MINISTRY OF EDUCATION AND SCIENCE OF UKRAINE CHERNIHIV NATIONAL UNIVERSITY OF TECHNOLOGY

QUALITY MANAGEMENT

METHODICAL GUIDELINES for studying the course and independent work of students for training Masters specialty 073 "Management"

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Preface

Quality management is the act of overseeing all activities and tasks needed to maintain a desired level of excellence. This includes the determination of a quality policy, creating and implementing quality planning and assurance, and quality control and quality improvement. A quality management system is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A quality management system helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis. Implementing a quality management system affects every aspect of an organization's performance.

The benefits to the design and implementation of documented quality management systems include: meeting the customer's requirements, which helps to instill confidence in the organization, in turn leading to more customers, more sales, and more repeat business; meeting the organization's requirements, which ensures compliance with regulations and provision of products and services in the most cost-and resource-efficient manner, creating room for expansion, growth, and profit.

Within these overarching benefits are advantages like helping to communicate a readiness to produce consistent results, preventing mistakes, reducing costs, ensuring that processes are defined and controlled, and continually improving the organization's offerings.

Establishing a quality management system helps organizations run effectively. Before establishing a quality management system, the organization must identify and manage various connected, multi-functional processes to ensure customer satisfaction is always the target achieved.

The methodical guidelines include the main themes that are provided by program of discipline, deals with complex issues of quality management systems in organizations, focuses on the problematic and controversial issues that are not addressed in the literature. Guidelines include the tasks for independent work, discussion questions, and questions for self-evaluation of students. In the end of methodical guidelines there is a list of references to literature that is recommended for advanced study of course.

1 Theme 1

Introduction to Quality Management

Discussion Topics

- 1. Defining Quality
- 2. What is Quality Management?
- 3. History of quality management

The word Quality does not mean the Quality of manufactured product only. It may refer to the Quality of the process (i.e., men, material, and machines) and even that of management. Where the quality of manufactured product referred as or defined as: Quality of product as the degree in which it fulfills the requirement of the customer. It is not absolute but it judged or realized by comparing it with some standards. It is usually determined by some characteristics namely design, size, material, chemical composition, mechanical functioning workmanship, finish and other properties. In the final analysis the Quality standards for the products are established by the customer. Quality can be defined as a state that meets the legal, aesthetic and functional requirement of a product or project by customers.

Quality begins with the design of a product in accordance with the customer specification further it involves the established measurement standards, the use of proper material, selection of suitable manufacturing process and the necessary tooling to manufacture the product, the performance of the necessary manufacturing operations and the inspection of the product to check the manufacturing operations and the inspection of the product to check on performance with the specifications.

Quality management is the process of identifying and administering the activities needed to achieve the quality objectives of an organization. Quality management is defined as (BS EN ISO 8402): "All activities of the overall management function that determine the quality policy, objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance, and quality improvement within the quality system." Quality management is coordinated activities to direct and control an organization in terms of quality (ISO 9000). Quality management system is management system to direct and control an organization with regards to quality (9000).

The history of quality management, from mere 'inspection' to Total Quality Management, and its modern 'branded interpretations such as 'Six Sigma', has led to the development of essential processes, ideas, theories and tools that are central to organizational development, change management, and the performance improvements that are generally desired for individuals, teams and organizations.

The roots of Total Quality Management can be traced to early 1920's production quality control ideas, and notably the concepts developed in Japan beginning in the late 1940's and 1950's, pioneered there by Americans Feigenburn, Juran and Deming.

Quality Management resulted mainly from the work of the quality gurus and their theories: the American gurus featured in the 1950's Japan: Joseph Juran, W Edwards Deming, and Armand Feigenbum; the Japanese quality gurus who developed and extended the early American quality ideas and models: Kaoru Ishikawa, Genichi Taguchi, and Shigeo Shingo; and the 1970-80's American Western gurus, notably Philip Crosby and Tom Peters, who further extended the Quality Management concepts after the Japanese successes.

Tasks for independent work

- 1. How does Quality Management contribute to the business success of the companies? Provide an example with explaining how the Quality management system implemented led to improved performance.
- 2. Use the Internet to research the latest offerings in Quality management system and their uses by companies. Prepare a report to summarize your findings and highlight new and innovative uses of systems.
- 3. Why do some companies adopt and deploy innovative approaches in Quality Management while others in the same line of business do not?

