# THE Global Quality Management System

## Improvement Through Systems Thinking

Suresh Patel

CRC Press
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A PRODUCTIVITY PRESS BOOK

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*I dedicate this book to Mr. K. K. Nair, executive director, Ahmedabad Management Association (AMA), who has encouraged me to write it after observing excellent feedback from the delegates at the first-ever Lean Six Sigma 3-day course at the AMA, June 23–25, 2011.*

*And this book is also dedicated to my dear wife, Pushpa, who had to bear many disruptions and inconveniences without my help and without whose full cooperation this book would not have materialized.*

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# Foreword

**Madan Mohanka**

- If you believe in a product, don't give it up halfway through. Be on it. And you will succeed one day and the results will be good.
- Have patience during difficult times. Don't lose your balance, and try to carry the team with you.
- If it is a new business, plan for 50% more money than what you think you require. At least plan for 50% more to stand by so that you don't have to close the business or run away.

There is a lot of scope in manufacturing. The world's emerging economies can become strong in the long run only through the manufacturing base rather than the service base. Service base is only temporary. This will not create long-term employment.

Suresh met me a month ago and requested that I write a Foreword for his book on global quality management systems.

When I met Suresh and came to know about his operational excellence experience of more than two decades with multinational corporations such as Eaton Corporation and Fiat Global, a bell rang inside me and I made up my mind not only to pen the Foreword, but also to leverage his command of the Spanish language to boost the performance of one of my South American Chilean units engaged in manufacturing wear-resistant products and material handling for the mining industry.

I knew Suresh well when I invited him to our Kolkata headquarters (HQ) to spend 1 week at the Tega HO and the main plant at Joka. It was evident from the feedback report I received from my plant management team that this book will clear the "cobwebs and prepare any organization for the journey of continuous quality improvement."

This book is a unique and comprehensive "how to understand and implement" a global quality management system (GQMS) to achieve world-class business excellence. The author has succinctly summarized the business excellence concept and the body of knowledge of this book by illustrating the business excellence pyramid with the foundation of

management systems at the system level, Lean system at the operational level, Six Sigma methodology at the tactical level, and business excellence at the strategy level.

This book is about the GQMS. It starts by paying homage to leading quality "gurus." Having illustrated systems thinking as opposed to the command and control system, the author then stresses the fact that a command and control system can, at the worst, "influence people to behave in ways that do not satisfy the customer and/or suboptimize performance."

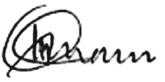
The main emphasis of any quality management system is on the process. This book stresses the importance of the process—its identification, definition, improvement, and control using "turtle diagrams" and its extension to supplier, input, process, output, customer (SIPOC) diagrams. The processes discussed include, among others, main business processes such as the human resource (HR) process, finance process, project management process, and, importantly, the "process of improving the process."

Every documented GQMS focuses on customer requirements and management system processes, which lead to customer satisfaction. To this end the author has included advanced processes to comply with ISO 9001, ISO/TS 16949, and AS 9100 standards, and he has elaborated on management improvement through extensive plan–do–check–act (PDCA) analysis and the problem-solving methodology involving the famous eight disciplines process ("8D"). The "check" and "act" phases are extensively discussed through audit processes and a process control plan audit (PCPA) process as practiced by most automotive and multinational corporations.

Finally, as you put this book of knowledge into practice, you will discover the shifting roles of leaders and managers in your organization. It is not enough for leaders to just keep on doing that which they have always done. It is not enough for them to merely support the work of others. Rather, leaders must lead the cultural transformation and change the mind-sets of their associates by building on the principles behind all these excellent tools.

The author's account of these difficult and vast subjects is very praiseworthy and proof of his vast industrial experience of over four decades working with multinational corporations in Asia, Europe, and the Americas.

This is an inspirational work that is easily learned and applied by the lay reader. I highly recommend this book to all those students, teachers, executives, and organizations who want to learn and implement GQMS Lean Six Sigma systems.



**Madan Mohanka**
*Chairman, managing director, and founder*
*TEGA Industries Limited*
*Kolkata*

# Preface

*The Global Quality Management System: Improvement Through Systems Thinking* creates and deploys the preventive quality culture within an organization. This book enhances customer value and satisfaction by fully integrating the customer's voice into design, manufacturing, supply chain, and field processes.

Almost all business organizations are engaged in providing services or products to their customers. But when it comes to providing service to customers and presenting them with an experience that will make them come back time and time again, only a small minority of organizations—who apply the energy, commitment, and innovative thinking to get it right—stand out from the crowd. There is an enormous difference between those who are truly focused on the customer and those who simply pay lip service to the concept.

This book has been written primarily for business entrepreneurs, business managers, engineering managers, and technocrats who wish to grasp global quality and Lean Six Sigma concepts, methodologies, and tools to improve and to promote their companies to world-class standards for profitability and sustainability.

This book can be used as a basic textbook for a Lean green belt or black belt, or bachelor's or master's degree business courses in global quality and Lean Six Sigma.

The word "quality" has been applied in many enterprises, mostly by quality professionals and consultants. Lately, "quality" has been replaced by "continuous improvement." These two words have become continuous improvement in ISO 9000 standards and, now, finally have become "continuous quality improvement." The subsequent proliferation of terms tends to confuse managers in the marketplace. ISO 9001, ISO/TS16949, AS 9100, JIT, Malcolm Baldrige National Quality Award (MBNQA), Six Sigma, kaizen, kanban, sort, straighten or set in order, shine, standardize, sustain (5S), Lean, total productive maintenance (TPM), total quality management (TQM), etc. are only a few of the initiatives confronting organizational leaders. No wonder managers are confused! Too many consultants are trying to sell the next "fad" or a "savior" to gain an advantage in the marketplace.

This book clears the cobwebs. It prepares the initiated person or organization for the journey of continuous improvement. The guiding principle has been stated by Taiichi Ohno (who created the Toyota production system): **"An organization must constantly measure the effectiveness of its processes and strive to meet more difficult objectives to satisfy customers."**

# Acknowledgments

Acknowledging the help and guidance in writing this book is to me like churning the oceans of the world and putting all the blessings in a teacup. I find it very daunting because during my more than 50 years of industry experience I have been guided and helped by many persons, companies, and institutions from whose associations I have learned, practiced, and taught these subjects and achieved modest to excellent results.

After I decided to return to Ahmedabad from Texas, Prof. R. D. Patel, finance professor at IIM Ahmedabad, asked me to address its SME program as a guest speaker to talk about Lean Six Sigma. The feedback from the attendees was good and Prof. Patel took me to the AMA to meet with its executive director, K. K. Nair, who asked me to conduct a first-ever 5-day AMA Lean Six Sigma seminar attended by industry representatives from Rajkot, Vadodara, Surat, and Ahmedabad. This led to another seminar at AMA and an invitation by the HR head of ISRO (equivalent to Indian NASA), J. Ravisankar, to address ISRO technicians and engineers on the subject of zero defects delivery of space systems, which was well received.

All of this caused Nair to ask me to write a book on Lean Six Sigma for Indian engineers. My learning and experience as an operations excellence and engineering manager at Eaton Corporation (Eden Prairie, Minnesota) and Fiat Global (Burr Ridge Operations, Chicago, Illinois) made me take a holistic view and include the global quality management system at the bottom rung and business excellence at the top level.

I thank the following individuals for their contributions to my knowledge and all the help and guidance they offered to me in my career, which resulted in creating this book:

C. S. Patel, former CEO of Anand Group, a leader among companies manufacturing automotive units and components

The late D. N. Sarkar, chairman and managing director of Gestetner Limited

Samir Kagalwala, consultant for design and manufacture of power magnetics

Stefan Lorincz, renowned electronics engineer and source developer for key electronic components worldwide at Phillips, Holland

Levy Katzir, former Motorola vice president, who, in 1994, put me in charge of quality and reliability of the newly developed electronic ballasts
G. P. Reddy, former director of quality at Universal Lighting Technologies
Inder Khatter, international QMS lead auditor for DNV, Houston, Texas
Dev Raheja, international consultant and author of *Assurance Technologies Principles and Practices*
Frank Kobyluch, global general manager at Klein Tools and former plant manager at Eaton Corporation
Don Johnson, director of quality at Fiat Global, Case New Holland Division

My special thanks and gratitude to my colleagues and team members at the following companies where I worked, learned, and developed and implemented many of the tools and techniques contained in this book:

Gestetner Limited (now Ricoh India)
Energy Savings Inc., Schaumburg, Illinois
United Lighting Technologies, Nashville, Tennessee
Eaton Hydraulics, Eden Prairie, Minnesota
Fiat Global—Case New Holland, Burr Ridge, Illinois

My abilities as an operations excellence manager in charge of providing quality products for CFL ballasts, hydraulic valves, hydraulic pumps, hydraulic hoses and fittings, automatic and manual transmissions for farm tractors, and rear axle backhoe loader assembly units were honed, tested, and appreciated by customers such as the following, among others:

GE CFL Lamps
Osram Sylvania
John Deere, Case New Holland
Oshkosh Corporation, manufacturers of heavy-duty all-wheel drive defense trucks
Caterpillar
GM trucks
Ford trucks
Volvo trucks
Zamboni ice resurfacer (for Olympic Games)

I remain grateful to the following suppliers, who collaborated with my team and me in developing components and major assembly units requiring extremely high precision and pre-/post-treatments:

Parker Hannifin, supplier of high-quality hydraulic seals and O-rings
Bosch, supplier of specialty hydraulic valves
Carraro, Pune, supplier of a complete four-speed transmission unit for agricultural tractors
TGL-Carraro, Pune, who developed precision gears and shafts for transmissions
Carraro, Quingdao, China, with whom we developed an entire rear axle assembly for backhoe loaders
Graziano, Noida, where we developed a continuously variable transmission unit for a tractor for the first time for the US market
GNA Group, Punjab, who supplied us forged and precision machined components for tractor transmission assemblies
Craftsman Automation Limited, Coimbatore, who machined our large castings for transmission bodies and covers using heavy CNC machines and digital CMMs

I have remained in touch with developing technology and professional knowledge through the American Society for Quality, where I have been a member since 1993.

Illustrations and design of charts and figures in this book are by Sanjay Trivedi and Minal Mehta.

**Suresh Patel**

# Introduction

## MAKING IT BIG IN MANUFACTURING PRODUCT AND PROVIDING SERVICE

It is a general belief that successful people in every field are blessed with talent or are just lucky. But the fact is that successful people work hard, work long, and work smart.

Marissa Ann Mayer, the current president and CEO of Yahoo, used to work 130 hours per week while working with Google. India-born Indra Krishnamurthy Nooyi, the chairman and chief executive officer of PepsiCo, worked midnight to 5:00 a.m. as a receptionist to earn money so that she could complete her master's degree at Yale University. In 1958 Qimat Rai Gupta left midway through his education and founded electric trading operations in the electric wholesale market of Old Delhi, India. With an investment of Rs.10,000 ($150), he started Havells Industries. Today Havells is a billion dollar company. In his own words: "overnight success means 25 years of hard work, devotion, and dedication."

The founder and CEO of Tega Industries, a Kolkata-based company in India, Madan Mohanka, has a unique story. When he went into business, he had the right combination: He hailed from a business family, had an engineering degree, earned an MBA from the Indian Institute of Management Ahmedabad (IIMA), and had a foreign collaboration as a joint partner. Yet this combination failed miserably. He was witnessing the imminent closure of his company in 1979, but like the epic hero Odysseus he never lost focus for a moment. He kept at it. Some three decades later, it is Madan's die-hard optimism that has seen Tega Industries become the second largest player in the world in rubber mill lining products for the mining industry.

In her book, *Stay Hungry, Stay Foolish*, Rashmi Bansal (IIMA graduate) depicted Madan Mohanka's story very aptly. She said that Madan faced all hurdles and challenges starting from scratch—but then, Madan had what you call an "obsession." Over the last three decades Madan has built

a strong foundation, combining three technologies: mechanical engineering, rubber (polymer) technology, and mineral processing and grinding. Over the last 5 to 6 years Tega has accepted challenges, grabbed overseas marketing opportunities, and maintained a consistent growth, keeping an eye on the margins.

Tega's presence in 19 international worldwide locations has enabled it to increase a turnover of $4 million in 2009 to $120 million in 2014.

According to Mehul Mohanka, Madan Mohanka's US-trained MBA son, the stage is now set for organic and inorganic growth: organically building up larger capabilities and inorganically looking for acquisitions for successful integration by leveraging Tega culture, values, and philosophy.

# 1

# *Homage to Quality and Lean Six Sigma Gurus*

## ORIGINS OF QUALITY

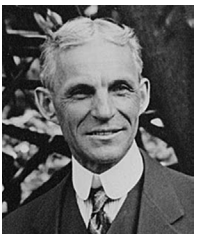
The structures made in India and Egypt BCE show evidence of measurement and inspection in the process of cutting and sculpting the stones to construct idols, forts, and pyramids. The quality improvement movement traces its roots back to thirteenth century Europe, where craftsmen began organizing into unions called guilds. Until the early nineteenth century, manufacturing in the industrialized world would follow this craftsmanship model. The factory system, with its emphasis on product inspection, started in Great Britain in the mid-1750s and grew into the Industrial Revolution in the early 1800s. In the early twentieth century, manufacturers began to include quality processes and practices.

After the United States entered World War II, quality became a critical component of the war effort. Bullets manufactured in one part of the United States had to perfectly match the rifles made in another part. The armed forces initially inspected almost every unit of product. Then, to simplify and speed up this process without compromising safety, the military began to use statistical sampling techniques for inspection, which ended in the publication of military-specification standards.

The honor and full credit go to many "quality gurus" who have changed the quality world forever.

The following are brief profiles of leading quality/Lean Six Sigma gurus.

**Carl Friedrich Gauss (1777–1855)**
The letter sigma (σ) (uppercase Σ), as a measurement standard, can be traced back to Carl Friedrich Gauss, who introduced the concept of the "normal curve."



**Henry Ford (1863–1947)**
Henry Ford defined the Lean concept in one sentence: "We will not put into our establishment anything that is useless." In 1913 he introduced interchangeable parts with standard work and moving conveyors to create what he called "flow production." Thus "waste" elimination and "speed" became hallmarks of Lean production.

**Philip B. Crosby (1926–2001)**
Philip B. Crosby entered the quality world in 1952, after his military service in Korea. In the nearly five decades that followed, he became widely renowned in business circles as a guru of quality management. He stressed the importance of "doing it right the first time." Crosby is perhaps best known for promoting a standard of excellence based on nothing—the concept of zero defects (ZD). In his own words:

- "Quality is free. It's not a gift, but it's free. What costs money are all the unquality things—all the actions that involve not doing jobs right the first time."
- "Why spend all this time finding, fixing and fighting when you could have prevented the problem in the first place?"
- "It isn't what you find; it's what you do about what you find."
- "Quality management is needed because nothing is simple anymore, if indeed it ever was."
- "Good things only happen when planned; bad things happen on their own."
- "The customer deserves to receive exactly what we have promised to produce—a clean room, a hot cup of coffee, a nonporous casing, a trip to the moon on gossamer wings."

**Walter A. Shewhart (1891–1967)**
Six Sigma, as a measurement standard for variation in processes, can be traced back to the 1920s when Walter Shewhart showed how three sigma from the mean is the point where a process requires correction and, at six sigma from the mean, the process runs at 3.4 defects per million (DPM).

**W. Edwards Deming (1900–1993)**
There is no greater example of W. Edwards Deming's belief in and devotion to quality than his contributions during and after World War II. In 1942, along with Walter Shewhart, he crafted the foundation for statistical quality control. This gave the United States a valuable edge during the war. But he was quickly forgotten in peacetime because, as Deming saw it, his knowledge rested with engineers rather than the management that drove the decision-making process. Five years after the war, in June 1950, Deming traveled to Tokyo to teach statistical methods at the behest of the Union of Japanese Scientists and Engineers (JUSE). Japan soon became the world leader in quality, leaving the United States far behind. Deming's cycle and Deming's 14 points are his most valuable contributions.

**Joseph M. Juran (1904–2008)**
In Juran's words:

- "In the USA, about a third of what we do consists of redoing."
- "Quality is fitness for use."
- "For quality in the sense of freedom from deficiencies, the long range goal is perfection."
- "Without a standard, there is no logical basis for making a decision or taking action."
- "Observing many companies in action, I am unable to point to a single instance in which stunning results were gotten without the active and personal leadership of the upper managers."
- "All managerial activity is directed at either breakthrough or control. Managers are busy doing both of these things, and nothing else."

In 1951, the first edition of Juran's landmark quality treatise, *Quality Control Handbook*, was published, cementing Juran's reputation as the authority on quality. Shortly after W. Edwards Deming's visit to Japan, Juran also made visits to Japan to share his knowledge of quality control. These visits were pivotal in world history because of how the two quality gurus strongly influenced Japanese business leaders to change the way they ran their organizations. From there, Japan became a quality and economic giant and the quality movement began to spread throughout the world.

**Kaoru Ishikawa (1915–1989)**

Kaoru Ishikawa is best known for the quality tool named after him: the Ishikawa diagram—also known as the fishbone or cause and effect diagram. As one of the seven basic quality tools, the diagram identifies many possible causes for an effect or a problem and it can be used to structure a brainstorming session. But Ishikawa accomplished much more than just developing the fishbone diagram concept. He graduated from the University of Tokyo with an engineering degree in applied chemistry and later returned to the university to teach as an associate professor. Ishikawa also wrote several books, including two that were translated into English: *Introduction to Quality Control* and *What Is Total Quality Control?*

**Armand V. Feigenbaum (1922–2014)**

Feigenbaum coined the term "total quality control"—known today as total quality management (TQM). Using financial performance as an indicator of poor quality, Feigenbaum was one of the first engineers to speak the management's language. In 1937, he began his career with General Electric (GE) as an apprentice toolmaker and management intern in the turbine, engine, and transformer group. In 1958, Feigenbaum was promoted to the level of corporate executive at GE headquarters in New York. Even now, after his demise, his brother, Donald, continues to promote quality concepts, at their company, General Systems Co., in their hometown of Pittsfield, Massachusetts. The company serves global clients, designing engineering systems and implementing proprietary TQM systems.

1985 Bill Smith coins the term "Six Sigma"


1987 Motorola trademarks the term "Six Sigma"

**Bill Smith (1929–1993): "Father of Six Sigma"**

Credit for coining the term "Six Sigma" goes to a Motorola engineer named Bill Smith. Born in Brooklyn, New York, Smith graduated from the US Naval Academy in 1952 and studied at the University of Minnesota's School of Management. In 1987, he joined Motorola, serving as vice president and senior quality assurance manager for the Land Mobile Products Sector. His new quality control process, named "Six Sigma," generated billions of dollars for Motorola. ("Six Sigma" is a federally registered trademark of Motorola.)

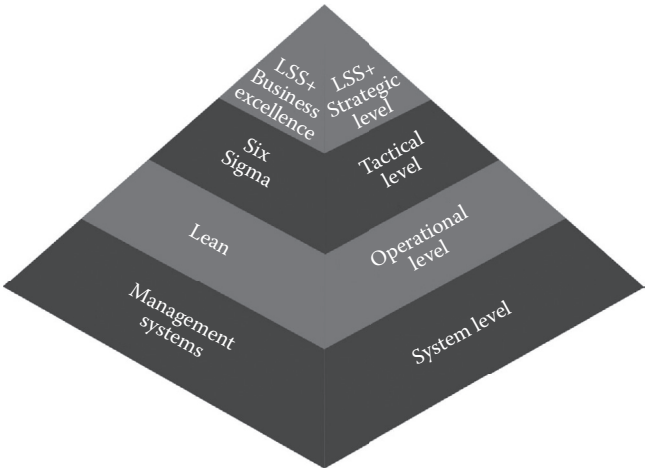
**John Krafcik (1962–)**

MIT researcher John Krafcik coined the term "Lean" under the auspices of the International Motor Vehicle Program (IMVP). The term first appeared in his 1988 article, "Triumph of the Lean Production System" when he was a research engineer with MIT. Later, he joined Ford Motor Company and after a ten-year executive stint at Hyundai, five of which he served as CEO, he has now joined TrueCar, the online auto pricing service as president. "Lean production" uses half the human effort, space, tools, and engineering hours to develop new products than mass production. Lean production has less inventory, fewer defects, and produces a greater variety of products.

# 2

# *Quality Management System as a Management Strategy*

## THE BUSINESS EXCELLENCE PYRAMID




Enterprise-Wide Deployment Model Showing Key Concepts and Tools

| Key Concept | Tools and Techniques |
|---|---|
| System level | Management systems |
| Operational level | Lean |
| Tactical level | Six Sigma |
| Strategic level | MBQNA, EFQM, and other business excellence models |

The pyramid illustrates the business excellence at the top. To attain excellence, organizations use a variety of improvement methodologies, such as shown here. The graphic also shows how quality management system and Lean and Six Sigma business excellence models like the Malcolm Baldrige National Quality Award (MBNQA) are related. The MBNQA excellence model does not replace these methodologies, but instead integrates these tools and methods to help companies achieve excellence. MBNQA criteria, Lean, Six Sigma, and quality management system are complementary, not mutually exclusive.

## QUALITY MANAGEMENT SYSTEM AS A SYSTEM-LEVEL STRATEGY

The pyramid depicts the stages through which an organization can reach the world-class status and can make itself sustainable in a national as well as global marketplace. The management system is the first rung of the ladder to the ultimate goal: to be a world-class organization.

During the last 20 or so years, Indian organizations have toyed with a wide range of programs of organizational change: customer care, International Organization for Standardization (ISO) 9001, total quality management (TQM), business process reengineering (BPR), Six Sigma, business excellence (European Foundation for Quality Management [EFQM], MBNQA), and so on. The fact that organizations employ such a variety of change programs proves the need for it. However, many change programs fail to achieve their intended outcomes. The latest "fads" seem often to do no better than their predecessors.

Why does this happen? The answer perhaps lies in the existing management system. Most of our management systems are based on the "command and control" principle.

The command and control organization is easily recognizable. It is a top-down functional hierarchy. Decision making is separated from work and is the given right of managers. Decisions are often made on the basis of opinions supported by data about budgets, standards, productivity measures, and so on.

Command and Control Assumptions

| **Perspective** | **Top-Down** |
|---|---|
| Design | Functional specialization |
| Decision making | Separated from work |
| Measures | Budget output, activity, standards |
| Productivity motivation | Extrinsic |
| Management ethic | Manage budgets, manage people |
| Attitude to customers | Contractual |

*Source:* Compiled from Peter Scholtes' presentation at 2008 Deming Institute Conference in Madison, Wisconsin.

The command and control organization has become the norm throughout the twentieth century, being ever further developed by custom and practice in various functional disciplines: Operations Management, Business Planning, Human Resources, Information Technology, Management Development, and so on.

## Change to the System Is Required to Change the Performance

The failure of many programs of change stresses the desire to "do things right" rather than "doing right things." Many of quality programs like Lean Six Sigma are employed because management thinks that if employees are trained to deliver good service, then good performance will result and the employees will do their best to please customers. However, this does not take into account the effect that the existing system has on the behavior of people.

## If Your System Will Not Let You, You Cannot Satisfy the Customer Fully

The influence of the system might cause a number of different forms of suboptimization ("a situation where a process, procedure, or system yields less than the best possible outcome," according to the Business Dictionary [BusinessDictionary.com]). Suboptimization can prevent people from serving customers by making them do things to serve the system rather than the customers. Check out the following examples:

- A departmental goal taking priority over the company goal
- Uncooperative behavior among departments; doing things that serve the departmental hierarchy but add no value to the work

- Doing things that are required by rigid procedures but add no value to the customer
- The system forcing people to do things that suboptimize company revenue: get sales by compromising quality; spend working time claiming for sales rather than getting sales, and so on

The following table is the transformation introduced by "systems thinking":

Command and Control versus Systems Thinking

| **Assumptions** | **Command and Control Thinking** | **Systems Thinking** |
|---|---|---|
| Perspective | Top-down | Outside-in |
| Design | Functional specialization | Demand, value, and flow |
| Decision making | Separated from work | Integrated with work |
| Measures | Budget, output, productivity | Related to purpose, capability, and variation |
| Motivation | Extrinsic | Intrinsic |
| Management ethic | Manage budget and people | Take action on the system |

*Source:* Deming, W. E. 2010. His "14 Recommendations" Changed the History of Japan and The World! Available at: http://www.leanexpertise.com/TPMONLINE/articles_on_total_productive_maintenance/management/deming14steps.htm.

In short, a system can influence people to behave in ways that do not satisfy customers and/or suboptimize performance.

# 3

# *Quality Management System*

## ISO

ISO refers to the International Organization for Standardization. ISO establishes common worldwide standards. (As the name suggests, the organization should be known as IOS!) It so happens that ISO was derived from the Greek word *isos* meaning "equal"—a standard for all.

## THE ISO 9000 FAMILY

This group of standards specifies the requirements for quality management systems. Together they make up the framework of the quality management system.

The ISO 9000 family consists of three standards:

- ISO 9000:2005—Fundamentals and Vocabulary
- ISO 9001:2008—Quality Management System Requirements (ISO 9001:2015—Revised ISO 9001:2008 will replace ISO 9001:2008)
- ISO 9004:2009—Managing for the Sustained Success of an Organization

## FUNCTION OF THE MANAGEMENT SYSTEM STANDARDS

These standards provide requirements or guidelines for organizations to develop and systematically manage their policies, processes, and procedures

to achieve specific objectives. Usually, they adopt a plan–do–check–act (PDCA) approach to achieve the objectives. The standards usually address the following components:

- Policy
- Planning
- Implementation and operation
- Performance assessment
- Improvement
- Management review

The purpose of a quality management system (QMS) similar to or based on ISO 9001 or ISO/TS16949 is to help reduce the variation not only in the product, but also in the complex and integrated business processes upon which we have become so dependent. The late W. Edwards Deming defined a system as "a network of functions or activities (subprocesses or stages) within an organization that work together for the aim of the organization, which is mainly to satisfy its customers."

The benefits of having a QMS include:

- Improve our organization.
- Bring consistency and definition to processes, which will result in fewer defects and more efficient practices.
- Meet a global requirement by the customers to fulfill their requirements and to be qualified as a supplier.
- Solve problems (Section 8 of the ISO 9001 standard).
- Increase market share by freeing up financial resources.
- Reduce waste, scrap, and rework.
- Increase customer confidence in our products and services.

In the ISO 9001:2000 Handbook, Jeff Hooper writes, "The system approach to management is a quality management principle that states: Identifying, understanding and managing interrelated processes as a system contributes to an organization's effectiveness and efficiency in achieving its objective."

Or we can state that a management system (based on the systematic, process-based, and internationally accepted standard) should be the foundation of the business excellence pyramid.

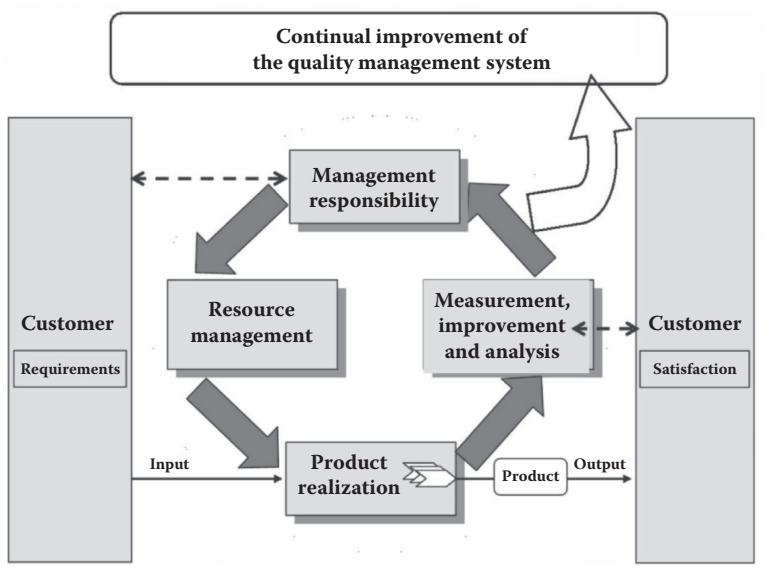



**FIGURE 3.1**
Integrated organizational processes.

A quality management system begins with customer requirements, and ends with customer satisfaction. Figure 3.1 shows how an organization's processes are integrated.

Later we will describe the interrelation of organizational processes in greater detail. First, let us try to understand and implement the QMS by assuming a system. ISO 9001:2008 has eight total sections. The first three sections are

1. Scope
2. Normative references
3. Terms and definitions (ISO 9000:2005)

The remaining five sections define the requirements:

4. Quality management system (the way we run our business: the structure)
5. Management responsibility (management supports the structure)
6. Resource management (people, buildings, machines, software)

7. Product realization (the way we provide goods and services: the core business)
8. Measurement analysis and improvement (of the product and process)

In the QMS, top management is defined as a person or a group of persons who direct and control an organization at the highest level. It is top management's responsibility to provide resources to implement, maintain, and continually improve the QMS.

## STEPS TO IMPLEMENT QMS

- Buy the appropriate QMS standard (e.g., ISO 9001:2008 standard, ISO/TS 16949 standard, or others from aerospace, healthcare, or environmental protection).
- Select, appoint, and train a management/customer representative so that the designated person is familiar with all the requirements of the standard.
- Form a high-level management team to determine the gaps in the existing management system.
- Prepare an action plan to eliminate the gaps between the existing process requirements and those required by the QMS.
- Understand the interrelation of the organizational processes:
  - Describe/show the interaction of quality management system processes (use Figure 3.2 as a reference).
  - Understand the interrelation of the organizational processes and the flow of the materials/product/service and information as shown in Figure 3.2.

## ARRIVAL OF ISO 9001:2015

First published in 1987, ISO 9000 has consistently been ISO's most popular series of standards. Now, building on 25 years of success, ISO technical committee ISO/TC 176 is busy laying the groundwork for the next generation of quality management standards.

At this stage it is wise to indicate that the ISO 9001:2008 standard is being revised NOW and it is expected to be replaced by ISO 9001:2015. The time line is shown in Figure 3.3.

The current ISO 9001:2008 and the revised proposed ISO 9001:2015 quality management processes (QMPs) are shown in Figure 3.4.

New clause numbers have been added to seven sections of ISO 9001:2015 (see Figure 3.5).

## QUALITY SYSTEM DOCUMENTS

Per the ISO 9001:2008 documentation requirements in its Section 4.2.1, documentation shall include:

- Documented statements of a quality policy, quality objectives, and a quality manual (Appendix: a typical quality manual combining ISO 9001:2008 and ISO/TS 16949 standards)
- Documented procedures required by the international standard
- Documents needed by the organization to ensure effective planning, operation, and control of its processes—process identification and documentation
- Records required by this international standard
- The QMS must define the "documented processes" that make up the quality management system

As we see in the preceding sections and clauses, it is quite clear that we need to have an all-inclusive approach to documented processes covering:

- ISO 9001:2008
- AS9100:2004 (Aerospace Industry Quality Management Standard)
- TS-16949:2002 (Automotive Industry Quality Management Standard)
- ISO 9001:2015 (Proposed QMS Standard)

## THE GLOBAL QMS PROCESSES

The following processes are prepared using (1) GM, Ford, Chrysler, and Automotive Industry Action Group (AIAG) quality requirements, and (2) quality system management standards ISO/TS 18969 and AS 9100:

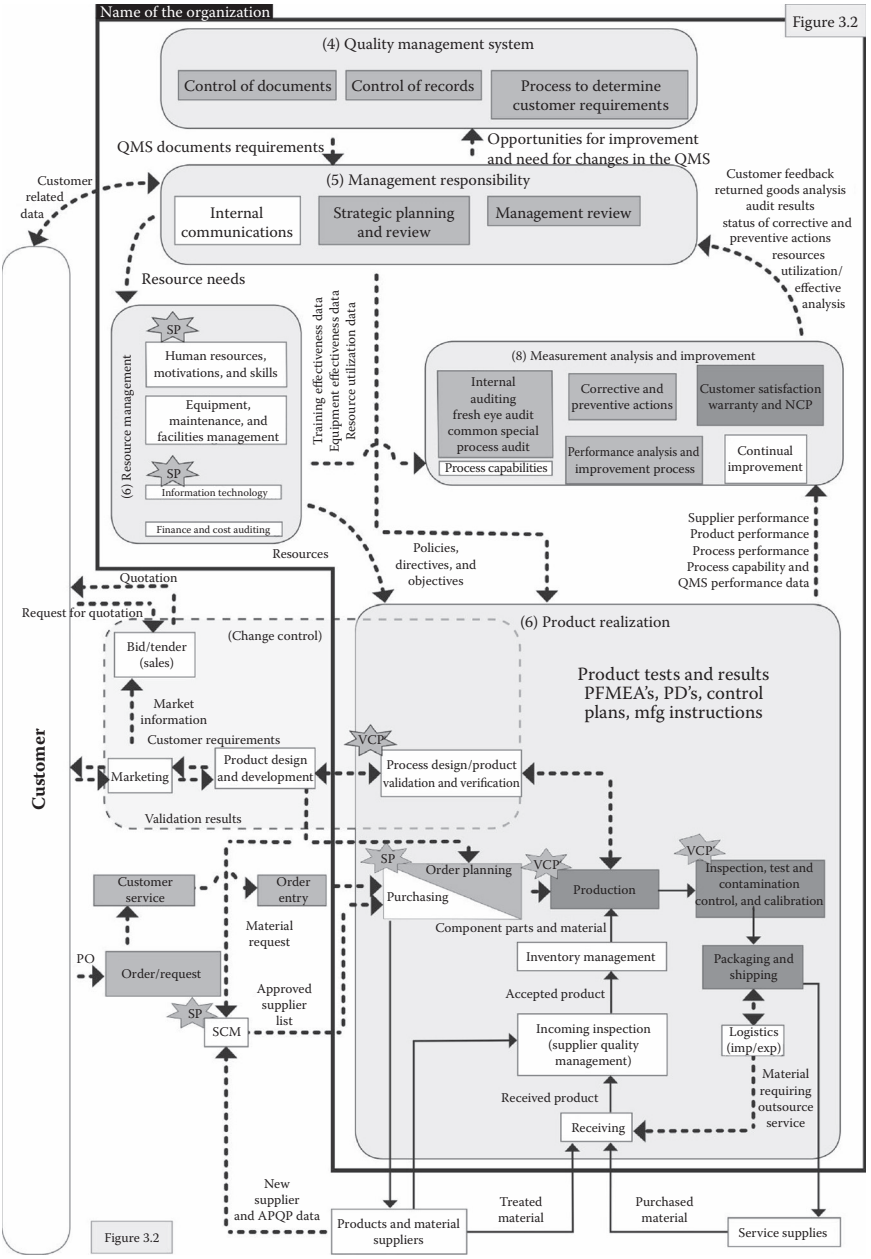
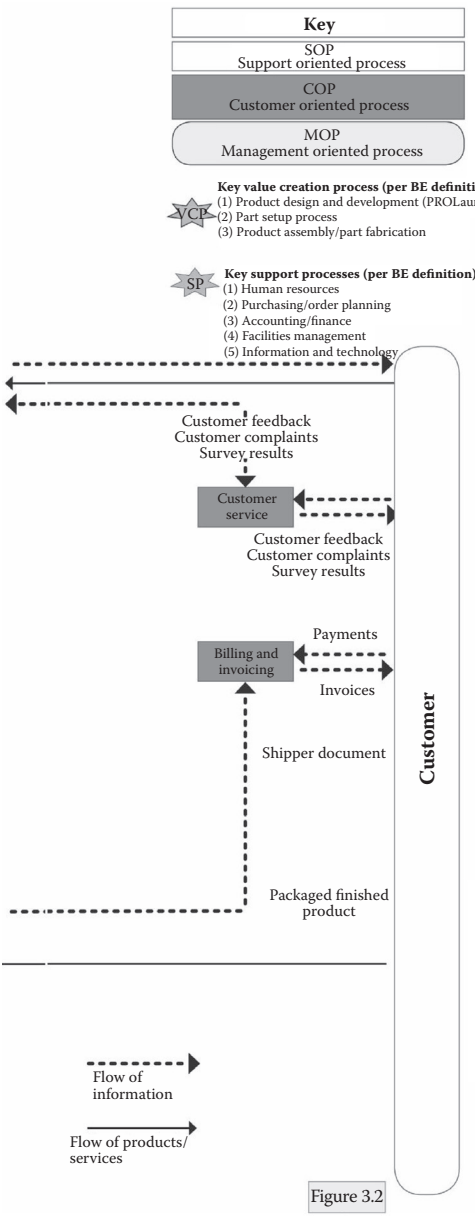



**FIGURE 3.2**
Interaction of quality management system processes. (*Continued*)




**So QMS must**

- Define or reference the "documented processes" that make up your quality management system, and
- Describe/show the interaction of quality management system processes (use Figure 3.2 as a reference). A sound QMS should include the following procedures:

**Important points about Figure 3.2**

- Bold boundary represents the unit concerned where the product/service is produced.
- This boundary includes sections 4, 5, 6, 7, and 8 of the ISO 9001 QMS.
- Each section describes main processes within that section. Here the name of each process owner and process reference number may be inserted such that the process document can be accessed just by clicking on the process reference number.
- As can be seen, each process receives an input through a process and after completing the process, supplies the output to the next process.
- The processes are shaded classify them as COP (customer oriented), MOP (management oriented), and SOP (support oriented).
- Star marked processes are key value creating processes and key support process.
- Material flow is indicated by a solid line.
- Information flow is indicated by a dotted line.

