CHAPTER 2

THEORETICAL CONSIDERATIONS

2. Theoretical Considerations

In this chapter, I have discussed the related theories that can be used and applied to the quality assurance for the distributed control system project. These include the meaning of quality, the quality management system and ISO 9000, the quality assurance system and management, the software quality assurance, the failure mode and effect analysis (FMEA), and the fault tree analysis (FTA). The details of each are as below.

2.1 The Meaning of Quality

People describe the term 'Quality' in different ways. They tend to view the 'Quality' by using different criteria based on their individual roles in the organisation. These roles include marketing, design, and manufacturing. For example, marketing people may view the quality as 'what a customer wants' whereas manufacturing people may view the quality as 'conformance to specifications'. If a dimension of a part is manufactured within the design tolerances (e.g. 0.2 ± 0.002 cm), then this part is acceptable because it conforms to the specification (Evans and Lindsay, 1996: 9-16).

Therefore it is important to understand the variations in the definition of quality. Some definitions of the term 'Quality' are shown below.

- Fitness for purpose – Dr. J M Juran
- Conformance to requirements – P Crosby
- The totality of features and characteristics that bear on the ability of a product or service to satisfy a given need – British Standard 4778
- The totality of proper characteristics or performance which are the objects of estimation to determine whether a product of service satisfies the purpose of use or not – The Japanese Industrial Standard (JIS)
- The total composite product and service characteristics of marketing, engineering, manufacture, and maintenance through which the product and service will meet the expectations of the customer – Dr. A V Feigenbaum

There are some comments about these definitions. Juran has described the quality as ' fitness for purpose'. However this may not be sufficient if a quality product or service that is fit for purpose is competing with another quality product that meets or exceeds the

expectations of the *customers*. In addition to the definition of Crosby, we believe that a product, which meets specification, is regarded as a quality product. It is important to understand that this product specification defined must also meet the requirements of the *customers*, otherwise it is meaningless (Warwick Note, Management for Quality: 1-2).

From the definitions above, we notice that in order to make a quality product we have to focus on the *customers'* expectation and satisfaction. Therefore the understanding of customers is very important. There are two kinds of customers, external customer and internal customers. Most people consider a 'customer' as the purchaser of a product. This is called an 'external customer'. Everybody in a company also has internal customers. For example the design department is an internal customer of the marketing department and the manufacturing department is an internal customer of the design department. The manager is an internal customer of his/her secretary.

Every employee in a company has to satisfy the requirements of both internal and external customers. The failure to meet requirements either internal or external customers leads to a poor quality product. Therefore the understanding of who are our customers and what are their expectations or requirements are important in order to achieve the customers' satisfaction.

2.2 The Quality Management System

Prior to discuss about the quality management system or QMS, it is better to understand the meaning of 'system' first. Regarding to Harrington and Mathers (1997: XVII), "A system is defined as the organisation structure, responsibilities, procedures, and resources needed to conduct a major function within an organisation or to support a common business need. Systems are usually made up of many major processes that take an input, add value to it, and produce an output. These processes may or may not be interconnected, such as the new product development process or the order entry process."

From the definition of a 'system' above, we see that every organisation normally has its own basic management system. This system defines the way the organisation currently operates and it may be documented formally or informally. However, to survive in the today business with high competition, it is known that the *quality* of the way the organisation operates and *quality* of its products is very important. If any organisation operates poorly or unsystematically, it is quite difficult to maintain its success in the long term. Therefore every organisation increasingly focuses on improving its current system or designing a new system.

There are four important factors that should be included in a system of any organisation and they are as below (Harrington and Mathers, 1997: XVII).

(a) Ways to prevent errors
(b) Ways to segregate good items from bad items
(c) Ways to correct bad items
(d) Ways to prevent errors from recurring

The quality management system can be simply defined as a system, including the organisational structure, procedures, processes, and resources, that is needed to implement the quality management. The quality management is the activities required to manage resources and the organisation. These activities include quality policy, quality planning, quality control, quality assurance, and quality improvement (Kriszd, 1998: 4).

The customers usually impose the quality management system requirements on their suppliers. This is used to make confidence in their suppliers' capability. It also used to ensure that their suppliers have good procedures to produce products/services and are able to provide quality products/services to them.

There are many national and international guidelines and procedures that can be used to define the elements of a quality management system that a company should have. These include MIL-Q-9858A and NATO military standards, ASME Boiler and Pressure Vessel Codes, Nuclear quality assurance standards, CSA's CAN3-Z299-1985 series, Ford's Q-101 programme, General Motor's Targets for Excellence Programme, and Chrysler's SPEAR programme (Harrington and Mathers, 1997: XX). However the most commonly used one is the ISO 9000 Series of International standards (updated in 1994) and it is discussed in the following section.

2.3 International Organisation Standard (ISO 9000)

Due to the increasing requirements of the quality organisations and businesses throughout the world to have a same common approach of the quality assurance system to evaluate their suppliers, the International Organisation for Standardisation (ISO) founded 'Technical Committee (TC) 176' in 1979. The committee team is established to define the basic requirements of the quality management system and it consists of practicing quality professionals, consultants, academicians, and standard professionals.

The ISO 9000 series of standards was released in 1987 and secondly released in 1994. These standards consisted of five important documents and they are illustrated as follows:

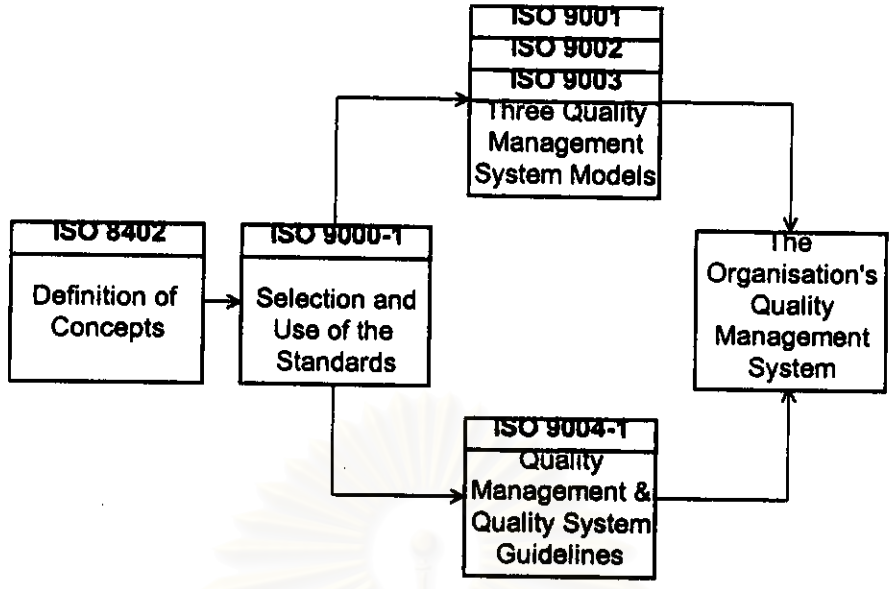


Figure 2.1 ISO 9000 Standards Structure
Adapted from ISO 9000 and Beyond by Harrington and Mathers (1997: 11).

