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-2-1.12

SUPERSEDES SOP #: N/A

Issue Date: 12.27.2022

TE AK 12.27.2022

Effective Date: ~~02/01/2022~~ 02/01/2023

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1. REVISION
   1.1. Significant Changes incorporated in this version include:
      1.1.1. Remove references to R3-C156 throughout. There are no longer any MRU housed in R3-C156.
      1.1.2. Section 3.2 reconfigured and abbreviations added to improve readability and shorten the section.
      1.1.3. Step 3.2.5 and Section 6.1.2 revised to reflect and define directives for the new TK 246 Mechanical Refrigeration Unit (MRU) storage room.
      1.1.4. Revised Step 4.1 to define that alarming and response is managed by SF-2-4 and/or other validated alarm system and the SOP(s) corresponding to that alarm system, since Sonicu will replace Siemens for alarm system management in the near future.
      1.1.5. Define in Step 4.2 that TK 250, although equipped to accommodate a single MRU, is outside scope of SSF SOPs since any MRU housed in TK 250 is managed by the IU Genetics Biobank.
      1.1.6. References to "Siemens" alarm are replaced with "alarm" throughout SOP.
      1.1.7. Section 6.1.1 revised to define directives for maintenance in TK 246.
      1.1.8. Section 6.1.2 revised to define acceptance criteria for all MRU storage rooms as <23°C. ISBER eliminated specific room temperature guidelines.
      1.1.9. Added Step 6.1.2.8 directive that room temperature thermostats and sensors are not to be obstructed.
      1.1.10. Section 6.2.3 substantially revised to define that entry directives are defined in SF-1-7 SOP for Personnel Safety Appendix E (Bloodborne Pathogens Safety Procedures).
      1.1.11. Section 9 revised to reflect elimination of the Appendix D posting.
      1.1.12. Appendix A revised to:
         1.1.12.1. Eliminate C156 and add Room TK-246
         1.1.12.2. Correct number and configuration of outlets in C135

1.1.12.3. Direct that each in-service MRU must have an available connection to the alarm system
1.1.12.4. Clarify that MS-B037 is accessed via the MS-B036 door.

1.1.13. Appendix C revised to reflect new temperature acceptance criteria and remove C156-related directive.
1.1.14. Appendix D removed since entry directives are included in SF-1-7 SOP for Personnel Safety Appendix E (Bloodborne Pathogens Safety Procedures) and posted at each MRU storage room.
1.1.15. Appendix E revised as follows:
1.1.15.1. Clarify that CBP are permitted to escort untrained personnel into the MRU Storage Rooms only if personnel are accessing or maintaining that biobank's freezer(s).
1.1.15.2. Clarify that if visitors will NOT access or perform function verification or maintenance on freezers, gowning and gloving is not required.
1.1.15.3. Entry directives revised to align with the Section 6.2.3 revisions.

2. PURPOSE
2.1. This Standard Operating Procedure (SOP) defines the upkeep of the Mechanical Refrigeration Units storage rooms 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 Units (MRU) Storage Rooms are located as defined below and designed to accommodate the number of MRUs defined below:
3.2.1. R3-C135 MRU Storage Room – 60 MRUs;
3.2.2. IB 097/MS-B046 Cage MRU Storage Room (i.e., SSF Annex) – 25 MRUs;
3.2.3. Annex III (MS-B036, MS-B036A, and MS-B037) MRU Storage Room – 36 MRUs;
3.2.4. TK 246 MRU Storage Room (i.e., Annex IV (Innovation Center)) – 35 MRUs

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 Response and Notification Management, and SF-2-4 Alarm Systems Management and Response and/or other validated alarm system and the SOP(s) corresponding to that alarm system.
4.2. TK 250, although equipped to accommodate a single MRU, is outside scope of SSF SOPs since any MRU housed in TK 250 is managed by the IU Genetics Biobank.

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 TK 246, contact CFS Switchboard and request mop and bucket with soapy water for TK 250 (access point for TK 246) and R3 C135.
6.1.1.2.2.2. For IB 097/MS-B046 Cage and MS-B037, email Denise Ford and request mop and bucket with soapy water for IB 097/MS-B046 Cage and MS-B037. 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, IB 097/MS-B046 Cage, MS-B037, and TK 246 are defined in SF-3-1 SOP for Mechanical Refrigeration Units.

6.1.2. **Routine Monitoring**
6.1.2.1. Daily Temperature Monitoring:
6.1.2.1.1. Acceptable parameter in MRU Rooms C135, IB 097/MS-B046 Cage, MS-B037, C156, and TK 246 is ≤ 23°C

6.1.2.2. 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).

