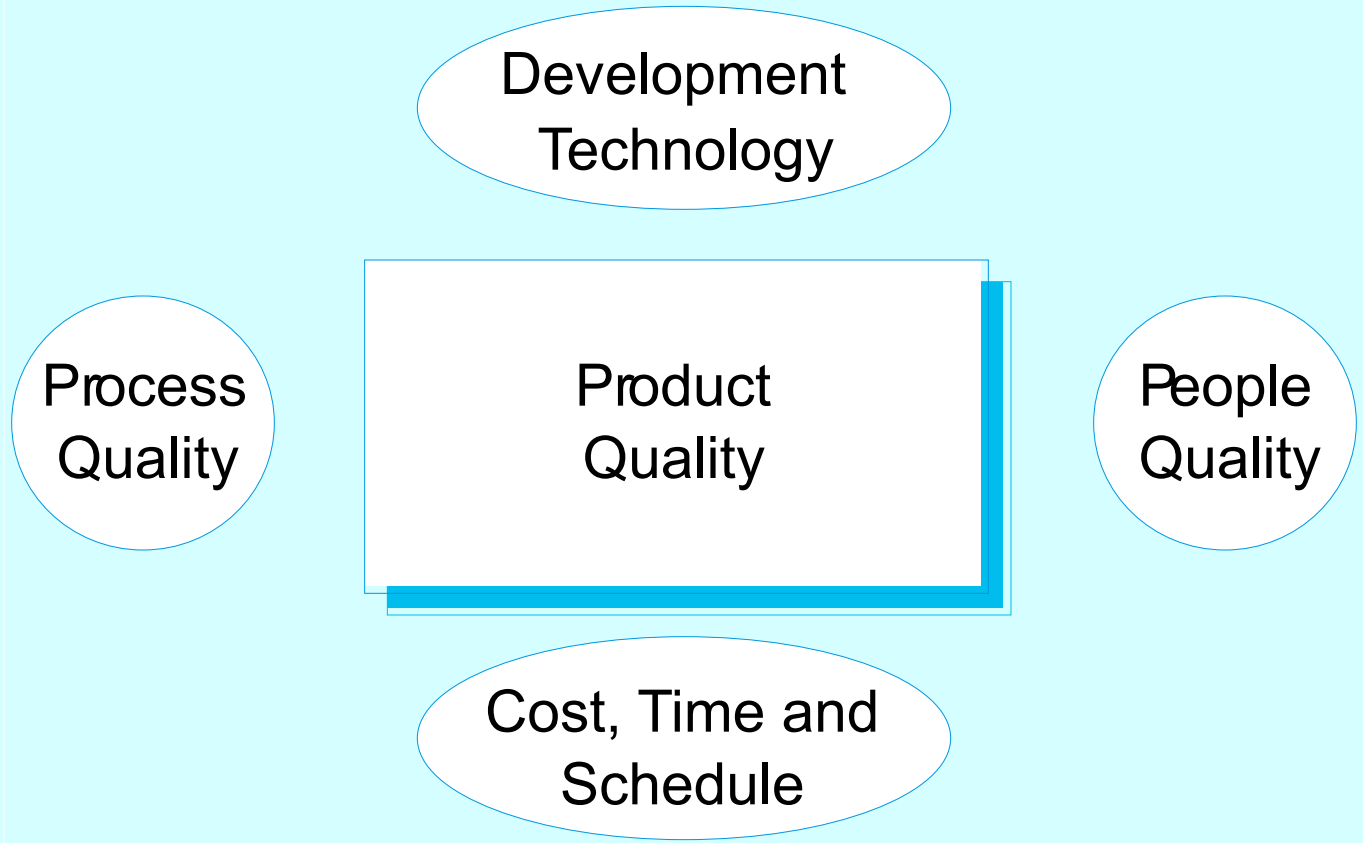
UECS3383 Software Quality Assurance

Lecture 02 – Methodologies for Quality Management

Process and Product Quality

- Process quality and product quality are closely related and process improvement benefits arise because the quality of the product depends on its development process.
- A good process is usually required to produce a good product.
- For manufactured goods, process is the principal quality determinant.
- For design-based activity, other factors are also involved especially the capabilities of the designers.

Software Product Quality Factors



Software Product Quality Factors

- For large projects with ‘average’ capabilities, the development process determines product quality.
- For small projects, the capabilities of the developers is the main determinant.
- The development technology is particularly significant for small projects.
- In all cases, if an unrealistic schedule is imposed then product quality will suffer.

