Development and testing of bespoke software to an ISO 9001 standard

Introduction

In order to meet the quality standards set out from ISO 9001, the correct development and testing of bespoke software must be undertaken. This plays a fundamental part in meeting quality assurance objectives to ensure product formality, completeness and security.

Before any development, a number of steps should be taken in order for the bespoke software to be accepted and used in the field. We will discuss these steps below and introduce terms such as Agile methodology for planning and managing the application development.

Our workflow

1. Prototype
   A small scale project which can be used to test out an idea or prove feasibility before a full-blown software development project is started.

2. Specification & Design
   Once a prototype has been created and the project ‘green-lit’ then a list of features has to been drawn up and agreed upon by interested parties.

3. Development
   The approved features are built. The software requirements contain information on how testing will be done.

4. Testing
   The features that have been built are tested against the feature specification. The tester must not be the same person as the developer.

5. Release
   Once an agreed list of features is completed, a release of a software product is made.

Process Example

In this example we will discuss how our implementation of the steps is put into practice regarding collection of our survey data via the ‘Survey Collection Template’ used by the medical physics technicians for IPEM Level B tests and helps us meet QA from a legal perceptive (IRR99, R32 QA).

The workflow as seen from the diagram is put into practice via an Agile software tool called ‘Axosoft OnTime’ once a prototype has been developed and verified. All software development is carried out in a development environment, separate from the production environment.

When a new Survey template is commissioned, the requirement based on the modality is created which is also known as the Product Specification. From this specification the feature requirements are put into a Product Backlog (wish list), prioritised and processed into a Release Backlog. The goal here is to find what it is required for a feature to work on the survey template.

Estimated time for each requirement is then planned into Sprints (short duration milestones) where member(s) of the development team can focus to tackle each Sprint throughout the development short meetings are held to ensure everything is on track and any issues are raised with the group, i.e. project leader, owner and the developer(s).

Once the survey template has been completed by the developer a test plan is created based on the features with guidance from IPEM 91. There are four levels of testing from Level A to D. New templates require all levels testing and these are defined as:

- **Level A** — a field test with the test equipment used
- **Level B** — any scientific formulae that affect or may affect the tolerances or interpretation of tolerances. This must be tested with test data.
- **Level C** — fairly minor or well contained features, involving formulae or cell references but none that may affect tolerance results or their interpretation. This may include using test data
- **Level D** — cosmetic features/changes; a visual check is sufficient

On successful completion of the testing the template is verified by an RPA and is then rolled out on the production network where the surveyors have access to one version of each template (the latest version). This testing procedure is also used for defects found with current survey templates deployed based on the nature of fix required.

Benefit

The benefit of using this tool and methodology in combination is that it enables multiple users to document developments in a consistent and traceable manner. This includes documentation of features as they are requested, approved, developed, tested and released to end users.

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