6.1.2.2.1. Readings are recorded in whole numbers or to the tenth of one degree, depending on the thermometer model.

6.1.2.3. 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 Response and Notification Management.

6.1.2.4. If the temperature appears to be trending upward, it is recommended, but not required, that SSF personnel contact CFS to inspect the HVAC system.

6.1.2.5. If the temperature has reached the maximum allowable temperature for two days within a 7-day time frame, contact CFS to inspect the HVAC system.

6.1.2.6. High and Low values are informational only.

6.1.2.7. 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.

6.1.2.7.1. Notify CFS if flow is not present.

6.1.2.7.2. Record actions and results (Appendix C)

6.1.2.8. Room temperature thermostats and sensors are not to be obstructed.

6.1.2.9. 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 SOP for Controlled Access.

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.

6.2.2.1. Non-SSF/non-collaborating biorepository authorized personnel must be accompanied at all times.

6.2.3. All personnel entering to access freezers or perform function verification or maintenance on freezers are expected to comply with safety directives defined in SF-1-7 SOP for Personnel Safety Appendix E (Bloodborne Pathogens Safety Procedures).

6.2.3.1. Visitors and untrained personnel are instructed to don PPE per SF-1-7 Appendix E.

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:	Intentionally Blank (1 Page)
APPENDIX E:	Collaborating Biobank Personnel (CBP) Training (1 Page)

10. COLLABORATING BIOBANK PERSONNEL (CBP) TRAINING DIRECTIVES

10.1. CBP comply with Read and Understand training on SOP SF-2-1, SOP for Mechanical Refrigeration Unit Storage Room Operations, by reading Collaborating Biobank Personnel Training, Appendix E, of this SOP.

10.2. CBP comply with directives defined in Appendix E.

Components of the Mechanical Refrigeration Unit (MRU) Storage Room (R3-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.
Electrical Outlets	
	There are 5 electrical outlets along the west wall of C135 and 54 hanging electrical outlets towards the center of the room.
Alarm Connections	
	Each in-service MRU must have an available connection to the alarm system.

Components of the MRU Storage Room SSF Annex (IB 097/MS B-046 Cage)	
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	
	Each in-service MRU must have an available connection to the alarm system.

Components of the MRU Storage Room (MS-B037)	
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, MS-B036. MS-B037 is accessed via door, MS-B036. Doors B037-1 and B037-2 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-B037 available for MRU and 13 hanging electrical outlets towards the center of the room.
Alarm Connections	
	Each in-service MRU must have an available connection to the alarm system.

Components of the MRU Storage Room (TK 246)	
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	
	TK 246 has one controlled access entry door accessible via TK 250, which is another security access door. There are three Exit-Only doors: • The door between TK 246 and TK 252 provides exit from TK 252 into TK 246 and is used in the event of an emergency. • The northern double doors exit to the main hallway from which personnel enter the TK 250 Ante Room. This door is used to move freezers or large equipment in and out of the facility and otherwise only in the event of an emergency. • The southeast door exits to the building's rear entry atrium and is used only in the event of an emergency.
Electrical Outlets	
	There are currently 23 electrical outlets along the walls of TK 246 available for MRU and 33 hanging electrical outlets towards the center of the room and available for MRU.
Alarm Connections	
	Each in-service MRU must have an available connection to the alarm system.

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* ≤ 23 °*	Air Flow** (On/Off) *Expected Result Is "On"*	Initials	Comments / Corrective Actions
	High	*Low*	Current			
1						
2						
3						
4						
5						
6						
7						
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9						
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Reviewed By/Date:

* Initiate CFS investigation into room temperature reaching maximum allowable temperature for two days within a 7-day time frame.

Initiation of CFS investigation into room temperature trending upward is recommended, but not required.

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Collaborating Biobank Personnel (CBP) Training

Standard Operating Procedure (SOP) SF-2-1, SOP for Mechanical Refrigeration Unit Storage Room Operations, defines the upkeep of the Mechanical Refrigeration Units (MRU) storage rooms in the Indiana CTSI Specimen Storage Facility (SSF).

MRU Storage Room Entry Requirements

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

- **You** are permitted to escort untrained personnel into the Mechanical Refrigeration Unit Storage Room **only if untrained personnel are accessing or maintaining your biobank's freezer(s)**.

ALL personnel entering to access or perform function verification / maintenance on freezers are expected to comply with safety directives defined in SF-1-7 SOP for Personnel Safety Appendix E (Bloodborne Pathogens Safety Procedures).

Visitors and untrained/unauthorized biobank personnel must be accompanied by trained biobank personnel or SSF personnel at all times.