

# Tutorial Sheet 10: Quality Management System and Audit (Part -2)

## Assignment 1: Process Audit

### Quality Management Systems-Fundamentals and Vocabulary (ISO 9000:2005) Evaluating of QMS

When evaluating quality management systems, there are four basic questions that should be asked in relation to every process being evaluated.

- Is the process identified and appropriately defined?
- Are responsibilities assigned?
- Are the procedures implemented and maintained?
- Is the process effective in achieving the required results?

**Auditing QMS** Audits are used to determine the extent to which the quality management system requirements are fulfilled. Audit findings are used to assess the effectiveness of the quality management system and to identify opportunities for improvement. systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled Three types

1. First party
2. Second party
3. Third party

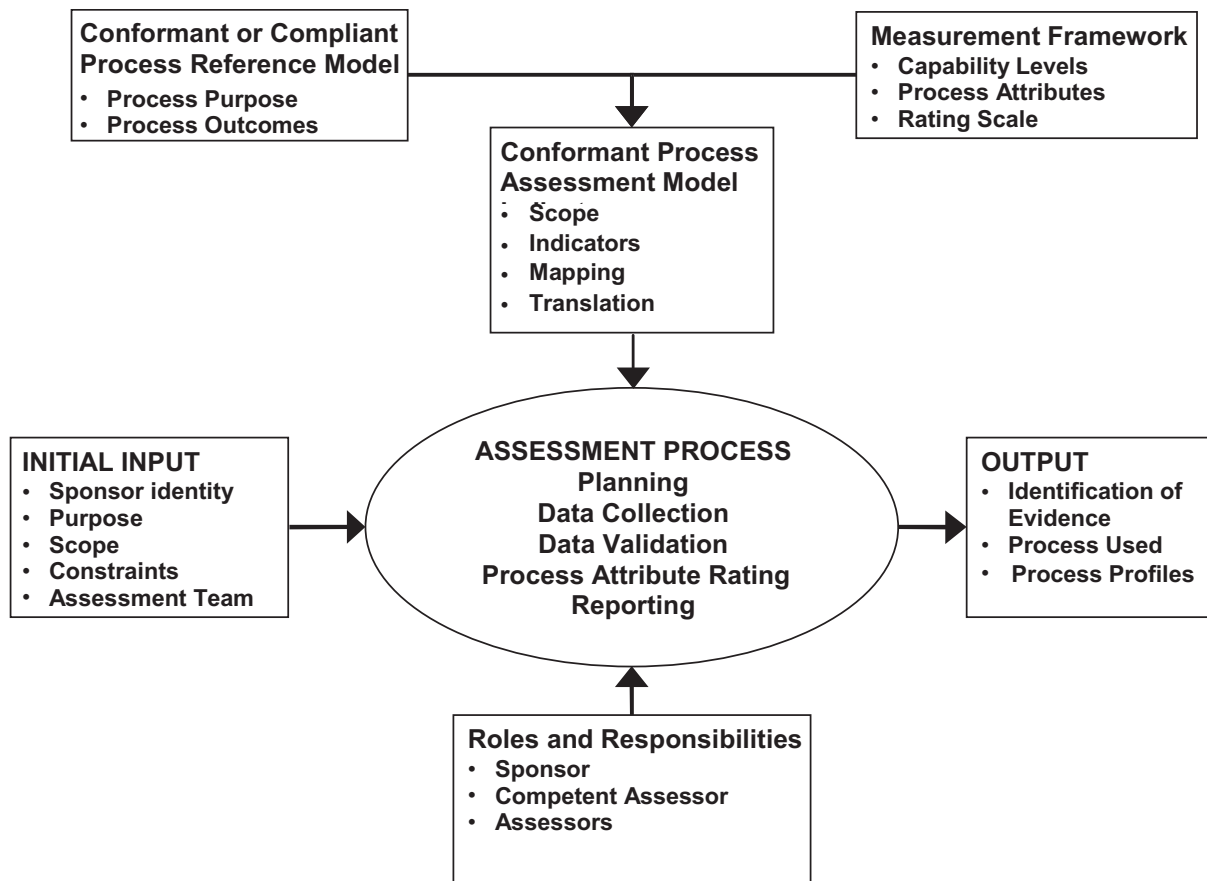
Necessary terms for the audit

- **Audit Criteria** set of policies, procedures or requirements
- **Audit Evidence** records statements of fact or other information which are relevant to the audit criteria and verifiable audit findings results of the evaluation of the collected audit evidence against audit criteria
- **Conformity** fulfillment of a requirement
- **Non conformity** non-fulfillment of a requirement
- **Defect** non-fulfillment of a requirement related to an intended or specified use

- **preventive action** action to eliminate the cause of a potential nonconformity or other undesirable potential situation
- **corrective action** action to eliminate the cause of a detected nonconformity or other undesirable situation

**Information technology – Process assessment – Part 2 (ISO/IEC 15504-2)** This standard defines a Measurement Framework for the assessment of process capability, i.e. process assessment. Assessment is defined as an action of applying specific documented assessment criteria to a specific software module, package or product for the purpose of determining acceptance. It determines the extent to which the existing and newly defined organization's standard processes support achievement of its business goals and to help the organization focus on the need for continuous process improvement. The figure shows main elements of the process assessments. It includes several components:

- **Plan:** An assessment plan shall be developed and documented considering input, activities, resource, responsibilities, criteria to verify, and assessment outputs.
- **Data collection:** data required for evaluating the process. It covers techniques for selection, collection, and analysis of data. each process identified in the assessment scope shall be assessed on the basis the objective evidence which gather for each attribute for each process. The evidence shall be recorded and maintained.
- **Data validation:** The data collected shall be validated to confirm that the evidence collected is objective, ensure that the objective of evidence is sufficient and representative to cover the scope and purpose, and ensure that the data as a whole is consistent.
- **process attribute rating:** A rating shall be assigned based on validated data for each process attribute
- **Reporting:** The assessment results including at minimum the outputs specified by the standard in clause 4.5 shall be documented and reported to the assessment sponsor or to their delegated representative.
- **Roles and responsibilities:** The sponsor of the assessment shall verify that the competent assessor who is to take responsibility for and oversee the assessment has the necessary competence and skills, ensure that resources are made available to conduct the assessment and ensure that the assessment team have access to the relevant resources.  
The competent assessor shall confirm the sponsor's commitment to proceed with the assessment, ensure that the assessment is conducted in accordance with the requirements of this part of ISO/IEC 15504, ensure that participants in the assessment are briefed on the purpose, scope and approach of the assessment, ensure that all members of the assessment team have access to appropriate documented guidance on how to perform the defined assessment activities, ensure that the assessment team has the competencies to use the instruments or tools chosen to support the assessment, and confirm receipt of the assessment result deliverables by the sponsor.



Three different levels with measuring attributes are used for the evaluation. Although Process Attributes are defined in such a way that they can be rated independently of one another, this does not imply that there are no other relationships between them. e.g. the achievement of one attribute may be linked to the achievement of another attribute within the capability dimension.

- **Level 0: Incomplete Process** The process is not implemented, or fails to achieve its process purpose. At this level there is little or no evidence of any systematic achievement of the process purpose.
- **Level 1: Performed Process** The implemented process achieves its process purpose. The following attribute of the process demonstrates the achievement of this level:

**Process performance attribute** The process performance attribute is a measure of the extent to which the process purpose is achieved. As a result of full achievement of this attribute i.e., the process achieves its defined outcomes.

- **Level 2: Managed Process** The previously described Performed process is now implemented in a managed fashion (planned, monitored and adjusted) and its work products are appropriately established, controlled and maintained. The following attributes of the process, together with the previously defined attributes, demonstrate the achievement of this level:
  - **Performance management attribute:** The performance management attribute is a measure of the extent to which the performance of the process is managed. As a result of full achievement of this attribute:

- \* objectives for the performance of the process are identified;

- \* performance of the process is planned and monitored;
  - \* performance of the process is adjusted to meet plans;
  - \* responsibilities and authorities for performing the process are defined, assigned and communicated;
  - \* resources and information necessary for performing the process are identified, made available, allocated and used;
  - \* interfaces between the involved parties are managed to ensure both effective communication and also clear assignment of responsibility.
- **Work product management attribute:** The work product management attribute is a measure of the extent to which the work products produced by the process are appropriately managed. As a result of full achievement of this attribute:
- \* requirements for the work products of the process are defined;
  - \* requirements for documentation and control of the work products are defined;
  - \* work products are appropriately identified, documented, and controlled;
  - \* work products are reviewed in accordance with planned arrangements and adjusted as necessary to meet requirements.

The following set shows the general practice indicators for the performance management attributes of level 2

- GPI 2.1.1 Identify the objectives for the performance of the process. Performance objectives may include quality of the artifacts produced, process cycle time and resource usage. Performance objectives are identified based on process requirements. Assumptions and constraints are considered when identifying the performance objectives.
- GPI 2.1.2 Plan the performance of the process to fulfill the identified objectives. Plan(s) for the performance of the process are developed. Responsibilities, commitments and authorities to perform the process are defined, assigned and communicated. Key milestones for the performance of the process are established. Schedule is defined and aligned with the approach to performing the process. Process work product reviews are planned. Responsibilities and authorities to verify process work products are defined and assigned.
- GPI 2.1.3 Monitor and control the performance of the process. The process is performed according to the plan(s). Process performance is monitored to ensure planned results are achieved. Appropriate actions are taken when planned results are not achieved. The plan(s) are adjusted, as necessary. Rescheduling is performed as necessary.
- GPI 2.1.4 Allocate and use resources to perform the process according to plan. The resources necessary for performing the process are identified, made available, allocated and used. The information necessary to perform the process are identified and made available. The necessary infrastructure and facilities are identified and made available.
- GPI 2.1.5 Manage the interfaces between involved parties. The individuals and groups involved in the process performance are determined. Responsibilities of the involved parties are assigned. Interfaces between the involved parties are managed.

The following is a set of management practices that indicate the achievement of the Work Product Management Attribute:

- GPI 2.2.1 Define the requirements for the work products. The requirements for the work products to be produced are defined. Quality criteria of the work products are identified. Appropriate review and approval criteria for the work products are defined.
- GPI 2.2.2 Define the requirements for documentation and control of the work products. Requirements for the documentation and change control of the work products are defined. Various degrees of control may be appropriate depending on the specific aspects of the work products. Specific identification may be necessary when traceability is a requirement. Dependencies between work products are identified and defined.
- GPI 2.2.3 Identify, document and control the work products. The work products are documented and controlled in accordance with requirements. The work products to be controlled are identified. The work products are controlled. The work products are made available through appropriate access mechanisms. The revision status of the work products may readily be ascertained. Change control is established for controlled work products.
- GPI 2.2.4 Review and adjust work products to meet the defined requirements. Work products are reviewed and approved according to defined criteria. Work products are reviewed according to planned arrangements. Issues arising from work product reviews are resolved.

**Deliverable:** Consider the process that you have developed in the last tutorial session. Write a audit report of the developed process. You should include the findings from the process and decide whether it compliance according to the process evaluation requirements. You may also include audit questions as a part of audit check list.