



ISAB Guidance on: "PROCESS APPROACH" BASED ACCREDITATION AUDITS

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1. Introduction

Using the process approach during an accreditation audit provides added value to the accreditation activity since the body under evaluation will typically be using a process approach itself.

Although not being a direct requirement of ISO/IEC 17011, feedback from Conformity Assessment Bodies (CABs) has indicated a desire that the Accreditation Body (AB) assessors understand and be able to apply the process approach to their audit activity.

The value of and need for a process approach is enforced in ISO/IEC 17021-1:2015 which requires CABs to operate a formal quality management system in line with the requirements of ISO 9001.

The process approach facilitates a focus on interested parties needs and expectations and provides a basis for continual improvement. The process approach is based on the identification of the key processes related to the CAB activities and on their proper management and control.

2. CAB's intended results

The ultimate objective of the CAB processes is to achieve a consistent attestation of the conformity of the client's QMS to the applicable requirements. The AB auditor should never lose sight of the CAB achievement of its intended results.

Typical processes of CABs needed to ensure achievement of intended results are:

Top management processes



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- Leadership and commitment
- Strategic planning
- Management review
- Impartiality Management
- Complaints Process
- Appeals Process

Resources Management Processes

- Information management
- Personnel (internal staff, auditors) qualification and monitoring processes
- Management outsourced processes
- Logistics

Certification process

- Application review process
- Preparation of Contract
- Establishment of certification program
- Planning and scheduling of audits
- Audit Teams Allocation
- Conducting audits
- Audit reporting
- Certification decision (including granting, refusing, maintaining, expanding or reducing the scope of certification, renewing, suspending, restoring or withdrawing of certification)
- Maintenance of certification

Measurement, analysis and improvement processes

- Internal audits
- Performance analysis
- Monitoring of client and other interested parties' satisfaction, including emphasis on the final users of certified goods and services
- Other measurement and monitoring activities included in the main processes above

3. Application by an AB

An Accreditation Body should ensure that all its assessors have received sufficient training



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regarding the requirements in ISO 9001:2015, particularly those on the process approach, since this is the approach used by the assessed body in witness audits.

For the above processes, the following general aspects should be considered by the AB assessors:

- Have the CAB's processes been identified and documented, including process objectives, and have related responsibilities been defined and assigned?
- Have the relevant resources and information been determined and deployed?
- Are methods in place to monitor and/or measure and analyse each process, including appropriate records, and has their validity been confirmed?
- Is the issue of continual improvement of the effectiveness of the CAB operation properly addressed?

AB assessors have to be aware that the application of the process approach may be different from CAB to CAB, depending on the size and complexity of the CAB and its activities.

4. Example questions to be addressed by an AB during a process based audit

Note: References to the clauses of the applicable standards and guidance documents are implicit in the questions themselves. These can be aligned with the formal accreditation requirements.

What follows is applicable, in principle, to any kind of assessed process.

Process characteristics

- What are the processes needed for the CAB's QMS? (see the list of typical processes of CABs)
- Are any of these processes outsourced?
- What are the inputs/outputs for each process? Do they comply with the accreditation requirements?
- Who are the "customers" of the processes?
- What are the requirements of these customers?
- Who are the "owners" of the process?
- Are these owners competent for the job?
- How is the competency of the people involved in the process defined, assessed and maintained?



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Criteria and methods

- What are the characteristics of intended results of the process? Do they comply with the accreditation requirements?
- What are the criteria for monitoring, measurement and analysis?
- How are these criteria incorporated into the planning of the processes?
- Are the business performance issues taken into proper account?
- Is there any impact on CAB impartiality and integrity?
- What methods are used for data gathering?

Resources

- What are the resources needed for the process? Are these resources appropriate and do they comply with the accreditation requirements?
- What are the communication channels?
- How is external and internal information about the process provided?

Feedback

- What data need to be collected?
- What records need to be kept?

Measurement, monitoring and analysis

- How is the process performance monitored (process capability, customer satisfaction)?
- What measurements are applied?
- How is the gathered information analyzed (statistical techniques)?
- How are the results of the analysis taken into account?