From Compliance to Confidence:
Mastering Process-Based Auditing in Conformity Assessment Systems

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About PJLA

Perry Johnson Laboratory Accreditation, Inc. (PJLA)

Established in 1999 by Mr. Perry L. Johnson

Headquartered in Troy, Michigan.

More than 2200 accreditations globally in 32 countries.

Perry Johnson Laboratory Accreditation NP, Inc. (PJLANP)
Michigan nonprofit organization established in 2016.

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PJLA's Global Network

PJLA Accreditation Programs

ISO/IEC 17025
Testing/Calibration Labs

- FCC OET Equipment Authorization
- FDA ASCA
- ENERGY STAR
- Cannabis Testing
- Hemp Testing
- Horseracing Laboratories Program
- CPSC
- AS6171A Testing
- Food, Feeds, and Pharmaceutical: *AOAC, AAFCO, LAAF*
- Environmental Testing: *TNI-NEFAP, DoD ELAP, DOECAP-AP, EPA NLLAP* TNI-EL: *MNELAP, CA ELAP, LELAP*

ISO/IEC 17020 – Inspection Bodies

ISO/IEC 17065 – Product Certification Bodies

ISO/IEC 17043 – Proficiency Testing Providers

ISO 17034 – Reference Material Producers

ISO 15189 – Medical Laboratories

ISO/IEC 17024 – Personnel Certification Bodies

ASTM E2659– Training Providers

Introduction

- The **process-based auditing** approach (as defined in ISO 9001 and guided by ISO 19011) is not limited to management systems like QMS or EMS

- It underpins all standards within the ISO/IEC 17000 series, which collectively define the conformity assessment ecosystem (testing, inspection, certification, accreditation, validation, proficiency testing, etc.)

- While traditional audits focus on verifying compliance with written procedures and documentation, process-based audits evaluate the **effectiveness**, **performance**, and **interrelation** of processes that achieve intended outcomes.

In this webinar we'll present a systematic analysis of how process-based auditing applies across the major ISO/IEC 17000-series standards, showing what "process focus" really means.

Defining Process

A process: Set of interrelated or interacting activities that use inputs to deliver an intended result
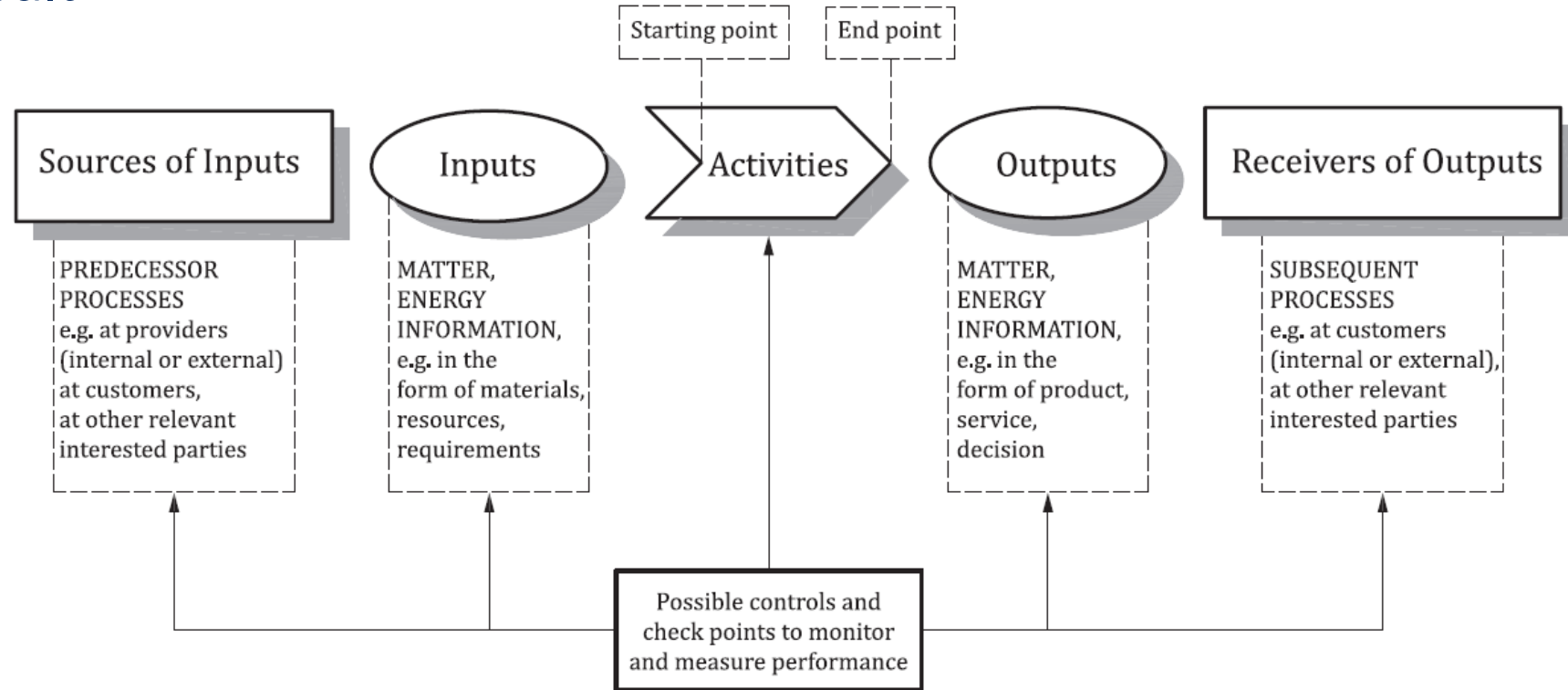
NOTE:

