above the third bar for that new sum. Continue the process for all the bars. Connect the dots, starting at the top of the first bar. The last dot should reach 100% on the right\ scale.

Example of a chart is as follows:



1. **5 – WHY’s:**
2. Ask 5 - Why for each probable root cause:

For example:

* The complete Analysis on Gas Chromatograph was invalid.Why?
* The Chromatogram is invalid in a sequence of injection for system suit. Why?
* The area of third Run was out of the trend, most probably there was carryover from previous run. Why?
* May be due to release of deposits (condensate) from inner wall of liner. Why?
* It had not been regularly checked for cleanliness. Why?
1. Benefits of 5 – Whys
* Simplicity. It is easy to use and requires no advanced mathematics or tools.
* Effectiveness. It truly helps to quickly separate symptoms from causes and identify the root cause of a problem.
* Comprehensiveness. It aids in determining the relationships between various problem causes.
* Flexibility. It works well alone and when combined with other quality improvement and troubleshooting techniques.
* Engaging. By its very nature, it fosters and produces teamwork and teaming within and without the organization.
1. 5 - Whys worksheet



1. **FLOW CHART:**

A flow chart is a pictorial representation showing all of the steps of a process.



1. Creating a Flow Chart:
* First, familiarize the participants with the flow chart symbols.
* Draw the process flow chart and fill it out in detail about each element.
* Analyze the flow chart. Determine which steps add value and which do not in the process of simplifying the work.
* When Activity Flow Chart Used?
* To identify all possible activity and suspected actions may be a root cause.
* To identify each Critical steps of process, so that we can assess the severity of risk.
* Communicate information to the team and to focus on all possible steps of decision making.
1. When Activity Flow Chart Used?
* Define and analyze processes.
* Build a step-by-step picture of the process for analysis, discussion, or communication.
* Define, standardize, or find areas for improvement in a process.
* To identify all possible activity and suspected actions may be a root cause.
* To identify each Critical step of process so that the severity of risk can be assessed.
* Communicate information to the team and to focus on all possible steps of decision making.
1. How to Use the Tool:
* Most flow charts are made up of three main types of symbols:
* Elongated circles, which signify the start or end of a process.
* Rectangles, which show instructions or actions.
* Diamonds, which show decisions that must be made

* Within each symbol, write down what the symbol represents. This could be the start or finish of the process, the action to be taken, or the decision to be made.
* Symbols are connected one to the other by arrows, showing the flow of the process.
1. **PROCESS CAPABILITY:**

Process capability means ability of the process to meet technological or requirement of Quality attributes to fulfill demands put on it. Measurement of process capability is determined by total variation caused by random reasons influencing the process. Variation is caused by variability of the measured quantity values that are not connected to the measurement conditions and must be excluded. Therefore, it is recommended to perform preventive measurements. Hence, the process capability measurement in concept helps in identifying the process variability and gives the signal whether the process is under control or not. Process capability provides a measurement of process performance, if the process is centered, measurement is always capable when capability index value (Cp, Cpk, respectively Cpm) exceeds 1.0. Practical recommendation considers minimal acceptable value 1.33. The status of the process control is given in following Figure 1.

Figure1



1. Use of process capability:
* Identify defined processes
* Identify measurable attributes of the process
* Characterize natural variation of attributes
* Track process variation
* If the process is in control, continue to track
* If the process is not in control:
* Identify assignable cause
* Remove assignable cause
* Return to “Track process variation”



1. Calculation of process capability:

A process capability index uses both the process variability and the process specifications to determine whether the process is "capable”. It is often required to compare the output of a stable process with the process specifications and make a statement about how well the process meets specification. To do this, we compare the natural variability of a stable process with the process specification limits. A process where almost all the measurements fall inside the specification limits is a capable process. This can be represented pictorially by the plot below:



There are several statistics that can be used to measure the capability of a process: Cp, Cpk, and Cpm. Most capability indices estimates are valid only if the sample size used is “large enough”. Large enough is generally thought to be about 50 independent data values. The Cp, Cpk, and Cpm statistics assume that the population of data values is normally distributed. Assuming a two-sided specification, if and are the mean and standard deviation, respectively, of the normal data and USL, LSL, and T are the upper and lower specification limits and the target value, respectively, then the population capability indices are defined as follows:





To get an idea of the value of the Cp statistic for varying process widths, consider the following plot in Figure 2.



