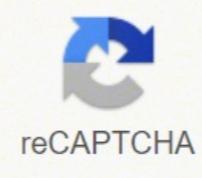




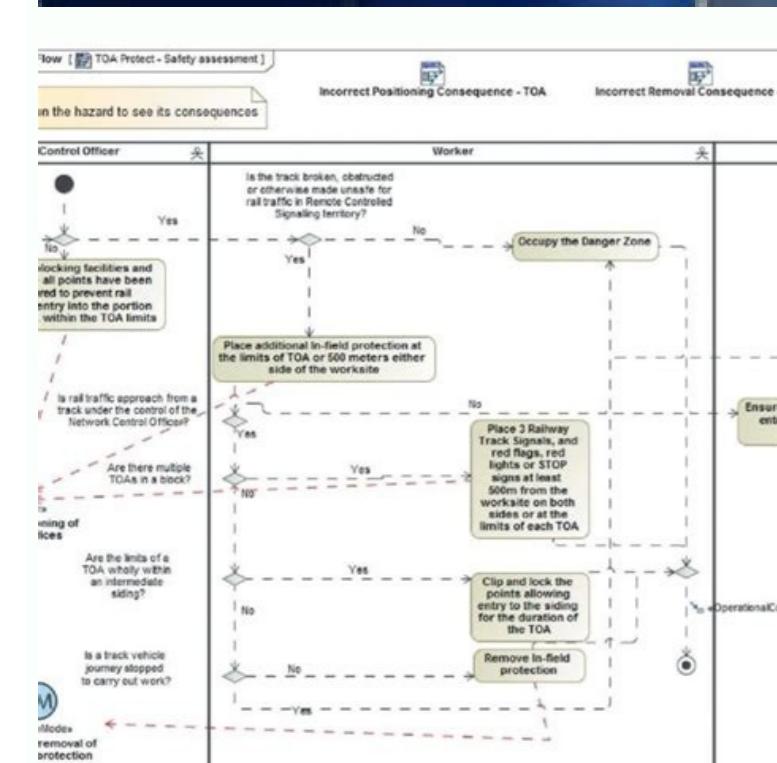
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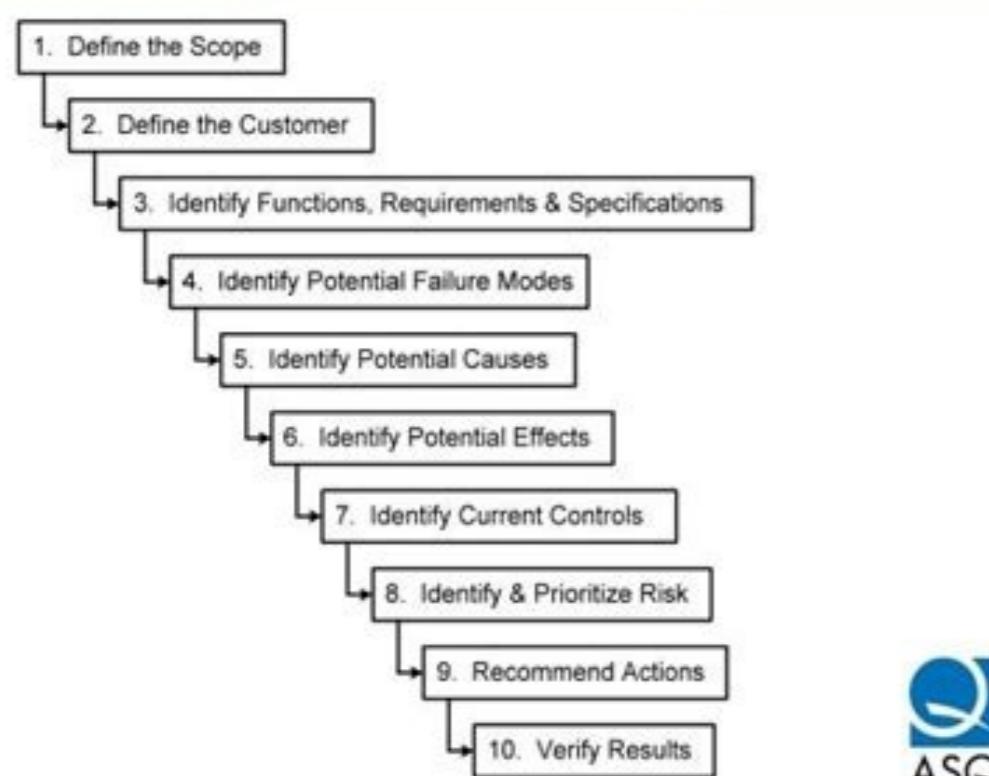
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Fmea steps pdf



