How to Audit FMEAs Using Quality Objectives

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Previous Webinar:
The 10 Most Common FMEA Mistakes

- In the previous Webinar in this series we learned the most common mistakes in performing any type of FMEA and the quality objectives for achieving uniformly effective FMEAs.

Learning Objectives:

How to Audit FMEAs Using Quality Objectives

- Students who attend this webinar will learn the following:
  - An effective FMEA audit procedure
  - How to audit each of the 10 FMEA quality objectives

Effective FMEA Audit Procedure

- It is a proven procedure and has helped hundreds of companies improve their FMEA process. It builds on the 10 FMEA quality objectives.

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

FMEA Audit Procedure

What is it?

- The FMEA quality audit procedure is an essential part of ensuring good quality FMEAs.
- FMEA quality audits are in-person audits of completed (or nearly completed) FMEAs, done with the FMEA facilitator and the FMEA core team present.
- Each of the ten FMEA Quality Objectives have a corresponding “How to audit” recommendation.

FMEA Audit Procedure
In a Nutshell

- FMEA audits can be done on a pre-scheduled or random basis.
- Someone, who is skilled and experienced with the content and quality of good FMEAs, performs the audit, from either management or an FMEA subject matter expert.
- The auditor evaluates the content of the selected FMEA with the FMEA team against each of the FMEA Quality Objectives, one by one, using the “How to audit” recommendation.

FMEA Audit Procedure
In a Nutshell (continued)

- Each quality objective is evaluated for how well it is achieved. This evaluation can be done on a yes/no basis or a variable evaluation, such as high-medium-low, or 1 to 5.
- The estimated time is one hour for this audit, about 5 minutes per FMEA Quality Objective.
- The results of the audit provide valuable feedback to improve future FMEAs.
- The focus is on improving the FMEA process, not on criticizing the person or team doing the FMEA.

FMEA Audit Procedure
In a Nutshell (continued)

- The auditor is looking for specific process-related issues that underlie deficiencies in achieving the quality objectives, such as lack of training, procedure, facilitation skills, standards, resources, support, etc.
- Action items from the FMEA quality audit should be documented and pursued to improve the overall FMEA process.
- Do not expect to achieve all ten FMEA quality objectives instantly. Rather, work to maintain steady improvement.

Example FMEA Audit

- For this presentation, a truncated portion of a fictitious Design FMEA on a Bicycle Hand Brake Subsystem will be audited
- This FMEA has been selectively modified with errors for evaluation of the 10 FMEA Quality Objectives.
- Exercise: for each of the 10 FMEA quality objectives, review the FMEA example to assess how well it achieves the FMEA Quality Objective. Make note of how well this objective was achieved. Explain.

Excerpt from Hand Brake Subsystem Design FMEA (with errors introduced for FMEA Quality Objectives evaluation)

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Classification	Potential Cause(s) of Failure	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET	RPN	Recommended Actions
Hand Brake Subsystem: Provide the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.	10		Cable Binds due to inadequate lubrication or poor routing	4	Design review of brake system	Bicycle system durability test # 789	2	80	Modify bicycle durability testing to include periodic brake cable checks for binding
					External foreign material reduces friction	2			3	60	Modify bicycle durability testing to include foreign material (dust, leaves, etc.) at interface of brake pad and wheel rim
					Cable breaks	6	Cable material selection based on ANSI #ABC.	Bicycle system durability test # 789	4	240	1. Require cable DFMEA / PFMEA from supplier approved by All-Terrain FMEA team. 2. Based on results of Cable DFMEA, develop cable strength test
					Brake Lever breaks	1	Design review of brake system	Bicycle system durability test # 789	1	10	
					Selected brake pad material does not apply required friction to wheel	2			2	40	Add bench test to evaluate adequate brake pad friction
Hand Brake Subsystem: Brake system is easy to adjust and keep in optimal working order.	Brake system misadjusted by bicycle user	Brake system does not stop bicycle in required distance or is erratic, potentially resulting in accident.	10		Brake cable mis-adjusted by user	6		Bicycle system durability test # 789	5	300	1. Develop new brake cable adjustment test that identifies mis-adjustment problems 2. Revise bicycle durability test regimen to periodically check for brake cable, pad and lever mis-adjustment
					Brake pad mis-adjusted by user	1	Design review of brake system	Bicycle system durability test # 789	1	10	
					Brake lever mis-adjusted by user	1	Design review of brake system	Bicycle system durability test # 789	2	20	
	Brake becomes mis-adjusted due to failure of interface between brake cable assy, brake pad assy and/or wheel assy.										

