



Minitab Statistical Software v22 Software Validation Kit Overview and Instructions

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To Our Valued Customers:

At Minitab, we recognize that our high-quality software products must meet the needs and expectations of our customers. We also recognize that many of our customers desire information on how we validate our software and may need information from us to help satisfy regulatory agency requirements. To support your validation efforts, we have created the tools and documents in this software validation kit.

In addition to instructions and templates, we include Minitab's Quality Statement which provides information about the processes and practices we use at Minitab to assure the accuracy and reliability of all statistical output and confirms our continued commitment to quality. We assure that Minitab Statistical Software Version 22 was developed and tested in accordance with the Minitab Quality Statement and the release was found to meet the project deliverables, requirements and design.

Note that no one part of this kit will necessarily satisfy all validation requirements of regulatory agencies. We validate for market readiness only and hope that these materials will facilitate your own efforts in validating the software and showing that it is fit for use in your environment.

Please use the remainder of this document as a recommended guide for your efforts. If you have any additional questions regarding our validation policies and processes, please contact our Technical Support Department by visiting <http://www.minitab.com/contacts> .

Thank you for using Minitab software!

Jennifer Roan

Vice President of Software Development

Overview:

The remainder of this document serves as an explanation of the Minitab Statistical Software (MSS) v2 Software Validation Kit and provides instructions for using the kit to support the validation of MSS v22 for your intended use. The instructions will reference other templates and files (also included in the kit). As you perform your validation efforts, you may customize any or all templates and files included in the Software Validation Kit to fit your specific needs; however, be aware that modifications made to one document will likely impact other documents.

Please note that this kit serves as a guideline, and you may require additional supporting information to validate MSS for your organization's specific use. For example, this validation kit does not cover macros supplied by Minitab or developed by our customers for their specific internal uses and utilizing their internal development processes. For this reason, customers using macros may require more evidence of testing within their validation efforts. Customers may choose to leverage the validation templates and kit by updating it for their macros.

Validation Kit Contents:

Before proceeding to the validation steps, please take a moment to confirm that you have received the following materials:

- A. **Supporting Quality Process Documentation** – documentation outlining processes and protocol utilized for the development of Minitab Statistical Software
 - 1. **Minitab Quality Statement** – an outline of the processes and practices we use to ensure the accuracy and reliability of our software. It includes a description of Minitab's Quality Policy, Company Mission and Guiding Principles, Software Development Life Cycle, and other supporting business processes
 - 2. **Requirements Traceability Matrix** – a document outlining Minitab commands and their associated automated test file directories used to validate results against requirements and design.
- B. **Validation Templates** – a set of templates to assist you in validating Minitab software
 - 1. **Minitab Validation Plan** – an overview of objectives, scope, activities, deliverables, responsibilities, and overall approach that you have outlined to validate Minitab Statistical Software
 - 2. **Minitab User Requirements and Functional Specifications** – a document to help you define your organization's intended use of Minitab Statistical Software
 - 3. **Minitab Installation Qualification Protocol** – the procedure that will be used to verify and document that installation specifications are met
 - 4. **Minitab Operational Qualification Protocol** – the procedure that will be used to verify and document that the MSS application functional specifications are met
 - 5. **Minitab Validation Trace Matrix** – a document that connects the requirements for the validation process and identifies the following:
 - Tracing from the Installation Specifications to the Installation Qualification (IQ) tests

- Tracing from the User Requirements (UR) to Functional Specifications (FS) and to the Operational Qualification (OQ) tests
6. **Minitab Validation Summary Report** – a document that addresses how the validation testing was conducted, summarizes the results of testing, and reports a conclusion for the overall outcome of the validation effort
- C. **Automated Validation Tests** – an automated script and associated results used to validate numeric and visual results within your environment. Two sets of tests and results are included within the folder, for regions that use either a period or a comma as a decimal separator. Please select the one appropriate for your regional settings.
1. **For regions that use a period as a decimal separator:**
Automated Validation Tests_Period – an automated script and associated results to validate numeric and visual results for environments that use a period as the decimal separator
 - a. **validate.mtb** – an automated script to test a representative set of commands and subcommands characterizing most functional areas of the software
 - b. **validate-EXPECTED.docx** – a file of expected output validated to contain numerically and visually accurate results
 - c. **validate.out** – a file of expected output validated to contain numerically accurate results
 - d. **graphs_period** – a folder of image files validated to contain visually accurate results
 2. **For regions that use a comma as a decimal separator:**
Automated Validation Tests_Comma – an automated script and associated results to validate numeric and visual results for environments that use a comma as the decimal separator
 - a. **validate_comma.mtb** – an automated script to test a representative set of commands and subcommands characterizing most functional areas of the software
 - b. **validate-EXPECTED_comma.docx** – a file of expected output validated to contain numerically and visually accurate results
 - c. **validate_comma.out** – a file of expected output validated to contain numerically accurate results
 - d. **graphs_comma** – a folder of image files validated to contain visually accurate results

