Quality Management Readiness Checklist

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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

Equipment

- 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)

Health & Safety

- 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

Health & Safety Management

Safety Policies / SOPs:

- Standard precautions
- Waste management
- Chemical Hygiene
- Safety Equipment
- General Safety
- Emergency Preparedness

Health & Safety

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 Management

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

Health & Safety

- **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

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