

# Processes

## *Some Clarifications*

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## What Will We Get From This?

- Hopefully a better understanding of:
  - How to identify a process
  - How to differentiate between a process and an activity
  - How to differentiate between a process and a procedure
  - The fact that individual clauses of the standard (ISO/AS) do not necessarily a process make

## What Will We *Not* Get From This?

- This will not be a how to on making process maps
- There will be no advice given as to what to call your processes
- There will be no advice given as to how you measure your processes



## Where Are We In The Process of The Process Approach to Auditing?

- Not nearly as far as one might expect
  - At least 10 years into the process based audit concept we have:
    - ❖ Organizations still unclear on the concept
    - ❖ Auditors still unclear on the concept
    - ❖ Industry sorts still unclear on the concept

In essence, we need to clear some things up

## What Is a Process?

- A “process” can be defined as a “set of interrelated or interacting activities, which, through the use of resources, transforms inputs into outputs”
- A process must have defined:
  - Objectives
  - Inputs
  - Outputs
  - Activities
  - Resources

## Who Determines (Identifies) The Process/Processes?

- The organization determines the processes needed for the quality management system (clause 4.1a)
- The auditor *does not* determine the processes...
- The industry *does not* determine the processes...

*Clue: Think “core or key” processes*



## Process or Activity?

Activity pertains to a singular event whereas a process pertains to a group of activities. Activities can be performed in isolation - but a process requires a group of activities in conjunction with resources to actually be, a process.

## Process or Procedure

Particularly frustrating is the still fairly common confusion between a process and a procedure.

*These are not interchangeable terms and do not mean the same thing.*

Procedure: A specified way to carry out an activity or a process.



## Are All Clauses of the Standard Actual Processes?

Simple answer: No

*Could they be?*

I suppose they could - but keep in mind all that goes into a process, including the requirement that as an organization you must monitor, measure and analyze your processes.

*Again – the organization determines their processes.*

## Some Simple Steps Toward a Process Approach

We'll start off by assuming that you have already defined the purpose of your organization and its policies and objectives.

- Determine the processes
  - All processes needed to produce the intended output.
  - Identify all inputs and outputs
- Determine the sequence of the processes
  - The process flow in sequence and interaction

## Some Simple Steps Toward a Process Approach

- Define process ownership
- Define process documentation
  - Processes exist within the organization and the initial approach should be limited to determining and managing them in the most appropriate way. There is no “catalogue”, or list of processes, that have to be documented.
  - The main purpose of documentation is to enable the consistent and stable operation of the processes



# Some Simple Steps Toward a Process Approach (Documentation)

- The organization should determine which processes are to be documented, on the basis of
  - The size of the organization and its type of activities,
  - The complexity of its processes and their interactions,
  - The criticality of the processes, and
  - The availability of competent personnel.

## Some Simple Steps Toward a Process Approach

- Define activities within the process
- Define the monitoring and measurement requirements
  - Determine where and how
  - Identify monitoring and measuring criteria for process control and process performance
- Define the resources needed

## Some Simple Steps Toward a Process Approach

- Verify the process against its planned objectives
  - Confirm that process characteristics are consistent with organization's purpose
- Implement and measure process
  - Apply controls and measurements as planned
- Analyze the process
  - Compare results with defined requirements



## Some Simple Steps Toward a Process Approach

- Corrective action and improvement
  - When planned results are not achieved, action should be taken. Also, when planned results are achieved examine process for opportunities to improve.

## Points of Note (Organizations)

- The organization determines and defines the processes (*not the auditor or the CB*)
- The organization determines criteria and methods to ensure control and effectiveness
- The organization monitors, measures and analyzes the processes
- The organization implements necessary actions to achieve planned results

## Points of Note (Organizations and Auditors)

- The organization shall maintain a Quality Manual that includes...a description of the interaction between the processes of the QMS

*This is what is often referred to as the IOP, or Interaction of Processes. This IOP will contain, among other things, the names of the organization's processes. These processes should be noted in the audit plan and any corresponding documentation (ex: AS9101 appendices) as they are noted in the IOP.*



## Summation

Hopefully there was some helpful information gleaned from this presentation. The confusion with the process approach is somewhat understandable but I believe we are making progress.

*All of the information regarding processes was taken from industry documentation and is available to all at the ISO Standards Development site:*

<http://isotc.iso.org>