

Appendix A – Quality Manual

The Quality Management System manual is a document that describes the planned and systematic activities used to ensure a certain level of quality will be achieved and maintained by the agency, laboratory and/or testing facility. This document should serve as the guideline for laboratory audits and for all questions related to quality management within the laboratory. There are two main sections to a quality management system: Management requirements and Technical requirements. Management requirements address the operation and effectiveness of the quality management system within the laboratory. Technical requirements address the competence of staff, methodology, equipment, environment and reporting.

The quality management system manual must include, but not limited to, the following sections:

Management requirements

- *Organization and Management*
- *Quality System*
- *Document Control*
- *Subcontracting Services*
- *Purchasing Supplies*
- *Complaints*
- *Control of Nonconforming Tests and Results*
- *Corrective and Preventative Actions*
- *Records*
- *Internal Audits*
- *External Audits*
- *Management Review*

Technical requirements

- *Personnel*
- *Environmental Conditions*
- *Test Methods*
- *Equipment*
- *Measurement Traceability*
- *Specimens*
- *Handling of Specimens*
- *Ensuring the Quality of Test results*
- *Reporting Test Results*

