# How to Implement a Successful FMEA Process

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# Previous Webinar:

## *How to Audit FMEAs Using Quality Objectives*

In the previous Webinar in this series we learned An effective FMEA audit procedure and how to audit each of the 10 FMEA quality objectives.

# Learning Objectives:

## *How to Implement a Successful FMEA Process*

- Students who attend this webinar will learn the following:
  - The characteristics of an effective company-wide FMEA process
  - The specific roles and responsibilities needed for effective FMEAs

# What is an FMEA Process?

- The company-wide systems and tasks essential to support development of high reliability products and processes through timely accomplishment of well done FMEAs.

[The following material is excerpted from the book *Effective FMEAs*, *by* Carl S. Carlson, published by John Wiley & Sons, © 2012]

# Why Implement an FMEA Process?

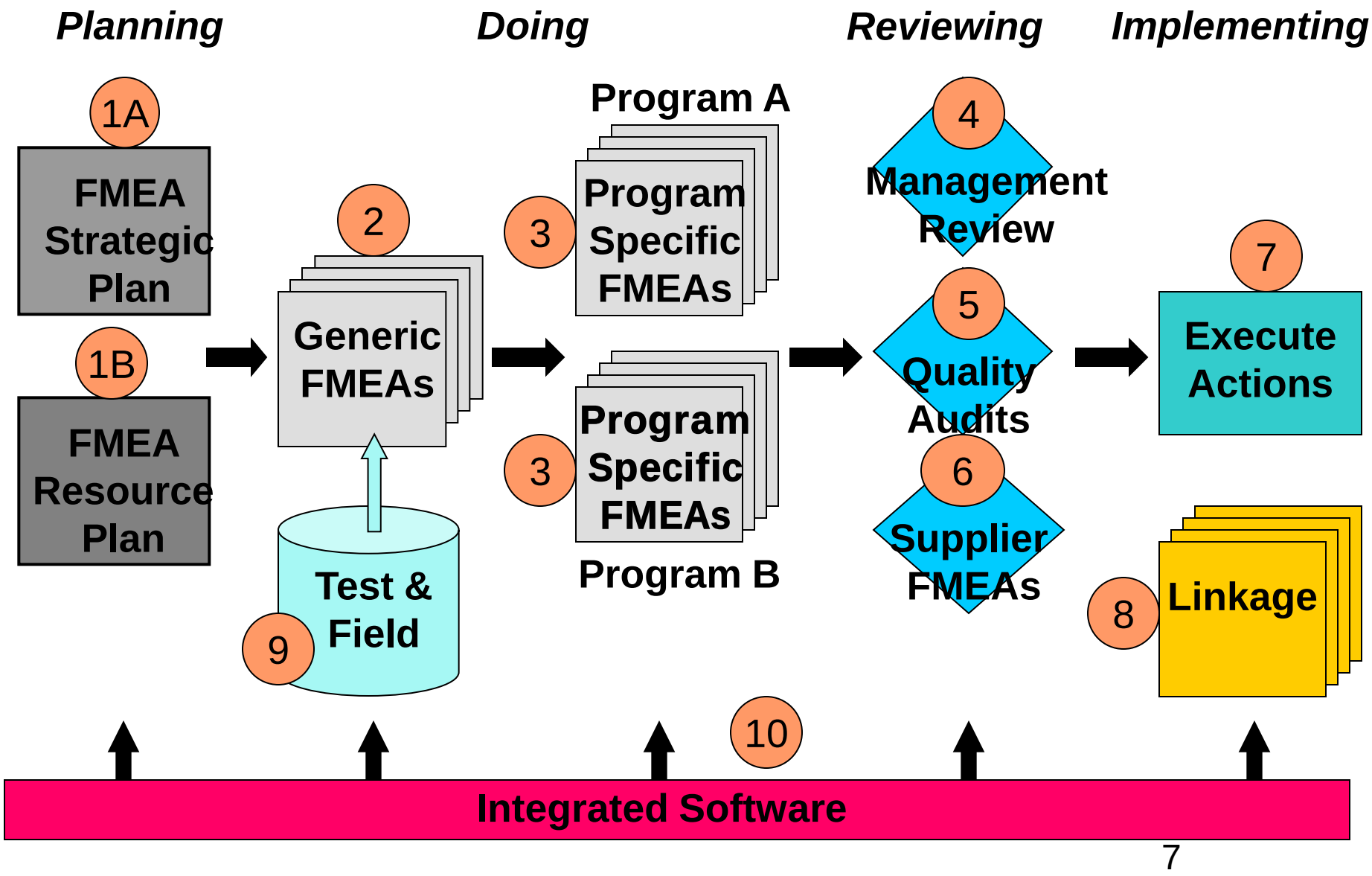
*(Why not just start doing FMEAs?)*

***Primary reasons for ineffective FMEAs (based on practical experience):***

1. Insufficient strategic or resource planning
2. Doing FMEAs improperly ("check off" item) or too late
3. Lack of management sponsorship and support
4. Failure to execute Recommended Actions for high risk issues
5. Not meeting FMEA Quality Objectives
6. Failure to address supplier issues
7. Failure to incorporate Lessons Learned from past FMEAs or test and field data
8. Failure to integrate FMEAs with other key processes

***An Effective FMEA Process addresses these issues and ensures successful FMEA application***

# EFFECTIVE FMEA PROCESS



# 1A FMEA Strategic Planning

***Strategic decisions to be made by management:***

1. What types of FMEAs will be done? (Design, Process, Equipment, Maintenance, etc.)
2. What selection criteria will be used to identify new FMEAs? (New designs, new processes, etc.)
3. What is appropriate FMEA timing? (*e.g.* prior to design freeze, while designs or processes are being developed)
4. What FMEA standard will be used? (SAE J1739, MIL-STD-1629A, etc.)
