

FMEA

Process/Product Name \_\_\_\_\_  
Responsible \_\_\_\_\_

Prepared By \_\_\_\_\_  
FMEA Date (day / month / year) \_\_\_\_\_

Process Step/Step	Process Failure Mode	Process Failure Effects	Severity (1-10)	Process Cause	Cause Controls	Control Effectiveness (1-10)	Process Control	Control Effectiveness (1-10)	Process Failure	Severity (1-10)	Control Effectiveness (1-10)	Control Effectiveness (1-10)	Control Effectiveness (1-10)	Control Effectiveness (1-10)
What is the process step, stage or failure mode investigated?	Is what might occur due to change or failure in step?	What are the effects on the customer if the failure is not prevented or corrected?		What causes the step change or failure to occur? (Don't know's okay)	What controls exist that affect the process or detect the failure?		What are the established actions for reducing the occurrence of the cause or detecting deviation?	Who is responsible for taking care the actions are completed?	What actions can be completed (and when) with respect to the other?					
<b>Example:</b> Administering medication through the device	Device dispenses incorrect dosage of medication	If when dispenser delivers dose, effects of multiple treatment of condition, potentially serious long-term health	8	Calibration error, incorrect volume of medicine, user error	Proper calibration and maintenance of device, use of double technique during medication administration	8	Operator will follow user training on proper medication administration	Training Manager	All operators at the medication device complete and adhere to a standard quality control training session	8	8	8	8	8
							Package design includes additional safety with spill/leak containment and tamper-proof	Medical Department	Package design integrates to highlight calibration event	8	8	8	8	8
							Consider adding a feature to alert users to potential dosage error	Medical Department	Add feature that highlights error and prompts user of device if potential dosage error is detected	8	8	8	8	8
														8
														8
														8

# FMEA TEMPLATE

# The Basics Of Fmea

**C Cleary**



## **The Basics Of Fmea:**

The Basics of FMEA Raymond J. Mikulak, Robin McDermott, Michael Beauregard, 2017-08-09 Demonstrates How To Perform FMEAs Step by Step Originally designed to address safety concerns Failure Mode and Effect Analysis FMEA is now used throughout the industry to prevent a wide range of process and product problems Useful in both product design and manufacturing FMEA can identify improvements early when product and process changes are The Basics of FMEA, 2nd Edition Raymond J. Mikulak, Robin McDermott, Michael Beauregard, 1996-09-06 Meeting requirements established by the big three automakers this volume introduces work teams to Failure Mode and Effect Analysis FMEA Mandated by the QS 9000 standard FMEA positions quality control personnel to identify special causes of variation before they occur thus preventing failures defects and errors mostly before they are manifested Recognized as a versatile and effective continuous improvement tool FMEA serves any industry in which error prevention is vital to profit The process establishes a systematic method for determining causes and creates a common language for FMEA teams a method easily transferred to other industries The Basics of FMEA Robin E. McDermott, 2009 The Basics of FMEA Raymond J. Mikulak, 2017-08-09 Demonstrates How To Perform FMEAs Step by Step Originally designed to address safety concerns Failure Mode and Effect Analysis FMEA is now used throughout the industry to prevent a wide range of process and product problems Useful in both product design and manufacturing FMEA can identify improvements early when product and process changes are

Effective FMEAs Carl S. Carlson, 2012-05-15 Outlines the correct procedures for doing FMEAs and how to successfully apply them in design development manufacturing and service applications There are a myriad of quality and reliability tools available to corporations worldwide but the one that shows up consistently in company after company is Failure Mode and Effects Analysis FMEA Effective FMEAs takes the best practices from hundreds of companies and thousands of FMEA applications and presents streamlined procedures for veteran FMEA practitioners novices and everyone in between Written from an applications viewpoint with many examples detailed case studies study problems and tips included the book covers the most common types of FMEAs including System FMEAs Design FMEAs Process FMEAs Maintenance FMEAs Software FMEAs and others It also presents chapters on Fault Tree Analysis Design Review Based on Failure Mode DRBFM Reliability Centered Maintenance RCM Hazard Analysis and FMECA which adds criticality analysis to FMEA With extensive study problems and a companion Solutions Manual this book is an ideal resource for academic curricula as well as for applications in industry In addition Effective FMEAs covers The basics of FMEAs and risk assessment How to apply key factors for effective FMEAs and prevent the most common errors What is needed to provide excellent FMEA facilitation Implementing a best practice FMEA process Everyone wants to support the accomplishment of safe and trouble free products and processes while generating happy and loyal customers This book will show readers how to use FMEA to anticipate and prevent problems reduce costs shorten product development times and achieve safe and highly reliable products and processes

