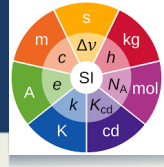

Applying ISO/IEC 17025 and PTS/IMS Requirements: A Case Study on Primary Calibration of Infrasound Sensors

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Why ISO/IEC 17025 Accreditation?

Benefits of Accreditation

- Formal recognition of technical competence by an independent third party.
- Builds trust and credibility through impartial external assessment.
- International recognition via ILAC Mutual Recognition Arrangement.
- Alignment with PTS/IMS requirements.
- Ensures consistent, reproducible, and traceable results.

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Calibration Method Overview

Primary Calibration Using a Laser Pistonphone (IEC TR 61094-10)

- The infrasound sensor to be calibrated is exposed to a calculable sound pressure produced in a coupler by a piston.
- The sound pressure is calculated from the acoustic impedance of the coupler and the measurement of the volume velocity of the piston.
- Calibration range: 10 mHz – 20 Hz
- Method in accordance with IEC TR 61094-10.

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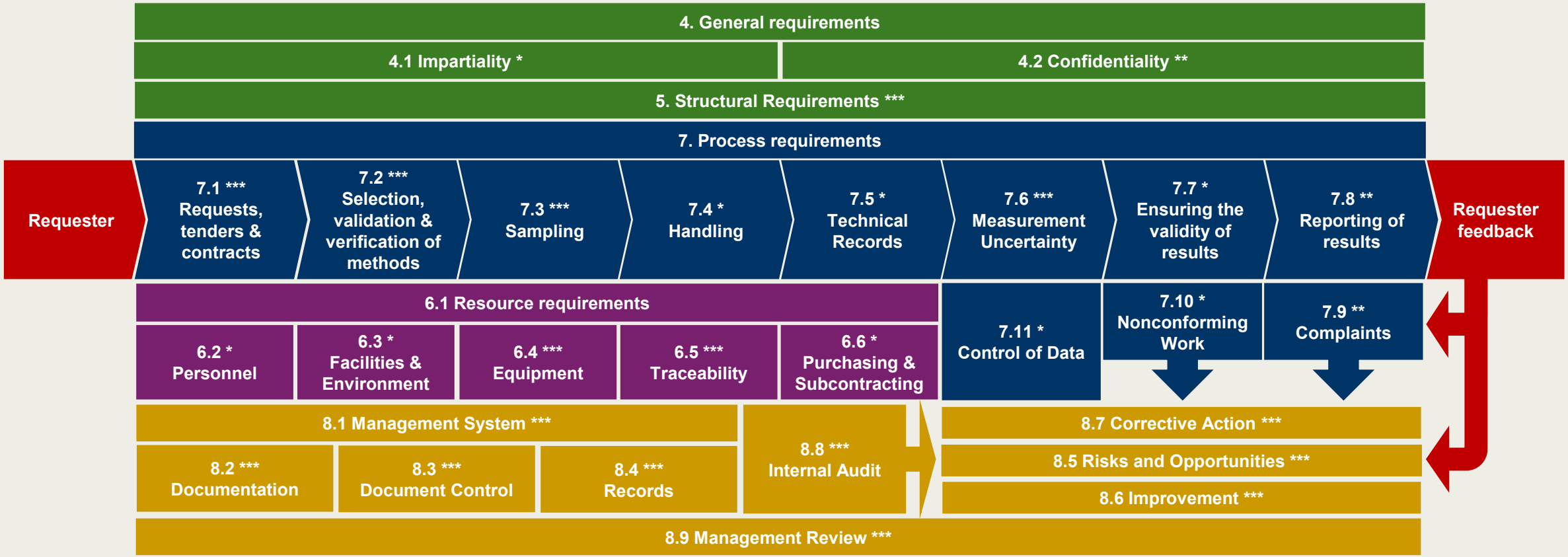
ISO/IEC 17025 Mapping to PTS/IMS Requirements for Service Providers



Legend - PTS/IMS Requirements mapping (in development):

* Whole clause is relevant

** Specific requirements apply

*** Some requirements may not apply

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Implementation: General & Structural Requirements (Clauses 4 & 5)

Key aspects:

- **Impartiality (4.1)**
  - Clear policy & preventive measures.
  - Formal staff commitment, reviewed annually.
  - Escalation to Ethics Committee if needed.
- **Confidentiality (4.2)**
  - Professional secrecy for staff.
  - Controlled access (premises & IT).
  - Secure data transmission & limited third-party sharing.
- **Structural Framework (5)**
  - Legal entity: Public Industrial and Commercial Establishment (EPIC)
    Governance: board with industry, consumers, administrations, staff.
  - Accredited scope clearly defined & limited.
  - Unified QMS across all sites, supported by quality actors.

