INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: Facility Commissioning and Validation/Revalidation

CHAPTER: 1-Administration and Quality Oversight

SOP #: SF-1-12.10

SUPERSEDES SOP#: N/A

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1. REVISION
   1.1. Significant changes incorporated in this version include:
      1.1.1. Section 6.1 table revised to remove Room C158C, removed from SSF scope per CVMP-001 v.09.
      1.1.2. Corrected erroneous CVMP-001 version reference in Section 6.1 footnote 6.

2. PURPOSE
   2.1. This Standard Operating Procedure (SOP) provides direction for the Indiana CTSI Specimen Storage Facility (SSF) start-up and continued operations and documentation of the design and functionality of critical operating systems.

3. PRINCIPLE
   3.1. The Indiana CTSI Specimen Storage Facility has been designed and constructed to provide a site for storage of research specimens according to ISBER. Documentation of the design, materials, and construction of the "as built" condition and documented assurance of installation and operation of critical systems that meet defined "User Requirement Specifications" provides confidence in the facility to support the intended use and baseline standard for ongoing operations. The facility is shown to be suitable for storage of GLP specimens.

4. SCOPE
   4.1. This SOP describes the approach for commissioning, validation (installation and operation qualification), and revalidation for critical aspects of the facility. The SOP defines the systems critical to supporting the mission of the SSF and the features of these systems and the rooms within the facility for which Commissioning, Validation and Revalidation are applicable. Some critical systems are deferred to general building documentation and documentation by specific entities that control these systems.

5. MATERIALS
   5.1. N/A

6. PROCEDURE
   6.1. CRITICAL SYSTEMS: The SSF critical systems and applicable rooms and requisite activities have been defined and are listed below:

	C-I/OQ Title					
	Facility/ Electrical C-I/OQ	Liquid Nitrogen C-I/OQ	HVAC C-I/OQ	Alarms and Monitoring C – I/OQ(2)	Controlled Access	Fire alarm and suppression
DNA and Serum Bank Freezer Room C135	Yes	No	Yes	Yes	Deferred to Vector Production Facility	Deferred to IUSOM institutional testing and documentation
Cell Repository Room C156	Yes	Yes	Yes	Yes	Deferred to Vector Production Facility	Deferred to IUSOM institutional testing and documentation
SSF Annex(4) Room IB 097/MS-B046 Cage	Yes(1)	No	Yes(1)	Yes(1)	Deferred to Vector Production Facility	Deferred to IUSOM institutional testing and documentation
(8)~~Special Handling Room C158C~~	~~Yes~~	~~No~~	~~Yes~~	~~Yes~~	~~Deferred to Vector Production Facility~~	~~Deferred to IUSOM institutional testing and documentation~~
SSF Annex III(4) Rooms MS-B036A & MS-B037(3)	Yes(1)	No	Yes(1)	Yes(1)	Deferred to Vector Production Facility	Deferred to IUSOM institutional testing and documentation
SSF Annex IV Room TK 246	Yes(1)	No	Yes(1)	Yes(1)	Yes5	Deferred to IUSOM institutional testing and documentation
SSF Annex IV Room TK 250	Yes(1)	No	Yes(1)	N/A	Yes5	Deferred to IUSOM institutional testing and documentation
SSF Annex IV Room TK 252	Yes(1)	Yes(1)	Yes(1)	Yes(1)	Yes5	Deferred to IUSOM institutional testing and documentation
SSF Annex IV Room TK 258	No6	Yes7	No6	No6	Yes5	Deferred to IUSOM institutional testing and documentation

Commissioning I/OQ: Installation and Operation Qualification

(1) Managed via RQ to the existing system or via I/OQ for new systems (as applicable)
(2) The addition or modification of a freezer alarm point is managed per SF-2-4 (SOP for Alarm Systems Management and Response) in lieu of an alarm point change (addition, deletion, or naming modifications) being considered to require a requalification.
(3) Room MS-B036 is excluded from HVAC RQ because there is no sample storage of any type in this room.
(4) Annex II consisted of UH5030 (decommissioned on 08.29.2016) and UH5049 (decommissioned on 04.10.2019).
(5) Controlled Access Validation/Revalidation transferred to SSF management per RQ-001-14-01 v01.

