Guidelines For Auditing FMEA'S per QS 9000:
(Source: Potential Failure Mode and Effects Analysis (FMEA) Reference Manual (AIAG): (Feb, 1996))

1. Is there evidence that a cross-functional team was used to develop the FMEA?
2. Is the FMEA header completely filled out with a tracking number, the component or (sub) system name, design responsible activity, preparer's name, model year and vehicle (if known), the initial FMEA due date, the date the original FMEA was compiled, the latest revision date and names/departments of team member?
3. Is the FMEA that is being audited the latest revision level?
4. **Function** – Has the component or (sub) system been identified? Has the nomenclature found on the engineering drawing been used? Has the function of the part been identified?
5. **Potential Failure Mode** – Is there at least one failure mode listed for every function?
6. **Potential Effects of Failure** – Are the effects of the failure defined and are they defined in terms of what the internal or vehicle level external customer might notice?
7. **Severity** – Is the severity (or seriousness) of the potential effect of the failure rated? (See Definitions provided above.)
8. **Classification** – Are the significant and critical characteristics identified in this column? (blanks are allowed) (See Special Characteristics model on other side)
9. **Potential Causes/Mechanisms of Failure** – Is there at least one potential cause of failure listed for every failure mode?
10. **Occurrence** – has an occurrence ranking been assigned to each of the potential causes/mechanisms of failure? (See Definitions provided above.)
11. **Current Design Controls** – Is there listed a prevention, design validation/verification (DV) or other activities which will maximize design adequacy of the failure mode and or cause mechanism?
12. **Detection** – Is there a detection ranking that assesses the ability of the design controls to detect a potential cause/mechanism or the ability of the design controls to detect the subsequent failure mode before the component or (sub) system is released for production. (See Definitions provided above.)
13. **RPN** – Has the RPN been calculated by multiplying S x O x D?
14. **Recommended Actions** – Have actions been identified for potential significant and critical characteristics and to lower the risk of the higher RPN failure modes? Has "none" been entered in the column if no actions are recommended?
15. **Responsibility** – Has an individual, SBU and target completion date been entered in columns where an action has been recommended? (Blanks are OK when no action is recommended)
16. **Actions Taken** – Has a brief description of the actual action and effective date been entered after the action has been taken? (Blanks are OK when no action is recommended)
17. Resulting severity, occurrence, detection and RPN – Have the new severity, occurrence, detection and RPN numbers been entered after an action has been completed and verified?
18. Has the design responsible engineer implemented or adequately addressed the recommended action?

Note: *A QS-9000 auditor may only audit the FMEA process. They may not question the content of the FMEA.*

Severity, Occurrence, and Detection Criteria for Design FMEA

Severity Evaluation Criteria		
Effect	**Criteria: Severity of Effect**	**Rank**
Hazardous - without warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning	10
Hazardous - with warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning	9
Very High	Vehicle/item inoperable, with loss of primary function.	8
High	Vehicle/item operable, but at reduced level of performance. Customer dissatisfied.	7
Moderate	Vehicle/item operable, but Comfort/ Convenient item(s) inoperable. Customer experiences discomfort.	6
Low	Vehicle/item operable, but Comfort/ Convenience item(s) operable at reduced level of performance. Customer experiences some dissatisfaction.	5
Very Low	Fit & finish/Squeak & Rattle item does not conform. Defect noticed by average customers.	4
Minor	Fit & finish/Squeak & Rattle item does not conform. Defect noticed by most customers.	3
Very Minor	Fit & finish/Squeak & Rattle item does not conform. Defect noticed by discriminating customers.	2
None	No effect.	1*

*Note: *Zero (0) rankings for Severity, Occurrence or Detection are not allowed*

Suggested Occurrence Evaluation Criteria			
Rank	**CPK**	**Failure Rates**	**Probability of Failure**
10	≥ 0.33	> 1 in 2	**Very High:** Failure almost inevitable
9	≥ 0.33	1 in 3	
8	≥ 0.51	1 in 8	**High:** Repeated failures
7	≥ 0.67	1 in 20	
6	≥ 0.83	1 in 80	**Moderate:** Occasional failures
5	≥ 1.00	1 in 400	
4	≥ 1.17	1 in 2000	
3	≥ 1.33	1 in 15 000	**Low:** Relatively few failures
2	≥ 1.50	1 in 150 000	

1*	≥ 1.67	≤ 1 in 1 500 000	**Remote:** Failure is unlikely

*Note: *Zero (0) rankings for Severity, Occurrence or Detection are not allowed*

Suggested Detection Eval. Criteria		
Detection	**Criteria**	**Rank**
Absolute Uncertainty	Design Control will not and/or cannot detect a potential cause/ mechanism and subsequent failure mode; or there is no Design Control.	10
Very Remote	Very Remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	9
Remote	Remote chance the Design Control will detect a potential cause/ mechanism and subsequent failure mode.	8
Very Low	Very Low chance the Design Control will detect a potential cause/ mechanism and subsequent failure mode.	7
Low	Low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	6
Moderate	Moderate chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	5
Moderately High	Moderately High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	4
High	High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	3
Very High	Very High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	2
Almost Certain	Design Controls will almost certainly detect a potential cause/mechanism and subsequent failure mode.	1*

*Note: *Zero (0) rankings for Severity, Occurrence or Detection are not allowed*