Transitioning to the new ISO 17025:2017 standard: How does it affect my current quality system?

Elements of the New Standard

The new Standard is organized to show relevance against the ISO 9001 standard. The Standard accounts for a laboratory that may be part of an organization adhering to a Quality Management System based on the ISO 9001 requirements. The new Standard applies to those principles.

The new Standard addresses the laboratories quality management system through **Option A** or **Option B** requirements for Section 8: Management Requirements.

Option A addresses the requirements for laboratories not required to meet other ISO Standard quality management system requirements. This is a laboratory seeking accreditation to the ISO 17025 with a quality management system focused on those requirements.

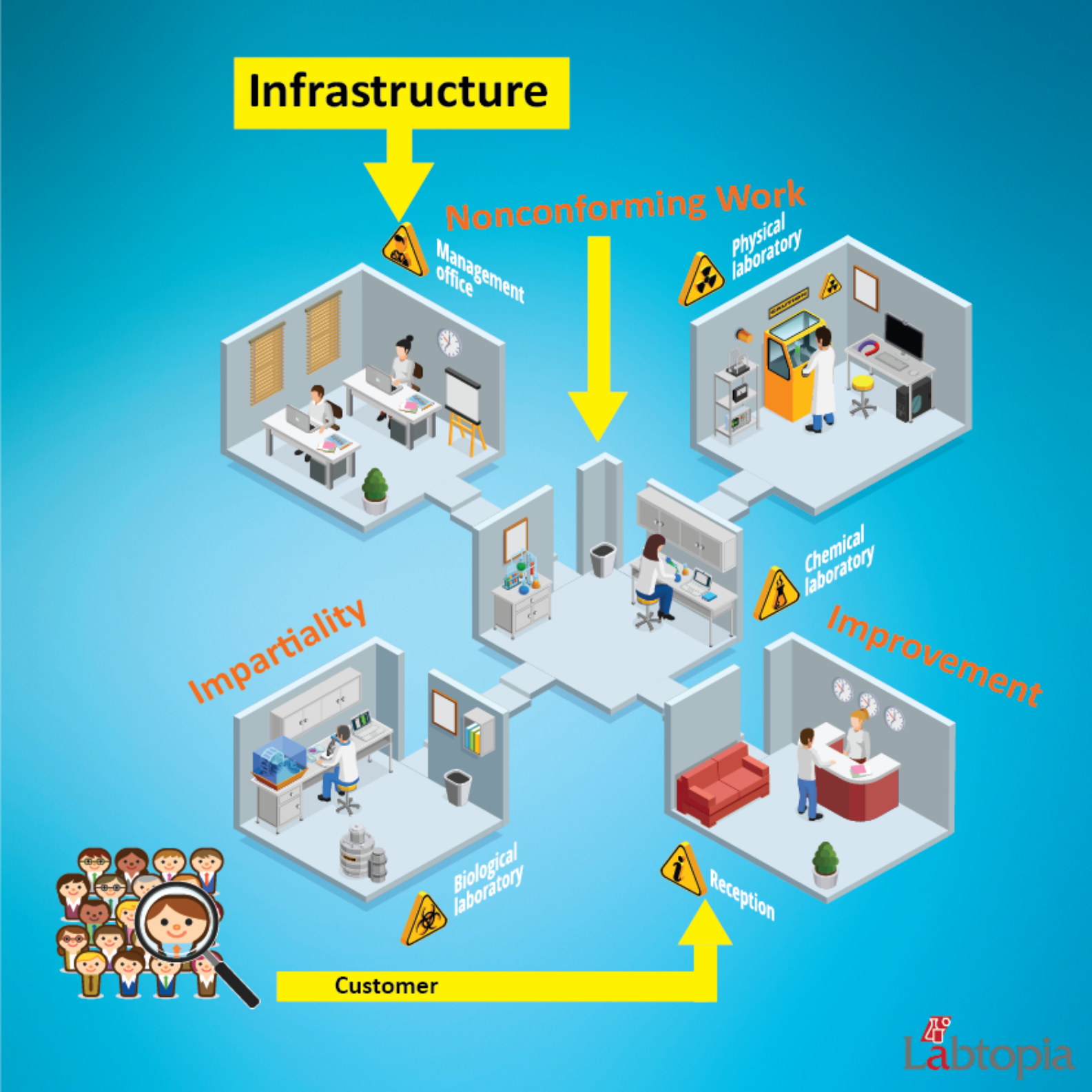
Option B relates to laboratories that are certified or part of the organization ISO 9001 certified. However, Option B only fulfills the intent of the Management Requirements. The extent of the ability to meet those requirements must be evaluated by the laboratory. Any areas that do not meet the requirements would require action by the laboratory.

OPTION A vs. OPTION B

The new Standard is organized by eight (8) sections total.

1. Scope
2. Normative Reference
3. Terms and Definitions
4. General Requirements
5. Structural Requirements
6. Resource Requirements
7. Process Requirements
8. Management Requirements

Labtopia


Infrastructure
Nonconforming Work
Management office
Physical laboratory
Chemical laboratory
Impartiality
Improvement
Biological laboratory
Reception
Customer
Labtopia

Current Quality System Procedures

The new Standard does not specify as many procedures as the previous standard.

Based on the reduced requirements for procedures, should the laboratory abandon its current documented quality policies and procedures?

Absolutely Not!

The current quality system documentation can be used to meet the requirements of the new Standard.

Got Procedures?

- Personnel
- Handling, Transport, Storage, Use and Planned Maintenance of Equipment
- Review and Approval of Suppliers (services, equipment, consumables, and services)
- Review of Requests, Tenders and Contracts
- Sampling
- Handling of Test or Calibration Items
- Monitoring and Trending of Laboratory Activities
- Nonconforming Work
- Quality System Procedures

Metrological Traceability

The standard requires all testing and measurement results are traceable to the International System of Units (SI).

AND

Each contributor to the measurement uncertainty must be quantified and identified through this unbroken chain.

Typically, accrediting bodies (organizations) have traceability policies specifically stating the requirements for traceability of results.

Labtopia

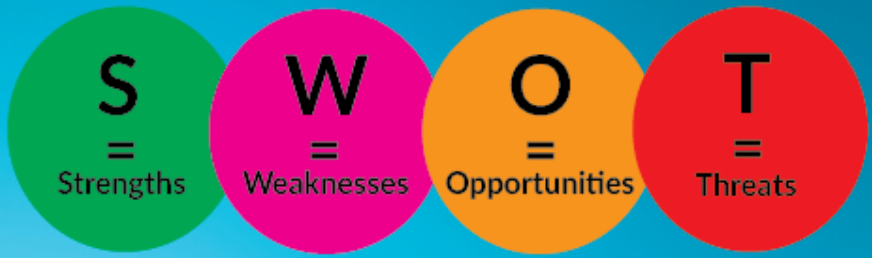
Time to Do the Work!

The laboratory will need to initiate the transition by determining the risks and opportunities external and internal to the organization.

Many organizations find this to be the hardest step.

To start the process, the laboratory can conduct a SWOT analysis. This will help discover those risks and opportunities for improvement.

SWOT Analysis



Once the SWOT analysis is complete....the next steps are **EASY**!

Evaluating Risk and Opportunities

Evaluating Risk and Opportunities are a key aspect of the new Standard.

There are specific references to Risk throughout the standard. In order to start the transition to the new standard, the laboratory will need to identify, evaluate, and provide initiatives related to the perceived risks.

References

ISO/IEC 17025:2017 - Draft international for the General requirements for the competence of testing and calibration laboratories.

Labtopia