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Standard Operating Procedure

**DOCUMENT NAME: FACILITIES
MANAGEMENT / OPERATION**

DOCUMENT NO. : ILBS#NLDB:D

FACILITIES MANAGEMENT / OPERATION**Physical Security at Facility**


Document Name : Physical Security at Facility
Document No. : SOP: ILBS#NLDB: D.1
Version No. : 1.0
Effective Date : 01/01/2025

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National Liver Disease Biobank, Institute of Liver & Biliary Sciences: D -1, Vasant Kunj, New Delhi-110070, India.			Page 2 of 5	
Document Name: SOP "Physical Security at Facility"				
Document No ILBS#NLDB:D.1	Approved & Issued by:		Dr. Chhagan Bihari HOD, Biobank	Issue Date: 01/01/2025
Rev. No.: 1.0				

FACILITIES MANAGEMENT / OPERATION

Physical Security at Facility

Number	Effective date	Pages	Author	Authorized by
ILBS#NLDB:D.1	01/01/2025	5	Mr. Satish Kumar	Dr. Chhagan Bihari
Version	Review period	No. of copies	Approved by	Date
1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

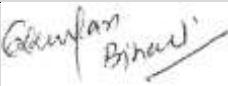
Location	Subject
Biobank Reception area Almira	Physical Security at Facility
Function	Distribution
To provide information on basic security systems that ensures a protected environment for controlled resources.	<ul style="list-style-type: none"> ➤ HOD ➤ Biobank Reception area ➤ Master files

SCOPE AND APPLICATION:

This SOP outlines the requirements for ensuring a safe, efficient, and secure physical environment for the biobank.

RESPONSIBILITY:

This policy applies to all NLDB personnel at the biobank site, including biobank technicians and custodians of the collection within the biobank.

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Rev. No.: 1.0				

FACILITIES MANAGEMENT / OPERATION

Physical Security at Facility

1.0 PURPOSE

NLDB is intended to manage the safekeeping of Human Biological Materials (HBMs) in their custody. HBMs are a precious resource and each biobank should use basic security systems to provide a protective environment for the resource they control.

2.0 SCOPE

This SOP outlines general elements and features that should be in place to provide a safe efficient and secure physical environment for the biobank.

3.0 ROLES AND RESPONSIBILITIES

The policy applies to all personnel from NLDB that work at the biobank site or are the responsible custodians of the collection within the biobank.

4.0 PROCEDURES

The facility should employ fundamental security systems to protect the collection. An efficient biobank should be designed and have elements in place to provide a safe, secure and efficient work environment. Measures should also be taken to protect expensive and specialized equipment at the facility.

4.1 Facilities - general procedures for maintaining security

4.1.1 Provide sufficient and secure space in the biobank for equipment being used and material being stored.

4.1.2 Provide basic security systems to ensure safekeeping of the collection. Monitor the systems adequately to allow for prompt response to any breach in security.

4.1.3 Designate a responsible individual (including designated back-up) to take necessary action in case of failure of systems.

4.1.4 Post the emergency contact information for responsible individuals and key personnel in a prominent location within the biobank.

4.1.5 Provide personnel with education and training about security and emergency procedures to ensure an appropriate response to any failure of systems that may occur.

4.2 Facilities - temperature

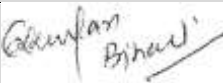
4.2.1 Provide a suitable heating system to maintain ambient temperature to prevent freezing of water and drain lines.

4.2.2 When needed, provide suitable cooling to maintain adequate ambient temperature for electronic and mechanical equipment.

4.3 Facilities - lighting

4.3.1 Provide adequate general and task lighting to ensure that the appropriate level of illumination is available to perform routine and specialized tasks undertaken at the biobank.

4.3.2 Provide back-up lighting for emergency situations.

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Physical Security at Facility

4.4 Security systems for fire

4.4.1 Ensure that the fire prevention system is compliant with the codes and regulations in effect.

4.5 Facilities – limiting access

4.5.1 Define and create physical barriers around biobank resources to prevent physical intrusion.

4.5.2 Lock all doors and control entry to biobank facilities.

4.5.3 Where possible, limit access to biobank facilities to appropriate personnel and authorized staff.

4.5.4 Use physical, electronic and/or procedural controls to limit access to restricted and sensitive areas of the biobank.