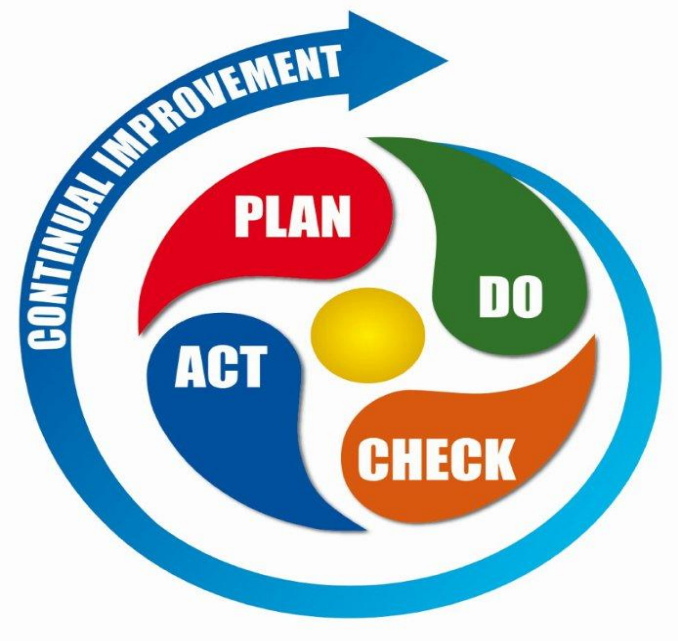
Process Improvement Models

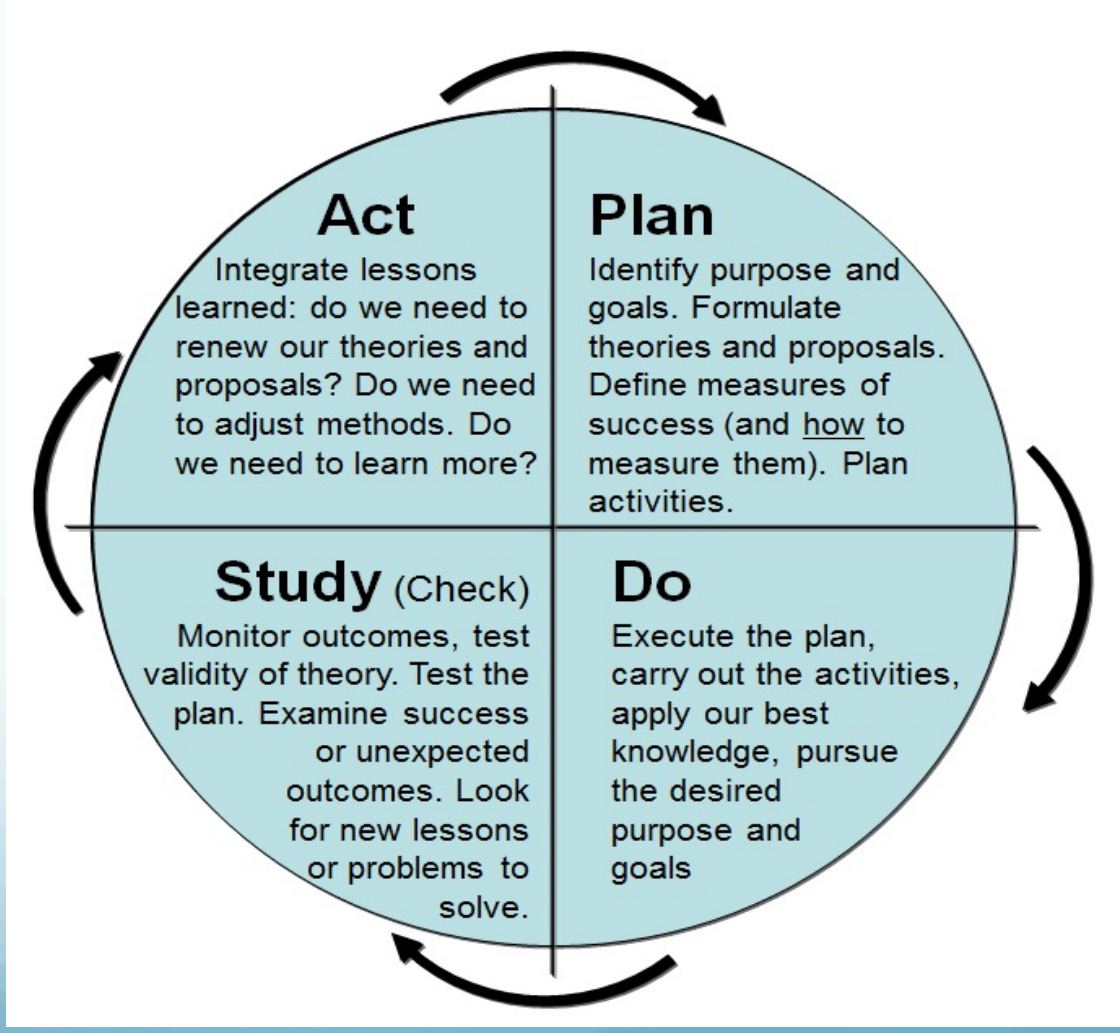
- **PLAN-DO-CHECK-ACT CYCLE (PDCA CYCLE)**
- **Software Process Improvement**
  - **Capability Maturity Model (CMM)**
  - **ISO Standards**
  - **Six Sigma**
  - **Information Technology Infrastructure Library (ITIL)**

PLAN-DO-CHECK-ACT CYCLE (PDCA CYCLE)

- As a model for continuous improvement:
  - When starting a new improvement project.
  - When developing a new or improved design of a process, product or service.
  - When defining a repetitive work process.
  - When planning data collection and analysis in order to verify and prioritize problems or root causes.
  - When implementing any change

PLAN-DO-CHECK-ACT CYCLE (PDCA CYCLE)





PDCA CYCLE

- **PLAN**
  - Establish the objectives and processes necessary to deliver results in accordance with the expected output (the target or goals).
  - By establishing output expectations, the completeness and accuracy of the specification is also a part of the targeted improvement. When possible start on a small scale to test possible effects.
- **DO**
  - Implement the plan, execute the process, make the product. Collect data for charting and analysis in the following "CHECK" and "ACT" steps.

PDCA CYCLE … (continued)

- **CHECK**
  - Study the actual results (measured and collected in "DO" above) and compare against the expected results (targets or goals from the "PLAN") to ascertain any differences.
  - Look for deviation in implementation from the plan and also look for the appropriateness and completeness of the plan to enable the execution, i.e., "Do".
  - Charting data can make this much easier to see trends over several PDCA cycles and in order to convert the collected data into information. Information is what you need for the next step "ACT”.

PDCA CYCLE … (continued)

- **ACT**
  - Request corrective action on significant differences between actual and planned results.
  - Analyze the differences to determine their root causes. Determine where to apply changes that will include improvement of the process or product.
  - When a pass through these four steps does not result in the need to improve, the scope to which PDCA is applied may be refined to plan and improve with more detail in the next iteration of the cycle, or attention needs to be placed in a different stage of the process.

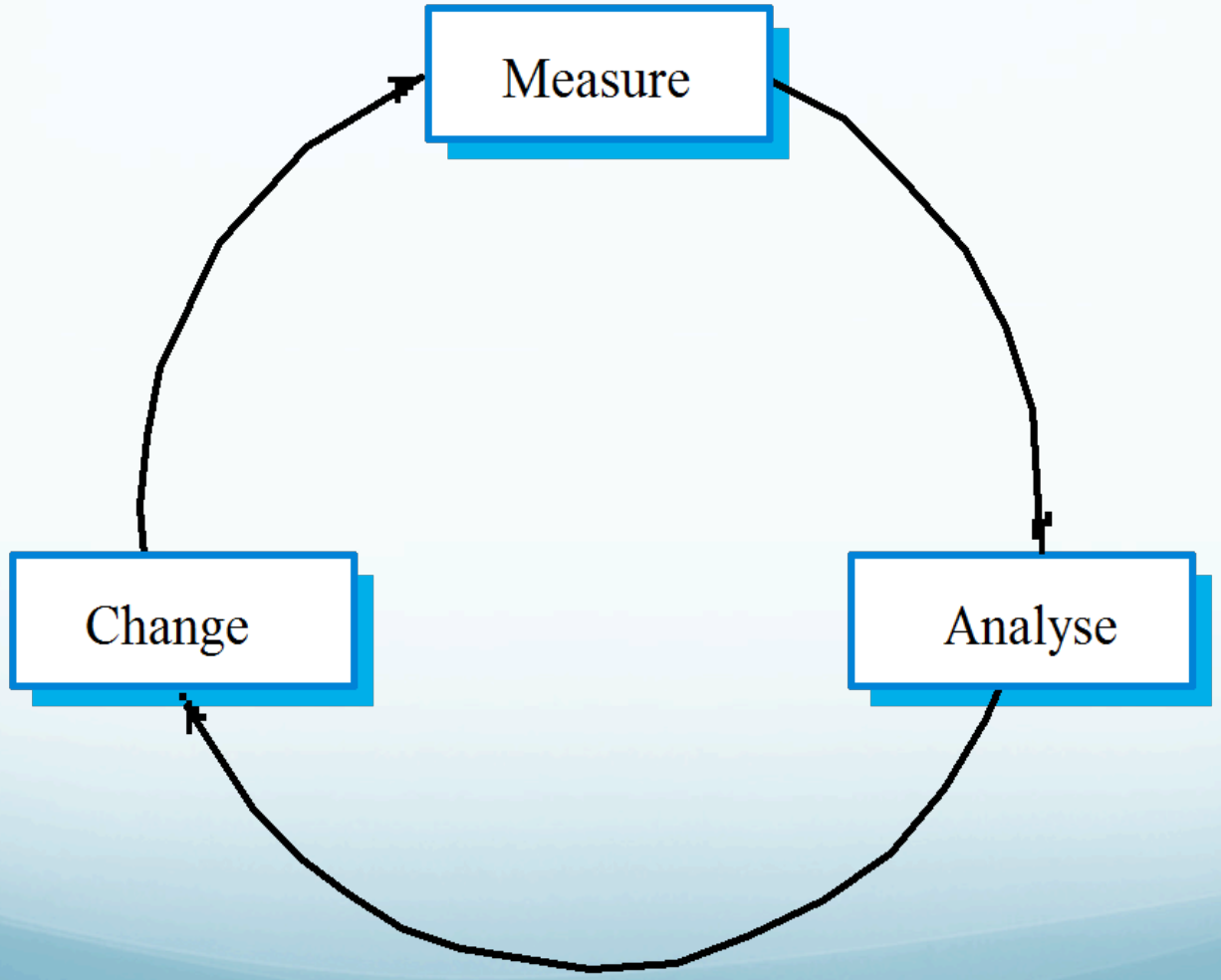
Software Process Improvement (SPI)