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Implementation: Resource Requirements (Clause 6)

Key Aspects:

- **Personnel (6.2)**
  - Qualified staff with a specific training plan.
- **Facilities & environmental (6.3)**
  - Controlled laboratory environments (temperature).
- **Equipment (6.4)**
  - Regularly maintained & calibrated equipment, with documented records.
- **Metrological traceability to SI units (6.5)**
  - Full traceability chain to SI units
- **External services and supplies (6.6)**
  - Approved suppliers and external services under QMS control

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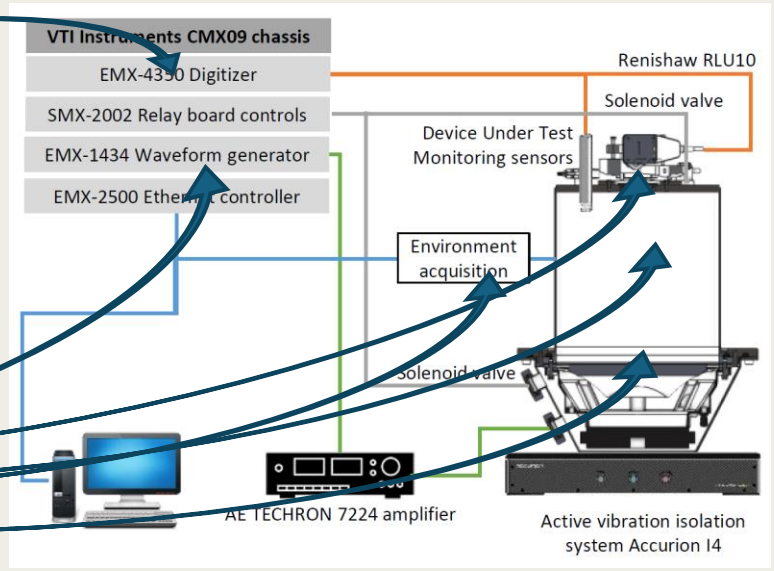
Implementation: Resource Requirements - Metrological Traceability (Clause 6.5)

Metrological Traceability

- Metrological traceability shall be ensured for all equipment that contributes to the validity of the reported results.

- Measurand: Sensor pressure sensitivity

$$M_P = \frac{U_m}{P_c} = \frac{U_m}{j\omega S_p \delta_z Z_T}$$



- Critical equipment calibrated by accredited labs.

  ↳ Unbroken chain of calibrations, each contributing to the measurement uncertainty.

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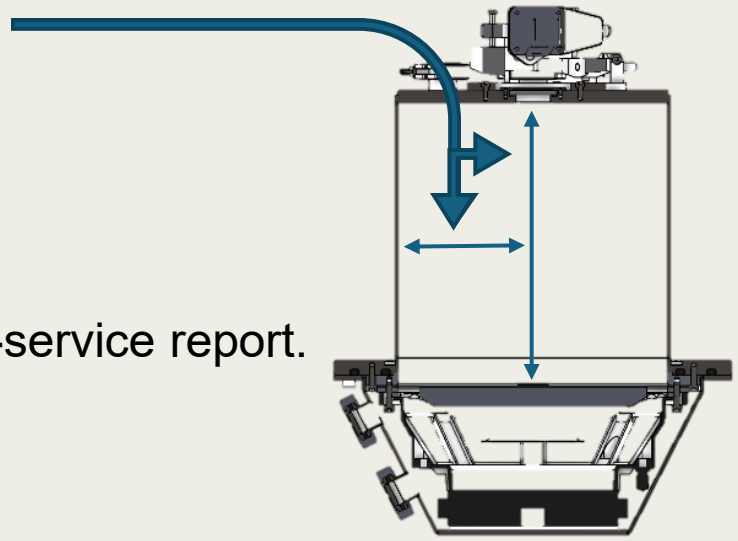
Implementation: Resource Requirements - Equipment (Clause 6.4)

Example : Provisions for the cylindrical coupling cavity

Documented procedure for handling, transport, storage, use and planned maintenance

Critical specifications identified: dimensions (radius & height)

- Calibration periodicity : every 5 years
- Conformance criteria: dimensional drift < 0,2 mm



Records maintained:

Manufacturing files, service history, calibration certificates, return-to-service report.

Safeguards: restricted access to trained staff.

Control: immediate tagging & withdrawal of non-compliant equipment.

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Implementation: Process Requirements (Clause 7)

Key Aspects:

- **Review of requests and contracts (7.1)** → Clarity on customer requirements.
- **Selection, verification & validation of methods (7.2)** → Appropriate and proven methods.
- **Sampling (7.3)** → Non applicable in this context
- **Handling of calibration items (7.4)** → identification, protection, traceability.
- **Technical records (7.5)** → Complete, accurate, retrievable.
- **Measurement uncertainty (7.6)** → Evaluation of all significant contributors.
- **Ensuring validity of results (7.7)** → QC, comparisons, repeat checks.
- **Reporting (7.8)** → Clear, traceable, compliant with requirements.
- **Complaints (7.9)** → Process to handle external feedback.
- **Nonconforming work (7.10)** → Detection, control, corrective action.
- **Data control (7.11)** → Integrity, backup, confidentiality.