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Example FMEA Audit
General Information

- The FMEA team is made up of a bicycle design engineer and a bicycle test engineer, in support of a new all-terrain bicycle due to be launched soon.
- The FMEA was completed 4 weeks after design freeze, after testing had begun.
- The FMEA team prepared for the FMEA project by studying drawings and sketches for the hand brake subsystem.
- When the FMEA was completed, the bicycle test engineer thought the result was value added; however the bicycle design engineer thought the analysis was a waste of time.

Auditing Quality Objective #1

- *The FMEA drives product design or process improvements as the primary objective*
- *How to audit*: Look at the recommended actions and observe whether or not most of them drive design improvements (in the case of a System or Design FMEA) or process improvements (in the case of a Process FMEA). Talk with the team to ensure focus was on improvements to design or process.

Excerpt from Hand Brake Subsystem Design FMEA (with errors introduced for FMEA Quality Objectives evaluation)

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Classification	Potential Cause(s) of Failure	OCC	Recommended Actions
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					External foreign material reduces friction	2	Modify bicycle durability testing to include foreign material (dust, leaves, etc.) at interface of brake pad and wheel rim
					Cable breaks	6	1. Require cable DFMEA / PFMEA from cable supplier approved by All-Terrain FMEA team. 2. Based on results of Cable DFMEA, develop cable strength test
					Brake Lever breaks	1	
					Selected brake pad material does not apply required friction to wheel	2	Add bench test to evaluate adequate brake pad friction
Hand Brake Subsystem: Brake system is easy to adjust and keep in optimal working order.	Brake system misadjusted by bicycle user	Brake system does not stop bicycle in required distance or is erratic, potentially resulting in accident.	10		Brake cable mis-adjusted by user	6	1. Develop new brake cable adjustment test that identifies mis-adjust problems 2. Revise bicycle durability test regimen to periodically check for brake cable, pad and lever mis-adjust
					Brake pad mis-adjusted by user	1	
					Brake lever mis-adjusted by user	1	Design review of brake system	Bicycle system durability test # 789	2	20	
	Brake becomes mis-adjusted due to failure of interface between brake cable assy, brake pad assy and/or wheel assy.										

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Auditing Quality Objective #1

Teaching Analysis

- To achieve this quality objective, there should be a number of effective design improvement actions in the Recommended Actions column.
- This FMEA has no design improvement actions and does not meet objective #1

Auditing Quality Objective #2

- *The FMEA addresses all high-risk failure modes with effective and executable action plans.*
- *How to audit*: Review high severity and high RPN issues to see if the corresponding recommended actions are adequate to reduce risk to an acceptable level. Talk with the team to ensure they are satisfied all high risk is addressed and no important concerns are left unaddressed. One way to do this is to ask the subject matter experts for their two or three biggest concerns on the project, and then to verify that these concerns are adequately addressed in the body of the FMEA.

Excerpt from Hand Brake Subsystem Design FMEA (with errors introduced for FMEA Quality Objectives evaluation)

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV		OCC		DET	RPN	Recommended Actions
Hand Brake Subsystem: Provide the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.	10		4		2	80	Modify bicycle durability testing to include periodic brake cable checks for binding
					2		3	60	Modify bicycle durability testing to include foreign material (dust, leaves, etc.) at interface of brake pad and wheel rim
					6		4	240	1. Require cable DFMEA / PFMEA from cable supplier approved by All-Terrain FMEA team. 2. Based on results of Cable DFMEA, [illegible]
Hand Brake Subsystem: Brake system is easy to adjust and keep in optimal working order.	Brake system misadjusted by bicycle user	Brake system does not stop bicycle in required distance or is erratic, potentially resulting in accident.			1		1	10	
					2		2	40	Add bench test to evaluate adequate brake pad friction
	Brake becomes mis-adjusted due to failure of interface between brake cable assy, brake pad assy and/or wheel assy.		10		6		5	300	1. Develop new brake cable adjustment test that identifies mis-adjust problems 2. Revise bicycle durability test regimen to periodically check for brake cable, pad and lever mis-adjust

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Auditing Quality Objective #2

Teaching Analysis

- To achieve this quality objective, every failure effect with high severity (9 or 10) and every failure cause with high RPN (based on FMEA team determination or company mandate) must be addressed with one or more effective actions in the Recommended Actions column. The team or reviewer should ask themselves if the recommendations will reduce the risk identified by high severity or high RPN to an acceptable level.
- This FMEA does not achieve this objective because the recommended actions only address detection risk and not severity or occurrence risk. For each of the high severity or high RPN line items, there needs to be actions (as many as needed) that first attempt to reduce severity (if possible) and reduce occurrence to a very low rating, in addition to reducing detection ratings.