Inputs and outputs may be tangible (e.g. materials, components or equipment) or intangible (e.g. data, information or knowledge).

Defining Process Approach

"Process approach" is one of the core quality management principles, which is given as:

"Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system".

- *The MS consists of interrelated processes.*

- *Understanding how results are produced by this system enables an organization to optimize the system and its performance.*

Defining Process Approach

The **process approach** includes establishing the organization's processes to operate as an integrated and complete system.

- The management system integrates processes and measures to meet objectives

- Processes define interrelated activities and checks, to deliver intended outputs

- Detailed planning and controls can be defined and documented as needed, depending on the organization's context.

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Auditing Processes
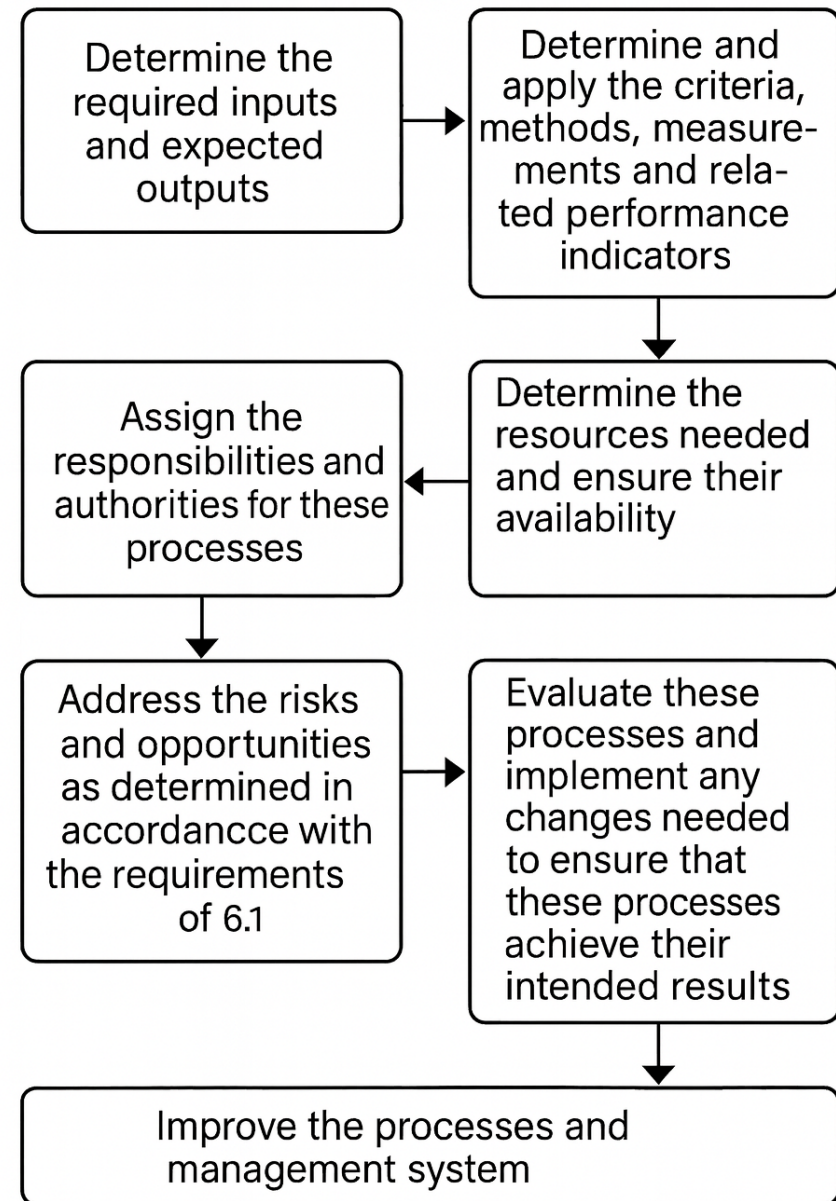
Traditional auditing asks:

