STANDARD OPERATING PROCEDURE	
SOP Number:	IQOQ001
Version Number:	03
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Supersedes:	02

TITLE: SAS Installation Qualification / Operational Qualification

OBJECTIVE:

The objective of this document is to provide an example SOP for the routine use of the SAS Qualification Tools. It is intended to provide SAS customers with a starting point for their own internal SOP with regards to IQ/OQ of SAS products in the Windows or Unix operating environment. This SOP is not intended to provide detailed instructions on the use of the tools. These details can be found in the user documentation that accompanies the tools.

SCOPE:

The scope of this procedure is limited to the Installation Qualification / Operational Qualification of the following products for SAS 8.2 (TS2M0) on Windows:

- Base SAS
- SAS/Stat
- SAS Enterprise Miner
- SAS/ETS
- SAS/IML
- SAS/OR
- SAS/QC

The scope also includes the following products for SAS® 9 on Windows and UNIX:

- Base SAS
- SAS Enterprise Miner
- SAS/ETS
- SAS/Graph
- SAS/IML
- SAS/Insight
- SAS/Lab
- SAS/OR

- SAS/QC
- SAS/Stat

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LIST OF ABBREVIATIONS

21 CFR Part 11	Title 21, the Code of Federal Regulations, Part 11
CFR	Code of Federal Regulations
GxPs	Good Laboratory, Clinical, and Manufacturing Practices
IQ/OQ	Installation Qualification / Operational Qualification
QA	Quality Assurance

REFERENCES

SAS 8.2 Qualification Tools
SAS 9 Qualification Tools
SAS Migration Community web site for validation

SECTION B: Overview

Application of 21 CFR Part 11 to the predicate rules of GxPs describes the requirements for validation, calibration, testing and standardization of tools or instrumentation. A plan to execute this process includes Installation Qualification and Operational Qualification (IQ/OQ). IQ/OQ is an element of this process to assure that the tools are installed in the intended manner and to further ensure that they meet operational qualification requirements.

SECTION C: Procedures

1 Perform Installation Qualification (IQ)

Once the SAS products have been installed according to the installation instructions provided in the accompanying documentation, execute the SAS IQ tool to verify the success of the installation. The SAS products must be installed according to the customer's IQ/OQ protocol on platforms that meet or exceed the published system requirements.

SAS 8.2

1. Download the SAS 8.2 Qualification tools from:

   http://www.sas.com/apps/demosdownloads/sasqualtools_PROD__sysdep.jsp?packageID=000278

2. Install the SAS IQ and SAS OQ tools by executing the Qual82SETUP.EXE program and following the instructions documented in the SAS 8.2 Qualification Tools User's Guide.

   The SAS IQ and SAS OQ tools are designed to be installed in the !SASROOT\SASTest directory.

   e.g. `C:\Program Files\SAS Institute\SAS\V8\SASTest`

3. Run the SAS IQ tool:
   a. The first time the tool is run, use the "SASIQ – Generate Benchmarks" program that was added to your SAS 8.2 Qualification Tools program group during installation.
   b. Use the "SASIQ Verification" program, also added to the SAS 8.2 Qualification Tools program group during installation, to compare the installation to the benchmark data.

SAS® 9

Windows:

There are three methods to run the SAS IQ Tool on a successful SAS 9.1 installation:

1. Use the AutoPlay (Install Utilities --> Installation Qualification Tool). This menu item is available only immediately after the SAS software has been installed in Windows.
2. Use the Windows start menu (Start → Programs → SAS → SAS 9.1 Utilities → SAS Installation Qualification Tool.

3. Open a command line in DOS and type the following command:

   c:\><*SASROOT*>\sastest\sasiq.exe -OutputPath <*dir*>

In this command, <*SASROOT*> is the location where the SAS System is installed, and <*dir*> is the directory where the resulting documentation is to be stored.

The SAS IQ Tool will direct output to the output directory identified during execution of the tool. The output is written to a folder labeled IVT_*yyyymmdd.xxx* where *yyyy* is the year, *mm* is the month, *dd* is the day, and *xxx* is a unique version number. If SASIQ is executed more than once on the same day, the version number will be incremented.

UNIX:

There are two methods to use the tools on UNIX.

Method 1: SAS Installation Representative Running the Installation Qualification Tool

The SAS Installation Representative can run the SAS IQ at any time by following the steps below:

1. Run SAS Setup from !SASROOT/sassetup. Make sure you have the appropriate privilege to update files in SASROOT.
2. Select Run Setup Utilities from the SAS Setup Primary Menu.
3. Select Perform SAS System Configuration.
4. Select Run the SAS Installation Qualification Tool.
5. Check the installation log file for a summary of the results or review the detailed report in the .xml file that SAS Setup lists on the screen.

This will create validation reports and logs in the !SASROOT/install/admin/validate_date.version directory.

Method 2: User Running the SAS Installation Qualification Tool

A user of SAS can run the SAS IQ at any time without needing write access to the SASROOT directory by passing the –validate and –valoutdir command flags to SAS Setup. These command flags redirect all log files and output to the specified directory. The user must have write access to the specified directory. An example of the command is:
$!SASROOT/sassetup –validate –valoutdir <directory>

where <directory> is a directory to which the user has write access.