**Document preparation**

Quality manual, quality policy, and quality objectives

Using the interaction of the processes diagram, QMS standard, and all processes in your organization, list the processes that are important for maintaining and improving the QMS continually.

**FIGURE 3.2 (CONTINUED)**
Interaction of quality management system processes.

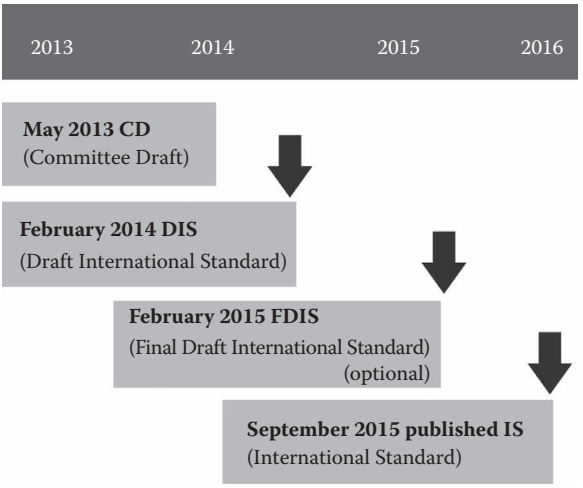



**FIGURE 3.3**
ISO 9001:2015 time line.

| **Current QMPs** | **Revised QMPs** |
|---|---|
| 1. Customer focus | 1. Customer focus |
| 2. Leadership | 2. Leadership |
| 3. Involvement of people | 3. Engagement of people |
| 4. Process approach | 4. Process approach |
| 5. System approach | 5. Improvement |
| 6. Continual improvement | 6. Evidence based decision-making |
| 7. Approach to decision-making | 7. Relationship management |
| 8. Mutually beneficial supplier relationships | |

**FIGURE 3.4**
Current and revised proposed quality management procedures.

- Management responsibility
  - Management review process—MR-1
- Resource management
  - Quality training process—RM-2
- Product realization policies
  - Change control process—PR-3
  - Processes to identify special characteristics—PR-4
  - Internal supplier PPAP/FAI—PR-5

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
   - Understanding the organization
   - Needs and expectations
   - Scope
   - Management system
5. Leadership
   - Management commitment
   - Policy
6. Roles, responsibility, and authority planning
   - Actions to address risks and opportunities
   - Objectives and plans to achieve them
7. Support
   - Resources
   - Awareness
   - Communication
8. Operation
   - Operational planning and control
9. Performance evaluation
   - Monitoring, measurement analysis, and evaluation
   - Internal audit
   - Management review
10. Improvement
    - Nonconformity and corrective action
    - Continual improvement

**FIGURE 3.5**
Added clause numbers to each ISO 9001:2015 section.

  - Supplier quality management process—PR-6
  - PFMEA—PR-7
  - Process control plans—PR-8
  - Measurement system analysis—PR-9
- Measurement analysis and improvement
  - "Fresh eyes" audit—MAI-10
  - Common manufacturing and special process audit—MAI-11
  - Process capability methods and requirements—MAI-12
  - Control of nonconforming material—MAI-13
  - Performance analysis and improvement process—MAI-14
  - Corrective and preventive action policy—MAI-15
  - Quality alert system—MAI-16
  - Risk management—MAI-17

Chapter 6 describes each process in detail.

There are several requirements of ISO 9001:2008 where an organization could add value to its QMS and demonstrate conformity by the

preparation of other documents, even though the standard does not specifically require them. Examples may include:

- Process identification, process maps, process flow charts, and/or process descriptions
- Organization charts
- Specifications
- Work and/or test instructions
- Documents containing internal communications
- Production schedules
- Approved supplier lists
- Test and inspection plans
- Quality plans

All such documents have to be controlled in accordance with the requirements of clause 4.2.3 and/or 4.2.4, as applicable.

A controlled document

- Is included in an up-to-date master list
- Is approved
- Has a date of initiation and revision
- Has a revision level
- Is reviewed by management periodically for effectiveness and efficiency

## RECORDS REQUIRED BY ISO 9001:2008

Established records shall be controlled to provide evidence of

- Conformity to requirements and
- The effective operation of the quality management system.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention, and disposition of records. Records shall remain legible, readily identifiable, and retrievable.

## List of Records

| Clause | Record Required |
|---|---|
| 5.6.1 | Management reviews |
| 6.2.2(e) | Education, training, skills, and experience |
| 7.1(d) | Evidence that the realization processes and resulting product fulfill requirements |
| 7.2.2 | Results of the review of requirements related to the product and actions arising from the review |
| 7.3.2 | Design and development inputs relating to product requirements |
| 7.3.4 | Results of design and development reviews and any necessary actions |
| 7.3.5 | Results of design and development verification and any necessary actions |
| 7.3.6 | Results of design and development validation and any necessary actions |
| 7.3.7 | Results of the review of design and development changes and any necessary actions |
| 7.4.1 | Results of supplier evaluations and any necessary actions arising from the evaluations |
| 7.5.2(d) | As required by the organization to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement |
| 7.5.3 | The unique identification of the product, where traceability is a requirement |
| 7.5.4 | Customer property that is lost, damaged, or otherwise found to be unsuitable for use |
| 7.6(a) | Basis used for calibration or verification of measuring equipment where no international or national measurement standards exist |
| 7.6 | Validity of the previous measuring results when the measuring equipment is found not to conform to requirements |
| 7.6 | Results of calibration and verification of measuring equipment |
| 8.2.2 | Internal audit results and follow-up actions |
| 8.2.4 | Indication of the person(s) authorizing release of the product |
| 8.3 | Nature of the product nonconformities and any subsequent actions taken, including concessions obtained |
| 8.5.2(e) | Results of corrective action |
| 8.5.3(d) | Results of preventive action |

# 4

# *Identification and Improvement of Processes*

## INTRODUCTION

Using these methods as a guide, an individual can prepare his or her own special process identifications, maps, and procedures such that he or she can improve these through regular reviews and the plan–do–check–act (PDCA) process. This chapter shows practical examples.

Process maps (Figure 4.1) and turtle diagrams (Figure 4.2) have both been used to graphically display a process.

## TURTLE DIAGRAMS

The name "turtle" is given because the diagram can be compared with a turtle where the input is the mouth, process is the body, output is the tail, and the four legs are the "what, who, how, and measures."

A process turtle diagram identifies:

- Inputs, including internal and external customer requirements
- Outputs: the process's results
  - For a system process, this includes information, reports, or data.
  - For a manufacturing process, the outputs include the finished product, statistical data, and other manufacturing-related records, as well as any scrap from the process.

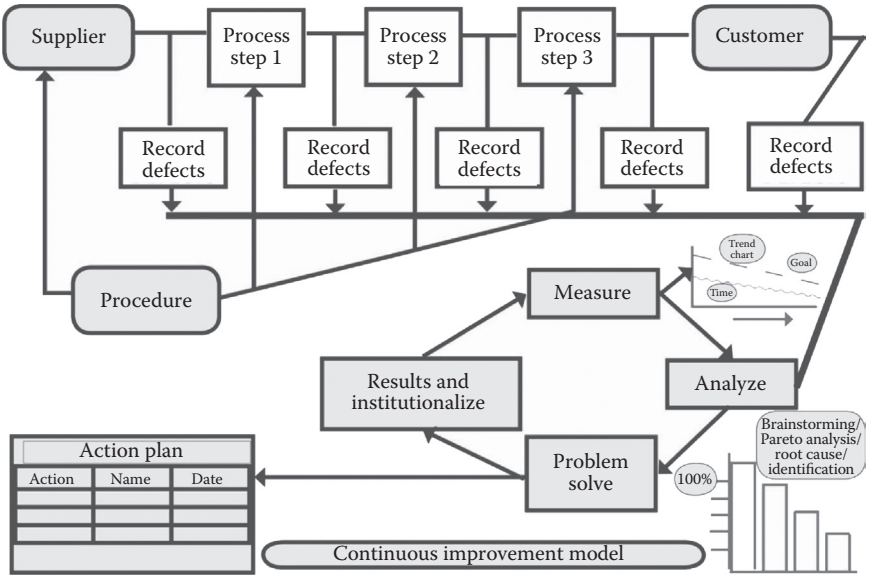



**FIGURE 4.1**
Quality process map.

- For any process, the actual output should represent the satisfaction of customer requirements.
- The process itself consists of
  - What: the nonhuman resources needed to perform the task
  - Who: the human resources needed to complete the process
  - How: insight into the operational controls required
  - Measures: a listing of the performance indicators that will indicate the success or failure of the process

Figure 4.3 shows a generic audit process using a turtle diagram.

## CHARTING PROCESSES TO CONTROL PROCESS VARIABLES

Earlier it was mentioned that the purpose of a quality management system (QMS), similar to or based on ISO 9001 or ISO/TS16949, is to help reduce the variation not only in the product, but also in the complex and integrated business processes upon which we have become so dependent. Following are some of the typical organizational processes that identify

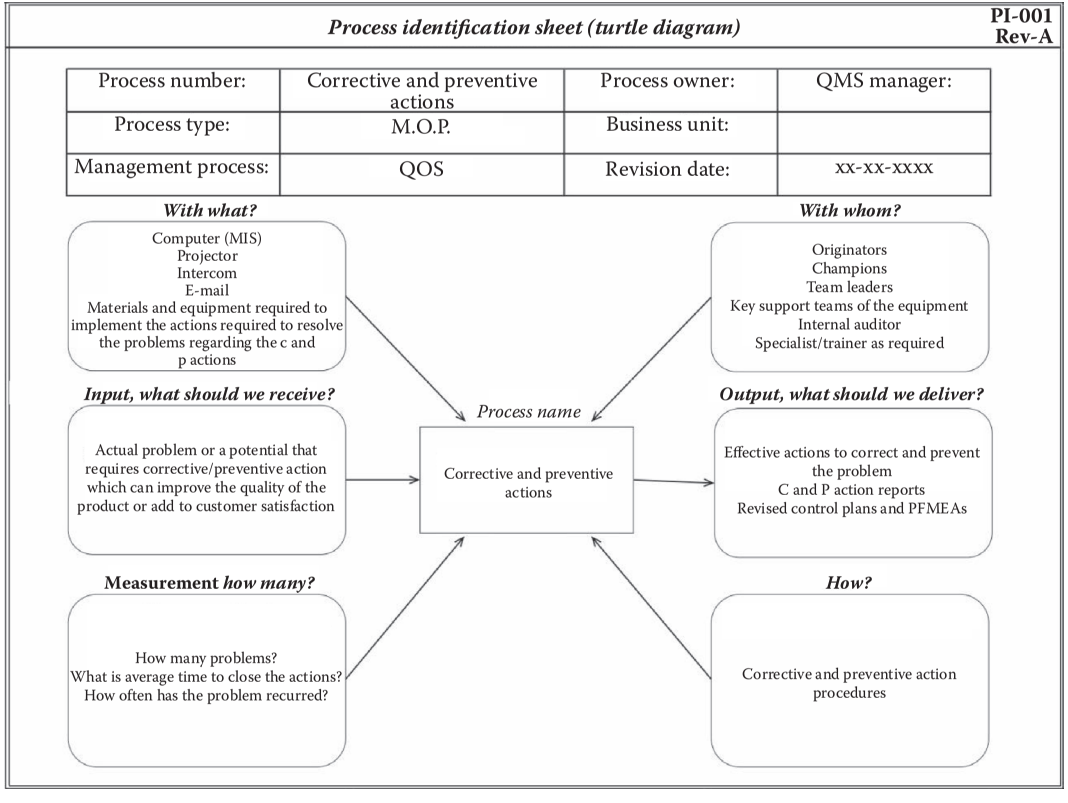
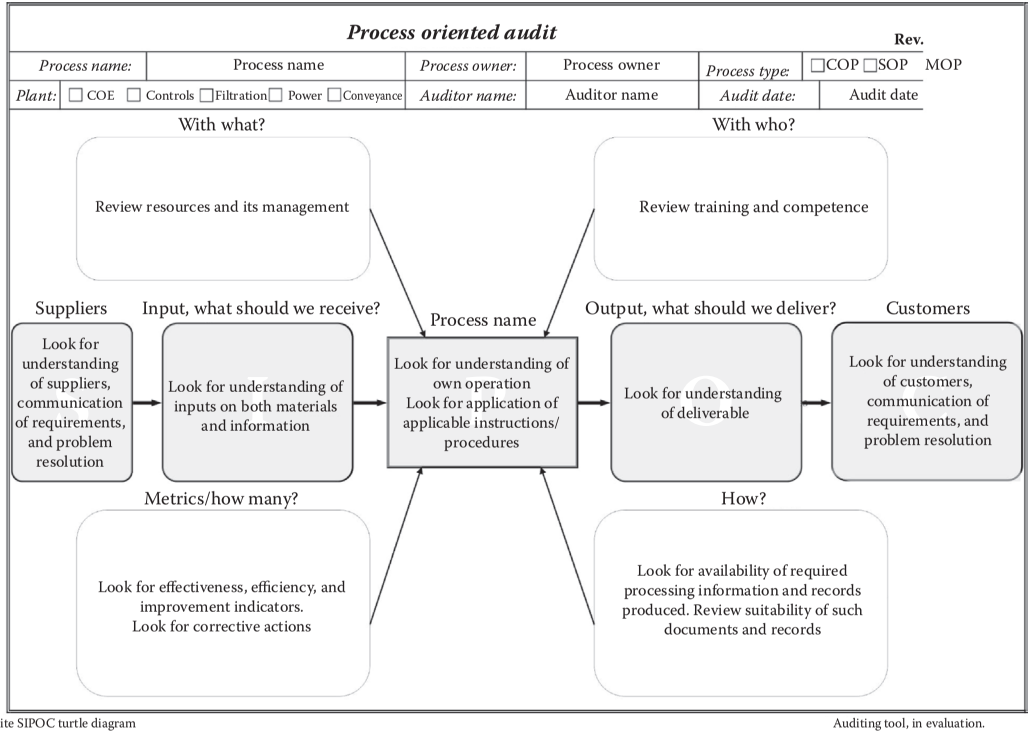
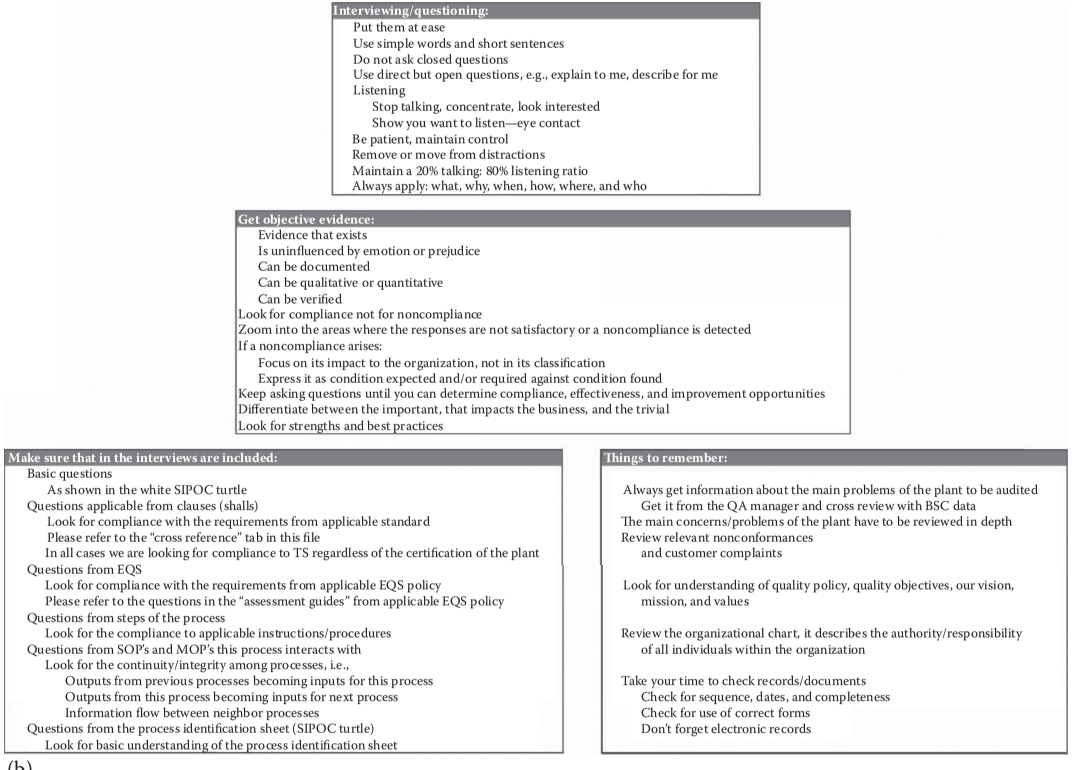



**FIGURE 4.2**
Corrective and preventive action (CAPA) turtle diagram.




(a)

**FIGURE 4.3**
(a) Generic quality audit process using a SIPOC diagram. (*Continued*)




(b)

**FIGURE 4.3 (CONTINUED)**
(b) Generic quality audit process guide.

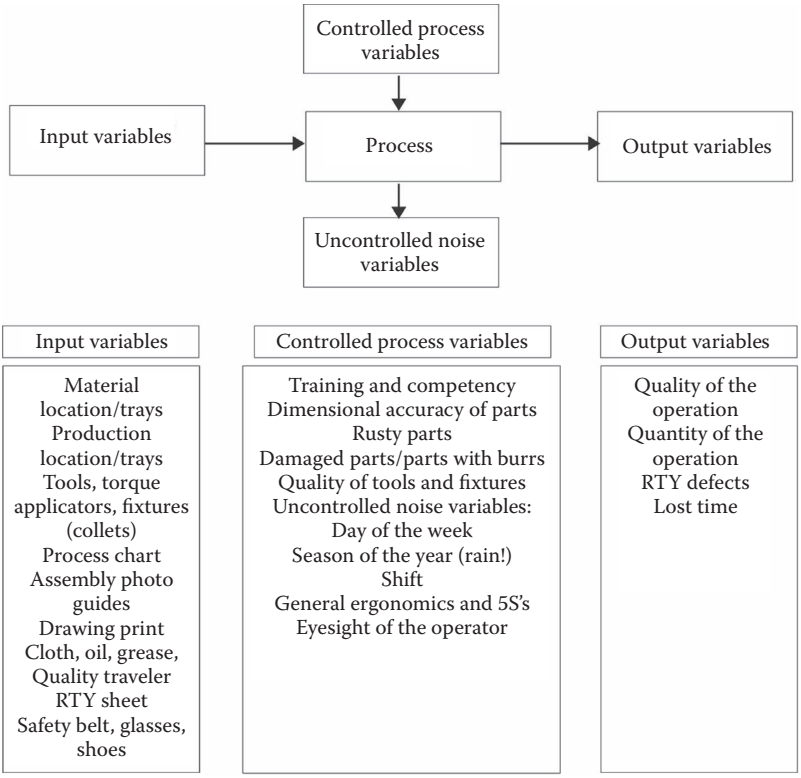



**FIGURE 4.4**
Hand assembly process.

the controllable and uncontrollable variables so that the process can be reviewed and controlled effectively.

Figure 4.4 shows a hand assembly process.

## The Finance Management Process

Figure 4.5 shows the finance management process.

### *Objectives and Their Measurement*

$$\text{Gross profit} = \text{sales} - \text{all variable expenses}$$

$$\text{Net profit} = \text{GP} - \text{OE}$$

$$\text{ROI} = \text{NP/I}$$

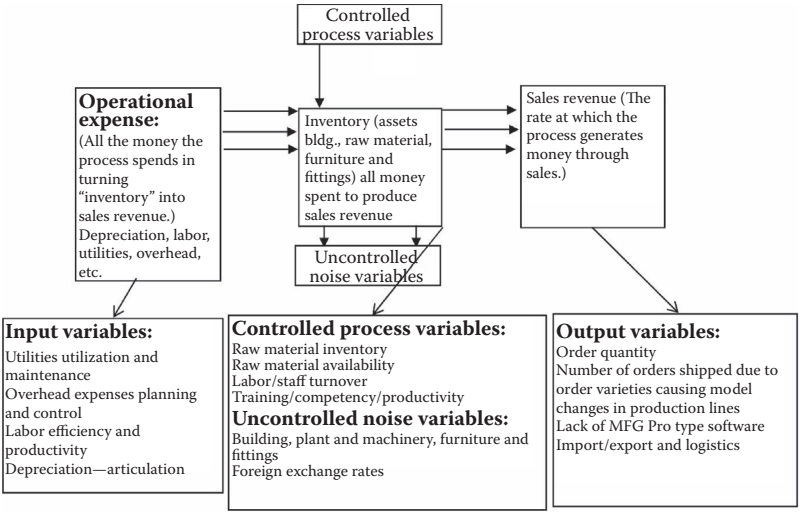



**FIGURE 4.5**
Finance management process.

$$\text{Inventory turns} = GP/I$$

$$\text{Productivity} = GP/OE$$

where
GP = gross profit
OE = operational excellence
ROI = return on investment
NP = net profit
I = inventory

A financial manager is responsible for supervising and handling financial reports, investment portfolios, accounting, and all kinds of financial analysis for an organization. Additionally, he oversees cash management strategies and financial legislation and regulation. He manages the cash flow for an organization by supervising balance sheets, income statements, and the costs and revenue model.

## The Project Management Process

Figure 4.6 shows the project management process.

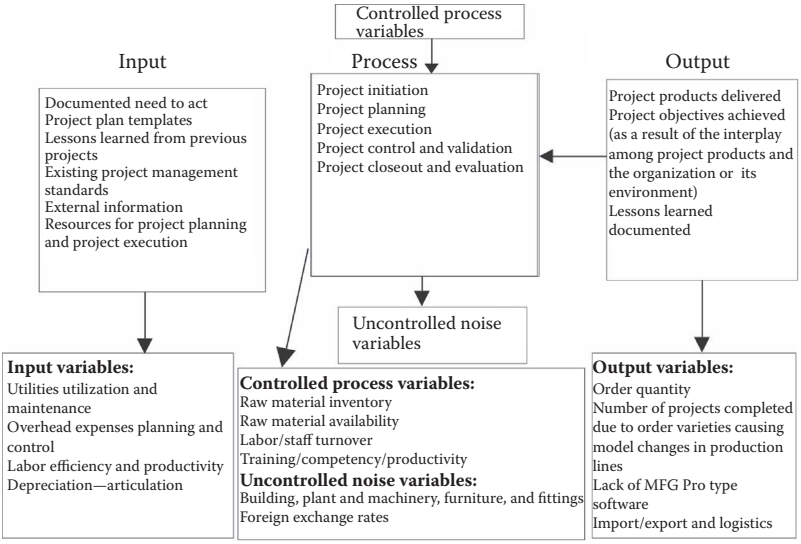



**FIGURE 4.6**
Project management process.

### *Common Responsibilities for IT Project Manager–Program Manager*

- Runs complex projects/programs from design and development to production.
- Defines requirements and plan project life cycle deployment.
- Defines resources and schedule for project/program implementation.
- Creates strategies for risk mitigation and contingency planning.
- Plans and schedules project deliverables, goals, and milestones.
- Directs and oversees project engineering team and manages conflicts within the group.
- Performs team assessments and evaluations.
- Efficiently identifies and solves project issues.
- Demonstrates leadership to define requirements for project risk.
- Develops requests for proposals (RFPs) for external services.
- Designs and maintains technical and project documentation.
- Strong organizational, presentation, and customer service skills.

### *Qualifications for IT Project Manager–Program Manager*

Project management professional (PMP) certification or equivalent preferred.

## The Purchasing Process

Procurement is the act of obtaining or buying goods and services. Figure 4.7 shows the purchasing process, which includes preparation and processing of a demand as well as the end receipt and approval of payment. It often involves

1. Purchase planning
2. Standards determination
3. Specifications development
4. Supplier research and selection
5. Value analysis
6. Financing
7. Price negotiation
8. Making the purchase
9. Supply contract administration
10. Inventory control and stores
11. Disposals and other related functions

The process of procurement is often part of a company's strategy because the ability to purchase certain materials will determine if operations will

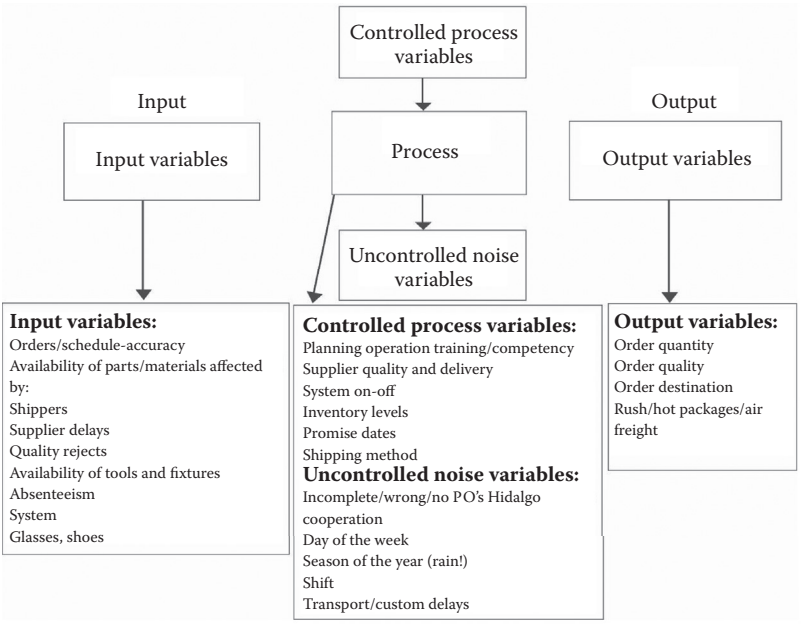



**FIGURE 4.7**
Purchasing process.

continue. A business will not be able to survive if its price of procurement is more than the profit it makes on selling the actual product.

Buyer planners compile requests for materials, prepare purchase orders, keep track of purchases and supplies, and handle inquiries about orders. They perform a variety of tasks related to the ordering of goods and supplies for an organization and make sure that what was purchased arrives when scheduled and meets the purchaser's specifications.

They are conversant with materials requirement planning (MRP) or an equivalent system.

They keep track of orders and determine the causes of any delays. If the supplier has questions, clerks try to answer them and resolve any problems. When the shipment arrives, procurement clerks may reconcile the purchase order with the shipment, making sure they match, notifying the vendors when invoices are not received, and making sure the bills concur with the purchase orders.

### The HR Process

Figure 4.8 shows the HR process. The HR manager

- Treats retention as a core value.
- Believes that employee retention produces customer retention.
- Sets retention goals and holds all managers accountable.
- Monitors the causes, costs, and consequences of turnover ("3 Cs").
- Creates and maintains an environment that is conducive to staying.
- Systematically determines job requirements, skills, knowledge, competency, and training requirements for each and every job.
- Believes in promotion from within.
- Imparts fair, nondiscriminatory treatment of employees regardless of gender, race, disability, etc.

## SIPOC DIAGRAMS FOR PERFORMANCE MANAGEMENT

Six Sigma's supplier, input, process, output, customer (SIPOC) diagram is a better way to hear the voice of the customer (VOC).

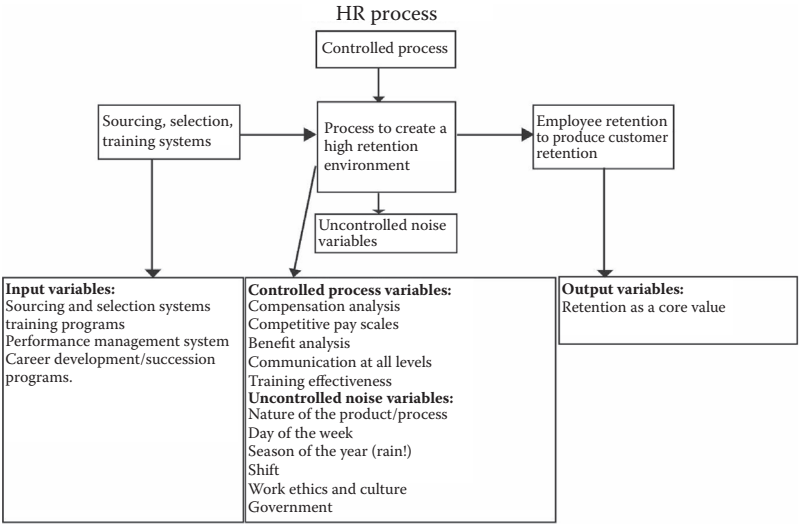



**FIGURE 4.8**
Human resources process.

Walmart's customer fulfillment SIPOC process is shown in Figure 4.9.

Suppliers deliver inputs to the distribution center, a process that Walmart uses to deliver the value-added output, which is affordable merchandise, to its customers.

Figures 4.9 through 4.12 show SIPOC charts including a feedback loop and control of variables of the process.

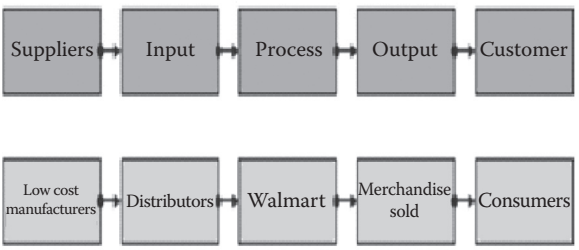



**FIGURE 4.9**
SIPOC at Walmart.

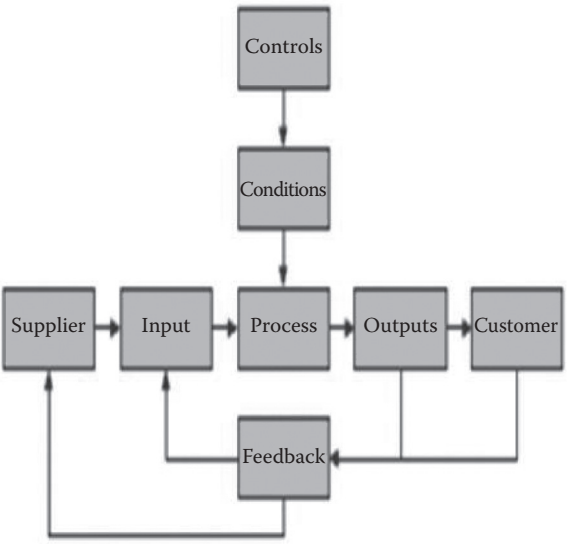


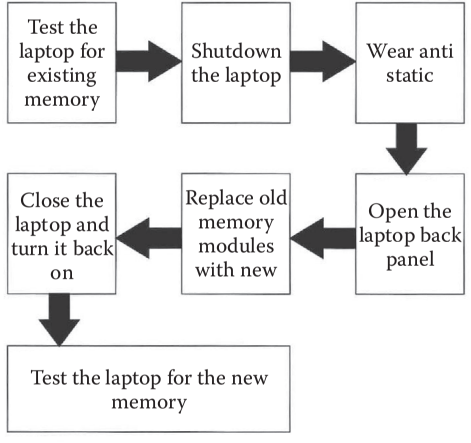

**FIGURE 4.10**
Performance management with SIPOC.

## GENERIC PROCESS TO IMPROVE A PROCESS USING PLAN–DO–CHECK–ACT—FIX, FOCUS, FLEX

### Plan (Fix)

**Stage 1: customer, stakeholders, and market focus.** The process owner views his process as a link in the interaction of processes (refer to Figure 3.2 in Chapter 3) and prepares the turtle diagram to identify the process (reviews QMS- and SIPOC-based model to clarify turtle requirements). The process owner also reviews health and safety rules that affect employees and can cause lost hours due to safety incidents. The process owner reviews and defines customer requirements and stakeholder expectations and implements cost-effective methods, provides resources, and provides products/outputs to the customers per the requirements. The process owner identifies the strengths, weaknesses, opportunities, threats (SWOTs) of his or her team.

