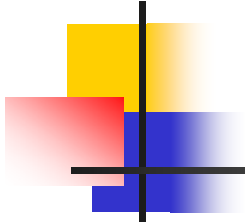


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LESSONS LEARNED FOR EFFECTIVE FMEAS



Agenda

1. Introduction
2. Risk Assessment
3. Key Factors for Effective FMEAs
4. FMEA Facilitation
5. Best practice for Successful FMEA process



Prerequisite

- This tutorial is “Intermediate” level
- It is not an introduction to FMEA/FMECA
- It presupposes familiarity with FMEA/FMECA



Purpose

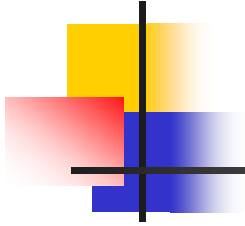
The purpose of this tutorial is to share the key factors for achieving success in FMEAs, and to highlight an FMEA process that is helpful for consistently good results.



Review

Failure Mode and Effects Analysis (FMEA) is a methodology designed to:

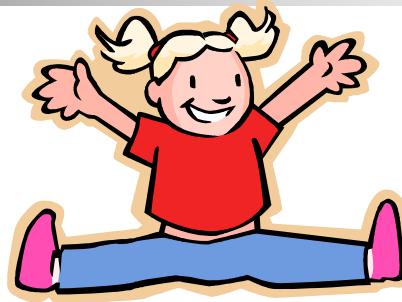
- Identify potential failure modes for a product or process.
- Assess the risk associated with those failure modes and prioritize issues for corrective action.
- Identify and carry out corrective actions to address the most serious concerns.



Introduction

Failure Mode & Effects Analysis

- you either love it



- or hate it



Everyone has an opinion!



Heard at the “Virtual” Water Cooler

- “waste of time,” “lack of support,” “don’t want anything to do with it”
- “powerful tool,” “effective way to prevent problems” and “needs to be done across the board”



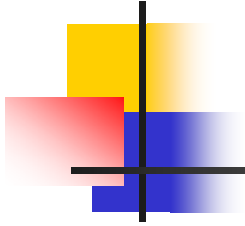
So, What's the Truth About FMEA?

- Is it a giant waste of time and resources?
- Or is it a powerful tool that is essential to the goal of designing in reliability?

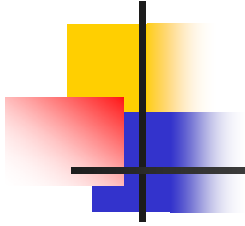


Drum Roll !

And the answer is ...



It depends



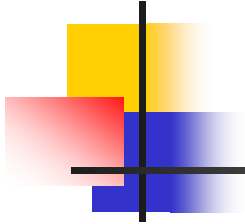
OK, so what does the success of this potentially powerful tool depend on?



FMEA Success Factors

There are four broad success factors that are critical to uniformity of success in the application of FMEA in any company:

- Understanding the basics of FMEAs and Risk Assessment
- Applying key factors for effective FMEAs
- Providing excellent FMEA facilitation
- Implementing a “best practice” FMEA process



Understanding the Basics of FMEAs and Risk Assessment



Basics of FMEAs

- There are many courses and tutorials that exist covering the basics of FMEAs
- It is essential to the success of FMEA applications that the FMEA facilitator and team thoroughly understand and can apply these basics
- Basics include FMEA terminology and how to perform FMEAs



Risk Assessment and FMEAs

- Risk assessment is used to identify which FMEAs that will be done as part of product and process development
- Risk assessment is also an integral part of the FMEA procedure
- FMEA costs money to perform and should be used where the highest risk is anticipated



Stay Focused on Risk

- Perform preliminary risk analysis
- Use FMEA method on higher risk areas, such as
 - New technology
 - New designs where risk is a concern
 - New applications of existing technology
 - Potential for safety issues
 - History of significant field problems
 - Potential for important regulation issues
 - Mission Critical
 - Supplier Capability
- Avoid excessive time on lower risk systems



Level of Detail

- Every part of FMEA procedure can have too much or too little detail
- It is up to the FMEA Team and Facilitator to navigate the treacherous waters of detail



Common Error

Too Much Detail

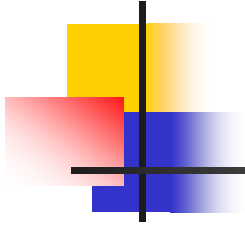
- One of the most common errors of FMEA Teams is too much detail
- FMEAs with 100s of pages (small font) come from:
 - Boiler plates
 - Brainstorming gone amuck
 - Poor facilitation
- Misses the “forest for the trees”
- Misses or obscures the high risk issues that make FMEA valuable
- FMEA Teams get frustrated and derailed
- FMEA gets a bad name



Common Error

Too Little Detail

- FMEAs that are too generalized or miss the high risk areas are all too common
- Not getting to **Root Cause**
- Not developing the analysis fully for the high risk areas
- Not developing “executable” actions
- FMEA gets a bad name



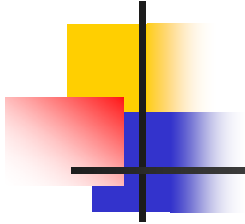
“The art of being wise is the art of knowing what to overlook.”

William James, American Philosopher

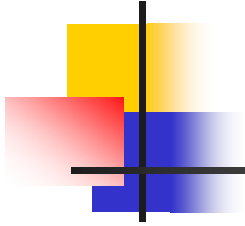


Stay Focused on Risk

*The Key is to be “Risk Conscious”
and to consistently keep the team
focused on risk*



Key Factors for Effective FMEAs

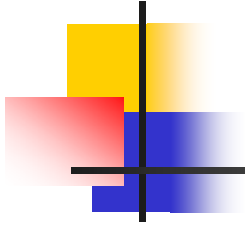


- Learning the FMEA procedure is not enough to be a successful FMEA practitioner
- Performing successful FMEAs requires understanding and implementing the Key Factors for Effective FMEAs



Maxim

“Good judgment comes from experience and experience comes from poor judgment”



What are the primary ways that FMEA can be done wrong? (Mistakes)

What are the Key Factors that make for effective FMEAs? (Quality Objectives)



Mistake #1

Failure to Drive Design or Process Improvements

- Some FMEAs do not drive any action at all
- Some FMEAs drive mostly testing
- Some FMEAs drive ineffective action



Quality Objective #1

The FMEA drives Product or Process Design Improvements as the primary objective



A Note on Quality Objective #1

- Reliability Engineering has a multitude of tools to choose from in driving design or process improvements
- The key is to use the FMEA “Recommended Actions” field to identify and execute best practice tools that can optimize designs
- This is one of the reasons that Reliability Engineers need to participate on FMEAs



Mistake #2

Failure to Address All High Risk Failure Modes

- Risk thresholds can be defined by FMEA Team, or set as company policy
- In addition to high RPN or criticality, high severity must be addressed
- Some companies fail to take effective action on all higher risk failure modes



Quality Objective #2

The FMEA addresses all high risk Failure Modes, as identified by the FMEA Team, with executable Action Plans.



A Note on Quality Objective #2

- The emphasis on this Quality Objective is to ensure that all of the higher risk failure mode/causes are adequately addressed with effective actions.
- Company policy or FMEA team will define which RPNs or Criticality will rise to the level of high risk
- The key is effective action that reduces or eliminates the risk



Mistake #3

Failure to Improve Test/Control Plans

- Some companies miss the opportunity to improve DVP&R Plan or Process Control Plans based on failure modes from FMEA
- Some FMEA teams do not include knowledgeable reps from test department
- Result is inadequate testing or control plans



Quality Objective #3

The Design Verification Plan & Report (DVP&R) or the Process Control Plan (PCP) considers the failure modes from the FMEA



A Note on Quality Objective #3

- The FMEA team will often discover Failure Modes/Causes that were not part of the Design Controls or Test Procedures
- The key is to ensure that the test plan (DVP&R) or Control Plan is impacted by the results of the FMEA
- This can be done by including test/control membership on FMEA team or through well written actions



Mistake #4

Not Including Interfaces in FMEA

- Empirical data shows that at least 50% of field problems can occur at interfaces
- Some companies focus on part or subsystem failures and miss the interfaces



Quality Objective #4

The FMEA scope includes integration and interface failure modes in both block diagram and analysis



A Note on Quality Objective #4

- Interfaces can be included as part of the item by item analysis or as a separate analysis
- It is recommended that the preliminary FMEA Block Diagram clearly show the interfaces that are part of FMEA scope



Mistake #5

Disconnect from Field Lessons Learned

- Some companies provide no linkage between FMEAs and field data
- It takes concerted effort to integrate problem resolution databases with FMEA
- Otherwise serious problems repeat



Quality Objective #5

The FMEA considers all major “lessons learned” (such as high warranty, campaigns, etc.) as input to failure mode identification



A Note on Quality Objective #5

- Field failure data can be brought into generic FMEAs on regular basis
- Then, when new program-specific FMEAs are started, they benefit from field lessons learned
- If generic FMEAs are not used, new FMEAs should be seeded with potential field problems and show how they will not repeat in the new design/process
- The key is to hold the FMEA team responsible to ensure that major field problems do not repeat



Mistake #6

FMEA Omits Key Characteristics

- Many companies have a Key Characteristics policy
- FMEA can identify Key Characteristics for special controls in manufacturing
- Some companies miss this opportunity



Quality Objective #6

The FMEA identifies appropriate Key Characteristics candidates, if applicable according to company policy



