INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR THE MECHANICAL REFRIGERATION UNITS STORAGE ROOM OPERATIONS

CHAPTER: 2-Facility

SOP #: SF-2-1.09

SUPERSEDES SOP #: N/A

Issue Date: 08.14.18

Effective Date: 08.17.18

AUTHORED BY: Melissa Taylor DATE: 08.06.18
Indiana CTSI SSF Staff

APPROVAL: DATE: 08.10.18
Indiana CTSI SSF Director

QA APPROVAL: DATE: 08.14.18
Quality Compliance Specialist

1. REVISION
   1.1. Significant Changes incorporated in this version include:
      1.1.1. Removed all references to UH5030 throughout the SOP text and Appendices A and D.
      1.1.2. Revised Section 3.2.3 to reflect the new capacity for MRUs in Annex II, since UH5030 has been removed.
      1.1.3. Added appropriate SOP SF-3-1 reference to Section 4.1.
      1.1.4. Section 6.1.1.1 modified to allow the use of a mop or broom to sweep the floors, rather than just a Swiffer mop. Section 5 updated accordingly.
      1.1.5. Sections 6.1.1.3 and 6.1.2.3 revised to state that re-validation of a room that has had no MRU for a time may be necessary, rather than will be necessary.
      1.1.6. Section 6.1.2.1 revised to define acceptable temperature parameters for each room at the beginning of the section,
      1.1.7. Section 6.1.2.1 revised to provide clarity and to remove redundancy of directives.
      1.1.8. Section 6.1.2.1.2 text was removed and added to Section 6.1.2.1 and revised for clarity to state that documentation of temperatures in UH5049 is optional rather than not required.
      1.1.9. Section 6.1.2.2 edited to allow for visual confirmation of airflow, since freezer compressor noise often precludes the ability to confirm via audible means. Additionally, the section now specifies that airflow documentation is optional for C156 and UH5049.
      1.1.10. Section 6.1.2.5 removed to eliminate redundancy, as the corresponding information was defined in Section 4.1.
      1.1.11. Appendix C revised to remove pre-printed footnotes and replace them with general information, represented by asterisks, in order to eliminate inconsistences and confusion among technicians when documenting.

2. PURPOSE
   2.1. This Standard Operating Procedure (SOP) defines the upkeep of the Mechanical Refrigeration Units storage room in the Indiana CTSI Specimen Storage Facility (SSF). This procedure satisfies guidance set forth in ISBER.

3. PRINCIPLE
   3.1. The design of the Mechanical Refrigeration Storage Rooms includes adequate ventilation and cooling of the room (to the extent possible) and electrical and monitoring support. The storage rooms provide safe and secure storage for approved biorepositories and to other Indiana CTSI entities. This SOP defines the process for monitoring and maintaining the storage room.
   3.2. Mechanical Refrigeration Storage Rooms are defined as follows:
      3.2.1. The C-135 Mechanical Refrigeration Units Storage Room - designed to accommodate 60 mechanical refrigeration units;
      3.2.2. MS B-46 Mechanical Refrigeration Units Storage Room (i.e., SSF Annex) - designed to accommodate approximately 25 mechanical refrigeration units;
      3.2.3. Annex II (UH5049) Mechanical Refrigeration Units Storage Room - designed to accommodate approximately 3 mechanical refrigeration units;
      3.2.4. C-156 may accommodate up to 3 mechanical refrigeration units;
      3.2.5. Annex III (MS-B36, MS-B36A, and MS-B37). – Designed to accommodate 36 mechanical refrigeration units.

4. SCOPE
   4.1. The scope of this procedure includes all personnel who have access into the SSF Mechanical Refrigeration Unit Storage Room. Persons who are not authorized for entry are instructed regarding applicable room operation procedures by SSF authorized staff prior to entering the Mechanical Refrigeration Unit Storage Room. Monitoring of the units is managed per the alarm and monitoring SOPs: SF-3-1 Mechanical Refrigeration Units, SF-1-10 Out of Specification Condition and Notification Management, and SF-2-4 Alarm Systems Management and Response.