**Stage 2: strategy design—alignment of the process with the strategic plan.** The process owner facilitates the team to think about its vision, quality policy, and goals. The process owner communicates to the

| Suppliers | Inputs | Process | Output | Customers |
|---|---|---|---|---|
| Mechanic<br><br>Memory/tools vendor. Example: radioshack electricity utility/ provider | Laptop<br><br>Anti static gloves/tools<br>Memory<br>Power supply<br>Toolbox |  | Upgraded laptop<br><br>Old memory modules | Owner of laptop |

SIPOC diagram for the example process of "upgrading laptop memory"

**FIGURE 4.11**
SIPOC diagram for laptop memory upgrading.

**Expanded SIPOC (supplier, inputs, processes, outputs, and customers) model**



| Process | ID | Process owner | Suppliers | Inputs | Outputs | Customers | Measures and goals | Procedures |
|---|---|---|---|---|---|---|---|---|
| Strategic planning process | 1 | Unit head | Stakeholders and process owners | Customer/regulatory requirements, stakeholder requirements and resources | Balance score card goals | Product users, employees, regulatory bodies and stakeholders | KBDs, KPIs, KSMs and KIs. BSC G | The organization process manual |
| NPI process, prototype, product eng. and engineering doc. process | 2 | Product engineering manager | Design center | Design drawings, engineering specifications and DFMEAs, product specifications, targets for productivity, process capability and cost. Customer requirements and experience from previous design for error proofing. | Process charts, process flow chart, PFMEAs, control plans, work instructions, process approval criteria, results of error-proofing activities, rapid detection of product and process nonconformities, ECNs and deviations | Other process owners, product users and regulatory bodies | COPQ calculated, customer related mfg. issues identified, customer DPPMs, calculated, 8Ds raised, VA/VE projects identified, warranty issues identified, process/assembly, capabilities calculated/monitored | See quality manual references |
| Eng. doc. control and ECN/MPS process | 2a | Eng. doc. controller | Design center | Mfg. process change/ECN requests, engineering drawings and specifications | Process charts, production test procedures, corrected BOMs and engineering prints, deviations | Production, quality purchase, and inventory | Number of ECNs/MPC closed vs pending, average days for closing ECN/MPC corrective actions for deviations | See quality manual references |
| Purchasing, inventory control, and import export | 3 | Materials manager | As per approved supplier list, doc. control dept. external customs and delivery services | Material requirements, made to orders, finished product | Purchase order and inventory accuracy, completed MTO and shipping documents | Production external delivery services, accounts receivables and external customer | Supplier DPPM, supplier OTD, inventory DOH, customer OTD, cost out, air-freight monitoring, past due orders | See quality manual references |
| Customer order receipt and review | 3a | Inside sales | CSRs | Orders received via Cincom/Tolas, and e-mails | Approved customer order and daily order reviews | CSRs | Accurate, complete and timely customer order prepared for production | See quality manual references |
| Production scheduling | 3b | Planners | Inside sales | Approved customer order | Material requisitions, materials kits and MTOs | Purchasing, inventory and production | Accurate, complete and timely MTO and kits prepared for production | See quality manual references |
| Production process | 4 | Production manager | Inventory control, product eng. and quality | MTO, qualified operators, machines and testers available and calibrated instruments | Accepted finished product shipped ontime. | Shipping and delivery, customers | Customer DPPM, customer OTD, COPQ, productivity | See quality manual references |
| HR process | 5 | HR manager | Personnel agencies, corporate HR | Resource requirement requisitions and job specifications | Qualified trainees | Product realization and support functions | Requisitions fulfilled and entry qualifications met | See quality manual references |
| Training process | 6 | Training manager | Qualified internal and external instructions | Job qualification requirements | Qualified operators | Product realization and support functions | Trained employees qualified and QMS resource needs met | See quality manual references |
| Facilities maintenance process | 7 | Facilities manager | Outside contractors and internal maintenance personnel | Maintenance schedule and campus facilities projects | Completed maintenance and projects | Campus unit managers and process owners | Complete, timely and effective maintenance and projects completed | PM software |
| Quality process | 8 | Quality manager | Design engineer, product engineering manager and production manager | Validated design of the product, capable processes, and sound production and maintenance processes | Compliance to established procedures and product specifications | Process owners and stakeholders | Customer DPPM, RTY, supplier DPPM | See quality manual references |

**FIGURE 4.12**
SIPOC-based QMS processes. (*Continued*)

| Process | ID | Process owner | Suppliers | Inputs | Outputs | Customers | Measures and goals | Procedures |
|---|---|---|---|---|---|---|---|---|
| Systems/IT process | 9 | IT manager | Hardware and software suppliers, suppliers of reprographic, telecommunication and misc. equipment requiring computer programming | Different campus systems, user skills and equipment | Timely resolution of complaints, standardized common software and hardware | All internal processes | Time to respond to a complaint, introduction and training for new and existing softwares and equipment | IT manual |
| Finance | 10 | Finance comptroller | Operational expense creators | Expenses incurred by the processes in turning inventory and resources into sales revenue | Sales revenue - the rate at which the process generates money through sales | Stakesholders | Gross profit, ROI, inventory DOH, COPQ, productivity | Finance manuals |

**FIGURE 4.12 (CONTINUED)**
SIPOC-based QMS processes.

team and makes sure that team members understand their roles, goals, and quality policy so that the team can achieve its objectives.

**Stage 3: planning and deployment—strategic plan alignment.** Team objectives include key business drivers, key support measures, and trackers, which are determined and documented in a "cascade goals" sheet for all team members.

### *Provide Leadership*

One should design and document system procedures based on team values and goals, form a team structure (an organizational chart), motivate team members to harness other team members of best capabilities, and act as a change agent by explaining how the team can achieve expected goals, as well as lead the effort.

## Do: Process Management (Customer Focus)

Identify key processes using flow diagrams, analyze each process step to eliminate/reduce non-value-added activities of the process, and define customer requirements. Carry out team-based process failure mode and effects analysis (PFMEA), work instructions, process audits, and product audits.

## Check: Performance Measurement (Minimum of Two Reviews per Year)

This step is tied to stage 3: planning and deployment. Key performance measures per the quality operating system (QOS) road map (Figure 4.13) and cascade goal sheets (Figure 4.14) belonging to the team must be

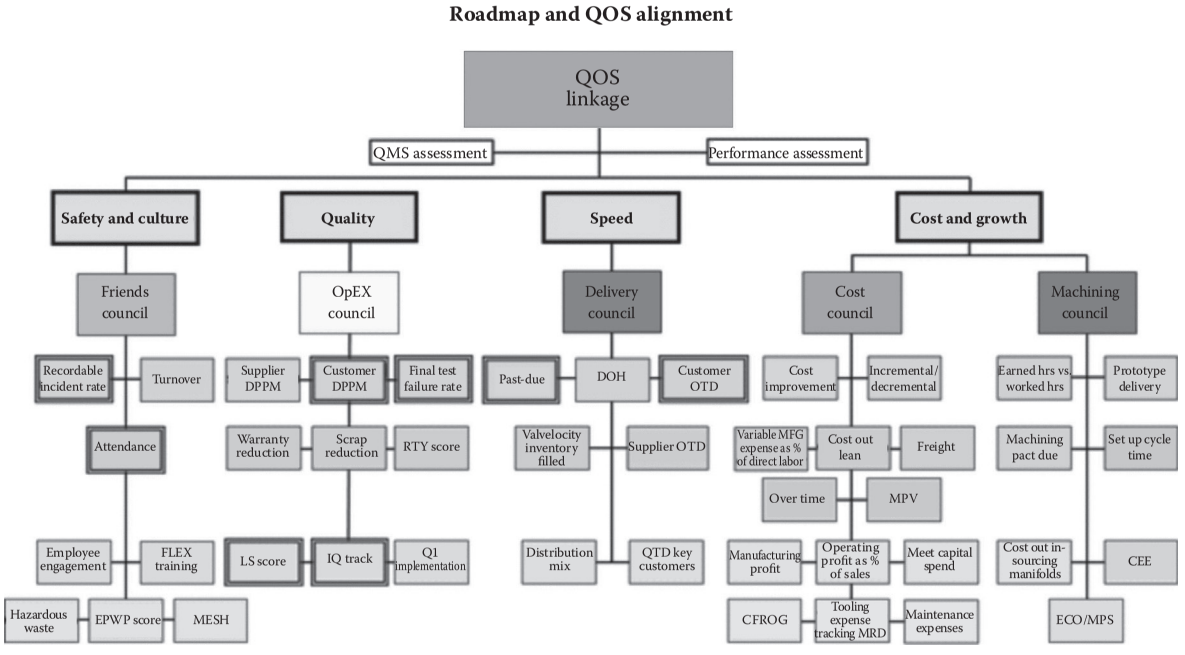



**FIGURE 4.13**
QOS road map.

| **2005 goal alignment and personal commitment** | |
|---|---|
| 2005 Chief Davidson | |
| 2005 Frank Kobyluch | |
| *2005 Suresh Patel* | ***GOAL*** |
| Culture | |
| Ensure the Plant Leadership system is based on Business System principles and drives a passionate and performance driven culture based on an empowered and well trained workforce that delivers an overall satisfaction score of 4.10 on the customer annual survey and a score of 3.75 on the overall dimension of manager effectiveness. The annual survey will be supplemented with a Policy on Work Practice assessment that delivers an assessed score of 2.0 in 2005. | |
| Create and successfully execute a plan to build organizational strength by developing employees in the quality area | 4.1 |
| Improve external customer satisfaction through quick RMA/QAR response | 3.75 |
| Maintain world-class level safety performance through dedication to ESP and VPP that yields total LDWCs and reportables to under 2.0 instances per 100 employees. Supplement these efforts with the accomplishment of all EHS initiatives in 2005. | |
| *Meet all campus EHS/safety objectives in terms of training and responsiveness* | 2.0 |
| Create a culture that every council and every floor team is measured and rated on their performance and recognized for their contributions through the plant employee recognition system. | |
| *Leverage leadership in quality council to drive results and recognition* | |
| Delivery | |
| Create a systematic delivery system in Reynosa that improves 2005 first half delivery performance to 90% OTD to MADD, and 2005 second half delivery performance to 95% to MADD. Create special emphasis through the customer care process, and the tracking of | |
| *Take part in supplier development projects to improve supplier OTD to reduce the shortages.* | Q2–90%, Q4 95% |
| Utilization of ELSS principles to reduce Reynosa DOH to 37. This will be done through the expansion of consigned inventory and the elimination of 1.5 DOH of WIP. | |
| *Limit MRBR inventory to < $40K at any time.* | <$40K |
| Continue driving the Lean journey as evidenced by a score 3.5 to the new ELS criteria by March 31, 2005. In addition, create at least 2 cellular flow MCD cells and self assess to 3.75 by the end of 2005. | |
| *Be a leader for error-proofing, TPM and set up reduction and obtain a score of >4 average in these three tools* | 4.30 |
| Quality | |
| Drive Reynosa 2005 cutomer DPPM to 300 DPPM by December 2005 | |
| *Improve external customer DPPM from 475 to 300 DPPM* | *300 DPPM* |
| *Improve supplier DPPM from 4890 DPPM to 2700 DPPM* | *2700 DPPM* |
| *Improve final test failure rate from 4.5% in 2004 to 3.6% in 2005* | *3.6%* |
| *Improve MCD RTY to 99.379% = 4 Sigma = 6210 DPPM* | *6210 DPPM* |
| *Provide leadership to improve value creation and support processes* | |
| Create partnership with Eden Prairie design group and customer service to deliver TS certificate for SICV product line | |
| *Obtain ISO/TS 16949 certification in June/July 2005* | *Certify in TS* |
| Modify current QOS system to comply with the GQMS system and attain an assessed score of 100% on phase I target and 70% on phase II targets by the end of 2005 | |
| *Implement phase 1 and phase 2 of the EQS with an assessment score of >80%* | 85% |
| Growth/Profitability | |
| Partnership with SCM to hit $1.390 million of material cost out and deliver in-plant Lean savings of $320K to hit 2005 plan cost out target of $1.692 million | |
| *Leverage prototype manifold machining to hit planned financial goal of $1.692 million* | |
| Hit incremental/decremental plan target of 32%. | |
| *Control department check book not to exceed the budget* | |

**FIGURE 4.14**
Cascaded goals.

measured. Internal audit for the process must be performed. Consider retraining, provision of required resources, and guidance.

### Act: Initiative Management (Flex)

Proactive gap analysis and corrective actions will bridge the gap between achieved and desired goals. This is done through monthly QOS meetings, special team meetings, and strategic plan review and actions twice a year. The process owner judges the effectiveness of his or her management system and recommends necessary changes based on the analysis of the data collected during the last 6 months. These reviews ensure that the team members and the team leader follow the plant business excellence (BE) model and TS16949 standard.

# 5

# *Global Quality Audit Processes*

## PROCESS CONTROL PLAN AUDIT (PCPA)

Figure 5.1 shows a PCPA form. Like any audit process, this one requires a minimum of 1 hour of training for a qualified process/quality engineer and at least one complete audit under the guidance of a trained auditor of this method.

PCPA can be used for assessing (1) the capability of a new or existing supplier, (2) a new product process, or (3) an organization's own capabilities regularly—say, twice a year.

This comprehensive audit for an organization covers the following nine areas:

1. Documentation (1A to 1E items)
2. Tooling/Equipment (2A to 2E items)
3. Process (3A to 3E items)
4. Human resources (HR) (4A to 4E items)
5. Product/service qualification—1-day production (5A to 5E items)
6. Implementation of quality—1 (6A to 6E items)
7. Implementation of quality—2 (7A to 7E items)
8. Logistics (8A to 8E items)
9. Continuous improvement (9A to 9E items)

### Audit Points Allocation Method for Each Criterion

Each one of the preceding areas is assessed for five criteria: A, B, C, D, and E. Each one carries a maximum of 5 points. After each criterion is audited, points are given from 1 to 5 depending on how the observations have met

| PCPA | Result: 2 | Date: |
|---|---|---|

| Part number | Odm: | Project: | Supplier name: | |
|---|---|---|---|---|
| Part description: | | SQE: | Supplier code: | Supplier plant: |

| Process verification (VP) | Pre-series (PS) | Release to prod. (DaP) | Current production |
|---|---|---|---|
| Mat'l request: Availability: | Mat'l request: Availability: | Mat'l request: Availability: | Mat'l request: Availability: |

| | 1 - Documentation | 2 - Tooling/ equipment | 3 - Process | 4 - Human resources and organization | 5 - Product qualification/ one day | 6 - Implementation of quality | 7 - Implementation of quality | 8 - Logistics | 9 - Continuous improvement |
|---|---|---|---|---|---|---|---|---|---|
| A | Drawings ☐ F-C 2 | Die status (quality, capacity and timing) ☐ F-S | Tier 2 approval ☐ F | Have operators been properly trained? ☐ F | Self-qualification status ☐ F-S | Incoming material controls ☐ F | Control recording ☐ F | Traceability ☐ F | Lessons learned ☐ F |
| B | Flow chart ☐ F | Equipment status (quality, capacity and timing) ☐ F-S | Tier 2 components approval ☐ F | Management involvement ☐ | Integrative tests status ☐ F-S-C | Production approval ☐ F | Controls recording regarding report characteristics ☐ F | Identification ☐ | Improvement activities for tier 2 suppliers ☐ F |
| C | Process FMEA ☐ F-S | Preservation conditions of dies machines and equipment ☐ F | Are clear operator instructions available and updated for each operation? ☐ F | Are the resources dedicated to controls sufficient? ☐ | Matchability and benestare status ☐ F-S-C | Process controls and tests ☐ F | Control instruments management ☐ F | FIFO ☐ | Warranty ☐ F |
| D | Process control plan ☐ F-S | Ordinary and preventive maintenance (machines/dies/ equipment) ☐ F | Process capability ($P_{pk}$, $C_{pk}$ and $C_{mk}$) ☐ F-S | If more than one shift, does information get passed across shifts? ☐ F | One day production ☐ F-S | Outgoing quality ☐ F | Re-works ☐ F | Appropriate handling and packaging ☐ F | Periodic Re-qualification ☐ |
| E | IMS (Mgt. of use limitation for dangerous or forbidden substances) ☐ | Is the special maintenance effective? ☐ F | Restart of production ☐ F | Cleanness/ environment ☐ | Strengthened pre-launched control plan ☐ | SQE audit ☐ F-S | Non-conforming products management ☐ | Appropriate process flow ☐ F | Quality and environmental certifications ☐ F |

| NA - Not applicable NV - Not evaluated | 1 - Job stopper | 2 - Job stopper risk | 3 - 2nd level issue | 4 - Planned activity according to | 5 - Implemented activity | Remarks and observations | ☐ Attached document F = Doc. of supplier C = Doc. of Customer S = Doc. of SQE |
|---|---|---|---|---|---|---|---|

| Supplier resp.: Sign. Name | Progr. msgr. Sign. Name | SQE: Sign. Name | SQM: Sign. Name |
|---|---|---|---|

**FIGURE 5.1**
PCPA form. (Please refer to the book's CRC Press webpage download file for a full-size editable version of Figure 5.1 at www.crcpress.com/The-Global-Quality-Management-System-Improvement-Through-Systems-Thinking/Patel/9781498739801.)

with the prescribed guidelines. If none of the criteria is applicable or not validated, NA or NV is applied instead of 1 to 5 points.

***Explanations of Actions Required for Each Point***

NA: not applicable
NV: not evaluated—may be audited later or the next time
1: JOB STOPPER—process cannot proceed unless the corrective actions are approved.
2: JOB STOPPER—RISK—process can only proceed if 100% sorting aided by proper fixtures and gauges is in place. The supplier takes the risk of the penalties for stoppage and delays in production.
3: Second-level issue—a corrective action is needed to be implemented before the next audit.
4: Activity is planned according to the project.
5: Activity is implemented.

An example of an actual audit is shown at the end of the chapter.

## AUDIT GUIDE FOR EACH OF THE NINE AREAS

### 1. Documentation (1A to 1E Items)

***1A—Drawings***

The supplier must be in possession of drawings that reflect the change level of the part being produced.
The drawings must reflect some form of customer approval—that is, design engineer's signature, approved design change order, etc.
The supplier must be able to show that the "customer-approved" drawing agrees with the part being shipped.
The technical documentation (drawings, technical specs., standards, and norms) for the part, product, or component under examination shall be updated and available, whether the part is produced internally or purchased from external sources.
The correct management of documents shall be shown. The auditor shall verify the existence of a list having all the drawings used, in

order to ensure they are updated to avoid the retention and use of obsolete drawings.

Tolerances must be shown on the drawing.

The link between the customer's standards shall be shown (e.g., through a tree chart).

Geometric dimensioning and tolerancing (GD&T) must relate back to data.

Key product characteristics (KPCs) must be identified for characteristics that are critical to variation in the part and potentially impact fit, form, or function of the product. (Note that it is not necessary that all parts have KPCs; the customer's product engineering group is responsible for the identification and approval of KPCs.)

If the technical documentation supplied by the customer does not indicate the existence of significant characteristics like safety, homologation (the certification of a product to indicate that it meets regulatory standards), etc., at a minimum the supplier should select characteristics that affect close tolerances, fit, function, finish, reliability, durability, or characteristics affected by process parameters and/or characteristics that affect the successive/final process.

**Note:** The author has found 1A to attract many observations. More observations = less number of points!

### *1B—Flow Chart*

The process flow diagram must be available at the supplier's manufacturing facility. This diagram must begin at the material receiving area and continue through the entire process to the shipping dock, identifying labeling and product storage areas. Any rework or repair operations must be shown on the diagram and indicate the flow of material back into the process. A critical point to check is the flow of repaired or reworked material back to the normal process, where production test equipments must recheck and pass the parts.

Gauging and inspection areas must be shown in the process, whether they are on the production line or off-line. If any of the part inspections or checks result in scrapping the parts, this should be identified on the chart.

### *1C—Process FMEA*

Is there a potential failure mode and effect analysis (PFMEA) available and is it acceptable? Are risk priority numbers (RPNs) acceptable? Are they consistent with design failure mode and effects analysis (DFMEA)? Do the numbers match process flow and are KPCs, product quality characteristics (PQCs), and key control characteristics (KCCs) included as applicable? Is there any evidence that it is a living document?

Corrective actions to product or process shall be used to update FMEAs and control plans.

Since many product failures can be the result of problems in the manufacturing process, the supplier must use the DFMEA as a reference document when developing the PFMEA (e.g., PFMEA severity related to DFMEA severity).

The supplier must be able to describe how critical design characteristics that impact part performance were considered in the PFMEA development.

Process/product FMEA shall be available for review by the customer.

Verify that the process FMEA was generated by a cross-functional team and followed the elements of the process flow chart, with rankings for severity, occurrence, and detection appearing consistent with available quality performance data.

Activities on RPN reduction should be visible and should be carried out as an ongoing process.

A preliminary analysis on the manufacturing, activities and controls means has to be conducted (using process FMEA at a customer's plant, design of experiment [DOE], knowledge of successive processes, knowledge of how the product is used, etc.). At a minimum the supplier should analyze characteristics that affect close tolerances, fit, function, finish, reliability, durability, and/or are affected by process parameters and/or characteristics that affect the successive/final process. For family PFMEA you need to have a periodically reviewed document that shows evidence of periodic PFMEA evaluation for potential improvement.

All the activities that cause a cost increase for nonquality (rejects, reworks, additional controls, etc.) shall be monitored/managed.

Actions aimed to restore initial/optimal conditions shall be planned and implemented and the effectiveness of these actions shall be evident.

### *1D—Process Control Plan*

Is the process control plan (PCP) available?

Is it acceptable (numbers and controls match PFMEA and process flow chart; includes KPCs, PQCs, and KCCs; recalls suitable frequencies and sampling sizes; includes latest engineering work order [EWO]/original design manufacturer [ODM] requirements)?

Did the supplier use the right approach to create the PCP (ref. ISO TS 16949)?

PCP must include receiving, incoming inspection, and all processes up to labeling and shipping.

During the launch period there shall be an early production PCP (strengthened plan).

There shall be an organized structure to guarantee the updating of the control methods/conditions along with the updating of the engineering documents.

Any significant characteristic shall be designated by appropriate symbols throughout the entire documentation.

The classification of product characteristics shall be indicated on each control plan or operating instruction. This shall be compliant with the technical specifications and/or preventive analysis performed on the product when requested (FMEA, DOE, etc.).

Control plans and/or inspection instructions, compliant with updated drawings, safety, and significant characteristic classifications, shall be available for all purchased parts.

Documentation used to conduct inspections (cycles, drawings, instructions, etc.) shall be available at each workstation as required.

Review the content of the PCP.

The adequacy of the contents of the PCP or written instructions (characteristic, control frequency, sample size, measure, equipment recording, reaction rules, etc.) shall be ensured.

For family PFMEA you need to have a periodically reviewed document that shows evidence of PCP review for potential improvement.

Ensure that the process FMEA was utilized in compilation of the PCP with emphasis placed on KCCs/KPCs.

Seek evidence that the control plan is a "living" document subject to regular review.

Process/machine parameters subject to significant alterations over time (e.g., temperatures, times, speed, pressures, etc.) must be

systematically monitored, automatically or manually, with respect to set tolerances.

Check the evidence of controls related to highest RPNs.

The control frequencies, size, and methodological criteria shall be defined. It is necessary to take into account the effect of the characteristic on the functionality of the product as defined by preliminary analysis (e.g., FMEA) and the stability of the process generating the characteristic.

### *1E—IMDS for Management of Use and Limitation for Dangerous or Forbidden Substances*

The International Material Data System (IMDS) is a collective, computer-based material data system used primarily by automotive OEMs (original equipment manufacturers) to manage environmentally relevant aspects of the different parts used in vehicles. It has been adopted as the global standard for reporting material content in the automotive industry.

This criterion is applied only when forbidden materials are used in a process.

## 2. Tooling/Equipment (2A to 2E Items)

### *2A—Die Status (Quality, Capacity, and Timing)*

The auditor shall verify die status in terms of timing and functionality during building and tryout.

The auditor shall verify the number of cavities and the consistency of lifetime with the estimated needs.

The auditor shall verify the implementation of all requirements contained in the tooling sign-off agreement.

### *2B—Equipment Status (Quality, Capacity, and Timing)*

The auditor shall verify tooling status in terms of timing and functionality during building.

The auditor shall verify the presence of all necessary equipment required for the process.

### *2C—Preservation and Conditions of Die Machines and Equipments*

The auditor shall verify the environment where the dies are stored, with particular attention to the conditions of humidity, rust protection, lubrication, and identification. Do the conditions guarantee the functionality through time?

### *2D—Ordinary and Preventive Maintenance (Machines/Dies/Equipment)*

There shall be a programmed, preventive, or predictive maintenance plan for all production equipment directly connected with the product (including machine tools).

This plan shall be complied with, and all ordinary/extraordinary maintenance interventions performed shall be recorded in a logbook.

The records shall be analyzed to identify any weakness in the equipment and/or in its maintenance plan.

Spare parts shall be readily available for those machines/tools that may cause production stoppage.

Customer-owned tooling, gauges, etc. must be permanently identified and included in the maintenance plan.

### *2E—Is the Special Maintenance Effective?*

There shall be a trained maintenance team, internal or external, available for intervention during all working times and also in case of emergency. Special maintenance interventions must be recorded.

## 3. Process (3A to 3E Items)

### *3A—Tier 2 Approval*

Does an approved supplier list exist for all components needed for the assembled part?

Is there a list of qualified suppliers for each commodity or technology?

Have there been any changes on the supplier list agreed during the advanced product quality planning (APQP) or the part approval? There shall be a list indicating one or more qualified suppliers for each specific drawing, technology, commodity, or standard parts. This list should be kept up to date.

There should be some method to assess the adequacy of tier 2 supplier performances.

For a critical supplier, there should be a provision to switch production among PPAP-approved suppliers.

### *3B—Tier 2 Components Approval*

How does the supplier qualify purchased product/material prior to its being used for the product being audited? (Relevant documentation, as well as completion and validity of the controls performed or certified, must exist; if obtained from multiple molds, dies, or multicavity dies, approval shall be given for each mold, die, and cavity.)

Before starting production, the subsupplier shall receive part approval on samples submitted to the supplier; samples must be produced on the actual production tooling under normal production conditions. Part approval must ensure that the samples produced meet all of the requirements of the part drawing and technical specifications and are compatible with the customer's processes and use on the final product.

When a part is obtained from multiple molds, dies, or multicavity equipment, each mold/die/cavity shall be identified in a permanent way on the part. A separate sampling shall be provided for each of them, in order to carry out separate dimensional controls.

The separate sampling is also required for parts of the same size but different characteristics (color, hardness, embossing, etc.).

If the approval is granted via deviation, this shall be temporary and shall indicate the quantity and/or the valid time period.

Deviation on characteristics that may affect the fit or functionality of the component shall be authorized in writing by the supplier's specific approval authority.

When applicable, the auditor shall verify the existence of any master samples.

The auditor shall verify the conformity of the part to the technical specifications.

### *3C—Are Clear Operator Instructions Available and Updated for Each Operation?*

Workstations shall be provided with clear operator instructions and parameter setup instructions according to the needs and method of production. During the planning and development of these

instructions, special attention should be given to operations where inspections occur. Such documents shall be easily identifiable for the various steps related to the usage (e.g., classification, colors, pictures/sketches/drawings, etc.) to avoid any possible mistake.

The auditor shall verify that the operators are properly trained in procedures and job instructions. The auditor shall walk the production line with the control plan to cross check the control instructions and to review the adequacy of visual controls.

### *3D—Process Capability (Process Performance Index, Process Capability Index, and Machine Capability Index)*

For all important measurable characteristics, the process capability indexes must be calculated.

Machine capability (Cm) and machine capability index (Cmk), for machine capability studies, and process capability (Cp) and process capability index (Cpk) (process capability index), for ongoing process capability, will be calculated.

It is necessary to consider the process specific characteristics (e.g., presence of one or more molds/cavities) and the characteristics under examination (e.g., unilateral, bilateral limits) when defining the statistical model to be used.

Acceptable values shall meet customer requests for Cm, Cmk, Cp, and Cpk, short and long term.

If the process capability result is not found to be capable, 100% product inspection must be performed. Such processes must be improved and developed to meet the capability objective.

Capability must be determined under the normal production conditions (e.g., machine or equipment installed in the final environment).

Process capability must be monitored over time to guarantee its ongoing stability. This must be done using adequate statistical process control (SPC) techniques and/or recalculations at fixed intervals by the same initial method.

Machine capability must be recalculated when there are any modifications to the product or process, major maintenance is done on the machine, or when the machine is moved.

All the preceding data, as well as any corrective actions implemented as a result of the elimination of special causes of variation, shall be recorded on the relevant forms.

In the event the results of process capability are less than the agreed objective, provision should be made for

- Reviewing periodic data processing and recalculating control limits
- Reviewing sampling frequencies
- Increasing inspections accordingly
- Availability and traceability of actions recorded in a logbook
- Determining the effectiveness of actions

If the process utilized does not operate at the required capability, it is useless to maintain such a control in the plan. It shall be replaced with a more robust 100% control. Reference documentation shall be updated accordingly.

The auditor shall request all values of Ppk, Cpk, and Cmk and shall verify if they meet specifications. If it is necessary, the auditor shall verify the data directly taken from the process.

#### *3E—Restart of Production*

The instructions concerning equipment management in case of production changes or restarts (setup) shall be made available.

Necessary parameter values shall be recorded at the start of production and analyzed to verify the absence of any drift.

### 4. Human Resources Organization (4A to 4E Items)

#### *4A—Have Operators Been Properly Trained?*

Personnel shall be qualified to carry out the assigned tasks (use of equipment, compliance with work instructions, accident prevention, product handling and identification, consequences of nonconformities to product, activities not properly performed, reaction in case of product and/or machine failures) and the management/setting of new equipment/machines.

Further qualifications shall take place after training.

Training plans shall be commensurate with the importance of the characteristics controlled.

The personnel shall be trained on the product's critical points in general and in particular on the difficulties that may take place in the specific workstation (particular attention to be given to "report/safety"

characteristics). A record of training courses completed, as well as a skills matrix chart identifying the versatility of the employees, shall be available. This matrix shall be consistent with the days of work and number of shifts per day.

A periodic updating of the training plan shall be defined.

The responsibility for the management/updating of the versatility matrix shall be defined.

The auditor shall verify the effective conducting of training courses to operators.

### *4B—Management Involvement*

Is top management involved in quality issues?

Are action plans made, shared with the customer?

Is responsibility for implementation assigned and do people understand their responsibilities?

### *4C—Are the Resources Dedicated to Controls Adequate?*

Is the number of resources involved in the process adequate?

Is resource allocation to all working shifts guaranteed?

### *4D—If More Than One Shift Is Working, Does Information Get Passed across Shifts?*

Seek evidence that effective, well defined lines of communication are in place, particularly across shifts, departments, etc., and that problematic issues reach the correct personnel quickly.

### *4E—Cleanliness/Environment*

There shall be a cleanliness plan for workplaces in order to maintain the right level of cleanliness according to product criticality. A time dedicated to clean the workstation should be allotted for each cycle or shift. Implementation of 5S (sort, straighten or set in order, shine, standardize, and sustain) is preferable.

Is the supplier certified or have a plan to meet ISO 14001 certification?

## 5. Product Qualification/One-Day Production (5A to 5E Items)

### *5A—Self-Qualification Status*

Has the self-qualification procedure been completed?
Are the test results positive?
Have the test reports been shared with the customer?
If not, are clear recovery actions related to the underlined anomaly determined?

### *5B—Integrative Tests Status*

Have the samples for integrative tests been delivered?
Are the test results positive?
If not, are the recovery actions related to the underlined anomaly clearly mentioned?

### *5C—Matchability and Approval Status*

Have the samples for matchability tests been delivered?
Are the test results with all existing attributes positive?
If not, are the recovery actions related to the anomaly clearly mentioned?

### *5D—One-Day Production*

Has the production capacity process been verified?
Is the production capacity sufficient to meet the customer requests?
Does the verified production capacity include the amount for spare parts and possible production increases requested by the customer for a limited period of time?

### *5E—Strengthened Prelaunch Control Plan*

The auditor shall verify the existence of the strengthened prelaunch control plan, characterized by the presence of "in-process" controls with sampling frequencies and/or sampling sizes higher than usual and by the presence of a final control station off-line for the certification of delivering material.
This station shall be adequately prepared for the right functioning (lighted place, necessary equipment available, etc.).

The auditor shall verify the adequacy of the strengthened prelaunch control plan, for example:

- Check if the highest RPNs of process FMEA correspond to more severe controls.
- Check if all important key and critical characteristics have been taken in account.

The auditor shall verify that the responsible person for execution of the plan has been identified to certify all batches correctly before shipping.

## 6. Implementation of Quality (6A to 6E Items)

### *6A—Incoming Material Controls*

For purchased material/raw material having significant characteristics assigned, what is the subsupplier's procedure for the correct management of supplier's processes (i.e., control plan), including the recording and filing of inspection results? When is it necessary to purchase from nonqualified suppliers? Effective controls, using adequate sampling plans, shall be exercised both in the incoming inspection area and during the manufacturing process to prevent and block the use of nonconforming parts or raw material.

The control plan used shall be available and the related results of inspections and tests shall be accessible on request.

The methodologies for retaining the performed/certified quality check records shall be defined.

All components must comply with customer requirements.

When applicable, the existence of deposited reference samples must be verified.

If there is a computerized system to manage incoming products, sampling plans, and acceptance/reject criteria, an alternative method shall be available in case the system does not operate.

Control plans shall be developed and used (characteristics, frequencies, sample sizes), assuring the appropriateness of contents referring to significant characteristics, in order to allow periodic reexamination, data processing, and acceptance criteria evolution.

Subsuppliers may qualify for self-certification status if they have quality system certification, positive process audit evaluation, and quality performances suitable to the importance/product quality goals.

Procedures shall be defined for suspension/reestablishment of the self-certification status when nonconformities occur.

Results of inspections and tests shall always be available and sent to the customer if required.

A specific symbol showing the self-certification status shall appear on the material shipping documents, product identification sheet, and package.

Audits on incoming lots shall be done randomly and statistical evaluation of the results shall be made in order to compare them with the subsuppliers' indicators.

The auditing process for each deviation and new/modified product/process of the subsupplier must be laid down for analysis and sharing of control plans. This activity shall be shown through a correct management of product/component change control policy.

Any product produced before a modification shall be considered as nonconforming unless otherwise provided by the customer.

### *6B—Production Approval*

Controls on the first part produced shall be defined and implemented in case of restart of production, after any modification, or change of manufacturing process.

Conformity to specification shall be guaranteed through

- Part approval by appointed personnel with specific approval instructions; the correct and complete instructions shall be available
- "OK to produce" permission given by responsible person after verification of conformity to specifications of the first batch of parts realized with steady process
- Availability of the related documentation concerning parts (charts, instructions, etc.)
- Availability of production tools, control and handling equipment

### *6C—Process Controls and Tests*

The supplier shall have a procedure for the detection and immediate action on the process, when process drift or degradation becomes evident.

Are the process and machine parameters defined according to prescribed specifications, norms, and drawings from both customer and supplier (temperature, pressure, voltage, current, load, capacity, torque, etc.)?

Check that process control limits are not confused with tolerances.

Control limits have to show continuous improvement process in place.

The method of recording control data for checks should be verified for the checks being performed. Out-of-control conditions or special causes of variation should be clearly identified, documented, and linked to a robust corrective action support system involving the operator.

The supplier shall use a system for the easy identification of conforming products already produced (lot breaker, control charts, etc.).

The supplier shall have a procedure to inspect parts back to the last "in-control" point/part, when a nonconformity is found.

Defined rules shall be applied for the management of major nonconformities including:

- Identification of the nonconformity root cause analyses
- Interim and long-term corrective actions
- Verification of effectiveness
- Extension of improvements to similar processes

Corrective actions to the process shall be used to update FMEAs and control plans.

The auditor shall verify the management of a corrective action subsequent to a nonconformity.

### *6D—Outgoing Quality*

An adequate product audit plan should be implemented:

- The results of previous audits shall be made available.
- If defective parts are discovered, a reaction plan shall be made available.

### *6E—SQE (Supplier Quality Engineer) Audit*

In the incoming material area, select a sample from previously accepted/approved lots and inspect it.

In the manufacture area, the auditor shall require parts to be selected from different machines and different operators and witness the execution of the inspections, checking the consistency of the results with the previously recorded inspections and comparing them to the

specifications. In case of nonconformity, the results shall be investigated to determine the root cause.

The auditor shall verify that the raw material being used is the same as that approved by the customer.

During the examination of the complete sequence of operations, audits/inspections shall be performed by the auditor on finished or semifinished products selected from a minimum of three machines/processes and audited for selected characteristics.

At the auditor's option, check 15 pieces from each of the three machine/processes to demonstrate process control using a precontrol chart.

In the shipping area, select samples from previously accepted/approved lots that are ready to be shipped and inspect their characteristics.

During the product audit, did the inspection personnel seem to be adequately trained?

Are the inspection methods performed in a way that is consistent with and adequate for the inspection requirements?

Are the results of the audit conforming to the audit requirements?

## 7. Implementation of Quality (7A to 7E Items)

### *7A—Controls Recording*

Conditions and responsibilities shall be defined for the recording and filing of inspection and test results.

Procedures for storing the documents in suitable places shall be defined and applied.

### *7B—Records of Controls Regarding Report/Safety Characteristics*

For parts with report/safety and/or significant characteristics, the periods for storing the documentation shared with the customer and/or required by statutory provisions shall be guaranteed.

### *7C—Management of Control Instruments*

There shall be a sufficient quantity of inspection and test equipment to carry out the necessary controls (personnel included).

Are boundary samples available to operators and in use?

Do all gauges have operator instructions attached and clearly visible?

Are master parts available to confirm inspection and error-proofing devices?

Gauges and measurement equipment shall be of adequate measuring class commensurate to the requirements of drawings, regulations, and importance of the characteristics.

Availability, suitability, identification, efficiency, and correct storage for gauges, test equipment, and reference samples shall be ensured.

