What is this?

This is the LQSI tool - a tool in the form of a website that provides a stepwise plan to guide medical laboratories towards implementing a quality management system in compliance with ISO 15189. It may help laboratories to fulfil the requirements of the standard to enable achievement of accreditation. It was developed by the Royal Tropical Institute (KIT) for the World Health Organization. It is based on the Global Laboratory Initiative Stepwise Process towards Tuberculosis Laboratory Accreditation (GLI tool).

Why was this tool developed?

Until recently, laboratory services were amongst the weakest components of disease treatment and control efforts in high-burden, resource-limited countries. Strengthening laboratory services and systems is essential for universal access to high quality laboratory diagnostic services. One of the best methods of laboratory strengthening is to implement a quality management system that complies with the requirements of the international quality standard, ISO 15189, or with a (national) standard with similar requirements.

Who can use this tool?

This tool can be used by any laboratory performing diagnostic activities for clinical or public health purpose.

How does this tool work?

This tool is a stepwise plan for implementing a quality management system. Each step of this plan is called an activity that consists of:

- One sentence stating what should be done
- A description with an explanation of why the activity should be completed, what should exactly be done, how it should be completed (in chronological order) and who can best complete the activity
- Links to additional support materials such as further background reading, document templates and other tools
To implement the quality management system in a logical way the activities are divided over four phases of implementation, with each phase having a specific focus. The tool is constructed such that, even when a laboratory does not reach full implementation of the quality management system, it has already improved its quality service provision from the moment it completes phase 1, and as such has benefited already.

- Phase 1: Ensuring that the primary process of the laboratory operates correctly and safely
- Phase 2: Controlling and assuring quality and creating traceability
- Phase 3: Ensuring proper management, leadership and organization
- Phase 4: Create continuous improvement and prepare for accreditation

Click to read more about the phases of this tool. [4]

To view the activities in each phase you can choose between two frameworks:

1. Roadmaps [5], showing all the activities in an ideal sequence for day-to-day implementation
2. Quality System Essential framework, [6] showing the activities sorted per quality system essential (as formulated by the Clinical and Laboratory Standards Institute)

To assess correct completion of the activities this tool also provides an option to create checklists [7] based on the extent of implementing the quality management system.

In the User Instructions [8] section a you'll find an extensive explanation on how to use the tool.

Click to start! [9]

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