1. **Failure Mode Effect Analysis (FMEA):**

FMEA provides for an evaluation of potential failure modes for processes and their likely effect on outcomes and/or product performance. Once failure modes are established, risk reduction can be used to eliminate, contain, reduce or control the potential failures. FMEA relies on product and process understanding. FMEA methodically breaks down the analysis of complex processes into manageable steps. It is a powerful tool for summarizing the important modes of failure, factors causing these failures, and the likely effects of these failures.

* + 1. FMEA is essentially used to:
* Identify the equipment or subsystem, mode of operation and the equipment;
* Identify potential failure modes and their causes;
* Evaluate the effects on the system of each failure mode;
* Identify measures for eliminating or reducing the risks associated with each failure mode;
* Identify trials and testing necessary to prove the conclusions; and
* Provide information to the operating personnel, so that they understand the capabilities and limitations of the system to achieve best performance.
	+ 1. FMEA Process: At the beginning of an FMEA, it is important that a certain number of issues be agreed or set up. These are:
* Selecting the team.
* Defining the standard.
* Defining the reporting procedures.
* Defining the boundaries of the system to be analyzed.
* Organizing system design information.
	+ 1. During the FMEA, the process includes:
* Evaluating the effects of each failure mode on the system.
* Identifying failure detection methods.
* Arranging audits if required.
* Arranging practical FMEA tests.
* Identifying corrective actions.
* Advising of any recommendations.
	+ 1. Completion of the FMEA entails:
* Producing the FMEA Report.
* FMEA Documentation and conclusion.
1. **Fault Tree Analysis (FTA):**

The FTA tool is an approach that assumes failure of the functionality of a product or process. This tool evaluates system (or sub-system) failures one at a time, but can combine multiple causes of failure by identifying causal chains. The results are represented pictorially in the form of a tree of fault modes. At each level in the tree, combinations of fault modes are described with logical operators (AND, OR, etc.). FTA relies on the experts’ process understanding to identify causal factors.

* + 1. Potential Areas of Use(s): FTA can be used to establish the pathway to the root cause of the failure. FTA can be used to investigate in order to fully understand their root cause and to ensure that intended improvements will fully resolve the issue and not lead to other issues (i.e., solve one problem yet cause a different problem). Fault Tree Analysis is an effective tool for evaluating how multiple factors affect a given issue. The output of an FTA includes a visual representation of failure modes. It is also useful for risk assessment and in developing monitoring programs.
		2. FTA Process: FTA is a top-down failure analysis used for discovering the root causes of failures or potential failures. It uses Boolean logic to combine a series of lower-level events. The symbols used in a single FTA Logic Diagram are called Logic Gates and are similar to the symbols used by electronic circuit designers. An FTA is a status-driven analysis where the inputs to a Logic Gate represent the status of a part and/or other factor being included in the analysis. Other factors can include such things as training, tools, safety equipment, supervision, etc. The output from a Logic Gate is a logic state that represents a condition that exists in the system. An event occurs when the output of a Gate changes state. If a part or other factor is functioning correctly, the state is TRUE. If the part or other factor is malfunctioning, the state is FALSE. When a logic statement is TRUE it is assigned a Boolean logic value of one (1). When a logic statement is FALSE it is assigned a Boolean logic value of zero (0). All Boolean algebra rules are applicable.

An FTA is performed by systematically determining what happens to the system when the status of a part or other factor changes. The minimum criterion for success is that no single failure can cause a Quality or a system issue. Where extreme hazards/impact exists, the criteria may be increased to require toleration of multiple failures. An FTA requires consideration of both positive and negative events. The logic tree segments leading to a Negative Event defines all of the things that could go wrong to cause the negative event. Logic tree segments for negative events usually use more OR gates than AND gates, except for redundant safeguards. The logic tree segment leading to a positive event defines all of the things that must work together to achieve a process without any deviation/ incident/nonconformance/ failure or an event. Logic trees for positive events generally use more AND gates than OR gates, except for redundancy.