The supplier shall have a written and properly applied procedure to audit the capability of the gauges for accuracy, repeatability, reproducibility, and stability.

The consistency between capability of the gauges and tolerances shall be audited.

There shall be a gauge calibration system, including calibration frequency and recording of relevant results.

Gauge identification, calibration status, and expiration date (via calibration stickers, color code, etc.) shall be ensured.

The criteria adopted to guarantee the continuance of required inspections and tests during the absence of the gauge for calibration shall be defined (especially when the instrument is sent to external laboratories).

There shall be gauge history cards containing start-up date, interventions of calibration, "as found" condition, maintenance, repair, etc.

Gauge blocks and/or reference samples for gauge calibration shall be traceable to the national standard.

The appropriateness of the accuracy level of gauge blocks and/or samples required for a correct calibration shall be defined (primary and secondary work samples, etc.).

Reaction rules shall be defined in the event that any gauge is found out of calibration.

Identification and segregation of any nonconforming, incapable gauge shall be ensured.

Referability, metrological traceability, and calibration expiration date shall be shown.

A boundary sample and acceptance standards shall be available and used for inspection of parts having appearance items, etc. The acceptance standards shall be developed by either the customer or the supplier.

If required, the boundary sample shall be made available in each inspection/control station.

The identification and recording of the modifications on the boundary samples shall be recorded on specific charts.

There shall be evidence of referability and traceability of the master samples.

Storage, handling conditions, and preservation of the boundary samples shall be defined.

The instructions concerning gauge management in case of production changes (setup) shall be available.

Gauges shall be provided with clear operator instructions, and parameter setup instructions according to the needs and method of production. During the planning and development of these instructions, special attention should be given to operations where inspections occur. Such documents shall be easily identifiable for the various steps related to the usage (classification, colors, pictures/sketches/drawings, etc.) to avoid any possible mistake.

The master sample shall be available in each inspection/control station as applicable.

The identification and recording of the intervention actions shall be recorded on specific charts.

There shall be evidence of referability and traceability of the master samples.

Storage, handling conditions, and preservation of the master samples shall be defined.

The auditor shall verify the effectiveness of mistake proofing by simulating one or more nonconformities.

Reference samples used to verify the operating condition of gauges and inspection/test equipment shall be available.

Reference samples shall be used according to the frequencies set out in the control plans.

A 100% error-proofing objective requires that the detection and rejection of parts be performed in an automatic way and that, when the device breaks down or goes out of calibration, the parts be termed as "nonconforming."

### *7D—Reworks*

Written instructions shall be developed for reworking, repair, or touch-up of nonconforming parts. The instructions should define the

method of repair, the equipment, the material to be used, and the methods of identification and control of the reworked products.

The reworked/repaired products, when applicable, shall be clearly identified and traceable.

The reworked/repaired products shall be reinserted into the principal flow at the point previous to where the nonconformity was generated or at least rechecked with the same gauges or test equipment that discovered the nonconformity.

### *7E—Nonconforming-Products Management*

Nonconforming parts shall be adequately identified via signs/documents and properly segregated (well delimited areas, better if enclosed, or adequate containers).

The rules for the management of nonconforming products and relevant responsibilities for the following shall be defined:

- Identification
- Segregation
- Rework/repair
- Recheck
- Reject or scrap
- Deviations

When a nonconformity is discovered, the relevant management procedure shall be correctly applied with respect to the segregation and interventions on product, analysis of the causes, corrections on processes, and control of effectiveness of corrective actions.

## 8. Logistics (8A to 8E Items)

### *8A—Traceability*

Traceability shall be guaranteed for safety components and/or for components subject to specific regulation.

When the components have characteristics classified as "report/safety" or subject to homologation, it shall be possible to trace back the results of inspections and tests according to what is agreed with the customer and according to what is required by various national/international regulations.

There shall be a traceability link between the packaging label and the product, lot, packing list, quantity, revision level, component parts, and processing controls used in both internal and external processes.

Lot traceability to the raw material and/or subsupplier components shall be maintained when required by contract.

There shall be a clear identification of the batches assigned to Quality Department inspections/checks.

Materials stored in stock shall be rapidly identifiable by means of documentation reporting codes and lot number.

There shall be adequate procedures for the management of any modification concerning the product, process, and/or any issued deviation. This activity shall be shown through a correct management of product/component modifications.

Any product produced before a modification shall be considered as nonconforming unless otherwise provided by the customer.

### *8B—Identification*

The identification tag/label shall be visible for materials in stock.

All semifinished and/or finished products shall be positively identified (e.g., part number, lot code, quantity) and the progress shall be clearly shown with respect to the different phases of the manufacturing cycle (operations completed).

The application and appropriateness of the provisions to visualize the inspection status (e.g., color-coded tags) shall be guaranteed—for example:

- Product waiting to be inspected
- Product inspected and accepted
- Product waiting for a decision
- Nonconforming product
- Scrapped product to have segregation/identification in order to avoid any reinsertion into the process

The rejected product area, where the nonconforming material is stored waiting for its final destination, must be identified and forbidden to unauthorized personnel.

Identification conditions shall be commensurate with the risk and type of process.

Identification may be related to every single piece, the container, or the work cell and shall be able to be traced back, as necessary, to the information concerning inspections, gauges/test equipment, operator, date, team, etc.

Identification shall be clear, even after the partial use of the lot.

Consistency between identification and traceability requirements shall be guaranteed in particular for products with report/safety characteristics.

Each box, container, packaging, etc. shall be identified. Periodic controls shall be carried out to ascertain that identification and product/quantity correspond.

Nonconforming products shall be identified and segregated in the relevant areas.

Product identification/marking shall comply with the customer's specifications and must be provided:

- In case of assemblies, on all components of the assembly
- On the loose spare parts for market

The auditor shall ensure that all packaging is properly identified.

### *8C—First In/First Out*

There shall be a system guaranteeing first in/first out (FIFO) throughout the process flow.

Is the expiration date for perishable products managed?

Product lots shall be sent to the following operation in an organized manner (FIFO, identification of destination, and arrangement of machinery).

If there is an information retrieval system, in the event of its failure, FIFO shall be managed by means of an equivalent manual system.

### *8D—Appropriate Handling and Packaging*

Product storage areas at each workstation shall conform to customer requirements.

Packaging and repackaging used shall be designed to assure the integrity of every single component until its use in the production cycle.

Packaging shall be identified according to standards agreed with the customer (packaging specifications).

Operating instructions shall be defined in case of damaged packaging.

During unloading, staging, and storage operations, environmental conditions shall be such as to protect the integrity of the product and its packaging.

Handling, transport, and storage means (forklifts, pallets, etc.) shall be efficient and operated under safety conditions.

Storage done on pallets, shelves, etc. shall be suitable to facilitate cleanliness and maintenance, complying with the maximum piling to ensure safety and product integrity.

Storage/stockpiling areas shall be sufficiently sized to contain the material located in a logical way with respect to the flow and adequate to contain and protect the product, with easy access and safe handling.

The supplier shall not use customer containers/packaging for internal handling.

#### *8E—Appropriate Process Flow*

The technical documentation to be used in the workstations shall be easily accessible without disrupting the working activity.

Material flow shall be designed to avoid missed operations or mixing of parts of similar products.

Equipment for production of lots/work orders not currently under production shall be properly identified and isolated to avoid confusion in the flow management of components/products being manufactured.

Review the actual manufacturing area against the process flow chart, general layout, and process control plan, considering all processes from goods receiving to dispatch.

The workplace should be configured per the general layout and be provided with adequate space, lighting, etc.

Locations should be designated and, where necessary, secured for the storage of gauges, scrap, reworked parts, etc.

Provisions should also be made for display of process control plans, standard operation sheets, work instructions, process setting sheets, SPC sheets, etc.

### 9. Continuous Improvement (9A to 9E Items)

#### *9A—Lessons Learned*

Are the issues found on current products managed and analyzed? Are the relevant corrective actions implemented on the next products?

### *9B—Improvement Activities for Tier 2 Suppliers*

Does an improvement plan related to tier 2 suppliers exist in order to improve the quality of their product/process?

### *9C—Warranty*

Are the processes developed for an analysis/prevention system that will prevent and avoid any claim from the field?

Are the processes developed for the analysis of the data related to problems detected in the field?

Are the samples returned from the field analyzed?

Are corrective actions related to those that analysis implemented?

Does a system for collection and stratification of data exist?

Are the qualified tier 2 suppliers involved in these activities going back up the processes and FMEA reviews? Are the results of these activities transferred to the new products in development?

### *9D—Periodic Requalification*

Periodic process reviews and/or audit shall be performed in order to assure the maintenance over time of performances achieved during the qualification/approval of the process. A periodic requalification of the supplier system, assembly, or component shall be planned, with frequencies shared with the customer.

In case a specific request by the customer is not in place, the supplier shall arrange a plan with frequency not lower than once every 2 years.

The requalification process shall include all the necessary tests for the self-qualification of the system, assembly, or component for the achievement of a CCQ (certificate of quality and conformity). These tests that are written into the shared self-qualification test plan.

### *9E—Quality and Environmental Certifications*

The auditor shall require the supplier's copy of its quality system certificate and environmental management certificate (ISO/TS 16949 and ISO 14001 or equivalent).

The following is an example of a PCPA audit observation sheet:

| Question | Ranking | Observation | Corrective action | Responsible | Date | Status |
|---|---|---|---|---|---|---|
| 1a | 2 | No drawing on record for making sure that the part and specifications are in line with the customer requirement | | | | |
| 1b | 3 | No repair loop on the process flow; no incoming inspection on the process flow | | | | |
| 1c | 2 | Process FMEA is not updated with the current issues | | | | |
| | | PFMEA needs to be updated with the component critical and significant characteristics at appropriate stages of assembly or incoming inspection | | | | |
| | | Process FMEA needs to be done with a wider group of stakeholders; Needs to be coordinated with the DFMEA and design engineering team | | | | |
| 1d | 2 | Process control plan needs to be strengthened with the lessons learned | | | | |
| 3b | 2 | Tier 2 process control data needs to be monitored | | | | |
| | | We need to be able to find the goal post in case there is a field issue | | | | |
| | | Incoming inspection needs to be increased and recorded/monitored for preventive actions | | | | |
| 3d | 3 | Data is being recorder, but is not being analyzed | | | | |
| | | Data needs to be monitored and evaluated for process control | | | | |
| 4a | 3 | Need back up masters | | | | |
| 4d | 3 | Issue log should be readily available and passed to the next shift at the end of the shift | | | | |
| 5a | 3 | Needs data after supplier control was in place for heat treatment at the assembly station when the parts failed, they were not analyzed and recorded for failures before scrapping. (Example—failed o ring was discarded in the red bin without any analysis) | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 9b | 2 | Management of tier 2 is needed for preventive actions—data analysis, goal post determination | | | | |
| 9c | 3 | Warranty and qrr reports for customer need to be managed and reported to SQA | | | | |
| 9d | 3 | If periodic qualification is required, then customer engineering needs to ask for it and company needs to provide data to meet the requirement | | | | |

The overall ranking is 2. This is not an average of all scores but the minimum score among all observations.

A rating of 2 means that the plant processes are risky and may be job stoppers.

## CONDUCT ADDITIONAL AUDIT FOR THE EIGHT MANAGEMENT PRINCIPLES

The eight quality management principles are defined in ISO 9000:2005, "Quality Management Systems Fundamentals and Vocabulary," and in ISO 9004:2000, "Quality Management Systems Guidelines for Performance Improvements."

These eight management principles specified in ISO 9000 should become the subject of management audit:

Principle 1: Customer focus
Principle 2: Leadership
Principle 3: Involvement of people
Principle 4: Process approach
Principle 5: System approach to management
Principle 6: Continual improvement
Principle 7: Factual approach to decision making
Principle 8: Mutually beneficial supplier relationships

## AUDIT OF EIGHT MANAGEMENT PRINCIPLES BASED ON ISO 9001:2008

### Principle 1: Customer Focus

***Internal Audit Requirements***

1. Element 5.2: Ensure that customer requirements (CRs) are determined and met and that customer satisfaction (CS) is enhanced.
2. Element 5.5.2: Promote awareness of customer (internal and external) requirements.
3. Element 5.6.2: Input customer feedback to management review.
4. Element 5.6.3: Take actions based on management review related to customer requirements.
5. Element 6.1: Provide resources to enhance CS.
6. Element 7.2.1: Determine requirements specified and not stated. (Anticipate!)
7. Element 7.2.3: Communicate with customers (includes complaint handling and preventive actions and resources).
8. Element 7.5.4: Handle customer property.
9. Elements 8.2 and 8.4: Monitor, measure, and analyze CS information.

### Principle 2: Leadership

***Internal Audit Requirements***

1. Element 5.1: Communicate top management commitment.
2. Element 5.2: Determine customer requirements and enhance CS.
3. Element 5.3: Include commitment to continual improvement in quality policy (or exceed).
4. Element 5.4: Plan and establish measurable quality objectives.
5. Element 5.5.1: Assure responsibilities are defined and communicated.
6. Element 5.5.2: Appoint the management/customer representative.

### Principle 3: Involvement of the People

***Internal Audit Requirements***

1. Element 6.2.2: Determine the competency needs of the organization.
2. Elements 6.2.1 and 7.5.2: Determine individual competency and qualifications based on education, training, skills, and experience.

3. Element 6.2.2: Evaluate the effectiveness of training.
4. Element 6.2.2: Ensure that employees are aware of their contributions to quality objectives.
5. Element 6.4: Determine and manage the work environment.
6. Element 7.2.2: Assure awareness of changes related to product requirement.

## Principle 4: Process Approach

### *Internal Audit Requirements*

It is an audit requirement to identify, monitor, measure, analyze, and improve all quality management system (QMS) processes.

1. Element 4.1: Control outsourced processes.
2. Elements 5.6.2 and 5.6.3: Include process performance in management review as an input and actions to improve processes as output.
3. Element 8.4: Analyze data.

## Principle 5: System Approach to Management

### *Internal Audit Requirements (Refer to Audit Process Turtle Diagram)*

The QMS comprises a number of interrelated processes. The processes needed for the quality management system include not only the product realization processes (those that directly contribute to making the product or delivering the service), but also numerous management, monitoring, and measurement processes, such as resource management, communication, internal auditing, management review, and other processes.

## Principle 6: Continual Improvement

### *Internal Audit Requirements*

A key is to improve the effectiveness of the QMS using an improvement loop mentioned in 8.5.1 consisting of the following:

1. Quality policy (5.3)
2. Quality objectives (5.4.1)
3. Internal audit results (8.2.2)
4. Analysis of data (8.4)

5. Corrective and preventive actions (8.5.2 and 8.5.3)
6. Management review

The audit requirements are

- Plan (4.1, 5.4.2)
- Plan and implement improvement processes (8.1)
- Report on QMS effectiveness and need for improvement (5.5.2)
- Provide resources (6.1)
- Monitor and improve the loop (8.5.1)

## Principle 7: Factual Approach to Decision Making

### *Internal Audit Requirements*

The issue for audit is analysis and use of the data. The data should be available and used for measuring and improving:

1. Processes
2. Product quality and reliability
3. Customer satisfaction

The data must be gathered, analyzed, and assessed against the objectives.

1. Element 4.2.1: Document the quality objectives.
2. Elements 5.3, 5.4.1, and 5.4.2: Ensure that the objectives are measurable and consistent with quality policy.
3. Element 5.6.1: Assess the need for improvement and changes to the quality objectives.
4. Assess CS, product quality, processes, suppliers, and QMS.

## Principle 8: Mutually Beneficial Supplier Relationships

### *Internal Audit Requirements*

1. Element 4.1: Control outsourced processes.
2. Element 7.4.1: Control suppliers and supplied products.
3. Select, evaluate, and reevaluate the (grandfathered) suppliers.
4. Assess requirements prior to communication to suppliers.
5. Element 8.4: Use data analysis to improve suppliers.

# 6

# *Global Quality Management System Processes*

Objective

- Implement best practices in the area of quality management.
- Address weaknesses in current quality management system (QMS).
- Globally, customers are demanding an internationally accredited quality system if a supplier wants to do business with them.
- Improve customer satisfaction and reduce cost of nonconformance.

The following processes are included in this chapter:

- Management responsibility (MR)
  - Management review process—MR-1
- Resource management (RM)
  - Quality training process—RM-2
- Product realization (PR) policies
  - Change control process—PR-3
  - Processes to identify special characteristics—PR-4
  - Internal supplier PPAP/FAI—PR-5
  - Supplier quality management process—PR-6
  - PFMEA—PR-7
  - Process control plans—PR-8
  - Measurement system analysis—PR9
- Measurement analysis and improvement (MAI) policies
  - Fresh eyes audit—MAI-10
  - Common manufacturing and special process audit—MAI-11
  - Process capability methods and requirements—MAI-12
  - Control of nonconforming material—MAI-13

- Performance analysis and improvement process—MAI-14
- Corrective and preventive action policy—MAI-15
- Quality alert system—MAI-16
- Risk management—MAI-17

## 1. MANAGEMENT REVIEW PROCESS

### Preamble

How do you create a focus on action to accomplish the organization's objectives, improve performance, and attain your vision?
How do you address innovation, agility, and learning to help sustain your organization?
How do you emphasize and reinforce your code of ethics and philosophy and support the regulatory environment?
How is the personal performance and effectiveness of senior leaders and the leadership system evaluated?
How does your organization identify and proactively address any adverse impact on society of your products, services, and operations?
How do you promote, ensure, and monitor ethical behavior throughout your organization?
How do you measure compliance with ethical, regulatory, and legal requirements?
How does your organization actively support your key communities?

**The answers lie in regular Management Reviews, carried out as follows.**

### 1.1 Purpose

Management reviews are required to ensure the continual improvement and effectiveness of the quality management system.

### 1.2 Scope

This procedure describes requirements for conducting a management review of the QMS.

## 1.3 Procedure

1.3.1 It is the responsibility of the management representative to schedule management reviews at planned intervals and to provide the proposed agenda in advance to all attending team members.

1.3.2 Reviews shall be held at regular intervals (at least four times a year or more) at various different management levels within each organization—for example, (a) business unit manager and staff and (b) plant/site manager and staff.

1.3.3 The highest ranking individual at the site shall conduct the management review.

1.3.4 Refer to a typical agenda at the end of this procedure

1.3.5 For the required team to conduct the management review, refer to the supplier, input, process, output, customer (SIPOC)-based QMS process.

1.3.6 All participants should come prepared with the needed information, data, and analysis to address the required topics covered on the proposed management review agenda.

1.3.7 Conduct the management review, utilizing the requirements specified in the agenda.

1.3.8 The retention method and duration of management review meeting minutes shall be established at appropriate levels within the organization.

1.3.9 The management review agenda: (1) introductions, and (2) identification of scribe to record minutes for this meeting

| Time | Agenda item | Responsibility |
|---|---|---|
| | Actions from previous management reviews | |
| | Customer relationship review update<br>Customer satisfaction review<br>Customer feedback<br>Improvement of product/service related to customer requirements<br>Customer complaints (8D's)<br>Results of performance to customer-specific requirements | Sales/marketing/ quality |
| | Review of key business processes (quarterly or as required)<br>Appropriateness<br>Effectiveness (meets all requirements/objectives)<br>Efficiency (meeting all requirements/objectives<br>utilizing the minimum resources) | Process owners |
| | Quality management system review<br>Quality objectives and goals (review performance against existing objectives)<br>Review other performance metrics and trends<br>Cost of poor quality<br>Opportunities for OMS improvement | Top management team<br>Quality team |

| | | |
|---|---|---|
| | Employee satisfaction<br>Review survey results and actions<br>Top level overview of training emphasis<br>Employee issues | Human resources |
| | Supply chain management<br>Supplier performance metrics<br>Supplier issues<br>Supplier initiatives for current and future years | Quality |
| | Additional business<br>Organization's business excellence award and certifications progress<br>Lean Six Sigma deployment and assessment status<br>ISO 14001 certification status<br>New product development and launch progress<br>Safety process status | |

| | | |
|---|---|---|
| | Resource requirements review | Team |

| | | |
|---|---|---|
| | Review action items identified from this meeting<br>Decision, actions, improvements, resources and responsibilities<br>Finalize plan for publishing and maintaining review meeting minutes scribe | Adjourn |

Total time should not exceed 90 minutes.

## 2. QUALITY TRAINING PROCESS

### 2.1 Purpose

The purpose of this policy is to ensure that all employees receive a basic level of quality training. This training will assist in instilling a quality-minded culture in all of our associates.

### 2.2 Scope

2.2.1 The scope of this policy is to instill a quality-minded culture in the entire organization.

2.2.2 The training described in Section 2.3.1 shall be provided for all new employees as part of an orientation program or as part of regularly scheduled training for existing employees.

2.2.3 The training described in Section 2.3.2 shall be provided for employees working in operational excellence, quality, supplier quality, global sourcing, purchasing/materials, warranty, and those leading 8D problem-solving or quality improvement teams. This scope is to be considered as a minimum requirement; teams may choose to expand to meet their needs.

2.2.4 Division- or group-level Operational Excellence/Quality shall be responsible for providing the training material; Human Resources shall ensure that the training is included as required for all employees.

## 2.3 Procedure

2.3.1 Each employee shall receive training on the topics listed below (Sections 2.3.1.1 through 2.3.1.7). A question may arise about the resources. To avoid resource constraints, it is recommended that these topics be covered during routinely scheduled events, such as all-employee meetings, staff meetings, production kick-off meetings, continuous improvement meetings, etc. These topics should be reviewed in a manner established by the local site but in such a way that all topics are covered at least every 2 years. Topics to be covered are as follows:

2.3.1.1 Vision/mission/quality policy

2.3.1.2 Plant quality policy

2.3.1.3 Business system (BS) overview

2.3.1.4 Quality concepts

- What are an audit/assessment? Quality? Why is quality important to me?
- What are the consequences of poor quality? For me? For the customer?
- Basic corrective/preventive actions concepts
- Basic continuous improvements concepts

2.3.1.5 Quality system (QS) overview:

- History
- Reason for
- Relation to the quality management system that is used at the site
- A summary of the QS tools

2.3.1.6 8D problem solving overview including the following (at a minimum):

- Problem-solving approach
- Brainstorming
- Pareto diagrams
- 5-Whys
- Plan–do–check–act

2.3.1.7 Equipment calibration (for plants and design centers, as appropriate otherwise)

2.3.2 Employees, described in Section 2.2.2, must demonstrate competency on the following topics. Where appropriate, competency may be demonstrated by the function, team, or department as a whole (i.e., not required for each individual). Competency may be demonstrated via industry certifications, training tests or similar records, effective utilization of the tools, etc. Topics to be covered are as follows:

2.3.2.1 Advanced continuous improvements concepts
- Corporate business system
- ISO/TS requirements
- Quality system tools (process failure mode and effects analysis [PFMEA], control plans, etc.)

2.3.2.2 Concepts of auditing/assessments
- What is an audit/assessment?
- Why do we do audits/assessments?
- How do you conduct yourself if you are being audited?
- How does one become an internal auditor?

2.3.2.3 Data collection tools
- Sampling principles
- Check/inspection sheets

2.3.2.4 Analytical quality tools
- Histograms
- Scatter diagrams
- Pareto diagrams
- Affinity diagrams
- Matrix diagrams

2.3.2.5 Statistical Quality Tools
- Probabilities
- Distributions
- Process capability
- SPC/control charts

2.3.2.6 Advanced problem-solving training
- Cause and effect diagram
- Process mapping
- 8D problem solving

2.3.2.7 Advanced statistical tools (optional)
- Hypothesis testing

- DOE
- Analysis of variance (ANOVA)
- Regression analysis

## 3. CHANGE CONTROL PROCESS

### 3.1 Purpose

The purpose of this procedure is to provide guidelines and support the deployment of a systematic process for the control and reaction to changes that impact product realization. A key consideration is to have any changes assessed, verified, validated, and approved before implementation to ensure compliance with customer requirements.

### 3.2 Scope

This procedure describes the requirements for assessing, verifying, validating, and implementing any product and/or process changes that impact product realization—including changes caused by any supplier—to ensure compliance with customer requirements, prevention of defects and improvement of productivity. Changes refer to product and/or process modifications that can affect form, fit, or function of the product to customer requirements.

### 3.3 Procedure

The activities outlined next should be considered during the development of these procedures.

3.3.1 Define criteria for a formal change request to cover the following circumstances:

- Change to the manufacturing or assembly process of the product.
- Change to the qualification of the product. This includes characteristics, tolerances, frequencies, methods of recording, qualification-test techniques, or visual standards.
- Change to the fit, form, function, durability, or performance requirements of a product.

- Internal request to change a supplier's manufacturing or assembly process of a component or raw material.
- Revisions to internal/customer specifications and/or drawings.

3.3.2 Document the change request

Collect and mark up all necessary documentation to support the proposed change. The documentation can include the following, as appropriate:

- Drawings
- Specifications
- Bill of materials (consider disposition of possible obsolete inventory)
- Any customer-specific authorization forms or e-mails when required
- Any other internal/external documents

3.3.3 Assess the change

- Review the documentation submitted with the change request following the corresponding local procedures and/or instructions.
- The assessment of the change has to be completed by the appropriate functions and/or multifunctional teams.
- The assessment of the change should include a review of the need to follow the product design/development process. This would include the risk assessment to determine the corresponding risk classification associated with the change.
- Define the stakeholders that will be affected by the change to appropriately communicate the change prior to its implementation.
- Complete the corresponding documentation to include the results of the assessment of the change in the appropriate forms. This should include any interim status of approval/rejection of the change.

3.3.4 Validate and verify the change by planning the necessary validation and verification tests to ensure compliance to customer requirements. These tests can include the following, as appropriate:

- Prototype tests
- Life cycle tests
- Manufacturing and assembly feasibility tests
- Functional tests

- Laboratory tests
- Customer application tests
- Measurement system validation tests

3.3.5 Record the results from the validation and verification tests in the appropriate documents and/or forms, ensuring traceability and statistical significance of results.

3.3.6 Obtain the necessary internal and external approvals for the change. Include the approval status for the change in the corresponding form as appropriate.

3.3.7 Implement the change by updating the appropriate documents to reflect the change and ensure that cross references and linkages are accurate. The review of these documents should follow the appropriate local document control procedure or similar procedures. These documents could include the following:

- Specifications
- Drawings
- Control plans
- Design FMEA and process FMEA
- Process flow or routing
- Procedures and work instructions
- Gauge and measurement system plan or similar plans
- Training materials and plans

3.3.8 Periodically review the change control process to identify lessons learned and potential improvements. This activity may include the identification of "things gone right" and "things gone wrong" as a method of gathering facts for improvement.

## 4. PROCESSES TO IDENTIFY SPECIAL CHARACTERISTICS

### 4.1 Purpose

All products and the processes that create products have characteristics or features that are important and need to be controlled. Some characteristics or features may require additional controls because excessive variation might affect product safety, compliance to governmental regulations, fit, function, or the quality of subsequent manufacturing operations.

This procedure provides guidelines to be used by product development teams (new-product development and Six Sigma for design and development) for the identification of those characteristics that require additional controls.

## 4.2 Scope

Classification of characteristics must be implemented for all products designed and manufactured by the organization. These characteristics may include:

- Safety-related product characteristics
- Compliance-related product characteristics
- Fit- and function-related product characteristics
- Characteristics that may not be identified or verified by the direct customer but ultimately affect a subsequent operation or customer (i.e., pass-through characteristics).
- Process characteristics that assure variation of a product characteristic is minimized.

## 4.3 Procedure

Each operating group will define, document, and implement procedures to systematically accomplish the following activities:

- Definition of symbols used for classification of characteristics that require additional care or control. These should include product characteristics that potentially impact safety, compliance, fit, or function.
- Definition of the method used to classify and document these characteristics as defined by the operating group. This should include involvement from personnel with experience in the product application and manufacturing processes. Additionally, input from the potential design FMEA and potential process FMEA should be utilized as applicable.
- Definition of a method to communicate characteristics requiring additional control or care to personnel at the point of manufacture or assembly. This should include designation of appropriate symbols on prints, control plans, process sheets, product, etc. as appropriate.
- In general, defined classifications typically include:

- Product characteristics that require compliance to government or safety regulations
- Characteristics in which reasonably anticipated variation within specification could significantly affect customer satisfaction
- Characteristics in which the customer is equally satisfied across the entire specification, but customer satisfaction is impacted by product manufactured just outside specification limits

The potential design failure modes and effects analysis (DFMEA) should be used as one of the tools to facilitate the identification of special characteristics. These special characteristics should then be documented on the potential DFMEA form. Upon completion of the initial potential DFMEA, characteristics affecting failure modes with a severity rating of 9 or 10 are candidates for the safety/compliance classification. Characteristics with a severity rating range of 5–8 and an occurrence rating range of 4–10 are candidates for the customer satisfaction classification.

In all cases, customer-specific requirements will take precedence over any of the guidelines defined internally.

## 5. SUPPLIER PPAP/FAI

### 5.1 Purpose

The purpose of this procedure is to provide detail on the process of initiating and deploying Internal PPAP/FAI for a manufacturing plant or between internal manufacturing plant sites. The purpose of the Production Part Approval Process (PPAP)/First Article Inspection (FAI) is to determine if all customer/receiving site engineering design records and specification requirements are properly understood and that the process has the potential to produce product consistently meeting these requirements during an actual production run at the required and quoted production rate. It is not anticipated that requalification of products to this policy will apply retroactively.

### 5.2 Scope

This procedure provides the process of initiating the production part approval process (PPAP)/first article inspection (FAI). The purpose of is

to determine if all suppliers understand customer engineering design and specification requirements properly and that the process has the potential to produce product consistently meeting these requirements during an actual production run at the required and quoted production rate.

This procedure will set the qualification of products and processes and the level of performance to be achieved for short-term (pilot/sample) products and for the long-term (full production) products. Standard catalogue production items or service parts shall comply with PPAP/FAI unless formally waived by the receiving site (waivers for applicable items must be documented by the receiving plant site). In situations where product similarities exist, the use of a family of parts approach is appropriate at the discretion and approval of the receiving plant site and when not in conflict with final customer requirements.

## 5.3 Procedure

The initiation of production processes within the corporation boundaries will include written qualification requirements for samples and pilot material, expectations for performance metrics and levels, and ongoing requirements for periodic maintenance of the qualification system.

5.3.1 PPAP will be invoked in cases of the following scenarios:

- A new part or product not previously supplied (family of parts approach as applicable)
- Correction of a discrepancy on a previously submitted part
- Product modified by an engineering change to design records, specifications, or materials
- Product manufactured by a different process (equipment, technology, sequence, etc.)

5.3.2 The supplier must notify the customer whenever the following design and process changes are made:

- Use of other construction or material than was used in the previously approved part or product
- Production from new or modified tools (except perishable tools), dies, molds, patterns, etc., including additional or replacement tooling
- Production following refurbishment or equipment (as applicable)
- Production from tooling and equipment transferred to or from a different plant site

- Change of subcontractor for parts, nonequivalent materials, or services that affect customer fit, form, function, durability, or performance requirements
- Product produced after the tooling has been inactive for volume production for 12 months or more
- Product and process changes related to components of the production product manufactured internally or manufactured by subcontractors that impact fit, form, function, performance, and/or durability of the saleable product. Additionally, concurrence of any requests by a subcontractor must be done before submission to the customer
- Change in test/inspection method—new technique (no effect on acceptance criteria)

5.3.3 PPAP requirements are as follows:

- For production parts, product must be taken from a significant production run (i.e., 1 hour of production and with a minimum quantity of XX consecutive parts; quantity is dependent on volumes and concurrence must be obtained from the receiving site and should be specified on the purchase order).
- This run must be manufactured under production conditions and environment (tooling, gauging, process, materials, and operators).
- Parts from each unique production process (e.g., duplicate assembly line and/or work cell, each position of a multiple cavity die, mold, tool or pattern) must be measured and representative parts included in PPAP.

5.3.4 PPAP is not invoked under the following circumstances:

- Changes to component level drawings that do not impact the design record for the product supplied to the customer
- Tool or equipment movement within the same plant (no change in process flow)
- Changes in equipment with same basic technology or methodology and same process flow
- Identical gauge replacement
- Rebalance of operator job content with no change in process flow

5.3.5 Performance metrics and levels expected are as follows:

- For those characteristics deemed as key/significant/critical, statistical indices shall require a process capability index

(Cpk) or process performance index (Ppk) > 1.67 (see "Process Capability Methods and Requirements" for guidance).
- Calculation of production capacity and quality at full production rate should yield the ability to deliver product on time to the receiving site's stated needs. A documented receiving site waiver can be used in lieu of this requirement.
- Any issues related to document revisions must be resolved and the appropriate engineering change level reflected on the purchase order must be used. In the absence of documented revision levels, the issue must be raised prior to production/delivery of any product.

5.3.6 Documentation records shall reflect all appropriate and relevant information related to the qualification of the production process/product. Recommended document records/templates are noted in the Automotive Industry Action Group (AIAG) PPAP manual or the SAE AS9102 aerospace standard.

5.3.7 PPAP submittal status shall reflect one of the following:
- Full approval indicates that the part or material meets all customer specifications and requirements. The receiving site authorizes production quantities of the product upon release.
- Interim approval permits shipment of material for production requirements on a limited basis or piece quantity basis. No additional shipment of production parts is permitted unless an extension of the interim approval is granted by the customer.
- "Rejected" indicates that the submission, the production lot from which it was taken, and accompanying documentation do not meet customer requirements. Corrected product and documentation shall be submitted and approved prior to production quantity shipments.

5.3.8 It is highly recommended that a customer internal PPAP review be performed at appropriate intervals (annually) in order to ensure that all relevant performance, specification, and "run at rate" issues (if any) are documented and investigated. The intent of this recommendation is to have assurance that product and process capabilities issues are resolved prior to an actual nonconformance with the receiving site products.

5.3.9 Document requirements shall be established with consensus from the receiving plant. Here is the list of records required for PPAP submission:

1. Design records
2. Authorized engineering change documents
3. Customer engineering approval, if required
4. Design failure modes and effects analysis *applied in special situations*
5. Process flow diagram
6. Process failure modes and effects analysis
7. Control plan
8. Measurement systems analysis (MSA)
9. Dimensional results
10. Records of material/performance test results
11. Initial process studies
12. Qualified laboratory documentation
13. Appearance approval report (AAR)
14. Sample production parts
15. Master sample
16. Checking aids
17. Customer-specific requirements
18. Part submission warrant (PSW)

## 6. SUPPLIER QUALITY MANAGEMENT PROCESS

### 6.1 Purpose

The purpose of this procedure is to summarize the supplier quality processes and systems.

### 6.2 Scope

This procedure lays down requirements of the quality system and applies to group, division, or plant operation-level supplier quality activity. This includes intercompany transactions as appropriate.

## 6.3 Procedure

6.3.1 Supplier surveys/assessments

There are four supplier surveys or assessments that are considered standards as part of the quality system:

- Initial supplier profile survey (prequalification survey for potential suppliers)
- Quality system assessment (on-site assessment of potential suppliers)
- Process audit (on-site line review of current suppliers utilized for pre-PPAP/FAI, problem resolution, and development, or an on-site line review of potential suppliers)
- Continuous improvement survey (on-site Lean and/or Six Sigma projects' assessment of current suppliers)

6.3.2 Approved supplier list (ASL)

6.3.2.1 All organization divisions or sites shall maintain a list of all approved direct material and support process (e.g., heat treating, plating, etc.) suppliers and their current status, documented within the QMS document system.

6.3.2.2 The ASL shall include the supplier strategic classification code as defined and maintained within the QMS document systems.