4.5.5 Issue personnel with visible identification and controlled access keys. Upon termination of employment, make personnel surrender all identification and access keys.

4.5.6 Report lost or stolen access cards (if applicable), deactivate these cards immediately and issue a new card as appropriate.

4.5.7 Review and keep up-to-date access rights, remove access for individuals that no longer need access.

4.5.8 Grant restricted access to authorized visitors or third party personnel.

4.6 Facilities – Back-up Power System

4.6.1 Ideally have an auxiliary power generation system in place to deal with loss of commercial power.

4.6.2 Keep a sufficient fuel supply for the emergency power generation system to ensure it will provide emergency power for at least 72 hours.

4.6.3 Ensure that important equipment, such as computers and freezers are plugged into the emergency power supply system.

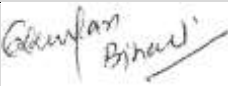
4.6.4 Avoid (if possible) opening of freezers and using sensitive equipment for the duration of the primary supply failure.

4.7 Facilities – Equipment Security

4.7.1 Protect equipment as needed to reduce risk of unauthorized access to data and HBMs stored in the biobank and to protect from loss and damage.

4.7.2 Maintain equipment correctly to ensure continued availability and integrity.

4.7.3 Allow only authorized maintenance personnel to carry out repairs and services to facilities equipment.

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Standard Operating Procedure

**DOCUMENT NAME: FACILITIES
MANAGEMENT / OPERATION**

DOCUMENT NO. : ILBS#NLDB:D

FACILITIES MANAGEMENT / OPERATION**Emergency procedures for freezer failure**


Document Name : Emergency procedures for freezer failure
Document No. : SOP: ILBS#NLDB: D.2
Version No. : 1.0
Effective Date : 01/01/2025

Address

National Liver Disease Biobank,
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Document No ILBS#NLDB:D.2	Approved & Issued by:		Dr. Chhagan Bihari HOD, Biobank	Issue Date: 01/01/2025
Rev. No.: 1.0				

FACILITIES MANAGEMENT / OPERATION**Emergency procedures for freezer failure**

Number	Effective date	Pages	Author	Authorized by
SOP: NLDB:D.2	01/01/2025	5	Mr. Satish Kumar	Dr. Chhagan Bihari
Version	Review period	No. of copies	Approved by	Date
1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

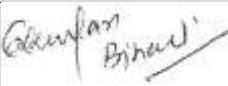
Location	Subject
Biobank Reception area Almira	Administration: Emergency procedures for freezer failure
Function	Distribution
To provide information on emergency procedures in the event of freezer failure, ensuring timely response to protect sample integrity and prevent loss.	<ul style="list-style-type: none"> ➤ HOD ➤ Biobank Reception area ➤ Master files

SCOPE AND APPLICATION:

This SOP outlines procedures to be followed during freezer or refrigerator failure for timely transfer of samples to backup equipment.

RESPONSIBILITY:

Technician: Responding to alarms, determining that equipment failure has occurred, transferring samples to back-up capacity.

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FACILITIES MANAGEMENT / OPERATION

Emergency procedures for freezer failure

1.0 PURPOSE

Appropriate storage is a core requirement for the operation of a successful biobank. On occasion this equipment may fail. Procedures must be in place to ensure that loss and damage to the collection is avoided.

2.0 SCOPE

This SOP outlines processes that should be in place when freezers or refrigerators fail and samples must be transferred to back-up equipment.

3.0 ROLES AND RESPONSIBILITIES

The SOP applies to all personnel from NLDB that are responsible for storing biobank samples and/or transferring samples when storage equipment fails. This may include the following personnel:

Technicians: Responding to alarms, determining that equipment failure has occurred, transferring samples to back-up capacity.