Discussion Questions

- 1. What property refers to the Craftsmanship Era of quality management development?
- 2. What property refers to the "Standardization, Mass Production and Quality Assurance Era" of quality management development?
- 3. What property refers to the "Quality Control Era" of quality management development?
- 4. What does a quality inspector do?
- 5. What are the elements of "Standards and Awards" approach?
- 6. What period of a quality management is associated with Lean and Six Sigma?

- 1. Give the Quality Hierarchy?
- 2. What is Quality management?
- 3. What is Quality management according to ISO 9000:2015?
- 4. What Paradigms of Quality do you know?
- 5. What does Inspection mean?
- 6. What does Quality Control mean?
- 7. What is Quality Assurance?

2 Theme 2

International Quality Standards

Discussion Topics

- 1. Introduction to Standardization
- 2. Family of ISO 9000 standards
- 3. Quality Management System (ISO 9001)
- 4. Managing for the sustained success of an organization (ISO 9004)

Standardization is defined by the International Organization for Standardization as "the process of formulating and applying rules for an orderly approach to a specific activity for the benefit and with the cooperation of all concerned, and in particular for the promotion of optimum overall economy, taking due account of functional conditions and safety requirements."

Standardization can be applied to specific products, as well as to, for example, norms, requirements, methods, terms, and designations commonly used in international trade and in science, engineering, industry, agriculture, construction, transportation, culture, public health, and other spheres of the national economy. A 'standard' is a result of a particular standardization effect, approved by the recognized authority. It may take the form of a document containing a set of conditions to be fulfilled, a fundamental unit or physical constituent or an object for physical comparison.

ISO is recognized as the short name for the International Organization for Standardization, an international agency within 160 member bodies. ISO derives from the same Greek root as the prefix to the words *iso* bar, *iso* metric, and *iso sceles*, which mean equal pressure, equal measurements, and equal sides to a triangle; that is, things that are equal.

There are three core standards in the family of ISO 9000: ISO 9000, ISO 9001, and ISO 9004. Standard ISO 9000:2015 "Quality management systems — Fundamentals and vocabulary" provides QMS principles and fundamentals, describes what the series is about, and lists basic definitions of terms for use by any organization. ISO 9001:2015 "Quality management systems — Requirements" states QMS requirements which explain when an organization must demonstrate that it is capable of effectively and efficiently meeting customer, statutory, and regulatory requirements. ISO 9004:2009 "Managing for the sustained success of an organization — A quality management approach" provides guidance for establishing a QMS that goes beyond ISO 9001 requirements by improving the efficiency of the system.

Quality management principles are: customer focus; leadership; engagement of people; process approach; improvement; evidence-based decision making; relationship management.

The revised standard ISO 9001:2015 was published by ISO on 23 September 2015. The scope of the standard has not changed, however, the structure and core terms were modified to allow the standard to integrate more easily with other international management systems standards. The 2015 version focuses on performance. Standard combines the process approach with risk-based thinking, and employing the Plan-Do-Check-Act cycle at all levels in the organization.

Tasks for independent work

- 1. What are the business benefits of International Quality Standards? In what ways can the companies have benefit? Provide several examples.
- 2. An important criterion in this area is the Certification and Accreditation of companies. Go online and research these processes in different kinds of companies. How it is related to Quality management. How companies are using International Quality Standards to manage their processes?
- 3. In what areas of business would you expect new version ISO 9000 to make inroads next? Where do you think it would be most beneficial, and how would it change the way employee work today? Provide several examples.

Discussion Questions

- 1. What is the Standardization process?
- 2. What is the Standard as a documented agreement?
- 3. What is the Standard as a result of a particular standardization effect?
- 4. Explain, what is Certification as Compliance with a standards or specification?
- 5. What is Accreditation as recognition of competence?
- 6. What standard provides QMS principles and fundamentals?
- 7. Describe Quality management principles.

- 1. What is the definition of standardization?
- 2. What is the standard?
- 3. What does certification mean?
- 4. What does accreditation mean?
- 5. What core standards constitute a series of ISO 9000?
- 6. What standard of ISO 9000 family is used for certification?
- 7. What is a sustained success?

3 Theme 3.

Total Quality Management

Discussion Topics

- 1. Introduction to TQM
- 2. TQM Basic Concepts
- 3. The Process of Implementing TQM

TQM is both a philosophy and a system of guiding principles for the application of quantitative methods and human resources to improve the materials and services supplied to an organization and the degree to which the needs of the customer are met, now and in the future.