- What is the SOFTWARE PROCESS:
  - The software process is “The set of Activities, Methods and Transformations that people use to Develop and Maintain Software and the Associated Products”.
  - For example: product plans, design documents, code, test cases and user manuals”
  - The Software Process is “the Set of Activities, Methods, and Practices that guide People in the Production of Software.” (Watts Humphrey 1993)
- SPI is the name given to the identification of the current state-of-the-practice of information systems development within an organization and then improving it.
- SPI focuses mostly on defect reduction and improving the development process

Software Process Improvement (SPI)

- Understanding existing processes and introducing process changes to improve product quality, reduce costs or accelerate schedules.
- Most process improvement work so far has focused on defect reduction. This reflects the increasing attention paid by industry to quality.
- However, other process attributes can also be the focus on improvement.
- **Process Improvement Stages**
  - **Process Measurement** – Attributes of the current process are measured. These are a baseline for assessing improvements.
  - **Process Analysis** – The current process is assessed and bottlenecks and weaknesses are identified.
  - **Process Change** – Changes to the process that have been identified during the analysis are introduced.

The Process Improvement Cycle



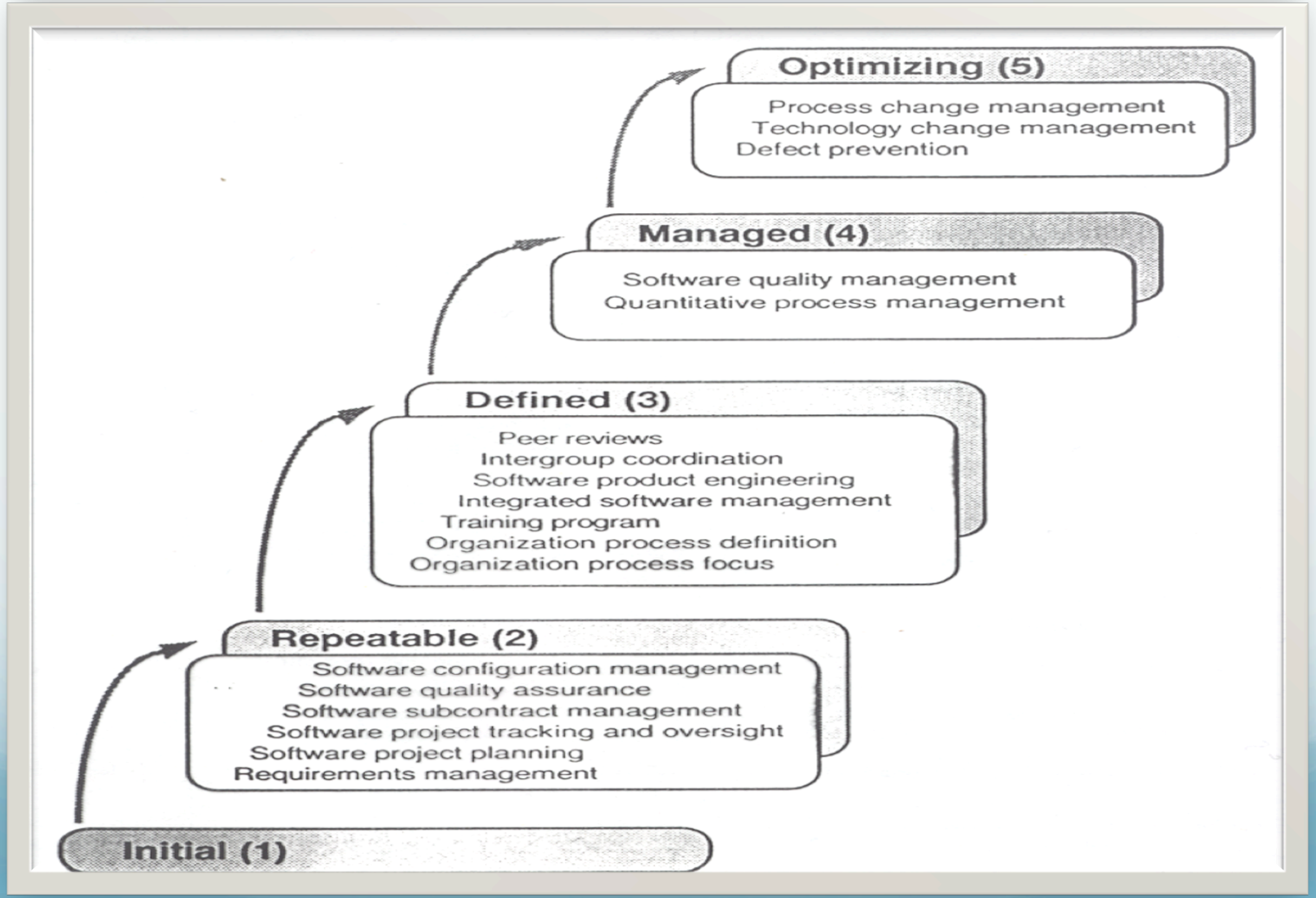
SPI : Capability Maturity Model (CMM)

- **SOFTWARE PROCESS MATURITY is:** The extent to which a specific process is explicitly defined, managed, measured, and effective. Maturity implies a potential for growth in capability and indicates both the richness and consistency with which software processes are applied across the Organization.
- **SOFTWARE PROCESS MATURITY Implies that**: "The Productivity and Quality resulting from an Organization's Software Process can be improved over time through consistent gains in the discipline by using the Software Process"
- When the model is applied to an existing organization's software development processes, it allows an effective approach toward improving them. Eventually it became clear that the model could be applied to other processes. This gave rise to a more general concept that is applied to business.

SPI : Capability Maturity Model (CMM)

- This Model is developed by Software Engineering Institute (SEI), Carnegie Mellon. Funded by U.S. Department of Defense, concerned with late and cancelled contracts.
- The CMM model's application in software development has sometimes been problematic.
- Applying multiple models that are not integrated within and across an organization could be costly in training, appraisals, and improvement activities.
- The Capability Maturity Model Integration (CMM-I) project was formed to sort out the problem of using multiple models for software development processes, thus the CMMI model has outdated the CMM model, though the CMM model continues to be a general theoretical process capability model used in the public domain.