"Are you doing what your procedure says?"

Process-based auditing asks:

"Does your process achieve what it is supposed to?"

The transition to process-based auditing aligns with the intent of ISO/IEC 17000-series standards, shifting the focus from procedural conformity to evidence-based confidence in outcomes and continual improvement.

The diagram will assist auditors/assessors in establishing the sequence to assess the processes of the CAB:

Determine the required inputs and expected outputs	Determine and apply the criteria, methods, measure-ments and rela-ted performance indicators
Assign the responsibilities and authorities for these processes	Determine the resources needed and ensure their availability
Address the risks and opportunities as determined in accordancce with the requirements of 6.1	Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results

Improve the processes and management system

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Auditing Processes – Fundamental Concept

| Aspect	Traditional Auditing (Procedure/Record-Based)	Process-Based Auditing
Focus	Checks compliance with documented procedures, manuals, and records.	Evaluates the effectiveness and interaction of processes in achieving objectives.
Objective	To verify conformity with prescribed documentation.	To verify performance, effectiveness, and continual improvement of processes.
Philosophy	"Are you following the written procedure?"	"Is the process achieving its intended results?"

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Auditing Processes – Audit Trail and Approach

Aspect	Traditional Auditing	Process-Based Auditing
Audit Trail	Starts from documentation (manuals, SOPs, records).	Starts from outputs or results, then traces backward to inputs and controls.
Method	Clause-by-clause or checklist approach.	PDCA and flow-based approach (inputs → process → outputs → results).
Evidence Emphasis	Primarily on existence and completion of records and documents.	On how processes function, interact, and perform (evidence includes data trends, performance metrics, and interviews).

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Auditing Processes – Good practices

If the description of a process is not interpreted in the same way by the auditor/assessor and the auditee, the auditor/assessor should seek to understand the auditee's point of view and not impose his own view, unless it is clear (and supported with enough objective evidence) that the requirements of the standard are not met.