The primary purpose of TQM is to achieve excellence in customer satisfaction through continuous improvements of products and processes by the total involvement and dedication of each individual who is in any way, a part of that product/process. The principles of TQM create the foundation for developing an organization's system for planning, controlling, and improving quality.

TQM is a structured approach to improvement. If correctly applied, it will assist a construction company in improving its performance. It involves a strong commitment to two guiding principles: customer satisfaction and continuous improvement. In a study of customer satisfaction factors for clients of the transportation, food, chemical and paper, utilities and other miscellaneous industries, it was found that timeliness; cost, quality, client orientation, communication skills, and response to complaints were most significant. Another study suggests that TQM methodology like quality function deployment (QFD), provide a structured framework for continuous improvement and customer satisfaction.

TQM Basic Concepts are: Leadership, Customer Satisfaction, Employee Involvement, Continuous Process Improvement, Supplier Partnership, and Performance Measures. All these present an excellent way to run a business.

The building blocks of TQM: processes, people, management systems and performance measurement. Everything we do is a Process, which is the transformation of a set of inputs, which can include action, methods and operations, into the desired outputs, which satisfy the customers' needs and expectations. In each area or function within an organization there will be many processes taking place, and each can be analyzed by an examination of the inputs and outputs to determine the action necessary to improve quality. In every organization there are some very large processes, which are groups of smaller processes, called key or core business processes. These must be carried out well if an organization is to achieve its mission

and objectives. The only point at which true responsibility for performance and quality can lie is with the People who actually do the job or carry out the process, each of which has one or several suppliers and customers. An efficient and effective way to tackle process or quality improvement is through teamwork. However, people will not engage in improvement activities without commitment and recognition from the organization's leaders, a climate for improvement and a strategy that is implemented thoughtfully and effectively.

The Process of Implementing TQM: first, the top management of the organization must establish that total quality is a top priority of the organization; second, the culture of the organization must be changed so that everyone and every process embrace the concept of total quality management; third, small teams need to be developed throughout the organization to define quality, identify customer wants, and measure progress and quality; finally, change and continuous improvement must be implemented, monitored, and adjusted based on analysis of the measurements.

Tasks for independent work

- 1. Implementing TQM seems to have other, less tangible, advantages beyond Improve Quality, Increase Productivity, Lower Costs, and Business Growth. What are some of those? How do you quantify them to make the case for investing in the quality? Provide at least two fully developed examples.
- 2. Information technology enhances the ability of educational institutes to reach students across geographic boundaries. One development in this area is ISO official website http://www.iso.org. Go online to check out the site and prepare a report summarizing its objectives, the kind of content available there, and how it could be used to support traditional modes of education delivery, such as lectures.
- 3. It widely known, that TQM requires cultural change. Discuss that.

Discussion Questions

- 1. Explain the meaning of acronym TQM.
- 2. How we can define Total Quality Management?
- 3. What does TQM require from organization?
- 4. Describe the building blocks of TQM?
- 5. What can you say about TQM Basic Concepts?
- 6. What stages of The Process of Implementing TQM do you know?
- 7. What transformations can TQM provide?

- 1. What components refer to the Leadership in TQM?
- 2. What kind of Project teams refers to basic concept "Employee Involvement"
- 3. What are the ways of continuous improvement?
- 4. How many steps include the Process of Implementing TQM?

- 5. What items are included in the first step of implementation TQM "Establish as top priority by top management"?
- 6. What items the step of implementation TQM "Cultural change" includes?
- 7. What items are included in the step of implementation TQM "Establish small teams give overall goals"?

4 Theme 4.

TQM for Middle Management & Workforce

Discussion Topics

- 1. Process Management
- 2. Continuous improvement process
- 3. Quality Improvement Teams

According to TQM a quality product comes from a quality process. This means that quality should be built into the process. Quality at the source is the belief that it is far better to uncover the source of quality problems and correct it than to discard defective items after production. If the source of the problem is not corrected, the problem will continue.

Process management is a concept that integrates quality/performance excellence into the strategic management of organizations. It is Category 6.0 of the Malcolm Baldrige National Quality Award. Process management includes (1) process design or engineering, which is the invention of new processes; (2) process definition, which requires the description of existing processes; (3) process documentation; (4) process analysis and control; and (5) process improvement.