5. What generic FMEAs will be developed? By whom?
6. What program-specific FMEAs will be developed? By whom?

# 1A FMEA Strategic Planning (continued)

***Strategic decisions to be made by management:***

7. What level of detail is needed for generic or program-specific FMEAS? (System, Subsystem, Component, etc.)
8. Will FMEA Quality Audits be used to gauge FMEA effectiveness and provide ongoing improvements to FMEA process? If so, how will this be done?
9. How will FMEA projects be archived and tracked?
10. How will FMEA Post-Analysis Lessons Learned be captured?
11. What linkages are needed to other processes? (FRACAS, DVPs, Design Reviews, Process Control Plans, etc.)
12. How will Supplier FMEAs be handled? Who will review and approve Supplier FMEAs for critical parts?

# 1B FMEA Resource Planning

***Resource decisions to be made by management:***

- What software is needed? (such as Xfmea or other relational database, FMEA project tracking, etc.)
- Where will the homeroom for FMEA expertise reside? (FMEA process, FMEA facilitators, etc.)
- Who will perform FMEA facilitation and administration?
- What is the FMEA training plan for facilitators, teams and management?
- What should be composition of core FMEA team?
- How will Management support be provided?

# 1B Some Notes on FMEA "Training"

- FMEA Facilitator training:
  - How to perform effective FMEAs
  - Overview of FMEA process from viewpoint of facilitator
  - How to facilitate effective meetings
- FMEA team member training:
  - Basics of FMEA procedure
- Management training:
  - Effective FMEA process from viewpoint of management
  - Roles and responsibilities needed to support effective FMEAs

# 1B High-level Management Roles and Responsibilities

***The importance of broad support from management in implementing an effective FMEA process cannot be overstated***

- Champion the subject of FMEA with management and employees.
- Provide agreement on FMEA strategy and support needed resources.
- Implement an effective FMEA training program.
- Define roles and responsibilities for all FMEA participants, and integrate with employee work instructions.