5. MATERIALS
   5.1. Gloves
   5.2. Lab Coat
   5.3. Hand Sanitizer
   5.4. Swiffer
   5.5. Swiffer Pads
   5.6. NIST-traceable thermometers calibrated at the range of use (ambient)
   5.7. Dust mop or broom
   5.8. Dust pan

6. PROCEDURE
   6.1. **Maintenance and Routine Monitoring**
      6.1.1. **Maintenance**
         6.1.1.1. Weekly
            6.1.1.1.1. Sweep the floors with a Swiffer, dust mop, or broom.
            6.1.1.1.2. Collect debris in dust pan and dispose.
            6.1.1.1.3. Record actions and results (Appendix B).

         6.1.1.2. Monthly

6.1.1.2.1. Schedule and supervise Campus Facilities Services (CFS) mopping the floors.

6.1.1.2.2. Alternately, SSF tech can mop using Swiffer pads or order mop and bucket with soapy water from CFS.

6.1.1.2.2.1. For C135 and C156, contact CFS Switchboard and request mop and bucket with soapy water for R3 C135. Use bucket for C156 before returning to R3 CFS personnel.

6.1.1.2.2.2. For MS-B46 and MS-B37, email Denise Ford and request mop and bucket with soapy water for MS-B46 and MS-B37. Notify her by email when mop and bucket can be returned to CFS personnel.

6.1.1.2.2.2.1. If Denise Ford cannot be reached, place request through CFS Switchboard and/or ask for new MS contact.

6.1.1.2.3. Record actions and results (Appendix B).

6.1.1.3. Weekly and monthly maintenance need not be completed in rooms containing no mechanical refrigeration storage units. Should units be returned to those facilities, validation may be required before MRU are placed in service in the facility.

6.1.1.4. As Needed

6.1.1.4.1. Escort Campus Facility Services in to change light bulbs.

6.1.1.5. Procedures for maintaining the specific mechanical refrigeration units located in C135, MS B-46, UH 5049, MS-B37, and C156 are defined in SF-3-1 SOP for Mechanical Refrigeration Units.

6.1.2. **Routine Monitoring**

6.1.2.1. <u>Daily Temperature Monitoring:</u>

Acceptable parameters:

C135:	$\leq 20°C$
MS-B37:	$\leq 22°C$
MS-B46 and C156:	$\leq 23°C$

NOTE: The units that are stored in UH5049 are not ISBER compliant. Therefore, room temp monitoring is not mandated but may be conducted and documented for informational purposes.

6.1.2.1.1. Read and record the high, low, and current readings from the digital thermometer, which can be found, along with Appendix C, in the designated location for room temperature monitoring (identified by signage).

6.1.2.1.1.1. If the current reading on the digital display reads outside of the acceptable parameters defined above, contact Campus Facilities to adjust the HVAC settings. Document OOS per SF-1-10 Out of Specification Management and Response.

6.1.2.1.1.2. If the temperature appears to be trending upward over the course of several days or has reached the maximum allowable temperature for two or more days within a week, contact CFS to inspect the dampers to ensure that they are open. If CFS cannot resolve the issue by opening the dampers, contact SSF management for directives.

6.1.2.1.1.3. Record actions and results (Appendix C). High and Low values are informational only.

6.1.2.2. Daily Airflow Monitoring: Listen for audible airflow. If the airflow cannot be heard, look for the presence of the airflow by observing the strips of paper which have been affixed to the air vents on the ceiling, checking for movement.
NOTE: Airflow monitoring is not mandated in UH5049 and C156 but may be conducted and documented for informational purposes.

6.1.2.2.1. Notify CFS if flow is not present.

6.1.2.2.2. Record actions and results (Appendix C)

6.1.2.3. Daily routine monitoring need not be completed in rooms containing no mechanical refrigeration storage units. Should units be returned to those facilities, validation may be necessary before MRU are in service in the facility.

