Quality Management Readiness Checklist
Contents

• Equipment

• Staff training

• Quality Management plan

• Health & Safety Measures
Equipment

- **All** equipment required to perform testing / analysis should be available for staff

- Laboratory must follow the **service guidelines** for all equipment and should be performed by certified technicians or trained lab staff
Equipment

• Preventative maintenance must be performed according to manufacturer recommendations

• SOPs & operating instructions must be readily available (instrument cleaned, inspected, maintained, validated & calibrated)

• Maintenance logs (signed & dated) must be available
Equipment

- **Documentation** should be available for scheduled & unscheduled maintenance

- An equipment service schedule which lists all relevant items & dates, planning the scheduled maintenance must available & updated

- Any equipment items **not** in use should be marked clearly
Equipment

- Automated pipettes,
- Thermometers,
- Refrigerators & freezers,
- Incubators & water baths,
- Centrifuges,
- Autoclaves,
- Timers,
- Analytical balances,
- Biosafety cabinets,
- Microscopes
• The laboratory must adhere to & document daily, weekly & monthly maintenance for all equipment in use

• Room temperatures must checked & monitored daily for all temperature dependent equipment using calibrated thermometers
Staff training

- Laboratory management must ensure that personnel clearly understand their roles & provide the appropriate training:
  - Technical
  - Health & Safety
  - Quality management system
  - Laboratory Information systems
Staff training

• Job specific training must be provided for the duties:
  - Before employees work independently
  - Any changes to procedures
  - After repeated performance problems
**Staff training**

- **Personnel files:**
  - Training & Orientation
  - Curriculum Vitae (updated)
  - Education & Qualifications
  - Competency (initial & ongoing)
  - Applicable License / Certification if applicable
  - Workshops & seminars attended
  - Safety training record
Staff training

- Covered in competency policy:
  - Direct observation of test performance,
  - monitoring the recording & reporting of test results,
  - review of intermediate test results,
  - QC records review,
  - proficiency testing or EQA,
  - preventative maintenance records,
  - analyzing previously tested samples
Staff training

• Competency assessment:
  - after training, the competencies must be assessed
  - for initial competency, should be reassessed after 6 months
  - ongoing competency should be reassessed annually.

• Direct observation of procedures, equipment maintenance
Quality Management Plan

- Documents the information required to effectively manage laboratory quality from study start-up & first sample receipt until the final results are reported
- It defines the laboratory quality policies, procedures, staff roles, responsibilities and authorities
- This can be described in the laboratory quality manual
Quality Management Plan

- Must be available to all staff and reviewed regularly by the laboratory director

- Designed to monitor, evaluate and rectify identified sample processing & general problems
Quality Management Plan

• Includes:
  - key measureable quality indicators, critical to & have significant impact on study outcomes (Specimen acceptability, TAT, contamination rates)
  - Details the recording of corrective & preventative actions
  - Describes laboratory quality control procedures and external quality control
Quality Management Plan

- Includes
  - the laboratory complaints & Incidents procedure
  - laboratory scope of testing
  - information on how quality information is collected & communicated
  - control activities (quality control, EQA)
• Lab management must ensure safety precautions are adhered to according to the regulations

• Safety of laboratory staff of the highest importance

• Adequate safety training should ensure the safety of all laboratory staff
Safety Policies / SOPs:

- Standard precautions
- Waste management
- Chemical Hygiene
- Safety Equipment
- General Safety
- Emergency Preparedness
All staff must receive training for:

- Pathogens (safe handling)
- PPE (proper usage)
- Chemical hygiene
- Use of safety equipment
- Transportation of infectious materials
- Accident reporting
- Waste management
Health & Safety

Safety Equipment:

- Eye wash
- Emergency shower
- Fire extinguishers
- Sharps containers
- Automatic fire detection (smoke detectors) & alarm system
- Separate sinks for hand hygiene
- First aid kit
• **Document** the **inspection** and **testing** of safety equipment by signing and dating and store that it can be easily available

• **Evacuation plan** must be **documented** and available to **all staff** and **visitors** & all lab staff should be trained

• Evacuation routes must be **clearly marked**
Health & Safety

PPE

• PPE available to all staff & must be used if potential exposure to infectious material

• Gloves, gowns or lab coats, eye protection (goggles / face shields / BSC), masks

• PPE available to visitors as applicable
Health & Safety

- **Material Safety Data Sheets** must be readily available for hazardous chemicals in use
- Must include chemicals used for testing & cleaning / general use

- **Gas Cylinder Storage** must be secured, preventing falling or damage
- Correct storage – separate, ventilated room **not** in passage or near heat source / open flame
Conclusion

• Monitors the evidence of the implemented quality management plan

• Ensures the quality of the service provided to the user
Thank you