Auditing Quality Objective #3

- *The Design Verification Plan (DVP) or the Process Control Plan (PCP) considers the failure modes from the FMEA.*
- *How to audit*: Review the recommended actions to see if there are improvements to the Design Verification Plans or procedures, or the Process Control Plans, based on risk associated with current detection controls. Talk with the team to determine if they had adequate representation from testing and if the FMEA benefited from the testing experience, and to learn whether the test regimens were improved if the current detection controls were not adequate.

Excerpt from Hand Brake Subsystem Design FMEA (with errors introduced for FMEA Quality Objectives evaluation)

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Classification		Current Design Controls (Detection)	DET	RPN	Recommended Actions
Hand Brake Subsystem: Provide the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.	10		Cal ina or	Bicycle system durability test # 789	2	80	Modify bicycle durability testing to include periodic brake cable checks for binding
					Ext ma fric		3	60	Modify bicycle durability testing to include foreign material (dust, leaves, etc.) at interface of brake pad and wheel rim
					Cal	Bicycle system durability test # 789	4	240	1. Require cable DFMEA / PFMEA from cable supplier approved by All-Terrain FMEA team. 2. Based on results of Cable DFMEA, develop cable strength test
					Bra	Bicycle system durability test # 789	1	10	
					Sel ma app to		2	40	Add bench test to evaluate adequate brake pad friction
Hand Brake Subsystem: Brake system is easy to adjust and keep in optimal working order.	Brake system misadjusted by bicycle user	Brake system does not stop bicycle in required distance or is erratic, potentially resulting in accident.	10		Bra adj	Bicycle system durability test # 789	5	300	1. Develop new brake cable adjustment test that identifies mis-adjust problems 2. Revise bicycle durability test regimen to periodically check for brake cable, pad and lever mis-adjust
					Bra adj				
					Bra adj				
	Brake becomes mis-adjusted due to failure of interface between brake cable assy, brake pad assy and/or wheel assy.								

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Auditing Quality Objective #3

Teaching Analysis

- To achieve this quality objective, there needs to be effective actions in the recommended actions column to improve the detection controls for any line item with detection risk identified. Typically this means where the detection rating is not low, and either the severity or RPN is high.
- This FMEA has good actions in the recommended actions column for each line item where detection risk exists.

Auditing Quality Objective #4

- *The FMEA scope includes integration and interface failure modes in both block diagram and analysis.*
- *How to audit*: Review items, functions, failure modes and other portions of the FMEA to ensure that interface and integration issues were taken up and addressed within the scope of the FMEA. Look at the FMEA Block Diagram to verify. Talk with the team, inquiring how they ensured no interface issues were missed.

Excerpt from Hand Brake Subsystem Design FMEA (with errors introduced for FMEA Quality Objectives evaluation)

Item / Function	Potential Failure Mode
Hand Brake Subsystem: Provide the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.
Hand Brake Subsystem: Brake system is easy to adjust and keep in optimal working order.	Brake system misadjusted by bicycle user
	Brake becomes mis-adjusted due to failure of interaction/interface between brake cable assy, brake pad assy and/or wheel assy.

								rent Design Controls Detection)	D E T	R P N	Recommended Actions
								le system bility test # 789	2	80	Modify bicycle durability testing to include periodic brake cable checks for binding
									3	60	Modify bicycle durability testing to include foreign material (dust, leaves, etc.) at interface of brake pad and wheel rim
								le system bility test # 789	4	240	1. Require cable DFMEA / PFMEA from supplier approved by All-Terrain FMEA team. 2. Based on results of Cable DFMEA, develop cable strength test
								le system bility test # 789	1	10	
									2	40	Add bench test to evaluate adequate brake pad friction
								le system bility test # 789	5	300	1. Develop new brake cable adjustment test that identifies mis-adjustment problems 2. Revise bicycle durability test regimen to periodically check for brake cable, pad and lever mis-adjustment
Brake system is easy to adjust and keep in optimal working order.	bicycle user	required distance or is erratic, potentially resulting in accident.			Brake pad mis-adjusted by user	1	Design review of brake system	Bicycle system durability test # 789	1	10	
					Brake lever mis-adjusted by user	1	Design review of brake system	Bicycle system durability test # 789	2	20	
	Brake becomes mis-adjusted due to failure of interface between brake cable assy, brake pad assy and/or wheel assy.										

