

1. PURPOSE

- 1.1. To describe procedure for LIS Contingency when there is a breakdown of LIS systems

2. SCOPE

- 2.1. This procedure is applicable to all the staff members and work areas where the LIS process is used in the laboratory

3. REFERENCES

- 3.1. Relevant Process Manuals

4. RESPONSIBILITY

- 4.1. Quality Manager
4.2. Laboratory Director
4.3. IT In-Charge

5. CONTINGENCY PROCEDURE

- 5.1 Data backup process

Type of backup	Description	Frequency
Full backup	Complete Data backup check	Every 10 days
Differential backup	Between the intervals of complete backup	Every 5 days
Incremental backup	After every data change	Every day
Mirror backup	A parallel data structure	Every day

- 5.2 Backup IT systems

System/Component	Backup - Description	Responsibility
System Based Reporting	Manual Reporting	Lab Incharge
Computer Hardware	Manual Reporting	Lab Incharge
Broadband connection	Mobile Internet Connectivity	Lab Incharge

- 5.3 Contingency Planning Responsibility

- 5.4.1 Laboratory Director is designated as the Contingency Planning Incharge for the laboratory
- 5.4.2 The contingency planning Incharge makes the decision to unfold the contingency plan process
- 5.4.3 Provides the initial notification to activate the contingency plan

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- 5.4.4 Review and approves the contingency plan
 - 5.4.5 Advises other contingency plan team members as appropriate
 - 5.5.5 Issues a recovery declaration statement after the system has returned to normal operations
- 5.4 Contingency Planning – Coordinator
- 5.5.1 Quality Manager develops and documents the contingency plan as per instruction of the Contingency Planning Director
 - 5.5.2 Ensure annual contingency planning training is conducted to the laboratory staff
 - 5.5.4 Manages and monitors the overall recovery process
 - 5.5.4 Leads the contingency response efforts once the plan has been activated

6. RECORDS

- 6.1. The following records are maintained for refrigerator in the format mentioned below, for the period defined

S. No	Record	Responsibility	Retention Period
1	IT breakdown register	IT Incharge	1 Year
2	LIS Breakdown register	IT Incharge	1 Year
3	LIS - Incident report	IT Incharge	1 Year
4	CAPA records	IT Incharge	1 Year
5	LIS verification record	Quality Manager	1 Year

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