# Standard Operating Procedure CCTU/SOP056

# Validation and Verification of Software Systems

## 1. Scope

This SOP applies to software used within the CCTU that requires validation and verification to evidence that it is fit for its intended purpose.

The SOP also applies to purchased software as well as software written in-house where the data the system contains is used for the formal statistical analysis for the trial.

## 2. Purpose

The purpose of this SOP is to provide an overview of how to use the various templates and documents available to undertake the validation and verification process

## 3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

### 3.1. Definitions

| Term | Definition |
|---|---|
| Cambridge Sponsored | Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH); or the University of Cambridge (UoC); or jointly by CUH and UoC<br>OR<br>Sponsored by: Cambridge University Hospitals NHS Foundation Trust (CUH) or CUH jointly with the University of Cambridge<br>or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge |
| Validation | The assurance that a system meets the needs of the customer and other identified stakeholders |
| Verification | The evaluation of whether a system complies with the requirements and specification of the system |
| Software Requirements | The business needs for the system are defined in terms of the user, system and interface needs of the system. |
| Functional Specification | A functional specification documents the operations and activities that a system must be able to perform. |
| Installation Qualification | Installation Qualification verifies the proper installation and configuration of a system |
| Operational Qualification | Operational Qualification verifies the proper functioning of a system |
| Performance Qualification | Performance Qualification validates that a system performs according to the user requirements of the system and is therefore fit for purpose |

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| Story | In software development a story or user story is a term used to describe the processes that a user needs to perform in order to undertake their job function. |
| Vendor software | Software purchased from a software creator outside of the trial team |
| In-house software | Bespoke software written by or for the trial team |

### 3.2. Abbreviations

| Abbreviation | Meaning |
|---|---|
| SR | Software Requirements |
| FS | Functional Specification |
| IQ | Installation Qualification |
| OQ | Operational Qualification |
| PQ | Performance Qualification |

## 4. Undertaken by

CCTU staff wishing to provide assurance that a system is operating according to its specification and requirements and that it is fit for its intended purpose.

## 5. Items Required

- CCTU/TPL041 Software Requirements Template
- CCTU/TPL042 Functional Specification Template
- CCTU/TPL043 Software Validation and Verification Plan Template
- CCTU/TPL044 Installation Qualification Template
- CCTU/TPL045 Operational Qualification Template
- CCTU/TPL046 Performance Qualification Template

## 6. Summary of Significant Changes

1. Clarification of the scope of the SOP
2. Requirements when using vendor software
3. Further detail in Upgrades and Revisions

## 7. Method

The following sections provide a description of the processes to be followed when implementing this document's procedures.

### 7.1. Expectation

The following sections outline the supporting documents that should be completed in order to define the software business needs, as well as test that the provided software meets these business needs. This will provide assurance that a system is operating according to its specification and requirements and that it is fit for its intended purpose.

The process of verifying and validating software comprises of a set of procedures that compares the realised output of software development with the expected output. This requires the expected output is documented clearly and provides sufficient detail to the developer whilst keeping the language in the everyday or job-specific domain

## 7.2. Software Requirements

Software Requirements (SR) are written by system stakeholders and define the business needs that users require from the system. These are written prior to the existence of the system, although this is not a strict requirement.

An example of this may be where a simple system exists but requires further development and the users and developers require a formal document to help understand the system due to the expected increase in complexity.

The document will cover many aspects of the system, but a key part is the documentation of User, System and Interface requirements. Refer to the Software Requirements Template CCTU/TPL041.

The SR document provides the basis of the future testing process to test that the system produced matches the defined business needs.

Once agreed by stakeholders the SR document must be approved and signed off.

## 7.3. Functional Specification

The Functional Specification (FS) details the operations and activities that a system must be able to perform.

It covers aspects of the system that must be documented. At its core it documents the list of stories that specify the functions of the system that enable a user to perform their job role and provides a mapping between the SR and technical functions that the system must perform.

