UNIVERSITY OF NAIROBI

Document: **PROCEDURE FOR GOOD LABORATORY PRACTICES**	
College: **CORPORATE**	Doc. No: **UON/OP/71**
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0.1 DOCUMENT CHANGES

DATE	CLAUSE	AUTHORIZED BY
October 14, 2009	0.1 – Document changes	VC
March 21, 2011	3. University Quality manual added 4 Deleted acronyms and defined LM 5 Edited responsibility 6 Deleted and wrote new method	VC
June 30, 2013	Merged and revised UON/OP/70, UON/OP/71 and UON/OP/81 Changed procedure title 5. Changed title to **"definitions of terms and acronyms"** and inserted table	VC
March 31, 2015		VC
August 31, 2016	Changed the Authorising and Issuing Authority Removed Document Distribution List Changed Records to Documented Information Changed Process Maps to Procedure Flowcharts	UMB

1. PURPOSE

The purpose of this procedure is to define the Good Laboratory Practice (GLP) guidelines to be applied in all the laboratories and workshops.

2. OBJECTIVE

a) To ensure the generation of high quality and reliable test data
b) To fabricate quality products
c) To protect human health and the environment
d) To manage the laboratory and workshop more efficiently

3. SCOPE

This procedure applies to all laboratories and workshops in the University where experiments/tests are performed and products are fabricated.

4. REFERENCES

a) QMS Manual
b) Ministry of Health guidelines
c) Nairobi County and other County Authorities By-laws and Regulations
d) Material Safety Data Sheets
e) Laboratory Manuals
f) University Service Charter
g) NEMA Guidelines
h) Health and Safety Procedures

5. DEFINITION OF TERMS AND ACRONYMS

Term	Acronym	Definition
Good Laboratory Practice	GLP	A quality system concerned with the organizational process and the conditions under which laboratory experiments are planned, performed, monitored, recorded, archived and reported
Activity		One of the many different procedures that can be carried out within the laboratories such as a particular study, experiment, practical session or fabrication.
Personnel		Staff and student members making use of the laboratory
Standard Operating	SOP	A set of written instructions that document how an activity is performed

Term	Acronym	Definition
Procedure		
Hazardous Waste		Any unwanted material whose chemical or biological properties have the potential to endanger people, material, or the environment
Chemical Waste		Waste that may be potentially harmful to people, equipment or the environment, typically based on information provided in MSDS
Biological Waste		Waste material generated from biological sources
Sharps		Items that can lacerate or puncture the skin
Toxic		That which is harmful to human, animal and plant life
Neutralization		Rendering harmless
Fume Cupboard		Cupboard/chamber, which sucks and pumps out pungent/toxic gases
Laboratory		Buildings or rooms in which experiments or scientific work are carried out.
Workshop		Buildings or rooms in which manual or light industrial work is done
Equipment Logbook		Documented information of use, maintenance/repairs of equipment
	MSDS	Material Safety Data Sheets

6. RESPONSIBILITY

6.1 Dean/Director/Chairman/Chief Medical Officer

a) Shall be responsible for the efficient and effective operation of this procedure.

b) Shall ensure that individuals engaged in the conduct of or responsible for the supervision of an activity have an educational background, training and experience to enable each individual to perform the assigned tasks.

6.2 Principal/Chief Technologist

Shall ensure that the following is adhered to and implemented:

a) Suitable storage areas are available for supplies and equipment and that these areas provide protection against contamination and deterioration.

b) There are provisions to regulate environmental conditions such as temperature and humidity.

c) Health and safety precautions are observed in the laboratory.

d) Appropriate SOPs are established and followed.

e) Waste is collected, stored and disposed appropriately

f) Wastes which are suspected to be hazardous are neutralized before being disposed.

7. METHOD

7.1 Personnel

a) Takes necessary personal health precautions designed to avoid any contamination.

b) Wears appropriate clothing for the duties they perform.

c) Report any medical condition/s that may be considered to have an adverse effect on an activity.

7.2 Equipment

a) Maintain Logbook for each major equipment.

b) Equipment used in the generation, measurement or assessment of data is suitably located, of adequate capacity to function according to the activities that are carried out.

c) Periodically inspect, clean, maintain and calibrate the equipment according to the prepared maintenance schedule.

d) Documented information of the maintenance are kept in respective equipment logbook.

e) Equipment and other materials shall be uniquely identified.

