

			Problem Solving – Corrective/Preventive Action
QMS PQ-5	Rev F	Date 02-08-19	Procedure Authority: Quality Assurance Manager

Purpose: This procedure was created to direct actions related to problem solving; presented from both realized and/or anticipated circumstances.

Scope: The process includes all problem-solving activities, up to and including associated corrective and/or preventive actions, as appropriate.

Responsibility: The Quality Manager is responsible for administering this procedure.

Definitions:

Field Failures¹ = This expression is specific to parts that were installed on automobiles, failed and were returned for analysis.

Reference Documents:

PQ4 - Control of Non-Conforming Material

Procedure:

1. A problem can present itself in a variety of phases along the business cycle, i.e. new product development, current manufacturing issues, field failures¹, customer complaints or concerns, and audit findings. Problem related information will be captured and an appropriate problem-solving approach will begin, depending on where in the cycle the problem is identified, and the significance of impact to all parties concerned. Our goal is to satisfy all requirements and to drive continual improvement.
2. Upon discovery of a problem, the Quality Manager will notify key management personnel and initiate the problem-solving actions.
3. The Quality Manager and relevant department manager, will collectively review all identified problems (both, realized or anticipated), and respond with an appropriate action based on risk. These actions may include Corrective Action, Preventive Action, changes to APQP documents, i.e. Process Flow, Control Plans, PFMEA's, and/or changes to work instructions, procedures and forms.
4. During the initial identification of a problem, any resulting non-conforming material will be contained in accordance with procedure PQ4 and appropriate interim actions will be taken to protect subsequent processes and/or the customer.

Procedure contd:

5. With the problem contained and interim actions in place, a cross functional team, facilitated by the Quality Manager and/or the Department Manager, will begin Root Cause analysis and develop appropriate improvement ideas or corrective measures.
6. Consistent with the team’s conclusion, the improvements or corrective measures will be implemented by the process owner, with strict attention to product and process specifications.
7. After implementation, process performance will be monitored to assess effectiveness of all changes.
8. Within this “problem solving” process, an opportunity to amend APQP documents (e.g., PFMEA and Control Plans) may exist. The Quality Manager will consider this and facilitate document changes as applicable.
9. Any successful process improvements will be considered and potentially carried forward to other similar processes.
10. Finally, our problem-solving process will have a general effectiveness review by management, consistent with our management review process.

Note: For an illustration of this process, see the “Problem Solving Model” on page 3.

AMENDMENT RECORD

Revision	Date	Details	Authority
A	04-14-03	Originated	E. Ide
B	04-15-04	Minor changes to step #1	E. Ide
C	04-19-13	Added notes and reference to 8D model	E. Ide
D	12-11-13	Note added to consider changes to APQP Documents	E. Ide
E	08-10-17	Combined problem solving, CA, & PA into one procedure.	E. Ide
F	02-08-19	Added note 10; effectiveness rev. and updated model pg. 3.	E. Ide

Problem Solving Model

With a goal to satisfy all requirements and to drive continual improvement.