Since the first release of the ISO 9000 series of standards in 1987, more than 100 countries have approved them as their national standard. These standards have been translated to each country's language with the new control number. For example, they have been released in Thailand as the TISI ISO 9000 series.

These ISO 9000 standards can be divided into two important parts, requirements and guidelines. The lists of the requirements and guidelines are shown as below (Harrington and Mathers. 1997: 11-13):

(a) Requirements Standards for Quality Management Systems

- Models for quality assurance

ISO 9001: In design development, installation, and customer service
ISO 9002: In production, installation, and customer service
ISO 9003: In final inspection and test

- Supporting tools and techniques

ISO10012-1: Metrological confirmation system for measuring equipment
ISO 10012-2: Control of measurement processes

(b) Guideline Standards

- Guidelines for applying and implementing quality assurance standards

ISO 9000-1: Selection and application
ISO 9000-2: Application of ISO 9001, ISO 9002, and ISO 9003
ISO 9000-3: Application of ISO 9001 to development, supply, and maintenance of software

ISO 9000-4: Application of dependability (reliability) management

- Guidelines for quality management and elements of quality management systems

ISO 9004-1: General guidelines

ISO 9004-2: Guidelines for service

ISO 9004-3: Guidelines for processed materials

ISO 9004-4: Guidelines for quality improvement

ISO 9004-8: Quality principles applied to management practices

- Supporting tools and techniques

ISO 10005: Guidelines for quality plans

ISO 10006: Quality in project management

ISO 10007: Guidelines for configuration management

ISO 10011-1: Auditing

ISO 10011-2: Qualification criteria for quality systems auditors

ISO 10011-3: Management of audit programmes

ISO 10013: Quality manuals

ISO 10014: Economic effects of quality

ISO 10015: Continuing education and training

ISO 10016: Quality documentation

2.3.1 ISO 9000-1: Guidelines for Selection and Use

This part provides an introduction and concepts of the ISO 9000 series and guides the user how to use these series. The concepts focus on three important things. These include the quality management systems, management's involvement and review, and treating work as a process. ISO 9000 standards emphasise that the work processes in a company should be defined and their procedures should be documented appropriately. Every employee in the company should perform his/her work according to written procedures. In addition, the records should be kept to check whether the defined procedures are followed or not.

2.3.2 ISO 9001, ISO 9002, and ISO 9003: Quality Systems

ISO 9001 is the model for quality assurance in various processes. These include design, development, production, installation, and servicing. This model is used to indicate that a company implementing the quality systems (ISO 9001, ISO 9002, or ISO 9003) is capable to supply quality products that meet the customer's requirements.

ISO 9001 is used for companies that have product design activities whereas ISO 9002 does not address this issue. ISO 9001 consists of 20 key elements relating to management of a quality system and these elements are listed as below.

- Management responsibility
- Quality system
- Contract review
- Design control
- Document and data control
- Purchasing
- Control of customer supplied product
- Product identification and traceability
- Process control
- Inspection and testing
- Control of inspection
- Inspection and test status
- Control of nonconforming product
- Corrective and preventive action
- Handling, storage, packaging, and delivery
- Control of quality records
- Internal quality audits
- Training
- Servicing
- Statistical techniques

From the lists above, ISO 9002 does not address on the item 'Design control'. ISO 9003 applies for companies that supply less complex products. The products of such companies can be evaluated only by inspection and testing. The differences between ISO 9001, ISO 9002, and ISO 9003 are shown on the following figure.

Cross-Reference of ISO 9000 Quality Assurance Requirements

ISO 9000 Clause and Title		Quality Assurance Requirement		
		ISO 9001	ISO 9002	ISO 9003
4.1	Management responsibility	○	○	☆
4.2	Quality system	○	○	☆
4.3	Contract review	○	○	○
4.4	Design control	○	●	●
4.5	Document and data control	○	○	○
4.6	Purchasing	○	○	●
4.7	Control of customer supplied product	○	○	○
4.8	Product identification and traceability	○	○	☆
4.9	Process control	○	○	●
4.10	Inspection and testing	○	○	☆
4.11	Control of inspection, measuring, and test equipment	○	○	○
4.12	Inspection and test status	○	○	○
4.13	Control of nonconforming product	○	○	☆
4.14	Corrective and preventive action	○	○	☆
4.15	Handling, storage, packaging, preservation, delivery	○	○	○
4.16	Control of quality records	○	○	☆
4.17	Internal quality audits	○	○	☆
4.18	Training	○	○	☆
4.19	Servicing	○	○	●
4.20	Statistical techniques	○	○	☆

Note: ○ Required ● Not Required
☆ Less stringent requirement than ISO 9001 and ISO 9002

Figure 2.2 Comparative Table of Contents for ISO 9001, 9002, and 9003
Adapted from ISO 9000 and Beyond by Harrington and Mathers (1997: 17).

Note that the elements indicated in the ISO 9000 series outline 'what should be done', without describing 'how it should be done'. Harrington and Mathers (1997: 6) have explained the differences and their interrelationships between these two things and they are as following:

'What should be done' in the ISO 9000 series includes:

- The need for leadership and involvement of management in the QMS
- The need to apply the principles of process management and control
- The need to provide some supporting-system infrastructure
- The need for ongoing process and system improvement

'How it should be done' includes:

- Primary focus on customers
- Leadership through involvement and by example
- Involvement of people
- Factual approach to decision making
- A focus on mutually beneficial supplier partnering

2.3.3 ISO 9004-1: Guidelines for Quality Management and Quality System Elements

The ISO 9004 is designed to help organisations in defining how each element could be applied to their own applications. It also addresses some issues which are not included in the ISO 9001, such as product safety and liability.