1.1 Review IQ Report

The SAS IQ Tool stores the raw output data in XML files. SAS is used to translate the raw XML data into PDF and HTML reports. The PDF and HTML reports are identical, but each has its own purpose – the PDF should be used to generate a hardcopy of the final results, while the HTML is a more convenient means of interactively examining the output. The HTML report contains links to other HTML files - one per installed SAS component.

Review the IQ report to identify exceptions:

- Perform a review of the results using the HTML format. This format allows you to quickly determine the PASS/FAIL status of the install and to drill into various levels of detail for each software component.
- Once the review is complete, print the IQ report in PDF format for the regulatory record.
- Sign and date the IQ report.

NOTE: The customer can choose to store the regulatory record in hard copy, soft copy or a combination of both. For purposes of this SOP, the example procedures use the hard copy as the official regulatory record with signatures.

1.2 Record Exceptions

For each exception noted on the report:

- Complete an exception report. An example blank exception report is attached to this SOP.
- Begin the exception numbering at 1 and increment sequentially.
- In the *Reference #* field, enter the name of the file for which the qualification failed (e.g., APPEND.SAS). If the qualification failed for all files in a component, it may be more efficient to write one exception for the component and include the component name as the Reference # (e.g., BASA00EN).
- Describe the exception in the *Description* field.
- Sign and date Section 1.
- Clearly write the number of the exception report on the printed IQ report to provide a cross reference between the IQ report and the appropriate exception report.

1.3 Resolve Exceptions

Go through each exception and resolve the issues. As each exception is resolved:

- Complete and sign Section 2 of the appropriate exception report.
- Fully describe the resolution in the Resolution*/Workaround/Explanation* field of Section 2.
- Test the resolution and describe the testing activities in *Test performed to verify exception is resolved* field in Section 2.
- Sign and date Section 2 of the exception report.
- Obtain final sign-off of each exception. One signature should be from internal QA.

1.4 Archive Records

Once all exceptions have been successfully resolved:

- Sign and date the IQ report
- File the exceptions and signed IQ report for regulatory archival.

2 Perform Operational Qualification (OQ)

Once the IQ has been completed and all exceptions resolved, execute the SAS OQ tool to verify that SAS is operational.

Generally, the user environment includes the customer tests, SAS supplied tests, test output area, and the SAS image to be tested. Additionally, the customer can add their own suite of tests to the SAS OQ tool to enhance the test coverage. The customer tests must be organized in the same format as the SAS supplied tests. The SAS supplied tests are segregated by product in subdirectories. Each product subdirectory contains the SAS programs and the test tables. A directory for the test output will be needed. Attempting to write to a directory with existing test data will cause an error message. Refer to the user documentation for more details.

To run the SASOQ tool, follow the directions in the accompanying documentation. The tool will automatically manage the parameters passed to the SASOQ executable and direct output to the output directory identified during installation. The output is written to the FTT_*yyyymmdd.xxx* subdirectory in the designated output directory. *yyyy* is the year, *mm* is the month, *dd* is the day, and *xxx* is a unique version number. If SASOQ is executed more than once on the same day, the version number will be incremented.

To review the results of SASOQ execution, navigate to the folder created and open SASOQ.HTM or SASOQ.PDF.

This command line would cause the SAS OQ Tool to execute all the available tests for each product named on the command line, and put the test output and data in the current directory.

<SASOQ path>sasovt –tables *:<product>

The SAS OQ Tool stores the raw output data in XML files. SAS is used to translate the raw XML data into PDF and HTML reports. The PDF and HTML reports are identical, but each has its own purpose – the PDF should be used to generate a hardcopy of the final results, while the HTML is a more convenient means of interactively examining the output. The output report separates the tests by product and then by test table. The test summary lists all data pertinent to the test execution – command line, return codes, output files compared against benchmarks (if any).

Following the same procedures as defined above for IQ, review the OQ report, record and resolve exceptions and archive the regulatory records.

3 Execute Qualification Tools on a Ongoing Basis

Once the installation of SAS has been qualified, it is important to periodically evaluate the system to ensure ongoing validation. Some times to consider rerunning SAS IQ and SAS OQ are:

- When you apply hot fixes
- When you add new hardware to your system
- When you update any of the software in your system

The SAS IQ and SAS OQ tools can be executed and the above procedures followed at any point to ensure the SAS system continues to be operational.

Revision History

Date	Version	Description	Revised by
May 29, 2003	.01	Initial Publication	SAS Quality Assurance and Regulatory Affairs
December 4, 2003	.02	Include SAS 8.2 Qualification Tools	MIV
May 12, 2008	.03	Updated for SAS® 9.1.3	HLS

IQ/OQ Exception Report

Section 1			
	System Name:	**Reference #:**	**Exception #:**
	Exception Description: **Reported by:** _____ **Date:** _____		

Section 2	
	Resolution/Workaround/Explanation: **Test performed to verify exception is resolved:** **Resolved by:** _____ **Date:** _____

Section 3	
	Approved by IT Manager: _____ **Date:** _____ **Approved by QA Manager:** _____ **Date:** _____