A Note on Quality Objective #6

- This is an underutilized element of FMEAs
- SAE J1739 or the AIAG FMEA standard uses the “Classification” column



Mistake #7

Doing FMEAs Late

- Many companies do FMEAs late, and this reduces their effectiveness
- FMEAs should be completed by design or process freeze dates, concurrent with the design process



Quality Objective #7

The FMEA is completed during the “window of opportunity” where it can most effectively impact the product or process design



A Note on Quality Objective #7

- The key to getting FMEAs done on time is to start the FMEAs on time
- FMEAs should be started as soon as design or process concept is determined
- Exception is FMEAs done during trade off studies, which can be started earlier



Mistake #8

Inadequate Team Composition

- Some FMEA teams do not have the right experts on the core team
- Some FMEA teams do not have good attendance
- Some FMEA team members just sit in their chairs and don't contribute to team synergy



Quality Objective #8

The right people participate on the FMEA team throughout the analysis, and are adequately trained in the procedure



A Note on Quality Objective #8

Participation of Subject Matter Experts

- Actual survey of Reliability Engineering internal customers on FMEAs:
 - FMEAs are too important to not do
 - But too time consuming to participate
- FMEA Facilitator must value the time of team members and not waste time



Added Note on Quality Objective #8

- People have blind spots (scotomas)
- Key is to get the people who are knowledgeable and experienced about potential failures and their resolutions actually showing up at the meetings
- Attendance takes management support
- Team size is best between 4 to 8 people
- If team gets too large, consider breaking into additional limited scope FMEAs



Mistake #9

Improper Procedure

- There are 100s of ways to do FMEAs wrong
- Some companies do not encourage or control proper FMEA methodology
- Training, coaching, reviews are all necessary to success



Quality Objective #9

The FMEA document is completely filled out “by the book”, including “Action Taken” and final risk assessment



A Note on Quality Objective #9

- One of the most common FMEA errors is to fail to get to root cause
- Expert input is necessary
- Follow up actions based on poorly defined causes will not work and FMEA will not be successful



Mistake #10

Lack of Efficient Use of Time

- Some companies mandate FMEAs, then do not ensure the time is well spent
- Pre-work must be completed, meetings well run, efficient follow up of high risk issues
- Ask FMEA team if their time is well spent, and take action to address shortcomings



Quality Objective #10

The time spent by the FMEA team, as early as possible, is an effective and efficient use of time with a value added result



A Note on Quality Objective #10

- If this Quality Objective is met, then future FMEAs will be well attended and supported by subject matter experts and management



FMEA Quality Objectives

1. **DESIGN IMPROVEMENTS** *FMEA primarily drives Design Improvements*
2. **HIGH RISK FAILURE MODES** *FMEA addresses all high risk Failure Modes*
3. **DVP&R/CONTROL PLAN** *Comprehends failure modes from the Design FMEA*
4. **INTERFACES** *FMEA scope includes integration and interface failure modes*
5. **LESSONS LEARNED** *Warranty, field issues, “hardy perennials” included*
6. **KCDS CONNECTION** *The FMEA identifies appropriate KPC candidates*
7. **TIMING** *The FMEA is completed during the “Window of opportunity”*
8. **TEAM** *The right people participate as part of the FMEA team*
9. **DOCUMENTATION** *FMEA document is completely filled out “by the book”*
10. **TIME USAGE** *Effective and efficient use of time by FMEA Team*



Meeting FMEA Quality Objectives

- Make FMEA Quality Objectives part of FMEA training
- Review them at each meeting
- Participate in FMEA Quality audits
- Keep FMEA open until Quality Objectives are met



FMEA Pre-Work Lesson Learned

- Time spent prior to the first FMEA team meeting can save valuable subject matter expert time in meetings
- Try to predict all of the documents that will be needed during team meetings and provide hard copies or on line access



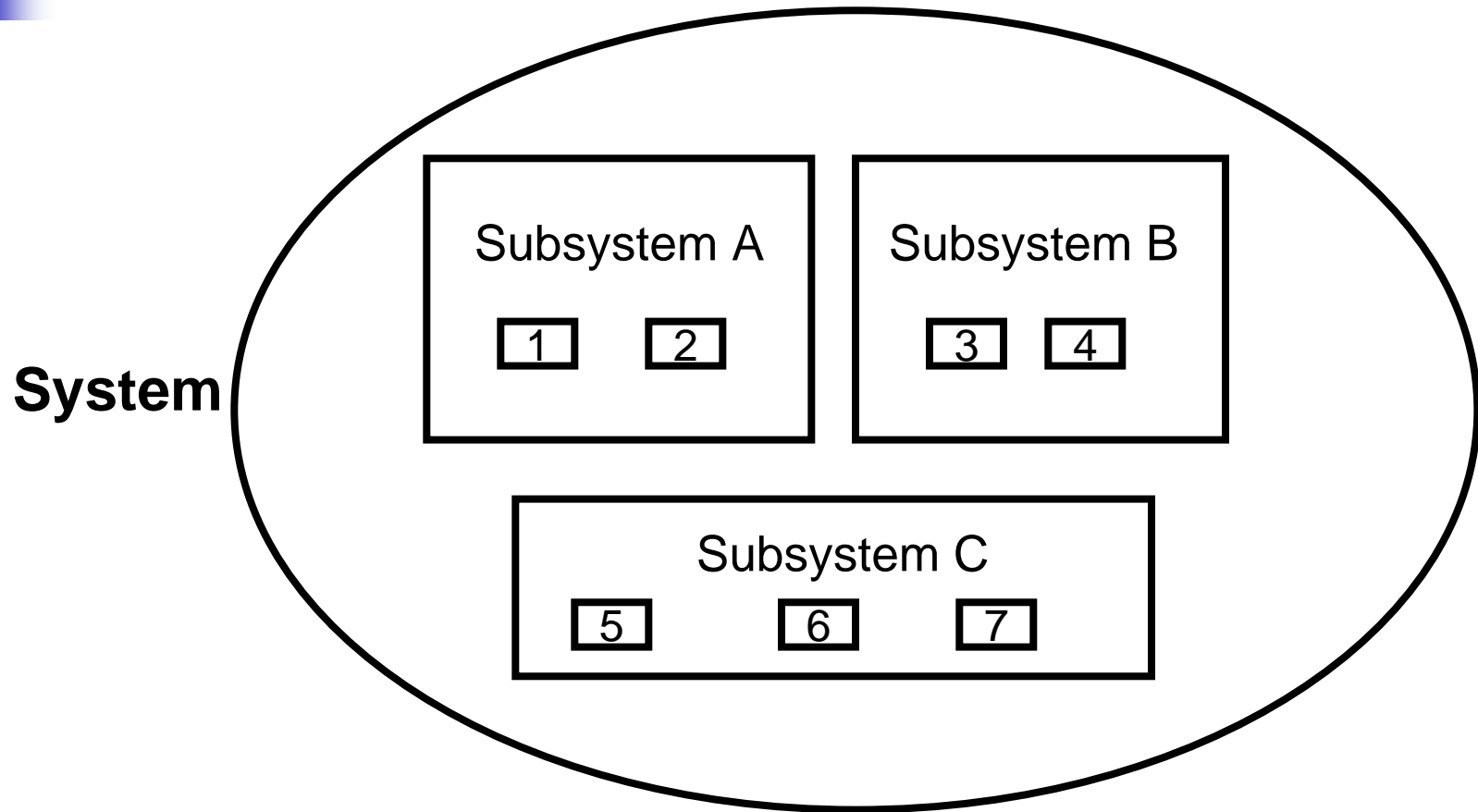
FMEA Scope Lesson Learned

A common problem with the scope of an FMEA project:

- Starting the FMEA meetings before the exact scope is agreed upon
- For example, need to agree on the exact configuration of subsystems and components, interfaces, indenture level, role of suppliers, etc.



FMEA Scope

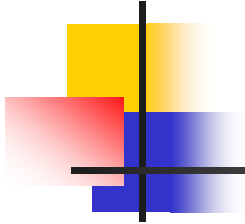




FMEA Assumptions & Limitations

A common problem with the assumptions and limitations of an FMEA project:

- Starting the FMEA meetings before the all assumptions and limitations are agreed
- For example, need to agree on assumptions relating to design and process, part quality/usage, analysis level of detail, etc.



Excellent FMEA Team Facilitation



The Subject of FMEA Facilitation

- FMEA facilitation is a different subject than FMEA methodology.
- To be successful, FMEA leaders need to develop expert facilitation skills



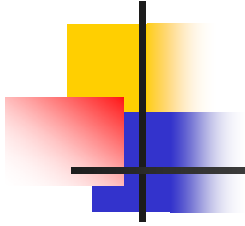
What are Characteristics of successful FMEA Facilitation?

- Facilitator must be well trained in effective meeting facilitation techniques
- Facilitator must know FMEA procedure and use of software
- FMEA team members need to be trained in overview of FMEA procedure
- Good facilitation is key to prevention of high risk problems without wasting time



Primary FMEA Facilitation Skills

- Brainstorming and Probing Questions
- Encouraging Participation
- Active Listening
- Controlling Discussion
- Making Decisions
- Conflict Management
- Managing Level of Detail
- Managing Time
- Common Facilitation Problems



Best Practice for Successful FMEA Process



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.

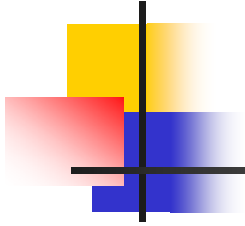


Why Implement an FMEA Process?