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Implementation: Process Requirements
Selection, verification & validation of methods (Clause 7.2)

Method Selection

- Calibration based on IEC TR 61094-10
  - Laser pistonphone → internationally recognized primary method

Verification

- Confirm method performance to achieve required uncertainty:
  - Equipment performance checks
  - **Interlaboratory comparisons (PTSAVH.A-C1, INFRA.AUV-C1, LNE internal comparison)**

Validation

- Non-standard methods shall be validated:
  - Assessment of influencing factors
  - Evaluation of measurement uncertainty
  - **Comparison with other validated methods (pressure reciprocity, static pressure sensors)**
  - Interlaboratory comparisons

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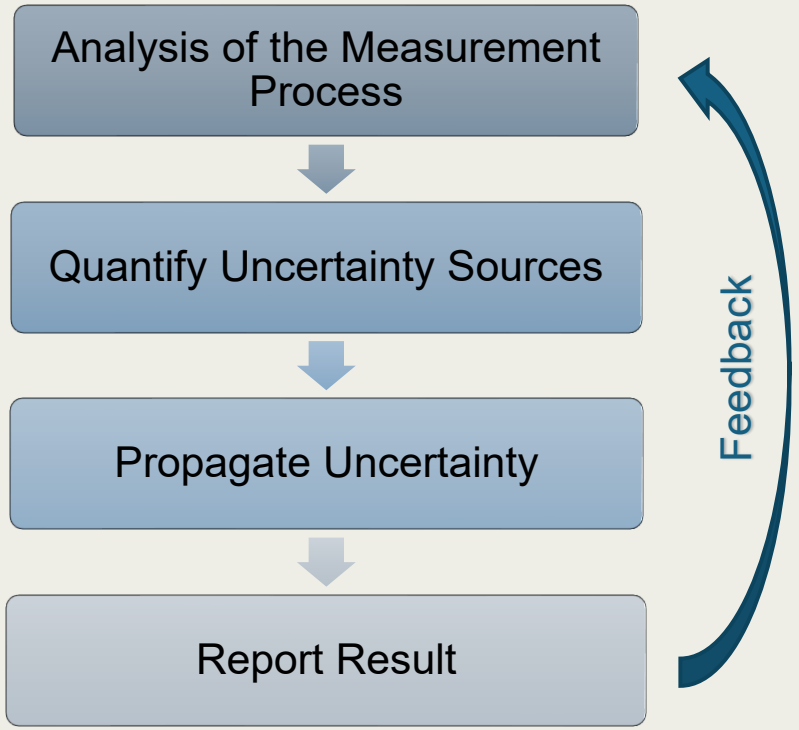
Implementation: Process Requirements
Measurement uncertainty (7.6)

- ISO/IEC 17025 requires laboratories to evaluate all significant sources of uncertainty.
- Evaluation is performed according to the GUM methodology.
- For the laser pistonphone method, main contributors include:
  - Measurement of sensor output
  - Piston properties
  - Coupler properties
  - Sensor parameters
  - Imperfection of theory
  - Processing of results
  - Repeatability of measurements
- Expanded uncertainties (k=2, 95% confidence): typically in the range
  - 0.04 dB – 0.08 dB (magnitude)
  - 0.22° – 0.90° (phase)



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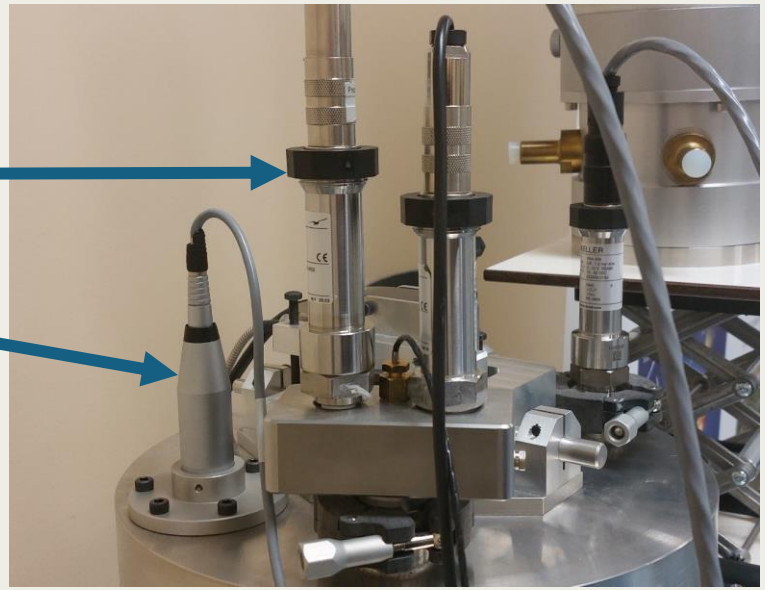
Implementation: Process Requirements Ensuring validity of results (7.7)

- ISO/IEC 17025 requires labs to monitor validity of results continuously.
- Aim: detect anomalies, ensure ongoing reliability and comparability.

