

Standard Operating Procedure

Title: Computerised Systems Validation

A Functional Specification is a more general response to the **URS** and describes the detailed functions of the system (i.e. *what* the system will do) in a manner that is understandable to the user. Design Specifications translate the **URS** into full details for system developer use (i.e. *how* the system will work). It should be derived from the Functional Specification and contain enough details to enable the system to be built and maintained. Various Design Specifications may be required to address separate aspects, (e.g. software, hardware). All specifications should be written in a manner that allows requirements to be verified, (e.g. by inspection or testing).

Specifications should be subject to documented review processes prior to implementation. Ideally this will include approval by the site management. This review should address the completeness of design, (i.e. are all the **URS** functions addressed) and the integrity of design (i.e. what are risks of potential failures in this design). SOP **VAL 055** identifies a number of methods for Risk Assessment and Design Review that should be considered for use in this process. It is expected that site analysis will be to the Functional Specification level; the supplier may manage more detailed analysis.

Developers should establish suitable techniques to ensure that the developed or configured software meets the specified requirements. They should implement a Quality Management System to monitor the software development and configuration; maintain specifications throughout the development; and control the deployment of version changes. The supplier should also ensure that programming rules and conventions are followed.

A site representative should monitor progress of the development against an agreed timeline.

The Impact Assessment (**SOP VAL 045**) will identify where review of the actual code is appropriate. This is known as Structural Testing and utilises expertise in programming to assess the code for compliance with technical, (i.e. specified functionality) and quality (i.e. programming standards) requirements. The system programmer must not complete the Structural Testing.

Regulatory authorities may expect to be able to inspect a copy of the source code for application software. Availability may also be critical for long-term support, maintenance and enhancements. Arrangements should be made with the supplier regarding access to the source code. The access arrangement should be recorded in the IQ report.

2.4. Testing, Installation and Acceptance

This phase is a planned process of challenging and evaluating a system, and its components, throughout its development. The Impact Assessment, and any Risk Assessments, will guide the overall scope and depth of testing. **SOP VAL 050** describes the process for functional testing. Each test should be part of an overall strategy that is designed to make the whole process coordinated, efficient and effective. Since it is impossible to test every potential combination of input, output and function of a system, testing should be structured to:

- Consider those aspects that are of critical importance
- Specify what coverage can be achieved
- Find errors in the software (not merely confirm correct operation in normal conditions).

Test Protocols (sometimes called Test Plans, Test Specifications or Test Scripts) should define in detail the areas to be tested, the test data to be used, and the expected results. The **Test Protocols** must be reviewed and approved prior to commencing formal testing. Tests are conducted at various levels, corresponding to the hierarchy of details developed in the specification phase. Documented traceability should be provided between **Test Protocols** and their controlling documents, such as Functional and Design Specifications, to demonstrate complete coverage of specified requirements. This is illustrated in [Figure 2](#).

Testing must be documented as it is performed and this raw data is to be referenced, dated and retained to demonstrate the testing was performed to an agreed standard. Each test result should contain a clear pass or fail statement. All results will be kept, as primary evidence of testing, and so should be filled out with care.