SPI : Capability Maturity Model (CMM)



SPI : Capability Maturity Model (CMM)

1. **Initial.** The software process is characterized as ad hoc, and occasionally even chaotic. Few processes are defined, and success depends on individual effort and heroics.
2. **Repeatable.** Basic project management processes are established to track cost, schedule, and functionality. The necessary process discipline is in place to repeat earlier successes on projects with similar applications.
3. **Defined.** The software process for both management and engineering activities is documented, standardized, and integrated into a standard software process for the organization. All projects use an approved, tailored version of the organization's standard software process for developing and maintaining software.
4. **Managed.** Detailed measures of the software process and product quality are collected. Both the software process and products are quantitatively understood and controlled.
5. **Optimizing.** Continuous process improvement is enabled by quantitative feedback from the process and from piloting innovative ideas and technologies.

SPI : ISO Standards

- **What is a standard?**
  - A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.
- ISO has published over 19000 International Standards that can be purchased from ISO or its members.

SPI : ISO Standards

- What are the benefits of ISO International Standards?
  - ISO International Standards ensure that products and services are safe, reliable and of good quality. For business, they are strategic tools that reduce costs by minimizing waste and errors and increasing productivity. They help companies to access new markets, level the playing field for developing countries and facilitate free and fair global trade.

SPI : ISO Standards

- Some examples of ISO Standards
  - ISO 31000 Risk management
  - ISO 9000 Quality management
  - ISO 26000 Social responsibility
  - ISO 14000 Environmental management
  - ISO 50001 Energy management
  - ISO 22000 Food safety management
  - ISO 3166 Country codes
  - ISO 4217 Currency codes
  - ISO 639 Language codes

SPI : ISO Standards

- The **ISO 9000** family of standards is related to quality management systems and designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to the product.
- The standards are published by ISO, the International Organization for Standardization, and available through National Standards bodies.
- ISO 9000 deals with the fundamentals of quality management systems, including the eight management principles on which the family of standards is based.
- ISO 9001 deals with the requirements that organizations wishing to meet the standard have to fulfill.

SPI : ISO Standards

ISO 9000 Series	Guidelines for Selection and Use		
ISO 9004	Quality Management and Quality Systems Elements Guidelines		
ISO 9001	Quality Systems, Models for Quality Assurance		
ISO 9002			
ISO 9003			
Product Phase	ISO Standard		
	9001	9002	9003
Development	√		
Design	√		
Production	√	√	
Final Inspection	√	√	√
Test	√	√	√
Installation	√	√	
Service	√		

SPI : Six Sigma

- It is important to recall that every customer always values consistent and predicable services and/or products with near zero defects. Therefore they experience the variation.
- If we can measure process variations that cause defects i.e. unacceptable deviation from the mean or target, we can work towards systematically managing the variation to eliminate defects.
- Six Sigma is a methodology focused on creating breakthrough improvements by managing variation and reducing defects in processes across the enterprise.
- Sigma is a Greek symbol represented by "σ"
- Sigma is a statistical term that measures process deviation from the process mean or target. Mean is also referred to as average in common language. The figure of six was arrived statistically by looking at the current average maturity of most business enterprises.

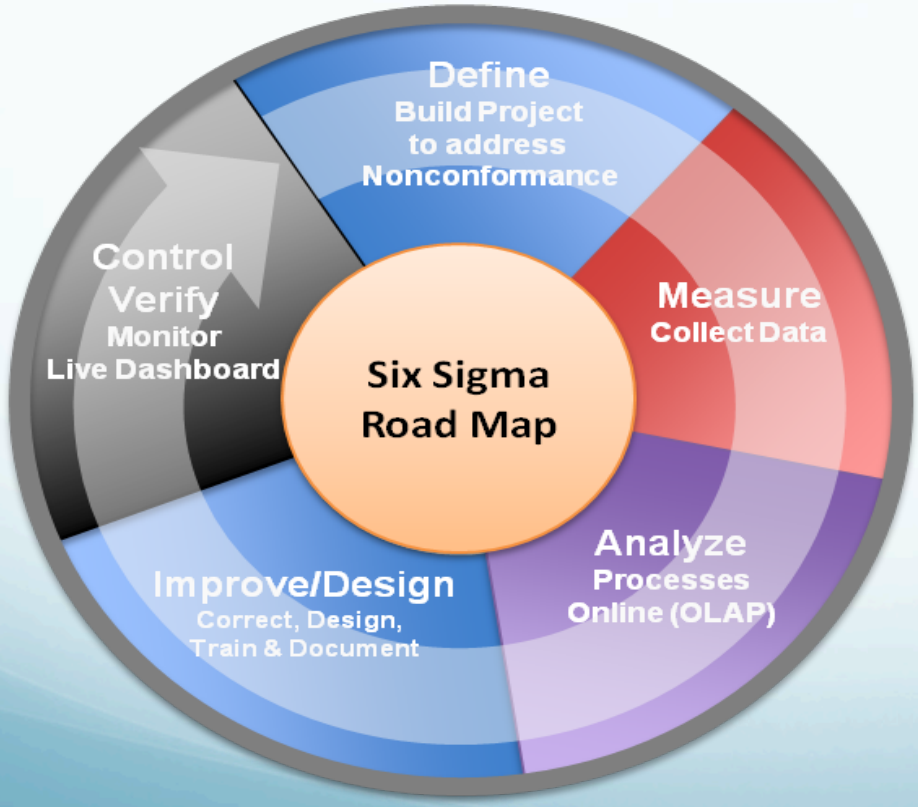
SPI : Six Sigma

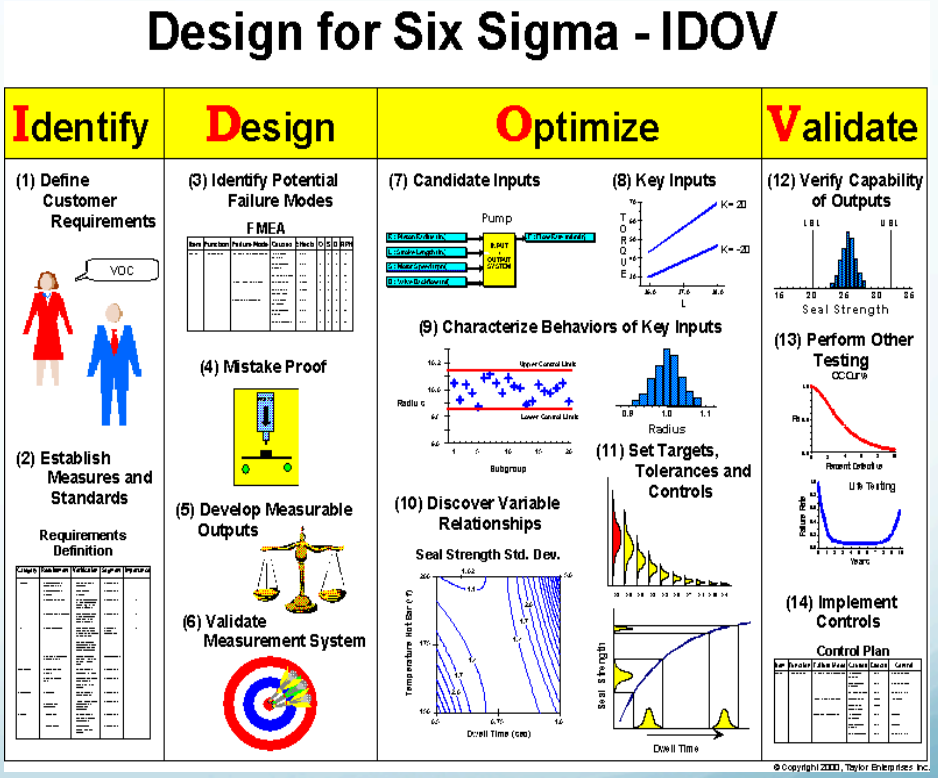
- **There are two potential scenarios –**
  - **First**, there is already an existing process(s) that is working "reasonably" well;
  - **Second,** there is no process at all. A bad process is as good as no process.
- The first scenario focuses on significant process improvements and requires use of DMAIC:
- **Define** process goals in terms of key critical parameters (i.e. critical to quality or critical to production) on the basis of customer requirements or Voice Of Customer (VOC)
- **Measure** the current process performance in context of goals
- **Analyze** the current scenario in terms of causes of variations and defects
- **Improve** the process by systematically reducing variation and eliminating defects
- **Control** future performance of the process