2.4 Quality Assurance System and Management

2.4.1 History of Quality Assurance

In the past, the customer judged the level of quality of a product purchased by just looking, smelling or touching at a product. The customer was also responsible for the product that he/she purchased. If problems of the products occurred, the customer had no choice but to accept that this was happened due to his/her poor judgement. However, the customer would also spread the information of poor product quality to friends or other people. The manufacturer, therefore, tried to protect these problems by trying to ensure that defective products were not delivered to the customer.

Due to the increasing pressure of the cost reduction during the past decades, the manufacturers have produced products by using the mass-production techniques. The manufacturers tried to make the customer having confidence of their products by issuing a

'warranty certificate' to the customer to ensure that the manufacturers were responsible for their defective products for a certain period. However, this is not enough to obtain the customer's trust on the product by simply compensating defective products though repair or replacement. The manufacturers considered that it was important to *establish a system* that would guarantee the product quality even after the expiry of the warranty period.

At the beginning period, an established 'quality assurance system' was focused only on the inspection process before the delivery of products. For simple products, the inspection or testing is possible and useful. However for complex products, it is necessary to focus on reviews of plans and audits of the execution of plans as well (Juran and Gryna, 1993: 566). Therefore, the focus of the QA system was moved to be all activities related to the planning and development of a product. These activities include marketing, supplier relations, planning, design, manufacture, inspection, and after-sales/service.

2.4.2 The Meaning of Quality Assurance

'Quality assurance' has been defined by the Japanese Industrial Standard (JIS) as "the systematic *activities* carried out by a manufacturer to guarantee that the quality required by the consumer is fully satisfied". Juran and Gryna (1993: 565) have defined the QA as 'the *activity* of providing the evidence needed to establish confidence, among all concerned, that the quality-related activities are being performed effectively." ISO 8402-1986 defines QA as related to a product or service: all those planned or systematic *actions* necessary to provide adequate confidence that a product of service will satisfy given requirements for quality.

The *activities* to provide assurance can be described further into two concepts as follows (Komatsu Career Creation or KCC, 1993: 1).

1. Systematic activities: to assure that manufacturer provides the customer with a sense of trust, positively and with confidence.
2. Systematic activities: to guarantee compensation in the event of a problem in the use of a product, for which the manufacturer is responsible, and to implement problem recurrence preventive measures.

Komatsu Career Creation has also indicated the major assurance items. These assurance items are divided into two important factors, safe purchase and satisfactory use. These assurance items are as follows (KCC, 1993: 5):

Items to assure a safe purchase	(1) Service/parts system that provides safety (2) Option to select the product suiting the customer's purpose (3) Better understanding of the product (4) Product meeting a social requirement (5) Reasonable conditions of warranty
Items to assure satisfactory use	(1) Good workability (2) Ease of operation (3) Ease of transportation (4) Application to various conditions (5) Safety (from pollution as well) (6) Convenience of daily check and maintenance (7) Durability with minimal failure (8) Minimal expenses (9) Good quality of appearance (10) Ease of repair in case of failure (11) Provision of instructions for use of machine (12) Good response by manufacturer/distributor

Table 2.1 Major Assurance Items

Each functional department in an organisation can perform its assurance activities. Some examples of these activities are as follows.

Marketing: Product evaluation by a test market, special surveys, and competitive evaluations

Product development: Design review, reliability analysis, and value engineering

Production: Failure mode, effect, and criticality analysis for processes

Inspection and test: Interlaboratory tests

2.4.3 Forms of Companywide Quality Assurance

Juran and Gryna (1993: 567) have divided the quality assurance into three forms : quality audits (a review of an activity), quality surveys, and product audit (a review of physical product). Each form of the quality assurance is discussed as below.

(1) Quality Audit

A quality audit is a systematic examination and evaluation conducted to determine whether the activities and results comply with planned arrangements. A quality audit can also be described as a review conducted to compare some aspect of quality performance with a standard for that performance. Note that the review should be independent in order to provide an unbiased picture of the performance. In other words, the reviewer or auditor is neither the person who is responsible for the performance under review nor the immediate supervisor of the person. Companies can use the quality audit to evaluate their own quality performance and to evaluate their suppliers.

The purpose of quality audits is to provide assurance that (Juran and Gryna, 1993 : 567):

- Products are fit for use and safe for the user
- There is conformance to specifications
- Procedures are adequate and are being followed
- Deficiencies are identified and corrective action is taken
- Opportunities for improvement are identified and the appropriate personnel alerted

The subject matter of the quality audit can be divided into four approaches. These include organisational units, product lines, quality systems, and specific activities (Juran and Gryna, 1993: 568).

In order to obtain a successful audit, it requires the coordination between three participating groups.

(a) The heads of the activities which are to be the subject of audit
(b) The heads of the auditing department(s)
(c) The upper management, which presides over both

The audit process consists of several steps. The steps and the involvement of each participating group above are shown on the table below.

	Audit department	Line department	Upper department
Discussion of purposes to be achieved by audits and general approach for conducting audits	O	O	O
Draft of policies, procedures, and other rules to be followed	O	O	
Final approval			O
Scheduling of audits	O	O	
Conduct of audits	O		
Verification of factual findings		O	
Publication of report with facts and recommendations	O		
Discusssion of reports	O	O	O
Decisions on action to be taken		O	
Subsequent follow-up	O		

Table 2.2 Steps in Structuring an Audit Programme

Adapted from Quality Planning and Analysis by Juran and Gryna (1993 : 570).

(2) Quality Surveys

The quality audit above provides the useful information whether the evaluated performance complies with the standard or not. This is an important element of the quality assurance. Quality surveys provide a *wider* view than the quality audit. Some of the examples of quality surveys are (Juran and Gryna, 1993: 578).

- Relative standing in the marketplace with regard to quality
- Analysis of users' situation with respect to cost, convenience, etc., over the life of the product
- Opportunities for reducing costs of poor quality
- Employee perceptions on quality

The quality surveys can be carried out in different ways. The examples include (Juran and Gryna, 1993: 579).

- Assessing the quality system using published criteria which emphasises quality results (Malcolm Baldrige National Quality Award)
- Assessing the quality system using published criteria which emphasises defined elements of the quality system (ISO 9000 specification)
- Assessing the quality system using criteria developed within a company for use in evaluating its own operations or its suppliers.
- Assessing the quality system for a specific assessment purpose.

