



UNDERSTANDING ISO 17025 CLAUSE 8.5 – ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

Why Risk-Based Thinking Matters – Proactive Quality, Stability and Preventive Control

Clause 8.5 is the clause that shifts the laboratory from reactive quality management to proactive quality leadership. It ensures that **risks are identified** before they become non-conformities, and **opportunities are recognised** before they are lost. Risk-based thinking is not a formality — it is a mindset that strengthens stability, competence and impartiality.

Risk-based thinking protects the laboratory from disruptions, errors, inconsistencies and operational surprises. It ensures that technicians and management anticipate problems, strengthen controls and prevent failures. Clause 8.5 requires laboratories to establish processes for identifying risks, evaluating their significance, determining actions, implementing those actions and reviewing their effectiveness.

Risk-based thinking supports competence. It ensures that personnel, equipment, methods and workflows are protected from foreseeable issues. It strengthens training, oversight and operational discipline.

Risk-based thinking supports impartiality. It ensures that decisions are made consistently, transparently and without undue influence. It protects the laboratory from conflicts, pressures and vulnerabilities.

Risk-based thinking supports continual improvement. It ensures that opportunities are recognised, evaluated and implemented. **Opportunities strengthen efficiency, capability, reliability and client confidence.**

The core principle: **Risk-based thinking is not paperwork — it is leadership.**

Clause 8.5 ensures that the laboratory thinks ahead, acts intentionally and strengthens stability.

Identifying Risks and Opportunities – Sources, Triggers and Practical Methods

Clause 8.5 requires laboratories to **identify risks and opportunities** in a structured, practical and meaningful way. ISO/IEC 17025 does not prescribe a specific method — it allows laboratories to choose approaches that fit their size, complexity and operations. Identification must be intentional, consistent and aligned with daily work.

Sources of Risks

Risks can arise from:

- Equipment (failure, drift, maintenance gaps)
- Personnel (competence, training, workload)
- Methods (validation gaps, unclear instructions)
- Environment (temperature, humidity, contamination)
- Suppliers (materials, calibration services, delays)



- Clients (incorrect information, unrealistic expectations)
- Data integrity (transcription errors, software issues)
- Impartiality (pressures, conflicts, bias)
- Workflow (bottlenecks, inconsistencies, unclear roles)

Sources of Opportunities

Opportunities may arise from:

- New equipment or technology
- Improved methods or workflows
- Training enhancements
- Client feedback
- Audit findings
- Technician suggestions
- Process optimisation
- Digitalisation

Practical Identification Methods

Laboratories can identify risks and opportunities through:

- Checklists
- Brainstorming sessions
- Trend analysis
- Internal audits
- Management reviews
- Technician feedback
- Incident investigations
- Workflow observations



Clause 8.5 ensures that identification is not theoretical — it must reflect real operations. Risks and opportunities must be visible, relevant and meaningful.

Evaluating Risks – Likelihood, Impact and Control Strength

Clause 8.5 requires laboratories to **evaluate risks** to determine which ones require action. Evaluation ensures that **actions** are targeted, meaningful and aligned with operational priorities. ISO/IEC 17025 does not prescribe a specific evaluation method — laboratories may use qualitative scales, structured matrices or simple decision tools.

Risk evaluation considers:

- **Likelihood** – how probable the risk is
- **Impact** – how severe the consequences would be
- **Detectability** – how easily the risk can be identified
- **Existing controls** – how strong current protections are
- **Operational relevance** – how the risk affects competence, impartiality or reliability



A simple evaluation method may include:

- Low, medium or high likelihood
- Low, medium or high impact
- Overall risk rating based on combined factors

More structured methods may include:

- Risk matrices
- Scoring systems
- Weighted criteria

Evaluation ensures that laboratories **focus on risks that matter** — not every risk requires action. Clause 8.5 emphasises that evaluation must be practical, consistent and aligned with the laboratory's operations.

Risk evaluation strengthens decision-making, supports resource allocation and protects stability. Clause 8.5 ensures that risk evaluation is disciplined, structured and effective.