SPI : Six Sigma

- The second focuses on process design using **Design For Six Sigma** (DFSS) approach. DFSS typically requires **IDOV**:
  - **Identify** process goals in terms of critical parameters, industry & competitor benchmarks, VOC
  - **Design** involves enumeration of potential solutions and selection of the best
  - **Optimize** performance by using advanced statistical modeling and simulation techniques and design refinements
  - **Validate** that design works in accordance to the process goals

SPI : Six Sigma





SPI : Information Technology Infrastructure Library (ITIL)

- ITIL is defined as a set of concepts and rules for managing infrastructure, development and operations inside information technologies
- It gives detailed description of important IT practices with detailed written procedures, tasks and metrics which can help IT organizations, as well as IT service providers inside the company
- It is a framework and does not require a license to practice and is independent of any commercial solution or platform
- For the past 24 years, ITIL has become a de-facto standard and a most widely used and accepted approach in defining processes for IT service-oriented organizations. It informs IT management what needs to be done and how it will get done from the process perspective

SPI : Information Technology Infrastructure Library (ITIL)

- It provides best practice guidance to implement a true life cycle of service management.
- It pays more attention to the areas of designing services suitable for the business and creating a strategy around the area of emphasis.
- It gives more advice on Continual Service Improvement and it addresses the life cycle of service management.
- Furthermore, it embraces more holistic service management practice that includes business and IT at strategic, tactical and operational layers

Roles and Responsibilities

- Role of SQA in software development process:
  - Monitoring the software engineering processes
  - Reducing the risk of problems
  - Ensuring the quality of the software
  - Providing information for decision-making
  - Help meeting standards:
    - Contractual or legal requirements
    - Industry-specific standards

Who Involves QA Activities?

- Software engineers, project managers, customers, sale people, SQA group
- **Engineers** involved the quality assurance work:
  - apply technical methods and measures
  - conduct formal technical review
  - perform well-planned software testing
- The **SQA group's role:** serves as the customer's in-house representative assist the software engineering team in achieving high-quality
- The **SQA group's responsibility**: quality assurance planning oversight, record keeping, analysis and reporting

Who Involves QA Activities?

- The **SQA group's tasks**:
  - Prepare a SQA plan for a project
  - Participate in the development of the project's software process description
  - Review engineering activities to verify compliance with the defined process
  - Ensure the deviations in software work and products according to a documented procedure

Audits

- Audits are document verification systems in which project documents and records are compared with organization's standards or defined processes
- It is used as a QA tool to ensure conformance of project execution to organization's defined software development processes
- It is to ensure a project is being executed in conformance with the organzation's defined processes
- Its' purpose is uncovering non-conformance (NCs)
- NCs is the deviations of project documents or project records from the processes described in the organization's defined processes
- The output is a non-conformance report (NCR)

Who is in the Audits team?

- Auditors
  - the people who conduct the audit
  - Has specialized training in conducting audits
  - Auditors within and organization must receive internal audit training
  - Auditors conducting certification audits or surveillance audits for other organizations must be trained and certified to do so
- Auditees – the people whose project is being audited
- Usual duration of project audit is one to two hours

Audit Process

- **Components of Audit Process:**
  - **Purpose**
    - Define the process for conducting audits in the organization. It covers both “periodic” audits and “phase-end” audits
  - **Scope**
    - Applicable for all software projects executed in the organizations
  - **Entry Criteria**
    - The entry criterion for periodic audits is approval of yearly audit plans. The entry criterion for phase-end audits is completion of a software development phase
  - **Exit Criteria**
    - The audit is conducted, all non-conformance reports are closed, non-conformance reports are analyzed, findings are presented to management, and the results of the non-conformance report analysis are tracked until improvements is effected in the organizational process

Audit Process

- Auditor verifies all project documents and notes any NCs
- Auditor prepared the NCR.
- The completed NCR is handed over to the auditee
- Auditee must take necessary action specified in the NCR to address the NCs and have them closed by the auditor within the time allowed
- Necessary action as specified in an NCR:
  - Taking corrective action so that the NC is resolved
  - Putting in place preventive action so that the NC is not repeated in the project later

Types of Audit

- Conformance Audits versus Investigative Audits
- Vertical Audits versus Horizontal Audits
- Periodic Audits versus Phase-End Audits
- Internal Audits versus External Audits

Types of Audit

- Conformance Audits versus Investigative Audits

Conformance Audit	Investigative Audit
Focus on the efficacy of implementation of organizational processes during project execution	Focus on finding the causes for a failure; sometimes focus o finding the causes for an extraordinary success
Conducted to compare and contrast the project documents with the organizational processes	Project execution documents are carefully verified and in-depth interviews are held with project personnel
To uncover NCs, prepare an NCR	To uncover the specific reasons that caused a failure or grand success
Track the NCR to its resolution	Used un special scenario only

Types of Audit

- Vertical Audits versus Horizontal Audits

Vertical Audit	Horizontal Audit
It is conformance audits conducted across organization on either a few selected projects or on all projects	It is conformance audits conducted across organization on either a few selected projects or on all projects
Focus on all aspects of the project(s)	Focus on only **ONE** aspect of the project(s). Focus on the efficacy of implementation of one crucial aspect.
NIL	E.g. Configuration management audits

Types of Audit

- Periodic Audits versus Phase-End Audits

Periodic Audit	Phase-End Audit
Conformance audits conducted at the organization level based on calendar duration	It is triggered by project events. The SPM arranges for audits in coordination with the QA department.
E.g. ISO certified organizations conduct this audits once every two or three calendar months	NIL
Each audit covers a few of the organization's current project. All projects under execution (not closed projects) in the organization are covered within a one-year period.	E.g. This kind of audits are conducted after the phases of "Project initiation", "Software requirements analysis", "Software design", "Software construction", "System testing" and "Project closure".
At the end of every cycle of audits, the audit findings are consolidated and presented to management and to the auditees	NIL

Audit Process – Periodic Audits

- **Audit Schedule**
  - The actual schedule for each cycle if the audit is prepared one week in advance of the audit cycle dates
  - The schedule consists of the projects to audited, assignment of auditors to projects and service departments, and date and time of the audit
  - Schedule is circulated to all audits and auditees included in the audit schedule
- **Auditors**
  - QA department arranges for periodic training of selected candidates in the precepts and practices of conducting internal audits and maintains a list of internal auditors
  - Mainly selected from the technical, QA and other service departments
  - Internal audit training is conducted by a lead auditor