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Auditing Quality Objective #4

Teaching Analysis

- Since the scope of this FMEA is at the subsystem level, to achieve this quality objective the component interfaces should be included in the Functions column and potential failure modes for these interfaces should be identified and analyzed. The interfaces and integration of the handbrake subsystem with the various other subsystems should be included in the System FMEA.
- The interaction of the brake lever, brake cable, brake pad, and brake caliper is not well described in the Functions column of this FMEA, and the one failure mode that attempts to deal with interfaces (the last failure mode in the FMEA) is not analyzed.

Auditing Quality Objective #5

- *The FMEA considers all major "lessons learned" (such as high warranty, campaigns, etc.) as input to failure mode identification.*
- *How to audit*: Review failure modes and causes to ensure that they contain supplemental field failure data. Preferably, there is a visual way to see which failure modes are from field information and how they are addressed. Talk with the FMEA team to ensure that the FMEA benefited from field lessons learned and that high-risk issues from the field will not be repeated.

Excerpt from Hand Brake Subsystem Design FMEA (with errors introduced for FMEA Quality Objectives evaluation)

Item / Function	Potential Failure Mode	Potential Cause(s) of Failure	DET	RPN	Recommended Actions
Hand Brake Subsystem: Provide the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	Cable Binds due to inadequate lubrication or poor routing	2	80	Modify bicycle durability testing to include periodic brake cable checks for binding
		External foreign material reduces friction	3	60	Modify bicycle durability testing to include foreign material (dust, leaves, etc.) at interface of brake pad and wheel rim
		Cable breaks	4	240	1. Require cable DFMEA / PFMEA from supplier approved by All-Terrain FMEA team. 2. Based on results of Cable DFMEA, develop cable strength test
		Brake Lever breaks			
		Selected brake pad material does not apply required friction to wheel			
	Brake system misadjusted by bicycle user	Brake cable mis-adjusted by user	1	10	
		Brake pad mis-adjusted by user	2	40	Add bench test to evaluate adequate brake pad friction
		Brake lever mis-adjusted by user			
Hand Brake Subsystem: Brake system is easy to adjust and keep in optimal working order.	Brake becomes mis-adjusted due to failure of interaction/interface between brake cable assy, brake pad assy and/or wheel assy.		5	300	1. Develop new brake cable adjustment test that identifies mis-adjustment problems 2. Revise bicycle durability test regimen to periodically check for brake cable, pad and lever mis-adjustment
		Brake pad mis-adjusted by user	1	10	
		Brake lever mis-adjusted by user	2	20	
	Brake becomes mis-adjusted due to failure of interface between brake cable assy, brake pad assy and/or wheel assy.				

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Auditing Quality Objective #5

Teaching Analysis

- To achieve this quality objective, all of the field failures for similar bicycle systems should be reviewed to ensure that there is no repeat of such failures within the scope of this FMEA.
- There is no indication in the problem introduction that this has taken place, and there is no indication in the body of the FMEA that “seen” failure modes have been included. Anyone reviewing this FMEA would have to satisfy themselves that all applicable field failures have been reviewed and will not reoccur.

Auditing Quality Objective #6

- *The FMEA provides the correct level of detail in order to get to root causes and effective actions.*
- *How to audit*: Verify that the level of detail on higher risk issues is adequate to fully understand root causes and develop effective corrective actions. Review the different columns of the FMEA to see if the overall level of detail is proper and adequate. Too much detail shows up as endless pages of FMEA material, including areas that no one on the FMEA team is concerned about; too little detail shows up as under-defined functions, failure modes, effects, causes or controls, or as areas of unaddressed concern from one or more FMEA team members. Talk with the FMEA team to determine how they addressed the level of detail and ensured all concerns were included in the scope of the FMEA project.