6.2. **Entry**

6.2.1. SSF and collaborating biorepository authorized personnel gain authorization for access per the SF-2-3 Controlled Access Operations SOP.

6.2.2. Escort non-SSF/non-collaborating biorepository authorized personnel into the Mechanical Refrigeration Unit Storage Room per SF 2-3 SOP for Controlled Access.

6.2.3. For personnel entering to access or perform function verification or maintenance on freezers:

6.2.3.1. Instruct non-SSF/non-collaborating biorepository authorized personnel to don lab coat and gloves before entering the Mechanical Refrigeration Unit Storage Room

6.2.3.2. Direct non-SSF/non-collaborating biorepository authorized personnel to the freezers to which they have access and monitor for compliance.

6.2.3.3. Instruct non-SSF/non-collaborating biorepository authorized personnel on how to remove coat and gloves, where to dispose of PPE, and to clean hands with sanitizer prior to leaving the Mechanical Refrigeration Unit Storage Room.

6.2.4. For personnel entering who will NOT access or perform function verification or maintenance on freezers: gowning and gloving is not required. Non-SSF/non-collaborating biorepository authorized personnel must be accompanied at all times.

6.3. **Non-Routine Monitoring**

6.3.1. Documentation of OOS conditions that occur at times other than routine monitoring which DO NOT generate an alarm is optional.

7. REFERENCES
   7.1. ISBER Best Practices (current version)
   7.2. Campus Facilities Services (CFS) Switchboard: 317-278-1900
   7.3. Denise Ford, CFS: denford@iupui.edu

8. DOCUMENTATION
   8.1. Documents are retained in the SSF Operation's office per the SOP for Controlled Document Management (SF-1-6).
   8.2. Deviations are managed per SF-1-9 SOP for Deviation Management.

9. APPENDICES
   9.1. The current version of each of the following appendices is used to guide and/or implement this SOP:

APPENDIX A - Components of the Mechanical Refrigeration Unit Storage Room and Annex (2 Pages)
APPENDIX B - Mechanical Refrigeration Unit Storage Room Maintenance Log Form (1 Page)
APPENDIX C - Mechanical Refrigeration Unit Storage Room HVAC Monitoring Log Form (1 Page)
APPENDIX D - Posting: Entry Requirements for Room C-135/MS-B046/MS-B37/UH 5049/C156 (1Page)

Components of the Mechanical Refrigeration Unit Storage Room (C135)	
HVAC System	
	Room temperature is monitored by the Siemens building system.
	Air supply and exhaust is managed by the building HVAC system.
Controlled Access Points	
	There are three controlled access doors; two from the main corridor C199C and one from corridor C199M accessible via another security access door.
60 Hanging Electrical Outlets	
	Hanging electrical outlets in use are in room C135.
Alarm Connections	
	Connections are available to the Siemens system for each of the 60 mechanical refrigeration units.

Components of the Mechanical Refrigeration Unit Storage Room SSF Annex (MS B-46)	
HVAC System	
	Room temperature is monitored by the Siemens building system.
	Air supply and exhaust is managed by the building HVAC system.
Controlled Access Points	
	There is one controlled access door accessible via IB097, which is another security access door.
Electrical Outlets	
	There are 21 electrical outlets along the walls of the Annex. There are 4 hanging electrical outlets towards the center of the room.
Alarm Connections	
	Connections are available to the Siemens system for each of the 25 mechanical refrigeration units.

Components of the Mechanical Refrigeration Unit Storage Room SSF Annex II (UH 5049)	
HVAC System	
	Room temperature is not monitored by the Siemens building system.
	Air supply and exhaust is managed by the building HVAC system.
Controlled Access Points	
	The doors on all mechanical refrigeration units will be locked and the keys kept at SSF Management office.
Electrical Outlets	
	There are 3 electrical outlets along the walls of UH 5049.
Alarm Connections	
	Connections are available to the Siemens system for each mechanical refrigeration unit.