A process is a series of connected steps or actions with a beginning and an end that can be replicated. Organizations should be viewed as a set or hierarchy of processes that produce outputs of value to a customer, as well as a set of functions such as engineering, manufacturing, accounting, and marketing. Processes are of two types – value-added processes and support processes.

The process owners (the people who actually do the jobs) are the most knowledgeable about the processes by which they accomplish their work. Therefore, if process evaluation and improvement becomes an integral part of daily work, safety improvement, defect prevention, and cycle-time reduction can become a reality. Process owners are those empowered to do work, improve how they do the work, and accept accountability as process owners.

A continuous improvement process (CIP or CI) is an ongoing effort to improve products, services, or processes. These efforts can seek "incremental" improvement over time or "breakthrough" improvement all at once. Delivery (customer valued) processes are constantly evaluated and improved in the light of their efficiency, effectiveness and flexibility. Some successful implementations use the approach known as Kaizen (the translation of kai ("change") zen ("good") is "improvement").

This method became famous by the book of Masaaki Imai "Kaizen: The Key to Japan's Competitive Success."

Quality Improvement Teams are made up of a sufficient number of individuals with expertise in the function or process being studied to fully address the identified opportunity. Each team will have a Team Leader appointed by the Quality Council (QC) that is assigned the responsibility of coordinating the interdisciplinary evaluation of the identified opportunity or problems.

There are two types of QI teams: Project teams and Quality circles. A project team is a team whose members usually belong to different groups, functions and are assigned to activities for the same project. A team can be divided into sub-teams according to need. Usually project teams are only used for a defined period of time. They are disbanded after the project is deemed complete. A quality circle or quality control circle is a group of workers who do the same or similar work, who meet regularly to identify, analyze and solve work-related problems. Normally small in size, the group is usually led by a supervisor or manager and presents its solutions to management; where possible, workers implement the solutions themselves in order to improve the performance of the organization and motivate employees.

Tasks for independent work

- 1. TQM for Middle Management & Workforce is an approach to systems development and implementation that use special kaizen programs. Three things required for successful kaizen program: operating practices, total involvement, and training. Go online and research these requirements. Prepare a report to summarize your work.
- 2. The Toyota Production System is known for kaizen, where all line personnel are expected to stop their moving production line in case of any abnormality and, along with their supervisor, suggest an improvement to resolve the abnormality which may initiate a kaizen. Give examples of using kaizen at other enterprises.
- 3. What results can obtain company that use TQM? Can you see any disadvantages?

Discussion Questions

- 1. What are the benefits of employee involvement?
- 2. What are the basic ways for a continuous process improvement?
- 3. What are the phases of a Continuous Process Improvement Cycle?
- 4. What are the characteristics of successful teams?
- 5. Give some common team problems?
- 6. What are the common barriers to team progress?
- 7. Give the steps involved in training process?

Questions for self-evaluation

1. What is the Process management?

- 2. What are the types of business processes?
- 3. What is a support process?
- 4. What is the subject to continual improvement?
- 5. What things required for successful Kaizen program?
- 6. How can workers engage in Process improvement?
- 7. What are the types of Quality Improvement Teams?

5 Theme 5.

7 Quality Control Tools

Discussion Topics

- 1. Cause & Effect Diagram
- 2. Flowchart
- 3. Check Sheet
- 4. Control Chart
- 5. Pareto Diagram
- 6. Histogram
- 7. Scatter Diagram

The Seven Basic Tools of Quality is a designation given to a fixed set of graphical techniques identified as being most helpful in troubleshooting issues related to quality.

Cause-and-effect diagrams (also called Ishikawa diagrams, fishbone diagrams) are causal diagrams created by Kaoru Ishikawa (1968) that show the causes of a specific event. Common uses of the Ishikawa diagram are product design and quality defect prevention to identify potential factors causing an overall effect. Each cause or reason for imperfection is a source of variation. Causes are usually grouped into major categories to identify these sources of variation.

A flowchart is a type of diagram that represents an algorithm, workflow or process, showing the steps as boxes of various kinds, and their order by connecting them with arrows. This diagrammatic representation illustrates a solution model to a given problem.

The check sheet is a form (document) used to collect data in real time at the location where the data is generated. The data it captures can be quantitative or qualitative.

Control charts, also known as Shewhart charts (after Walter A. Shewhart) or process-behavior charts, are a statistical process control tool used to determine if a manufacturing or business process is in a state of control.

