

Manual 070

5.3.3.1 Qualification Deliverables Flow

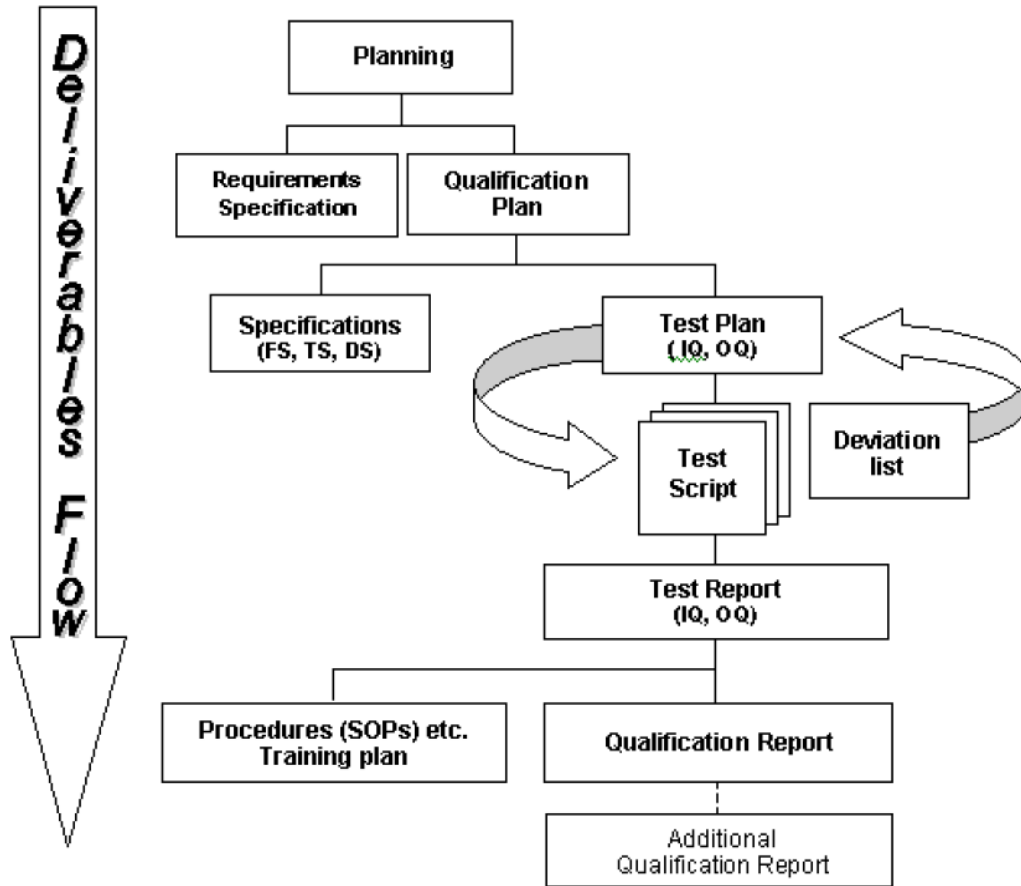


Figure: "Qualification Deliverables Flow"

5.3.3.2 Deliverables Description

Table 1 - Qualification Deliverables

Deliverable	Scope of Deliverable
Qualification Plan (QP)	The Qualification Plan outlines what information; documentation and processes will be produced or updated. This must include the scope of the activity and what elements need to be qualified based on a risk assessment. It is important to define which middleware components, if any, will be included. For small changes, a separate document is not required and the planning information may be contained in another document. For larger and more complex changes, a separate document will be required. Local procedures should be consulted for specific guidance.
Inventory Records (Asset Register)	The inventory must identify both hardware and associated software components (e.g. operating system).
Requirements Specification	Requirements must be documented so that the component can be properly specified, procured, installed and tested.
Technical Specifications	The technical specifications must include information about the functional, technical, and architectural and design aspects of the component.

Configuration Records	Each component with configurable items must have its configuration documented sufficiently to allow the component to be installed and operated correctly and to be maintained or replaced as required. Critical relationships, if they exist between different components, should also be documented.
Installation Qualification (IQ) Protocol	The IQ protocol confirms that each critical component, or representative sample of a common class of components, has been procured, installed and connected according to the installation instructions.
Operational Qualification (OQ) Protocol	The OQ protocol confirms that the correctly installed component operates according to requirements and includes testing of the operating system if this is necessary for the proper functioning of the hardware.
Traceability Matrix	The traceability matrix enables tests and test results to be correlated and traced back to their controlling specification.
Test Report	The test report is a summary of testing completed and make mention of any deviations, test failures or constraints and corrections. The test report may be combined with the IQ and OQ protocols.
Qualification Report	The results of the qualification work must be summarised and reported, either as a separate document, or combined with the change control documentation, for example.