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The process approach to **management systems auditing**

Contents

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Summary

As specified by ISO 9001:2008 "Quality management systems – requirements", the planning and preparation for a quality management systems audit is possibly the most important aspect in ensuring its effectiveness. With the advent of the version of ISO 9001 released in 2000, which described the implementation of the management system based on a "process approach", greater emphasis has been placed on using this same approach when conducting quality audits. Oddly, there is no guidance available on what this method of auditing entails so it has fallen to guidance based on recognised practice.

The planning of an audit typically includes the production of checklists, which are made up of audit questions based on audit criteria. These checklists are often in a format that does not reflect a process and, therefore, the process approach to auditing. The lack of relevance to a specific product (or 'core') process and its controls can lead to difficulty in use by the auditor and their interview questions being misunderstood by those responsible for the process. Experience shows that the other processes of the organisation's quality system – the so-called 'support processes' – can present a challenge to auditors when attempting to integrate their 'sequence and interaction' on the same checklist with the process to be audited.

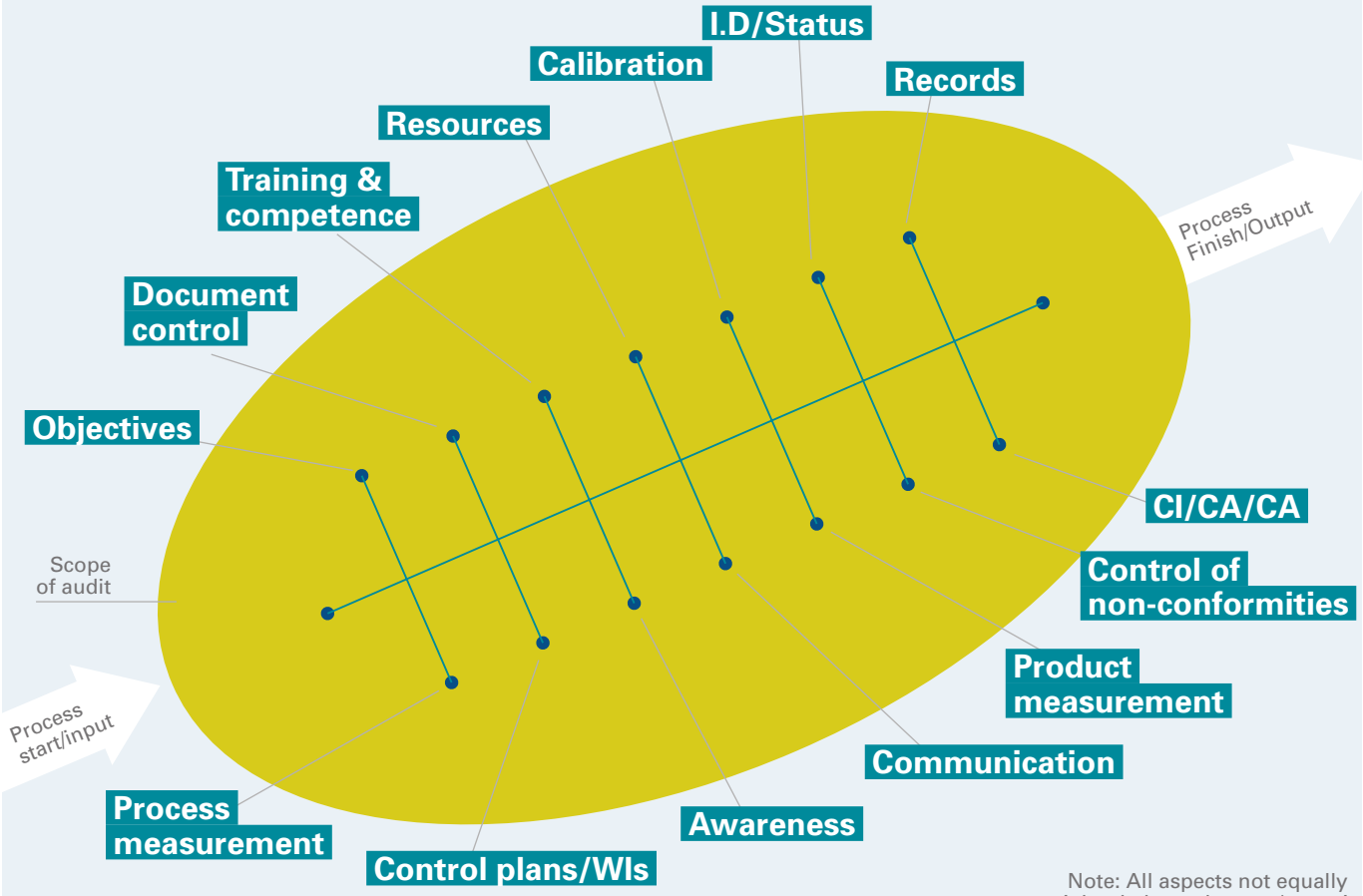
The use of the innovative *Audit Football*© diagram (see Figure 1) allows the auditor to visualise not only the core process to be audited, but also to plan for those supporting processes and controls that must be considered during the audit as well. This paper considers how the construction of the *Audit Football*© diagram during an auditor's preparation can be an effective means to ensure that internal quality systems audits are conducted using the process approach, and that the supporting processes are also included in an appropriate and relevant way.