(3) Product Audit

Product audit is an independent evaluation of product quality to determine its fitness for use and conformance to specification (Juran and Gryna, 1993 : 582). Product auditing performs after the inspections have been completed. The purposes of product auditing are as follows:

- Estimating the quality level as delivered to customers
- Evaluating the effectiveness of the inspection decisions in determining conformance to specifications
- Providing information useful in improving the outgoing product quality level and improving the effectiveness of inspection
- Providing additional assurance beyond routine inspection activities

From the three forms of quality assurance above, there are five ingredients which are essential for successful audits : emphasis on facts, attitude of service on the part of auditors, identification of opportunities for improvement, addressing human relations issues, and the competence of auditors.

2.5 Software Quality Assurance

Most people agree that a quality product is one that does what the customer expects it to do (fitness of purpose). The purpose for which a product is intended can be described in various ways depending on the type of products. It can be described in a user manual for simple products (hair dryer, refrigerator, etc). For software system which is quite complex, its

purpose of use is indicated in a document known as 'requirements specification' or 'system specification'.

To deliver a high quality software product, it is not enough to view only the fitness of purpose or, in other words, to do software only following to the requirements specification. There are also other important matters. For example, a software system, when implemented, satisfies function in its requirement specification but it may be highly unusable if the system has a very poor interface or is difficult to use.

The modern view of software quality assurance takes a more sophisticated view than that of fitness of purpose. A high quality software product should consist of several quality factors (often known as quality attributes). These factors are as below (Ince, 1994: 3-8).

(1) *Correctness:* a software system conforms to its requirements specification
(2) *Modifiability:* the ease with which a software system can be changed
(3) *Portability:* the effort required to transfer a system from one hardware platform to another
(4) *Testability:* the ease with which a system, or part of a system, can be tested
(5) *Usability:* the effort required to learn, operate and interrupt a functioning system
(6) *Reliability:* the ability of a software system to carry on executing with little interruption to its functioning
(7) *Efficiency:* the degree to which computing resources (file-space, memory and processor time) are used in an application
(8) *Integrity:* the extent to which the system and its data are immune to access by unauthorised users (describing the level of access allowed to the system)
(9) *Reusability:* the ease with which large parts of software in one system can be moved to another system
(10) *Interperability:* the ability of a system to operate in conjunction with another software system

Since the software programme can contain a large number of lines of programme code, it is possible that the software contains some errors. Juran and Gryna (1993 : 556-557) have recommended a programme to attack such problems. The programme consists of several elements. Each element is as following.

(1) Design Review

The purpose of the design review is to evaluate (a) the requirements for the software, (b) the software design approach, and (c) the detailed design. Since the errors usually exist during the requirements-definition and design phases, it is essential to evaluate the requirements, design approach, and detailed design as early as possible. If the errors are found at later phases, the time and costs of removing these errors increase dramatically.

Umbaugh (1991: 601) has stated the increases as ten times by the design phase, 1000 times by system acceptance, and 3000 times by actual systems production.

During the design review, it is possible to face many software errors. It is better to understand the types of software errors so that the inspection of review process is carried out effectively. Dobbins (1987: 147) have identified ten types of software defects and they are shown on the following table.

Type of defect	Definition
1) Design	Function description does not meet the requirements specification
2) Logic	Data is missing; wrong or extra information
3) Syntax	Does not adhere to the grammar of the design/code language defined
4) Standards	Does not meet the software standards requirements; this includes in-house standards, project standards, and military standards invoked in the contract
5) Data	Missing, extra, or wrong data definition or usage
6) Interface	Incompatible definition/format of information exchanged between two modules
7) Return code/message	Incorrect or missing values/messages sent
8) Prologue/comment	The explanation accompanying the design/code language is incorrect, inexplicit, or missing
9) Requirements	Change in the requirements specification which is the direct and proximate reason for the required change in the design and code
10) Performance improvement	Code will not perform in the amount of time/space/ CPU allocated

Table 2.3 Types of Software Defects

Adapted from Inspection as an Up Front Quality Technique by Dobbins (1987: 147)

(2) Documentation Review

This review emphasises the plans and procedures used to test the computer programmes. Note that the documentation of the test plan is one part of total documentation of the project.

(3) Validation of Software Tests

This is to review the results of the tests to evaluate the software. There are two kinds of software testing: static and dynamic testing. The static testing can be the document inspection or design reviews. The dynamic testing runs the programme on the computer and finds defects or weak points. The details of each testing are shown on the following table.

(4) Corrective Action System

The corrective action system for software product is similar to the system on physical products. This system includes the documentation of all software problems and actions taken to eliminate or solve problems.

(5) Configuration Management

The configuration management is the collection of activities to implement design changes. The objective is to identify different versions of the computer programmes accurately, prevent unauthorised modifications, and ensure that approved modifications are executed (Juran and Gryna, 1993: 557).

Phase	Static testing	Dynamic testing
Investigation	Document inspection	
Specification	Document inspection Cross-reference check to investigation documents	
Design specification	Design inspection Cross-reference check to documents Design analysis tools	
Code	Code inspection Style analysers Cross-reference check to design documents	Functional tests Reliability tests
System and user testing		Performance tests Configuration tests Installation tests
Release		Reliability tests Regression tests
Support	As above, by activity	As above, by activity

Table 2.4 Testing during Development Phases
Adapted from Software Reliability by Dudley (1988: 16.7-16.8)

2.6 Failure Mode and Effect Analysis (FMEA)

2.6.1 The Meaning of FMEA

A failure mode and effect analysis (FMEA) is an engineering technique used to define, identify, and eliminate known and/or potential failures, problems, errors, and so on from the system, design, process, and/or service before they reach the customer (Omdahl, 1988).

FMEA is a preventive technique which provides the users with a methodical approach for studying the causes and effects of failures *before* the system, design, process, or service is finalised. With this method, we identify all possible failures in our work process. Then we examine each failure about 'its effect on the system, design, process, or service', 'severity or seriousness', 'occurrence', and 'detection'. The product of frequency of occurrence, severity,

and detection is called 'risk priority number' or 'RPN'. We then use the RPN to prioritise the identified failures.

FMEA requires the users to identify corrective action required to prevent the identified failures or problems from reaching the hands of the customer. Therefore FMEA, if conducted appropriately, will provide the users the useful information to prevent problems from occurring in their work.

2.6.2 Types of FMEA

There are four types of FMEA. They are system FMEA, design FMEA, process FMEA, and service FMEA. The figure below illustrates their relationships.

