

LABELING COMPLIANCE - VALIDATION

1.0 DOCUMENTATION

The following twelve sections detail the various documentation elements that make up the life cycle documentation.

1.1 Validation Master Plan

The Validation Master Plan establishes the requirements of a validated system. This document is ultimately a customer responsibility; however we provide assistance and guidance. It is also key that the elements of this plan are reviewed for completeness and accuracy with the project plan.

1.2 Project Plan

As part of this program PRISYMLS provide a Project Plan that contains tasks, responsibility assignments, duration's and linkage with other activities. The plan also identifies critical path elements and agreed upon milestones for the project. A detailed plan is needed to establish, measure and control the software development and deployment at each respective location. It is key to point out that there are quite a number of project activities that are independent from the any software development activities.

1.3 User Requirement Specification (URS)

We provide assistance to investigate and document the functionality required at each operational station. The customer provides this information in the form of a User Requirement Specification. It is our job to review this specification and clarify any ambiguities or discrepancies in this document.

1.4 Functional Requirement Specification (FRS)

PRISYMLS is required to create a Functional Requirement Specification that details how each user need will be met and to confirm our understanding of those needs. The FRS contains a detail list of all system input and output data requirements referred to in the URS. Typically a copy of the Functional Requirement Specification is provided and reviewed with the customer before proceeding to the Design specification. This document also provides a list of design objectives on which to base the Design Specification.

The FRS should contain performance requirements that the software needs to meet, e.g. data throughput, reliability, timing. This document also establishes ranges, limits, defaults and specific values that the software will accept. The FRS needs to contain definition of the intended operating environment e.g. Microsoft Database Engine, SQL version, Windows, etc.

1.5 Design Specification (DS)

PRISYMLS will provide a Design Specification that details how the software and the front-ends form the whole system architecturally. The Design Specification also

establishes detail of any internal interface, i.e. between the core program and the front-ends. Any external interface definition is included in this specification, like a specification that defines the customer setup and the systems SQL database interface.

1.6 Unit Testing (UT)

Any previously completed unit testing performed on PRISYM [Medica](#) needs to be reviewed for accuracy relative to the requirements identified by the customer. We also need to establish and run system test scripts that prove the front-ends performance before integration into the main software module. This is effectively testing of the elements established in the Design Specification.

1.7 System Acceptance Testing (SAT)

Provide Systems Acceptance Test scripts to test and prove the complete system as detailed in the Functional Requirement Specification. Simply testing the separate design elements only proves performance in an independent state, consequently the entire system must be tested to look for any interactions between elements. This also needs to take place using hardware, software and interfaces that are used by the customer. We generate a set of test documentation to prove that the testing has been carried out and to confirm the system has performed as specified. Customers are encouraged to oversee and serve as witness to this portion of testing.

1.8 Installation Qualifications (IQ)

We provide electronic and hardcopy of Installation Qualification scripts used to ensure that the software has been installed correctly and to confirm configuration requirements during the installation process. The IQ scripts should be incorporated into the customer's IQ protocol and should initially be performed by PRISYM^{LS}'s own technical personnel. Subsequent IQ testing can be done by the customer. Approval and acceptance of the results is a mutual responsibility and should be documented in the customer's final report. The IQ will also record the presence of all other relevant hardware, software and documentation.

1.9 Operational Qualifications (OQ)

The Operational Qualification documentation is a series of scripts that provide documented evidence that the software meets the requirements laid down in the Functional Requirement Specification. OQ activity is done on-site with the customer's data and hardware. Our test scripts are designed to be incorporated into the customer's test plan/protocol. Effectively this documentation is to be used by the customer to test the system to its normal working extremities without the use of live data.

1.10 Performance Qualifications (PQ)

Provide Performance Qualification scripts to ensure the software as installed consistently meets the requirements laid down in the User Requirement Specification. This will be used to test the system to its normal working extremities using live data. It also provides evidence that the system consistently produces the desired results, demonstrates repeatability in the customer's environment using their users and data.

1.11 Printer Driver Tests

Perform printer driver tests on the chosen printers. Note that firmware of individual printers with the same model number can vary, consequently the performance of the firmware needs to be tested relative to the validated driver.

1.12 PRISYM Medica Documentation

Provide a complete set of PRISYM Medica life cycle development documentation, inclusive of all test scripts and actual test results.

2.0 PROJECT MANAGEMENT

Provide the support and services of the following PRISYM^{LS} staff. Note, all time relating to writing code &/or test script requires a programmer, this is handled within the Documentation portion of this project.

2.1 Project Manager

Project management, site liaison, site investigations and site meetings are to be coordinated by the Project Manager, they will act as the main interface between customer personnel and the PRISYM^{LS} development team. To keep all parties informed as regards to progress made against the Project Plan.

2.2 Quality Manager

Provide customer liaison regarding quality assurance and documentation matters. To oversee any software development and ensure coding and testing standards are followed. To review PRISYM^{LS} generated documents to ensure they are suitable for customer validation purposes.

For more information about validation of compliant labeling systems including our range of labeling and tracking products and services please contact +44 (0)118 936 4400 or email info@prisymid.com