

Risk-Based Calibration Register Worksheet

ISO/IEC 17025 practical template for scoring risk and assigning actions

Risk Register Core Fields

- [] Instrument ID, type, location, and process owner.
- [] Risk event/failure mode description.
- [] Current controls and detection method.
- [] Severity (1-5), Likelihood (1-5), Detectability (1-5).
- [] Total risk score (S x L x D) and risk band.
- [] Action, owner, due date, and review status.

Scoring Guide

- [] Severity: 1 negligible impact -> 5 critical compliance/product impact.
- [] Likelihood: 1 rare -> 5 frequent/expected before next interval.
- [] Detectability: 1 highly detectable -> 5 hard to detect before impact.
- [] Use consistent score definitions across all instrument classes.

Action Thresholds

- [] Score 1-20: monitor and maintain existing controls.
- [] Score 21-50: implement enhanced controls and interval review.
- [] Score 51-125: high-priority action and management escalation.
- [] Document rationale for any exceptions to threshold rules.

Interval Decision Link

- [] Low risk + stable trend: candidate for controlled extension.
- [] Medium risk: hold or reduce interval based on trend slope.
- [] High risk: shorten interval and add interim verification checks.
- [] Re-score after corrective action and two completed cycles.

Review Governance

- [] Review register at least annually and after major events.
- [] Trigger immediate review after failure, repair, or relocation.
- [] Record approver identity, date, and evidence source.
- [] Keep all updates in an append-only timeline for audit traceability.