(1) *System FMEA:* Used to analyse systems and subsystems in the early concept and design stage

(2) *Design FMEA:* Used to analyse products before the are released to manufacturing

(3) *Process FMEA:* Used to analyse manufacturing and assemble processes

(4) *Service FMEA:* Used to analyse services before they reach the customer

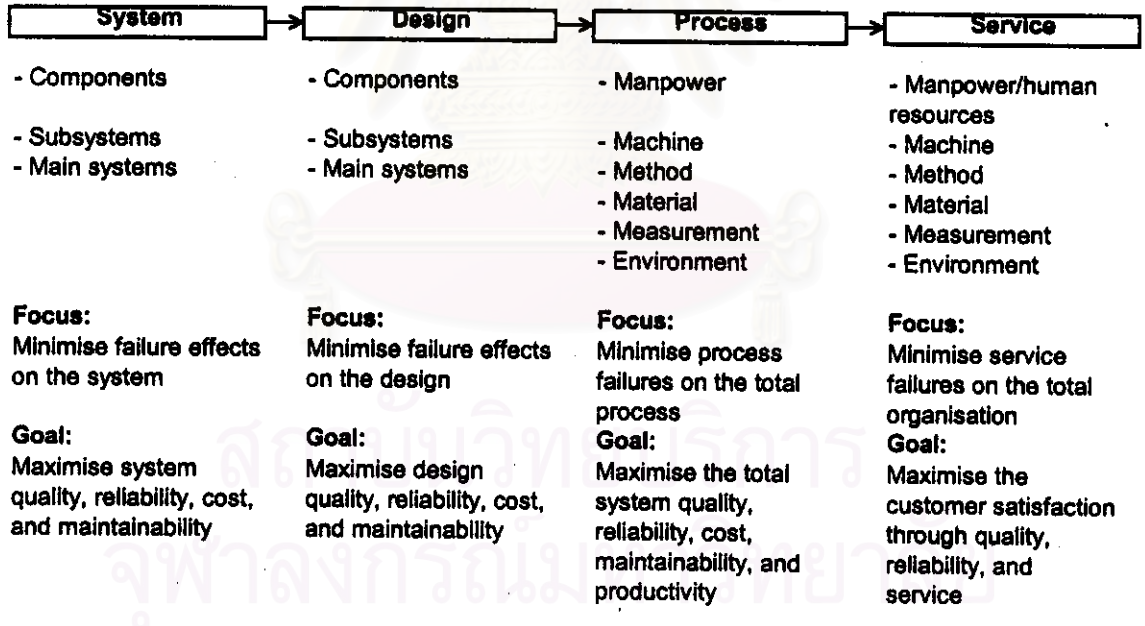


Figure 2.3 Types of FMEA
Adapted from Failure Mode and Effect Analysis by Stamatis (1995: 47).

2.6.3 Sources of Identifying Failures with FMEA

There are two ways which can be used to identify and define the failures. One is to use the historical data such as warranty data, customer complaints, or analysis of similar data

for similar products. The second way is the inferential statistics, mathematical modeling, simulations, concurrent engineering, and reliability engineering (Stamatis, 1995: 25).

2.6.4 Time to Start FMEA

In order to maximise the satisfaction of the customers by elimination and/or reducing problems, the FMEA should be started as early as possible even though all information are not known yet. Stamatis (1995: 29) has identified the starting time for an FMEA programme as follows.

- When new systems, designs, products, processes, or services are designed
- When existing systems, designs, products, processes, or services are about to change regardless of reason
- When new applications are found for the existing conditions of the systems, designs, products, processes, or service
- When improvements are considered for the existing systems, designs products, processes, or services

It is important to understand that, after the FMEA is implemented, FMEA becomes a living document. The FMEA should be continually conducted and the FMEA is considered finished on when the system, design, product, process, or service is considered complete, and/or discontinued (Stamatis, 1995: 30-32).

2.6.5 Persons to Conduct the FMEA

A single individual cannot do the FMEA because there may be biases based on his/her single perspective. Therefore a team must be established as appropriate for a specific project. Since the FMEA technique is to identify the specific potential failures in a system, design, product or service, therefore the persons within a team should be cross-functional and multidisciplined. If there is a time limitation for a full team discussion, it is possible to allow the leader of the FMEA team to present some of the failures in the meeting and follow with a full discussion within the FMEA team. An example of FMEA format used during the meeting is shown on the following figure.

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS (PROCESS FMEA)

Item _____ Process Responsibility _____
DCS System _____ Key Date _____
Core Team _____

FMEA Doc Number _____
Page _____ of _____
Prepared By _____
FMEA Date (Orig.) _____
FMEA Date (Rev.) _____

Process Function and Require-ments	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Potential cause(s) / Mechanism(s) of Failure	Occur	Current Process Controls	Detec	R.P.N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
											Actions Taken	Sev	Occ	Det	R.P.N.

Figure 2.4 Example of FMEA Format

2.6.6 Components of FMEA

The main important idea of the FMEA is to identify potential failures and find ways to prevent them from reaching customers. There may be many failures in the process and each failure cannot be prioritised at the same level of importance. Therefore finding the priority of each identified failure is important because it helps us solve the most serious problems first.

There are three components helping us define the priority of failures and they are as below.

(a) Occurrence (O) : the frequency of the failure

(b) Severity (S) : the seriousness (effects) of the failure

(c) Detection (D) : the ability to detect the failure before it reaches the customer

We can use numerical scales (called risk criteria guidelines) to represent the value of these above components. There guidelines can be either 'qualitative' or 'quantitative'.

If the guideline is qualitative, it must follow theoretical (expected) behaviour of the component. The expected behaviour for each component is as following (Stamatis, 1995: 34-35). Occurrence: the expected behaviour is normality. Severity: the expected behaviour is lognormal. Detection: the expected behaviour is that of a discrete distribution.

If the guideline is quantitative, it must be specific and it must follow actual data, statistical process control data, and historical data. The table below illustrates some of the guidelines for the selection guideline.

If	Then use	Select
The *design* is similar to others or historical data exist.	Statistical data from either historical or surrogate systems: Reliability data, actual distribution, mathematical modeling, and simulation.	Actual data and/or CpK.
Failure history is available with the *design* itself or similar, or surrogate parts.	Historical data based on reliability, design, actual distributions, mathematical modeling, simulation, cumulative data, and/or fraction defectives.	Actual data and/or cumulative number of failures.
The *design* is new and/or no quantification for any data is available.	Team Judgement.	Subjective criteria. Use team consensus and be conservative.
If	**Then use**	**Select**
The *process* is under statistical process control (SPC).	Statistical data; reliability data, process capability, actual distribution, mathematical modeling, simulation.	Actual data and/or CpK
The *process* is similar to others or historical data exist.	Statistical data from either historical or surrogate systems: Reliability data, process capability, actual distribution, mathematical modeling, and simulation.	Actual data and/or CpK.
Failure history is available with the *process* itself or similar, or surrogate parts.	Historical data based on reliability, process, actual distributions, mathematical modeling, simulation, cumulative data, and/or fraction defectives.	Actual data and/or cumulative number of failures.
The *process* is new and/or no quantification for any data is available.	Team Judgement.	Subjective criteria. Use team consensus and be conservative.