Audit Process – Periodic Audits

- **Agency Responsible for Conduction Audits**
  - QA department plans and arrange audits
  - QA department is the repository for non-conformance reports, tracking them to their resolution
  - QA department consolidates audit findings at the ed of every periodic audit, present them to management, and, in coordination with the SE process group, effect the necessary improvements
- **Audit Planning**
  - QA department prepares annual audit plan for periodic audits
  - Normally, audits are conducted once every quarter
  - Audit plan is review by the SE process group and approved by the head of the QA department
  - Types of audits are conformance audits and vertical audits

Periodic Audit Process

1) Opening meeting among auditors, auditees and management representative

2) Head of QA dept. presents audit objectives and schedule, resolving issues and seeking corporation from ALL involved to conclude audit sucessfully

3) Auditor reaches the auditee's location five minutes in advance; auditee is present to receive the auditor

4) Auditee submits all requested records and data to the auditor, including evidence of the action taken on previous non-conformance reports. When asked to produce a document, the auditee must do so in three minutes or less

5) Auditor examines the project records and compare with corresponding organizational process to uncover non-conformances

Periodic Audit Process... (continued)

6) Auditor records any non-conformances, observations, best practice, worst practice implemented in the project or department

7) Non-conformance and observations are discussed with auditee; auditee's explanations are taken into considerations before the auditor finalizes the non-conformance report. Auditor might also record any recommendations that he/she believes to be fit and proper.

8) Non-conformances are classified as either major or minor by the auditor. If the auditee disagrees with the appropriateness or classification of a non-conformance, the matter can be escalated to the head of QA dept.

9) Auditor has the non-conformance report reviewed by the head of the QA department, QA dept. also retains a copy

10) Auditee resolves all non-conformances in two calendar weeks or less and arranges for closure meeting

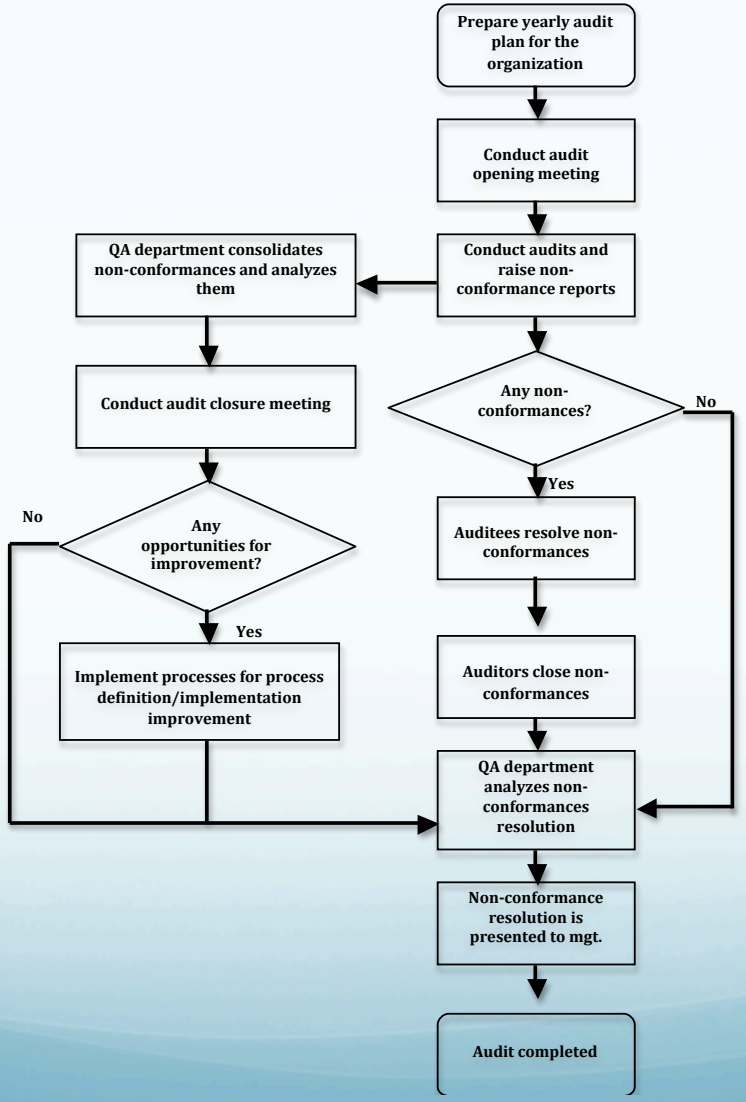
Periodic Audit Process ... (continued)

11) The closed non-conformance report is signed off by both the auditor and the auditee and is made part of the QA department's audit records

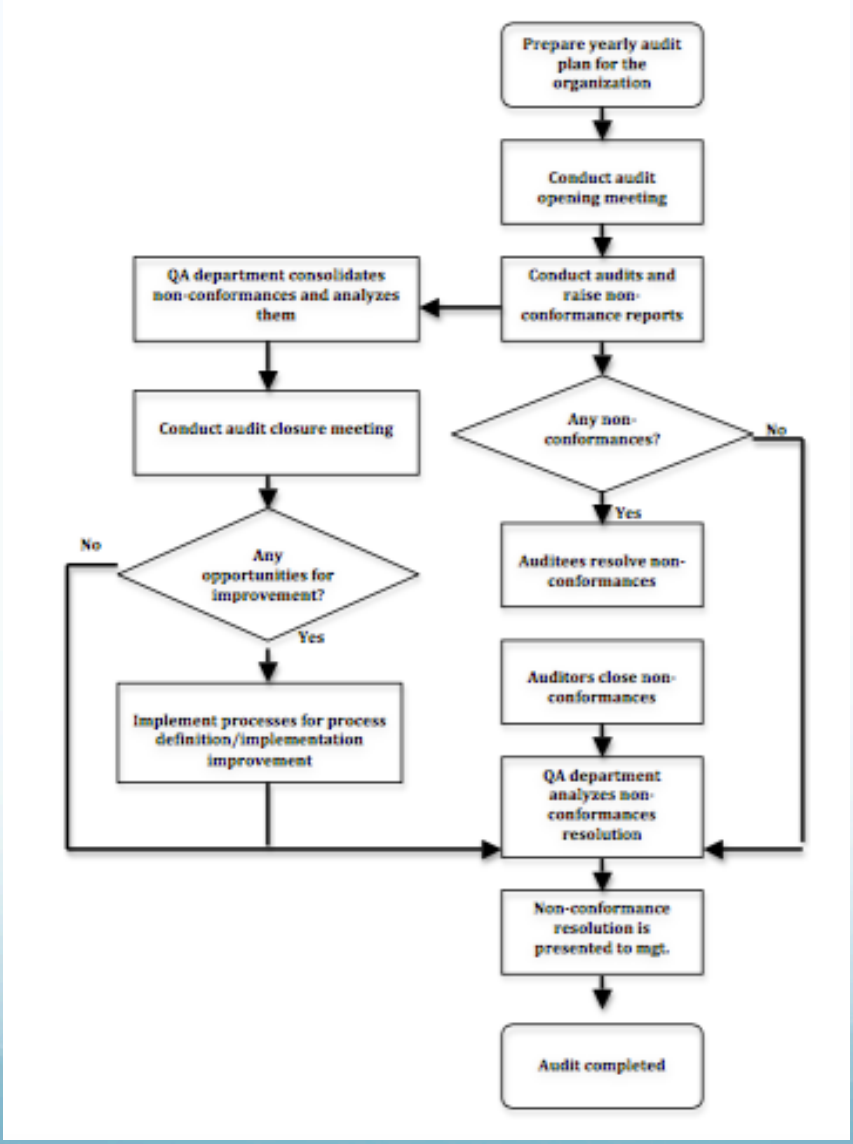
12) The head of the QA department arranges for consolidation of the audit findings. Auditees and auditors are informed of these findings in the audit closure meeting