# 1B High-level Management Roles and Responsibilities (continued)

- Assist in integrating FMEA with other business processes, including Design Reviews, Design Verification Plans, and others.
- Provide ongoing reviews of high-risk failure modes and recommended actions.
- Support attendance of expert FMEA team members.
- Help ensure FMEAs are fully executed.
- Establish a FMEA audit process to continuously improve the quality of FMEAs, based on agreed upon quality criteria.

# Heroes

"Heard at a seminar. One gets a good rating for fighting a fire. The result is visible; can be quantified. If you do it right the first time, you are invisible. You satisfied the requirements. That is your job. Mess it up, and correct it later, you become a hero."

--W. Edwards Deming
*Out of the Crisis*

# 1B FMEA Facilitator Roles and Responsibilities

- The FMEA facilitator leads the FMEA team to successful completion of the project, by ensuring the following:
  - FMEA team is well trained on the fundamentals of FMEA
  - Each FMEA is technically correct
  - Each FMEA meets the 10 quality objectives
  - Risk is reduced to an acceptable level
  - FMEA preparation steps are adequately completed before FMEA begins
  - Proper cross functional team is present from beginning to end of FMEA
  - The full set of facilitation skills are used to ensure excellent results in least amount of time
  - Agreed upon meeting norms of behavior are followed
  - The team stays focused on issues that affect safety and high reliability

# 1B FMEA Team Member Roles and Responsibilities

- The FMEA team member actively participates in FMEAs by carrying out the following responsibilities:
  - Becomes well trained on the fundamentals of FMEA
  - Attends all FMEA meetings
  - Provides any needed FMEA preparation
  - Maintains the agreed-upon norms of behavior
  - Provides candid and honest input to team discussions, within area of responsibility
  - Listens attentively to all team communications
  - Helps team stay focused on issues that affect safety and high reliability

# 2 Generic FMEAs

***Definition:***

- FMEAs that contain both *historical* (empirical) and *potential* failure modes, causes, controls, etc.
- Done at the generic level of the system, subsystem or component, not program-specific
- Done once, then updated (as needed) from Test and Field data and/or new technology

***Generic FMEAs can be used for:***

- Design Trade Studies
- Input for program-specific FMEAs
- Most useful if the product line is relatively stable over time

# 3 Program-Specific FMEAs

***Definition:***

- FMEAs that focus on specific applications
- Either tailored from generic FMEAs or newly done
- Completed through entire FMEA worksheet

# 4 Management Review

## *(Sometimes Called Failure Review Board)*

- Management reviews FMEA high-risk issues and recommended actions *(essential to ensure understanding, buy-in, support and adequacy)*
- FMEA reports/charts should be generated per FMEA Strategic Plan
- Feedback from management goes back to FMEA teams for review and incorporation
- There may already be a process in place to review failure modes from field or test
- Most companies “piggy-back” the review of FMEA failure modes with the review of field or test failure modes

# 5 FMEA Quality Audits

***Quality Audits (based on FMEA Quality Objectives)***

- In-person audits of FMEAs, done with FMEA facilitator and core team, performed by management in an interview format
- Done on random basis, one hour maximum per audit
- Provides valuable feedback to improve future FMEAs, with Action Items identified for follow-up
- Focus on improving the FMEA process, not on the person/team doing the FMEA
- Don’t expect to instantly achieve all 10 objectives; work to maintain steady improvement
- Management audits demonstrate commitment; in the words of W. Edwards Deming: “Quality is the responsibility of management. It cannot be delegated.”