Table 2.5 Criteria for Selecting Ratings

Adapted from Failure Mode and Effect Analysis by Stamatis (1995: 37-38).

There is no standard of the ranking for the criteria of the 'occurrence', 'severity', and 'detection'. However the most widely used is the ranking based on 1 to 10 scale. This is because it provides ease of interpretation, accuracy, and precision in the quantification of the ranking.

The product of the 'occurrence', 'severity', and ' detection' is called RPN (risk priority number). The purpose of this number is used for the ranking order of the identified failure nodes. It is important to understand that not all the failure modes are solved. It depends on the *'threshold of examining the failures'*. We have to check how critical of the system, design, product, process, and/or service is and set the percent of the statistical confidence level. The critical one may require that 99 percent of all failures must be addressed whereas the non-critical one may require 90 percent.

For example, we require that 90 percent of all failures must be prevented or solved for a system on a guideline scale of 1 to 10. The maximum number possible for the RPN is 10*10*10 (from occurrence, severity, and detection) or 1000 and 90 percent of 1000 is 900. Subtract 1000 – 900 = 100. Therefore the *threshold of examining failures* is an RPN equal to or greater than 100 based on a 90 percent confidence and a 1 to 10 guideline scale. In other words, if the potential failure mode has the RPN greater than or equal to 100, that failure mode must be addressed.

The occurring risks should be classified by the team before starting the evaluation process. They can be defined as minor, moderate, high, and critical risks. The level of actions taken is also different based on different risks. The example of action taken is shown below (Stamatis, 1995: 39).

- Under minor risk: no action is taken.
- Under moderate risk: some action may take place.
- Under high risk, definite action will take place. (Selective validation and evaluation may be required).
- Under critical risk, definite actions will take place and extensive changes are required in the system, design, product, process, and/or service.

2.6.7 The Process of Conducting an FMEA

In order to conduct an FMEA effectively, it is better to follow a systematic approach as recommended by Stamatis (1995: 42-44) as below.

1. *Select the team and brainstorm:* to collect appropriate persons
2. *Functional block diagram and/or process flowchart:* to make sure that everyone in a team has the same understanding about the system, design, process, and/or service.
3. *Prioritise:* to select where the team should start from (what part is important?).
4. *Data collection:* to collect the data of failures, categorise them, and to fill in the failures identified in the FMEA form.
5. *Analysis:* to analyse the problems by using techniques such as brainstorming, cause-and-effect analysis, quality function deployment or QFD, fault tree analysis or FTA. The information from this step is used to fill in the columns of the FMEA form in relationship to effects of the failure, existing controls, and estimation of the severity, occurrence, and detection.
6. *Results:* to quantify the severity, occurrence, detection, and RPN.
7. *Confirm/evaluate/measure:* to evaluate whether the situation of such problems is better than, worse than, or the same as before, In addition this step also requires

the team to define the recommended actions and see the results of those actions taken.

8. *Do it all over again:* to repeat the process all over again because FMEA is a never ending process and it is continuous improvement.

2.6.8 The Process after the FMEA Completion

After the FMEA has been conducted completely, there are also the steps that require the team to follow as below (Stamatis, 1995: 45-46)

1. Review the FMEA: to ensure that all problems have been addressed and the actions have been recommended or implemented.
2. Highlight the high-risk areas: to inspect the high-risk areas at the column 'RPN' of the FMEA. If RPN of any failure is higher or equal to 100, that failure is risky.
3. Identify the critical, significant, and major characteristics: to ensure that there is correlation between the potential failure mode column, effects of the failure, and the severity columns. To classify these failures into *critical characteristics* (items that affect compliance with governmental regulations or safe product), *significant characteristics* (internal characteristics of a process or product that affect quality requirements and customer expectations). The last one is the *major characteristics* (items that provide rapid feedback to the process and provide opportunity to immediately correct quality issues and the customers are dissatisfied with these quality issues).
4. Ensure that a control plan exists and is being followed: to make sure that all critical, significant, and major characteristics have a documented plan for controlling, improving, and/or handling changes. The control plan is used to monitor the identified characteristics in the process and to ensure that the workers make products/services that are acceptable to the customers.
5. Conduct capability studies: to establish a statistical control and perform a potential capability.
6. Work on processes which have a CpK less than or equal to 1.33: to continually improve the process by eliminating variation until the processes reach a minimum goal (Cpk~1.33).
7. Work on processes which have CpK greater than or equal to 1.33: try to exceed all standards. And try to go beyond the CpK of 1.33 for further improvement and try to reduce variation until it reaches or exceed a CpK of 2.00.

2.7 Fault Tree Analysis (FTA)

Fault tree analysis is a technique of reliability and safety analysis. It is generally used for complex dynamic systems. It provides an objective basis for analysis and justification for changes and additions (Blanchard, 1986).

The FTA is a model which represents the combinations of possible events (both normal and abnormal) in a system in the logical and graphical form. These possible events lead to the single failure at the top of the tree. The FTA uses a tree to represent the cause-and effect relationships between the single failure at the top of the tree and various causes. After the tree has been constructed and the root causes of the problem have been identified, the countermeasures to prevent the problem can be determined.

The FTA always supplements the FMEA. Its application may be in a system or subsystem environment with a focus on identifying the root factors that could cause a failure and their interdependent relationships (Stamatis, 1995: 52).

The elements of the FTA are shown on the following figures.

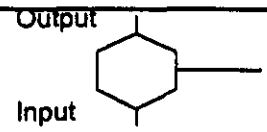
Name of gate	Symbol of gate	Input-Output relationship
AND gate		The output event occurs if all of the n input events occur.
OR gate		The output event occurs if at least one of the n input event occurs.
m-out-of-n voting gate		The output event occurs if m or more out of n input events occurs.
Priority AND gate		The output event occurs if all input events occur in a certain order.
Exclusive OR gate		The output event occurs if only one of the input events occurs.
Inhibit gate		The input event causes the output event only if the conditional event occurs.