13) Lastly, the head of QA coordinates with the software engineering process group to effect any necessary improvements in the organizational process

Periodic Audit Process



Periodic Audit Process



Audit Process – Phase-End Audits

- Phase-end audits are conducted for every project at the end of the project initiation, requirement analysis, software design, construction, testing, and project closure phases.
- **Audit Plans**
  - On a monthly basis
  - The head of QA consolidates the requirements and prepares a phase-end audit plan (i.e. projects, probable completion dates, assigned auditor, ensuring project dates and periodic audits and phased-end audits dates do no clash
  - The plan is circulated to all software project managers and auditors
- **Auditors:** Phase-end audits are conducted by executives or trained internal auditor of the QA departments

Phase-End Audit Process

1) Software PM inform the QA department at east one business day in advance
2) Auditor arrives at the agreed-upon time and conducts the audit.
3) Auditee has all necessary artifacts ready and provides them to auditor as requested
4) Auditor conducts the audit and records any non-conformances uncovered after considering any prior explanation from auditee

Phase-End Audit Process... (continued)

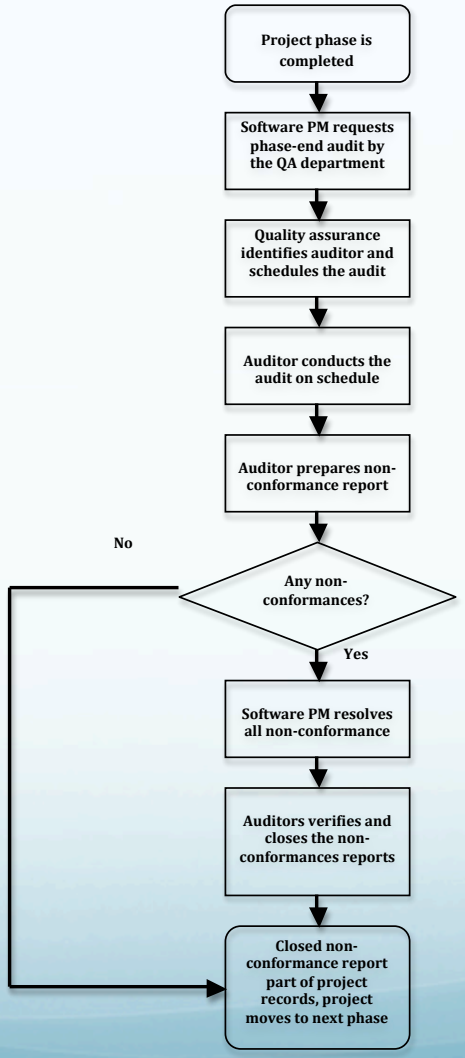
5) Auditor prepares the non-conformance report and obtains approval from the head of the QA department

6) Auditor submits the non-conformance report to the software PM. Software PM arranges resolution of the non-conformances and close the non-conformance report

7) Auditors verifies the resolution and informs the software PM if it is not satisfactory

8) When all the non-conformances are satisfactory resolved, auditor closes the non-conformance report and hand it over to the software PM for inclusion in the project records which concludes the requested phase-end audit

Phase-End Audit Process



Types of Audit

- Internal Audits versus External Audits

Internal Audit	External Audit
It can be conformance audits, investigative audits, periodic audits or phase-end audits; but are conducted by people internal to the organization	Conducted by external agency that specializes in the audit process
Internal auditors are independent of the project being audited, meaning they can be from either the QA department or from other projects.	Organizations that seek certification for compliance with the ISO 9000 series of standards or any other similar standards use external auditors
To ensure conformance or investigate the occurrence of a special event	Individuals who are certified as lead auditors can conduct audits for certification or to ensure continue compliance with ISO standards.
External audits consist the same process as internal audits, the NCR is the vehicle for recording and reporting NCs uncovered during the audits	

Classification of External Audits

- **Precertification audits**
  - Conducted as a prelude to certification audits
  - Serves as a rehearsal for organization so that it can pass the certification audit
  - Allows organization to smooth out any uncovered rough edges in preparation for a certification audit
- **Certification and recertification audits**
  - These audits culminate in either awarding or denying the coveted certificate to the organization
  - Certification audit is conducted only ONCE, unless it result in denial of the certificate to the organization
  - Most quality certification models **mandate** periodic recertification, such as once every three years.
  - A certification audit is conducted or an organization that has never been certified
  - A recertification audit is exactly the same as a certification audit, except that it is conducted

Classification of External Audits

- **Surveillance audits**
  - ISO 9000 certification mandates a surveillance audit once every six months to ensure process implementation is at the same level it was at the time of the certification audit.
  - The **SAME** external agency that originally awarded the certificate conducts these surveillance audits. It is scaled down slightly from the certification audits, and a smaller sample of project is audited

Corrective Actions and Preventive Actions (CAPA)

- CAPA involves systematic activities that implement organization-wide improvements of effectiveness and operational efficiency
- These activities are NOT intended to deal with immediate correction of detected defects but to eliminate the causes of those defects throughout software development departments
- As a means of continuous improvement of effectiveness and efficiency, the CAPA process is one of the tools used to achieve the performance-oriented objective of ASQ: fulfillment of functional and managerial requirements while reducing the costs of carrying out software development, maintenance and QA activities

