Internal Audit

Site Assessment: Priority Quality System Essentials (Quarterly)

Laboratory: _____   Section (if applicable) _____

Audit date: _____   Auditor name _____

Person(s) consulted: _____

Policy references for this audit: National Laboratory Quality Manual, QSE sections on organisation, personnel, inventory control and equipment. Selected items from WHO LQSI tool, phase 1 and 2 checklists (https://extranet.who.int/lqsi/content/pick-your-checklist). For all national resources, including LQMS Information sheets, refer to https://path-png.org .

Checklist	Compliance?	References / Notes
QSE: Organisation and QSE: Inventory		
Has the Laboratory description, test list and organisational structure been completed as per national template?	y/ n / partial	Refer to Diagnostic Lab Guides, http://path-png.org
Is the authorised (signed and dated) organisational structure displayed in the lab for staff to see?	y/ n / partial	
Has there been minuted sectional (or all of lab) staff meetings in the past 1 month?	y/ n / partial	Refer to Information Sheet: staff meetings
Are lab testing updates, EQA, internal QC, non-conformances and biosafety agenda items routinely considered in agenda?	y/ n / partial	
Are minutes recorded with "SMART" action plans?	y/ n / partial	
Are action plans tracked meeting to meeting?	y/ n / partial	
Is there an appointed biosafety officer (BO) who has been publicised to staff (e.g. displayed on a memo)?	y/ n / partial	
Has the BO completed CDC lab training and GMPP training modules specified in the Laboratory Quality Manual?	y/ n / partial	
Are there at least two staff trained in first aid (online)?	y/ n / partial	
Are there at least two staff trained in basic life support within the past 12 months?	y/ n / partial	
Is there an appointed equipment officer who has been publicised to staff (e.g. displayed on a memo)?	y/ n / partial	
Has the EO completed WHO LQM Equipment eLearning module?	y/ n / partial	
Is there an appointed stock officer who has been publicised to staff (e.g. displayed on a memo)?	y/ n / partial	
Has stock officer completed the WHO LQM stock eLearning module?	y/ n / partial	
Is there a stock inventory register?	y/ n / partial	
Are all items available in the laboratory stock recorded in the Stock Inventory Register?	y/ n / partial	

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Checklist	Compliance?	References / Notes
Is the stock register in accordance with the actual stock (i.e. is it up-to-date)?	y/ n / partial	
Are stocktakes performed at least monthly?	y/ n / partial	
Do staff members know the correct procedure of taking items from the stock? I.e. is there a logsheet for withdrawals from each stock storage location	y/ n / partial	
Is there an appointed quality officer (QO) who has been publicised to staff (e.g. displayed memo)?	y/ n / partial	
Has the QO completed the 5 x WHO LQM eLearning modules?	y/ n / partial	
Does the QO regularly meet with the lab/section manager?	y/ n / partial	
Is there an up-to-date routine work schedule for all staff?	y/ n / partial	
Is it displayed for staff to see?	y/ n / partial	
Is the national Laboratory Quality Policy endorsed and displayed locally for staff to read?	y/ n / partial	
Are staff aware of the National Laboratory Quality Manual and its associated website http://path-png.org ?	y/ n / partial	
Is there a locally authorised (endorsed) printed version of the Lab Quality Manual for staff to read and acknowledge?	y/ n / partial	
QSE: Personnel management		
Have personnel files been created for every staff member?	y/ n / partial	Refer to Information Sheet: Human Resources
Are they filed securely, accessible only to the lab manager?	y/ n / partial	
Has the personnel file front page template been completed for all staff?	y/ n / partial	
Are the personnel files structured in an orderly fashion?	y/ n / partial	
Are the Personnel Files up-to-date; i.e. have all certificates and diplomas been collected for all staff members and been stored in their personnel files?	y/ n / partial	
Does the laboratory have a job description for each position in the laboratory?	y/ n / partial	
Does the laboratory have an Authorization Matrix, showing for each position in the laboratory the authorizations, responsibilities and tasks?	y/ n / partial	
Has laboratory management commenced discussion about how it will record specific qualitative and objective staff competencies against key SOPs	y/ n / partial	Refer to Section 13, National Laboratory Quality Manual via path-png.org
Have all staff read and signed the code of ethics? (store in personnel file)	y/ n / partial	Available from path-png.org
Is the orientation and biosafety checklist completed for all new staff?	y/ n / partial	
Does the laboratory manager regularly speak with individual staff about their performance development needs and facilitate these?	y/ n / partial	
Are performance appraisals performed for all staff members at least every two years?	y/ n / partial	
Is there a performance development calendar (i.e. local educational activities) for staff that is publicised and updated at least monthly?	y/ n / partial	

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Checklist	Compliance?	References / Notes
QSE: Equipment		
Has the hospital assets register been accessed in the past year and amended to reflect the operational equipment in the lab?	y/ n / partial	
Is there an equipment folder for each major instrument type?	y/ n / partial	
Is each equipment folder well organised? Does it include a completed equipment front page template or the BSC Servicing Form (for BSC cabinet)?	y/ n / partial	
Are SOPs or JobAids present for all key equipment?	y/ n / partial	
Have staff read and acknowledged the equipment SOPs?	y/ n / partial	
Do the equipment labels include the following data: Lab/section equipment number; Date of last service/calibration; Date of next service/calibration?	y/ n / partial	
Is it documented who is responsible for each piece of equipment and who is authorized to use the equipment?	y/ n / partial	
Is a preventive maintenance program in place for major pieces of equipment?	y/ n / partial	

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Action(s) required:

Actions to be prioritised	Who is responsible for taking action?	Date to be completed
1		
2		
3		
4		
5		

Section/Lab manager reviews actions and endorses/amends as required	Sign/date
Auditor endorses final actions and enters same onto the Lab/Section Action Log sheet (which is subject to regular management review)	Sign/date
Quality Officer/Lab Manager consults Action Log reviews to confirm all actions completed (unless unresolvable) at 3 months	Sign/date
Section/Lab manager closes off the audit after actions resolved	**Sign/date**

Changes to the last authorized version:

Version	Date	Amendments
G_10_Audit_3_A	6/3/23	New document

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