(6) Outside the scope of SSF SOPs and Validation/Revalidation per IU Genetics Biobank (IUGB) per C/VMP-001 rev. 08.
(7) Per URS-17 and IUGB, within the scope of SSF SOPs and Validation/Revalidation inside TK 258 are ONLY:
  (7a) LN_2 Piping from bulk tank to first shut off valve inside TK 258, excluding shut off valves in TK 258
  (7b) LN_2 Piping from bulk tank into TK 258 and branching east through TK 258 towards TK 252
  (7c) O_2 monitors
(8) R3-C158C is outside the SSF scope effective 12/01/2022 per C/VMP-001 rev. 09.

NOTE: Installation of a new facility/Annex requires revision of, at minimum, SF-1-4, SF-1-7, SF-1-12, the applicable Facility SOP (SF-2-1 or SF-2-2), SF-2-3, SF-2-4, and the applicable Equipment SOP (SF-3-1, SF-3-2, or SF-3-16).

6.2. A set of records are compiled to support the completion of these activities:

6.2.1. Commissioning and Validation Master Plan identifies the overall approach for these activities and is a joint effort of the SSF Director and Associate Director with Quality Assurance approval of the final document required. This document is identified as C/VMP 001. Version numbers are assigned sequentially to documents with subsequent changes in version after final approval by all signatories. Addenda may be added as the facility matures. A final report for each separate phase (original or addenda) is written and approved by the SSF Director, Associate Director and Quality Compliance.

6.2.2. User Requirement Specifications (URS):

6.2.2.1. URS are organized by Critical System.

6.2.2.2. URS documents identify the specific needs of each system for each location within the facility.

6.2.2.3. The SSF Director, IU Architects Office, and IUSOM Facility Design and Construction Representatives are responsible for developing these documents and the documents are approved by Quality Assurance.

6.2.2.4. The documents are assigned a numbering system unique to the Specimen Storage Facility, with URS – nn representing the system and revision indicating subsequent changes in version after final approval by all signatories.

6.2.2.5. The commissioning per the URS results in a compilation of documents that provides the as-built condition of the facility prior to operations.

6.2.2.6. Satisfaction of URS is documented in the C/VMP Final Report.

6.2.3. Installation/Operation Qualification (I/OQ):

6.2.3.1. I/OQ are organized by Critical System.

6.2.3.2. I/OQ protocols identify the specific features of each system within each location in the facility and define the critical aspects of installation and operation. They further identify the requisite activities, observations and the approach for execution and documentation.

6.2.3.3. The SSF Director, SSF Management, or SSF Management designee are responsible for developing the I/OQ protocol, and the document is approved by Quality Assurance.

6.2.3.4. The documents are assigned a numbering system unique to the Specimen Storage Facility, with the I/OQ – nnn representing the system (where the last 2 digits are consistent with URS if applicable) and revision indicating

subsequent changes in version after final approval of the I/OQ by all signatories and the version is signified by vxx where v indicates version and xx is the number of that version. (Revalidation activities are described below.)

6.2.3.5. The execution of the I/OQ protocol generally follows completion of the document; however, retrospective activities may be used to demonstrate satisfaction of the requirements if the activity is traceable to having been performed by competent individuals in a controlled manner with documentation that satisfies the protocol.

6.2.3.6. A final report is compiled summarizing the activities and conclusion for each specific I/OQ. The report must be approved by the SSF Director, Associate Director and Quality Compliance.

6.2.4. Requalification (RQ):

6.2.4.1. RQ are processes that evaluate changes to a critical system following completion of the initial validation process.