Keywords

Internal audit; planning; auditor; audit program; visual metaphor; quality management; process audit; process approach.

The process approach to management systems audits

Fig 1: Process Auditing Football



With the introduction of the revision of ISO 9001 "Quality Management Systems – requirements" in 2000 (later revised in 2008), came the need for an organisation to adopt a process-based quality management system. This version also emphasised the roles that quality objectives and process measurements – rather than just traditional product measurements – play in demonstrating to management and other so-called "interested parties" that the implementation of the quality management system is effective in meeting requirements, and not merely compliant to a set of documentation. Furthermore, the need for top management to review the quality management system to ensure its "continuing suitability, adequacy and effectiveness" could be viewed as a clear direction from the authors of the International Standard, the ISO Technical Committee 176, that implementing the requirements of ISO 9001 was no longer simply a matter of "say what you do, document it, and then do what you say"!

Section 2.4 of ISO 9000, the vocabulary and normative reference for ISO 9001, defines (in part) "the process approach" as follows:

> *"Any activity, or set of activities, that uses resources to transform inputs to outputs can be considered as a process.*
>
> *For organisations to function effectively, they have to identify and manage numerous interrelated and interacting processes. Often, the output from one process will directly form the input into the next process. The systematic identification and management of the processes employed within an organisation and particularly the interactions between such processes is referred to as the "process approach".*
>
> *The intent of this International Standard is to encourage the adoption of the process approach to manage an organisation."*

To that end, the diagram found in section 0.2 of the Introduction of ISO 9001:2008 assists implementers and auditors alike in understanding the roles that management system objectives, processes and measurements play in meeting the requirements of customers, regulations and the organisation's management. It can be seen that this model for implementation is based on the well-known Plan-Do-Check-Act cycle, with top management setting objectives for the processes of the organisation and, subsequently, considering the results from process measurements in their review of the overall system. Included in that review are the results from audits.

Simply put, a management systems auditor must consider the following:-

- What is planned to occur (including the "product realisation processes", the resources required, inspections, testing, measurements and any records produced)
- The management system processes for implementing the plan
- The requirements of the ISO 9001 standard, related to the plan and processes
- How effectively the processes are being done
- Whether the defined processes are being implemented and kept up to date.

These requirements, when taken together, can look daunting to even the most seasoned auditor. It may appear that they will be required to consider an overwhelming amount of information in the planning and execution of an audit and, while it is true to say that a process-based audit can be more complex and complicated than one using elements of the ISO standard, auditing a process does not have to frighten an auditor – if they are well prepared!