A Pareto Diagram, named after Vilfredo Pareto, is a type of diagram that contains both bars and a line graph, where individual values are represented in descending order by bars, and the cumulative total is represented by the line. The left

vertical axis is the frequency of occurrence, but it can alternatively represent cost or another important unit of measure. The right vertical axis is the cumulative percentage of the total number of occurrences, total cost, or total of the particular unit of measure.

A histogram is a graphical representation of the distribution of numerical data. To construct a histogram, the first step is to "bin" the range of values—that is, divide the entire range of values into a series of intervals—and then count how many values fall into each interval. The bins are usually specified as consecutive, non-overlapping intervals of a variable. The bins (intervals) must be adjacent, and are often (but are not required to be) of equal size.

A scatter Diagram (also called a scatter graph, or scatter plot) is a type of plot or mathematical diagram using Cartesian coordinates to display values for typically two variables for a set of data. The data is displayed as a collection of points, each having the value of one variable determining the position on the horizontal axis and the value of the other variable determining the position on the vertical axis.

Tasks for independent work

- 1. 7 Quality Control Tools have received a great deal of attention in the last few years due to renewed regulatory focus on the integrity and reliability of Quality Management information System. Go online and research how companies are deploying technology to deal with these issues. Prepare a report to summarize your findings.
- 2. A number of Quality issues were involved in the implementation of the modern approaches to Quality management. Can these obstacles be overcome simply by mandating compliance from top management? What else should companies do to help ease these transitions?
- 3. What is the business value derived from the successful providing of control? What can executives do now that could not before? Provide some examples.

Discussion Questions

- 1. What are the benefits of Using Flowcharts?
- 2. Explain the elements of Cause & Effect Diagram?
- 3. What can Check Sheet do as a Quality Management tool?
- 4. Discuss about Pareto Diagram as a QM tool?
- 5. What is used to examine a process to see if it is stable or to maintain the stability of a process?
- 6. What is a role of Histogram in Quality Management?
- 7. What are the steps of creating Scatter Diagram?

- 1. What is the need for Cause & Effect Diagram?
- 2. What is a Flowchart?

- 3. What is Check sheet?
- 4. What tool uses marks to collect the data?
- 5. For what purpose are dots plotted on the Control Chart?
- 6. What is a Histogram?
- 7. What are the benefits of Scatter Diagram?

6 Theme 6.

Quality Costs

Discussion Topics

- 1. Hierarchy of quality cost
- 2. Prevention Costs
- 3. Appraisal Costs
- 4. Failure costs

The quality costs are the costs incurred in the design, implementation, operation and maintenance of a quality management system, the cost of resources committed to continuous improvement, the costs of system, product and service failures, and all other necessary costs and non-value added activities required to achieve a quality product or service (Dale and Plunkett,1995).

Crosby (1979) sees quality as "conformance to requirements" and therefore defines the cost of quality as the sum of price of conformance and price of non-conformance. The price of conformance is the cost of making certain things that are done right the first time. And the price of non-conformance is the money wasted when work fails to conform to customer requirements.

No matter which quality costing approach is used, the main idea behind cost of quality analysis is the linking of improvement activities with associated costs and customer expectations, thus allowing targeted action for reducing quality costs and increasing quality improvement benefit (Schiffauerove and Thomson, 2004).

Cost of Quality is broken down into these two major categories which are called the: Cost of Conformance and the Cost of Non-conformance. The Cost of Conformance may be further broken down into Prevention Costs and Appraisal Costs. Prevention Costs represent the investment of keeping the defects from happening at all. This could include extra training for staff members and sophisticated equipment that accurately assembles a product. Appraisal Costs are the expenses of checking the product in order to find any defects that may have occurred. This could include visually inspecting the product, turning the product on to see if it works, and using equipment that detects products that are not within the set parameters.

The Cost of Non-conformance may also be broken down into two categories— Internal Failure Costs and External Failure Costs. If a defective product is discovered in-house before being sent to the customer, the costs of scrapping or re-doing the product are Internal Failure Costs. If the product is sold to the customer, the costs of handling returns, complaints, lawsuits, and lost business are called External Failure Costs.

Prevention Costs are incurred to keep future and appraisal costs at a minimum. It includes: Quality Planning, New Product review, Training, Process control, Quality data acquisition and analysis, Quality reporting, Improvement Projects.

Appraisal Costs incurred to discover the conditions of the products, mainly during the "first come through". These costs include: Incoming material inspection, Inspection and test, Maintaining accuracy of test equipment, Materials and services consumed, Evaluation of stock.