(Why not just start doing FMEAs?)

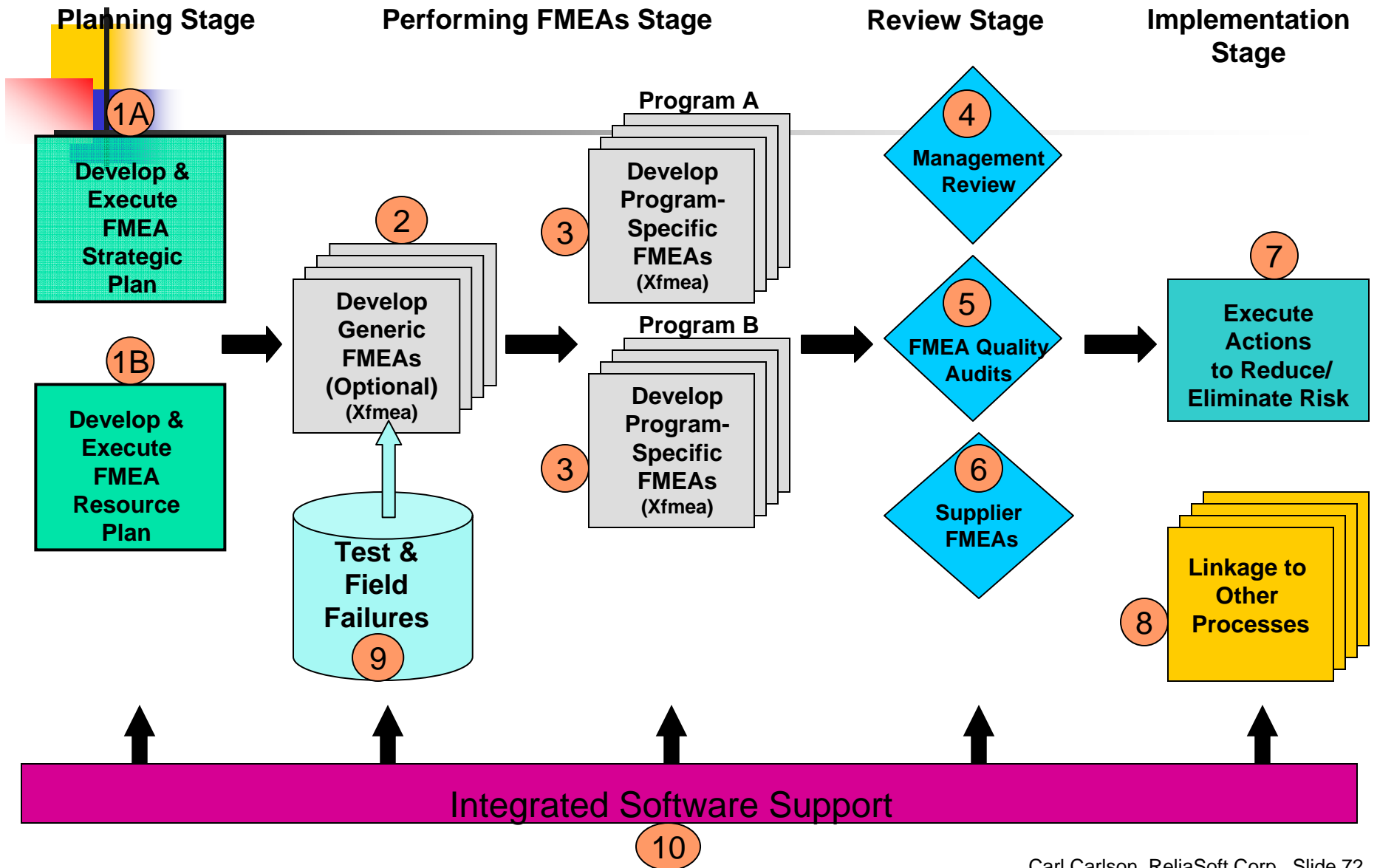
Primary reasons for ineffective FMEAs (based on practical experience):

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

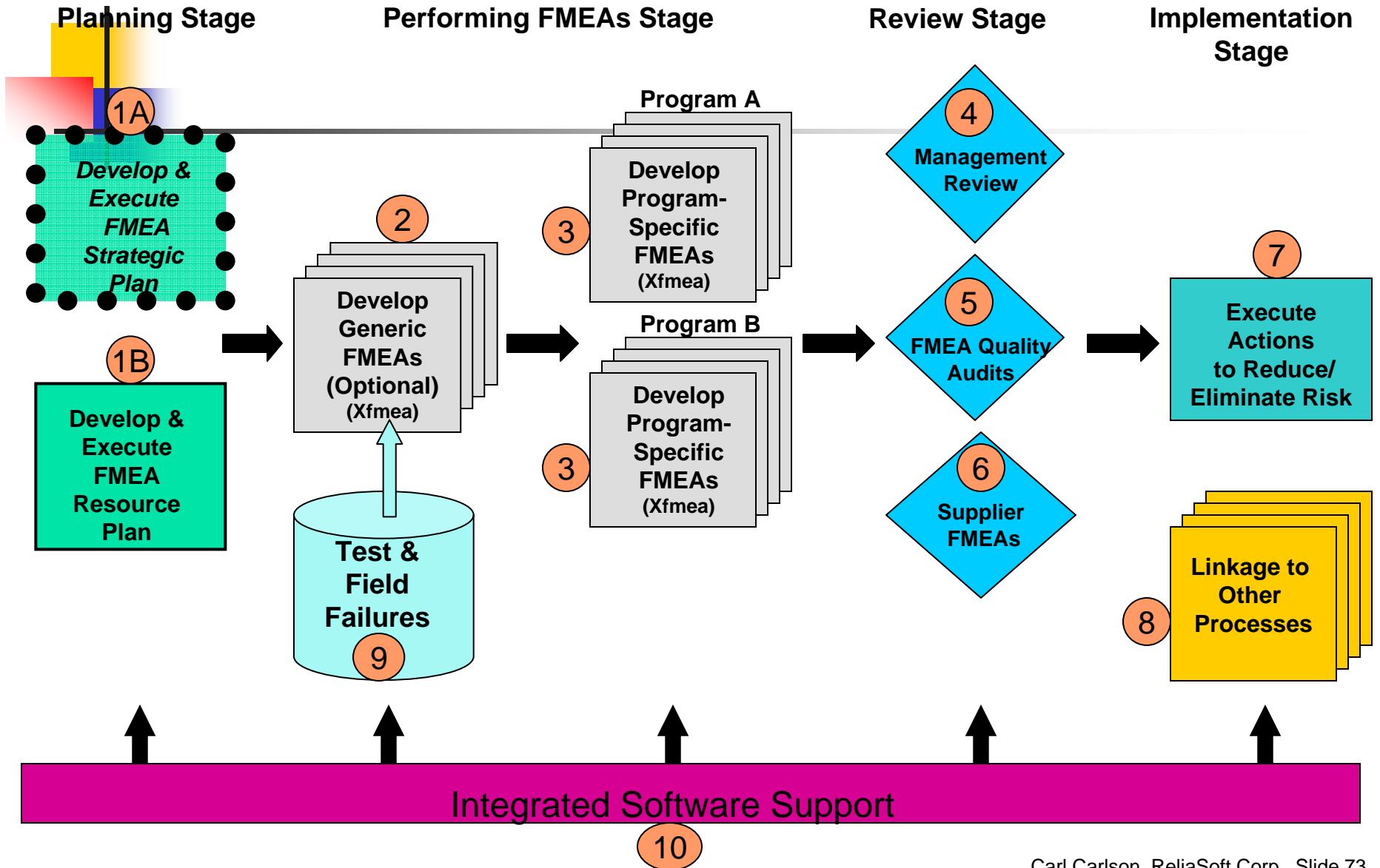


FMEA Process addresses these issues and ensures successful FMEA application.

EFFECTIVE FMEA PROCESS



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? (*for example*: prior to design freeze, while designs or processes are being developed)
4. What FMEA standard will be used? (J1739, MIL-STD-1629A, etc.)
5. What Generic FMEAs will be developed? By whom?
6. What Program-specific FMEAs will be developed? By whom?
7. What level of detail is needed for Generic or Program-Specific FMEAs? (System, Subsystem, Component, etc.)

1A

FMEA Strategic Planning (continued)

Strategic decisions to be made by management:

8. Will FMEA Quality Surveys be used to gauge FMEA effectiveness? If so, how will this be done?
9. How to implement Quality Audits for ongoing improvements to FMEA process?
10. How will FMEA projects be tracked?
11. How will FMEA Post-Analysis Lessons Learned be captured?
12. How will FMEAs be archived for easy retrieval?
13. What linkages are needed to other processes (FRACAS, DVP&R Plans, Design Reviews, Process Control Plans, etc.)
14. How will Supplier FMEAs be handled? Who will review and approve Supplier FMEAs for critical parts?

