FMEA Quality Audit Procedure

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. The audit 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. Here is the procedure.

Each of the ten FMEA Quality Objectives have a corresponding “How to audit” recommendation. In a nutshell, an FMEA subject matter expert or management person reviews the FMEA results with the FMEA team against each of the FMEA Quality Objectives, one by one, using the “How to audit” recommendation. 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 or low. 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 the person or team doing the FMEA. 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.

FMEA Ten Quality Objectives

1. **DESIGN IMPROVEMENTS** *The FMEA drives product design or process improvements as the primary objective.*
2. **HIGH RISK FAILURE MODES** *The FMEA addresses all high-risk failure modes with effective and executable action plans.*
3. **DVP&R/CONTROL PLAN** *The Design Verification Plan & Report (DVP&R) or the Process Control Plan (PCP) considers the failure modes from the FMEA.*
4. **INTERFACES** *The FMEA scope includes integration and interface failure modes in both block diagram and analysis.*
5. **LESSONS LEARNED** *The FMEA considers all major "lessons learned" (such as high warranty, campaigns, etc.) as input to failure mode identification.*
6. **LEVEL OF DETAIL** *The FMEA provides the correct level of detail in order to get to root causes and effective actions.*
7. **TIMING** *The FMEA is completed during the "window of opportunity" whence it can most effectively impact the product or process design.*
8. **TEAM** *The right people are adequately trained in the procedure and participate on the FMEA team throughout the analysis.*
9. **DOCUMENTATION** *The FMEA document is completely filled out "by the book," including "Action Taken" and final risk assessment.*

10. **TIME USAGE** *Time spent by the FMEA team is an effective and efficient use of time with a value added result.*

Mistake # 1

Failure of the FMEA to drive design or process improvements

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.

Mistake # 2

Failure of the FMEA to address all high-risk failure modes

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.

Mistake # 3

Failure of the FMEA to improve Test/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.

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.

Mistake # 4

Not including interfaces or integration in FMEA

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.

Mistake # 5

Disconnect between FMEA and information from the field

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.

Mistake # 6

Wrong Level of Detail in the Analysis

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.

Mistake # 7

Performing FMEAs late.

Quality Objective # 7

The FMEA is completed during the "window of opportunity" whence it can most effectively impact 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.

Mistake # 8

FMEAs with inadequate team composition and lack of participation

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.

Mistake # 9

FMEAs with improper procedure

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.

Mistake # 10

Inefficient use of time

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.