HOD & Biobank Technicians: Responding to alarms, overseeing or transferring material to back-up capacity, and updating lists and procedures

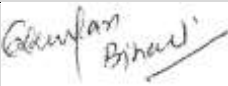
4.0 MATERIALS, EQUIPMENT AND FORMS

- Back-up storage capacity, freezers and refrigerators.
- Cryo cart / trolley move samples rapidly
- Thermometers
- Adequate Liquid Nitrogen, ice and dry ice supply
- Insulated containers to temporarily hold dry ice and samples
- Cryogenic safety faces shield, apron and gloves.
- Alarm systems & contact lists

5.0 PROCEDURES

The storage facility (and storage equipment) is a key element in the operation of a biobank. In the case of freezer or refrigerator failure, appropriate action should be taken to transfer the samples to backup storage capacity without damage to samples or loss of sample identity and tracking.

5.1 Back-up capacity

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FACILITIES MANAGEMENT / OPERATION

Emergency procedures for freezer failure

5.1.1 Provide adequate back-up capacity for a minimum of 72 hours for low temperature units such as freezers and refrigerators in anticipation of equipment failure.

5.1.2 Have extra capacity, equal to at least the capacity of the largest storage unit, and equivalent to 10% (or other percentage as specified) of the total storage capacity, maintained at operating temperature at all times.

5.1.3 Identify and number back-up equipment.

5.1.4 Monitor back up equipment as other units are monitored.

5.2 Transfer initiation and sample transfer

5.2.1 Have trained personnel determine that equipment failure has occurred and that samples have to be transferred.

5.2.2 Make sure that adequate number of biobank personnel are assigned to emergency response and trained to perform the transfer when required. Prominently post a 24-hour contact list for responsible personnel assigned to deal with an emergency situation (including in the evenings/nights or on weekends and holidays) on all storage units.

5.2.3 Train personnel in processes ensuring rapid transfer of HBMs to back-up units when the need arises.

5.2.4 Alert assigned personnel that a sample transfer has to be performed.

5.2.5 Avoid opening the failed freezer too often to avoid large temperature fluctuation to occur before transfer.

5.2.6 If back-up equipment is not situated close by, assemble carts or trolleys to aid in the transfer.

5.2.7 Fill insulated containers with dry ice or ice and place them on the carts.

5.2.8 Remove sample boxes from the freezers and place them on dry ice for transfer. Place sample boxes from refrigerators on ice for transfer. Essentially do not permit temperature fluctuations for extended periods of time.

5.2.9 Rapidly move samples to the back-up equipment.

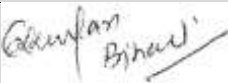
5.2.10 If it is not possible to place samples in the same order as in the failed equipment make sure to maintain a logical or sequential pattern of storage.

5.2.11 Record details of back-up storage pattern.

5.2.12 Document sample transfer to back-up unit, and track samples to ensure return to correct location when corrective action has been taken.

5.2.13 Ensure that alarm systems are operational and monitored on back-up equipment as well.

5.2.14 Document reasons for equipment failure and corrective action.

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Rev. No.: 1.0				

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Standard Operating Procedure

**DOCUMENT NAME: FACILITIES
MANAGEMENT / OPERATION**

DOCUMENT NO. : ILBS#NLDB:D

FACILITIES MANAGEMENT / OPERATION**Maintenance of storage facility and equipment**


Document Name : Maintenance of storage facility and Equipment
Document No. : SOP: ILBS#NLDB: D.3
Version No. : 1.0
Effective Date : 01/01/2025

Address

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Document Name: SOP "Maintenance of storage facility and equipment"				
Document No ILBS#NLDB:D.3	Approved & Issued by:		Dr. Chhagan Bihari HOD, Biobank	Issue Date: 01/01/2025
Rev. No.: 1.0				

FACILITIES MANAGEMENT / OPERATION**Maintenance of storage facility and equipment**

Number	Effective date	Pages	Author	Authorized by
ILBS#NLDB:D.3	01/01/2025	7	Mr. Satish Kumar	Dr. Chhagan Bihari
Version	Review period	No. of copies	Approved by	Date
1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024


Location	Subject
Biobank Reception area Almira	Maintenance of storage facility and equipment
Function	Distribution
To give information about storage conditions.	<ul style="list-style-type: none"> ➤ HOD ➤ Biobank Reception area ➤ Master files

SCOPE AND APPLICATION:

This SOP outlines the procedures for the maintenance of storage facilities and equipment to ensure their proper functioning and optimal performance.