Guidance on audit planning can be found in ISO 19011:2011 "Guidelines for auditing management systems", which includes the following:

> *6.3 Preparing audit activities*
> *6.3.1 Performing document review in preparation for the audit*
> *The relevant management system documentation of the auditee should be reviewed in order to:*
> *• Gather information to prepare audit activities and applicable work documents (see*

6.3.4) eg on processes, functions

- *Establish an overview of the extent of the system documentation to detect possible gaps. The documentation should include, as applicable, management system documents and records, as well as previous audit reports. The document review should take into account the size, nature and complexity of the auditee's management system and organisation, and the audit objectives and scope.*

Further guidance appears as defined in section 6.4.3 entitled "Preparing work documents", which states (in part):

> *"The audit team members should review the information relevant to their audit assignments and prepare work documents as necessary for reference and recording audit proceedings. Such work documents may include:*
> *a) checklists and audit sampling plans; and*
> *b) forms for recording information, such as supporting evidence, audit findings and records of meetings.*
> *The use of checklists and forms should not restrict the extent of audit activities, which can change as a result of information collected during the audit."*

Experience shows that the use of a planning tool that enables auditors to gather the correct information, format it and then develop their audit strategy can help an auditor to visualise the process approach to an audit. A conventional checklist format, typically one that lists questions related to the chosen audit criteria, may be insufficient to support the process approach when performing an audit. Although not a specified requirement of ISO 9001 section 8.2.2 per se, this process approach has become the preferred method and was adopted by the Oversight Bodies (Accreditation Bodies) for use by Conformity Assessment Body auditors when auditing organisations to the requirements of ISO/TS 16949 and AS9100.

Constructing the audit plan

Using the ISO 9000 definition, we know that a process is defined as "activities that transform inputs into outputs". If we apply this definition to a typical assignment, eg a manufacturing process, it might be a reasonable expectation that an auditor should study and understand the defined process inputs, activities and outputs, as described by the organisation's quality system documentation. Not only is the identified process important to audit fully, but the auditor must be aware of the impact that the various support processes have on that process. At various points throughout the audit, the auditor must be prepared to stop a particular line of inquiry and focus instead on the support process. Having performed their evaluation, they must "re-engage with the subject process and continue their journey".

In addition to these process basics, others may be added as identified in ISO 9001 section 7.1 – the "planned arrangements" for the process – which can include customer, regulatory and/or management requirements and are likely to be related to the objectives of that process. When the auditor is considering process objectives, it is also helpful at this point to establish what criteria management use to measure the process to show effectiveness.

As the flow of the process is followed, the auditor should be prepared to ask about the use of documented controls by operators. These may include work instructions, visual aids or control plans that define product and process characteristics. Naturally, the auditor will want to ensure that any process control documents have been reviewed and approved for use, are available to the operator and that no obsolete versions are still available.

Since the auditor is on that topic, it is going to be a good time to interview those people who are responsible for process control – the operator(s). The auditor is well placed to discover a lot about their competencies, eg their skills and knowledge, and what responsibilities and authority they possess for making decisions about the control of the process. If the person is new to the role, the audit might probe into what kind of training may be required to qualify them. At the same time, the auditor can also determine the awareness that the operator has of the job, including what is important to the customer and understanding the organisation's quality policy.

Progressing along the process, reviewing each activity, there will come a point at which some form of product or process verification (inspection or measurement) is required. There may be specific documentation that describes these verification activities, or it may be included in the established and previously viewed Control Plan/Work instructions. Also related to the verification activities is the status of the product, which can be evaluated by the auditor as well. There is also a natural link from the measurement activities to whether the equipment used to perform the verifications has been calibrated (or verified) as giving accurate results, so the auditor should plan to check for the relevant indicators/identifiers that are appropriate.

Another supporting process, usually linked to product measurement, is the control of non-conforming products. The internal auditor should always be aware of the correct methods and controls (possibly defined in an associated document) for identification, recording, tagging, segregating and dispositioning of any product that does not meet its specification. The specific authority for control can be evaluated, as can any rework and re-inspections that may be performed.

At this stage in the performance of the audit, it is likely that a number of records have been created. These may include records of product characteristics, personnel competencies, non-conforming products, equipment checks and process parameters. The auditor should check to see if these records are managed in the manner defined in the organisation's documented procedure. Records are a vital source of data regarding the trends in product and process conformance to specifications and, therefore, should be being analysed for opportunities to take action.