**The Basics of FMEA, 2nd Edition** Robin E. McDermott, Raymond J. Mikulak, Michael R. Beauregard, 2009

*Risk-Reduction Methods for Occupational Safety and Health* Roger C. Jensen, 2012-03-15 This book covers system safety methods related to occupational health and safety. It argues for anticipating hazards, risk reduction strategies for hazards processes, and making sure workers' tasks correspond to human capabilities. To this end, the text provides proactive methods for identifying hazards, assessing risk, analyzing hazards using tools from system safety, conducting post-incident investigations, considering human errors, applying risk reduction strategies, and managing process safety. While emphasizing methods suitable for all countries, it includes references to U.S. military and Department of Energy documents, as well as a discussion of fault tree construction.

**Airport Passenger Screening Using Millimeter Wave Machines** National Academies of Sciences, Engineering, and Medicine, Division on Engineering and Physical Sciences, National Materials and Manufacturing Board, Committee on Airport Passenger Screening: Millimeter Wave Machines, 2018-01-28 The Transportation Security Administration requested a study by the National Research Council (NRC) to establish the Committee on Airport Passenger Screening Millimeter Wave Machines to evaluate two models of active millimeter wave scanners: the L3 ProVision 1 and L3 ProVision 2. Airport Passenger Screening Using Millimeter Wave Machines provides findings and recommendations on compliance with applicable health and safety guidelines and appropriateness of system design and procedures for preventing over-exposure. This study addresses the issue of whether millimeter wave machines used at airports comply with existing guidelines and whether it would be possible for anything to go wrong with the machines so that by mistake it exposes a person to more than  $10 \text{ W m}^2$ .

**Proceedings of the 2000 ASME Design Engineering Technical Conferences and Computers and Information in Engineering Conference: 14th Reliability, Stress Analysis, and Failure Prevention Conference, and 7th Flexible Assembly Conference**, 2000 [Risk and Uncertainty in Dam Safety](#)

Desmond N. D. Hartford, Gregory B. Baecher, 2004 Intends to assist the dam owner in evaluating the needs for dam safety improvement, selecting and prioritizing remedial and corrective actions, and improving the operation, maintenance, and surveillance procedures. This book is intended not only for industry specialists but also for readers outside the dam engineering community.

*Hazard Analysis Techniques for System Safety* Clifton A. Ericson, 2005-08-03 A practical guide to identifying hazards using common hazard analysis techniques. Many different hazard analysis techniques have been developed over the past forty years. However, there is only a handful of techniques that safety analysts actually apply in their daily work. Written by a former president of the System Safety Society and winner of the Boeing Achievement and Apollo Awards for his safety analysis work, Hazard Analysis Techniques for System Safety explains in detail how to perform the most commonly used hazard analysis techniques employed by the system safety engineering discipline. Focusing on the twenty-two most commonly used hazard analysis methodologies in the system safety discipline, author Clifton Ericson outlines the three components that comprise a hazard and describes how to use these components to recognize a hazard during analysis. He

then examines each technique in sufficient detail and with numerous illustrations and examples to enable the reader to easily understand and perform the analysis Techniques covered include Preliminary Hazard List PHL Analysis Preliminary Hazard Analysis PHA Subsystem Hazard Analysis SSHA System Hazard Analysis SHA Operating and Support Hazard Analysis O SHA Health Hazard Assessment HHA Safety Requirements Criteria Analysis SRCA Fault Tree Analysis FTA Event Tree Analysis ETA Failure Mode and Effects Analysis FMEA Fault Hazard Analysis Functional Hazard Analysis Sneak Circuit Analysis SCA Petri Net Analysis PNA Markov Analysis MA Barrier Analysis BA Bent Pin Analysis BPA HAZOP Analysis Cause Consequence Analysis CCA Common Cause Failure Analysis CCFA MORT Analysis Software Safety Assessment SWSA Written to be accessible to readers with a minimal amount of technical background Hazard Analysis Techniques for System Safety gathers for the first time in one source the techniques that safety analysts actually apply in daily practice Both new and seasoned analysts will find this book an invaluable resource for designing and constructing safe systems in short for saving lives