1A

A Note on FMEA “Timing”

(for Design and Process FMEAs)

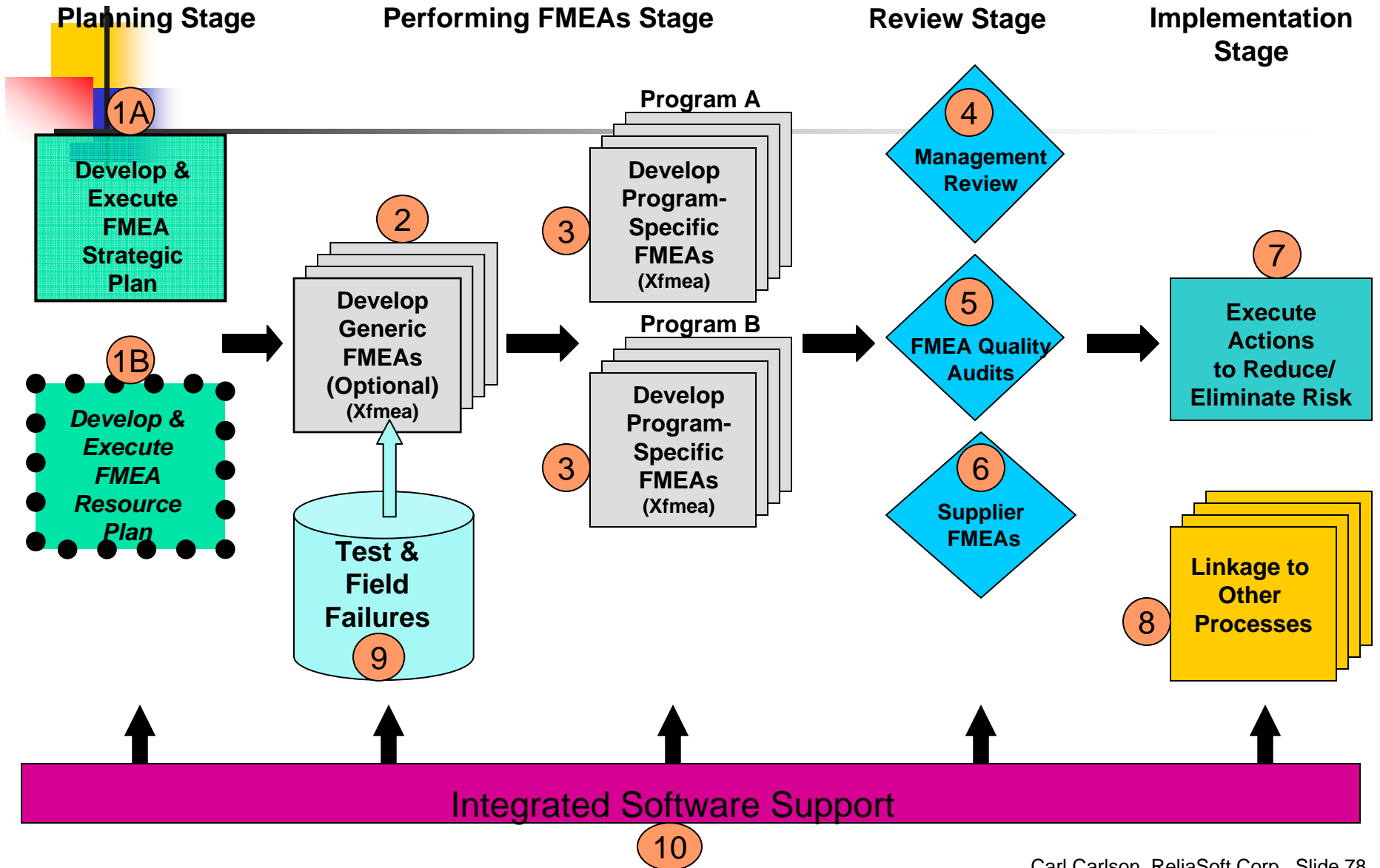
- FMEAs need to be done during the “window of opportunity” to best impact design of product or process.
- For Design FMEAs:
 - Too early: before design concept is established
 - Too late: after design freeze
 - Ideal: while design of product is being developed
- For Process FMEAs:
 - Too early: before manufacturing or assembly concept is established
 - Too late: after manufacturing or assembly process is finalized
 - Ideal: while design of the manufacturing or assembly process is being developed

1A

A Note on FMEA “Level of Detail”

- FMEAs can be done at system, subsystem or component level.
- When deciding the scope of FMEA, keep in mind:
 - Size of FMEA team should be in range of 4 to 8 for an effective core team focus and efficiency
 - Too few participants can result in absence of important expert input
 - Too many can result in unmanageable FMEA team meetings and wasted time
- Assign as many FMEA projects as is necessary to address risk, and still keep teams to manageable size

EFFECTIVE FMEA PROCESS



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 homerom 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?
 - What is content and frequency of management reviews?
 - What approval for FMEA Recommended Actions?
 - What FMEA reports are needed and when?

1B

A Note on FMEA “Homeroom”

- A “homeroom” is important to support FMEA process and execution
- Roles and responsibilities include:
 - FMEA facilitators
 - FMEA training support
 - FMEA common process and standards
 - FMEA software
 - FMEA methodology expertise
 - FMEA quality audits
- Without an effective “homeroom,” the results of FMEA can vary and become ineffective

1B

A Note 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



A Note on FMEA “Management Support”

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

- Provides agreement on strategy and supports needed resources
- Assists in integrating FMEA with other business processes
- Provides effective reviews of higher risk failure modes and recommended actions
- Provides attendance of expert FMEA team members



Heroes

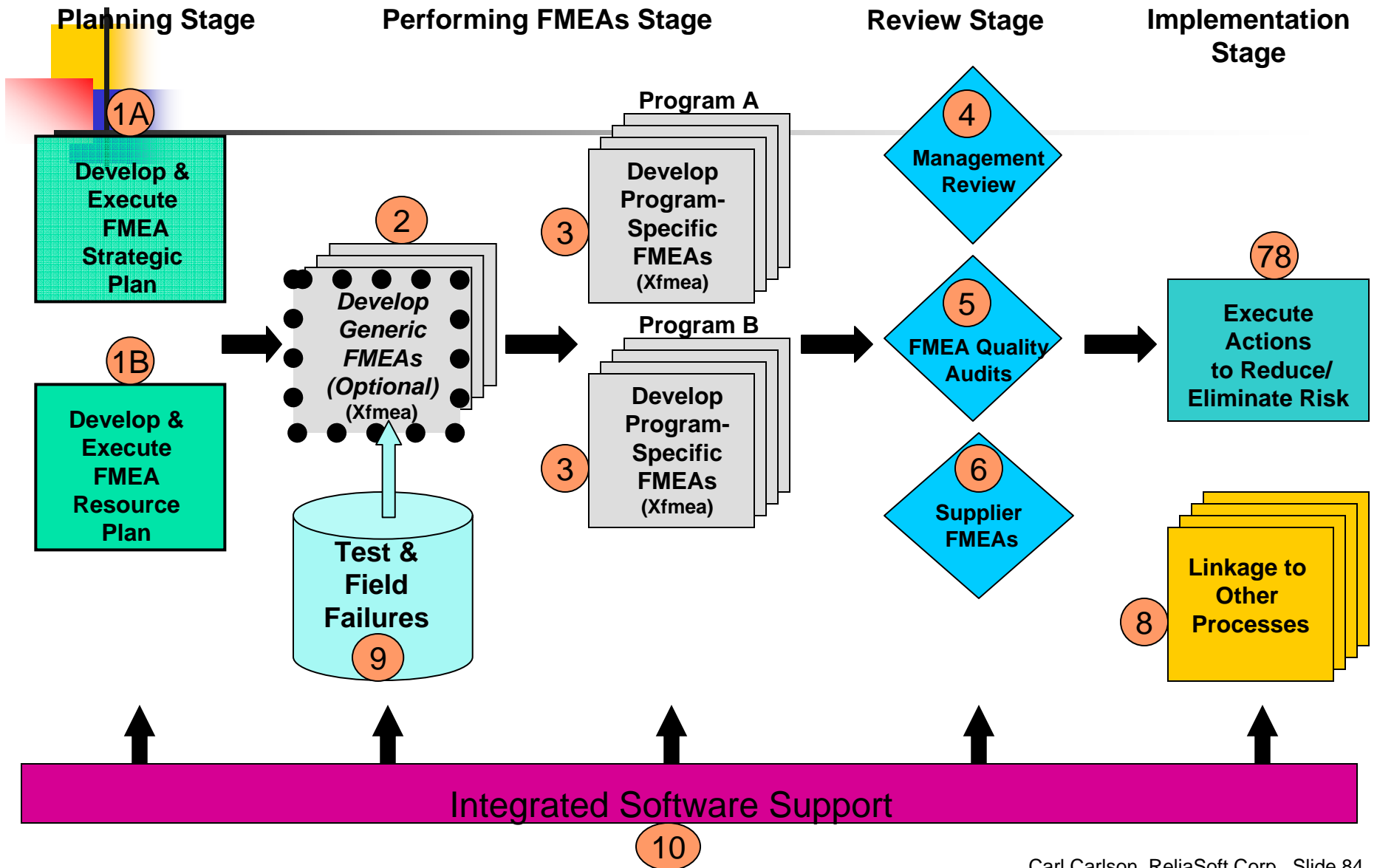
“Heard at a seminar. One gets a good rating for fighting a fire. The result is visible; can be quantified. If you do it right the first time, you are invisible. You satisfied the requirements. That is your job. Mess it up, and correct it later, you become a hero.”

W. Edwards Deming

Out of the Crisis

Carl Carlson, ReliaSoft Corp., Slide 83

EFFECTIVE FMEA PROCESS





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

Strategic Decisions:

- Will Generic FMEAs be done?
- Which ones, what content, standard, level of detail, etc.?