RESPONSIBILITY:

Technician: Responsible for responding to alarms and ensuring that maintenance procedures are properly carried out.

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Rev. No.: 1.0				

FACILITIES MANAGEMENT / OPERATION

Maintenance of storage facility and equipment

1.0 PURPOSE:

NLDB is intended to store and manage the Human Biological Materials (HBMs) in its custody. Appropriate storage is a core requirement for the operation of a successful biobank. HBMs are a precious resource and each biobank should maintain their storage facilities and equipment to provide optimal conditions for maintaining sample quality.

2.0 SCOPE:

This SOP outlines elements and processes that should be in place to provide appropriate and optimal storage conditions.

3.0 ROLES AND RESPONSIBILITIES:

The SOP applies to all personnel from NLDB that are responsible for storing biobank samples or maintaining the storage facility or equipment. This may include the following personnel:

Technicians: Responding to alarms and checking that maintenance procedures are carried out.

HOD & Biobank technicians: Responding to alarms, overseeing that maintenance procedures are carried out and updating lists and procedures

4.0 MATERIALS, EQUIPMENT AND FORMS:

- Back-up storage capacity, freezers and refrigerators, lighting.
- Thermometers
- Adequate Liquid Nitrogen Supply
- Alarm systems & contact lists

5.0 PROCEDURES:

The storage facility (and storage equipment) is a key element in the operation of a biobank. Proper maintenance of the facility and equipment should be the responsibility of designated personnel.

5.1 Storage facility – Temperature:

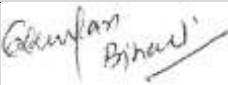
5.1.1 Ensure appropriate air-cooling and ventilation to maintain ambient temperatures at approximately 18°C to 22°C. Freezers and refrigerators contribute heat to the environment and conditions should prevent overheating of equipment.

5.2 Storage facility – Air flow:

5.2.1 Ensure conditions of humidity to prevent fungal growth in the storage area of the biobank.

5.2.2 Ensure adequate air circulation around freezers and refrigeration units to prevent excessive moisture and condensation.

5.2.3 Provide adequate ventilation to ensure that sufficient oxygen levels are maintained in areas where dry ice or liquid nitrogen is used.

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Maintenance of storage facility and equipment

5.2.4 If needed, ensure filtration for air flow is sufficient to prevent excessive dust in the storage facility.

5.3 Storage facility – Lighting:

5.3.1 Have adequate general and task lighting to ensure that the appropriate level of illumination is available to perform routine and specialized tasks undertaken at the biobank. Lighting should be of correct intensity to facilitate accurate reading of labels for proper storage and retrieval of samples.

5.3.2 Ensure back-up lighting for emergency situations.

5.4 Storage facility – Back-up capacity

5.4.1 Provide adequate back-up capacity for low temperature units in anticipation of equipment failure.

5.4.2 Extra capacity, equal to at least the capacity of the largest storage unit, and equivalent to 10% (or other percentage as specified) of the total storage capacity, must be maintained at operating temperature at all times.

5.4.3 Train personnel in processes ensuring rapid transfer of HBMs to back-up units when the need arises.

5.4.4 Document sample transfer to back-up unit, and track samples to ensure return to correct location when corrective action has been taken.

5.5 Equipment – General maintenance

5.5.1 Routinely inspect equipment for cleanliness, sanitation, malfunctions, possible contamination and proper calibration (yearly calibration is sufficient for freezers).

5.5.2 Put into place a system for maintenance and repair of storage equipment and supporting systems.

5.5.3 Preventative maintenance should be in place for all operations and facility systems and should be performed at intervals as per manufacturer's recommendations.