Refer to the Functional Specification Template CCTU/TPL042

The FS document also provides a basis for future testing. It is used to verify that the implementation of the system performs according to the specification.

Once agreed by stakeholders, the document must be approved and signed off.

## 7.4. Plan the Validation and Verification Process

Use CCTU/TPL043 the Software Validation and Verification Plan Template to record the process to be followed and document all the necessary deliverables, time-lines etc. so that the process will be understood by all those involved.

The plan ensures that the process is smooth and timely and all the compliance requirements for the process are met.

Once agreed by stakeholders, the document should be approved and signed off.

## 7.5. Installation Qualification

The Installation Qualification (IQ) is a process that verifies that the system has been installed and configured according to the requirements of the system.

It is used to document that all necessary precursory steps have been taken to ensure that the available system is in a known state prior to any further testing. Refer to the Installation Qualification Template CCTU/TPL044.

Once testing is complete and all items have passed, the document must be approved and signed off.

## 7.6. Operational Qualification

The Operational Qualification (OQ) is undertaken to demonstrate that the FS is adhered to by the system under test.

It is undertaken by the developer and provides evidence that the individual components and modules that together comprise the system are implemented correctly according to the FS.

This process is usually undertaken prior to the release of the system.

The documented tests may be run manually. They may also be the output from industry standard methods of running automated tests, for example unit tests and integration tests.

Test coverage should be sufficient to ensure the system is fit-for-purpose. Refer to the Operational Qualification Template CCTU/TPL045.

Once testing is complete and all items have passed, the document must be approved and signed off.

## 7.7. Performance Qualification

The Performance Qualification (PQ) process tests that the system performs according to expectation in a real-world setting.

It validates that the system produced is fit for its intended purpose and that the requirements have been met.

This process is undertaken once the IQ and OQ have been performed and provides evidence of user acceptance testing undertaken by the stakeholders of the system. Refer to the Performance Qualification Template CCTU/TPL046.

Once testing is complete and all items have passed, the document must be approved and signed off.

## 7.8. Vendor and In-house software

For best practice, any software written in-house should be supported by evidence that it is operating correctly and is fit-for-purpose.

For software developed in-house where the data it contains are used for the formal analysis of the trial outcomes, the full suite of documentation MUST be completed and should document and test all pertinent aspects of the software.

However, for purchased software the vendor will usually have gathered their own requirements, created their own functional specification and performed operational qualification prior to selling their software. These documents should be available from the vendor on request. Users of the software MUST undertake the installation and performance qualification to ensure the software meets the requirements and is operating as expected.

## 7.9. Final Approval

After completion of the PQ, the system developed is available for use.

There is no final approval document as such, but upon request each of the individual parts of the validation and verification process should be available for inspection.

For vendor systems, usually some formal method of approval would be required to inform the vendor that users are content that the provided software is fit-for-purpose. For example, for remotely hosted applications the final release of the revised software may not be available until formal approval is made.

### 7.10. Upgrades and Revisions

After initial release, the system will usually be subject to revision as a result of bug fixes, code improvements and new requirements. All of these change requests should be fully documented with details of the change required, who made the request, how the request was handled and the final outcome.

All the required specification and qualification documents should be available and these should accurately reflect the new specification and implementation of the system. The documents should clearly show which version of the system is being tested.

## 8. Monitoring Compliance with and the Effectiveness of this Document

**a. Process for Monitoring Compliance and Effectiveness**

As part of routine monitoring visits, audit and inspection

**b. Standards/Key Performance Indicators**

This process forms part of a quality management system and is reviewed according to CCTU procedures. Standard Operating Procedures are reviewed every two years.

## 9. References

The Institute of Clinical Research, Abbreviations used in Clinical Trials.

MHRA, Good Clinical Practice "Grey Guide"

## 10. Associated Documents

NA

## 11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

## 12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

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| Review date | 2 years (or earlier in light of new evidence) from approval date |
| Owning department: | CCTU QA |
| Supersedes: | CCTU/SOP056V1 |

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| Local reference: | CCTU/SOP056V2 |