7.3 Materials and Reagents

Chemicals, reagents and solutions shall be labeled with the following:

a) Identity

b) Concentration and purity (if applicable)

c) Hazard posed

d) Expiry date

e) Storage instructions

f) Source (if applicable)

7.4 Standard Operating Procedures

a) Laboratory shall have a set of approved SOPs where applicable.

b) Personnel shall have access to the appropriate SOPs for use during their activity and also to comply with the instructions given in these documents.

c) SOPs, manuals, published text books, analytical methods and articles relative to the activities that are being undertaken shall be available.

7.5 Samples/Specimen

a) Specimens /samples shall be acquired and handled in accordance to a developed SOP

b) Toxic waste shall be handled in Fume Cupboard or Chamber as necessary.

c) Specimens/Samples shall be preserved appropriately.

7.6 Waste Disposal

a) Waste shall be segregated by type.

b) Hazardous waste shall be segregated as Chemical, Biological or Sharps and put in appropriate containers labeled **"HAZARDOUS WASTE".**

c) The waste shall be disposed as per a developed SOP which shall stipulate the disposal method and the documented information of the waste. The record shall contain the type and quantity of waste.

8. DOCUMENTED INFORMATION

Relevant documented information shall be maintained.

9. APPENDIX

9.1. PROCEDURE FLOWCHART

Principal/Chief Technologist initiates the acquisition of the specimen

Technologist positively identifies the specimen

Technologist collects and label specimen for each required test

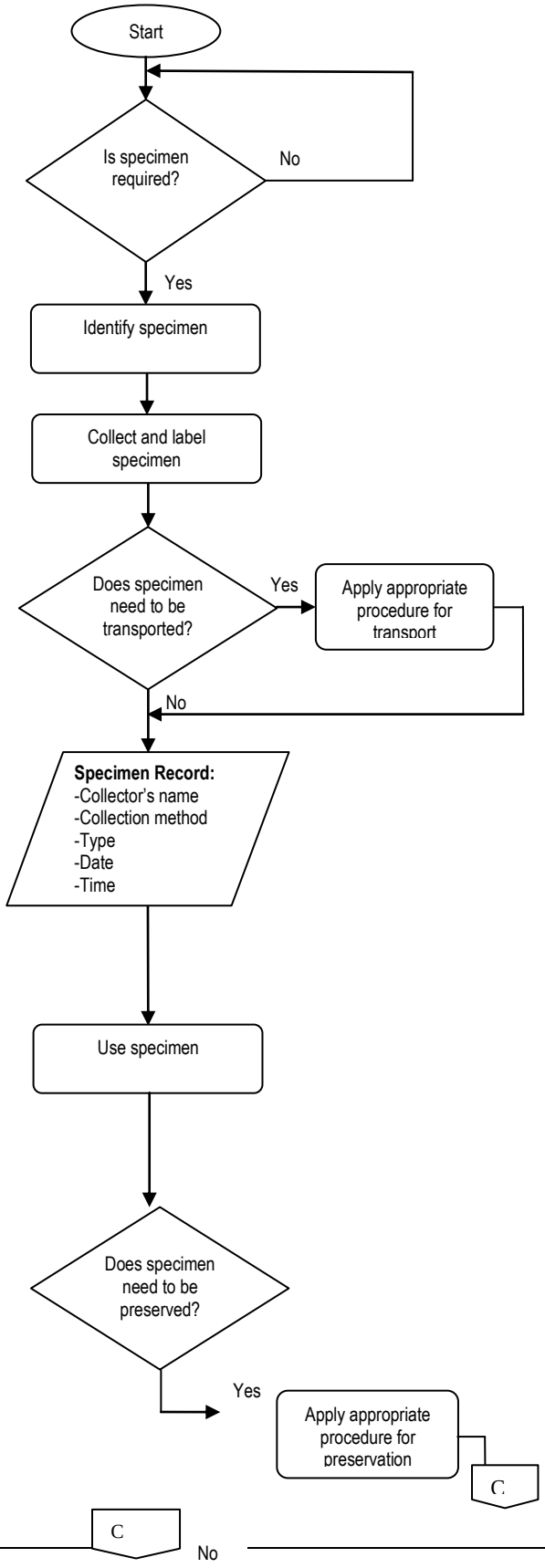
Technologist follows the appropriate procedure developed for transporting the specimen

Technologist enters the following information once the specimen is received in the laboratory

- Collector's name
- Collection method
- Type
- Date
- Time

Specimen is used wearing PPE and using Chamber/Fume cupboard where necessary

Principal/Chief Technologist identify the need and type of specimen to be preserved



Technologist verifies if hazardous waste has been generated Technologist segregates hazardous waste into appropriate disposal containers Technologist discharges the hazardous waste into the chamber Technologist checks if the waste has been neutralized Technologist disposes waste Technologist writes report