If you have received all materials, please continue with your efforts to validate MSS for your intended use. **Please note that the results of each activity, including information pre-populated by Minitab, should be reviewed by your validation team for accuracy and completeness.**

Validation Steps:

Step 1 – Create a Plan

Use the *Minitab Validation Plan* template to help you identify and document the objectives, scope, activities, deliverables, responsibilities, and overall approach for the validation effort. Parts of this document apply to all users and have been filled in for you. Other parts (indicated in *blue, italic text*) require the specific knowledge of your organization and have been left for you to fill out. ALL parts of the document should be reviewed by your validation team for accuracy and completeness.

Step 2 – Define Requirements and Functional Specifications

Use the *Minitab URFS* (User Requirements and Functional Specifications) template to help you define and document the ‘what’ and ‘how’ associated with your organization’s use of Minitab Statistical Software. Most of this document applies to all users and has been filled in for you. Other parts (indicated in *blue, italic text*) require the specific knowledge of your organization and have been left for you to fill out. ALL parts of the document should be reviewed by your validation team for accuracy.

Section 2 of the *Minitab URFS* template (*System Description*), describes how project data is stored. This is specific to your organization, so the statements and diagram should reflect how your business operates.

Section 3 (*User Requirements*) describes the high-level functions offered in the software that are part of the validation test suite (*validate.mtb*).

Section 4 (*Installation Specifications*) describes the software components required to support the Minitab application.

Section 5 (*Functional Specifications*) provides a detailed description of the requirements and describes the functional specifications and applicable controls that the system must provide in order to meet those requirements.

Step 3 – Document the Testing Protocols and Validation Trace Matrix

There are three documents involved in this step: *Minitab IQ Protocol*, *Minitab OQ Protocol*, and *Minitab Validation Trace Matrix*.

Installation Qualification (IQ) Protocol

The *Minitab IQ Protocol* template documents the procedure that will be used to verify that installation specifications are met per Section 4 of the *Minitab URFS* document. Most of this document applies to all users and has been filled in for you. Other parts (indicated in *blue, italic text*) require the specific knowledge of your organization and have been left for you to fill out. ALL parts of the document should be reviewed by your validation team for accuracy.

Operational Qualification (OQ) Protocol

The *Minitab OQ Protocol* template documents the procedure that will be used to verify that the MSS application functional specifications are met per Section 5 of the *Minitab URFS* document. Most of this document applies to all users and has been filled in for you. Other parts (indicated in *blue, italic text*) require the specific knowledge of your organization and have been left for you to fill out. ALL parts of the document should be reviewed by your validation team for accuracy.

Minitab Validation Trace Matrix (VTM)

The *Minitab VTM* template identifies the link between the Installation Specifications (section 4 of the *Minitab URFS*) and the Installation Qualification (IQ) tests. It also traces the link from the User Requirements (section 3 of the *Minitab URFS*) to the Functional Specifications (section 5 of the *Minitab URFS*) to the Operational Qualification (OQ) tests. Most of the VTM applies to all users and has been filled in for you. Other parts (indicated in *blue, italic text*) require the specific knowledge of your organization and have been left for you to fill out. ALL parts of the document should be reviewed by your validation team for accuracy.

Step 4 – Execute the Testing Protocols

After the IQ and OQ protocol templates have been documented, finalized, and reviewed by your validation team, they are ready for execution by the tester(s). All steps of the testing protocols contain a pre-defined objective, action steps, and an expected result, as well as a place for the tester to document the actual result and a pass/fail designation. Detailed instructions for performing the test steps, recording results, reviewing results, and addressing deviations can be found in the protocols and should be followed as written in the finalized documents.

Installation Qualification Protocol

Tester(s) should read and perform all steps of the *Minitab IQ Protocol* to verify the minimum system requirements are met for Minitab's intended use.

Operational Qualification Protocol

Tester(s) should read and perform all steps of the *Minitab OQ Protocol* to demonstrate that the Minitab application functions as specified. Included in the Minitab Validation Kit is an automated test script for testing a representative set of Minitab commands and an output file validated for accuracy. As part of the OQ protocol, testers will use the materials in *Automated Validation Tests* to generate output and compare it to the expected results.

Step 5 – Summarize the Test Results

Use the *Minitab Validation Summary Report* template to address how the validation testing was conducted, summarize the results of the testing, and report a conclusion for the overall outcome of the validation effort. Most of this document applies to all users and has been filled in for you. Other parts (indicated in *blue, italic text*) require the specific knowledge of your organization and have been left for you to fill out. ALL parts of the document should be reviewed by your validation team for accuracy.