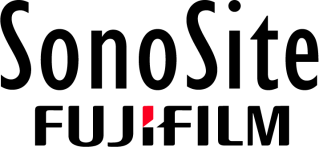
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| **Document Number:** | **D25739** |
| **Revision:** | **A** |
| **Title:** | **Root Cause Analysis Procedure** |

**CHANGE HISTORY:**

|  |  |  |
| --- | --- | --- |
| **Revision** |  | **Description of Change** |
| A |  | First Release |

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1. PURPOSE AND SCOPE

To establish a procedure for documenting and investigating nonconformities, product-quality related failure trends, or process related issues, to determine root cause. This procedure may be applied within Quality Management System elements such as D00054 Corrective and Preventive Action, D00064, Control of Nonconformances, D00067, Complaint/Incident Reporting Procedure, or D00090, Engineering Issues System and may be applicable within other business processes.

1. PROCESS OWNER

CAPA Review Board Chair

1. DEFINITIONS
   1. Root Cause: The most basic cause (or causes) that can reasonably be identified through failure/incident investigation.
2. PROCEDURE
   1. Recording Root Cause Analysis
      1. Root Cause Analysis may be recorded within D00054 Corrective and Preventive Action, D00064, Control of Nonconformances, D00067, Complaint/Incident Reporting Procedure, or D00090, Engineering Issues System.
      2. Root Cause Analysis that is not QMS relevant may recoded on **F00736, Eight Discipline** **(8D) Report**
   2. Root Cause Analysis
      1. Root Cause Analysis is often a multi-step process to understand and narrow possible causes until the Root Cause(s) is identified. The Root Cause is the most basic cause (or causes) that can reasonably be identified.
      2. Define the Problem Statement
         1. A good problem statement includes enough information to facilitate decision making:
            1. Provide a brief description of the problem and the metric used to describe the problem.
            2. Convey relevant information to someone unfamiliar with the problem.
            3. Specify the problem by identifying in quantifiable terms the who, what, where, when, why, how, and how many (5W2H) for the problem.
         2. **F00737, Is / Is Not Template** may be helpful in refining the scope of a problem statement
         3. **F00738, Check sheet** may be used if additional data collection is required in order to understand when defects occur to develop the Problem Statement. A Check Sheet is a structured, prepared form for collecting and analyzing data. The Check Sheet template includes:
            1. Histogram: The most commonly used graph for showing frequency distributions, or how often each different value in a set of data occurs.
            2. Bar Chart: Shows the number/count of defects.
            3. Pareto chart: A bar graph that shows which factors are more significant
         4. When data analysis is used valid statistical methods must be employed per **D00098, Statistical Techniques**. Rates, trends, pareto diagrams, and/or control charts may be useful in conveying the problem statement.
      3. Identify Root Cause
         1. Identifying the correct Root Cause is essential to ensuring the right actions are taken to correct the problem.
         2. The following tools and templates are available for Root Cause Analysis.:
            1. **F00741, Flow Chart and Gemba Observations** are used to develop understanding of how a process works. Often used in conjunction with the Fishbone Diagram and/or the Five Why Tool.
            2. **F00739, Fishbone Diagram** (also called Ishikawa or Cause-and-Effect diagrams): Identifies many possible causes for an effect or problem and sorts ideas into useful categories. The results of the Fishbone diagram are often narrowed by the use of additional Root Cause Analysis Tools, such as the Five Why Tool and/or the Flow Chart and Gemba Observations template.
            3. **F00740, 5-Why Tool:** a questioning process designed to drill down into the details of a problem. Often used in conjunction with the Fishbone Diagram and/or the Flow Chart and Gemba Observations template. This tool can be used in solitary when the problem is not complex.
            4. **F00723, Template, Root Cause Analysis (QVS)** is a checklist consisting of possible design-related causes that may be considered. The results of the analysis may be narrowed by the use of additional Root Cause Analysis Tools, such as the Five Why Tool and/or the Flow Chart and Gemba Observations template.
         3. Additional Problem Solving templates are made publicly available by the American Society for Quality (ASQ).
         4. When adequate information is not available to determine Root Cause (e.g. a unit related to a complaint is not returned for failure analysis), then Probable Cause may be determined by engineering analysis, history review, and/or trend analysis.
      4. Verifying Root Cause
         1. The identified Root Cause(s) may be verified against the Problem Statement by using the following tool:
            1. F00742, Change, How
3. REFERENCES/ATTACHMENTS:

* D00044, Corrective and Preventive Action
* D00064, Control of Nonconformances
* D00067, Complaint/Incident Reporting Procedure
* D00090, Engineering Issues System
* D00098, Statistical Techniques
* F00736, Eight Discipline (8D) Report
* F00737, Is / Is Not Template
* F00738, Check sheet
* F00739, Fishbone diagram
* F00740, 5-Why tool
* F00741, Flow Chart and Gemba Observations
* F00723, Template, Root Cause Analysis (QVS)
* F00742, Change, How