6.3.3 Production part approval process and first article inspection

Submission of following information shall be maintained and communicated:

- PPAP submission level or FAI documentation requirements
- Reason for submission (initial submission, engineering change, change in part processing, etc.)
- Submission timing
- List of persons who will review the PPAP/FAI
- Approval status (accepted, rejected, pending approval, etc.)
- Customer- and/or industry-specified requirements must be followed, as appropriate (e.g., ISO/TS 16949, AS9102, AIAG, etc.)
- Revalidation requirements

6.3.4 Advanced product quality planning (APQP)

6.3.4.1 APQP shall be performed in conjunction with a supplier that is supplying critical components, assemblies, or outside processes, as determined by the new-product-development

launch team (or equivalent), and as mandated by the customer.

6.3.4.2 The APQP process will be managed and maintained within the QMS in conjunction with the supplier, as appropriate.

6.3.5 Corrective action request (CAR) and discrepancy material report (DMR)

6.3.5.1 When supplier nonconformances are identified within an organization's facility and are determined to be significant in nature, a CAR shall be initiated and sent to the supplier as a DMR via the system.

6.3.5.2 Each organization location will determine when a CAR will be generated and will provide an appropriate feedback format that may include a customer-specified format. If a format is not specified, the supplier will default to the standard CAR format of the organization.

6.3.6 Receiving-inspection plans

6.3.6.1 When receiving inspection is necessary for critical parts, outside processes, or assemblies, receiving-inspection plans shall be documented and controlled as receiving characteristics.

6.3.6.2 Both variable and attribute inspection data will be included, as appropriate.

6.3.7 Skip lot/ship to stock

6.3.7.1 A supplier may have its product/parts placed on a skip-lot program. The skip-lot inspection programs will be managed by each organization facility.

6.3.7.2 The ship-to-stock program exempts a supplier's product/parts from the receiving-inspection process; however, the supplier's product/part will be subject to inspections based on a random order or frequency determined by the organization's facility.

In order to qualify for a ship-to-stock status for a facility, a supplier must have completed or be involved in the following:

- Successful skip-lot program
- Passed process audit
- Acceptable quality certification
- Acceptable quality contract

6.3.7.3 A supplier's ship-to-stock or skip-lot status will change when a DMR is issued for a part or product. A new inspection frequency may be established by the facility.

6.3.7.4 The ship-to-stock program shall be managed and maintained within QMS.

6.3.8 On-going performance monitoring

6.3.8.1 Supplier quality performance

Supplier performance methodology will be conveyed via the supplier excellence manual.

The details and appropriate points for each element are available and will be maintained in the QMS system.

6.3.8.2 Each facility shall review key suppliers' quality and delivery performance at a minimum of once per month and shall develop action plans to address the worst performing suppliers.

## 7. FAILURE MODE AND EFFECTS ANALYSIS FOR PRODUCT DESIGN AND PRODUCTION PROCESSES

### 7.1 Purpose

The purpose of this document is to provide guidelines and support a systematic process to ensure that potential failure modes and their associated causes have been considered and addressed. An FMEA (used interchangeably with PFMEA) can be described as a systematic group of activities intended to

- Recognize and evaluate the potential failure of a product/process and the effects of that failure.
- Identify actions that could eliminate or reduce the chance of the potential failure occurring.
- Document the process.
- Be complementary to the process of defining what a design or process must do to satisfy the customer.
- Be timely—one of the most important factors for the successful implementation of an FMEA program. It is meant to be a "before-the-event" action, not an "after-the-fact" exercise. To achieve the greatest value, the FMEA must be done before a product or process failure mode has been incorporated into a product or process.

Up-front time spent in properly completing an FMEA will minimize late-change crises, and product/process changes can be most easily and inexpensively implemented. An FMEA can reduce or eliminate the chance of implementing a preventive/corrective change that would create an even larger concern.

## 7.2 Scope

The FMEA must be implemented for processes determined to be "key" to the operation, as shown in Figure 3.2 earlier in Chapter 3 or, when required by the customer, local management, new-product development (NPD), or Lean system as an error-proofing tool. There are three basic cases for which FMEAs may be generated, each with a different scope or focus:

- Case 1: New designs, new technology, or new process. The scope of the FMEA is the complete design, technology, or process.
- Case 2: Modifications to existing design or process (assumes there is an FMEA for the existing design or process). The scope of the FMEA should focus on the modification to design or process, possible interactions due to the modification, and field history.
- Case 3: Use of existing design or process in a new environment, location, or application (assumes there is an FMEA for the existing design or process). The scope of the FMEA is the impact of the new environment or location on the existing design or process.

The need for taking effective preventive/corrective actions, with appropriate follow-up on those actions cannot be overemphasized. A thoroughly thought out and well-developed FMEA will be of limited value without positive and effective preventive/corrective actions.

The responsible engineer is in charge of assuring that all recommended actions have been implemented or adequately addressed. The FMEA is a living document and should always reflect the latest level, as well as the latest relevant actions, including those occurring after the start of production.

7.2.1 Potential FMEA in design (design FMEA): A design potential FMEA is an analytical technique utilized primarily by a design-responsible engineer/team as a means to ensure that, to the extent possible, potential failure modes and their associated causes/

mechanisms have been considered and addressed. Send items, along with every related system, subassembly, and component, should be evaluated. In its most rigorous form, an FMEA is a summary of the team's thoughts (including an analysis of items that could go wrong based on experience) as a component, subsystem, or system is designed. This systematic approach parallels, formalizes, and documents the mental disciplines that an engineer normally goes through in any design process.

The design potential FMEA supports the design process in reducing the risk of failures (including unintended outcomes) by

- Aiding in the objective evaluation of the design, including functional requirements and design alternatives
- Evaluating the initial design for manufacturing, assembly, service, and recycling requirements
- Increasing the probability that those potential failure modes and their effects on system and vehicle operation have been considered in the design/development process
- Providing additional information to aid in the planning of thorough and efficient design, development, and validation programs
- Developing a ranked list of potential failure modes according to their effect on the "customer," thus establishing a priority system for design improvements, development, and validation testing/analysis
- Providing an open issue format for recommending and tracking risk-reducing actions
- Providing future reference (e.g., lessons learned) to aid in analyzing field concerns, evaluating design changes, and developing advanced designs

7.2.2 The design FMEA is a living document and should

- Be initiated before or at design concept finalization.
- Be continually updated as changes occur or additional information is obtained throughout the phases of product development.
- Be fundamentally completed before the production drawings are released for tooling.

Considering that manufacturing/assembly needs have been incorporated, the design FMEA addresses the design intent and assumes the design will be manufactured/assembled to this intent.

Potential failure modes and/or causes and mechanisms that can occur during the manufacturing or assembly process need not but may be included in a design FMEA. When not included, their identification, effect, and control are covered by the process FMEA.

A design FMEA should begin with a block diagram, for the system, subsystem, and/or component being analyzed. The block diagram can also indicate the flow of information, energy, force, fluid, etc. The objective is to understand the deliverables (input) to the block, the process (function) performed in the block, and the deliverables (output) from the block.

The diagram illustrates the primary relationship between the items covered in the analysis and establishes a logical order to the analysis. Copies of the diagrams used in FMEA preparation should accompany the FMEA.

7.2.3 Potential failure mode and effects analysis in manufacturing and assembly (process FMEA)

A process potential FMEA is an analytical technique utilized by a manufacturing/assembly responsible engineer/team as a means to assure that, to the extent possible, potential failure modes and their associated causes/mechanisms have been considered and addressed. In its most rigorous form, an FMEA is a summary of the engineer's/team's thoughts (including an analysis of items that could go wrong based on experience) as a process is developed. This systematic approach parallels and formalizes the mental discipline that an engineer normally goes through in any manufacturing planning process. The process potential FMEA does the following:

- Identifies the process functions and requirements
- Identifies potential product- and process-related failure modes
- Assesses the effects of the potential failures on the customer
- Identifies the potential manufacturing or assembly process causes and identifies process variables on which to focus controls for occurrence reduction or detection of the failure conditions:
  - Identifies process variables on which to focus process controls
  - Develops a ranked list of potential failure modes, thus establishing a priority system for preventive/corrective action considerations

- Documents the results of the manufacturing or assembly process
- During the initial process potential FMEA development, the responsible engineer is expected to directly and actively involve representatives from all affected areas. These areas should include, but are not limited to design, assembly, manufacturing, materials, quality, service, and suppliers, as well as the area responsible for the next assembly. The FMEA should be a catalyst to stimulate the interchange of ideas between the areas affected and thus promote a team approach.

The process FMEA is a living document and should

- Be initiated before or at the feasibility stage
- Be initiated prior to tooling for production
- Take into account all manufacturing operations, from individual components to assemblies

The process FMEA assumes the product, as designed, will meet the design intent. Potential failure modes which can occur because of a design weakness may be included in a process FMEA. Their effect and avoidance is covered by the design FMEA.

## 7.3 Procedure

The FMEA is to be completed at appropriate steps as determined by the operation or based on customer-specific requirements utilizing the format identified by the AIAG or Society of Automotive Engineers (SAE) standards identified in the reference section of this policy.

The PFMEA should serve as an input to the development of control methodologies and control plans.

Unless otherwise identified by the customer or group/division/local management the FMEA is to be reviewed and updated at a minimum of annually. In the event that an FMEA is updated as a result of a nonconformity, the appropriate corrective action tracking number should be referenced in the FMEA.

Unless otherwise identified by the customer or the operation, risk priority number (RPN) reduction plans shall be identified for severity rankings of 9 or 10 and for RPNs greater than 100. Additionally, in the event that no RPNs are greater than 100, the operation should identify RPN reduction plans for the top five RPNs.

## 8. PROCESS CONTROL PLANS

### 8.1 Purpose

The purpose of this procedure is to outline the minimum tools/methods that must be implemented to ensure that the processes of a manufacturing operation are carried out under defined controlled conditions.

### 8.2 Scope

This policy describes the minimum requirements for establishing controlled conditions in a manufacturing process and should be complemented with local and/or customer-specific requirements. These requirements include but are not limited to a control plan and work instructions.

The policy described in this document shall be applied from material acquisition (raw materials) through shipping.

### 8.3 Procedure

The control plan provides a written summary description of the system used to minimize process and product variation. It also describes the actions that are required at each phase of the manufacturing process to assure that it is in a state of control. Control plans do not replace the information contained in detailed operator instructions. The control plan is an integral part of the quality process and it is to be utilized as a living document.

Control plans or alternate control methods must be implemented for all of the organization's manufacturing processes. Control plans that meet the requirements specified under item 8.3.1 of this section must be implemented for manufacturing processes determined to be "key" to the operation or, when required by the customer, local management, NPD, or Lean. For all other manufacturing processes, alternate control methods, described in item 8.3.2 of this section, are acceptable unless otherwise specified by the customer or local management.

8.3.1 Control plans

Control plans must comply with the requirements/guidelines and content of the control plan methodology described in the AIAG "APQP and Control Plan" reference manual.

During the development of the control plan, the multidisciplinary team must address (as a minimum) the following items:

Review the process flow diagram.

Review the potential process failure mode and effects analysis (PFMEA) and incorporate the identified control methods as part of the control plan as appropriate. If one does not exist, it must be developed per the FMEA procedure.

Review existing system and design FMEAs.

Review all known related customer and internal quality concerns and incorporate all appropriate control methods that resulted from a corrective/preventive action process. If corrective actions are still pending, address them per the corrective/preventive action procedure.

Review lessons learned from similar processes/products and incorporate any relevant control methods.

Identify all customer and internal special/critical characteristics and ensure that appropriate control methods are incorporated as part of the control plan.

Perform appropriate measurement system analysis (MSA) for all key gauges and testing equipment identified in the control plan per the MSA procedure.

Implement the appropriate controls to ensure that all special/critical characteristics meet the process capability requirements outlined in the process capability procedure.

The control plan must be approved by the quality manager or designee.

Appropriate work instructions that specify which characteristics need to be inspected and controlled, and how, by the operator when doing a job or verifying quality requirements must be developed and implemented. These instructions shall be derived from the control plan and other relevant sources and must be accessible for use at the workstation.

8.3.2 Alternate control methods

This type of control approach must include as a minimum:

Work instructions that specify which characteristics need to be inspected and controlled by the operator when doing a job, or verifying quality requirements. (These instructions shall be derived from relevant sources and must be accessible for use at the workstation.)

Appropriate MSA for all key gauges and testing equipment used, per the MSA procedure

**Note:** Alternate control methods are acceptable for non-key-manufacturing processes.

8.3.3 Review and audit

The control plan and relevant work instructions shall be reviewed/audited and updated as appropriate at a frequency determined by the local facility. At a minimum this must occur

- As part of the local Internal Audit Process
- As a result of customer feedback/warranty issues and/or corrective actions
- Whenever the process or product is changed (refer to the change control procedure)
- When any PFMEA revision occurs (refer to the FMEA procedure)

### Reference

Automotive Industry Action Group (AIAG), "Advanced Product Quality Planning and Control Plan" reference manual.

## 9. MEASUREMENT SYSTEM ANALYSIS

### 9.1 Purpose

The purpose of this procedure is to provide policy guidelines and support for a uniform methodology (driven by the site specific most stringent customer requirement), to be utilized to assess MSAs and provide appropriate corrective actions to meet corporate or industry performance goals.

The long-standing tradition of reporting measurement error only as a percent of specification tolerance is inadequate for current marketplace challenges, which emphasize strategic and continuous process improvement. The measurement system used to measure current status and improvement opportunities is critical to an organization's success.

## 9.2 Scope

This policy describes the minimum requirements and controls for assuring that organizations systematically assess, analyze, and provide corrective actions as needed to measurement systems. Operations processes are intended to include production activities and quality system (ISO, QS, TS, AS, etc.) activities where measurement systems can have direct impact on product or quality performance, detection of variation, or customer satisfaction.

Calibration activities are not considered part of the scope of this document and are determined by the user based on usage and criticality of measurement accuracy.

This procedure is not intended to limit evolution of analysis methods suited to particular processes or commodities.

## 9.3 Procedure

9.3.1 An MSA needs to be performed in all cases related to control systems, as indicated in the control plan, for key characteristics, pass-through characteristics, etc. Frequencies related to redundant studies of the systems are to be set by the site, with concurrence as needed by the customer.

9.3.2 The measurement systems analysis needs to be reviewed in cases when the specifications change, when process improvements occur, or at intervals documented in site-specific instructions and aligned with site customer requirements.

9.3.3 The methods and procedures used to conduct an MSA must follow the requirements specified under AIAG-MSA unless an alternative method is specified by the customer.

9.3.4 It should be noted on % RandR requirements (9.3.5.2 in this section) that, when the process variation is small, on occasion the % RandR will be above the 30% target. In these cases the current process capability (CPK) must be high and the improvement opportunity balanced with knowledge of the risks incurred by taking no action.

Customer concurrence must be obtained, as applicable, if this logic is used.

9.3.5 Measurement system properties include the following:

9.3.5.1 The system must be in control. This means that the variation in the measurement system is due to common causes only and not due to special causes (statistical stability).

9.3.5.2 The variability of the measurement system must be small compared with the manufacturing process variability (% RandR). The requirement is that % RandR < 30% (10% is acceptable; 10%–30% depends on application, >30% unacceptable). These are minimum requirements and must be driven by the site-specific most stringent customer requirement.

9.3.5.3 The variability of the measurement system must be small compared with specification limits (% of tolerance = % P/T). The requirement is that % P/T < 30% (10% is acceptable, 10%–30% depends on application, >30% is unacceptable). These are minimum requirements and must be driven by the site-specific most stringent customer requirement.

9.3.5.4 The increments of measure must be small relative to the smaller of either the process variability or the specification limits (discrimination). A common rule of thumb is for the increments to be no greater than one-tenth of the smaller of either the process variability or the specification limits. Several formal methods exist to assess discrimination. (See Reference in this section for related reference material.)

9.3.5.5 Three fundamental issues need to be addressed in evaluating a measurement system:

1. Does the system have adequate discrimination?
2. Is the measurement system statistically stable over time?
3. Are the referenced statistical properties consistent over the expected range and acceptable for process analysis or control (% RandR, % P/T)?

9.3.6 The following items (9.3.6.1 through 9.3.6.6) are meant to standardize local terminology and methods in order to offer an MSA policy that is central to the theme of consistent approaches and methods. The items are offered in anticipation that the information contained is relevant to identifying measurement systems that are

- Appropriate for decision making for acceptance against customer standards
- Proper for assessing the magnitude and source(s) of variation content within a process
- Assessing improvement in variation reduction (either in the measurement system itself or in the actual process under investigation)

9.3.6.1 The following table indicates preferred methods in measurement systems:

| Type of Measurement System | MSA Method |
|---|---|
| Basic variable | Range, average and range, ANOVA, bias, linearity, control charts |
| Basic attribute | Signal detection, hypothesis test analysis |
| Destructive test | Control charts, nested gauge studies |

9.3.6.2 Measurement system data are assessed as to the quality of the data gained most commonly by the terms bias and variance. Much of the variation in a set of measurements is due to the interaction between the measurement system and its environment.

9.3.6.3 The measurement process should be viewed as a manufacturing process that produces numbers (data) for its output. The process of assigning the numbers is defined as the measurement process and the value assigned is defined as the measurement value.

9.3.6.4 An ideal measurement system would produce only "correct" measurements each time it was used and would be said to have the statistical properties of zero variance, zero bias, and zero probability of misclassifying any product measured.

9.3.6.5 The purpose of any analysis of a measurement system should be to better understand the sources of variation that can influence the results (data) produced by the system. Classification of procedures for assessing measurement systems should include (at a minimum) the following statistical properties (measurement system error categories): (a) location–bias–linearity, and (b) width or spread–repeatability–reproducibility.

9.3.6.6 One of the objectives of a measurement system study is to obtain information relative to the amount and types of measurement variation associated with a measurement system when it interacts with its environment. Applications of such a study provide the following:

- A criterion to accept new measuring equipment
- A comparison of one measuring device against another
- A basis for evaluating a gauge suspected of being deficient
- A comparison for measuring equipment before and after repair
- A required component for calculating process variation and the acceptability level for a production process capability

### Reference

AIAG, "Measurement Systems Analysis" reference manual.

## 10. FRESH EYES AUDIT

### 10.1 Purpose

In order to improve the effectiveness of the quality management system at each unit location a fresh eyes audit will be conducted at a prescribed frequency by auditors from locations other than the site being audited. This will allow unbiased feedback on a site's quality management system and also allow visiting auditors the opportunity to benchmark the processes and procedures of other locations.

### 10.2 Scope

Fresh eyes audits will be conducted at all company locations. The duration of the audit will vary depending on whether the site is a manufacturing facility or a support facility. All sites will undergo an audit of various aspects of their quality management system (ISO 9001:2008, ISO/TS 16949:2002, etc.). If desired, the fresh eyes audit can be utilized as the site's formal internal audit process as long as all the requirements of the quality management system internal audit are satisfied. If not, the fresh eyes audit can be a stand-alone additional audit.

## 10.3 Procedure

10.3.1 Typically, a team of four auditors (one lead auditor and three supporting auditors) will be utilized. The number of auditors on the team may be adjusted to meet the needs of the location, the number of auditors available, and/or the available time to conduct the audit. A suggested agenda for the audit is as follows:

- Day 1—Team travels to site in the morning. Have opening meeting in the late morning or in the early afternoon. Spend afternoon reviewing all processes, procedures, and work instructions for which each person is responsible.
- Day 2—Conduct the audit. Check implementation on all shifts.
- Day 3—Finish off-shift implementation checks. Complete audit, prepare comments, conduct closing meeting in early afternoon. Travel home mid-afternoon.

10.3.2 The team size and number of audits per year can be adjusted depending on the scope of the audit. The scope for fresh eyes audits is determined between the site and the division and may take into consideration the following factors:

- Quality management system processes
- Value creation processes
- Customer-oriented processes
- Support processes
- Customer defect levels (defect parts per million [DPPM])
- Third-party audit results
- Internal audit results
- Special audit requests made by the site
- Customer-specific requirements
- Customer complaints
- Scrap levels

10.3.3 Fresh eyes audits are to be conducted at a minimum of once per year. These guidelines will be utilized regardless of the plant/site size.

10.3.4 All auditors will be from facilities other than the host facility but preferably from within the same operation, division, or group.

10.3.5 Some sites may choose to utilize fresh eyes audits to satisfy their internal audit requirements. In this case the lead auditor may be from the host facility if so allowed by the division quality management. The lead auditor shall not audit any activity that he or she is responsible for.

10.3.6 All auditors shall be trained, qualified, and/or certified per auditor qualification requirements that exist for the site being audited as defined by division.

10.3.7 Nonconformances and observations will be documented and issued using the internal audit processes established by the site being audited.

10.3.8 All nonconformances shall be closed by the site within 90 days after completion of the audit and verified by a qualified auditor from the site being audited. The corrective actions identified in the nonconformances must address the root cause or systemic issue and may not address only the symptomatic issue.

10.3.9 The receiving site must evaluate all issued observations. Action plans must be developed and executed as appropriate.

10.3.10 The fresh eyes audit requirement may be waived or modified if corporate travel restrictions or other factors affect the availability of auditors. A written waiver must be received from the divisional quality manager.

## 11. COMMON MANUFACTURING AND SPECIAL PROCESS AUDIT

### 11.1 Purpose

The objective of this procedure is to define common manufacturing and special process audit approaches and methodologies.

The goal of the process audit is to assure that the customer's product requirements are met through an efficient, effective, and reliable manufacturing process.

### 11.2 Scope

The processes and systems referenced in this document are considered to be minimum requirements of the quality system and may apply to group-, division-, or plant-level manufacturing and special process audit activity. Consideration should be given to include processes associated with test and research and development laboratories.

## 11.3 Procedure

11.3.1 Manufacturing and special process audits

Manufacturing and special process audits must be conducted as part of each plant's internal audit activities.

Each facility will determine the manufacturing and special processes to be audited.

Special processes will be defined throughout all manufacturing systems.

This should include processes that require special controls, special knowledge expertise, or process complexity. Examples include heat treating, plating, painting, welding, and others.

**Note:** Assembly lines that produce a single family of products with many variations in part configurations and part numbers need only be audited once for the entire family. A separate audit of each unique part number is not required.

It is suggested that each facility compile a list of both manufacturing and special processes to be audited and track those completed such that the same processes are not audited consecutively.

The manufacturing process audit can proceed from any point of convenience (e.g., start of the process, end of the process, preventive maintenance, etc.).

Key factors that lead the audit are the performance specification(s) required by the customer, the component or final assembly drawing specifications, and the design of the process.

11.3.2 Frequency of audits

Manufacturing and special process audits will occur on an established frequency, taking into consideration the criticality of the process and other relevant factors (e.g., inherent variability, risk of failure, relation to product characteristics, probability of pass-through defects, product specifications, customer/industry expectations, etc.).

11.3.3 Auditors

Qualified auditors must perform the manufacturing and special process audits. Qualifications will be defined at the organization's head office (HO), division, operation, or group level.

The process auditor(s) will be provided a personal guide (preferably someone very familiar with the process to be audited) to aid in gathering necessary documentation, to help answer questions, etc.

11.3.4 Process audit checklist

The process audit checklist will be used to perform and document the audit, unless there is a special requirement that is driven by industry, customer, or special process requirements.

"P" (pass) or "F" (fail) will be recorded for both documentation and process, depending on the level of compliance.

If the item is not applicable for the operation or process being audited, "NA" will be designated.

Observations, nonconformities, and corrective action responses will be clearly stated and documented on the process audit checklist in order to properly communicate the audit activity and findings.

The heat treat audit will be utilized to conduct a fully comprehensive heat treat audit, unless there is an industry- or customer-specified requirement.

Other special processes that are identified by the division or group quality activity are required to have a documented and controlled audit approach designed specifically for the special process.

### Reference

NADCAP (National Aerospace and Defense Contractors Accreditation Program).

## 12. PROCESS CAPABILITY METHODS AND REQUIREMENTS

### 12.1 Purpose

The purpose of this policy is to provide guidance in the approach, deployment, and expected results utilizing a standardized methodology to ensure that key manufacturing input process parameters and output product characteristics are assessed for variation monitored for special causes vs.

common causes and suitable action is taken in response to the variation created by special causes.

## 12.2 Scope

This policy describes the minimum process capability indices, process controls, and process audits expected for manufacturing operations with applicability to process parameters as well as product characteristics deemed as "special characteristics" specified either by the customer or the organization. In the absence of customer-specified special characteristics, plants are expected to identify special characteristics applicable to their product lines using a systemic approach.

To assure standardization of the statistical approach (i.e., terminology, calculations, applications to be used), this procedure will rely heavily on already established and recognized industrially quality reference manuals (i.e., the "statistical process control [SPC]" and the "production part approval process" from the AIAG.

This policy applies to all facilities and to all manufacturing processes:

## 12.3 Procedure

Manufacturing processes require a systematic approach and deployment for the identification of special characteristics (products or processes), the measurement of their inherent capabilities, and the implementation of ongoing controls and audits to assure the integrity and effectiveness of the process.

12.3.1 Special characteristics

- 12.3.1.1 Definition: key product or process characteristics that affect subsequent operations, product function, or customer satisfaction as specified by the customer and/or company divisional/operational procedures.
- 12.3.1.2 Application: the use of customer-specified and/or company-specified special characteristics such as critical, significant, major; CTQ is the initiation point for the evaluation of processes via the capability of product characteristics.
- 12.3.1.3 Identification: special characteristics are to be identified on drawings, FMEAs, and control plans as specified by customer requirements and/or company divisional/operational policies.

12.3.2 Quality indices

12.3.2.1 There are two key quality indices (capability and performance), which are to be determined as follows:

- The capability index, Cpk, is used for stable processes with the requirement of Cpk > 1.67. The estimate of sigma is based on within-subgroup variation.
- The performance index, Ppk, with the requirement of Ppk > 1.67, should be used when stability cannot be determined (due to sample size or other issues) or when the process is chronically unstable with output meeting specifications and a predictable pattern. The estimate of sigma is based on total variation.

12.3.2.2 Improvement actions must be taken for processes having quality indices (Ppk and Cpk), for special characteristics <1.67.

12.3.3 Process controls: The controls associated with product/process special characteristics are as follows:

12.3.3.1 FMEAs: The identification of special characteristics is to be listed in the design and process FMEAs stating those corrective actions taken as appropriate including the use of poka-yokes.

12.3.3.2 Control plans: The identification of special characteristics is to be listed in the control plans stating gauging method (variable gauging preferred), sample size based on process capability, poka-yokes, and appropriate reaction plans.

12.3.3.3 Machine run-off: This is to be performed at the time of initial acceptance by the company at the supplier and verified again upon arrival at company.

12.3.3.4 Unstable process: The process must undergo corrective actions for special cause variation. As the process reaches a stable condition of common cause variation, ongoing statistical process controls are applied as required by customers and/or company divisional/operational policies.

12.3.3.5 Statistical process control: The use of ongoing SPC (e.g., x-bar and range charts, up to and including 100% inspection and/or appropriate controls to meet capability requirements) should be implemented as appropriate.

12.3.4 Process audits, refer to procedure 11, "Common Manufacturing and Special Process Audit."

## 13. CONTROL OF NONCONFORMING MATERIAL

### 13.1 Purpose

The purpose of this document is to provide guidelines and support the deployment of a systematic process for the control of suspect as well as nonconforming material or product (NCMP) that may have been received and/or generated during the product realization process and/or otherwise damaged.

A key consideration is to prevent the inadvertent use of any suspect or NCMP and then to implement effective actions to prevent the recurrence of such events.

### 13.2 Scope

This procedure describes the requirements to ensure that product that is suspect and/or product that does not conform to specified requirements is prevented from unintended use or installation. This includes the identification of NCMP, documentation, evaluation, segregation, disposition, and notification to the functions concerned. A closed-loop system to prevent recurrence of the generation of NCMP will span across several procedures—namely, quality alert, corrective action, preventive action, FMEA, control plan, etc.

### 13.3 Procedure

The organization shall develop and deploy appropriate procedures to systematically assess, verify, validate, and implement a closed-loop system that will enable communication, containment, root cause analysis, and implementation of corrective action, preventive action, and error proofing as appropriate. The activities outlined next should be considered during the development of these procedures.

13.3.1 Establish criteria that define when material and/or product is considered suspect and/or nonconforming.

13.3.2 Define the methods used to effect containment/segregation of all suspect and/or NCMP. Scope of containment to include all potential areas of opportunity:

Supplier, in transit from supplier, within the facility (pre- and post-processing), in-transit to the customer, at the customer, etc.

Define checks/methodology to ensure that all product is contained.

Use color coding, labeling, and/or appropriate visual methods of identifying suspect and/or NCMP.

Use segregated (as feasible) areas to separate NCMP from conforming goods

13.3.3 Define methods of assessing NCMP disposition. The criteria shall include:

Some form of material review board (MRB). The assessment of the NCMP is to be reviewed in accordance with documented procedures upon defined timing.

Final disposition of the NCMP should include decisions that may include scrap, deviation, usage without deviation, etc.

Identify timing guidelines for how long NCMP products remain in the MRB.

13.3.4 Define methods of rework/NCMP recovery.

Identify who is responsible for review of NCMP and who has authority of disposition.

Demonstrate where and how rework instructions are accessible and utilized by the appropriate personnel in their work area.

If performed, describe how reworked NCMP meet specified requirements.

Describe how repaired/reworked products are reinspected and/or tested according to the control plan and/or documented procedures.

Describe how (if appropriate) NCMP can be regarded for alternative applications.

13.3.5 Describe how notification of all appropriate functions is performed via a quality alert (or other appropriate methodology). Include all stakeholders, as appropriate, in the process:

Quality alert (external customer, etc.)

Quality alert (internal production personnel, receiving, sales, marketing, engineering, etc.)

Quality alert (supplier, etc.)

13.3.6 Define how corrective/preventive actions are taken to prevent recurrence.

For identified NCMPs, identify how a prioritized reduction plan is used to reduce/eliminate recurrences and how it is tracked. Include process changes.

**Note:** Paynter chart methodology might be considered.

Review if the effectiveness of the corrective/preventive action is verified and documented?

For external supplier NCMP issues, define how corrective and preventive actions are verified as being effective.

Describe if heightened sampling methods and/or other forms of protective actions are taken with supplier NCMPs until actions are verified as complete.

Identify how NCMP events are updated in FMEA/control plans (CPs) to reflect exposure risks. Assess RPN changes (detection/occurrence). Include experienced supplier and consider handling of risks.

Identify how process changes as a result of NCMP findings follow PPAP criteria.

Identify the timing guidelines for the corrective and preventive action (CAPA) process.

13.3.7 Describe how the change control process is deployed.

Define how customer authorization is obtained prior to shipment whenever the product is different from the current PPAP and/or product specifications.

Define how records of expiration dates for deviations and/or customer approvals with approved quantities are maintained.

Describe how the nonconformity that has been accepted and/or the types of repairs that have been made are recorded to denote actual condition.

As feasible, define how service application products with visible exterior rework are approved by the customer service parts organization prior to release.

Define how the material is shipped on an authorization properly identifying the product as NCMP.

Define how, as appropriate, inventories are validated as being purged.

13.3.8 Describe how handling, storing, packaging, and delivery systems are used to prevent NCMP.

Describe how systems are assessed to prevent the material handling, delivery. and receiving methods from generating NCMP.

Record specified packaging standards to protect product integrity.

Develop and demonstrate that there is an inventory management system to optimize inventory turns and stock rotation.

Define how an obsolescent product is managed.

If there are products with shelf-lives, define how the system prevents inadvertent delivery after expiration of shelf-life.

13.3.9 General considerations include:

Customers are proactively alerted when NCMPs are identified.

Full containment of all potential NCMPs is effected.

Systems outside the organization should be proactively reviewed to minimize the potential of generating NCMP.

Appropriate documents (FMEA/CP/8D's/quality alert's, etc.) are updated and managed to track system alerts, improvements, and verification of results.

A closed-loop system is developed to identify root-cause, generate corrective action and then implement preventive action to prevent recurrence.

Containment Review Diagram:


## 14. PERFORMANCE ANALYSIS AND IMPROVEMENT PROCESS

### 14.1 Purpose

The Performance Analysis and Improvement Process (PAIP) is a disciplined system used to promote and manage continual improvement.

It establishes a systematic process for selection of key operational measurements (related to the business strategy); establishes related performance standards and goals; and ensures that these align with the Vision Statement, Strategic Architecture, and Development Plan.

## 14.2 Scope

This procedure describes the minimum requirements and controls for ensuring that organizations systematically implement the PAI process. This policy applies to all organization levels in (Corporate, Groups, Operations, Divisions, and Sites) and all areas of the business.

## 14.3 Procedure

14.3.1 The management team for the site will meet, at minimum, annually to review and update the strategic plan (initiatives, goals, etc.) and to ensure that it complies and aligns with respective corporate/operating group/divisional strategic plans.

14.3.2 The approved strategic plan shall be communicated and available to all affected managers.

14.3.3 All levels of management (executive to shop floor) shall develop plans and determine the key processes and key measurements (preferably leading), with related performance standards and continuous improvement goals for their areas of responsibility in line with the focus and objectives of the strategic plan.

14.3.4 Tracking methods shall be created to track the key measurements for the manager's respective area of responsibility. Tracking via trend analysis and Pareto and Paynter charts is strongly recommended, including action plans as appropriate.

14.3.5 Periodic meetings (at a minimum, quarterly) shall be conducted to review the measurements within the manager's responsibility (corporate, group, operations, division, business unit, plant, department, and work cell).

Performance of the measurements shall be tracked at the designated frequency.

Action plans shall be generated for metrics that are not trending toward the desired goal. A structured problem-solving method, such as the 8D process, will be used to determine

the root cause and develop corrective actions for items that are underperforming. Employees at all levels will be involved, as applicable, to facilitate the improvement process. Meeting minutes shall be tracked.

14.3.6 Correlation between the metrics and the final stakeholder desired results shall periodically (minimum annually) be established and reviewed as part of the management review process. Metrics and goals will be adjusted as required to adapt to the changing business requirements.

## 15. CORRECTIVE AND PREVENTIVE ACTION PROCESS

### 15.1 Purpose

The purpose of this document is to provide guidelines and support for a uniform methodology to be utilized throughout units, to provide early and accurate identification of potential and actual problems, necessary containment actions, root cause analysis, corrective and preventive actions, and closed-loop communication with the customer where appropriate.

### 15.2 Scope

This process describes the requirements and controls for assuring that product and operations process nonconformances are identified, defined, contained, and/or eliminated.

### 15.3 Procedure

15.3.1 Each operating unit will define, document, and implement procedures to systematically accomplish the following activities:

- Prevention of product and process nonconformance through systematic monitoring, identification, and elimination of potential failure events (prevention of occurrence)
- Correction of nonconformance, including prevention of recurrence

These operating procedures shall comply with the requirement of this policy.

15.3.2 Identification and prevention of product and process nonconformance

This procedure will define the means to systematically seek out and identify opportunities for improvement, emerging unfavorable trends or potential product or process nonconformances, and take appropriate action to prevent or eliminate the issue before significant unfavorable consequences occur.

15.3.2.1 The procedure will define the roles, responsibilities, and frequency for reviewing available information to identify areas of potential improvement or potential nonconformity. Items that may be reviewed include:

- Failure modes and effects analysis review specifically analyzing special characteristics or characteristics with high risk priority numbers (RPNs)
- Customer complaints and visit reports
- Process capability data, focusing on special characteristics
- Internal audit concerns
- Audit/test rejection rates, focusing on special characteristics
- Cost of nonconformance performance
- Customer satisfaction survey data
- Training effectiveness data
- Management review findings

15.3.2.2 Preventive actions will be performed using a multidiscipline structured problem-solving method consistent with Section 15.3.3 of this policy.

15.3.2.3 When preventive actions involve process changes, they are to be handled in accordance with corporate product/process change policies. Error-proofing methodology will be implemented where appropriate.

