	SECTION 9: PROCESS FAILURE MODE EFFECTS ANALYSIS (PFMEA)	Ref: TM-QA-DO-06-329-E
		Revision Level: 2
		Date: 08/09/04
		Page: 1

PURPOSE: To explain creation and submission of the PROCESS FAILURE MODE EFFECTS ANALYSIS (PFMEA)

SCOPE: Applies to all **TMI suppliers**

EXPLANATION: The PFMEA is the tool used to identify potential problem areas in product manufacturing and assembly by identifying areas of possible failure within the product manufacturing and assembly. The recommended reference guide for creation of PFMEA is the AIAG supplemental manual - “Potential Failure Mode and Effects Analysis”.

RELATED DOCUMENT(S):


TMI QUALITY ASSURANCE PROJECT PLAN (QAPP) (TMI SQAM Section 25)

REQUIRED DOCUMENT(S):

PROCESS FAILURE MODE EFFECTS ANALYSIS (PFMEA) – TMI APPENDIX 9A

RESPONSIBILITIES:

- 1) The supplier should use the AIAG supplemental manual “Potential Failure Mode and Effects Analysis” as the guideline and instruction for conducting the PFMEA process.
- 2) The supplier must develop a cross functional team to study each step within the process to determine possible failure modes, effects of failures, and potential causes.
- 3) The supplier must calculate RPN (Risk Priority Number) for each possible failure cause. RPN is calculated by rating degree of severity [S], likelihood of occurrence [O], and likelihood of detection [D]. The product of these three is the RPN. The supplier should reference the AIAG manual for evaluation criteria guidelines.
- 4) The supplier must conduct problem investigation and implement countermeasures based on RPN. Per the AIAG manual, any ranking of “HIGH” should be addressed. As countermeasures are implemented, the RPN is recalculated and the PFMEA is revised.
- 5) After conducting the RPN process, the supplier must complete the PFMEA (TMI APPENDIX 9A) and submit to TMI QC per **QAPP** timing. The target time frame will be at 1A level.
- 6) As the PFMEA must always reflect current manufacturing conditions and environment, and as the result of ECI and PCR, the supplier must revise the PFMEA as needed and resubmit. Resubmission timing should be negotiated with TMI plant QC.

	SECTION 9: PROCESS FAILURE MODE EFFECTS ANALYSIS (PFMEA)	Ref: TM-QA-DO-06-329-E
		Revision Level: 2
		Date: 08/09/04
		Page: 2

REVISION	REVISION DATE	SECTION	CHANGE DESCRIPTION
0	07/09/01	ALL	Initial release
1	05/20/03	ALL	Revision record added
2	08/09/04	Resp – 5:	Added QAPP timing