Quality Systems

ISSI Quality systems have evolved to comply to ISO/TS 16949 compliance. While not all ISSI products are shipped to automotive, the system requirements have been embraced to attain more robust quality processes.

1. ISO 9001 Year 2015 Revision

The Management team has defined the quality policy and objectives for ISSI and has established a quality management system to ensure that the quality policy and quality objectives are understood, implemented and maintained. The Quality System defined in ISSI Quality Manual is in compliance with the requirements of ISO 9001: 2015. It is stratified and compiled into documents with the Quality Manuals at the top supported by procedures, specifications, regulations, rules and detailed work instructions, etc (see Figure 1-2).

Employees are trained and keep records of duties carried out according to the prescribed methods based on the latest documents to ensure that the constructed quality system is implemented in the prescribed manner.

The quality system is periodically checked and evaluated through the internal quality audits and external audits by ISO certified agencies to provide opportunities for continuous improvement.

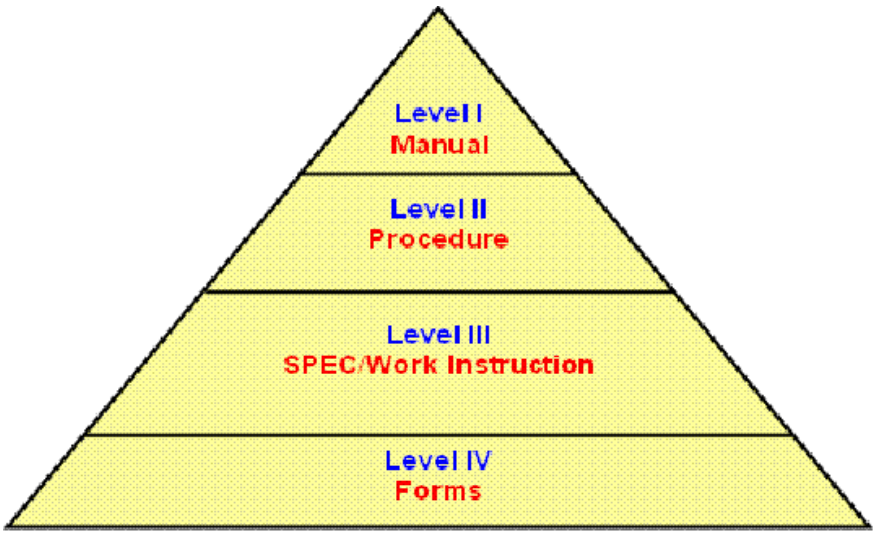

Figure 1-2 Quality Document System

ISSI in USA was certified to ISO 9001:1994 in Sept 1995. With the continuous effort in quality improvement, ISSI achieved the ISO 9001: 2000 standard in July 2002. And, ISSI is certified to ISO 9001:2008 in 2009. All ISSI locations passed ISO9001 assessments in 2005 conducted by UL (Underwriters Laboratories) current DQS one of the leading international certification bodies, as shown by the certificate issued in Figure 1-3. Since the ISO9001:2015 has been published in Sep 2015, ISSI is compliance with new revision as well as planned schedule.

ISSI is not only certified to ISO/9001 but also achieved the required quality system level as required by ISO/TS16949 through team effort in the past few years. ISSI has implemented ISO/TS16949 quality system requirements and has successfully passed several automotive customer audits that are leaders in the international automotive industry. All employees are moving forward through continuous improvement. The IATF 16949 has been published in Oct. 2016, ISSI is on the way to comply of the new quality standard.

2 Process Map

The inter-relationship of ISSI systems is shown in the Fig 1.