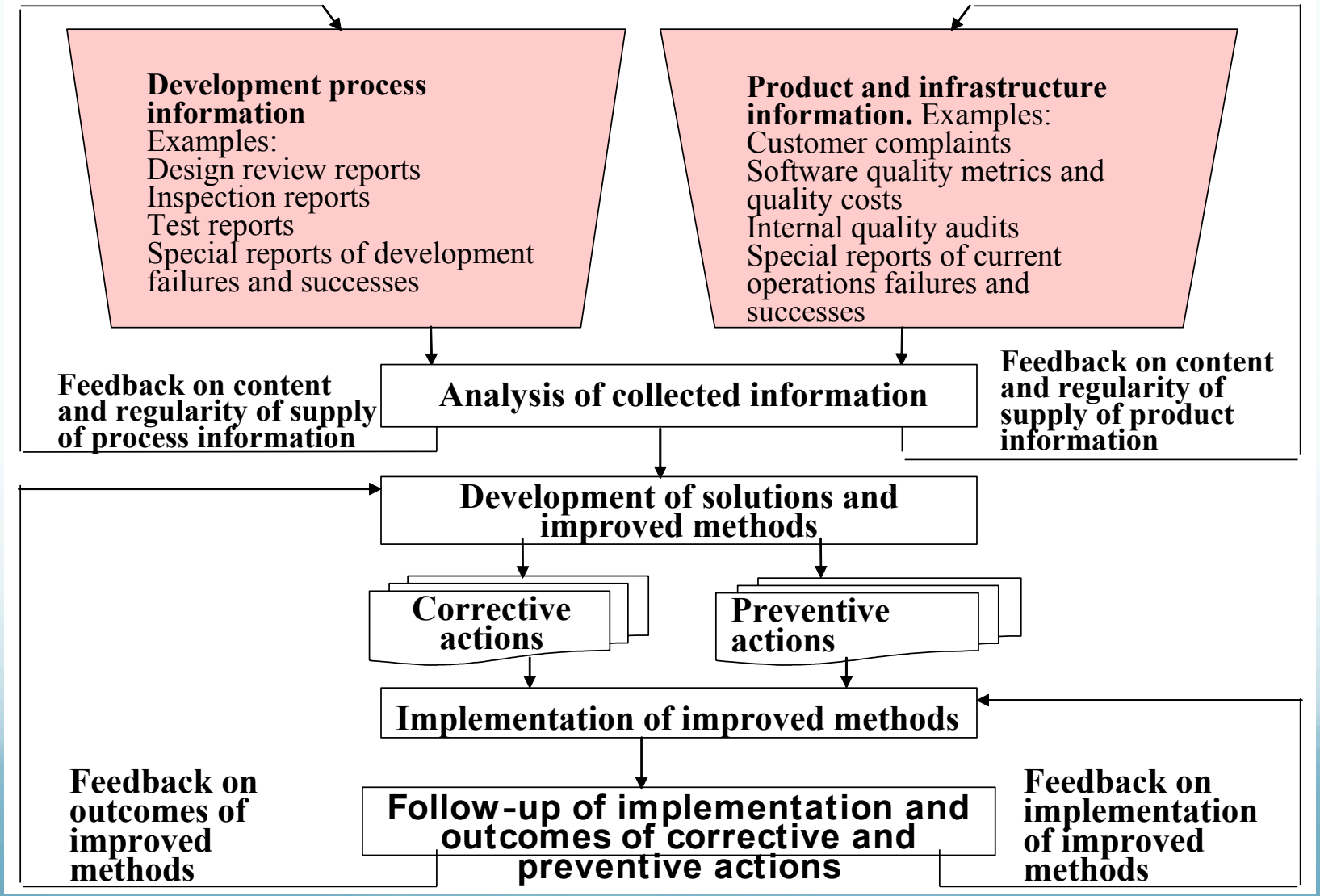
Definitions of CAPA

- Corrective actions – A regularly applied feedback process that includes collection of information on quality non-conformities, identification and analysis of sources of irregularities as well as development and assimilation of improved practices and procedures, together with control of their implementation and measurement of their outcomes.
- Preventive actions – A regularly applied feedback process that includes collection of information on potential quality problems, identification and analysis of departures from quality standards, development and assimilation of improved practices and procedures, together with control of their implementation and measurement of their outcomes.

The Corrective and Preventive Actions Process

- Successful operation of a CAPA process includes the following activities:
  - Information collection
  - Analysis of information
  - Development of solutions and improved methods
  - Implementation of improved methods
  - Follow-up CAPA activites
- For successful estimation of the CAPA process, a closed feedback loop is applied to control the flow of information, implementation of the resulting changes in practices and procedures together with measurement of the outcomes

The Process of CAPA



CAPA Process – Information Collection

- Information sources : Internal and External
- Four main sources of information collection
  - Internal
    - Software development process
    - Software maintenance
    - SQA infrastructure class of sources
    - Software quality management procedure class of sources
  - External
    - Customer complaints
    - Customer service statistics
    - Customer-suggested proposals

Sources of CAPA Information

- **Internal information sources**
- **Software development process**
  - Software risk management reports
  - Design review reports
  - Inspection reports
  - Walkthrough reports
  - Experts opinion reports
  - Test reviews
  - Special reports on development failures and successes
  - Proposals suggested by staff members
- **Software maintenance**
  - Customer applications statistics
  - Software change requests initiated by customer applications
  - Software change requests initiated by maintenance staff
  - Special reports on maintenance failures and successes
  - Proposals suggested by staff members

SQA infrastructure class of sources

* Internal quality audit reports
* External quality audit reports
* Performance follow-up of trained and certified staff
* Proposals suggested staff members

Software quality management procedures class of sources

* Project progress reports
* Software quality metrics reports
* Software quality cost reports
* Proposals of staff members

External information sources

* Customer complaints
* Customer service statistics
* Customer-suggested proposals

Source of Information

- The initiation of inquiries into major project failures is almost instinctive. The conclusions reached by these inquiries affect a project's immediate environment; in many cases they also contribute to improved practices and procedures through the application of CAPA
- Success stories, however, are rarely investigated. Although the staff immediately responsible for the success are usually rewarded, the likelihood of applying a CAPA analysis is low. Such a process can yield meaningful information about which aspects of the process led to the project's success as well as identify elements that could benefit from further improvement

CAPA Process – Analysis of Information

- Regular operation of the CAPA process is expected to create a massive flow of documents related to a wide range of information
- Analysis of information involves:
  - Screening the information and identifying potential improvement
  - Analysis of potential improvements
  - Generating feedback

Analysis of Information

- The staff responsible for information analysis are expected to face mounds of documents, making it unfeasible for all the documents to be screened. One approach to reduce the load is to report only those cases that the units believe are amenable to initiation of a CAPA process.

- This approach can induce a situation of “no fault” reporting through use of the “no importance” excuse. Another approach is to ask the units to indicate the priority of each case in their reports. This information will induce the CAPA team to deal with the high-priority items first. A third approach is to sample the fault documents.

- Application of random sampling to each type of information and document can reduce the load toa a manageable level and increase the probability of identifying the most important cases. Sampling can also be used in combination with the second approach, where it is applied to low- and medium-priority cases. A combination of the second and third approaches is preferable in most instances.

CAPA Process – Development of solutions and improved methods

- Solutions to identified causes of recurrent software system faults are required to:
  - Eliminate recurrence of the types of faults detected
  - Contribute to improved efficiency by enabling higher productivity and shorter schedules
- Several directions for solutions are commonly taken:
  - Updating relevant procedure
  - Changes in practices, including updating of relevant work instructions (if any exist)
  - Shifting to a development tools that is more effective and less prone to the detected faults
  - Improvement of reporting methods, including changes in report content, frequency of reporting and reporting tasks.
  - Initiatives for training, retraining or updating staff

CAPA Process – Follow-up Activities

- Three main follow-up tasks:
  - Follow-up of the flow of development and maintenance CA records enables feedback regarding cases of no reporting or low-quality reporting
  - Implementation follow-up determines whether a CAPA has been performed as required
  - Outcomes follow-up ascertains the degree to which a CAPA has achieved the expected results

Organizing the CAPA

- The CAPA process is carried out by the joint efforts of a permanent CAPA body together with ad-hoc team participants. The permanents CAPA body, commonly called the CAB, activates the CAPA process by screening information, appointing members of targeted ad hoc CAPA teams, promoting implementation and following up the process
- The ad hoc CAPA team's task is to analyse information about a given topic in addition to developing solution and a CAPA process. The team members are expected of a d hoc CAPA teams are department staff members experienced in the subject matter