LABORATORY QUALITY MANAGEMENT SYSTEM

COLLECTION OF FORMS

1. Environment Temperature and Humidity Recording Form
2. Complaint Registration Form for Laboratory Samples
3. Waste Disposal Form
4. Record for Culture Media Quality Test
5. Record of Non-Conforming Work
6. Training Records for Laboratory Services Unit, NCAH
7. Staff Vaccination Details
8. Record of Non-Conforming Events at Laboratory Reception
9. Staff Induction Checklist
10. Person Responsible for Coordinating the Laboratory's Internal Audit

LSU/LQM/6.3 Environment Temperature and Humidity Recording Form

Name/Section :

Month :

Room Temperature in degree Celsius

Date	Room Temp.		Humidity		Remarks
	Morning	Evening	Morning	Evening	
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
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19					
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26					
27					
28					
29					
30					
31					

Comments :

Sign By Section In charge

Date :

LSU/LQM/ Complaint Registration Forms for Laboratory Sample

Sl No	Complaint registration No.	Date of receipt	Client/Owner Name	Complaint received By	Complaints Details	Investigation Findings	Date of Action	Corrective Action	Status of complaint	Verified by

Compiled by:

LSU/LQM/6.3 Waste Disposal Form

Sl. No	Type of waste	Quantity (kg)	Date of collection	Date of disposal	Treatment method (autoclave/disinfection / incineration, etc)	Disposal Site	Disposed by	Authorized by	Remarks

Form No.	Title	Version No.	Total Pages
LSU/LQM/6.5/01	**Record for culture media quality test**	001	

Function	Name	Designation	Signature

Record for culture media quality test

• **Media details**		
Name of culture media and code:	Make:	Batch No:
Supplement (1):	Make:	Batch No:
Supplement (2):	Make:	Batch No:
Supplement (3):	Make:	Batch No:
Volume prepared:	Media used:	

• **Physical quality control**			
Media colour normal and free flowing: Yes No		Defects:	
Expected pH-value:	Measured pH:	Quality confirmed: Yes: No:	Defects :

• **Microbial Contamination (Negative control)**			
No. of tested plates or tubes:	Result:	Quality confirmed: Yes : No:	No. of contaminated plates or tubes:
Incubation:			

• **Microbiological growth - Productivity**		
Method of control: Quantitative Qualitative		Control strain:
Incubation:	Criteria:	
Characteristics:	Result:	
Reference medium:		
Quality confirmed: Yes: No:		Defects:

• **Release of the batch**	
Details of storage:	Release of the batch: **Yes** **No**
Media GPT checked by:	**Date/Signature:**

RECORD OF NON-CONFORMING WORK

Section and Test details		
Section:	SOP Title :	SOP No.:
Details of non-conformance:		
Root cause analysis:		
Corrective action :		
Information on non-conformance conveyed to the client	Yes / No	Method of Communication :
Date:		
Signed	Test performer : Verified by :	

LSU/LQM/6.2 (III) Training records for Laboratory Services Unit, NCAH

S.N.	Name of Lab personnel	Designation	Training area	Place	Purpose (Skill upgradation/ Orientation)	Duration (With Dates)	Signature

LSU/LQM/ Staff Vaccination Details

Sl. No	Date of vaccination	Name	CID No	Contact No	Age	Sex	Vaccine type	Pre-Exposure Prophylaxis	Post-Exposure Prophylaxis	Due Date	Remarks

Record of non-conforming events at lab reception

Sl.No	Received Date	Specimen Type & Nos.	Sender	Sender Ref. No.	Non-conforming events	Date of intimation	Received by (initial)	Remarks (Outcome)

LSU/LQM/6.2 (VI) Staff Induction Checklist

Name:		Date of employment:	
Buddy:		Status (Please Circle):	Employee/Visitor
Biosafety Focal point:		Supervisor/Incharge:	

Notes for completion of this document

1. This document is to be completed by the staff member BEFORE starting work in the laboratory with the assistance of the Supervisor/Incharge and the Biosafety Section Incharge.
2. This document is used to familiarize the new staff member with the physical and safety aspects of LSU/NCAH.
3. This document is also used to identify training requirements.
4. A buddy must be appointed to the staff member to assist the new staff member for the first week of employment/attachment with familiarization of the laboratory and surroundings. In case of visitors working for research/any other laboratory work at NCAH for a short duration (any number of days), a buddy shall be appointed and assisting throughout their work period.
5. If you are unclear about any aspect of this document or have any safety concern please contact your buddy.
6. It is your responsibility to read and understand the safety policy. You must not start work in the laboratory unless you have read and understood this document.