Generic FMEAs (continued)

For each Generic FMEA (complete these steps):

- Assign Generic FMEA facilitator and team
- Establish Generic FMEA timing and scope
- Gather past relevant FMEA(s) from Archive, and all needed pre-work documents and information
- Perform FMEA analysis (according to FMEA standard) up to Design or Process Controls

Generic FMEAs can be used for:

- Design Trade Studies
- Input to Program-specific FMEAs

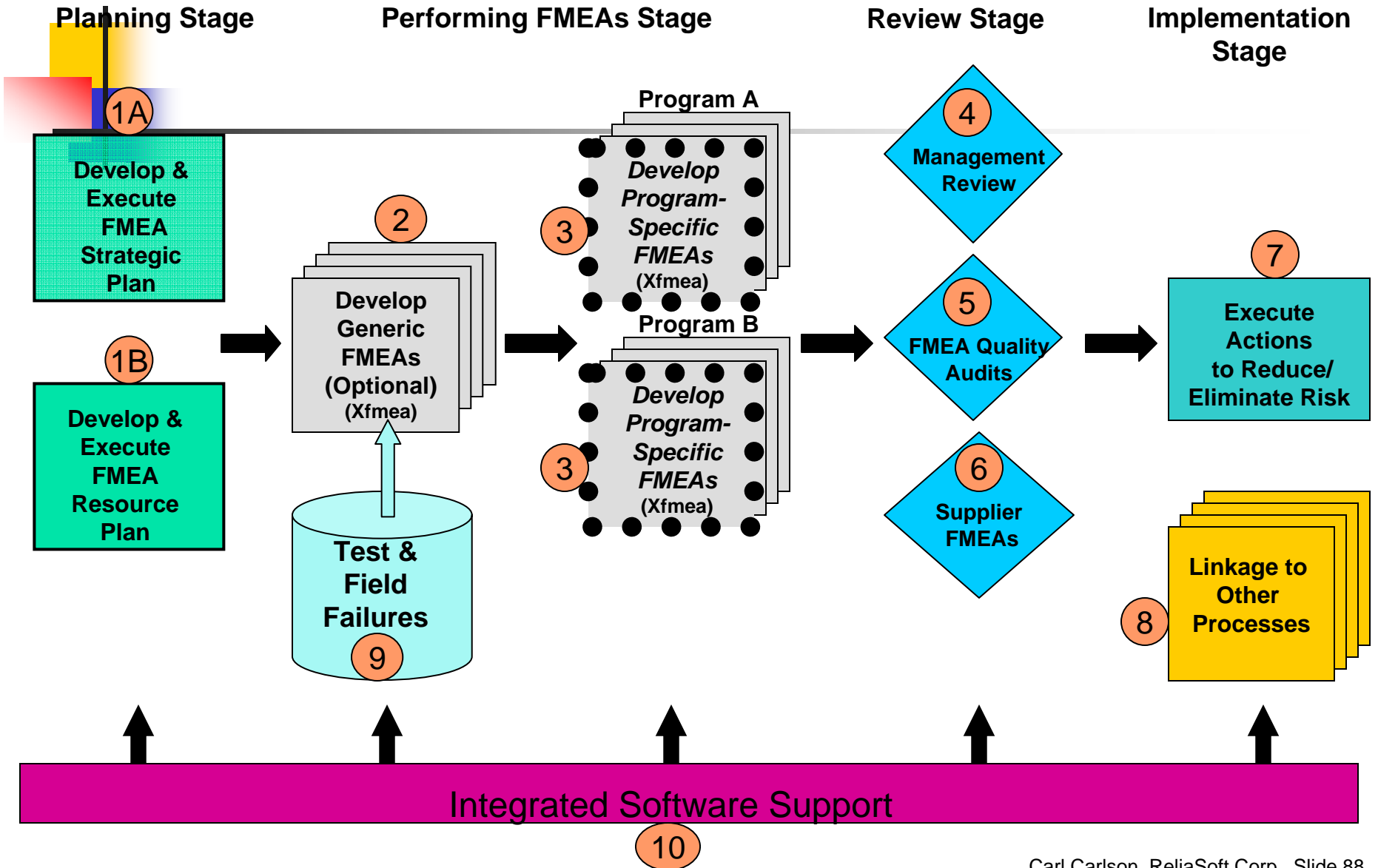
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A Note on Doing Generic FMEAs

- Generic FMEAs are optional
 - Requires up-front commitment
 - Payoff is not immediate
- Most useful if the product line is relatively stable over time

EFFECTIVE FMEA PROCESS





Program-Specific FMEAs

Definition:

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

Strategic Decisions:

- Which programs will get FMEAs?
- What FMEAs will be done for each program?
- What FMEA types, timing, standard, level of detail, how to handle suppliers, etc.?
- How will management review and approval be achieved?
- How will Program-Specific FMEAs be tracked to assure timely and successful completion and risk reduced to acceptable level?

Program-Specific FMEAs (continued)

For each Program-Specific FMEA (complete 10 steps)

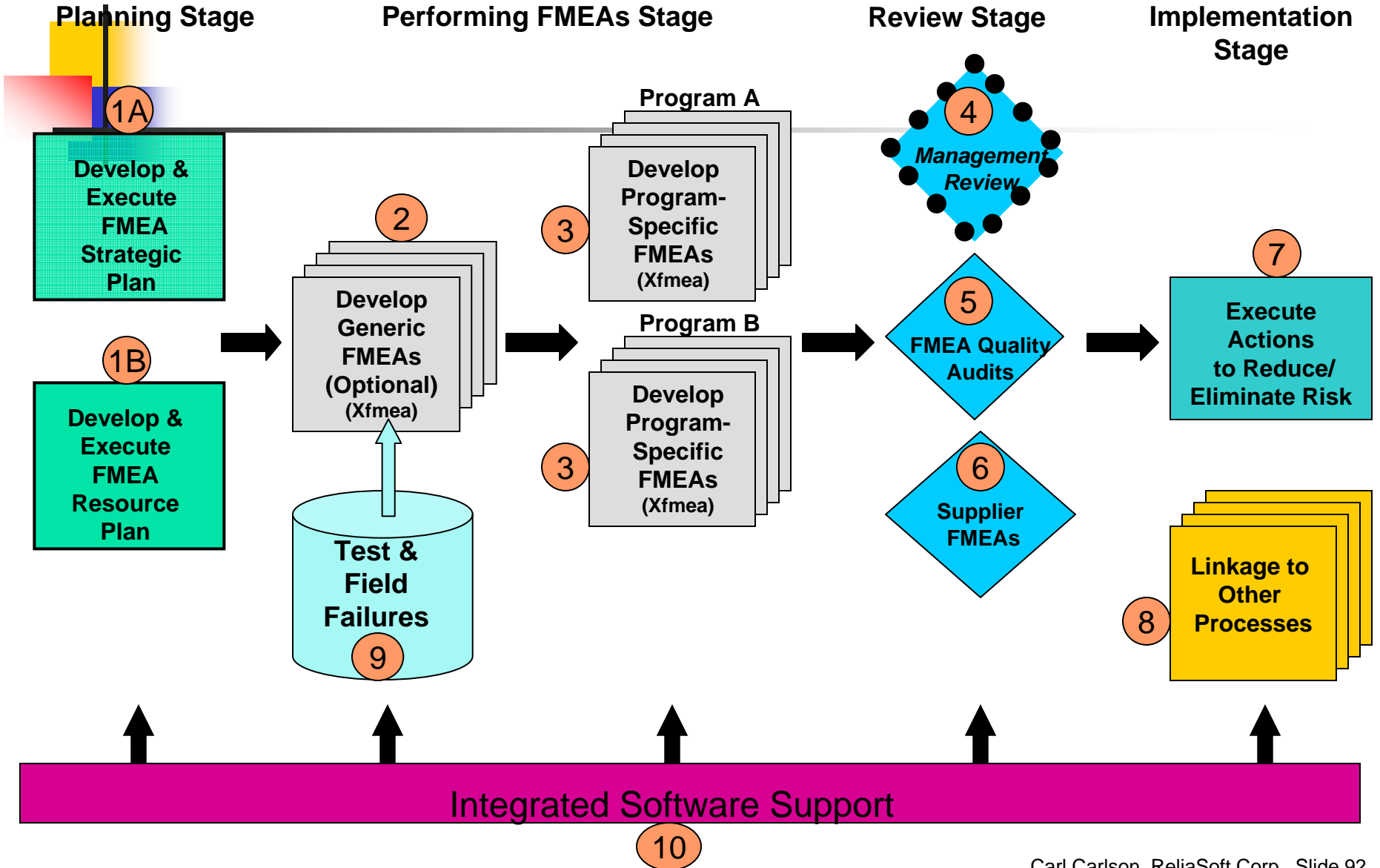
1. Assign FMEA facilitator and team
2. Establish FMEA timing and scope
3. Gather relevant documentation
4. Perform FMEA analysis (according to FMEA standard) up through Recommended Actions
5. Provide input to DVP&R or Process Control Plan
6. Review risk and recommended actions with management
7. Update FMEA project tracking
8. Execute Recommended Actions, and do new risk assessment
9. Review and approve all critical Supplier FMEAs
10. Ensure risk reduced to acceptable level and FMEA is completed “by the book”



A Note on Doing Program-Specific FMEAs

- Most companies have an FMEA “history”
 - Some successful
 - Some not successful
- It helps to “clear the air”
 - What has been done right
 - What has been done wrong
- Make a fresh start with “best practice”