Determining and Implementing Actions – Preventive, Mitigating and Opportunity-Driven

Clause 8.5 requires laboratories to determine **actions** to address risks and opportunities. Actions must be intentional, structured and aligned with the management system. They may include preventive actions, mitigating actions, process improvements, training, equipment upgrades, workflow changes or documentation updates.

Preventive Actions

Preventive actions stop risks before they occur. Examples include:

- Additional training
- Equipment maintenance
- Workflow redesign
- Environmental monitoring
- Clarifying procedures

Mitigating Actions

Mitigating actions reduce the impact or likelihood of risks. Examples include:

- Backup equipment
- Additional checks
- Enhanced supervision
- Improved communication
- Strengthened controls



Opportunity-Driven Actions

Opportunity actions strengthen capability, efficiency or reliability. Examples include:

- New technology
- Improved methods
- Digitalisation
- Process optimisation
- Technician development

Actions must be implemented, communicated and reviewed. Clause 8.5 ensures that actions are not theoretical — they must be effective and aligned with continual improvement.

Technician and Management Responsibilities – Ownership, Insight and Continual Improvement

Technicians and management play critical roles in ensuring that risk-based thinking is implemented, effective and consistently applied. Clause 8.5 emphasises that risk management is not the responsibility of one person — it is shared across the laboratory.

Technician Responsibilities

Technicians must:

- Identify risks during daily work
- Report issues, inconsistencies or vulnerabilities
- Suggest improvements and opportunities
- Support implementation of actions
- Follow updated procedures and controls
- Participate in training and discussions
- Maintain discipline in daily operations

Technicians are the frontline observers of risk. Their insight strengthens stability and prevents failures.

Management Responsibilities

Management must:

- Establish risk-identification processes
- Evaluate risks and opportunities
- Approve actions and allocate resources
- Monitor effectiveness of actions
- Communicate updates and expectations
- Integrate risk thinking into audits and reviews
- Lead continual improvement

Management provides the oversight that keeps risk-based thinking structured, strategic and effective.



Technicians and management form a **risk-handling structure** that protects stability, strengthens capability and drives continual improvement. Clause 8.5 ensures that risk-based thinking is owned, implemented and strengthened at every level.

Risk Thinking, Opportunity Recognition and Preventive Action Discipline

Clause 8.5 – Actions to Address Risks and Opportunities uses risk-based thinking to shift the management system **from reacting to problems to anticipating them**.

Why Risk-Based Thinking Matters – Proactive Quality, Stability and Preventive Control

Risk-based thinking ensures that laboratories **identify risks** before they become non-conformities and **recognise opportunities** before they are lost. It protects competence, impartiality and reliability. Clause 8.5 embeds preventive thinking into daily operations, strengthening stability and operational confidence.

Identifying Risks and Opportunities – Sources, Triggers and Practical Methods

Risks arise from equipment, personnel, methods, environment, suppliers, clients, data integrity, impartiality and workflow. **Opportunities** arise from technology, training, feedback, audits and technician insight. Identification must be intentional, consistent and aligned with daily work.

Evaluating Risks – Likelihood, Impact and Control Strength

Evaluation considers likelihood, impact, detectability, existing controls and operational relevance. Evaluation ensures that actions are targeted and meaningful — not every risk requires intervention. Risk evaluation strengthens decision-making and protects stability.

Determining and Implementing Actions – Preventive, Mitigating and Opportunity-Driven

Preventive actions stop risks before they occur. **Mitigating actions** reduce likelihood or impact. **Opportunity-driven actions** strengthen capability, efficiency and reliability. Clause 8.5 ensures that actions are implemented, communicated and reviewed. Actions must be aligned with the management system and support continual improvement.

Technician and Management Responsibilities – Ownership, Insight and Continual Improvement

Technicians identify risks during daily work, report issues, suggest improvements and support implementation. **Management** evaluates risks, approves actions, allocates resources, monitors effectiveness and leads continual improvement.

Clause 8.5 ensures that the management system is forward-looking, resilient and continually improving.