- **Induction Checklist**

	Action	Remarks (Circle one)
Introduction	Have you met the Program Director?	Yes/No/NA
	Have you met the Head, LSU?	Yes/No/NA

Security	Do you require swipe card?	Yes/No/NA
	Inform of after hour procedures, e.g. Exits available and times of locking?	Yes/No/NA
Safety	Have you made an appointment to meet the Biosafety section focal points on Safety Policy of LSU?	Yes/No/NA
	Have you been shown fire exits, fire equipment and fire assembly points?	Yes/No/NA
	Have you been provided with any necessary PPE's	Yes/No/NA
	Have you read and understood the Occupational Health and Safety Policy? I am not sure name of this policy. If it is called Institutional then it is OK.	Yes/No/NA

- **Training Requirements**
  This section must be completed in conjunction with the Supervisor/Incharge. The supervisor/Incharge is responsible for ensuring all training is completed.

	Training Required	Training signed off by trainer
Centrifuge (Use and cleaning)		

BSC class II (Use and cleaning)		
BSC class III (Use and cleaning)		
Fume hood (Use and cleaning)		
Autoclave (Use and cleaning)		
Electrophoresis equipment (Use and cleaning)		
Low temperature freezers (Use and cleaning)		
Flammable chemicals (Use and storage)		
Disposal of infectious wastes		
Disposal of carcinogenic/mutagenic waste (E.g.: ethidium bromide)		
Disposal of non-infectious waste		
Disposal of solvent waste		
Disposal of glass ware		
Handling of sharps/disposal		
Handling of biological materials		
Appropriate use of PPE		
Good Laboratory Practice: basics/requirements		
Appropriate hand washing		

- **Short Course/Training/Practical**
  - Section/Subject:…….....
  - Scope:……...
  - Training/Coordinator: ……
  - Date/Month/Year: .....

- **Declaration**

Please read the this section carefully

I declare that I have,

- Read and understood the Institutional safety policy; and
- Received all necessary training to perform my work in a safe manner.

Therefore, I shall comply with all the safety practices that centre has adopted and will not default any Biosafety practice/basic GLP standards. I shall report any accidents/spills occurring in the laboratory while I am working.

Signed (staff/member/visitor) Date:

Signed (Supervisor/Incharge) Date:

Signed (Biosafety Section Incharge) Date:

LABORATORY NAME :	DATE:
ADDRESS:	

Person responsible for managing the laboratory's Quality Management System

NAME:	E-MAIL ADDRESS:
TITLE:	PHONE:

Quality Management System Requirements

Sl. No	**Quality Manual Elements**	**Changes made**	**Manual Update**
1	Legal Name and Address		
2	Organizational Charts		
3	Staff Position Description		
4	Staff Biographical Sketches		
5	Staff Training Methods		

6	Staff Evaluation Methods		
7	Staff Training/Evaluation Form		
8	Equipment Inventory List		
9	Equipment Calibration/Standardization/Check/Maintenance		
10	Equipment Calibration/Standardization/Check Procedures		
11	Equipment Calibration/Standardization/Check Cerificates		
12	Test Record Production Procedures		
13	On-site Inspections and Corrective Action Policies		
14	Sample Identification,Storage, Retention and Disposal Policies		
15	Proficiency Sample Testing and Corrective Action Policies		
16	External Technical Complaint Policies		
17	Internal Audit Policies		
18	Subcontracting Policies		

Describe any changes and /or updates made to the laboratory quality management.

Person responsible for coordinating the laboratory's Internal Audit

NAME	E-MAIL ADDRESS
TITLE	PHONE

1. Are the "Internal Audit" requirements mentioned earlier being met?	Yes	No
2 Are the "Management Review" requirements of being met?	Yes	No
3 Are the "Corrective Action" requirements of being met?	Yes	No
4 Are the "Records Retention" requirements of being met?	Yes	No

Equipment Calibration

Equipment Name	**Maintenance Requirement** **S= Standardization** **C= Calibration** **Ch = Check** **M= Maintenance**	**Minimum Time Interval Required for Performing Maintenance Requirement**	**Date of Maintenance Requirement Performed.**

Does the laboratory have certifications and other documentation that establish traceability of in-house reference standards (fluids, thermometers, gauge blocks, calipers, weights, etc.) ?

Yes No. If "No", state reason(s) below.

Has the laboratory calibrated, standardized, checked all applicable testing equipment that may be used for testing ?

Yes No. If "No", state reason(s) below.