Clinical and Translational Support Laboratory

Facility Commissioning and Validation/Re-validation

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Department: Processing Laboratory

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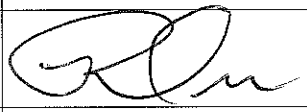
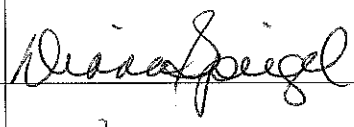
Signature			
Date	28 Dec 2016	28 Dec 2016	Dec 29, 2016

1. OBJECTIVE

This Standard Operating Procedure (SOP) provides direction for the Clinical and Translational Support Laboratory (CTSL) start-up and continued operations and documentation of the design and functionality of critical operating systems.

2. SCOPE

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

3. RESPONSIBILITIES

CTSL Director or designated personnel is/are responsible for facility commissioning and validation activities.

4. DEFINITIONS

4.1. Principle: The CTSL has been designed and constructed to provide a site for processing and, as applicable, distributing or temporarily storing specimens in support of approved protocols. Documentation of the design, materials, and construction of the "as built" condition and documented assurance of installation and operation of critical systems provides confidence in the facility to support the intended use and baseline standard for ongoing operations.

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	I/OQ: Installation and Operation Qualification
PL: Processing Lab	RQ: Re-qualification
SOP: Standard Operating Procedure	VMP: Validation Master Plan
URS: User Requirements Specifications	

5. ASSOCIATED DOCUMENTS

5.1. CTSL Validation Master Plan

6. PROCEDURE

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

C-IoQ Title	Processing Laboratory (RI 2632)	Storage Room (RI 2632 A)	CRC Laboratory (UH 5582C)
	Applicability	Applicability	Applicability
Facility I/OQ	Yes	Yes	Yes
Alarms and Monitoring I/OQ	Yes	Yes	Yes
Controlled Access	Deferred to IU University and Riley Hospital Security		
Fire Alarm And Suppression	Deferred to IUH Institutional testing and documentation		

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

6.2.1. Validation Master Plan identifies the overall approach for these activities and is a joint effort of the CTSL Director and CTSL staff, and Director, Indiana CTSI with Quality Assurance approval of the final document required. This document is identified as VMP 001. Version numbers area 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 CTSL Director and Quality Compliance.

6.2.2. User Requirement Specifications (URS): Are not generated for this facility aside from the IU School of Medicine and IU Health facilities group.

6.2.2.1. The commissioning results in a compilation of documents that provides the as-built condition of the facility prior to operations. This is deferred to the IU School of Medicine and IU Health facilities group per their standard commissioning practices. Enhanced commissioning is not required.

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

6.2.3.1. I/OQs 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 CTSL Director is responsible for developing the I/OQ protocol and the document is approved by Quality Assurance Contractor and Director of Indiana CTSL.

6.2.3.4. The documents are assigned a numbering system unique to the CTSL Facility, with the I/OQ- n representing the system 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=number of that version. (Revalidation activities are described below).

6.2.3.5. The execution of the I/OQ protocol generally follow 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 of each specific I/OQ. The report must be approved by the CTSL Director and Quality Compliance.

6.2.4. Re-qualification (RQ):

6.2.4.1. RQ are processes that evaluate changes to 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 CTSL, with the RQ-n-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 = version and xx = 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: A new freezer is brought into the CTSL. The electrical receptacle is changed to accommodate the freezer and the freezer is connected to a new alarm line set-up. The alarm line requires alarm system requalification and this document (RQx) may also be used to describe the associated electrical modification.

6.2.4.5. RQ protocol 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 conclusions, actions and results of the activities. If the conclusion is such that no action is requires for the described modification, this conclusion (with the corresp9onding justification) is recorded as the sole action. For example, (a) if a door is replace with similar model, no requalification activities would be indicated, whereas (b) if a critical alarm connection 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 CTSL Director is 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 number format for the templates would be RQ-nn-aa(bb) Version xx where:
  - 6.2.4.7.1.1. nn= system most applicable to the change requalification
  - 6.2.4.7.1.2. aa= sequence of the protocols assigned to the system
  - 6.2.4.7.1.3. (bb)= instance for repeat executions of an approved protocol
  - 6.2.4.7.1.4. Vxx = revision identifier where v= version and xx = 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 CTSL Director and Quality Assurance Contractor. No final reports are required if no requalification activities were required.

7. REFERENCES

None

8. APPENDICES

None

9. AMENDMENT HISTORY

Date of Amendment:	12 Dec 2016
Amendment Request by:	Robert Orr
Change Control No, if applicable:	CTSI-CRC-PL-DC-2016-002
Details of Amendment:	Updated to footer file location; Updated table in section 6.1 to reflect current location and responsibilities.