6.2.4.2. RQ are organized by Critical System.

6.2.4.3. The documents are assigned a numbering system unique to the Specimen Storage Facility, with the RQ – nnn-vxx representing the system (consistent with I/OQ) and the chronologic identification of the modification to the system. Revisions may indicate subsequent changes in version after final approval of the RQ by all signatories and the version is signified by vxx where v indicates version and xx is the number of that version.

6.2.4.4. If a modification affects additional systems and these systems are not re-qualified because of the modification, all system modifications may be described in the RQ assigned to the primary system to be re-qualified.

6.2.4.4.1. Example: An alarm panel in the SSF Annex is relocated. This process requires rerouting of wiring within the facility. The alarm panel requires alarm system requalification and this document (RQ 005) may also be used to describe the associated electrical modification.

6.2.4.5. RQ protocols include the following:

6.2.4.5.1. Facility, System, and Equipment for which the RQ is applicable.

6.2.4.5.2. Scope of change to include items repaired, replaced or otherwise modified within the Critical Systems

6.2.4.5.3. The reason for the modification

6.2.4.5.4. The considerations regarding the expected impact of the modification.

6.2.4.5.5. The conclusions, actions, and results of the activities. If the conclusion is such that no action is required for the described modification, this conclusion (with the corresponding justification) is recorded as the sole action. For example, (a) if the pressure indicator "ball-in-the-wall" is replaced with a similar model, no requalification activities would be indicated, whereas (b) if a critical LN_2 valve is replaced, even with a similar model, the decision may be that a requalification is needed due to the potential impact of malfunction.

6.2.4.6. The SSF Director, SSF Management, or SSF Management designee are responsible for developing the RQ protocol and the document is approved by Quality Assurance.

6.2.4.7. If a system or systems is expected to have repeat instances of the same modification, a protocol template may be prepared and, once approved, may be used repeatedly for the like instance.

6.2.4.7.1. The numbering format for the templates would be RQ – nnn-aa (bb) Version xx where:

6.2.4.7.1.1. nnn is the system most applicable to the change requalification

6.2.4.7.1.2. aa is the sequence of the protocols assigned to the system.

6.2.4.7.1.3. (bb) is the instance for repeat executions of an approved protocol

6.2.4.7.1.4. vxx is the revision identifier where v indicates version and xx is the number of that version. Revisions may indicate subsequent changes in version after final approval of the RQ by all signatories.

6.2.4.8. The execution of the RQ protocol generally follows completion of the document; however, retrospective activities may be used to demonstrate satisfaction of the requirements if the activity is traceable to having been performed by competent individuals in a controlled manner with documentation that satisfies the protocol.

6.2.4.9. A final report is written summarizing the activities and conclusion for each specific RQ. The report must be approved by the SSF Director, Associate Director and Quality Compliance. No final reports are required if no requalification activities were required.

6.3. Execution of IOQ or RQ documents comply with the following:

6.3.1. The IOQ or RQ document must be approved by the SSF Director, Associate Director, and QA prior to execution.

6.3.2. The Signature Log must be completed by **each individual** who has documented or will document information on the I/OQ or RQ. However, the Signature Log does not need to be completed by all persons who will be involved in the protocol execution before initiation of the execution.

6.3.3. All critical deviations and some major deviations (as defined within the "Protocol Exceptions Resolution" section of each I/OQ and RQ validation protocol) must be signed as completed by the SSF Director and by QA prior to resuming execution according to the approved corrective action described in the approved deviation.

7. REFERENCES

7.1. ISBER Best Practices (current version)

7.2. 21 CFR Part 58 Good Laboratory Practices, Subpart C, Facilities

8. DOCUMENTATION

8.1. The documents are retained for the functional life of the facility per SOP SF-1-6 Controlled Document Management.

8.2. Deviations are managed per SOP SF-1-9 Deviation Management.

9. APPENDICES

9.1. No Appendices are applicable to this SOP.

10. COLLABORATING BIOBANK TRAINING DIRECTIVES

10.1. N/A