Figure 2.5 Fault Tree Gate Symbols

Adapted from Failure Mode and Effect Analysis by Stamatis (1995: 53).

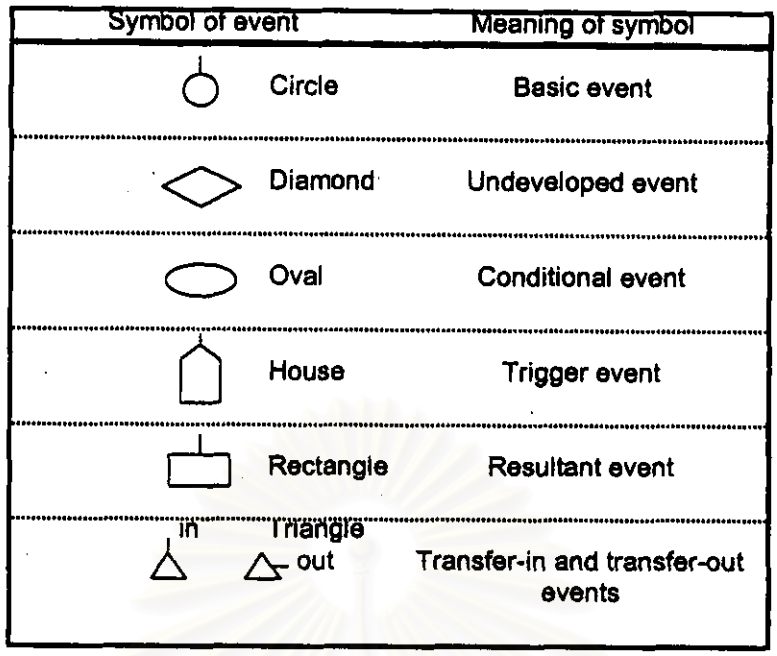


Figure 2.6 Fault Tree Event Symbols

Adapted from Failure Mode and Effect Analysis by Stamatis (1995: 54).

The example of the FTA is shown on the figure below.

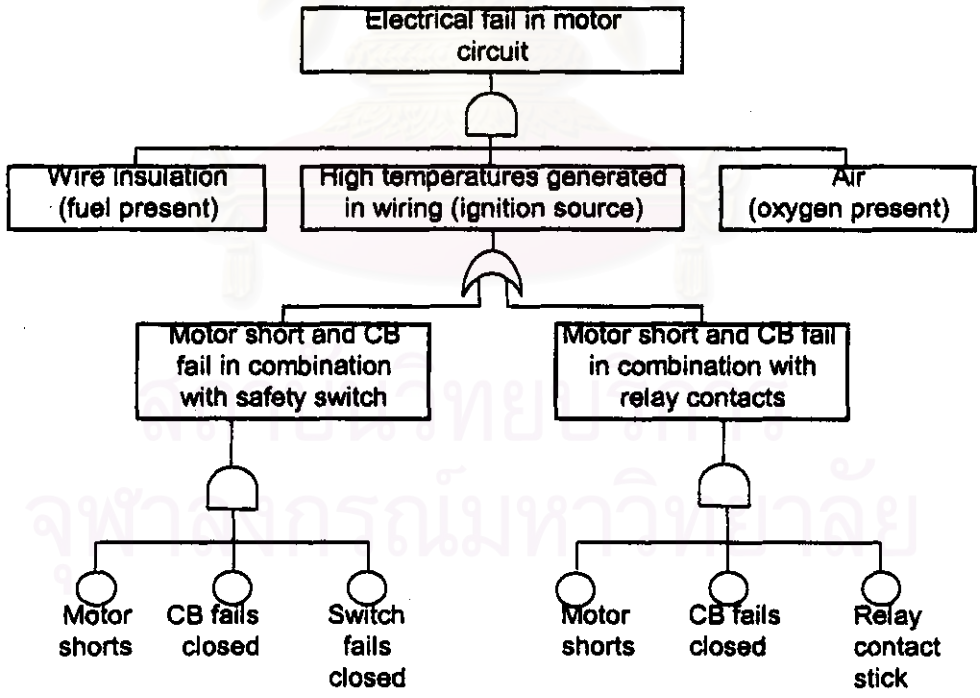


Figure 2.7 FTA and FMEA (Possible Specific Failures)

Adapted from Failure Mode and Effect Analysis by Stamatis (1995: 55).

2.8 Literature Reviews

H.V. Elson (1984) detined the quality assurance as "all activities and functions concerned with the attainment of quality".

John S. Oakland (1992) defined the quality assurance as "the prevention of quality problems through planned and systematic activities (including documentation). These will include : the establishment of a good quality management system and the assessment of its adequacy, the audit of the operation of the system, and the review of the system itself"

ISO/DC 8402-1 defined the quality assurance as "all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality"

Dale H. Besterfield (1994) He has suggested that each failure has a root cause, causes are preventable, and prevention is cheaper. He also recommended the quality improvement strategy as following :

1. Reduce failure costs by problem solving.
2. Invest in the 'right' prevention activities.
3. Reduce appraisal costs where appropriate and in a statistically sound manner.
4. Continuously evaluate and redirect the prevention effort to gain further quality improvement.

Frank M. Gryna (1988) defined the quality costs as "the cost of poor quality". These costs can be divided into four broad categories as following:

1. Internal failure costs: these are costs associated with defects that are found prior to transfer of the product to the customer.
2. External failure costs: these are costs associated with defects that are found after product is shipped to the customer.
3. Appraisal costs: these are the costs incurred to determine the degree of conformance to quality requirements.
4. Prevention costs: these are costs incurred to keep failure and appraisal costs to a minimum.

Chrysler, Ford, General Motor (1994) this reference manual is used to communicate to their suppliers and contractors about the product quality planning and control plan guidelines. These guidelines will be used to support the development of a product that will satisfy the customer. The big three suggests the product quality planning cycle, which is explained as below:

1. Plan : technology and concept development.

1. Do : Product/process development and prototype verification.
2. Study : confirmation product and validation process.
3. Act : continual improvement.

The main idea of the product quality planning cycle is that the quality improvement is a never-ending process. That is, the experience taking from one quality programme shall be applied to the next programme.

Frank M. Gryna (1988) suggests the approaches to the quality improvement as following:

1. Quality circles: the concept is one of setting up and training voluntary teams of workers to solve problems within their own department.
2. Statistical quality control (SQC): the concept is to employ the tools of statistics to solve quality problems.
3. Exhortation: this method consists of using skillful propaganda to arouse awareness among subordinates that quality is important.
4. Quantify quality costs: the main idea is to use the quality costs to identify the problems.