As the audit progresses, the auditor will need to make copious notes of what was viewed, sampled, etc during the audit. Since the audit should have started with a clear understanding of the objectives and process measurement(s) for the process being audited, at this stage of the proceedings it should now be fairly obvious to the auditor (from the records reviewed and data analysis) whether those objectives are being met. If they are, questions may now be phrased around any improvements that may have been identified by management for that process. Of course, if the objectives are not being met, then it should be clear to the auditor that some form of actions – corrective and/or preventive – may be necessary and should be planned/recorded.

Keeping to scope

While performing a process-based audit, it can become quite a challenge for an auditor to remain true to the assignment they were given. There are many potential audit trails, which can lead the auditor to spend time evaluating not the process they were assigned to audit, but one or more of the supporting processes – this is known as being 'out of scope'. Care must be exercised by an auditor not to drift out of scope, but at the same time to remain aware of the condition of the support processes, which is why they must be tested to some extent. At the same time, when an issue is detected with a support process, the auditor can note it and make their observations known to the internal audit programme manager for follow-up action.

As can be seen from the path the auditor takes, evaluation of supporting processes (for example, document control, training, calibration, control of non-conforming products) is included. By visualising the connections these processes have to the main process being audited, the auditor is able to maintain control over the scope of the audit – depicted by the outside shape of the football in **Figure 1.** Imagining these support processes as the "laces" of the football, the auditor can establish limits on the amount of time or depth of their evaluation, thus ensuring that time is not wasted outside the defined audit scope.

One issue an auditor following the process will have to deal with is when there are signs that one of the supporting processes appears not to be effectively implemented. Examples include the control of documentation and, in a manufacturing organisation, the control of inspection and measuring equipment. These are 'target-rich environments' for

an auditor, meaning that it is common to encounter observed evidence of apparent nonconformity. During the audit of the subject process, the auditor may encounter, through observation or during interviews, that there are extra documents available in the work area or that measuring equipment being used is not identified for use at that operation, or exhibiting indications it is within the control system.
The temptation will be for the auditor to trace back to the point of control – the document control center or the calibration laboratory – to determine the status of the observed items. If the auditor does fall prey to this temptation, there are a number of issues the auditor should consider:

- The personnel responsible for the supporting process(es) are not prepared to deal with the "surprise" audit, if they are actually available
- The perception of the audit is diminished
- Time to perform the audit assignment is diminished
- The audit objective may not be met, since the scope has been expanded/broken
- Managements' view of the value of audits and the overall quality management system will become fragmented
- Corrective actions and improvements may be delayed as a result.

It is suggested that the auditor make a note of the observed issues and bring them to the attention of the management of the process for their action and, crucially, that the auditor incorporates the same details – plus a recommendation for another audit – in the audit notes/reports that are returned to the audit programme manager. Making recommendations in this manner can trigger other audits, as a picture may be developed from the feedback that indicates that a systemic weakness has developed.

Results count!

On arriving at the end of the process, the auditor will be able to evaluate what they have seen demonstrated. They can then compile their report to top management on whether the process is compliant, in control to the defined quality management system and, also, effective in meeting (planned) requirements, eg management's objectives, customer requirements and schedules. Where the results do not validate the plan, it will be appropriate to then ask what actions are being taken to correct the situation.

Conclusion

Adopting the process approach to the way in which quality management systems are audited may, at first sight, seem to be an overwhelming task for any auditor. However, as with most complex and complicated assignments, the use of effective and efficient planning tools can soon remove a lot of the fear and trepidation that people may encounter. Breaking down the audit assignment into its component parts and placing them into a structure that assists the auditor with planning a "pathway" through all the process steps and supporting requirements brings many benefits:

- The process is evaluated for its ability to achieve stated objectives.
- Multiple processes of the quality management system and, therefore, ISO 9001, are included in each audit, thereby making audits more efficient.
- The auditor has a clear plan to demonstrate that a process approach was implemented.
- The auditor develops control over the defined scope or boundary of the audit, while at the same time evaluating the effect of support processes on the subject process. This allows for feedback to the audit programme manager if concerns are raised, without becoming a distraction to the auditor.
- Improved time management of the audit.
- A clearer input to management review on the status of the processes of the quality system.

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References

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