EFFECTIVE FMEA PROCESS



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



A Note on Management Reviews

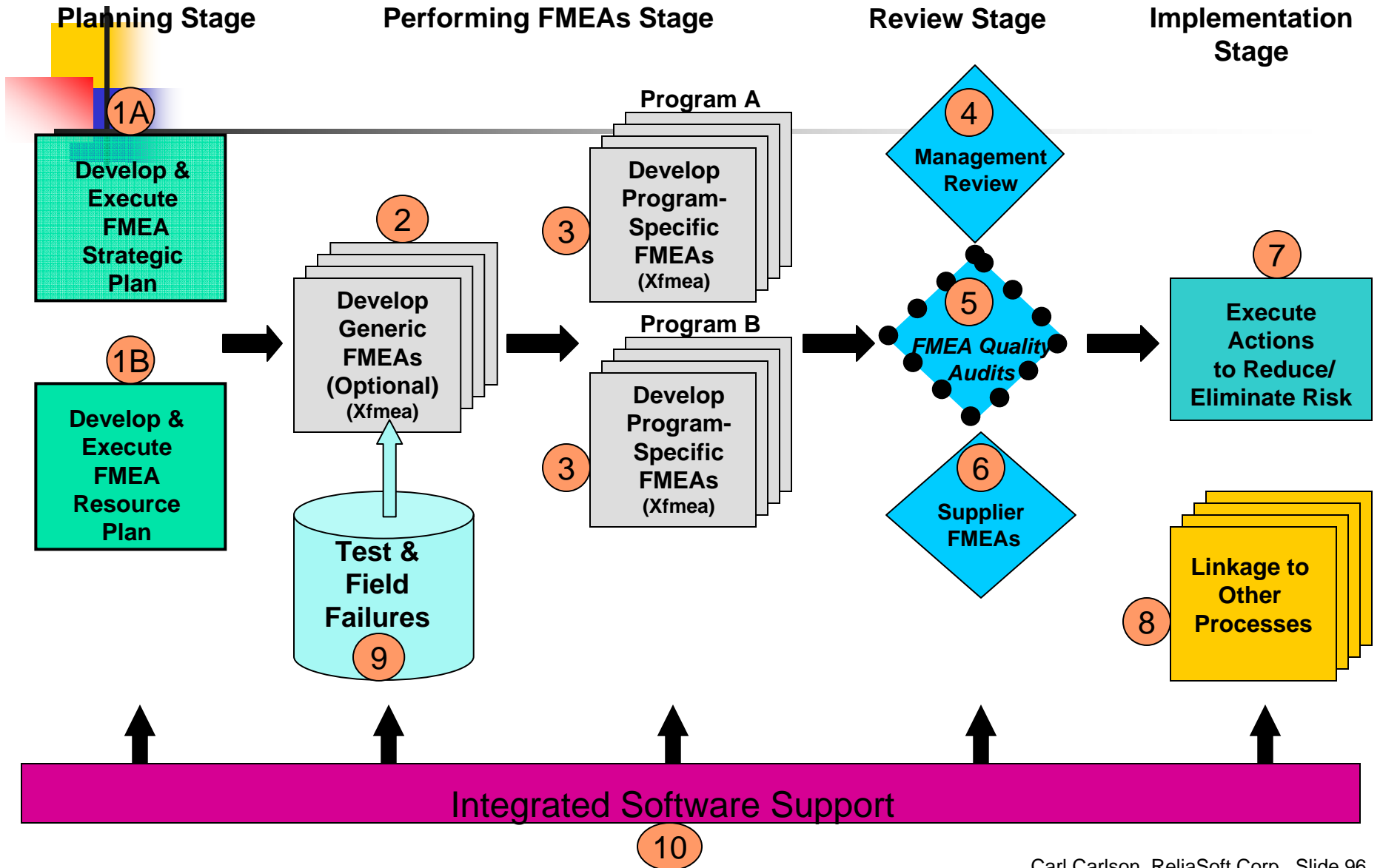
- There may already be a process in place to review failure modes from field or test
- Most companies “piggy-back” the review of FMEA failure modes with the review of field or test failure modes
- A few suggestions:
 - Review only high risk FMEA failure modes
 - Have the “natural owner” of the failure mode present problem/solution to management
 - Close the loop with FMEA Team to ensure overall risk is reduced to acceptable level



Getting and Keeping Management Support

Ask management “what is it worth to prevent high risk failure modes from showing up in product or process designs?”

EFFECTIVE FMEA PROCESS





FMEA Quality Surveys

- Each FMEA team (and internal customer of FMEA) should be surveyed for FMEA effectiveness
- Surveys are based on FMEA Quality Objectives
- Surveys are in writing, 1 or 2 pages
- Individual content can be confidential
- Provides valuable feedback to improve future FMEAs



FMEA Quality Objectives

1. **DESIGN IMPROVEMENTS** *FMEA adequately drives Design Improvements*
2. **HIGH RISK FAILURE MODES** *FMEA addresses all high risk Failure Modes*
3. **DVP&R/CONTROL PLAN** *Comprehends failure modes from the Design FMEA*
4. **INTERFACES** *FMEA scope includes integration and interface failure modes*
5. **LESSONS LEARNED** *Warranty, field issues, “hardy perennials” included*
6. **KCDS CONNECTION** *The FMEA identifies appropriate KPC candidates*
7. **TIMING** *The FMEA is completed during the “Window of opportunity”*
8. **TEAM** *The right people participate as part of the FMEA team*
9. **DOCUMENTATION** *FMEA document is completely filled out “by the book”*
10. **TIME USAGE** *Effective and efficient use of time by FMEA Team*



FMEA Quality Audits

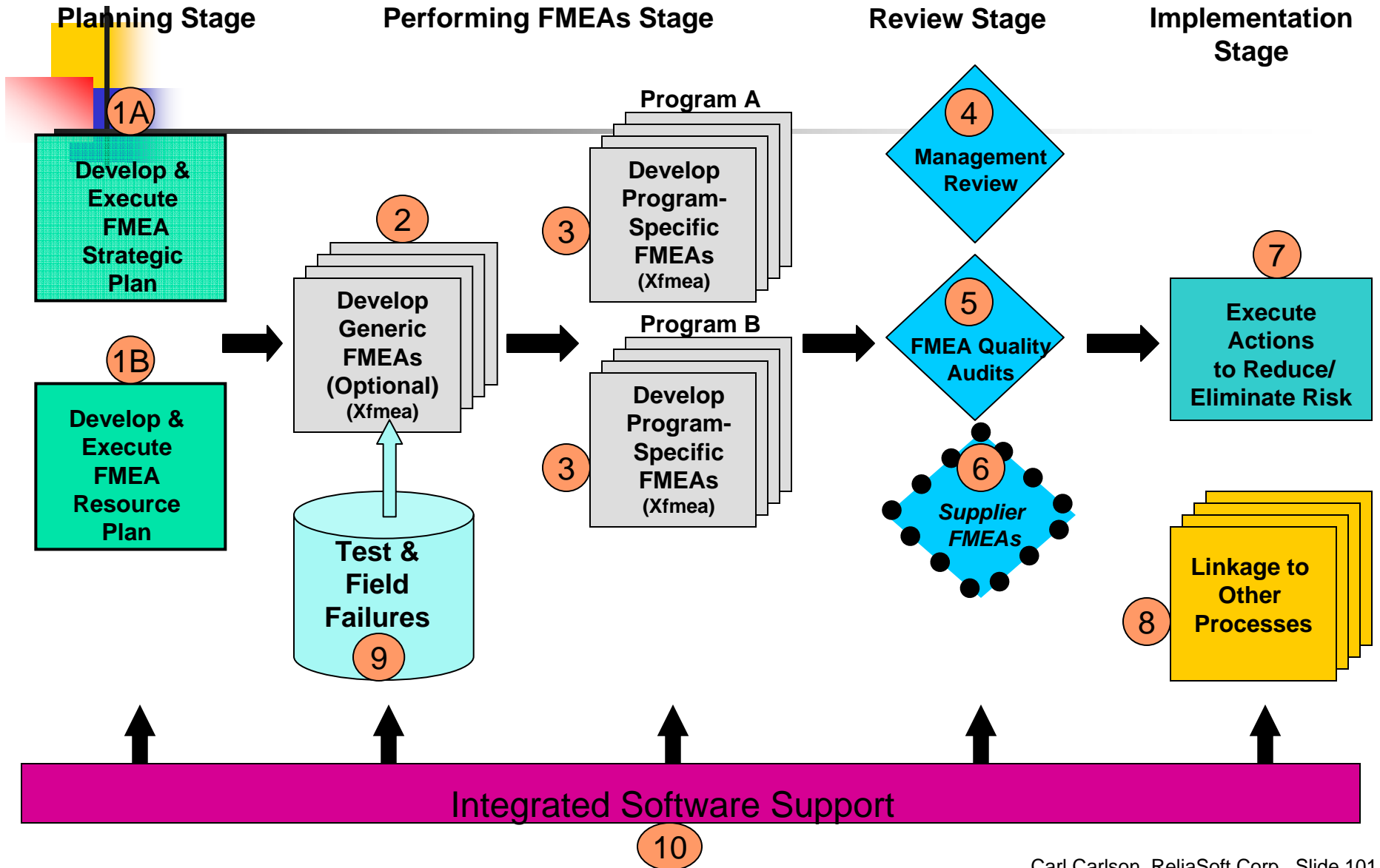
- In person audits of completed (or nearly completed) FMEAs
- Done with FMEA facilitator and core team
- Performed by management of FMEA Process
- Interview format
- Pre-scheduled or random basis
- Based on FMEA Quality Objectives
- One hour maximum per audit
- Provides valuable feedback to improve future FMEAs
- Action Items identified for follow up