Kenneth L. Arnold (1994) suggested the ideas for the implementation strategy of the design control, process control, inspection and testing, document control, corrective action, and Delivery.

2.8.1 Other Relevant Researches

Ananchal Sakolrak (1995)

This research is to study the proper method for the quality control improvement of sanitary ware processing in model factory. The author has proposed the quality control system such as to redesign the structure of quality control organisation, setting the method of calculating standard value of raw material, and design the proper documents for quality control system.

Attakorn Laosirihongthong (1994)

This research is about the development of the quality control system for a toy assembly process of a plastic toy factory. The research includes the redesigning of the structure of quality control organisation, establishment of quality control system for incoming parts, assembly process, and final quality control system.

Ben Sutarom (1995)

This research is to develop the quality problem solving methods in metal parts production process for the home appliance industry. The author has used the cause and

effect diagram or Ishigawa diagram to identify the cause of each selected quality problem, set up a basic system for quality assurance. After implementation, the percentage of defective products was reduced about 81 percent.

Boonroj Simabravornsut (1995)

This research is to search for any quality problem in automobile metallic press parts and to analyse the quality control system that is appropriate for the model factory. The proposed quality control system is to designing the structure of the quality-control organisation, designing the system of quality reporting, and determining the standard of quality controlling for metallic parts by quality inspection raw material, in-process inspection, and finished goods inspection.

Chalermphon Lelapatikul (1997)

This research is to determine and control the quality factors for the tyre industry by using the failure mode and effect analysis (FMEA). The author has also used the quality tools such as the cause and effect diagram, relation diagram and tree diagram. The check sheets, method study, and machine setting are established for the implementation. The results are the 50-90% decreasing of the risk priority number (RPN), comparing between the RPN before and after implementation.

Chumpol Monthatipkul (1996)

This research is to develop an appropriate quality control system for ladder cable tray products in hot-dip galvanizing process of a factory. The quality control techniques including check sheets, cause and effect diagram, control chart, chart, graph and Deming cycle have been used in the study. From the system, the main problems of the studied factory are the lack of product quality specifications, failure to follow the standard rules in the inspection process, and the lack of quality organisation department to maintain and develop the quality control system.

Jakrapong Karnjanasomwong (1995)

This research is about the development of the quality assurance for the recording magnetic head assemble factory. It also suggests the procedures to reduce the defective products resulting from the manufacturing process.

Jhakkrit Theppornpitak (1995)

This research is to analyse the ISO 9002 quality system implemented in an electronic parts factory from the commencement to the phase of certification. The result of the study has given the insight into the problem of working form used in the studied factory. The form was no compliant with the document control system ISO 9002. The author has suggested corrective actions to prevent the problem of document control system. Prior to the

implementation, there were 7 non-conformance items that came from the document control system. After implementation, no non-conformance on document control was found in the next 3 audits.

Niwat Pradubwong (1996)

This research is to improve the appropriate quality control system for the punch & dies for small arms ammunition manufacturing process. This study has proposed the reorganisation of the quality department and set up the job description of each employee, improved the process of incoming raw material, improved in-process quality control, and improved finished product inspection, set up quality records. The result of implementation was the 33% decreasing of the number of the defected example group (punch & dies).

Somkuan Tesapirat (1995)

This research is to propose the quality control system for a microwave oven assembly line for the model factory to increase the quality of product. The study shows that the factory does not have the quality control system during assembly process and the quality performance of worker and work in process which passes to each wok station has high variance. After establishing the quality control system and implementing the quality control system in the factory, the total defect rate was reduced from 17.88% to 12.37%.

Somnuk Liabma (1997)

This research is to establish the quality assurance of the supplied parts for hard-disk drive manufacturing. The author has applied the use of statistical process control and Gage R&R study (Repeatability and Reproducibility) to control and review supplier process variation, identified the potential product related process failure modes by using the process FMEA (failure mode and effect analysis). After implementation, about 85% of all machines meet with Cpk of 1.33 in June 1996 and increase to 100% in July. The corrective actions, taken on the major defect, can improve the quality more than 50%.

Somsak A.Kongkiat (1995)

This research is about the problems occurring after the implementation of the quality assurance of the Grease manufacturing plant. It suggests the improvements at the part of inspection, testing, and testing equipment of the quality assurance system.

Suwit Boonchoejarud (1996)

This research is to develop an appropriate quality control system for a car painting process. The author has used an automobile assemble factory as a case study. From the study, the factory did not have effective quality control system due to lacking of planning for inspection and effective quality control. The author has proposed the plans to develop quality control system. These plans include the improvement of incoming material inspection,

improvement of inspection and control production process, and improvement of product inspection.

Tawichart Dechwitayaporn (1997)

This research is to develop a quality assurance system for brake drum manufacturing process. The quality assurance system used in the brake drum manufacturing process includes quality planning, quality control, quality audit, and preventive procedures. The author also establishes the quality tools for the quality assurance system such as the check sheets, statistical method, and control chart. The established system can be a guideline for quality assurance system in the same area of manufacturing.

Thana Boonprasit (1994)

This research is to improve the quality inspection system of in-coming parts and production processes using a refrigerator factory as a case study. The author has proposed to designing and improving the document system used in the quality inspection task, setting the training courses for staffs and inspectors, and developing the performance indication and corrective action system. After implementation, the rejection of in-coming parts was reduced by 22% and the quantity of the defective product using the sampling inspection was reduced by 41%.

Thavachchai Lovichit (1996)

This research is to design the quality management system and propose an appropriate quality system in documentary forms for the manufacturing process of metal casting and lathing. The result of the study by statistical techniques proposed in the quality system revealed that the percentage of the finished products, which did not pass the hydrostatic pressure test, decreased from 19% to 6.5% by improving the lathing method.

Jhakkrit Thepporpitak (1995)

This research is about the analysis of the document control for quality system ISO-9002 in a factory. The analysis is from the phase of commencement to the phase of certification. The main problem for this analysis is the problem of the used working form, which was not compliant with the document control system ISO-9002.

Weerawat Svastdi-xuto (1996)

This research is about the development of the quality management system for large-scale computer centre. The quality management system focuses on the processes of report production, which its defects are about 9 percent of total defects. This research also defines the essential inspection in the process, develop the operating manuals for report production.