- Approaches include:
  - **Systematic evaluation of bias using reference standards**
    - Keller PAA-33X (freq. < 0.1 Hz)
    - B&K 4160 (freq. > 0,1 Hz)
  - Review of reported results
  - **Participation in interlaboratory comparisons**



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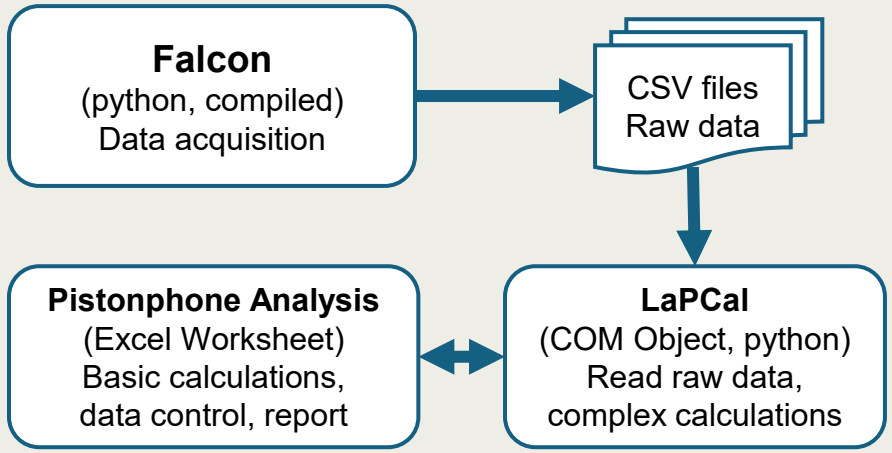
Implementation: Process Requirements
Data control (7.11)

- ISO/IEC 17025 requires controlled management of data & information.
- Reliable data control ensures integrity, transparency and reproducibility of results.

- Software managed like equipment
  - Version & change history
  - Secure storage

- Validation of data collection, processing & reporting through:
  - Cross-checks with independent systems
  - Independent/manual calculations on the same dataset
  - Reference datasets with known results
  - Interlaboratory comparisons



Software Workflow for Laser Pistonphone Calibration

Applying ISO/IEC 17025 and CTBTO IMS Requirements: A Case Study on Primary Calibration of Infrasound Sensors

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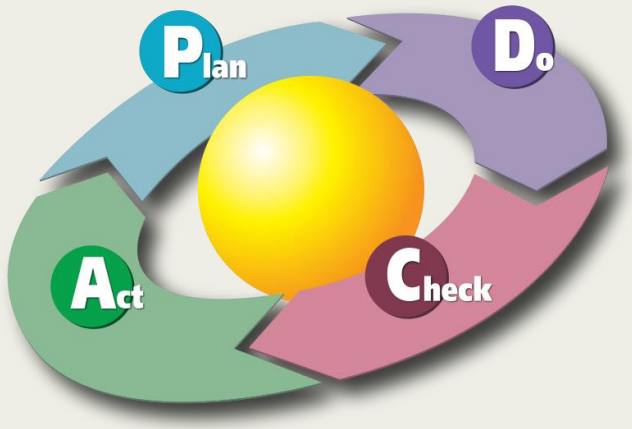
Implementation: Management system requirements (Clause 8)

- ISO/IEC 17025 requires a management system to support technical activities.
- Two implementation options:
  - Option A → follow Clauses 8.2–8.9 (quality system within the lab).
  - Option B → operate under ISO 9001-certified management system.
- Core elements (Clause 8.x):
  - Document control & records management
  - Management of risks & opportunities
  - Corrective actions & continual improvement
  - Internal audits & management reviews



- Ensures consistency, impartiality, and confidence in calibration services.

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Conclusion

- ISO/IEC 17025 accreditation ensures competence, reliability, and international recognition of calibration results.
- LNE's capability: pioneer in ISO/IEC 17025-accredited laboratory for primary infrasound calibration (COFRAC accreditation n°2-28, Scope available on www.cofrac.fr)
- Contribution to PTS/IMS: supports sensor reliability, global comparability, and confidence in monitoring results.
- Opportunities for collaboration: interlaboratory comparisons, method development, and knowledge sharing.