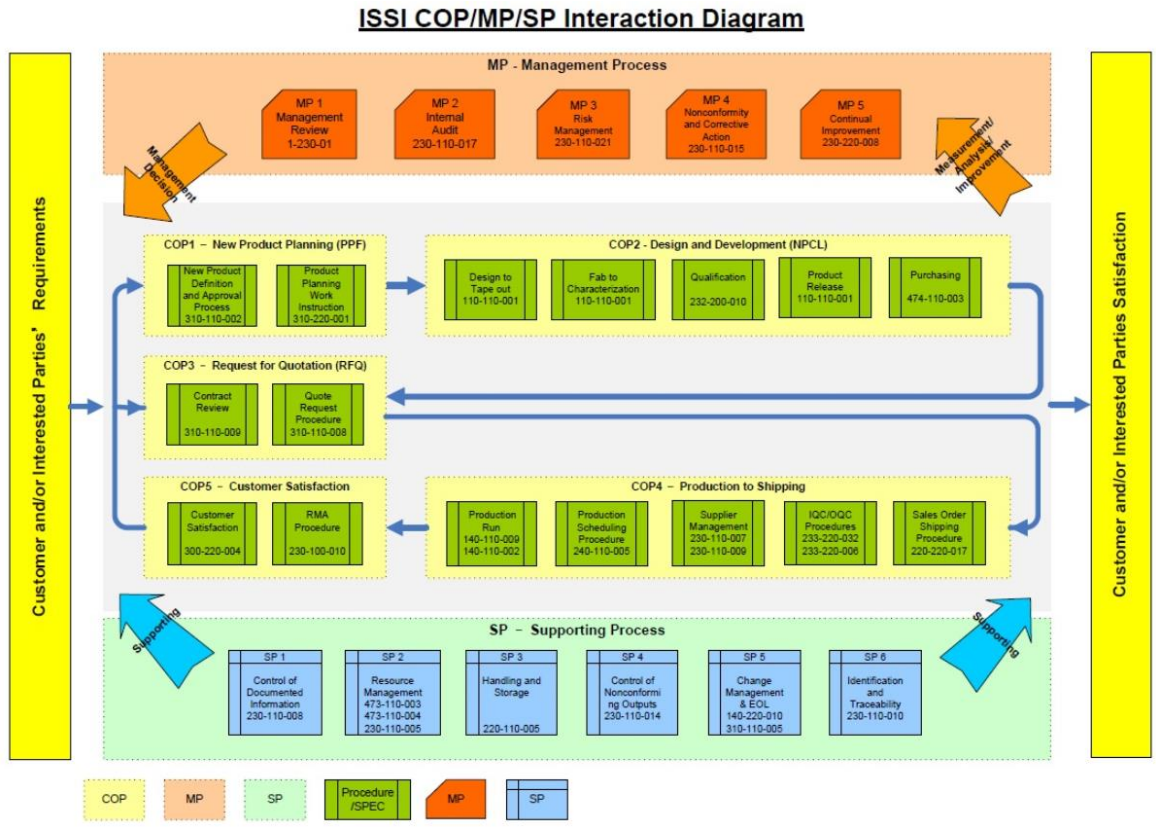

Fig 1 Process Map – Interaction Diagram

3 Advanced Product Quality Planning

ISSI linked together the requirements of the automotive Advanced Product Quality Planning by setting up Product Planning Form (PPF) and New Project Checklist (NPCL) System. The system is web based and can be accessed by all the team members. In the NPCL system, all the steps and requirements for the life of a product can be documented and tracked. The following processes contribute to the success of the NPCL

1) Product Planning – Marketing gets the new project approved

2) New Product Plan – Marketing endorses the project to Design who will work with Marketing, Development and Engineering to put the product plan together

3) Design and Development – at this stage, Design works with Technology Development for the actual Design of the product taking into consideration customer requirements for the product. One tool used at this stage is the Design FMEA. FMEAs are discussed in the succeeding section.

4) Process Development – it is at this stage that Design and Technology Development work with Product Engineering and Assembly Engineering and QRA to develop the Production Design and Product Flow. It is also at this point that the requirements for qualifying the product are planned to verify if the actual performance of the product meets the intended characteristics. At this stage, additional tools are identified such as Production flows, Control Plans and Statistical Methods for controlling the characteristics of the product. It is also at this stage that the tool Product Part Approval Process is utilized.

5) Product Verification – the plans for verifying the conformance of the product to required characteristics is executed

6) Prototypes – ISSI also builds product prototypes which are a limited quantity of risk builds are produced as needed. During these builds the conditions and controls are the same as actual production. At this point, preliminary Cpks are already computed and studied.

7) After the successful production of risk builds, then the product is ready for full production and ramp up. Samples for customer qualification have already passed and customers have already given feedback to ISSI on the product performance in their application.

8) Any problems encountered during the steps of the NPCL requires corrective action and lessons learned are recorded. For problem solving, ISSI uses the 8Discipline (8D) method.
Any problems encountered during the life of the product will undergo this process of problem resolution.

The interrelation shown in Figure 2 represents the activities and different department's involvement during each phase of Advanced Product Quality Planning.