15.3.2.4 Preventive action plans and implementation progress will be reviewed at appropriate intervals by the responsible management team. Overall effectiveness of the preventive action process will be discussed in the management review.

15.3.3 Corrective and Preventive Action: This procedure shall be based on the industry standard "8 Discipline" (8D) methodology unless otherwise specified by the Customer. The procedure shall address

the roles and responsibilities for accomplishing each of the disciplines or activities in the corrective and preventive action process as described below and shall specify that formal corrective action be initiated per Section 15.3.4 of this policy.

15.3.3.1 Form team and scope project: The procedure shall define a process to identify those events that shall be subject to corrective action and who is responsible to initiate the process. An appropriate team drawn from functions that may impact, or be impacted by, the problem will be identified to conduct the investigation. Internal and/or external suppliers should be included when appropriate. Team members should be knowledgeable about the product and/or to support the effort. The multifunctional team shall be provided with a charter or problem scope for investigation and action.

15.3.3.2 Define and describe the problem: The procedure shall assure that verified problems are investigated to define the nature and scope of the problem. The specific symptoms of the problem are to be defined, and their consequences, if evident, are to be documented. The team is also to determine if the problem is limited to a specific unit, lot of material, design change, date range, machine, department, etc. It may also be necessary to investigate environmental conditions, maintenance practices, or other circumstances to quantify when and where the problem has been detected or is likely to be found. The significance of the quality problem must be evaluated in terms of performance, reliability, safety, cost, and customer satisfaction. A specific quantified definition of the problem is to be generated. If the problem cannot be verified or replicated through this process, the procedure shall provide a means to record the incident and investigation. The record will be used to identify if any future incidents are similar in nature to spot trends as they emerge.

15.3.3.3 Implement containment actions: The procedure shall define responsibilities and actions to prevent or minimize the expansion of the problem. After the problem has been defined and quantified, containment actions are to be defined and implemented. Suspect product in the plants or warehouses may be quarantined and/

or subject to additional test or inspection. Incremental process controls may be implemented in administrative, production, or service processes to prevent additional nonconformities. A special effort must also be made to contain any suspect products that may have escaped the immediate control of the originating site. The procedure will define the means to identify all applications of the subject product or issue as well as making a careful review of similarly processed items that might also be potentially nonconforming. Processes to identify and contain all of the locations of suspect product within control of the factory to avoid recontamination of verified product at a later date will also be addressed. The procedure will also define the criteria and process to assess and conduct any necessary Field Action Campaigns that should be initiated in accordance with Group, Corporate, or Regulatory requirements.

15.3.3.4 Identify and evaluate potential root causes: The procedure shall define appropriate activities and/or tools to determine root cause through the logical elimination of likely causes using data obtained from completed product testing, Cause and Effect analysis, Potential Failure Modes and Effects Analysis (PFMEA), Designed Experiments, Fault Tree Analysis, and other techniques. Procedures shall assure that the root cause analysis is not to be superficial—the intent is to identify the underlying process action or omission that allowed the problem to occur. The investigation should address both the root cause that allowed the nonconformity to be produced and the root cause that allowed the nonconformity to escape. Multiple root causes may contribute to a problem—it is their coincidence in time and impact that results in the nonconformity. When multiple causes contribute to the nonconformity, each significant cause should be defined and its contribution quantified. The procedure shall provide for documentation of the ultimate Root Cause(s). "Operator Error" or "More Training Needed" is NOT acceptable Root Causes. Root Cause should be identified at a level that will have a meaningful impact on the

prevention of the problem and similar events, but not so far removed in the causal chain that the project team does not have the mandate to resolve the problem.

15.3.3.5 Define and verify permanent corrective actions: The procedure shall provide for the creation and evaluation of the effectiveness of proposed Solution Alternatives designed to eliminate the Root Cause(s). The irreversible Corrective Action(s) MUST meet all customer requirements. The best solutions are process and/or product changes with on-going controls to ensure that the root cause(s) are eliminated. Effectiveness of the corrective action is to be assessed to assure that the root cause and symptoms of the problem have been minimized or eliminated. The organization may verify the proximate cause of the nonconformance through the use of a "Light Switch" test (verify that the nonconformance can be turned on and off by applying and removing the source of the nonconformance). The organization will likewise verify that the corrections prevent the proximate and root causes.

15.3.3.6 Implement and validate permanent corrective actions: The procedure shall define roles, responsibilities, and timelines to assure that the corrective action is implemented by the team in a timely manner consistent with the magnitude and severity of the problem. Appropriate process controls are to be implemented as part of the corrective action to assure that the actions are applied in a consistent manner. Process Control Plans will be updated to reflect the corrective action. Only after the effectiveness has been verified are any incremental inspections or controls implemented as part of the Containment effort to be terminated.

15.3.3.7 Prevent recurrence: The procedure shall define responsibilities and timelines to modify all affected systems, written procedures, processes, control plans, etc. as necessary, to prevent recurrence of this and similar problems. These changes are to be documented and distributed to other potentially affected areas. The procedure shall provide criteria to determine if it is appropriate to monitor and measure the improved process on a continuing basis to ensure

that there are no repeat problems and that improvements are maintained.

15.3.3.8 Complete project and recognize team: The procedure shall define responsibilities and actions to confirm that all corporate and customer required deliverables have been satisfied, or that schedules and resources are provided for their timely completion. Progress on any open issues shall be reviewed at appropriate intervals to assure that all actions are accomplished. Provide a means to assure "positive reinforcement" to the team by recognizing the success of the dedicated and cooperative efforts of all team members in permanently solving the problem. The procedure shall define appropriate management, customer, or other reviews and approvals to formally close a corrective action project.

15.3.4 Application of Corrective Action: The procedures shall specify that formal corrective action is initiated—at a minimum—under the following circumstances:

15.3.4.1 When corrective action specified by a customer, registrar, or other authoritative organization.

15.3.4.2 When a reported product or process nonconformity has, or can have, significant impact on product or process safety, quality, or efficiency.

15.3.4.3 Under other circumstances at the discretion of the operating units.

For minor nonconformances, with primary impact only on secondary or supporting processes and no significant impact on process or product safety or quality, corrective action may be limited to problem definition, containment, and proximate cause resolution at the discretion of the organization.

15.3.5 Records: Records of the corrective action process shall be maintained by the organization. Formats used to capture and communicate findings and status shall be in accordance with approved Group procedures. The records shall be kept in such a manner to support ongoing tracking of open issues, trend analysis, and identification of emerging issues, and the process shall meet corporate, customer, legal, and regulatory requirements.

15.3.6 Management Review: Corrective and Preventive action status, including the number and nature of issues, timeliness of resolution, and repeat issues, will be subject to formal management review at least at the plant level plus one level higher (Business Unit, Division, or other organization as appropriate) at least once per year. Revisions to procedures or implementation will be identified and implemented to address any significant issues.

### 15.4 Records

Records of the corrective action process shall be maintained by the organization. The records shall be kept in such a manner to support ongoing tracking of open issues, trend analysis, and identification of emerging issues, and the process shall meet corporate, customer, legal, and regulatory requirements.

## 16. QUALITY ALERT SYSTEM

### 16.1 Purpose

The purpose of this process is to provide detail of the process of initiating and deploying a quality alert communication.

### 16.2 Scope

The quality alert process applies to any corporate-wide or group-wide supplier or site-specific communication on unique quality matters. The corporate quality alert process will only be used to deploy communication of quality issues that affect or are of interest to general manager levels and higher in the corporation. The process may also be used to communicate issues to divisional quality/operational excellence managers. The intent of the corporate quality alert is to deploy the specific communication more broadly across divisions, groups, or corporate-wide and to warn other locations about potential issues that need to be prevented.

**Note:** The procedural quality alert system may be used within a group/division to reflect specific quality concerns affecting only that group/division.

Proper procedures and distribution controls shall be written for these types of communications. Current local procedures are not affected by this policy outside the prescribed format of the communication document.

## 16.3 Procedure

Initiation of a quality alert may be from two sources following recognition of an issue pertinent to more than one division/group within the company. For a corporate quality alert, following recognition of the potential need, all associated documentation and related data shall be forwarded to the office of the vice president, Quality. A meeting will be convened of the relevant quality leadership team members to discuss the specific occurrence and decide if a quality alert is to be initiated. If the decision is that a corporate quality alert is not necessary, appropriate discussions of alternative methods of deployment will be held with the initiator. If a corporate quality alert is deemed necessary, the person preparing the text of the document will enter the required information on the quality alert report log (see below). The preparer will then record the text of the quality alert on the quality alert form (see below).

Review of the text will be conducted by the corporate quality alert initiator and also by the vice president, Corporate Quality, or his or her designee and approved for distribution. Once approved, a proper distribution list, determined based on the specific incident, will be prepared and distribution accomplished by the office of the vice president, Corporate Quality, and the date entered on the quality alert report log.

For a group/division alert, local procedures shall delineate process steps and shall specify appropriate decision-making authority and timing relative to initiation of the alert and also retention period for the communication relative to the point of use. Communication format shall be similar to the corporate alert document and must be consistent across the corporation and be easily viewed at the point of display.

**Note:** When issuing a quality alert, sites must have a process in place to address notification to external organizations in compliance with industry and governmental requirements.

**Corporate Quality Alert Communication Process Alert Report Log**

| Date | Report number | Prepared by | Requested by | Subject |
|---|---|---|---|---|
| | | | | |
| | | | | |

**Quality Alert Form**

**Corporate Quality Alert**

**Customer Quality Communication—Urgent**

Date:

Problem description:

Action to be taken:

Report deployed (date):

## 17. RISK MANAGEMENT

ISO 9001:2015 will have this as a requirement.

Organizational risks related to global quality management reside in

- Quality system
- Quality management
- Design control
- Production control
- Materials system
- Facilities/equipment system
- Laboratory and test/verification system
- Packaging and labeling system
- Logistics
- Field service

## Definitions

**Risk:** The chance of occurrence of an undesired event and the severity of the resulting consequences

**Risk assessment:** The process of qualitative or quantitative risk estimation

**Risk management:** Is the process of risk identification, risk assessment, risk disposition, and risk tracking and risk control

**Risk assessment methods**

1. Process control plan audit (PCPA) (Chapter 5)
2. Statistical process control (SPC), refer to Book 3 "Tactical Guide to Six Sigma Implementation"
3. Manufacturing process capability, refer to Book 3 "Tactical Guide to Six Sigma Implementation"
4. Qualitative and quantitative potential failure mode and effect analysis for processes and design through risk priority number (RPN), refer to Book 2 "Lean Transformation: Cultural Enablers and Enterprise Alignment"
5. Six Sigma, refer to Book 3 "Tactical Guide to Six Sigma Implementation"
6. Qualitative and quantitative fault tree analysis (FTA)
7. Probabilistic risk assessment (PRA)
8. Reliability allocation
9. Reliability prediction
10. Reliability demonstration
11. Trend analysis

This book series deals with the top 5 risk assessment methods. The rest of the methods are not covered by this book series.

# 7

# *Fast Customer Response*

## SCOPE

- Assembly area
- Manufacturing operations
- Shipping/receiving/logistics
- All service and field operations
- Other support functions like finance and HR

## PURPOSE

- Immediately addresses external and internal quality failures
- Defines the process to be followed
- Defines method of displaying important information as a visual management tool, supporting status at a glance
- Applies a systematic approach and discipline in responding to customer issues

## RESPONSIBILITY

The unit operations manager has responsibility for the fast response.

## BENEFITS

- Improves quality metrics; reduces parts per million defects (PPM) and warranty costs.
- Reduces problem resolution requests (PRRs) and increases customer satisfaction.
- Provides a systematic approach for problem solving and communication of quality issues.
- Ensures the natural owner is assigned to each issue.
- Supports continuous improvement.
- Strengthens documented implementation of lessons learned.
- Prevents repetitive mistakes and reduces waste of resources.
- Engages all stakeholders in an organization.

## PROBLEM IDENTIFICATION

Fast response meeting will take place every day, at the start of the day. It should be a 10- to 20-minute stand-up meeting held on the shop floor. Quality function shall identify significant quality concerns from the past 24 hours, including:

- External concerns
  - Customer concerns (PRRs, liaison issues, customer calls, warranty)
  - Supplier concerns (suppliers should be notified in advance when they are to report out at the meeting)
- Internal concerns
  - Test/verification station findings
  - Process audit systemic issues
  - Line stops and teardown issues
  - Other internal quality concerns (dock audits, containment activity)
  - Poka-yoke (error-proof) equipment issues

See Figures 7.1 and 7.2.

**Fast response tracking board**

| Overall status | Issue no. | Cust. | Issue ref. no. | Issue description | Date opened | P/N | Owner | Next report due to cust. | Exit criteria: Next date (of owner report-out to staff) | Containment | Root cause analysis | Corrective action implemented | Error proof/ detection | Corrective action verified | PFMEA/control plan updated | Standardized work instructions | Layered process audits | Date closed |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
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| | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | |

| Overall and exit criteria status key | |
|---|---|
| R | Required but not initiated |
| Y | Initiated but not complete |
| G | Complete |
| N/A | Not applicable |

For R or Y status
--Include target date

| Points to review at report-out: |
|---|
| Ownership |
| Exit criteria |
| Overall status |
| Investigation/implementation status |

**FIGURE 7.1**
Fast response tracking board. (From http://markerboardsplus.com/.)

**Fast response process key steps**

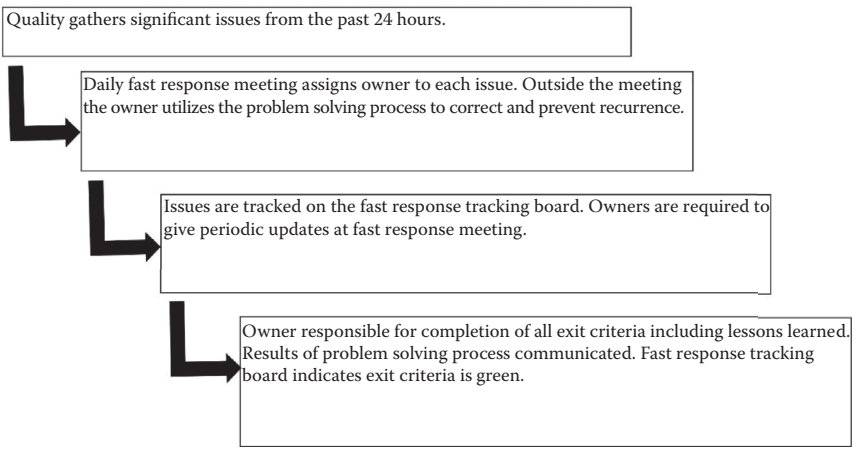



**FIGURE 7.2**
Fast response.

# 8

# *Problem Solving*

## PROBLEM-SOLVING PROCESS DEFINITION

The problem-solving process is a structured process that identifies, analyzes, and eliminates the discrepancy between the current situation and an existing standard or stakeholder expectation and prevents recurrence of the root cause.

## PROBLEM DEFINITION

- It is the *gap* between the current situation and customer satisfaction.
- It is also defined as a discrepancy between an existing standard or expectation and the actual situation.
- Problems are positive opportunities.

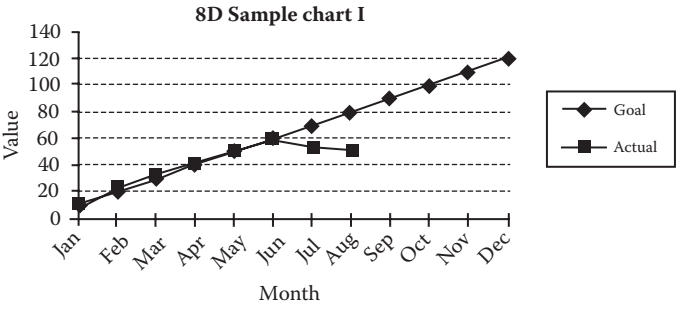
## PROBLEM-SOLVING PRINCIPLES

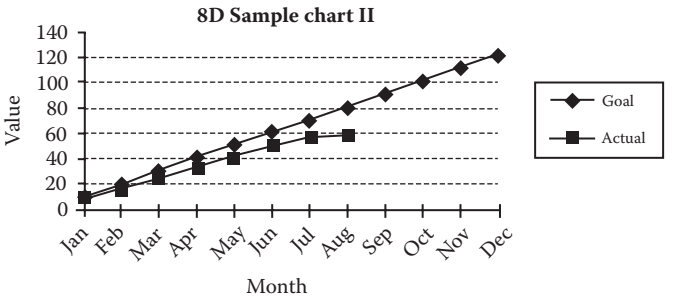
- Set aside preconceived ideas. Collect data.
- Do not respond to problems without data.
- Break the problem down.
- "Go and see" abnormal occurrences and point of cause firsthand (by yourself).
- Delay cause analysis until you have a thorough grasp of what is actually happening.

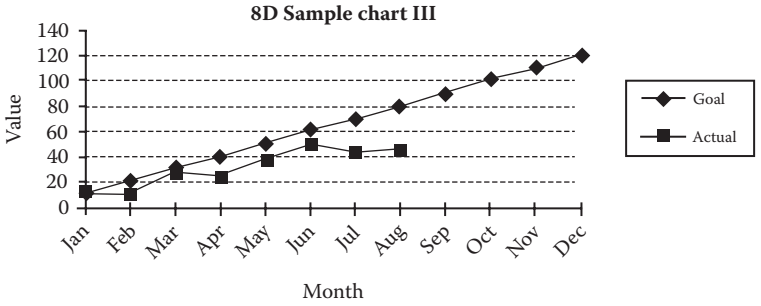
- What is the standard? What is the process? What is happening compared to what should be happening?
- Establish cause/effect relationships.
- Continue asking "why?" until you can prevent recurrence of the problem by addressing its root cause.

## EIGHT DISCIPLINES (8D) PROBLEM SOLVING

- When to use 8D
- 8D
- Lessons learned process
- Example charts for when to start the 8D problem solving process show the champion experiencing two consecutive periods of declining performance and experiencing consistent, positive performance—but below goal, and the gap to the goal is widening:






## What Is Eight Disciplines?

- 8D is a disciplined process that addresses problem solving in a methodical and analytical way.
- Each step of the 8D is preceded by the letter "D," which stands for "discipline."
- Each discipline has an input and an output.
- The output for one step becomes the input for the next.
- The process relies on facts, people (team based), and creative thinking (brainstorming) to reach a robust solution.

### *Description of the Disciplines*

D0—Start the process (emergency response action [ERA]).
D1—Establish the team.
D2—Describe the problem.
D3—Develop the interim containment action (ICA).
D4—Define and verify root cause (RC) and escape point (EP).
D5—Choose and verify the permanent corrective action (PCA).
D6—Implement and validate permanent corrective action.
D7—Prevent recurrence.
D8—Recognize team and individual contributions.

## D0—EMERGENCY RESPONSE ACTION

- If necessary, provide the following ERA to protect the customer:
  - Work in process (WIP) on hold
  - WIP checked

  - Warehouse stock on hold
  - Warehouse stock checked
  - Deliveries in transit identified
  - Deliveries in transit checked
  - Deliveries at customer checked
  - Other actions
- It starts even before the 8D is initiated.
- Evaluate the need and initiate the 8D process.
- The symptom is defined.
- The cause is unknown.
- Robust solution is needed.
- What to look for:
  - Symptoms described by the customer
  - Emergency response—such as advance knowledge about information, its creation, properties, and use, contact information, parts sorting, parts rework
  - Key dates (when occurred, when informed, actions, etc.); traceability records

## D1—TEAM FORMATION

- Define the team charter.
- Designate a champion.
- Empower the leadership.
- Allocate adequate and appropriate resources (include persons with specialized knowledge of the process).
- Build the team relationship and roles.
- Define very simply "what is wrong with what" (i.e., what object has what defect).

## D2—PROBLEM DESCRIPTION

- Use information to describe the problem by:
  - What object has the defect
  - What the defect is—"go and see" the defect

  - Where specifically on the object the defect is
  - Where geographically the defective object is observed
  - When in time the first defect was observed
  - When the defects were made in the facility
  - When were they seen? In the process flow? In the operating cycle? In the life cycle?
  - How many objects have defects? How many defects are there per object?
  - What is the trend since first observation and what is it now?
  - Could this happen to similar parts in other lines or other facilities?
- Identify "what is wrong with that."
- Detail the problem in quantifiable terms.
- Look for:
  - Customer/problem or issue statement
  - Engineering/specialist statement (translated from customer statement by what, when, where, and how; target or critical to quality aspect)—including metric

## D3—INTERIM CONTAINMENT ACTION

- Is an ICA required?
- Is ERA all right as an ICA?
- If ICA is not necessary, why not?
- Describe the ICA proposed.
- Who will do it and when?
- How will OK parts be identified?
- If changes are proposed, report to champion and obtain approval of control plan, work instructions, and audit sheets.
- Did your company or the supplier find a way to keep the production running?
- Protect the customer from the effect of the problem.
- "Buy time" to find the root cause.
- Contain the problem (minimize cost to the customer).
- What to look for:
  - Description of intermediate actions such as containment at the supplier plant
  - Key dates, verification method, service actions

## D4—ROOT CAUSE AND ESCAPE POINT

- Consider cause and effect (Ishikawa) diagram.
- Did your company or the supplier find the problem and a location where it happened?
- Isolate and verify root causes that addresses the problem statement in step D2.
- Do you have an inspection/control point that should have ensured that nonconformances were found?
  - If yes, why did the inspected/control point fail?
- Isolate and verify the phase where the problem could have been detected (escape point).
  - What to look for:
    - Root causes (For the theories that pass through the logic test, show the logical links [steps] between the root cause theory, the problem statement, and the symptom. Do this for each theory. Repeatedly ask "why?" to show the links [stairstep logic].)
- Proving the root cause—verification action plan:
  - What testing are you going to do to prove that this is (or these could be) the root cause?
  - How was it concluded that they were the root causes (verification of the root causes)?
  - What are key dates/personnel/methods that helped produce the root cause?

There are several tools available for problem solving and getting to the root cause. Their use is dependent upon how complex the process is, the type of failure mode, and the system used to measure the specific characteristic that failed.

The tools for root cause analysis are summarized in Figure 8.1.

Once the problem is identified, the following sequence of quality investigation should take place:

- Is the process correct?
- Is the tool correct?
- Is the part correct?
- Is the part quality correct?

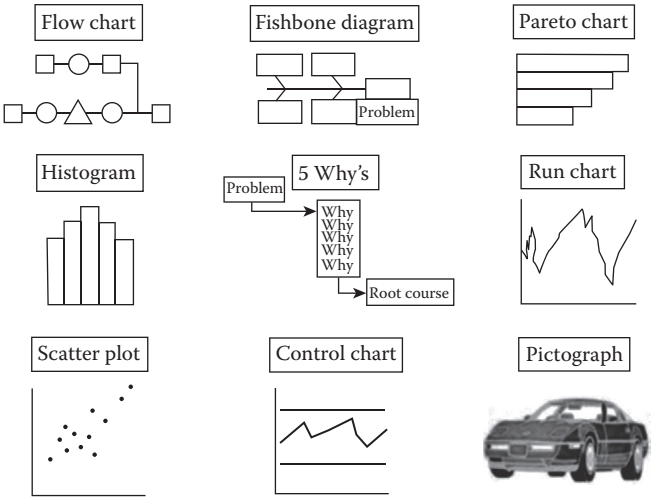



**FIGURE 8.1**
Root cause analysis tools. (From Chrysler quality requirements, http://www.iatfglobaloversight.org/docs/Chrysler%20Customer-Specific%20Requirements%20JAN%202013.pdf.)

If all of these are correct, then engineering support is requested:

- Will process change resolve the problem?
- Will the part design chance resolve the problem?

If the answer is uncertain, the problem is elevated to the Six Sigma team for statistical solution.

## D5—VERIFY PERMANENT CORRECTIVE ACTION

Did your company or the supplier verify and assess the impact of the solution?

- Do not rush into a solution.
- Select the "best quality for customer" solution:
  - To eliminate the root cause
  - To address and close the escape point
- Verify the solution.
- Assess the detrimental impacts of the solution.

- Look for:
  - The action to fix the root cause
  - How it is verified; how you know (give proof) that it will work
  - Key dates/verification methods

## D6—VALIDATE AND IMPLEMENT PCA

- Did you or your supplier validate the solution? Has the problem been "switched off"?
- Plan and implement PCA.
- Remove the interim corrective action.
- Monitor long-term results.

## D7—PREVENT RECURRENCE

- Take a moment to look back at this problem. Why did it happen in the first place? What lessons can be learned? What changes need to be made to ensure that this and similar problems never happen again? Also note down some specific improvements that need to be made in areas such as systems, procedures, machinery, maintenance, people, and training.
- Review process failure mode and effects analysis (PFMEA)/control plan.
- Identify what needs to be updated.
- Control is in place (key dates/responsibility).
- Was control plan updated?
- Update quality documents and training procedure if needed.
- Modify the necessary systems—including policies, practices, and procedures to prevent similar problems from happening again.

## D8—RECOGNIZE

- Make a log for key task actions and monitor it.
- Build relationships.

- Document lessons learned.
- Create and archive reports.
- Acknowledge team contribution.
- Look for congratulations or acknowledgments.

## LESSONS LEARNED PROCESS

This establishes a process for capturing information that will support continual improvement to all operations/processes. It prevents repeated mistakes, allowing an organization to capitalize on its successes and applies to all functions and responsibilities; therefore, everyone in the organization should participate. All documentation that will support continuous improvement should be entered into a lessons learned system.

Examples of activities to identify lessons learned include:

- The advanced product quality planning (APQP) process
- Process audits
- Error proofing verification failures
- Problem-solving activity for internal or external issues
- Verification test station findings
- Continuous improvement teams
- PFMEA team activity for risk reduction
- Suggestion programs
- Company business/quality operating system management reviews

A disciplined approach to problem prevention using lessons learned shall be established. Lessons learned may include activities within an organization to prevent future problems or to improve performance.

- Lessons learned communication may be performed by
  - Posting the lessons learned form
  - Including it on a lessons learned website
  - Utilizing a company newspaper or closed circuit TV
  - Distribution of pocket cards, etc.

# CORRECTIVE / PREVENTIVE ACTIONS REPORT
## THE DISCIPLINED PROBLEM SOLVING PROCESS

Commercial Controls Division
Reynosa, México

8D 8D#

Timeline

**Originator**

Customer Name: RMA:

Originator Name/Dept.: Phone: Fax:

Complaint source: ☐ Customer ☐ 3rd Party ☐ Internal ☐ Supplier

Date opened:

Date received in

Problem Name/Title:

Revision Date:

Part(s) / Process Num.(s):

Date closed:

Part(s) / Process Name(s):

Location where the problem was detected:

Qty./pcs.:

Filled and submitted same day of complaint

**Corrective / Preventive Action Team**

Business Unit / Dept. affected: Recurrent / secondary problem? ☐ YES ☐ NO

**D0.- CONSIDER EMERGENCY RESPONSE ACTION (ERA)** ☐ Required ☐ Not Required

24 hrs

**D1.-CONTACT TEAM** (Team that may impact or be impacted by the problem to conduct the investigation. Knowledgeable & available to suppor

Champion:
Team Leader:
Members:

**D2.-DEFINE & DESCRIBE THE PROBLEM** (Define: What, Where, When, How, How big, Who, Why as much as possible to describe the p

**D3.-DEVELOP, VALIDATE & IMPLEMENT INTERIM CONTAINMENT ACTIONS [ICA]**

(Protect the customer from the effect of the problem. Prevent or minimize the expansion of the problem) **(N/A FOR PREVENTIVE**

| Action | Start Date | Finish Date | Responsible |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

48 hrs after complaint is received or before

**D4.-IDENTIFY AND EVALUATE POTENTIAL ROOT CAUSE(S)** (Attach tools used such as: 5-Why analysis, Fishbone. D.O.E., FME

| (1) Root cause(s) that allowed the non-conformity **to be produced** AND (2) root cause(s) that allowed it **to** | Contribution % |
|---|---|
| | |
| | |
| | |
| | |
| | |

10 working days max.

**D5.-DEFINE & VERIFY PERMANENT CORRECTIVE ACTIONS (PCA)**

(Evaluate effectiveness of proposed solution alternatives to eliminate all root causes identified above) **(N/A FOR PREVENTIVE**

| Proposed Solutions (product / process changes with on-going controls) | Verification Method | Responsible | Effectiveness | Status |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**D6.-IMPLEMENT & VALIDATE PERMANENT CORRECTIVE ACTIONS (PCA)** (Implement chosen corrective actions to elim

| (Irreversible corrective action must meet all customer requirements) | Finish date | Responsible | Acknowledgment signature | Status |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Timely (consistent with the magnitude & severity of the problem)

**D7.-ACTIONS TO PREVENT RECURRENCE**

(Process, written Procedures, WI's, MI's, Control Plan, FMEA or other documents were revised and consider other areas with similar risk of

| (Update Control Plan. Product / Process changes must be approved before implementatio | Finish Date | Responsible | Status |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

In parallel with 5 & 6

**Auditor & Champion**

**D8.-CONGRATULATE THE TEAM** (Positive reinforcement to the team by recognizing the success of the dedicated and cooperative efforts)

| | Date | Responsible |
|---|---|---|
| Review and approval to formally close the corrective action report (attach sign-off sheet) | | |
| Congratulate the team | | |

After successful completion

NOTE: The Original is returned to Document Control when this 8'D is closed out. The originator may keep a copy.

# 9

# *Drill Deep/Drill Wide Method for Permanent Corrective Action*

## OBJECTIVE

- Develop a problem-solving tool that will address and draw in all elements of a quality system to ensure that a permanent corrective action is achieved.
- Develop a methodology that will take lessons learned from corrective actions and communicate all process/product corrections within the entire organization.

  **Why?** Simply because most of the failure modes treated with corrective actions recur again and again.

  **Where to start?** Where the problem was born!

## DESCRIBE THE PROBLEM

- This is the key to success; if you do this incorrectly, the problem will return.
- Spend the time necessary to ensure that you are working on the correct and complete problem.
- This description then begins your 5-Whys journey to a solution.
- Use the data at hand to confirm your description (Pareto charts, tick sheets, etc.).

### WHY Process

- This is an excellent technique to get from symptom to actual root cause.
- Anyone can do it, but a cross-functional team works best.
- You do not need to get to the fifth WHY to solve most problems.
- A weakness is that it identifies one root cause, but there may be others.

## WHY MOST QUALITY PROBLEMS OCCUR AGAIN AND AGAIN

One 5-Why is not enough: We need to drill deeper. A 3 × 5 why is required so that we can split the analysis into the three main components (see Figure 9.1):

- Why did the manufacturing system not PREVENT this failure mode?
- Why did the quality system not PROTECT the customer from this failure mode?
- Why did the quality planning system not PREDICT this failure mode?

Here we need to review three commandments of the drill deep process:

- Manufacturing system—prevention, error proofing and standardized work
- Quality system—control plan for detection
- Quality planning—failure mode and effects analysis (FMEA) for failure mode identification and control

### Root Causes Relating to "PREVENT"

- Lack of discipline to process control plan
- Lack of error proofing
- No effective error proofing validation
- Insufficient error proofing verification—at least one per shift required

**Drill Deep Worksheet**

Revision Date:

Name and Title: Phone:

Supplier Team Lead:

Provide a complete member list with contact information

JCI SQE:

Supplier Duns: Supplier Name and Location:

Issue Category: ☐ PRR ☐ PRTS ☐ CDP ☐ Other, Specify

Failure Mode:

Effects of Failure Mode:

Cause of Failure Mode:

| | | Drill Deep | Corrective Action |
|---|---|---|---|
| Why did the Manufacturing System Failure Mode **Prevent** Manufacturing System - Error Proofing and Standardized Work **Quality Assurance** | M1 | Cause of Failure Mode | |
| | M2 | | |
| | M3 | | |
| | M4 | | |
| | M5 | | |
| | M-RC | | |
| Why did the Quality System not protect JCI from this Failure Mode **Protect** Quality System - Error Detection & Containment **Quality Control** | Q1 | | |
| | Q2 | | |
| | Q3 | | |
| | Q4 | | |
| | Q5 | | |
| | Q-RC | | |
| Why did the Planning System not predict this Failure Mode **Predict** Planning System - informational content in all documentation **Quality Planning** | P1 | | |
| | P2 | | |
| | P3 | | |
| | P4 | | |
| | P5 | | |
| | P-RC | | |
| What are the key findings based on this quality issue? | A | | |
| | B | | |

**FIGURE 9.1**
Drill deep worksheet: prevent, protect, and predict. (From GM supplier quality manual, http://gm-avtovaz.ru/files/treb_ru/GM1927_Global_Supplier_Quality_Manual.pdf.)

- Setup error proofing insufficient
- Incapable production process relative to design needs
- Poor machine tool/equipment maintenance and repair
- Standard work instructions inadequate
- Standard work instructions missing
- Unauthorized process change
- Software program failure
- Inadequate material handling and control

### Root Causes Relating to "PROTECT"

- All root causes per PREVENT, and, additionally:
- Process control plan process checks not identified
- Frequency of control plan checks insufficient
- Inadequate self-controlled production quality audits
- Failure to control nonconforming part/product
- Ineffective functional testing of components

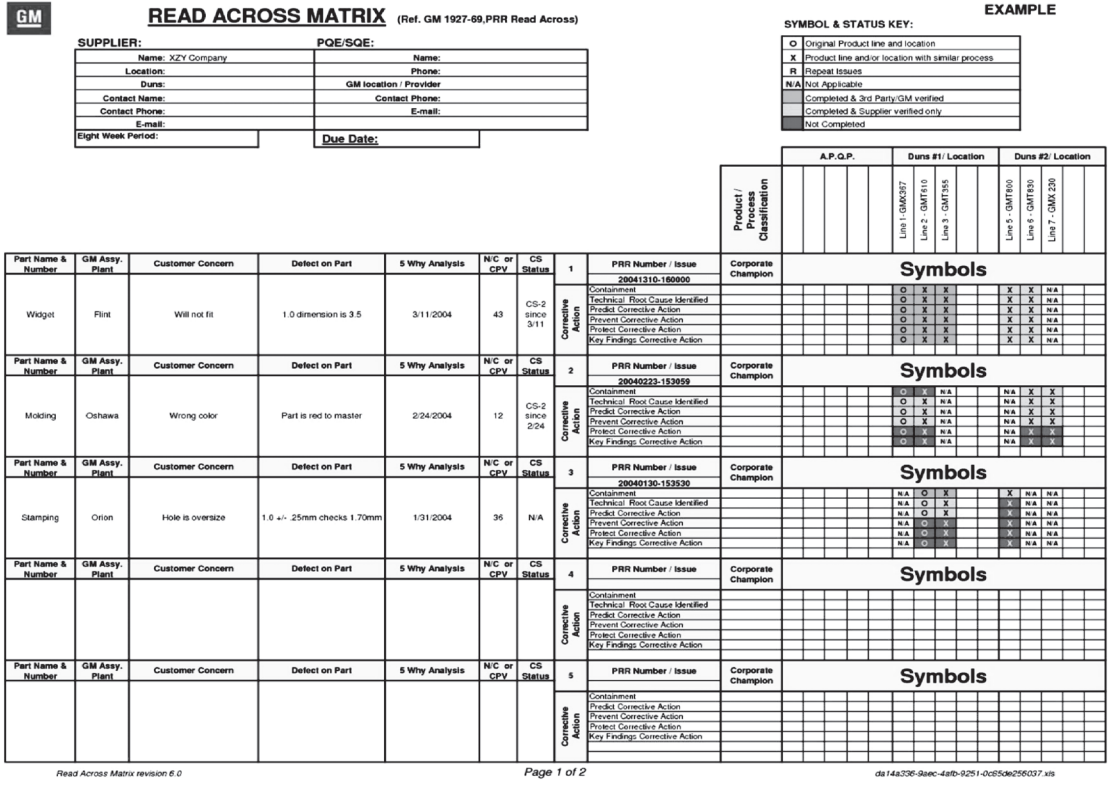
### Root Causes Relating to "PREDICT"

- No FMEA
- FMEA does not include all process flow steps
- Failure mode in FMEA not identified
- Cause of failure mode in FMEA not identified
- FMEA risk priority number (RPN) value too low
- FMEA cross-functional team lacks training and experience
- FMEA not a living document (not updated to reflect past concerns)
- FMEA not reviewed relative to process/product change

## DRILL WIDE AND INSTITUTIONALIZE

- Identify similar products and processes that potentially have or may produce the same failure mode.
- Send a copy of this problem solving report to other departments/plants with the potential of experiencing this problem.
  - Implement the solution across the organization.
  - Update the necessary documentation:
    - Process failure mode and effects analysis (PFMEA)
    - Control plan
    - Error proofing verification
    - Standardized work
    - Operator instructions
    - Lessons learned

See Figure 9.2.