(The same is true if the auditor/assessor believes that certain processes have not been correctly identified or are missing.)
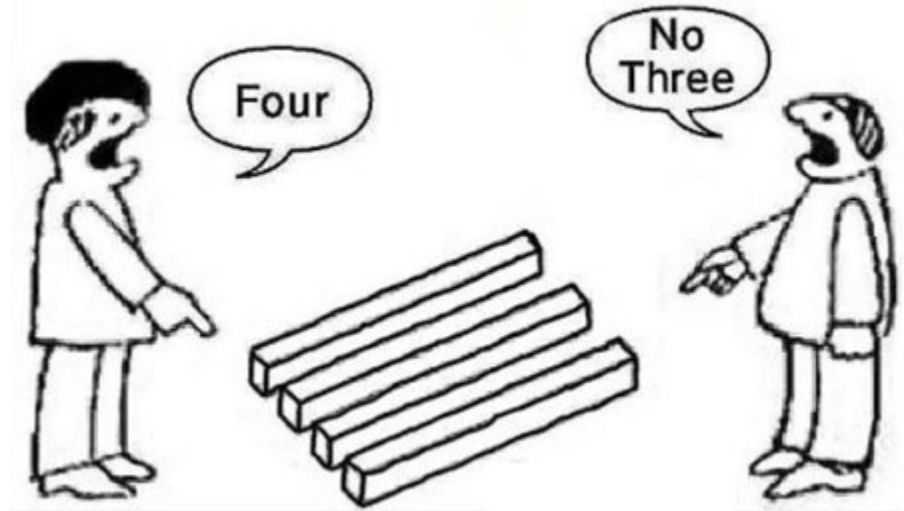
Auditing Processes – Good practices

- The auditee has the right to use its own terminology, provided the requirements of the standard are met.
- The auditor/assessor should mentally develop a cross-reference list to ensure consistency and better understanding.
- The ultimate objective of the CAB processes is to achieve a consistent attestation of the conformity of the client's MS to the applicable requirements.
- The auditor/assessor should never lose sight of the CAB achievement of its intended results.
- The level of monitoring, measurement and documentation of each process will depend on the organization's context, its strategic intent and its determined risks and opportunities.

Auditing Processes – Good practices

- It is important that the auditor/assessor keeps a close eye on the information provided by the auditee and especially on any information where the auditee defines the interaction of its processes.

- Interviews should also be performed in such a way that the auditors/assessors can determine the inputs and outputs of the process being audited.

- During an assessment, the auditor/assessor has an opportunity to check the auditee's description of the interrelation of its processes.

- The auditor/assessor should take some samples to see if the descriptions presented in the auditee's documented information are a proper reflection of the actual interrelation of the processes, as this will help determine if the process description is adequate.

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Auting Processes – CAB Example (Laboratory ISO/IEC 17025)

Purpose: Requirements for competence, impartiality, and consistent laboratory operations.

Process-based auditing focus:

- Every lab activity (sample handling, testing, calibration, data analysis, reporting) is a defined process.
- Auditors follow the **test/calibration** flow: request → method selection → equipment control → data → report.
- Evaluation covers:
  - Control of inputs (samples, standards, equipment)
  - Process performance (measurement traceability, method validation)
  - Outputs (results, reports)
- Links to management system processes (purchasing, corrective actions, continual improvement).
- Effectiveness judged by technical validity, repeatability, and turnaround time.
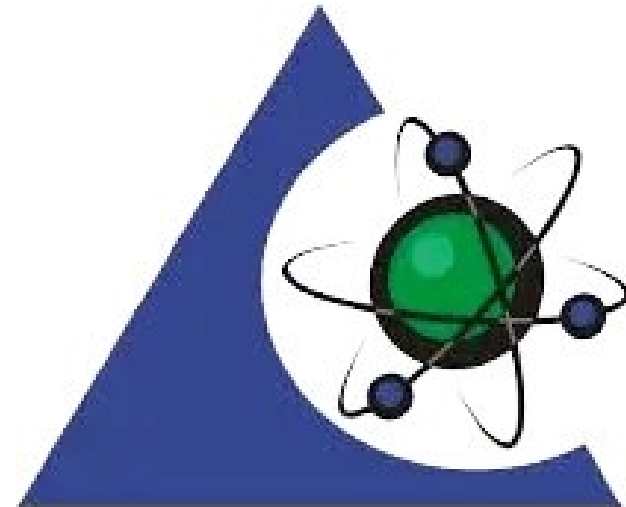
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Conclusion

Across all ISO/IEC 17000-series standards:

- Process-based auditing replaces checklist auditing.
- PDCA logic governs every conformity assessment function.
- Risk-based thinking ensures resources focus on significant risks to impartiality, competence, or validity.
- The outcome of every process-based audit is not just conformity, but **confidence** in results, services, and **trust** among users.

Thank You!

- Questions
- Discussion

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