A Note on FMEA Quality Surveys/Audits

- 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 cannot be delegated"

EFFECTIVE FMEA PROCESS





Supplier FMEAs

- Potential higher 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 on FMEA



Supplier FMEAs (continued)

For Suppliers who are identified as higher risk:

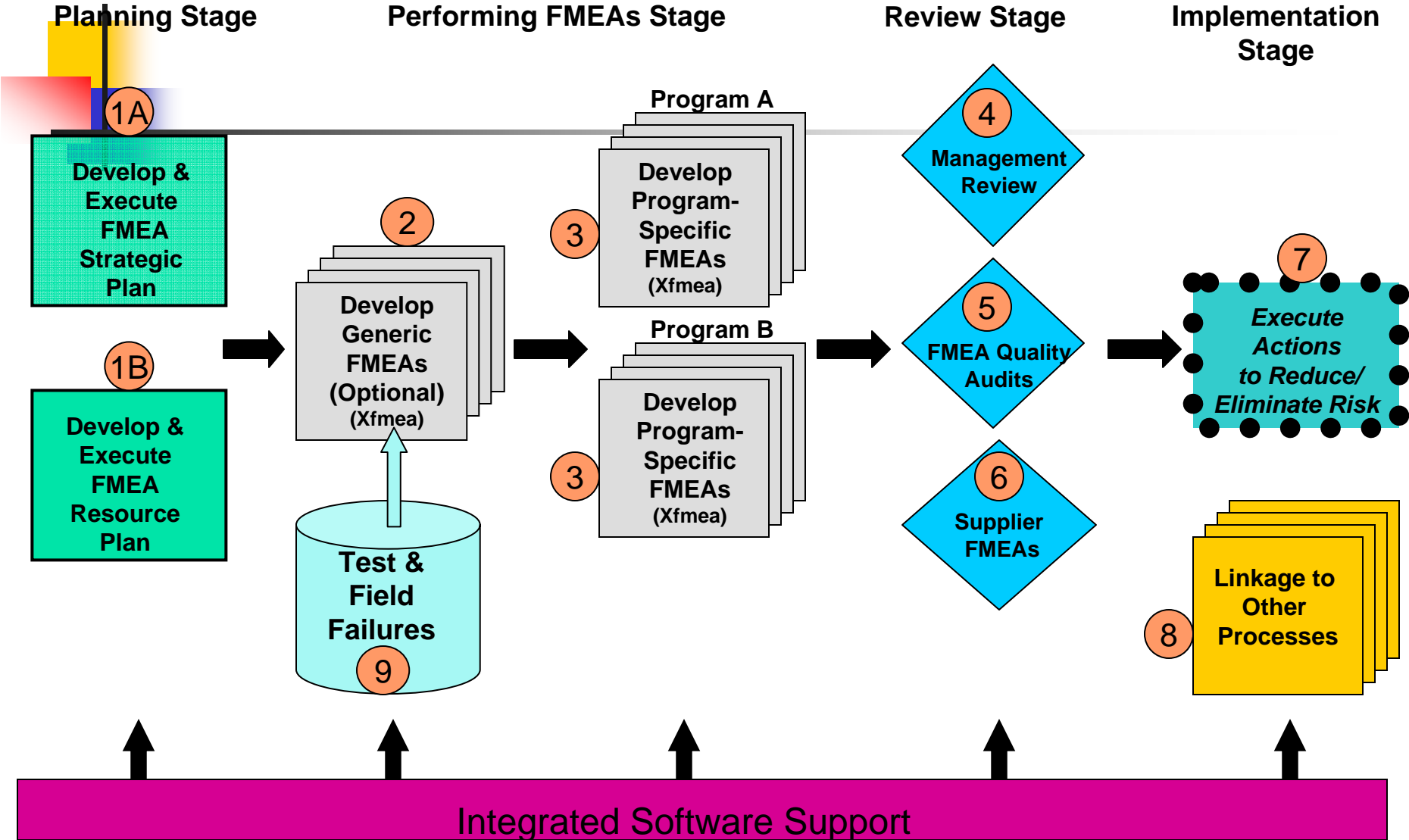
- Require submission of completed FMEA for review and approval, prior to part shipment
- Review conducted by FMEA team or qualified representative, based on FMEA Quality Objectives
- Supplier continues FMEA until Quality Objectives met



A Note on Supplier FMEAs

- It takes time to bring about the right relationship with suppliers on FMEAs and other Reliability tasks
- Suppliers must aspire to subsystems and parts that are failure-free during useful life
- This must be supported by purchasing contracts, supplier selection, specifications and follow-up activity
- Work in the direction of getting suppliers to do proper FMEAs

EFFECTIVE FMEA PROCESS



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

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A Note on Executing FMEA Recommended Actions

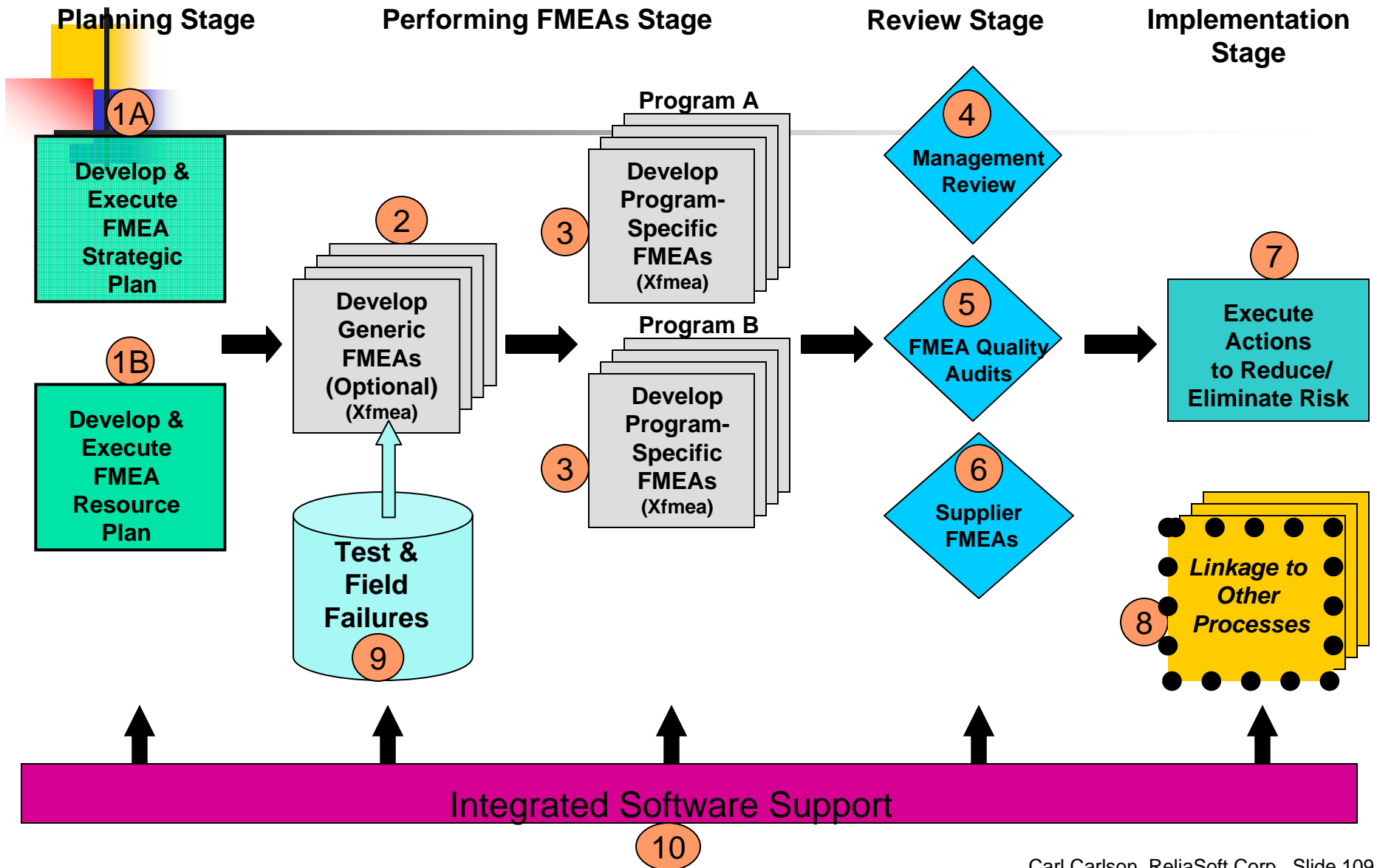
- Some companies file their FMEAs as soon as Actions are identified
- Some companies fail to follow up on Recommended Actions
- Some companies don't close the loop to ensure the risk is reduced
- “Best practice” closes out all FMEA Recommended Actions with risk reduced to an acceptable level

7

What are Characteristics of Successful FMEA Actions?

- FMEA Recommended Actions should be effective, detailed and executable
- They should have management buy in
- They should drive design improvements
- FMEA teams should use the full range of Reliability tools

EFFECTIVE FMEA PROCESS





Linkage to Other Key Processes

Look for software that integrates with requirements from Advanced Product Quality Planning (APQP) guidelines:

- Generate new Process FMEAs based on existing Design FMEAs
- Create integrated:
 - Design Verification Plan and Report (DVP&R)
 - Process Control Plan (PCP)
 - Process Flow Diagram (PFD)
- FMEAs can provide important input to other processes:
 - Design Reviews, Trade Studies, Reliability Growth Analysis, etc.

