

## Chapter 10

# Procedure Validation Tool for Operational Qualification (OQ)

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### Introduction

The Procedure Validation Tool for Operational Qualification (OQ) may be used to validate that the software is operating correctly. The tool verifies that one or more (up to all) procedures is/are functioning correctly by loading the procedure(s), executing calculations, and comparing the results to verified and expected outcomes. Summary and detailed validation reports are created and displayed in the Output Window. If all procedures pass operational qualification, then you can be certain that the software is functioning as expected.

Each procedure can also be validated individually by clicking **Validate This Procedure** in the Help Center or Help menu on any Procedure Window.

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### The Tool Window

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#### Loading the Tool Window

You can load the Procedure Validation Tool for Operational Qualification (OQ) window from within **PASS** using the menu by selecting **Tools**, then **Validation and Qualification (IQ/OQ)**, and then clicking **Procedure Validation Tool for Operational Qualification (OQ)**.

The tool window can also be loaded from the PASS Home window procedure tree by selecting **Tools**.

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#### Tool Window Options

The following components are included on the Procedure Validation Tool for Operational Qualification (OQ) window.

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#### Select Power and Sample Size Procedures to Validate

Two options are given to allow the user to specify which procedures to validate.

- **Validate All Procedures**

Every power and sample size procedure in **PASS** is validated. This process usually takes 3 to 5 minutes to complete, but the actual time will depend on the speed of your computer.

## Procedure Validation Tool for Operational Qualification (OQ)

- **Validate Only the Procedures Selected Below**

If this option is checked then you may select one or more procedures to validate from the alphabetical list of procedures. Your selections are recorded and will be the same each time the window is opened until you make a change. You can check or uncheck all items in the list using the buttons above the list.

Note that each procedure can also be validated individually by clicking **Validate This Procedure** in the Help Center or Help menu on any Procedure Window.

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### Run Validation

Click the Validate Procedures button to run the validation. The tool validates the selected procedures and generates a validation report in the Output window. The validation may take some time depending on the number of procedures being validated and the speed of your computer.

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### Procedure Validation Progress

This box displays the progress and information about the validation as it proceeds. You can copy the information from this box after selecting contents by right-clicking and selecting “Copy” or by typing Ctrl-C on the keyboard.

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## Procedure Validation

PASS procedures are validated for accuracy using example templates provided with the software. The validation tool loads each of the selected procedures in the background, loads a validation template, performs calculations as outlined in the template, and then records the results. Analytic procedures must match the expected result exactly to pass validation. Simulation procedures must generate a result within a specified tolerance of the expected value. Both the expected and actual values are included in the procedure validation detail report. Thousands of calculations are involved in a single procedure run for any template, so if the procedure passes this validation step, you can be certain that the software is installed and functioning correctly.

### Validation Results

The three possible validation results for each procedure are

- **Passed**

A procedure is reported as “Passed” if the actual result from the validation run matches the expected result exactly (or within a given tolerance for simulation procedures).

- **Failed**

A procedure is reported as “Failed” if the actual result from the validation run does not match the expected result exactly (or within a given tolerance for simulation procedures). If a procedure fails validation, then you likely have a problem with the installation and should repair the software installation.

- **Skipped**

A procedure is reported as “Skipped” if validation was not actually performed. This result will occur if the required validation template is not found (in which case you should repair the installation) or if the validation process is terminated (aborted) prematurely by the user.

## Reports

The results of the operational qualification are presented in two reports created in the Output Window. The reports are always formatted in the landscape page orientation (the page orientation cannot be changed—it overrides the system orientation).

### Report for Procedure Validation with No Errors

The following report is representative of a valid, complete, and functioning **PASS** software installation.

PASS 16 Procedure Operational Qualification (OQ) Results Summary					
Date & Time	5/28/2018 3:00:03 PM				
Product Version	16.0.1				
Installation Path	C:\Program Files (x86)\NCSS\PASS 16\				
Computer Name	JOHN-DESKTOP				
OS Name	Microsoft Windows 10 Pro				
Licensed User	John Doe				
Organization	XYZ Inc.				
License Key	xxxx-xxxx-xxxx-xxxx-1A2B				
License Type	Professional License				
Procedures Validated	All				
Passed	325/325	(100%)			
Failed	0/325	(0%)			
Normal Completion	Run Time = 193.077 seconds				
PASS 16 Procedure Operational Qualification (OQ) Results Details					
Procedure [ID]	Validation Template	Output	Expected	Actual	Result
Acceptance Sampling for Attributes [370]	Example 3a	Sample Size (N)	65	65	Passed
Analysis of Covariance [107]	Example 2	Sample Size (N)	98	98	Passed
Bartlett Test of Variances (Simulation) [306]	Example 2	Power	0.816 ± 0.048	0.826	Passed
Brown-Forsythe Test of Variances (Simulation) [308]	Example 1	Power	0.097 ± 0.016	0.089	Passed
Chi-Square Tests [114]	Example 3	Power	0.7484	0.7484	Passed
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[Report Continues for Several Pages]					

The summary report provides information about your computer, your **PASS** installation and license information, and a summary of the procedure validation results. The details report shows the complete results for the validation of each procedure.

## Procedure Validation Tool for Operational Qualification (OQ)

## Report for Procedure Validation with Errors

The following report is representative of a **PASS** software installation with calculation errors.

### PASS 16 Procedure Operational Qualification (OQ) Results Summary

Date & Time 5/28/2018 3:10:00 PM

Product Version 16.0.1  
 Installation Path C:\Program Files (x86)\NCSS\PASS 16\  
 Computer Name JANE-DESKTOP  
 OS Name Microsoft Windows 10 Pro

Licensed User Jane Doe  
 Organization XYZ Inc.  
 License Key xxxx-xxxx-xxxx-xxxx-8A9B  
 License Type Professional License

Procedures Validated All  
 Passed 323/325 (99.38%)  
 Failed 2/325 (0.62%)  
 1: Acceptance Sampling for Attributes [370]  
 2: Chi-Square Tests [114]

Normal Completion  
 Run Time = 197.364 seconds

### PASS 16 Procedure Operational Qualification (OQ) Results Details

Procedure [ID]	Validation Template	Output	Expected	Actual	Result
Acceptance Sampling for Attributes [370]	Example 3a	Sample Size (N)	65	47	Failed
Analysis of Covariance [107]	Example 2	Sample Size (N)	98	98	Passed
Bartlett Test of Variances (Simulation) [306]	Example 2	Power	0.816 ± 0.048	0.826	Passed
Brown-Forsythe Test of Variances (Simulation) [308]	Example 1	Power	0.097 ± 0.016	0.089	Passed
Chi-Square Tests [114]	Example 3	Power	0.7484	0.6487	Failed
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In the case of this **PASS** validation, there are two procedures that failed operational qualification. There may be a problem with the installation. The user should repair the installation and run the validation tool again.