*Patient Safety* Robert J. Latino, 2008-10-14 Are you ready and willing to get to the root causes of problems As Medicare Medicaid and major insurance companies increasingly deny payment for never events it has become imperative that hospitals and doctors develop new ways to prevent these avoidable catastrophes from recurring Proactive tools such as root cause analysis RCA basic failur **Statistics for Six Sigma Made Easy! Revised and Expanded Second Edition** Warren Brussee, 2012-07-17 A PLAIN ENGLISH GUIDE TO SOLVING REAL WORLD PROBLEMS WITH SIX SIGMA Six Sigma is one of the most effective strategies for improving processes creating better products and boosting customer satisfaction but business leaders often balk at its reputation for being too complex Don t fall into that trap Six Sigma is simple to understand and implement if you have *Statistics for Six Sigma Made Easy* Warren Brussee has helped businesses save millions of dollars with Six Sigma and he explains how you can achieve similar results in this step by step guide He presents a thorough overview of the Six Sigma methodology and techniques for successful implementation as well as a clear explanation of DMAIC the problem solving method used by Six Sigma Greenbelts *Statistics for Six Sigma Made Easy* provides A simplified form of the most common Six Sigma tools All the basic Six Sigma formulas and tables Dozens of Six Sigma statistical problem solving case studies A matrix for finding the right statistical tool to meet your needs Basic Greenbelt training in one concise reference Best of all no background in statistics is required you can start improving quality and initiating cost saving improvements right away *Statistics for Six Sigma Made Easy* is the only reference you need to facilitate real world application of Six Sigma tools *Failure Modes and Effects Analysis for Hydrogen Fueling Options* , 2004 **Maynard's Industrial and Systems Engineering Handbook, Sixth Edition** Bopaya Bidanda, 2022-09-16 The classic industrial engineering resource fully updated for the latest advances Brought fully up to date by expert Bopaya M Bidanda this go to handbook contains exhaustive application driven coverage of Industrial Engineering IE principles practices materials and systems Featuring contributions from scores of international professionals in the field Maynard s Industrial Engineering

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**Understanding Patient Safety, Second Edition** Robert Wachter, 2012-05-02 Gain a thorough understanding of the key principles of patient safety with the subject's pioneer text. Now in full color. This highly readable yet comprehensive book will appeal to every member of the healthcare team. It is a must for every physician's bookshelf. Abraham Verghese, MD, Professor, Stanford University, and author of the bestselling *Cutting for Stone*. Bob Wachter's quest to improve the safety of American healthcare represents the very essence of a physician's duty to put the patient first. His unflinching candor about the nature and magnitude of our current safety problems is matched only by his passion for improvement. Mark R. Chassin, MD, MPP, MPH, President, The Joint Commission. Amazingly readable for such a wealth of important information. This book should be required reading for every health professional and every healthcare executive. Christine Cassel, MD, President and CEO, American Board of Internal Medicine. In a single volume, Wachter accomplishes the seemingly impossible, furnishing the

novice with a highly accessible easy to read introduction to patient safety while providing a comprehensive fully annotated reference for the experienced patient safety practitioner All of the important issues are addressed in individual chapters each with a lively and relevant clinical example and a key points summary at the end bracketing full balanced and lucid descriptions A true gem destined to be a close companion for all of us who strive to make healthcare safe Lucian Leape MD Professor Harvard School of Public Health and Chair Lucian Leape Institute of the National Patient Safety Foundation There s no more prominent authority on patient safety than Bob Wachter And there s no more effective primer on patient safety than this one Atul Gawande MD MPH Associate Professor Harvard Medical School staff writer for the New Yorker and bestselling author of Complications and The Checklist Manifesto Compelling a must read for all concerned with patient safety Bob Wachter has a unique voice incorporating clinical experience research expertise and policy implications all with the patient front and center Peter J Pronovost MD PhD Professor and Director of the Armstrong Institute for Patient Safety and Quality Johns Hopkins Medicine Understanding Patient Safety Second Edition is the essential book for anyone seeking to learn the core clinical organizational and systems issues of patient safety Written in an engaging and accessible style by one of the world s leading authorities on patient safety and quality Understanding Patient Safety is filled with valuable cases and analyses as well as tables graphics references and tools This classic reference is designed to make the patient safety field understandable to medical nursing pharmacy hospital administration and other trainees and to be the go to book for experienced clinicians and non clinicians alike The second edition has been revised to include coverage of the latest issues and trends including Information technology Measurements of safety errors and harm Checklist based interventions Safety targets Policy issues in patient safety Balancing no blame and accountability Understanding Patient Safety Second Edition delivers key insights to help you understand and prevent a a broad range of errors including those related to medications surgery diagnosis infections and nursing care The crucial contextual issues including errors at the person machine interface the role of culture patient engagement in their own safety and workforce and trainee considerations are also well covered Finally the book provides a practical overview of how to organize an effective safety program in both hospitals and clinics

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