# 6 Supplier FMEAs

- Potential high risk system or subsystem level failures can have their root cause in Supplier components
- FMEA Strategic Planning should determine how to address Supplier FMEAs and how to identify which Suppliers require FMEA review
- FMEA team can invite Suppliers to participate in FMEA

***For Suppliers who are identified as high risk:***

- Require submission of completed FMEA for review and approval prior to part shipment
- Review conducted by FMEA team or qualified representative based on FMEA Quality Objectives
- Supplier continues FMEA until Quality Objectives met

# 7 Execute Actions to Reduce or Eliminate Risk

***FMEA has little value unless the recommended actions are fully executed***

- Follow up each recommended action to ensure:
  - Completion to satisfaction of FMEA Team
  - Risk eliminated or mitigated to acceptable level
- Bring problems with execution back to Management
- Update Action Status and Risk Reduction in FMEA database

# 8 Linkages to Other Key Processes

***Look for software that integrates requirements from Advanced Product Quality Planning (APQP) or other quality guidelines***

- Transfer appropriate information from existing Design FMEAs to new Process FMEAs
- Create integrated:
  - Design Verification Plan (DVP)
  - Process Control Plan (PCP)
  - Process Flow Diagram (PFD)

# 8 Linkages to Other Key Processes (cont'd)

- FMEAs can provide important input for other processes:
  - Design Reviews, Trade Studies, Reliability Growth Analyses, etc.
- FMEA must be fully integrated with the Product Development Process
- FMEA can be implemented as a stand-alone process and make significant design improvements
- However, linking to other processes results in efficiencies and can make the other processes more effective

# 9 Test and Field Failures

***There needs to be a separate process and database to capture all test and field failure data***

- Often called “FRACAS”
- Provides updates to FMEAs, after initial FMEA analyses are completed (called “post analysis lessons learned)
- High-risk failure modes from FMEA are passed on to FRACAS
- The best way to prevent recurring problems is to backfill the FMEA with lessons learned from field or test

# 10 Integrated Software Support

*An effective FMEA process needs to be supported by integrated software*

- Relational Database for all FMEA Projects
- FMEA Standards: configurable to organization
- Maintains generic and program-specific FMEAs
- Import/Export and Attachment Features
- Linkages to Other Processes (DVP, PCP, etc.)
- Tracks Execution of Risk Reduction Actions
- Generates Plots and Reports for Management Reviews
- Simultaneous FMEA users accessing database

# 10 A Note on Integrated Software Support

- Some companies stay with Excel so they can tailor worksheets to specific formats
  - They miss out on features of a relational database

# Summarizing the Key Factors for a Successful FMEA Process

1. Broad management support
2. Strategic and Resource Planning
3. FMEA process integrated with Business Process
4. Well trained FMEA Facilitators and Teams
5. Management reviews and support
6. Follow-up on all high-risk issues
7. FMEA Quality Audits
8. Integrated FMEA software support
9. Supplier FMEAs for higher risk parts
10. FMEAs linked to other key processes

# More Information

- This webinar was based on the book *Effective FMEAs*, by Carl S. Carlson, published by John Wiley & Sons, © 2012
- Information about the book and links to useful FMEA articles and aids can be found on www.effectivefmeas.com.
- If you have questions or comments about this webinar, the subject of FMEAs, or the book *Effective FMEAs*, please send an email to the author at Carl.Carlson@EffectiveFMEAs.com.

# Future FMEA Webinars:

- From time to time, future webinars will be scheduled on relevant topics that affect FMEA application.
- If you have ideas for future topics or feedback/questions on any of the recent FMEA webinars, please send an email to Carl.Carlson@EffectiveFMEAs.com

# Author Biography

- Carl S. Carlson is a consultant and instructor in the areas of FMEA, reliability program planning and other reliability engineering disciplines, currently supporting clients of ReliaSoft Corporation.
- He has 30 years experience in reliability testing, engineering, and management positions, including manager of product reliability at General Motors.
- He co-chaired the cross-industry team that developed the commercial FMEA standard (SAE J1739, 2002 version) and was a past member of the Reliability and Maintainability Symposium (RAMS) Advisory Board.
- He holds a B.S. in Mechanical Engineering from the University of Michigan, is a senior member of ASQ and a Certified Reliability Engineer.
- He is the author of *Effective FMEAs*, published by John Wiley & Sons, 2012. He can be reached at Carl.Carlson@EffectiveFMEAs.com. Information about the book and useful aids to performing FMEAs can be found on www.effectivefmeas.com.