Laboratory Checklist

Laboratories can adopt a risk-based inspection programme and will need to have documented risk assessments. These will identify the issues that might compromise compliance and patient safety and evaluate the risks associated with exposure to those issues.

When conducting a risk assessment, the following should be considered (this list is not exhaustive):

- What are the risks to compliance and patient safety?
- What might go wrong?
- What is the likelihood it will go wrong? (probability)
- What are the consequences to the tests, facilities and systems? (impact)

Once the risks have been identified, the facility management should determine what controls they have in place that mitigate these risks occurring and would detect them if they were to occur. This checklist offers quality control activities. Such controls may reduce the risk of compromising compliance and support a reduced frequency or different scope of quality assurance monitoring.

System Validation:

System	System Validated yes	no	Comments
Environmental Monitoring System			

Planning:

Requirement	Interval	Monitoring Method	Comments
Measurement Value	10s to 15 minutes		
Control	Daily	SMS/E-Mail/Call	
Deviation	Upon warning/alarm		
Qualification			
Calibration			
Service (battery change, filter change, firmware update, software update)			

Documentation:

Requirement	Monitoring Method	Comments
Data integrity		
Procedures and SOP's		
Deviation		

Room Environmental Monitoring Overview:

Room	Environmental Parameter	Value min.	Value max.	Monitoring yes	Monitoring no	Room Qualified yes	Room Qualified no	Calibration Details[1]	Comments

Equipment Environmental Monitoring Overview:

Equipment	Environmental Parameter	Value min.	Value max.	Monitoring yes	Monitoring no	Equipment Qualified yes	Equipment Qualified no	Calibration Details[1]	Comments

[1] *IEC/ISO 17025 or traceble calibration; one (1) or multipoint calibration.*