Components of the Mechanical Refrigeration Unit Storage Room (C156)	
HVAC System	
	Room temperature is not monitored by the Siemens building system.
	Air supply and exhaust is managed by the building HVAC system.
Controlled Access Points	
	There is one controlled access door used to access the facility, located in proximity to required PPE; accessed via C158 lab, accessible via security access door from main 1st floor hallway in R3.
Electrical Outlets	
	There are currently 2 electrical outlets along the walls of C156 available for MRU.
Alarm Connections	
	Connections are available to the Siemens system for each mechanical refrigeration unit.

Components of the Mechanical Refrigeration Unit Storage Room (MS-B37)	
HVAC System	
	Room temperature is monitored by the Siemens building system.
	Air supply and exhaust is managed by the building HVAC system.
Controlled Access Points	
	There is one controlled access door used to access the facility, located in proximity to required PPE; accessed via MS-B036, accessible via security access door from basement floor hallway in MS. Doors B37-1 and B37-2 are Exit-Only doors to be used in the event of an emergency.
Electrical Outlets	
	There are currently 25 electrical outlets along the walls of MS-B37 available for MRU and 13 hanging electrical outlets towards the center of the room.
Alarm Connections	
	Connections are available to the Siemens system for each mechanical refrigeration unit.

Room: Month: Year:

MECHANICAL REFRIGERATION UNIT STORAGE ROOM MAINTENANCE LOG				
Weekly	Document Result (✓): *Note: Expected Result = Completed*	Initials	Date	Comments / Corrective Action
Sweep Floors	❑ Completed			
Sweep Floors	❑ Completed			
Sweep Floors	❑ Completed			
Sweep Floors	❑ Completed			
Sweep Floors	❑ Completed ❑ Not Required			
Monthly	*Note: Expected Result = Completed*			
Mop Floors	❑ Completed			
Reviewed By:				

Room:	Month:	Year:

MECHANICAL REFRIGERATION UNIT STORAGE ROOM HVAC MONITORING LOG

	High/Low Record Only		Temp °C *Expected Result* For Room C135: ≤ 20 ° For Room MS-B37: ≤ 22 ° For Room C156: ≤ 23 ° For Room MS B-46: ≤ 23 °*	Air Flow** (On/Off) *Expected Result Is "On"*	Initials	Comments / Corrective Actions
	High	*Low*	Current			
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						

Reviewed By/Date:

* Temperature monitoring in UH5049 is optional and may be documented for information purposes only.

** Air Flow monitoring in C156 and UH5049 is optional and may be documented for informational purposes only.

Entry Requirements for Entry into C-135/MS-B046/MS-B37/UH 5049/C-156

1. SSF and collaborating biorepository authorized personnel gain authorization for access per the SF-2-3 Controlled Access Operations SOP.

1.1. Escort non-SSF/non-collaborating biorepository authorized personnel into the Mechanical Refrigeration Unit Storage Room per SF 2-3 SOP for Controlled Access.

1.2. For personnel entering to access or perform function verification or maintenance on freezers:

1.2.1. Instruct non-SSF/non-collaborating biorepository authorized personnel to don lab coat and gloves before entering the Mechanical Refrigeration Unit Storage Room

1.2.2. Direct non-SSF/non-collaborating biorepository authorized personnel to the freezers to which they have access and monitor for compliance.

1.2.3. Instruct non-SSF/non-collaborating biorepository authorized personnel on how to remove coat and gloves, where to dispose of PPE, and to clean hands with sanitizer prior to leaving the Mechanical Refrigeration Unit Storage Room.

1.3. For personnel entering who will NOT access or perform function verification or maintenance on freezers: gowning and gloving is not required. Non-SSF/non-collaborating biorepository authorized personnel must be accompanied at all times.

1.4. For personnel entering to access or perform function verification or maintenance on freezers **in C156, refer to SOP SF-2-2, LN_2 System and LN_2 Freezer Room Operations**, the Entry Into LN_2 Freezer Room, Alarm Actions and Response, and Personal Low O_2 Monitor Alarm Response Sections**.**