Excerpt from Hand Brake Subsystem Design FMEA (with errors introduced for FMEA Quality Objectives evaluation)

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Class	Potential Cause(s) of Failure	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)
Hand Brake Subsystem: Provide the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.	10		Cable Binds due to inadequate lubrication or poor routing	4	Design review of brake system	Bicycle system durability test # 789
					External foreign material reduces friction	2		
					Cable breaks	6	Cable material selection based on ANSI #ABC.	Bicycle system durability test # 789
					Brake Lever breaks	1	Design review of brake system	Bicycle system durability test # 789

Brake system is easy to adjust and keep in optimal working order.	bicycle user	required distance or is erratic, potentially resulting in accident.										mis-adjustment problems 2. Revise bicycle durability test regimen to periodically check for brake cable, pad and lever mis-adjustment
					Brake pad mis-adjusted by user	1	Design review of brake system	Bicycle system durability test # 789	1	10		
					Brake lever mis-adjusted by user	1	Design review of brake system	Bicycle system durability test # 789	2	20		
	Brake becomes mis-adjusted due to failure of interface between brake cable assy, brake pad assy and/or wheel assy.											

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Auditing Quality Objective #6

Teaching Analysis

- To achieve this quality objective, the level of detail must be adequate to clearly identify risk, arrive at root causes, and clearly describe the line item being analyzed.
- This FMEA does a reasonably good job in level of detail: not too wordy and not missing clarity. Each column in the FMEA needs to have the amount of detail necessary to arrive at the next column, as well as providing enough clarity so that someone who was not involved in the FMEA should be able to understand the concept that is being described.

Auditing Quality Objective #7

- *The FMEA is completed during the "window of opportunity" whence it can most effectively influence the product or process design.*
- *How to audit*: Review the timing of the FMEA project against the product development process timing gates. Verify the FMEA was started and completed in the proper time frame for ensuring maximum value.

Auditing Quality Objective #7

Teaching Analysis

- To achieve this quality objective, the FMEA should begin shortly after the design concept has been identified and finished before design freeze.
- This FMEA was done late and does not meet this quality objective.

Auditing Quality Objective #8

- *The right people, adequately trained in the procedure, participate on the FMEA team throughout the analysis.*
- *How to audit*: Review the FMEA team membership roster to ensure that there was adequate representation from the various disciplines needed based on the type of FMEA and the scope of the project. Check FMEA team meeting records to ensure attendance was adequate at each meeting. Talk with the individual team members to see if their input was elicited in the decisions.

Auditing Quality Objective #8

Teaching Analysis

- To achieve this quality objective, the Design FMEA team needs to be comprised of the right cross - functional team.
- In this case, there should minimally be representation from bicycle system engineering, hand brake design engineering, test engineering, manufacturing, quality or reliability, and field service. Since the FMEA team was made up of a design and test engineer, this quality objective was not met.

Auditing Quality Objective #9

- *The FMEA document is completed "by the book," including "Action Taken" and final risk assessment.*
- *How to audit*: Look at the FMEA to see if the various columns were properly filled out and that FMEA best practice procedure was followed. Talk with the FMEA team to ensure they rigorously followed FMEA guidelines and practices.

Auditing Quality Objective #9

Teaching Analysis

- To achieve this quality objective, each of the columns of the FMEA needs to be procedurally accurate, technically correct, and all columns properly filled out.
- Although the example FMEA is truncated, there have been a number of errors in the body of the FMEA, as identified in earlier analysis of the quality objectives.

Auditing Quality Objective #10

- *Time spent by the FMEA team is an effective and efficient use of time with a value added result.*
- *How to audit*: Talk with the FMEA team to see if each member believes his time was well spent and a value added result was achieved. If any issues arise, find out why.

Auditing Quality Objective #10

Teaching Analysis

- To achieve this quality objective, all members of the FMEA team should agree that their time was well spent to a value - added result.
- This FMEA did not have a properly constituted FMEA team. Of the two members who performed the analysis, only one thought the result was value added. Future FMEAs will be poorly represented and attended unless proper teams are established and facilitated.

Summary

- An FMEA quality audit process can help ensure each and every FMEA is high quality and effective.
- Remember to focus on improving the FMEA process, not criticizing the FMEA team.

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.

Next Webinar:
Implementing a successful FMEA process

- In order to be fully effective, FMEA teams require an infrastructure and coordinated approach from many different departments and organizational functions.
- A *company-wide FMEA process* is the entire set of systems and tasks essential to support development of high-reliability products and processes through timely accomplishment of well-done FMEAs.
- This short course outlines a successful FMEA process, and the specific roles and responsibilities that must be implemented.

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.