Internal failure costs are incurred to remedy defects discovered before the product or service is delivered to the customer. It includes: Scrap, Rework, Retest, Down time, Yield losses.

External failure costs are incurred to remedy defects discovered by customers: Complaint adjustment, Returned material, Warranty charges, Allowances.

Tasks for independent work

- 1. Quality Management Systems are generally known for their emphasis on manufacturing products in accordance with the customer requirements, and not always for their efficiency. What are some of the approaches that we can use to increase efficiency? What other alternatives can you think of?
- 2. What offerings are available today that was not available when the companies started investing in the preventing of quality problems?
- 3. The ability to accurately forecast demand is one of the major issues for companies. Go online and research which technologies companies are employing today to reduce costs and increases profits. What is a role of Quality Management Systems?

Discussion Questions

- 1. What kinds of costs include the Cost of Quality?
- 2. What are the prevention quality costs?
- 3. What are the Appraisal costs?
- 4. What are the Internal failure costs?
- 5. Give the typical cost bases?
- 6. How will you determine the optimum cost?
- 7. What kinds of costs are related to the training programs?

- 1. Define Quality Costs?
- 2. What are the External failure costs?
- 3. Give the primary categories of Quality cost?
- 4. Give the sub-elements of Preventive cost category?

- 5. Give the sub-elements of Appraisal cost category?
- 6. Give the sub-elements of Internal failure cost category?
- 7. Give the sub-elements of External failure cost category?

7 Theme 7.

Lean Six Sigma

Discussion Topics

- 1. The Basics of Lean Six Sigma
- 2. Lean manufacturing (Lean enterprise)
- 3. Six Sigma Methodologies

Lean Six Sigma is a methodology that relies on a collaborative team effort to improve performance by systematically removing waste; combining lean manufacturing/lean enterprise and Six Sigma to eliminate the eight kinds of waste (muda): defects, overproduction, waiting, non-utilized talent, transportation, inventory, motion, extra-processing (abbreviated as "DOWNTIME").

Lean manufacturing or lean production, often simply "lean", is a systematic method for the elimination of waste ("Muda") within a manufacturing process. Lean also takes into account waste created through overburden ("Muri") and waste created through unevenness in workloads ("Mura"). Working from the perspective of the client who consumes a product or service, "value" is any action or process that a customer would be willing to pay for.

Lean enterprise is a practice focused on value creation for the end customer with minimal waste and processes. The term has historically been associated with lean manufacturing and Six Sigma (or Lean Six Sigma) due to lean principles being popularized by Toyota in the automobile manufacturing industry and subsequently the electronics and internet software industries.

There are two main Six Sigma methodologies. The first of these is DMAIC, which stands for: define measure, analyze, improve and control. The second is DMADV, which represents: define measure, analyze, design and verify.

DMAIC is used to apply the principles of Six Sigma to existing business processes. For instance, if you are trying to find out how to make a particular process more effective, you would use DMAIC to break down the process into its component parts. Using this Six Sigma model, you would start by defining the problems and project goals, measuring data relating to the current process and analyzing your findings to identify cause-and-effect relationships. The next step involves improving existing processes based on your data analysis. Finally, you need to implement controls to avoid variation in the process going forward.

While DMADV shares some steps in common with DMAIC, it is used for Six Sigma projects that create new product or process designs. Using the DMADV Six Sigma model, you would start by defining your design goals. The next step is to measure the required quality characteristics, product or production process capabilities, and associated risks. You would then conduct an analysis of your findings to develop an appropriate solution. After that, you're ready for the design phase of the new product or process. Once the design is complete, you must test it and verify that it works. Following these steps will result in a successful Six Sigma implementation.

Advantages of Six Sigma: Save millions without capital investment (making what you have already work better for you); Can be applied to almost business function (administration to production); Leads to trust and higher employee morale within the corporation; Ensures customer the same results no matter the division of a large corporation; Makes company practices more standard.

Tasks for independent work

- 1. Lean Six Sigma is central to the approach toward decision making in successful organizations. What other elements must be present for this approach to be successful (technology, people, culture, and so forth)?
- 2. A number of major companies have launched projects geared toward improving their performance by systematically removing waste, combining lean manufacturing/lean enterprise and Six Sigma to eliminate the eight kinds of waste. Go online and research other examples in this trend. What are the similarities? What are the differences? Prepare a report.
- 3. If you had to apply the ideas discussed in the theme to your career, what would your dashboard and/or scorecard look like? What would be the sources of information? How you would measure whether you are making progress toward attaining your goals?