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Linkage to Other Key Processes

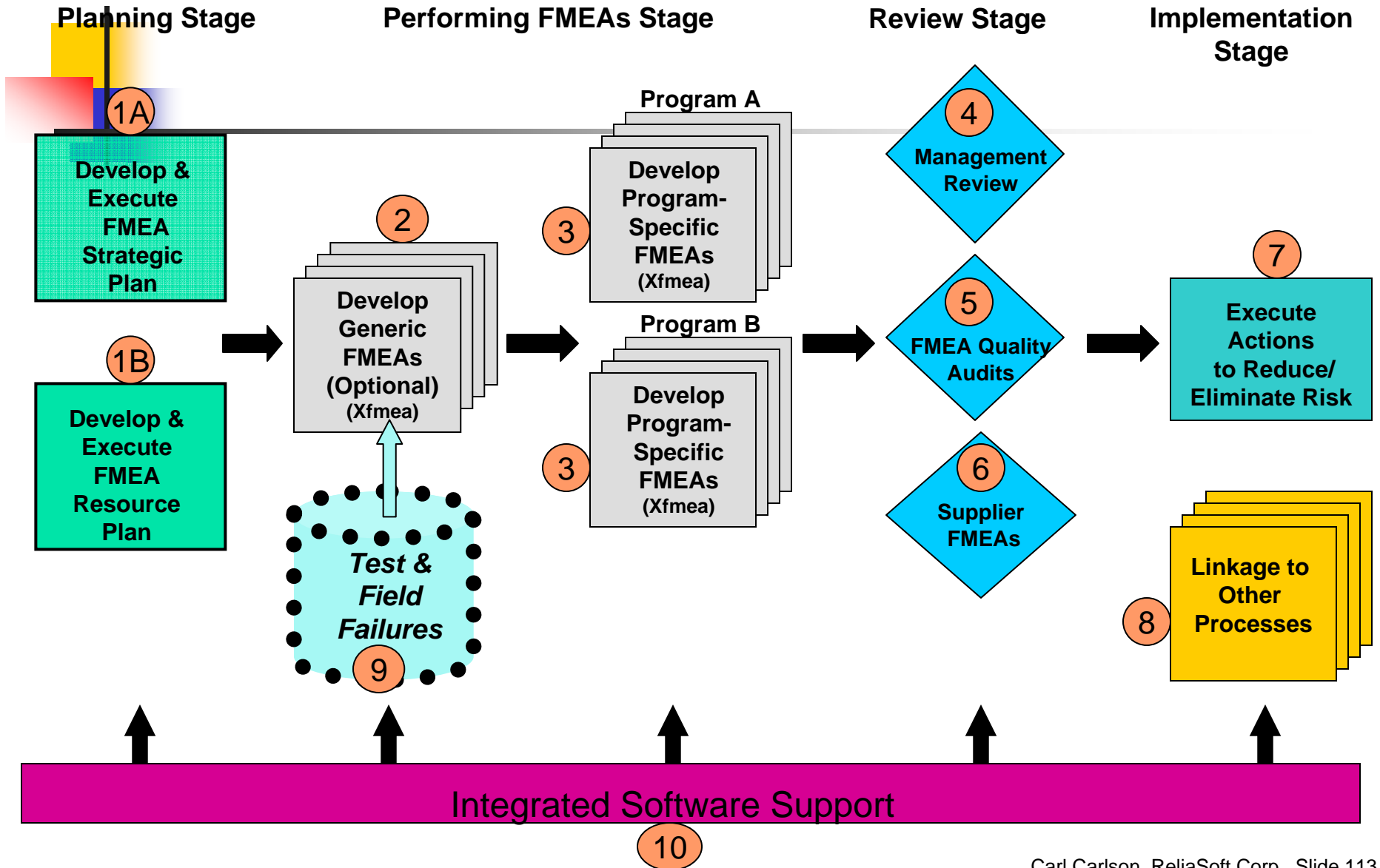
FMEA Process must be integrated with the overall Product Development Process

8

A Note on Linking FMEA to Other Processes

- FMEA can be implemented as a stand-alone process and make significant design improvements
- Linking to other processes results in efficiencies
- It can also make the other processes more effective

EFFECTIVE FMEA PROCESS





Test and Field Failures

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

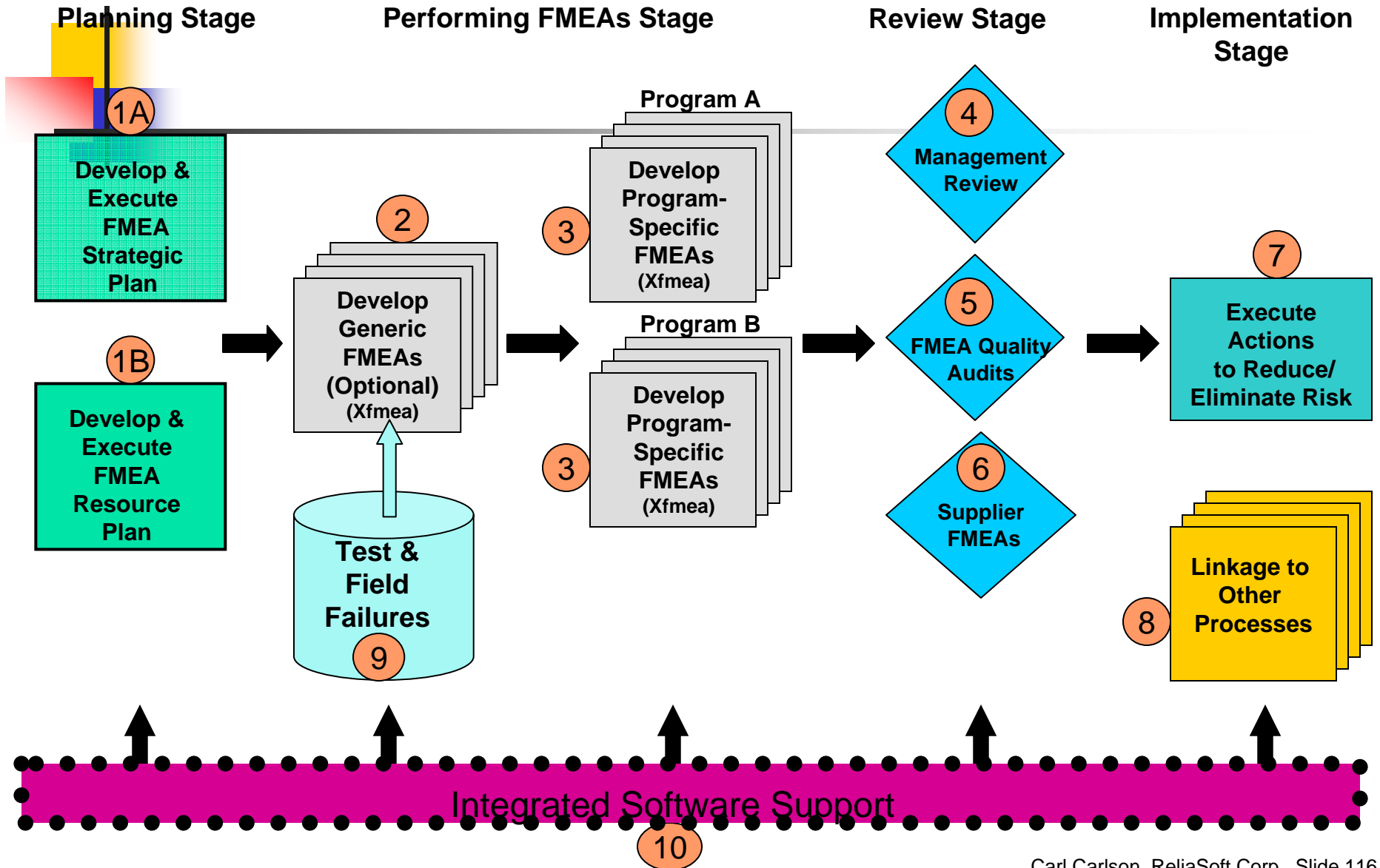
- Often called “FRACAS”
- Provides updates to FMEAs, after initial FMEA analyses are completed (called “post analysis lessons learned”)
- High risk failure modes from FMEA are passed on to FRACAS



A Note on Test and Field Failures

- The best way to prevent recurring problems is to backfill the FMEA with lessons learned from field or test
- Reference Peter Senge's book *The Fifth Discipline: The Art and Practice of the Learning Organization*, 1990

EFFECTIVE FMEA PROCESS





Integrated Software Support

- Relational Database for all FMEA Projects
- FMEA Standards: configurable to organization
- Maintains Generic and Program-Specific FMEAs
- Import-Export and Attachment Features
- Linkage to Other Processes
- Tracks Execution of Risk Reduction Actions
- Generates Plots and Reports for Management Reviews
- Simultaneous FMEA users accessing database



A Note on Integrated Software Support

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



Summarizing the Key Factors for a Successful FMEA Process

- Active FMEA Champion
- Broad management support
- Strategic and Resource Planning
- FMEA process integrated with Business Process
- Well trained FMEA Facilitators and Teams
- Management reviews and support
- Follow-up on all high risk issues
- FMEA Quality Audits
- Integrated FMEA software support
- Supplier FMEAs for higher risk parts
- FMEAs linked to other key processes