Approval and Authorization

Completion of the following signature blocks signifies the review and approval of this Document.

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Periodic Review Approval and Authorization

Completion of the following signature blocks signifies the review and approval of this Document.

Required by: *(03/2020)*

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1 OVERVIEW CONTENT

1.1 Process Overview

This document describes the managerial and technical accreditation requirements of Histopathology laboratory. The requirements for accreditation are laid down in ISO 15189, medical laboratories- requirements for quality and competence. These requirements apply to all types of medical testing but in certain instances, additional guidance is necessary to take to account the type of testing and technologies involved

1.2 Purpose

This document has been prepared by the Technical Committee on Medical laboratory and Point of Care Testing (POCT) and authorized for adoption by KENAS. It supplements ISO 15189 standard and provided specific guidance on the accreditation for Immunology laboratories for use by assessors and by laboratories preparing for accreditation

1.3 Scope

This document covers the application of ISO 15189 for accreditation of Histopathology laboratories, and should be read in conjunction with KENAS rules and procedures as well ISO 15190 and Good Clinical Laboratory Practices.

1.4 Role(s) and Responsibility

Role	Responsibility
Health and Safety Team	• Development of draft for Technical Committee Review. • Administration and Periodic review
Medical Lab and Point of Care Testing Technical Committee	• Technical Draft Review and approval
Medical Labs	• Compliance
Assessors	• Utilization during assessments

2 DEFINITIONS / ABBREVIATIONS

The table below defines new or changed terms that are included in or associated with this process.

Term	Definition
KENAS	Kenya Accreditation Service

POCT	Pont of Care Testing

3 PROCESS INSTRUCTIONS

3.1 INTRODUCTION

Name of laboratory----------

Address of the medical/clinical laboratory----------

Name of the Laboratory Director----------

Qualification of the Laboratory Director----------

Name of the Quality Manager ----------

Qualification of the Quality Manager ----------

Standard: the laboratory management shall maintain records of the relevant educational and professional qualifications, training and experience, and competence of all personnel. (Clause 5.1.2)

Standard: there shall be staff resources adequate to the undertaking of the work required (clause 5.1.5).

Standard: there shall be continuing education programme available to ***all staff level*** (clause 5.1.9)

3.1.2 Staffing:

List the number of full time:

- Laboratory Pathologist----------
- Laboratory scientist----------
- Supervisor technologist----------
- Laboratory technologists/technicians----------

- Laboratory assistants----------
- Clerical staff----------
- Support staff----------
- Other staff (specify)----------

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Standard: There shall be continuing education programme available to ***all staff level*** (clause 5.1.9)

Laboratory consultants

- Name of consulting pathologist……
- Name of consulting scientist……

3.1.2.1 Qualifications for persons authorized to review and release the results or authorized signatories are listed below:

Test classification	**Qualifications**	**Experience**	**Other requirements/Remarks**
Highly Specialized Tests	M.B.B.S and M.D. (Histopathology) *or* Equivalent Qualification	2 years	Demonstrate knowledge and high competence Clinical and Technical Experience
Special Tests	As above	As above	Demonstrate knowledge and high competence
Routine Tests	As above	As above	Demonstrate knowledge and high competence

Note: Providing Opinions and Clinical interpretations of test results should be done by personnel having appropriate qualifications, training and experience in Histopathology discipline.

Work load	**Work Load units**	**Tests**
Inpatients	----------	----------
Out patients	----------	----------
Referred in patients	----------	----------
Others	----------	----------
Total	**----------**	**----------**

3.1.3 TYPES OF SPECIMENS PROCESSED

No.	**Type of specimen**	**Number of specimen per month**
1	Blood	
2	CSF	
3	Tissue	
4	Bone	
5	Bone marrow	

REFERENCE LABORATORY:

NAME: ----------

ADDRESS: ----------

3.2. LABORATORY SPACE

3.2.1 The overall space adequate for this section shall be adequate for its function

Adequate space shall be allocated to:

a) Administrative and clerical functions
b) Technical functions (benches)
c) Incubators (adequate number available)
d) Instruments
e) Storage (including adequate number of refrigerators)
f) Work areas which shall be shaded from direct sunlight
g) Biological Safety Cabinets – (Adequate Number Present) - Which shall be adequately serviced
h) Media Preparation area sufficient

3.2.2 In order to attain effectiveness of operations, laboratory should ensure adequate space in relation to patient reception, sample collection area.

3.2.3 The tissue cut up room should be separated from the rest of the lab and should be ventilated with fans to take away the formalin vapour, sink with tap water, tables and cupboards to keep the sample bottles.

3.2.4 Laboratory should have proper disposal of unwanted samples and tissues (garbage bags, tins).

3.2.5 The main laboratory should be clean, spacious, adequately ventilated with plenty of light, (air condition, if possible); enough space for workbench and equipment.

3.2.6 Space should be availed for proper storage of chemicals, first aid box, equipment, used paraffin blocks and slides.