Discussion Questions

- 1. What is the Lean Six Sigma?
- 2. What does abbreviation "DOWNTIME" means?
- 3. What are the benefits of Lean Six Sigma?
- 4. What does the Lean mean?
- 5. How many levels Lean Six Sigma organizational structure involves?
- 6. What are the Lean Six Sigma 8 Wastes?
- 7. What sets of methodologies Six Sigma uses?

- 1. What are principles for lean enterprise?
- 2. Describe the Principle "Value" for lean enterprise.
- 3. Describe the Principle "Value Stream" for lean enterprise.
- 4. What is Principle "Flow" for lean enterprise?

- 5. What is Principle "Pull" for lean enterprise?
- 6. Describe the Principle "Perfection" for lean enterprise.
- 7. What advantages of Six Sigma do you know?

8 Theme 8.

Auditing Process-based Quality Management Systems

Discussion Topics

- 1. Introduction to audit
- 2. The Process Approach to Auditing
- 3. Preparing for an Audit

An audit is a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Possible reasons to audit: ensure compliance with ISO 9001; ensure compliance with organization requirements; ensure compliance with regulatory requirements; ensure the QMS is effectively implemented and maintained.

Auditing for improved performance: look for opportunities for improvement; look for best practices that could be applied in other areas; look for preventive action; look for outstanding emphasis on customer satisfaction.

Principles of auditing: Ethical conduct, Fair presentation, Professional care, Independence, Objectivity, Impartiality, Evaluations based on evidence, Competence, Cooperation, and Trust.

External independent audits – third party. It is conformity to a specific standard.

Customer audits of suppliers – second party. This is conformance to customer requirements and customer's special interest items.

Internal audits – first party. It is performance to the organization's objectives. Identification of problem areas! Finding opportunities for improvement!

Evolving nature of quality management: Internal focus vs. customer focus; Control vs. improvement; QA (Quality Assurance) by QA vs. QA by organization; Leadership: from QA or from management; Documented procedures vs. manage processes; Independence of QA vs. integration; Alignment of business, policy and objectives.

Principle #4 – Process Approach. A desired result is achieved more efficiently when activities and related resources are managed as a process. Principle #5 – System approach to management. It means Identifying, understanding, and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

Process is a group of interrelated activities and related resources that transforms inputs into outputs.

A group of interrelated activities and related resources that transforms inputs into outputs: processes from suppliers to final customers, feedback from customers to the organization, feedback from the organization to suppliers. Process of Preparing for an Audit consist of stages: Define audit objectives, Define audit scope, Define audit resources, Define audit criteria, Prepare and distribute an audit notification to auditee, Gather and understand relevant documents, Prepare work plan i.e. audit plan. First four steps are typically done by audit boss.

Audit Scope is determined by answers of next questions: What are the boundaries of an audit? What processes will we audit? What organizational functions are included? What is the audit emphasis? What is the timeframe? Audit Criteria are concerned with questions: What policies, procedures, instructions or other requirements will we use as a reference? What are external requirements? What are internal requirements?

Tasks for independent work

- 1. Are Auditing Process-based Quality Management Systems is one just an innovation on the way of improving quality of products and services? Or this is the potential to radically reinvent the way these companies work? Explain your reasons.
- 2. What enterprises could benefit from deployments of Auditing Process-based Quality Management Systems? What new products or services could you envision within those enterprises? Provide several examples.
- 3. What is the Process Approach to Auditing, and how are companies using it? Go online to research this topic and prepare a presentation to share your work.

Discussion Questions

- 1. What is an audit?
- 2. What are possible reasons to audit?
- 3. What are principles of auditing?
- 4. What is external independent audit?
- 5. What type of audit the expression "Conformity to a specific standard" refer to?
- 6. What type of audit the expression "Customer's special interest items" refer
- 7. What type of audit the expression "Performance to the organization's objectives" refer to?

- 1. What is auditing for improved performance?
- 2. What does Audit of third party mean?

- 3. What does Audit of second party mean?
- 4. What does Audit of first party mean?
- 5. What is Evolving nature of quality management?
- 6. Describe the Principle #4 of auditing Process Approach.
- 7. Describe the Principle #5 System approach to management.

Recommended literature

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