GM

**READ ACROSS MATRIX** (Ref. GM 1927-69,PRR Read Across)

**EXAMPLE**

**SUPPLIER:**

| | |
|---|---|
| Name: XZY Company | |
| Location: | |
| Duns: | |
| Contact Name: | |
| Contact Phone: | |
| E-mail: | |
| Eight Week Period: | |

**PQE/SQE:**

| | |
|---|---|
| Name: | |
| Phone: | |
| GM location / Provider | |
| Contact Phone: | |
| E-mail: | |
| Due Date: | |

**SYMBOL & STATUS KEY:**

| | |
|---|---|
| O | Original Product line and location |
| X | Product line and/or location with similar process |
| R | Repeat Issues |
| N/A | Not Applicable |
| | Completed & 3rd Party/GM verified |
| | Completed & Supplier verified only |
| | Not Completed |

| Part Name & Number | GM Assy. Plant | Customer Concern | Defect on Part | 5 Why Analysis | N/C or CPV | CS Status | | PRR Number / Issue | Corporate Champion | A.P.Q.P. | | | | Duns #1/ Location | | | Duns #2/ Location | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | Product / Process Classification | | | | Line 1 - GMX397 | Line 2 - GMT610 | Line 3 - GMT355 | Line 5 - GMT800 | Line 6 - GMT930 | Line 7 - GMX 236 | |
| | | | | | | | 1 | 20041310-160000 | | | | | | Symbols | | | | | | |
| Widget | Flint | Will not fit | 1.0 dimension is 3.5 | 3/11/2004 | 43 | CS-2 since 3/11 | Corrective Action | Containment | | | | | | O | X | X | X | X | N/A | |
| | | | | | | | | Technical Root Cause Identified | | | | | | O | X | X | X | X | N/A | |
| | | | | | | | | Predict Corrective Action | | | | | | O | X | X | X | X | N/A | |
| | | | | | | | | Prevent Corrective Action | | | | | | O | X | X | X | X | N/A | |
| | | | | | | | | Protect Corrective Action | | | | | | O | X | X | X | X | N/A | |
| | | | | | | | | Key Findings Corrective Action | | | | | | O | X | X | X | X | N/A | |
| Part Name & Number | GM Assy. Plant | Customer Concern | Defect on Part | 5 Why Analysis | N/C or CPV | CS Status | 2 | PRR Number / Issue | Corporate Champion | | | | | Symbols | | | | | | |
| | | | | | | | | 20040223-153059 | | | | | | | | | | | | |
| Molding | Oshawa | Wrong color | Part is red to master | 2/24/2004 | 12 | CS-2 since 2/24 | Corrective Action | Containment | | | | | | O | X | N/A | N/A | X | X | |
| | | | | | | | | Technical Root Cause Identified | | | | | | O | X | N/A | N/A | X | X | |
| | | | | | | | | Predict Corrective Action | | | | | | O | X | N/A | N/A | X | X | |
| | | | | | | | | Prevent Corrective Action | | | | | | O | X | N/A | N/A | X | X | |
| | | | | | | | | Protect Corrective Action | | | | | | O | X | N/A | N/A | X | X | |
| | | | | | | | | Key Findings Corrective Action | | | | | | O | X | N/A | N/A | X | X | |
| Part Name & Number | GM Assy. Plant | Customer Concern | Defect on Part | 5 Why Analysis | N/C or CPV | CS Status | 3 | PRR Number / Issue | Corporate Champion | | | | | Symbols | | | | | | |
| | | | | | | | | 20040130-153530 | | | | | | | | | | | | |
| Stamping | Orion | Hole is oversize | 1.0 +/- .25mm checks 1.70mm | 1/31/2004 | 36 | N/A | Corrective Action | Containment | | | | | | N/A | O | X | | | X | N/A |
| | | | | | | | | Technical Root Cause Identified | | | | | | N/A | O | X | | | X | N/A |
| | | | | | | | | Predict Corrective Action | | | | | | N/A | O | X | | | X | N/A |
| | | | | | | | | Prevent Corrective Action | | | | | | N/A | O | X | | | X | N/A |
| | | | | | | | | Protect Corrective Action | | | | | | N/A | O | X | | | X | N/A |
| | | | | | | | | Key Findings Corrective Action | | | | | | N/A | O | X | | | X | N/A |
| Part Name & Number | GM Assy. Plant | Customer Concern | Defect on Part | 5 Why Analysis | N/C or CPV | CS Status | 4 | PRR Number / Issue | Corporate Champion | | | | | Symbols | | | | | | |
| | | | | | | | Corrective Action | Containment | | | | | | | | | | | | |
| | | | | | | | | Technical Root Cause Identified | | | | | | | | | | | | |
| | | | | | | | | Predict Corrective Action | | | | | | | | | | | | |
| | | | | | | | | Prevent Corrective Action | | | | | | | | | | | | |
| | | | | | | | | Protect Corrective Action | | | | | | | | | | | | |
| | | | | | | | | Key Findings Corrective Action | | | | | | | | | | | | |
| Part Name & Number | GM Assy. Plant | Customer Concern | Defect on Part | 5 Why Analysis | N/C or CPV | CS Status | 5 | PRR Number / Issue | Corporate Champion | | | | | Symbols | | | | | | |
| | | | | | | | Corrective Action | Containment | | | | | | | | | | | | |
| | | | | | | | | Predict Corrective Action | | | | | | | | | | | | |
| | | | | | | | | Prevent Corrective Action | | | | | | | | | | | | |
| | | | | | | | | Protect Corrective Action | | | | | | | | | | | | |
| | | | | | | | | Key Findings Corrective Action | | | | | | | | | | | | |

Read Across Matrix revision 6.0

Page 1 of 2

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**FIGURE 9.2**
Drill wide worksheet. (From GM supplier quality control.)

# 10

# *Quality Operating System: The Engine That Perpetuates Continuous Improvement*

## PURPOSE OF QOS

The quality operating system (QOS) is a well-structured process for the purpose of promoting and managing continuous improvement.

- The QOS process was developed by Fred King of Ford Motor Company.
- The process was benchmarked and deployed within the aerospace industry in the early 1990s.
- Much of the business success was attributed to the QOS disciplined approach of setting goals, team problem solving, and focusing on the "vital few."

## WHAT IS QOS?

QOS is the assembly and analysis of existing data on key team measurables in a manner that is quickly reviewed and acted upon by the team. (i.e., data that are team user friendly and resulting in external and internal customer satisfaction).

## UNDERSTANDING QOS

- Enables gauging (sizing up) problems
- Determines targets
- Studies the impact of improvement activities
- Checks the results
- Makes appropriate adjustments

### QOS Metrics

QOS metrics are the same as BSC (balanced scorecard) metrics.

- Key metrics that need to be reviewed each month:
  - Safety incidents
  - Past dues/ship-ahead metric
  - On-time delivery (OTD)—customer
  - Customer defective parts per million (DPPM)
  - Inventory days on hand
  - Inventory accuracy
  - Supplier OTD
  - Supplier DPPM
  - RTY (rolled throughput yield)
  - Overall equipment effectiveness (OEE)
  - Throughput—widgets per man-hour or dollars per man-hour
  - Cost of nonconformance (CONC) expense ledger
  - HR—hourly employee turnover rate
  - HR—days lost due to safety/health issues

### QOS Process

Step 1: Determine goals for each metric.

Step 2: Appoint a champion for each metric. This should be done through process management and process owners.

Step 3: Champions will hold departmental meetings before attending the plant QOS meeting so that they are ready with results and actions—say, the seventh day of the month.

Step 4: QOS agenda champion calls for QOS meeting—say, the 12th day of the month.

The QOS process overlaps and supplements other programs, such as:

- ISO 9001
- ISO/TS 16949:2002
- Business excellence based on the Malcolm Baldrige National Quality Award
- Lean implementation
- Other continuous-improvement initiatives

### Two Steps

There are two steps to achieving synergy (from *The 8th Habit: From Effectiveness to Greatness*, Stephen R. Covey):

"Would you be willing to search for a solution that is better than what either of us have proposed?"

"Would you agree to a simple ground rule: No one can make his or her point until they have restated the other person's point to his or her satisfaction?"

### Rules for QOS

- A monthly meeting is absolutely required.
- Attendance for plant manager and staff is required.
- Meetings are usually limited to 1 hour, but 2 hours max.
- There are preassigned, fixed time limits for each reportable measurement.
- The facilitator must keep the meeting on track with the schedule.

## THE QOS MEETING

- Prior to meeting, process owners are held accountable.
- All meetings have agendas.
- Meeting minutes detail action items and accountability and track progress.
- Charts are used effectively to communicate results.

- The QOS meeting spends 75% of the time on reviewing problem-solving activities.
- There is employee involvement (teams participate) in the QOS meetings.
- All participants are responsible for success (teamwork).

## Typical QOS Agenda

| **Plant Meeting** | **Date:** |
|---|---|
| **Attendees** | |
| Plant/unit manager | Invited suppliers |
| Quality manager | Purchasing manager |
| Production manager | Manufacturing manager |
| Accounts manager | Logistics manager |
| HR manager | IT manager |
| Test engineer | Six Sigma specialist |

## QOS Focus Example

- Cell manufacturing move status—on track
- Staffing status—update
- Critical hires—in focus: second shift superintendent recruited; Kit supervisor position approved; cycle count analyst approved
- Center of excellence—shared service issues: customer survey results submitted to CEO
- Shipping issues—bottlenecks
- Outsourced maintenance issues—getting better
- Safety issues—keep the gemba walk going
- Staff issues—team is complete

### *Hot Items—Customer Issues*

- OTD fires: none
- Quality fires: none

### *Financial Update*

- Expense crunch—keep eye on expenses; daily meetings with facility manager at 7:00 a.m. for all expense approvals

### *Transferable Practices in Focus—Knowledge Management, Technology*

- Share gemba walk success story with all plants.

### *Recorded Minutes Form Sample*

**Action Items and Follow-Ups**

| # | Description | Owner | Entered | Due | Status |
|---|---|---|---|---|---|
| 0701 | | | | | |

## QOS ASSESSMENT

- Ten questions are provided for assessing QOS effectiveness.
- Each question may be scored from 0 (low) to 5 (high).
- Detailed scoring sheets are provided for each question.

| Rating | Question |
|---|---|
| | 1. Is management involved in and supportive of the continuous improvement opportunities initiated through the QOS process? |
| | 2. Have customer expectations been identified and addressed by the QOS? |
| | 3. Does the QOS documentation facilitate the QOS process? |
| | 4. Is there effective use of structured problem solving? |
| | 5. Results: Is there evidence of quantifiable improvement resulting from the QOS? Is the customer experiencing this improvement? |
| | 6. Is QOS part of the overall management strategy? Is the organization committed to the QOS process? |
| | 7. Are QOS meetings regularly scheduled and run in a manner consistent with the QOS methodology and objectives? |
| | 8. Are problem solving tools used? |
| | 9. Do QOS team members work together in the meeting to generate future courses of action to generate improvements? |
| | 10. Is there a system to maintain the effectiveness of the QOS in satisfying customer expectations over time? |
| | Total score (Maximum 50 points) |

**Scoring procedure**

| | |
|---|---|
| 1 | Is management involved and supportive of the continuous improvement opportunities initiated through the QOS process? (Management is defined as the highest level of authority at the location being evaluated.) |

| Rating | | |
|---|---|---|
| 0 | No involvement | Management has delegated completely responsibility for the QOS process |
| 1 | Some involvement | Management infrequently attends QOS meetings and does not regularly review the QOS process |
| 2 | Involvement | Management reviews all improvement ideas and permanent corrective action recommendations are made by QOS teams |
| 3 | Involvement and understanding | Management demonstrates a clear understanding of the QOS process and methodology |
| 4 | Active facilitation | Management works with QOS teams and team champions to identify management actions that can support implementation of improvement plans or permanent corrective actions |
| 5 | Management | Management has championed the QOS process including deployment of the QOS methodology to their supply base, has communicated clear expectations and provided focus for the QOS team members |

## Areas to Address

1. Does management attend QOS meetings?
2. Are there regularly scheduled meetings for all areas/departments as well as top-level QOS meetings?
3. Is there evidence to support the scheduled meetings, such as a sign-in sheet or attendees' list?
4. In discussions with the manager, is the process for QOS readily articulated?
5. When actions are identified, does management take an active role in making sure that all resources are available to implement the actions identified in a timely manner?
6. What evidence is there to support this?
7. What has management done to take the QOS methodology to the supply base? This does not just mean having suppliers do 8Ds. Have they helped them in training to the DDDW (drill deep, drill wide) process? Is there a standard format for reporting OTD to the supply base? What evidence is there to support this?

## QOS Scoring

- 50 Points max. (10 questions × 5 points each)

## Assessment

- Excellent: above 45 points
- Satisfactory: 35 to 45 points
- Unsatisfactory: below 35 points

### QOS Benefits

- Continuous improvement
- Tracking of key measurables
- Management participation in problem solving
- Root cause versus fixing symptoms
- Communications
- Decision by facts

# 11

# *Conclusion*

Management system is a group of interrelated and interdependent processes that transform inputs into outputs. Inputs to a process are generally outputs of other processes. Processes in an organization are generally planned and carried out under controlled conditions to add value to the customer or the stakeholder.

Between the principle and process definitions, you can see that the process approach is a more powerful way of organizing and managing how work activities create value. We have seen that a command-and-control type of organizational structure organizes and manages work activities vertically by function, where quality problems occur frequently at the boundaries or the "hand offs" of functional departments. The process approach organizes and manages work horizontally and, this way, work activities flow toward creating a customer value.

Once the processes needed for the quality management system (QMS) and their sequences and interactions have been identified (see Figure 3.2 in Chapter 3), it is necessary to establish management responsibilities and accountabilities for the performance of these processes.

Process management and improvement methodology can be organized in a series of steps as follow:

1. Establish the responsibilities of the process manager/owner for managing the process. The process manager is responsible for the following activities:
   Form a process management team that includes representatives from each major function of the process.
   Document, track, monitor, and allocate resources as required by the process to ensure that the process operates in a controlled state of predictable performance.

Establish process performance measures that adequately characterize the efficiency and effectiveness of the process in meeting the needs of all customers and other interested parties.

2. Identify and define the process as explained earlier in the turtle diagrams.
3. Identify, measure, and rank customer requirements and needs carefully, including how customers use the outputs of the process. Communicate frequently with the customers to understand their needs from their viewpoints.
4. Establish measures of process performance. Translate customer needs and requirements into measures of process performance. This is one of the most important and difficult steps in process management. Include customer satisfaction, in-process measures, and measures of supplier performance. Relate all important customer needs, such as on-time delivery and service performance, defect or error rates, tolerance intervals, product reusability, and worker health and safety, to performance measures.
5. Compare the process performance measures with the needs and requirements of the customers. Use a variety of statistical tools for analyzing process measurement data to help quantify process performance. Identify critical process improvement opportunities through gaps in process performance.
6. Improve the process performance continually using the plan–do–check–act process to improve each process.

# Appendix: Quality Manual

QMS-001
Rev. 0
This Quality Manual is hereby formally authorized and approved as the organization's policy by the undersigned:

APPROVAL SIGNATURES

| Function | Name | Signature | Date |
|---|---|---|---|
| General Manager | | See hard Copy | |
| Plant Manager | | See hard Copy | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

REVISION HISTORY

| Revision | Description of Change | Approval Date |
|---|---|---|
| 0 | Initial Release | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

## INTRODUCTION

This manual describes the quality system in operation within the plants of XYZ Company, located at _____ _____. In the documents pertaining to the quality system, the terms plant and XYZ Company can be used interchangeably.

The quality system is organized in five sections to comply with the requirements of the current issue of the ISO 9001 standard and the needs of the company's customers and to improve our products and processes.

The items in this quality manual that comply with the ISO 9001 standard are written using font size 12. The items that comply with ISO/TS 16949 are written in font size 14 and are marked (TS). As continual improvement, this company plans to comply with TS requirements starting this year.

This manual is supported in the appropriate areas by detailed quality system procedures, work instructions, and other documentation. Together they describe the documented quality system.

## 1. SCOPE

The quality management system described in this manual applies to all activities associated with the quality of all products and services of this company.

For the ISO/TS 16949:2002 registration, the scope of the certificate will be the design and manufacture of all our products.

## 2. PURPOSE

This manual is designed to

1. Confirm the company's ability to consistently provide product that meets the customer and applicable regulatory requirements.
2. Enhance customer satisfaction by the effective application of the quality management system and assurance of conformity to customer and applicable regulatory requirements.

3. Provide our customers with products and services that fully meet their requirements and expectations.
4. Provide all employees with principles that guide their activities that relate to quality, thus giving them a proven chance for a secure, enjoyable, and gainful workplace.
5. Provide clear guidelines to the management team for their responsibility regarding quality.
6. Provide our investors the assurance that the business will continue and grow, thus yielding a return on their investment.
7. Provide our suppliers the opportunity of continued business with us.
8. Provide the parameters for the quality side of our processes.
9. Provide a system based on a process approach to our business.
10. Provide a factual method for decisions.
11. Provide the tools for continual improvement.
12. Apply corrective actions to assure consistent delivery of a quality product.

## 3. TERMS, DEFINITIONS, AND NOTES

The term "documented procedures" means the procedures are established, documented, implemented, and maintained.

Our size and type of operation, the complexity and interaction of our processes, and the competence of our personnel determine the extent of our quality management system documentation.

Product realization is the sequence of processes that are required to achieve the product. Planning of the realization processes is consistent with the other requirements of the company's quality management system and is documented in a form suitable for the method of operation.

A qualified process is one that has demonstrated the ability to fulfill specified requirements.

A review is the activity undertaken to determine the suitability, adequacy, and effectiveness of the subject matter to achieve established objectives. A management review is a review conducted by top management.

The audit scope is the extent and boundaries of an audit. Audit criteria are the policies, procedures, or requirements determined as a reference.

Audit evidence is records, statements, or other information relevant to the agreed criteria that can be cross checked. Audit findings are the result of the audit.

## 4. QUALITY MANAGEMENT SYSTEM

### 4.1 General Requirements

The company must establish, document, implement, and maintain the quality management system. The company continually improves the quality management system as follows:

a. Identifies the processes needed for the quality management system and the application throughout the organization
b. Determines the sequence and interaction of these processes
c. Determines the criteria and methods needed to ensure that both the operation and control of these processes are effective
d. Ensures the availability of resources and information necessary to support the operation and monitoring of these processes
e. Measures, monitors, and analyzes these processes
f. Implements action necessary to achieve planned results and continual improvement of these processes

The company outsources the following processes (give an example). These processes are responsible for the area in charge of receiving the processed materials and services:

1. Plating and anodizing (service suppliers)
2. Custom handling
3. Transportation of employees

#### *4.1.1 Supplemental (TS)*

The controls for the first two processes just listed are exercised by the purchasing and incoming inspection processes to maintain the product conformity with the design and customer requirements.

### 4.2 Documentation Requirements

#### *4.2.1 General*

The quality management system documentation includes:

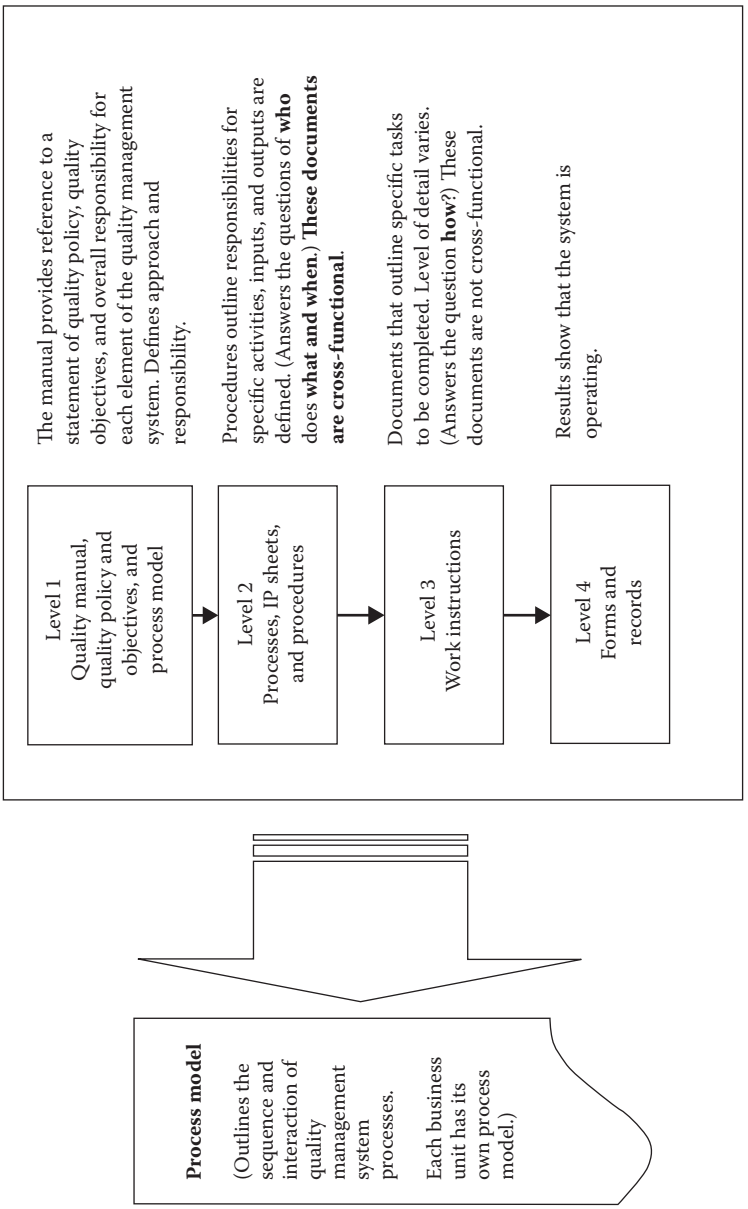
a. Documented quality policy and quality objectives and goals
b. Quality system manual
c. Documented procedures
d. Work instructions and process diagrams required by company to ensure the effective planning, operation, and control of its processes
e. Quality records

The quality policy, quality objectives and goals, quality manual, and procedures and work instructions are all a part of electronic media.

#### *4.2.2 Quality Manual*

1. The scope of the quality management system covered by this manual is described in Section 1 ("Scope").
2. The company establishes a quality management system as a means of ensuring that products conform to the specified requirements. This manual documents the quality management system and makes reference to the quality management system processes and procedures.

The following diagram outlines the structure of the quality system documentation:



3. The quality management system applies to all processes either associated with or affected by the quality of the product. See the process model (process, application, sequence, and interaction; see process model Figure 3.2 in Chapter 3).

### *4.2.3 Control of Documents*

Documents required by the quality management system are controlled by documented procedures. Records are included and controlled according to Section 4.2.4 ("Control of Records").

There are documented procedures established to define the controls needed:

a. To approve documents for adequacy prior to issue
b. To review and update as necessary and reapprove documents
c. To ensure that changes and the current revision status of documents are identified
d. To ensure that relevant versions of applicable documents are available at points of use
e. To ensure that documents remain legible and readily identifiable
f. To ensure that documents of external origin are identified and their distribution is controlled
g. To prevent the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose

#### *4.2.3.1 Engineering Specifications (TS)*

A process exists to assure the timely review, distribution, and implementation of all customer engineering standards/specifications as well as changes based on customer-required schedules. Timely review does not exceed two working weeks. A record of the date on which each change is implemented in production and, as applicable, the updated production documents like failure mode and effects analysis (FMEA), control plans, and production part approval process (PPAP) are maintained.

#### *4.2.4 Control of Records*

Evidence of conformity to requirements and of the effective operation of the quality management system is provided by retained legible, readily identifiable, and retrievable records. Documented procedures define the controls needed for identification, storage, protection, retrieval, retention time, and disposition of quality records.

**Note**: Disposition includes disposal. Quality records also include customer-specified records.

##### *4.2.4.1 Records Retention (TS)*

The control of records is provided to satisfy regulatory and customer-specified requirements.

## 5. MANAGEMENT RESPONSIBILITY

### 5.1 Management Commitment

The following activities and actions provide evidence of our commitment to the development and continual improvement in the effectiveness of the quality management system:

a. The importance of meeting the customer as well as the statutory and the regulatory requirements is communicated to all personnel in the plant.
b. Both companies' quality policy and quality objectives are defined by this quality management system.
c. Plant management reviews are conducted twice a year.
d. Needed resources are provided.

#### *5.1.1 Process Efficiency*

Top management monitors the product realization processes and the support processes to assure their effectiveness and efficiency throughout the management review process.

## 5.2 Customer Focus

Customer needs and expectations are determined and converted into requirements and fulfilled with the aim of achieving customer satisfaction.

## 5.3 Quality Policy

The quality policy

a. Is appropriate to the purposes of the company
b. Includes a commitment to comply with requirements and continual improvement of the effectiveness of the quality management system
c. Provides a framework for establishing and reviewing quality objectives
d. Is communicated and understood at appropriate levels in the organization
e. Is controlled and reviewed for continued suitability

**Quality policy example:** "It is the policy of the company to provide products and services that meet or exceed customer expectations and satisfy them by anticipating their needs and requirements. We comply with the requirements by setting and reviewing objectives and continually improving the effectiveness of the quality management system."

## 5.4 Planning

### *5.4.1 Quality Objectives*

Quality objectives

1. Include those needed to meet requirements for the product
2. Are established at relevant functions and levels within the company
3. Are measurable and consistent with the quality policy, including the commitment to continual improvement

#### *5.4.1.1 Quality Objectives—Supplemental (TS)*

Top management has defined quality objectives and their measurements to address customer expectations as well as key performance measurements. Quality objectives are included in the business plan and balanced scorecard (BSC) that are used to deploy quality policy.

### *5.4.2 Quality Management System Planning*

Planning of the quality management system is carried out to meet quality objectives and to meet the general requirements of the quality management system. Changes are conducted in a controlled manner and the integrity of the quality management system is maintained during these changes. Refer to quality management processes in Chapter 6.

## 5.5 Responsibility, Authority, and Communication

### *5.5.1 Responsibility and Authority*

The company's business units are responsible for day-to-day activities required to run manufacture and timely delivery of quality products and services. Functional support areas define, coordinate implementation, and audit systems to ensure that business units can perform their functions effectively.

The responsibilities and authorities are defined and communicated within each business unit. Refer to the organizational charts and job descriptions.

All employees have the organizational responsibility and authority to

a. Initiate action to prevent the occurrence of any nonconformity
b. Identify and record any problems
c. Recommend, provide, and verify solutions
d. Control further processing and delivery of nonconforming products until the deficiency or unsatisfactory condition has been corrected

Personnel responsible for quality have the authority to stop production, and, if necessary, to correct quality problems (nonconforming parts from suppliers, equipment malfunction, missing engineering documents, lack of appropriate tools, unsafe conditions, etc.).

#### *5.5.1.1 Responsibility for Quality (TS)*

Departmental managers with the responsibility and authority for corrective actions are promptly informed about products or processes that do not conform to requirements through corrective actions or internal memorandums.

Personnel responsible for quality have the authority to stop production to correct quality problems.

Production operations across all shifts are staffed with personnel in charge of or delegated responsibility for ensuring product quality.

#### *5.5.2 Management Representative*

The quality system manager is the appointed management representative and has the responsibility and authority to

a. Ensure that processes of the quality management system are established, implemented, and maintained
b. Report to top management on the performance of the quality management system, including needs for improvement
c. Promote awareness of customer requirements throughout the organization
d. Liaise with external parties on matters relating to the quality management system

##### *5.5.2.1 Customer Representative (TS)*

The quality manager and the manufacturing/engineering team are designated as customer representative personnel with responsibility and authority to address quality requirements, including selection of special characteristics, setting quality objectives, related training, corrective and preventive actions, and product design and development.

#### *5.5.3 Internal Communications*

Internal communication processes are established within the company. The processes of the quality management system and its effectiveness are communicated to all levels and functions.

### 5.6 Management Review

#### *5.6.1 General*

The quality management system is reviewed at planned intervals to ensure its continuing suitability, adequacy, and effectiveness. The management review includes assessing opportunities for improvement and evaluates the need for changing the organization's quality

management system, including the quality policy and its objectives. The management review consists of monthly reviews of quality objectives and metrics (performance metrics, key performance indicators [KPIs], quality road map metrics), as well as the revision of the quality management system of which its processes are conducted a minimum of twice a year. Also, business planning includes revision of some processes of the QMS.

Records of these reviews are maintained.

#### *5.6.1.1 Quality Management System Performance (TS)*

The management reviews include all elements of the quality management system and its performance trends as an essential part of the continual improvement process. These reviews monitor quality objectives, report, and evaluate the cost of poor quality.

Management review records provide the evidence of the achievement of

a. The objectives specified in the business plan
b. Customer satisfaction with products supplied

### *5.6.2 Review Input*

Inputs to management review include current performance and improvement opportunities related to the following:

a. Results of audits
b. Customer feedback
c. Process performance and product conformance
d. Status of preventive and corrective actions
e. Follow-up actions from earlier management reviews
f. Changes that could affect the quality management system
g. Recommendations for improvement

#### *5.6.2.1 Review Input—Supplemental (TS)*

Input to management review includes an analysis of actual and potential field failures and their impact on quality, safety, and environment.

#### *5.6.3 Review Output*

The outputs from the quality management review are recorded and include actions related to

a. Improvement of effectiveness of the quality management system and its processes
b. Improvement of a product related to customer requirements
c. Resource needs

## 6. RESOURCE MANAGEMENT

### 6.1 Provision of Resources

The company determines and provides, in a timely manner, the resources needed to

1. Implement and maintain the quality management system and continually improve its effectiveness
2. Identify and provide resources needed to improve customer satisfaction

### 6.2 Human Resources

#### *6.2.1 General*

Personnel performing work that affects product quality, as defined in the quality management system, are competent on the basis of applicable education, training, skills, and experience (reference to job descriptions, personnel training, and personnel summary file).

#### *6.2.2 Competency, Awareness, and Training*

The company

a. Identifies competency needs for personnel performing activities affecting product quality
b. Provides training or other actions to satisfy these needs

c. Evaluates the effectiveness of the training provided/actions taken
d. Ensures that its employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives
e. Maintains appropriate records of education, experience, training, and qualifications

#### *6.2.2.1 Product Design Skills (TS)*

The company ensures that personnel at the design locations who are responsible for product design are competent to achieve design requirements and are skilled in applicable tools and techniques.

#### *6.2.2.2 Training (TS)*

The company documents procedures for identifying training needs and achieving competence of all personnel performing activities affecting product quality. Personnel performing specific assigned tasks are qualified on the basis of education, training, skills, and/or experience, as required, with particular attention to the satisfaction of customer-specific requirements. This applies to all employees having an effect on quality at all levels of the organization.

#### *6.2.2.3 Training on the Job (TS)*

The company provides on-the-job training for personnel in new or modified jobs affecting product quality, including contract or agency personnel. Personnel are informed of the consequences of the customer orders that are overdue and to the nonconformities to quality requirements.

#### *6.2.2.4 Employee Motivation and Empowerment (TS)*

The company has a process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment that promotes innovation. This process includes the promotion of quality and technological awareness throughout the company.

There is a process that measures the extent to which personnel are aware of the relevance and importance of their activities as well as how they contribute to the achievement of the quality objectives.

## 6.3 Infrastructure

The company determines, provides, and maintains the facilities it needs to achieve conformity to product requirements, including:

1. Building, work space, and associated facilities
2. Process equipment, both hardware and software
3. Supporting services

### *6.3.1 Plant, Facility, and Equipment Planning (TS)*

The company uses a multidisciplinary approach for developing plant, facility, and equipment plans. Plant layouts optimize material travel, handling, and value-added use of floor space. The layout promotes synchronous material flow. The effectiveness of the existing operations is continuously monitored through implementation of new methods based on Lean manufacturing principles (Lean Six Sigma) linked to the effectiveness of the quality management system.

### *6.3.2 Contingency Plans (TS)*

In the event of an emergency such as utility interruptions, labor shortages, key equipment failures, and field returns, the company prepares contingency plans to satisfy customer requirements.

## 6.4 Work Environment

The company identifies and manages the work environment needed to achieve conformity of product according to ISO 14001-based environmental management system procedures.

### *6.4.1 Personnel Safety (TS)*

Product safety and means to minimize potential risks to employees are addressed by the company, especially in the design and development process as well as in the manufacturing process activities.

#### *6.4.2 Cleanliness of Premises (TS)*

The company maintains its premises in a state of order, cleanliness, and repair through implementation of the 5S (sort, straighten or set in order, shine, standardize, sustain).

## 7. PRODUCT REALIZATION

### 7.1 Planning of Product Realization

The company plans and develops the processes needed for product realization.

The planning of product realization is consistent with requirements of the processes of the quality management system.

In planning processes of realization of product, the company determines the following, as appropriate:

a. Quality objectives and specifications for the product or contract
b. The need to establish processes and documents and provide resources and facilities specific to the product
c. Verification, validation, monitoring, inspection and test activities, and the criteria for acceptability
d. The records needed to provide confidence of conformity of the processes and resulting product

#### *7.1.1 Planning of Product Realization—Supplemental (TS)*

While planning "product realization" as a component of the overall quality plan, customer requirements and references to its technical specifications are included.

#### *7.1.2 Acceptance Criteria (TS)*

The company has defined acceptance criteria for all incoming, in-process, and outgoing products. The customer, when required, approves these criteria. For attribute data sampling, acceptance of criteria is zero defects.

#### *7.1.3 Confidentiality (TS)*

The company ensures the confidentiality of customer-contracted products and projects under development, including the related product information.

#### *7.1.4 Change Control (TS)*

The company impacts product realization, including the changes initiated by it. Effects of all changes are assessed. Verification and validation activities are defined to ensure compliance with customer requirements. All changes are validated before implementation.

For proprietary designs, impact on form, fit, performance functions, and/or durability is reviewed with the customer so that all effects can be properly evaluated.

When required by the customer, additional verification/identification requirements are met.

### 7.2 Customer-Related Processes

#### *7.2.1 Determination of Requirements Related to Product*

The company determines the following:

a. Requirements specified by the customer, including the requirements for delivery and postdelivery activities
b. Requirements not stated by the customer but necessary for specified use or intended use where known
c. Statutory and regulatory requirements related to the product
d. Any additional requirements determined by the company

##### *7.2.2.1 Customer-Designated Special Characteristics (TS)*

The company demonstrates conformity to customer requirements for designation, documentation, and control of special characteristics.

#### *7.2.2 Review of Requirements Related to the Product*

The company reviews the requirements related to the product. The reviews are conducted before the company commits to supply a product to the

customer (e.g., submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures the following:

a. Product requirements are defined.
b. Contract or order requirements, differing from those previously expressed, are resolved.
c. The company has the ability to meet defined requirements.

Records of the results of the review and resulting actions are kept.