5.5.4 Where appropriate, calibrate all automated, mechanical, electronic and other equipment according to established procedure or as recommended by the manufacturer.

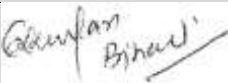
5.6 Storage equipment – Cryogenic freezers

5.6.1 Maintain an adequate supply of liquid nitrogen to fill cryogenic freezers or containers. A minimum 3-day supply should be maintained with the assumption that re-supply is available.

5.6.2 Monitor all liquid nitrogen containers to ensure that the optimal vapour phase is maintained.

5.6.3 Utilize a centralized alarm system to monitor liquid nitrogen levels where feasible. If a centralized alarm system is not feasible, ensure a security walk-through is carried out at appropriate intervals to detect temperature deviations and take timely corrective action.

5.6.4 Establish alarm set points to permit sufficient time for corrective action before damage to the collection occurs and ensure that the alarm system is functional.

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FACILITIES MANAGEMENT / OPERATION

Maintenance of storage facility and equipment

5.6.5 Post a 24-hour emergency contact list with multiple personnel that can be contacted in case of freezer malfunction.

5.6.6 Review list (at least once annually) and modify to reflect changes in personnel or contact information.

5.6.7 Number all freezers so that they can be easily identified in case of an emergency.

5.6.8 Avoid temperature fluctuations. Advise personnel to minimize the number of times the freezer is opened within a given time.

5.7 Storage equipment – Mechanical freezers

5.7.1 Mechanical freezers used in the biobank may be in -20°C to -150°C range. Because they run on commercial power sources, make sure that adequate back-up power is available in case of emergency situations.

5.7.2 Ensure that the freezers have an alarm system in place.

5.7.3 Establish alarm set points to permit sufficient time for corrective action before damage to the collection occurs. This will permit some leeway for warming that occurs during operational variation.

5.7.4 Ensure that the alarm is functional both for temperature variation and electrical power supply interruption.

5.7.5 Post a 24-hour emergency contact list with multiple personnel that can be contacted in case of freezer malfunction.

5.7.6 Review list (at least once annually) and modify to reflect changes in personnel or contact information.

5.7.7 Number all freezers so that they can be easily identified in case of an emergency.

5.7.8 Do not leave freezer doors open for more than 2 minutes.

5.7.9 Only one rack or box should be removed at a time.

5.7.10 It is optimal to have mechanical freezers that are not self-defrost. Monitor freezers for build-up of frost around doors and storage units that could prevent normal operation or inhibit proper sealing of freezer doors.

5.7.11 At regular intervals (based on usage and frost build-up) these units should be defrosted. Have adequate back-up capacity at the correct temperature for these occasions.

5.7.12 Train personnel in defrost procedures ensuring rapid transfer of HBMs to back-up units.

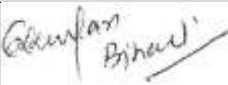
5.8 Storage equipment – Refrigerators

5.8.1 Refrigerators must be kept at temperatures between 2°C and 8°C.

5.8.2 Monitor high and low set points.

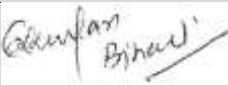
5.9 Storage facilities for Tissue blocks

5.9.1 There is no international standard for the storage of tissue blocks or cut tissue section. Options may include the following:

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FACILITIES MANAGEMENT / OPERATION**Maintenance of storage facility and equipment**

- a. Room temperature storage in a well-ventilated and air-conditioned area to avoid fluctuations in temperature from season to season.
- b. Refrigerated environment where temperatures are maintained between 2° and 8° C. This could be a refrigerator or a cold room. Care should be taken to ensure a low level of humidity.
- c. Cut sections may be stored in appropriate slide boxes, vacuum packed, or paraffin dipped. The storage method chosen should be validated for the recovery of common antigens using immunohistochemistry (IHC) techniques.
- d. A second site for storage should be identified in the event that an emergency impacts on the safe storage in the primary location. Duplicate Tissue Micro Arrays (TMAs) should be stored in separate locations.

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