Process	Sales/ Marketing	Design Engineering	Technology Development	Product Engineering	Assembly Engineering	Reliability Engineering	Testing Engineering	QA	Purchase	Production Control
Product Planning Form	1. Issue Product planning form 2. Prepare Data sheet	1.Resource arrangement 2. Plan/ Schedule	1.Foundry/ Technical selection	1. Resource arrangement 2. Production flow identification	1. Assembly selection 2.Resource survey	1. Reliability survey	1. Soft ware development 2. Wafer sort/ Final test survey		1. cost survey	1. Resource survey 2. Cost analysis

Figure 2 New Project Checklist Activity

The major milestones determine the status of each new product including project approval, design development, and release to production. Each of the indicated departments must approve the new product release to production based on defined objectives that include product performance and quality.

4 Failure Mode And Effects Analysis (FMEA)

FMEA is a structured procedure for identifying and minimizing effects of as many potential failure modes as possible. FMEA was formalized as a failure analysis technique in the 50s and 60s in the aerospace industry -NASA, etc. And FMEA training program was developed by FORD in 1972 and used by all big 3 U.S. automakers.

The factors contributing to spread of FMEA are rapid advancements in technology, which are forcing manufactures to develop new products more quickly to remain competitive. With less time for testing and re-design, they must achieve their reliability target the first time around. Both of foreign and domestic competition has raised customers' expectations for quality and reliability. Also, the trend toward litigation has forced manufacturers to exercise greater care in the design and manufacture of their products.

FMEA is one of quality improvement tools. It helps reduce the effects of potential failure modes associated with key product characteristics. In general, there are three applications for purpose of design, process and service FMEA. In ISSI current situation, we started FMEA in Oct 2004 by reviewing three kinds of data and experiences, QA, FA & RMA, by concentrating on abnormality case in production line, reliability issue, case of failure analysis, customer feedback study, and case of products returned. All of FMEAs focus on design and process which helps to minimize effects of failure that results from shifting in process variables, i.e., out of spec conditions, such as misplacing ball bonds, die misalignment, holes in package, burrs on lead frame, etc. It is useful for existing products or processes that are undergoing a major design change which could affect their reliability.

The FMEA addresses the following issues:
- What function(s) is the product supposed to perform?
- How could the product fail to perform that function(s)?
- What effect would the failure have on the end product and the end user?
- How severe is the effect?
- What could cause the failure?
- How likely is the cause to actually result in the failure mode?
- What is being done to prevent or detect the cause?
- How effective is this prevention or detection method?
- What is the overall risk associated with the failure mode?
- What corrective actions can be taken to eliminate the cause of failure, or to improve the prevention or detection measure, and thus reduce the risk?

Basic Steps to Develop FMEA

1) A cross function team, made up of people from all affected functions should be formed to develop an FMEA. These could be, but are not limited to, design, process, manufacturing, marketing, operators, technicians, QA, etc., Having involvement early on from these areas will help ensure that all significant areas of potential failure are addressed.

2) The cross function team can draft the FMEA by determining the information indicated on the form as following:
   a) potential failure mode
   b) Potential effects of failure
   c) Ranking of severity
   d) Potential cause/mechanisms of failure
   e) Ranking of occurrence
   f) Current process controls
   g) Ranking of detection
   h) Calculate the risk priority number
   i) Recommended actions
   j) Countermeasures and plans
   k) Responsibility & target completion date
   l) Action taken

In fact, the above items are included in the FMEA format (Fig 1-17). Although the purpose of FMEA is not to simply complete the form, the FMEA is a tool that helps provide new insights about the product or process. The management commitment, a cross functional team that understands and supports the FMEA process and team members with as much information about the product or process as possible are basic requirements for success of FMEA implementation.

Recommended Priority for the Corrective Action Taken

1) Priority number #1 always falls on the item with the highest score of severity. (Example Sev. □ 9)
2) To prioritize item by top 20% of Pareto of RPN which is a product of the Severity, Occurrence and Detection numbers (SxOxD).
3) Customer's instruction
4) Government regulations
5) Degree of easiness in implementing corrective actions

FMEA

ISSI products

S: severity, O: occurrence, D: detection, RPN: Risk Priority Number (S x O x D)

Process/ Function	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s)/ Mechanism(s) Failure	Occur	Current Design Controls		Detect	R.P.N.	Recommended Action(s)	Responsibility & Target Completion Date	Actions Taken	Action Results			
							Prevent	Detect						Sev	Occ	Det	RPN

Fig 1-17