When the customer provides no documented statement of requirements, the customer requirements are confirmed by the company before acceptance.

When product requirements are changed, the company ensures that relevant documents are amended and relevant personnel are made aware of the changed requirements.

*7.2.2.1 Review of Product Related Requirement—Supplemental (TS)*

The company asks for customer authorization in case a waiver is required for the requirement in Section 7.2.2.

*7.2.2.2 Organization Manufacturing Feasibility (TS)*

The company investigates, confirms, and documents the manufacturing feasibility of the proposed products. Necessary risk analysis is also carried out, where applicable.

### *7.2.3 Customer Communications*

Arrangements for customer communication are established. These relate to

a. Product information
b. Inquiries, contracts, or order handling, including amendments
c. Customer feedback, including customer complaints

*7.2.3.1 Customer Communications—Supplemental (TS)*

The company has the resources, means, and ability to communicate necessary information, including data, in customer-specified language and format like computer-aided design (CAD) and electronic data exchange.

## 7.3 DESIGN AND DEVELOPMENT

The design functions are centralized at divisional headquarters. These centers are either certified in ISO 9001:2000 or ISO/TS 16949:2002.

### *7.3.1 Design and Development Planning*

Plan and control of the design and development of the product is performed through the PRO-Launch System. This system allows business units to manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. It determines

a. The design and development stages
b. The review, verification, and validation appropriate to each design and development stage
c. The responsibility and authority for the people doing this work

Planning output is updated as the design and development activity progresses.

#### *7.3.1.1 Multidisciplinary Approach (TS)*

The company uses a multidisciplinary approach for product realization that includes:

a. Development/finalization and monitoring of special characteristics
b. Development and review of FMEA including actions to reduce potential risks
c. Development and review of control plans

### *7.3.2 Design and Development Inputs*

Inputs relating to product are determined; the records are maintained and they include:

a. Functional and performance requirements
b. Applicable statutory and regulatory requirements

c. Pertinent information from similar designs, if it is applicable
d. Other requirements essential for design and development

The inputs are reviewed for adequacy and the requirements are completed.

*7.3.2.1 Product Design Input (TS)*

This section is outside the scope of this manual.

*7.3.2.2 Manufacturing Process Design Input (TS)*

The company identifies, documents, and reviews manufacturing process design input requirements including:

a. Product design output data
b. Targets for productivity, process capability, and cost
c. Customer requirements, if any
d. Experience from previous developments
e. Error-proofing methods depending on magnitude of problems

*7.3.2.3 Special Characteristics (TS)*

The company identifies special characteristics and

a. Includes all special characteristics in the control plan
b. Where applicable, complies with customer-specified symbols and definitions
c. Identifies process control documents including drawings, FMEA, control plans, and operator instructions with them

### *7.3.3 Design and Development Outputs*

The outputs of design and development are approved prior to release and are provided in a form that enables verification against the design and development input.

The output of design and development includes:

a. Enough information to verify that meets input requirements for design and development

b. The information needed to purchase component materials, manufacture the product, and service the product
c. Contain or reference product acceptance criteria
d. Product characteristics essential for its safe and proper use

*7.3.3.1 Product Design Outputs—Supplemental (TS)*

This section is outside the scope of this manual.

*7.3.3.2 Manufacturing Process Design Output (TS)*

Manufacturing process design output is expressed in terms that can be verified and validated against manufacturing process input requirements. Manufacturing process design output includes:

a. Specifications and drawings
b. Manufacturing process flow chart/layout
c. Manufacturing process FMEA
d. Control plan
e. Work instructions
f. Process approval acceptance criteria
g. Data for quality, reliability, maintainability, and measurability
h. Results of error-proofing activities, as applicable
i. Methods of rapid detection and feedback of product/process nonconformities

### *7.3.4 Design and Development Review*

Systematic reviews of design and development are performed in accordance with PRO-Launch System to

a. Evaluate the ability of the results of design and development to meet requirements
b. Identify any problems and propose necessary actions

The participants in these reviews are representatives from each function concerned with the design and the development stage being reviewed. The records of the results of the reviews and any necessary actions are kept.

*7.3.4.1 Monitoring (TS)*

This section is outside the scope of this manual.

### *7.3.5 Design and Development Verification*

Through the PRO-Launch System the verification is performed in accordance with planned arrangements to ensure that the design and development outputs meet design and development input requirements. The records of the results of these verification activities are kept.

### *7.3.6 Design and Development Validation*

Through the PRO-Launch System the validation is performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified applications or intended use, where known. Wherever possible, the validation is performed prior to the delivery or implementation of the product. The records of the results of these validation activities are kept.

*7.3.6.1 Design and Development Validation (TS)*

This section is outside the scope of this manual.

*7.3.6.2 Prototype Program (TS)*

The company has a prototype program and a control plan. For this program, suppliers, tooling, and manufacturing processes are used that are similar to those used for existing production.

Performance testing activities are monitored for timely completion and conformance to requirements.

*7.3.6.3 Product Approval Process (TS)*

The company conforms to a product and process approval procedure recognized by the customer. This procedure is also applied to suppliers.

### *7.3.7 Control of Design and Development Changes*

Design and development changes are identified and the appropriate records are maintained. The changes are reviewed, verified, and validated, as appropriate, and approved before implementation. The review of design

and development changes includes evaluation of the effect of the changes on components and product already delivered. The records of results of this review are kept.

## 7.4 Purchasing

### *7.4.1 Purchasing Process*

Purchasing processes are controlled to ensure that the purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product are dependent upon the effect of the purchased product on subsequent product realization or the final product.

Suppliers are evaluated and selected based on their ability to supply product in accordance with the company's requirements. Criteria for the selection, evaluation, and reevaluation are established. Records of the results of evaluations and any necessary actions arising from the evaluation are kept.

#### *7.4.1.1 Regulatory Compliance (TS)*

All purchased products or materials used in the product conform to applicable regulatory requirements.

#### *7.4.1.2 Supplier Quality Management System Development (TS)*

The company performs supplier quality management system development with the goal of supplier conformity with the ISO/TS 16949. Conformity with ISO 9001:2015 is the first step in achieving this goal.

Unless otherwise specified by the customer, suppliers to the company are third-party registered to ISO 9001:2015 by an accredited third-party certification body.

#### *7.4.1.3 Customer-Approved Resources (TS)*

Where specified by the contract, the company purchases products, materials, or services from such resources; the company remains responsible for ensuring the quality of the purchased products.

### *7.4.2 Purchasing Information*

Purchased documents describe the product to be purchased, including, where appropriate:

a. Requirements for approval of product, procedures, processes, and equipment
b. Requirements for the qualification of personnel
c. Quality management system requirements

The adequacy of specified purchase requirements is ensured prior to the company's communication to the supplier.

### *7.4.3 Verification of Purchasing Product*

Inspection or other activities necessary for ensuring that the purchased product meets specified purchase requirements are established and implemented.

When the company or its customer intends to perform verification at suppliers' premises, the company facilitates the intended verification arrangements and method of product release in the purchasing information.

#### *7.4.3.1 Incoming Product Quality (TS)*

The company's processes are in place to assure the quality of purchased products utilizing one or more of the following methods:

a. Receipt and evaluation of statistical data
b. Receiving inspection using sampling plans based on performance of suppliers
c. Second- or third-party assessments or audits to supplier sites, when coupled with records of acceptable delivered product quality
d. Part evaluation by a designated laboratory
e. Any other method agreed with the customer

#### *7.4.3.2 Supplier Monitoring (TS)*

The company monitors supplier performance through the following indicators:

a. Delivered part quality (defective parts per million)
b. Customer disruptions including field returns

c. Delivery schedule performance (including incidents of premium freight)
d. Special-status customer notifications related to quality and delivery issues

The company encourages its suppliers to monitor the performance of their manufacturing processes.

## 7.5 Production and Service Provision

### *7.5.1 Control of Production and Service Provision*

As applicable, production and service provision are planned and carried out under controlled conditions, which include:

a. The availability of information that specifies the characteristics of the product
b. The availability of work instructions, as necessary
c. The use of suitable equipment
d. The availability and use of monitoring and measuring devices
e. The implementation of monitoring and measurement
f. The implementation of release, delivery, and postdelivery activities

*7.5.1.1 Control Plan (TS)*

The company has developed control plans at product, assembly, subassembly, component, and/or material levels for the product supplied. The company plans to cover three distinct phases—prototype, prelaunch, and production—to take into account the design FMEA and manufacturing process FMEA outputs.

This control plan

a. Lists the controls used for the manufacturing process control
b. Includes methods for monitoring of control over special characteristics jointly defined by the company and the customer
c. Includes the customer-required information, if any
d. Initiates the specified reaction plan when the process becomes unstable or statistically incapable

The company reviews control plans and updates them by supplying them with sources or FMEA whenever changes occur that affect product, manufacturing process, measurement, and logistics.

*7.5.1.2 Work Instructions (TS)*

The company prepares documented work instructions for all employees having responsibilities for the operation of processes that impact product quality. These instructions are accessible for use at the workstation and are derived from quality planning and product realization processes.

*7.5.1.3 Verification of Job Setups (TS)*

Whenever performed job setups are verified, such as an initial run of a job, material changeover, or job change, work instructions are available for setup personnel. The company uses statistical methods of verification where defined by the control plan.

*7.5.1.4 Preventive and Predictive Maintenance (TS)*

The company identifies key process equipment, provides resources for machine/equipment maintenance, and develops an effective planned total preventive maintenance system. As a minimum, this system includes the following:

a. Planned maintenance activities
b. Packaging and preservation of equipment, tooling, and gauging
c. Availability of replacement parts for key manufacturing equipment
d. Documenting, evaluating, and improving maintenance objectives

The company uses predictive maintenance methods to continually improve the effectiveness and efficiency of production equipment.

*7.5.1.5 Management of Production Tooling (TS)*

The company provides resources for tool and gauge design, fabrication, and verification activities per the following production tooling management system:

a. Maintenance and repair facilities and personnel
b. Storage and recovery
c. Setups
d. Tool-change programs for perishable tools

e. Tool design modification documentation and engineering change level
f. Tool modification and revision to documentation
g. Tool identification, defining the status such as production, repair, or disposal

In cases where such activities are outsourced, the company has a system to monitor such activities.

*7.5.1.6 Production Scheduling (TS)*

The company has processes in place for production scheduling in order to meet on-time delivery requirements of the customer that permit access to production information to the customer that are order driven.

*7.5.1.7 Feedback of Information from Service (TS)*

The company has a process to communicate information on "service concerns" to manufacturing, engineering, and design activities through customer complaints/returns.

*7.5.1.8 Servicing Agreements with Customers (TS)*

Presently, there are no service provision agreements between the company and its customers.

### *7.5.2 Validation of Processes and Service Provision*

The company validates any processes for production and service provision where the resulting outputs cannot be verified by subsequent measurement or monitoring. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

As applicable, validation demonstrates the ability of the processes to achieve the planned results. Arrangements are established for validation, including the following:

a. Defined criteria for review and approval of processes
b. Approval of equipment and qualification of personnel
c. Use of specific methods and procedures
d. Requirements for records
e. Revalidation

*7.5.2.1 Validation of Processes for Production and Service Provision—Supplemental (TS)*

The requirements of Section 7.5.2 apply to all processes for production and service provision.

### *7.5.3 Identification and Traceability*

Where appropriate, the product is identified by suitable means throughout product realization.

The status of the product is identified with respect to monitoring and measurement requirements.

If traceability is a customer requirement, the unique identification of the product is controlled and recorded.

*7.5.3.1 Identification and Traceability—Supplemental (TS)*

The words "where appropriate" do not apply to Section 7.5.3.

### *7.5.4 Customer Property*

Customer property, provided for use or incorporation into the product, is identified, verified, protected, and safeguarded. Any customer property that is lost, damaged, or otherwise found to be unsuitable for use is reported to the customer and records are kept.

*7.5.4.1 Customer-Owned Production Tooling (TS)*

Customer-owned tools, for manufacturing, for testing, or for inspection, and other equipment are permanently marked so that the ownership of each item is visible and can be determined.

### *7.5.5 Preservation of Product*

The conformity of a product is preserved during internal processing and delivery to the intended destination. This includes identification, handling, packaging, storage, and protection. Constituent parts of a product are included.

*7.5.5.1 Storage and Inventory (TS)*

The condition of the product in stock is assessed at appropriate planned intervals. The company has a first in/first out (FIFO) inventory

management system. Obsolete products are treated as nonconforming products.

## 7.6 Control of Measuring and Monitoring Devices

Monitoring and measurements are to be undertaken. The measuring and monitoring devices need to provide evidence of conformity of the product.

Processes to ensure that monitoring and measuring can and will be carried out in a manner that is consistent with the monitoring and measuring requirements are established. Where necessary to assure valid results, measuring devices are

a. Calibrated or verified at specified intervals or prior to use, against measurement standards traceable to international or national standards (where no such standard exists, the basis used for calibration or verification is recorded)
b. Adjusted or readjusted as necessary
c. Identified to enable the calibration status to be determined
d. Safeguarded from adjustments that would invalidate measurement results
e. Protected from damage and deterioration during handling and storage

When the equipment is found not to conform to the requirements, the validity of the previous measuring results is assessed and recorded. The company takes appropriate action on the equipment and any products affected. Records of the results of calibration and verification are maintained.

The ability of software used to satisfy the intended application is confirmed prior to initial use and reconfirmed as necessary for measuring and monitoring specified requirements.

### *7.6.1 Measurement System Analysis (TS)*

Statistical studies are conducted on each type of measuring and testing equipment mentioned in the control plan. The methods of analysis and acceptance criteria used conform to those in customer reference manuals

on measurement system equipment. Other analytical methods and acceptance criteria may be used if approved by the customer.

### *7.6.2 Calibration/Verification Records (TS)*

Records of the calibration/verification activity for all gauges and measuring and testing equipment are needed to provide evidence of conformity of products. Applicable requirements are kept and include:

a. Equipment identification and applicable measurement standards against which the equipment is calibrated
b. Revisions following engineering changes
c. Any out-of-specification readings as received for calibration/verification
d. An assessment of the impact of out-of-specification condition
e. Statements of conformity to specification after calibration/verification
f. Notification to the customer if suspect product or material has been shipped

### *7.6.3 Laboratory Requirements (TS)*

#### *7.6.3.1 Internal Laboratory (Metrology Laboratory) (TS)*

The internal laboratory has a defined scope that includes its capability to perform the required inspection, test, and calibration services. The laboratory scope is included in this quality management system documentation. It specifies and implements technical requirements for

a. Adequacy of the laboratory procedures
b. Qualification of laboratory personnel conducting measurements and tests
c. Testing of parts and materials
d. Capability to perform tests traceable to the current process standard
e. Review of the related quality records

#### *7.6.3.2 External Laboratory (TS)*

The company ensures that in cases where external/commercial/independent laboratories are used, such laboratories will have a defined laboratory

scope that includes the capability to perform the required inspection, test, or calibration and either

a. Is accredited to ISO/IEC 17025, or national equivalent

or

b. Has evidence that the laboratory is acceptable to the customer

## 8. MEASUREMENT, ANALYSIS, AND IMPROVEMENT

### 8.1 General

The company plans and implements the monitoring, measurement, analysis, and improvement processes needed to

a. Demonstrate conformity of the product
b. Ensure conformity of the quality management system
c. Continually improve the effectiveness of the quality management system

The need for and use of applicable methods, including statistical techniques, has been determined.

#### *8.1.1 Identification of Statistical Tools (TS)*

Appropriate statistical tools for each process are determined during advanced quality planning and are included in the control plan.

#### *8.1.2 Knowledge of Basic Statistical Concepts (TS)*

Basic statistical concepts, such as variation, control (stability), process capability, and overadjustment are understood and utilized by applicable personnel involved in the quality management system.

## 8.2 Monitoring and Measurement

### *8.2.1 Customer Satisfaction*

Information relating to customer perception as to whether the company has met customer requirements is monitored as one of the measurements of performance in the quality management system. The methods for obtaining and using this information are determined for both external and internal customers.

*8.2.1.1 Customer Satisfaction—Supplemental (TS)*

Customer satisfaction is monitored through continual evaluation of performance of the realization processes. Performance indicators are based on objective data and include but are not limited to

a. Delivered product/part quality performance
b. Customer disruptions including field returns
c. Delivery schedule performance (including incidents of premium freight)
d. Customer notifications related to quality or delivery issues

The company monitors the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and efficiency of the process.

### *8.2.2 Internal Audit*

Internal audits are conducted at planned intervals to determine whether the quality management system

a. Conforms to the planned arrangements, to the requirements of ISO 9001, and to the quality management system requirements
b. Is effectively implemented and maintained

The audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods are defined. Selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Auditors do not audit their own work.

Documented procedures define the responsibilities and requirements for planning, conducting, and reporting the results as well as maintaining audit reports.

Management responsible for the area being audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up actions include the verification of the actions taken and the reporting of verification results.

#### *8.2.2.1 Quality Management System Audit (TS)*

The company audits its quality management system to verify compliance with ISO/TS 16949 and any additional quality management system requirements.

#### *8.2.2.2 Manufacturing Process Audit (TS)*

The company audits each manufacturing process to determine its effectiveness.

#### *8.2.2.3 Product Audit (TS)*

The company audits products at appropriate stages of production and delivery to verify conformity to all specified requirements, such as dimensions, functionality, packaging, and labeling, at a defined frequency.

#### *8.2.2.4 Internal Audit Plans (TS)*

Internal audits cover all quality management related processes, activities, and shifts. The audits are scheduled according to an annual plan.

Audit frequency is appropriately increased when internal/external nonconformities or customer complaints occur. Each audit uses a specific checklist/approach.

#### *8.2.2.5 Internal Auditor Qualification (TS)*

The company ensures that its internal auditors are qualified to audit the requirements of ISO/TS 16949.

### *8.2.3 Monitoring and Measuring Processes*

Suitable methods are used for monitoring and, where applicable, measuring the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When

planned results are not achieved, correction and corrective actions take place accordingly to ensure conformity of the product.

*8.2.3.1 Monitoring and Measuring of Manufacturing Processes (TS)*

Process studies on all new manufacturing processes, including assembly, are performed to verify process capability and to provide input for process control. These results are documented with specifications, where applicable, for means of production, measurements, tests, and maintenance instructions. They also contain objectives for manufacturing process capability, reliability, maintainability, availability, and acceptance criteria.

The manufacturing process capability, or performance as specified by the customer part approval process requirements, is maintained. The control plan and flow diagrams are implemented while adhering to the specified

a. Measurement techniques
b. Sampling plans
c. Acceptance criteria
d. Reaction plans when acceptance criteria are not met

Significant process events like tool change, machine repair, etc. are recorded. The company initiates a reaction plan from the control plan for characteristics that are either not statistically capable or are unstable. These reaction plans include containment of product and 100% inspection as appropriate. To assure that the process becomes stable and capable, a corrective action plan is completed, indicating specific timing and assigned responsibilities. The plans are reviewed with and are approved by the customer when so required.

The effective dates of process changes are recorded, as appropriate.

### *8.2.4 Monitoring and Measurement of Product*

Characteristics of the product are monitored and measured to verify that product requirements are met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

Evidence of conformity with the acceptance criteria is kept. Records indicate the person(s) authorizing release of the product.

A product release does not proceed until all the planned arrangements have been satisfactorily completed unless otherwise approved by a relevant authority and, where applicable, by the customer.

*8.2.4.1 Layout Inspection and Functional Testing (TS)*

As applicable, layout inspection (a complete measurement of all part dimensions shown on the design records), functional verification to customer engineering material, and performance standards are performed for the control plan. Results are available for customer review.

*8.2.4.2 Appearance Items (TS)*

The company does not manufacture parts designated by the customer as "appearance items."

## 8.3 Control of Nonconforming Product

Products that do not conform to requirements are identified and controlled to prevent unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming products are defined in documented procedure(s).

A nonconforming product is dealt with in one or more of the following ways:

a. Taking action to eliminate the detected nonconformity
b. Authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer
c. Taking action to preclude its original intended use or application

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are kept.

When a nonconforming product is corrected, it is subject to reverification to demonstrate conformity to the requirements.

When a nonconforming product is detected after delivery or use has started, appropriate action is taken to avoid effects, or potential effects, of the nonconformity.

#### *8.3.1 Control of Nonconforming Product—Supplemental (TS)*

A product with an unidentified or suspect status is classified as a nonconforming product.

#### *8.3.2 Control of Reworked Product (TS)*

Instructions for rework, including reinspection requirements, are accessible to and utilized by the appropriate personnel.

#### *8.3.3 Customer Information (TS)*

Customers are informed promptly in the event that a nonconforming product has been shipped.

#### *8.3.4 Customer Waiver (TS)*

A deviation permit or a customer concession is obtained before processing a product (including a purchased product) or a manufacturing process that is different from that currently approved.

A record of the expiration date or quantity of such waivers is maintained. Once the waiver has expired, original specifications and requirements are fulfilled. Material shipped on an authorization is identified on each shipping container.

### 8.4 Analysis of Data

Appropriate data are determined, collected, and analyzed to demonstrate the suitability and effectiveness of the quality management system as well as to evaluate where continual improvements of the effectiveness of the quality management system can be made. This information is collected through Six Sigma DMAIC (define, measure, analyze, improve, and control) process. This includes data generated by monitoring and measurement and from other relevant sources.

These data are analyzed to provide information on

a. Customer satisfaction
b. Conformity to product requirements

c. Characteristics and trends of processes and product including opportunities for preventive action
d. Suppliers

### *8.4.1 Analysis and Use of the Data (TS)*

Trends in quality and operational performance are compared with progress toward objectives and lead to action to support

a. Developing priorities for prompt solutions to customer-related problems
b. Determination of key-customer-related trends and correlation of status review, decision making and long-term planning
c. Developing an information system for the timely reporting of product information arising from usage. (Such data become a basis for competitor/appropriate benchmarks.)

## 8.5 Improvement

### *8.5.1 Continual Improvement*

The effectiveness of the quality management system is continually improved by implementing the company's initiatives through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management reviews.

#### *8.5.1.1 Continual Improvement of the Organization (TS)*

The company has implemented a process for continual organizational improvement called Lean Six Sigma.

#### *8.5.1.2 Manufacturing Process Improvement (TS)*

Through continually improving objectives for process capabilities, for the incoming materials, test yield improvement through root cause analysis of test failures of various products, operating equipment efficiency for key production equipment, and quality planning, the company focuses upon control and reduction of variation in product characteristics and manufacturing process parameters.

### *8.5.2 Corrective Action*

Action is taken to eliminate the cause of nonconformities in order to prevent recurrence. Corrective action is appropriate to the effects of the nonconformities encountered.

Procedures define requirements for

a. Reviewing nonconformities (including customer complaints)
b. Determining the causes of nonconformities
c. Evaluating the need for action to ensure that nonconformities do not recur
d. Determining and implementing action needed
e. Records of the results of action taken
f. Reviewing corrective action taken

#### *8.5.2.1 Problem Solving (TS)*

The company has implemented a problem-solving process leading to root cause identification and elimination. If a customer-prescribed problem-solving format exists, the company will use the prescribed format.

#### *8.5.2.2 Error Proofing (TS)*

The company uses error-proofing methods in its corrective action process.

#### *8.5.2.3 Corrective Action Impact (TS)*

The corrective action and controls implemented to eliminate the cause of nonconformity are applied to other similar processes and products.

#### *8.5.2.4 Rejected Product Test/Analysis (TS)*

The company analyzes products rejected by customers and dealerships. Records of such analysis are kept and made available upon request. Corrective actions are performed to prevent recurrence.

Cycle time, related to rejected product analysis, is kept consistent with determination of root cause of corrective action and monitoring effectiveness of the implementation.

### *8.5.3 Preventive Action*

Action to eliminate the causes of potential nonconformities in order to prevent occurrence is determined. Preventive actions are appropriate to the impact of the potential problems.

The documented procedure for preventative action defines requirements for

a. Determining potential nonconformities and their causes
b. Evaluating the need for action to prevent occurrence of nonconformities
c. Determining and implementing action needed
d. Records of results of action taken
e. Reviewing preventive action taken

# Glossary

**5S:** Five Japanese words that begin with the letter "s." The words as translated in English as sort (*seiri*), straighten or set in order (*seiton*), shine (*seso*), standardize (*seiketsu*), and sustain (*shitsuke*); together they mean orderly, well organized, well inspected, clean, and efficient workplaces.

**5-Whys:** A simple process of determining the root cause of a problem by asking "why" after each situation to drive deeper into more detail to arrive at the root cause of an issue.

**7 Wastes:** Originally identified by Taiichi Ohno, these are (1) overproduction, (2) waiting, (3) transportation, (4) overprocessing, (5) stock on hand, (6) movement, and (7) making a defective product.

**8D:** A popular method for problem solving because it is reasonably easy to teach and effective. The 8D steps and tools used are as follows:

**D0:** Prepare for the 8D
**D1:** Form a team
**D2:** Describe the problem
**D3:** Interim containment action
**D4:** RCA (root cause analysis) and escape point
**D5:** Permanent corrective action
**D6:** Implement and validate
**D7:** Prevention
**D8:** Closure and team celebration

This process is known as global 8D by Ford.

**A3:** A report prepared on 11- × 17-inch plain paper by the owner of the issue. The plan–do–check–act (PDCA) format is used. It gathers current information and its analysis, creates goals and metrics, and builds buy-in from stakeholders.

**Andon:** A Japanese word meaning light or lantern. It is a form of communication for an abnormal condition or a machine malfunction. It often resembles a stop traffic light where red = stop, yellow = caution, and green = go. Another form can be an andon cord, which is pulled by the operator to communicate an abnormal situation.

**AS 9100:** A widely adopted and standardized quality management system for the aerospace industry.

**BE:** Business excellence.

**Black belt:** A professional who can explain and practice Six Sigma philosophies and principles, including supporting systems and tools.

**BPR:** Business process reengineering is the analysis and redesign of work flow within and between enterprises. BPR reached its maximum popularity in the early 1990s.

**Budget:** An estimate of costs, revenues, and resources over a specified period, reflecting a reading of future financial conditions and goals.

**CA:** Corrective action taken to eliminate the cause of the nonconformity.

**Cause and effect diagram:** A diagram-based technique that helps identify all of the likely causes of the problems faced in working environments.

**Changeover:** Setting up a machine or production line to make a different part number or product.

**Changeover time:** The time from the last good piece of the current production run to the first good piece of the next run.

**Constraint:** Anything that limits a system from achieving higher performance; also called bottleneck.

**Continual improvement:** "Continual" indicates duration of improvement that continues over a long period of time, but with intervals of interruption (e.g., a plant modification disrupted by logistics/traffic for nearly 2 years).

**Continuous improvement:** An approach of making frequent and small changes to a process whose cumulative results lead to higher levels of quality, cost, and efficiency.

**Countermeasure:** Corrective action taken to address problems or abnormalities.

**Customer:** Party that receives or consumes products (goods or services) and has the ability to choose between different products.

**Cycle:** A sequence of operations repeated regularly.

**Cycle time:** The time for one sequence of operations to occur.

**Effectiveness:** The degree to which objectives are achieved and the extent to which targeted problems are solved. In contrast to efficiency, effectiveness is determined without reference to costs and, whereas efficiency means "doing the thing right," effectiveness means "doing the right thing."

**EFQM:** European Foundation for Quality Management.

**Equipment availability:** The percentage of time equipment (or process) is available to run. This is sometimes called "uptime."

**Error proofing:** See poka-yoke.

**External setup:** Procedures that can be performed while a machine is running.

**FAI:** First article inspection.

**FIFO:** First in, first out; in other words, material produced by one process is consumed in the same order (FIFO) by the next process.

**Fishbone diagram:** Identifies many possible causes for an effect or problem. It can be used to structure a brainstorming session. It immediately sorts ideas into useful categories. Major categories of causes of the problem are methods, machines (equipment), people (manpower), materials, measurement, and environment.

**Flow:** The completion of steps within a value stream so that product or service "flows" without waste from the beginning of the value stream to the customer.

**Flow production:** See flow.

**FMEA:** Failure mode and effects analysis. A step-by-step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service. "Failure mode" means the way, or mode, in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual. "Effects analysis" refers to studying the consequences of those failures.

**FPY:** First pass yield is defined as the number of units coming out of a process divided by the number of units going into that process over a specified period of time. Only good units with no rework are counted as coming out of an individual process. Also known as TPY (throughput yield).

**Gemba:** A Japanese word meaning "real place," where action takes place: a shop floor or work areas.

**Gemba walk:** A walk carried out by a coach (a Lean sensei) and student or students to look for abnormal conditions, waste, or opportunities for improvement.

**Heijunka:** A method for leveling production for mix and volume.

**Hoshin kanri:** A strategic decision-making tool used for policy deployment.

**Internal setup:** Procedures that must be performed while the machine is stopped.

**Ishikawa diagram:** See fishbone diagram.

**Jidoka:** A device that stops production or equipment when a defective condition arises. Attention is drawn to this condition and the

operator who stopped the production. The jidoka system has faith in the operator who is trained in the job.

**Just in time (JIT):** Originally developed by the TPS (Toyota production system). JIT presupposes that all waste is eliminated from the production line and only the inventory in the right quantity and at the right time is used for the production where the rate of production is exactly as required by the customer.

**Kaikaku:** A Japanese word meaning innovation or a radical breakthrough. Kaikaku requires radical thinking and takes more time in planning and implementation.

**Kaizen:** A Japanese word meaning change for the better or doing good. It is a process of making continual improvements by everyone keeping quality and safety in mind.

**Kaizen event:** A short, team-based improvement project. Also called kaizen blitz.

**Kanban:** Means "signboard" or a label. It serves as an instruction for production and replenishment.

**KCC:** Key critical characteristic.

**KPC:** Key performance characteristic.

**KPI:** Key performance indicator.

**Lead time:** Time required to move one piece from the time that the order is taken until it is shipped to the customer.

**Line balancing:** A technique where all operations are evenly balanced and staffing is also balanced to meet the takt time.

**Materials requirement planning (MRP):** A computerized system of determining quantity and timing requirements for production and delivery of products for customers as well as suppliers; this is a push production system.

**Manufacturing resource planning (MRP II):** An MRP but takes into consideration the capacity planning and finance requirement. It works out alternative production plans through the simulation tool.

**MBNQA:** Malcolm Baldrige National Quality Award, which is given to an organization for achieving highest quality standards.

**Milk run:** The routing of supply and delivery trucks and vehicles to make multiple pickups and deliveries at various locations to reduce transportation waste.

**Muda:** Japanese word for waste; an element that does not add value to the product or service. Also known as no-value-added activity

carried out on a product or service that does not add value and the customer will not pay for it.

**Mura:** Japanese word for variability or unevenness.

**Muri:** Japanese word for physical and mental strain or overburden.

**One (single) piece flow:** Practiced in a JIT system; one workpiece flows from process to process to minimize waste.

**Operational excellence (Opex):** An element of organizational initiative that stresses the application of a variety of principles, systems, and tools toward the sustainable improvement of key performance metrics. This philosophy is based on continuous improvement, such as the quality management system, Lean manufacturing, and Six Sigma. Operational excellence goes beyond the traditional methods of improvement and leads to a long-term change in organizational culture.

**Overall equipment effectiveness (OEE):** A product of the following key measures: (1) operational availability, (2) performance efficiency, and (3) first pass yield quality.

**PAIP:** A process for performance analysis and improvement.

**PCP:** Process control plan.

**PDCA:** Plan–do–check–act cycle for continual improvement.

**PFMEA:** Potential failure mode effect analysis.

**Point-of-use storage (POUS):** Storing or keeping materials, tools, information and items near to where they are used.

**Poka-yoke:** Also known as "mistake proofing." "Poka" in Japanese means inadvertent mistake and "yoke" means prevention. These can range from simple, low-cost devices to sophisticated electromechanical devices to prevent production of defective products.

**Process:** Sequence of interdependent and linked procedures that, at every stage, consume one or more resources (employee time, energy, machines, money) to convert inputs (data, material, parts, etc.) into outputs. These outputs then serve as inputs for the next stage until a known goal or end result is reached.

**Productivity:** Measured as an output for a given input. Productivity increase is critical to improving living standards.

**Product realization:** Term used to describe the work that the organization goes through to develop, manufacture, and deliver the finished product or service to the customer.

**Pull:** Alternatively known as pull production, where the upstream supplier does not produce until the downstream customer signals the need.

**Push:** Alternatively known as push production, where the upstream supplier produces as much as it can whether or not the downstream customer needs it.

**QOS:** Quality operating system originally implemented by Ford. The methodology was established to measure the effectiveness of the quality system and to drive continuous improvement.

**RPN:** Risk priority number**.** In FMEA, RPN = severity × occurrence × detection.

**RTY:** Rolled throughput yield; probability that a single piece will pass through all production steps without a single defect.

**Shadow board:** A board where each tool has a place and which tools are missing can be easily seen.

**Single minute exchange of dies (SMED):** A group of techniques developed by Shiego Shingo for changeover of production equipment in less than 10 minutes.

**SIPOC:** A process identification where the requirements for supplier, input, process steps, output, and customer are defined.

**Six Sigma:** A set of tools and techniques for process improvement originally developed by Motorola in 1981.

**Spaghetti diagram:** Shows layout and flow of information, material, and people in a work area; generally used to highlight motion and transportation waste.

**SPC:** Statistical process control is for quality control where process variations are measures and controlled.

**Standard work:** An accurate description of every process step specifying takt time, cycle time, minimum inventory needed, and sequence of each process step. The entire process is carried out with minimum human motion and other waste.

**Supermarket:** Parts storage before they go to the next operation. The parts are managed using minimum and maximum inventory levels.

**Sustainability:** Continued development or growth, without significant deterioration of the environment and depletion of natural resources on which human well-being depends.

**SWOT:** Strength, weakness, opportunity, and threat. Strength and weakness analysis guides us to identify the positives and negatives inside the organization (S–W), while opportunity and threat analysis guide us to identify positives and negatives outside it. Developing a full SWOT analysis can help with strategic planning and decision making.

**System:** The American Society for Quality (ASQ) defines system as "a group of interdependent processes and people that together perform a common mission."

**Takt time:** Available production time divided by the rate of customer demand.

**TPM:** Total productive maintenance is a system to ensure that every production process machine is able to perform its required tasks such that production is not interrupted.

**TQM:** Total quality management is a management approach that originated in the 1950s. The TQM culture requires quality in all aspects of the company's operations, with processes being done right the first time and defects and waste eradicated from operations. To be successful implementing TQM, an organization must concentrate on eight key elements: (1) ethics, (2) integrity, (3) trust, (4) training, (5) teamwork, (6) leadership, (7) recognition, and (8) communication.

**VAA:** Value-added activity.

**Value:** Capability provided to a customer at the right time at an appropriate price that is defined by the customer.

**Value stream:** Sequence of actions required to design, produce, and provide a specific good or service, along which information, materials, and worth flow.

**Visual factory:** Term to describe how data and information are conveyed to a Lean manufacturing environment. Here, time and resources dedicated to conveying information are a form of waste. By using visual methods, information is easily accessible to those who need it. Visual information makes the current status of all processes immediately apparent.

**Work in process (WIP):** Incomplete product or services awaiting further processing.

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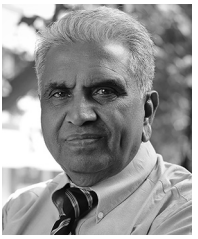
# About the Author



**Suresh Patel** is a former Technical Director and Operations Excellence Executive. He earned a BE degree in electrical engineering from M.S. University of Baroda, India, a Master's degree in production technology from South Bank University, London, and an MBA degree from the University of Texas at Brownsville, Texas, USA. He is qualified as a Certified Reliability Engineer, Certified Quality Engineer, and Certified Management Systems Auditor certified by the American Society for Quality.

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