3.2.7 Fire equipment also should be kept in the same laboratory as well.

3.2.8 The laboratory should have adequate lighting, power plugs and uninterrupted power supply.

3.2.9 The laboratory shall have procedures in place to ensure the integrity of refrigerated and/or frozen stored samples/reagents/consumables in the event of an electrical failure and emergency exist

3.2.10 A separate room shall be allotted for tissue processing with a fume hood for handling osmium tetroxide.

3.2.11 A separate dust-free facility, with air-conditioning shall be available for preparation of specimen and performing electron microscopy.

3.2.12 The electron microscopy room shall have:

i. facilities in place for temperature control and chilled water supply
ii. insulated cabling kept away from the work areas
iii. proper seating available to allow for optimal ergo metric positioning of the person using the microscope dark room with adequate ventilation
iv. warning light on the door of the dark room indicating usage

3.3 Laboratory Equipment

3.3.2 Laboratory should maintain documented programme for the maintenance, calibration and performance verification of all test equipment.

3.3.3 The equipment should be calibrated from an accredited calibration laboratory where applicable.

3.3.4 Depending on the workload the laboratory should develop a procedure to change the tissue processing fluids and maintain a record of it.
3.3.5 A log recording of the 'time setting schedule' for an automatic tissue processor should be maintained.
3.3.6 Temperature of the wax bath should be checked and recorded daily.
3.3.7 The setting of the microtome indicating the thickness of sections should be checked before use.
3.3.8 Microtome with non-disposable knife should have a safety shield.
3.3.9 Temperature of slide warming stage should be checked weekly
3.3.10 The fluid in the flotation bath shall be changed at least once a day.
3.3.11 The surface of the water bath shall be skimmed regularly during section cutting to remove floaters.
3.3.12 Frozen section Microtome should be kept in a safe area as aerosols, infective material can be spread.
3.3.13 Cryostat has to be calibrated and the temperature has to be set daily.

3.4 **Pre-examination procedures**

3.4.2 Specific instructions for the proper collection and handling of primary samples shall be documented in a primary sample collection manual.
3.4.3 Sample collection manual should include specific instructions for sample collections to be followed at the collection centre.
3.4.4 Specimen should be properly & adequately fixed in formal saline (10%) and the formal saline volume should be 10 times more than the specimen.
3.4.5 For renal and testicular Biopsy, a different fixative may be used and it has to be stated.
3.4.6 For frozen sections prior arrangements with the laboratory is mandatory and specimen should reach the lab within 5-10 minutes after surgery.
3.4.7 A responsible person must accompany the specimen and contact number of the surgeon should be stated in the request form.
3.4.8 High risk samples (HIV) shall be labelled and identified.
3.4.9 All the samples should be retained until the reports are received by the physician.
3.4.10 The examined specimens shall be stored for re-examination and/ or additional tests for a minimum period should be specified.

3.5 **Examination Procedures**

3.5.1. Follow Standard Histopathology Text Books or WHO Recommended Methods

3.6 **Assuring Quality of examination procedures**

3.6.2 The laboratory should design and implement internal quality control systems that verify the attainment of the intended quality of results.
3.6.3 The Laboratory should participate in inter-laboratory comparisons provided through external quality assessment schemes.
3.6.4 When formal inter-laboratory comparison programmes are not available, laboratory should adopt mechanisms to determine the acceptability of procedures not evaluated.

3.6.5 The effectiveness of the quality control programmes should be measured and included in the laboratory management review.

3.7 **Reporting of Results**

3.7.2 The names of the person reporting the macroscopic and microscopic findings along with signatures shall be entered on each report.

3.7.3 Laboratory should provide adequate description of the macroscopic/microscopic findings.

3.7.4 Report should be in accordance with recent terminology/ classification, grading, scoring, nature of lesion and relevant information necessary for disease management.

3.7.5 Report should also mention all additional tests performed (such as special stains, immunohistochemistry etc.).

3.7.6 All reports should be checked for accuracy by a pathologist before authorization and issue.

3.7.7 The Turn Around Time for issue of reports should be 07 days but for larger specimens & tissues which need special examinations the Turn Around Time varies (10-14 days). Histochemical & Immunochemical specimens the time period is 7-12 weeks.

3.7.8 For any special procedures are carried out to further characterize the pathology, a interim report should be issued to facilitate immediate management of the patient.

4 REFERENCE AND RELATED DOCUMENTS

Ref	Document Identifier	Document Title
1.	ISO/IEC 17011	Conformity Assessment-General requirements for accreditation bodies accrediting conformity assessment bodies
2.	KENAS-QM-MAN-001	KENAS Quality Manual
3.	ISO 15189	Medical Laboratories – Requirements for Quality and Competence
4.	ISO 15190	Medical Laboratories – Requirements for Safety

5 TRAINING

None required except for notification and awareness by Medical Laboratories. Assessors need to be aware of this criterion for utilization during assessments.

6 REVISION HISTORY

Date	Ver	Revised By	Reason For Revision
03/08/2013	01	ADHS	• Initial
14/03/2017	02	CO H&S	• Align guideline to the right template. • Incorporate references in the guideline • Amend technical committee name to include POCT