A *Process Flow* for FMEA



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Mode Discovery Perform an FMEA occasionally throughout the life of a process. There are seven steps to develop a FMEA: FMEA prÃ©-work and assemble the development of the FMEA team 1 Development (requirements through severity classification) Path 2 Development (possible causes and controls of prevention through occurrence classification) Path 3 Development (tests and controls of detection through % of detection Ranking) Action Priority and Assignment Actions Takes / Design Ranking RPN and Closure The steps for the realization of FMEA are as follows: FMEA prÃ©-work and assembly of the FMEA team prÃ©-work involves the collection and creation of key documents. Completed columns are: review recommended actions and assign RPN for additional monitoring Monitoring Actions to ensure appropriate actions ACTION DATES OF ACTIONS TUMAR / Design Review FMEA actions are closed when counter measures have been taken and are successful in risk reduction. The FMEA approach used by quality - one has been developed to avoid topical pitfalls that make analysis slow and ineffective. The original RPN is compared to the revised RPN and the relative improvement for the project or process was confirmed. The hands % all problem solving are completed faster, using easy localization, pre-ordered information % brainstromed from an FMEA. This is % done commonly and is a practice that leads to bad behavior of the team. FMEs that do not encounter risk are considered weak and not valued. The objective of a FMEA is % discover and mitigate the risk. Actions should not be determined based on an RPN threshold value. Data collected from problem solving are placed in an FMEA for future planning of new products or process quality. The columns completed in path 2 are: possible causes / mechanisms of failures current prevention controls (this is %, standard work, revloser revloser arap sadivlovesed ofÃš sadacidni sejÃšÄa es ,siaicepse sacitsÃretcarac ed ofÃšÄacifissalc adac arap aicnÃÄrroco ed sgniknaR).cte ,sodidecus-meb etnemroiretna risk Severity and Occurrence combinations, defined in the Quality-One Criticality Matrix Path 3 Development- (Testing and Detection Controls through Detection Ranking) Path 3 Development involves the addition of Detection Controls that verify that the design meets requirements (for Design FMEA) or cause and/or failure mode, if undetected, may reach a customer (for Process FMEA). FMEA Three Path Model FMEA Three Path Model Boundary Diagram Example Boundary Diagram Example Parameter Diagram Example Process Flow Diagram Process Flow Diagram Characteristics Matrix FMEA Severity Table FMEA Severity Table FMEA Occurrence Table FMEA Occurrence Table FMEA Detection Table FMEA Detection Table RPN Action Example FMEA Criticality Matrix FMEA Example FMEA Criticality Matrix FMEA Example Quality-One offers Quality and Reliability Support for Product and Process Development through Consulting, Training and Project Support. The Quality-One Three Path Model allows for prioritization of activity and efficient use of team time. FMEA is one of many tools used to discover failure at its earliest possible point in product or process design. The steps are separated to assure that only the appropriate team members for each step are required to be present. Functions should be written in verb-noun context. Failure Mode and Effects Analysis is designed to identify, prioritize and limit these failure modes. Quality-One does not recommend the use of RPN thresholds for setting action targets. Possible causes in an FMEA are immediately used to jump start Fishbone or Ishikawa diagrams. Columns completed in Step 7: Re-ranked Severity Re-ranked Occurrence Re-ranked Detection Re-ranked RPN Generate new Actions, repeating Step 5, until risk has been mitigated Comparison of initial RPN and revised RPN FMEA Document Analysis Deciding when to take an action on the FMEA has historically determined by RPN thresholds. Effects are the ways in which these failures can lead to wastes, defects or results that are harmful to the customer. There are numerous examples of high-profile product recalls resulting from poorly designed products and/or processes. The examination of a FMEA shall include consideration of non-compliant groups, including: 9/10 Severity or Security and Regulation in isolation (Failure Mode Action) Criticality to Severity and Occurrence (Cause %) Detect (Action) Controls One for a lower risk position. Discovering a Product Development Failure (PD) using FMEA provides the benefits of: Multiple choices to mitigate risk Increased ability to verify and validate changes Collaboration between product design and process Improved design for manufacturing and assembly (DFM/A) % lower cost solutions Legacy, Ultimately this methodology is effective in identifying and running early process failures, so that you cannot avoid the consequences of these failures Poor performance traits. RPN Action Priority When the risk is considered unacceptable, Quality-One recommends a priority of Action to be applied as follows: Error Proof (Eliminate Failure Mode or Address Cause) Failure Mode (Severity Only of 9 or 10) Causes with High Occurrence Improve the Potential Ability of the Process Improve the Tool or Process Error Proof Controls Improve FMEA inspection / evaluation techniques Failure Modes in a FMEA are equivalent to Problem Statement or Problem Description in Troubleshooting. More examples of this relationship are: The statements % and descriptions % the problem are linked between the two documents. Instead, it improves good engineering experience of a Cross Functional Team (CFT) to review the design progress of a product or process by assessing its risk of failure. This allows an FMEA to consider actual failures, categorized as failure modes and causes, making the FMEA more effective and complete. Failure modes are the ways in which a process can fail. Today it is still a highly effective method of lowering the possibility of failure. Design FMEA Design FMEA (DFMEA) explores the possibility of product malfunctions, reduced product life, and safety and regulatory concerns derived from: Material Properties Geometry Tolerances Interfaces with other components and/or systems Engineering Noise: environments, user profile, degradation, systems interactions Process FMEA Process FMEA (PFMEA) discovers failure that impacts product quality, reduced reliability of the process, customer dissatisfaction, and safety or environmental hazards derived from: Human Factors Methods followed while processing Materials used Machines utilized Measurement systems impact on acceptance Environment Factors on process performance Design FMEA Worksheet Design FMEA Worksheet Process FMEA Worksheet Historically, the sooner a failure is discovered, the less it will cost. FMEA is not a substitute for good engineering. Recommended Actions should address weakness in the testing and/or control strategy. Preparatory documents may include: Failure Mode Avoidance (FMA) Past Failure Eight Disciplines of Problem Solving (8D) Boundary/Block Diagram (For the DFMEA) Parameter Diagram (For the PFMEA) Process Flow Diagram (For the PFMEA) Characteristics Matrix (For the PFMEA) A pre-work Checklist is recommended for an efficient FMEA event. FMEA Example This FMEA Example has one item with a progression through multiple recommended Actions. The new state should be captured as Standard Work. 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