Avenue E. Mounier 83/11
1200 Brussels
Belgium
Tel: +32 2 774 1611
Email: eortc@eortc.be
www.eortc.org

SAS Macro Development and Validation

ST-003-WIN-01

Version 2

ALWAYS REFER TO THE INTRANET TO CHECK THE VALIDITY OF THIS DOCUMENT

Author: *Statistical Analyst* Gaëlle Isaac	Signature:	Date: *(ex:10-Feb-2017)* 20-JUL-2017
Approved and authorized by *Head of Statistics Department* Laurence Collette	Signature:	Date: *(ex:10-Feb-2017)* 20.07.2017 July

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1 PURPOSE

To describe how EORTC SAS macros are developed and validated by the EORTC Statistics Department.

2 DEFINITIONS

- **Developer:** A member of the statistical department responsible for writing the macro and performing the first-line validation tests (development testing). The developer cannot be the same person as the tester.
- **Tester:** A member of the statistical department responsible for testing the macro and performing the core of the validation. The tester cannot be the same person as the developer.
- **A Program defect:** An error or issue in the code resulting in unexpected results or in stopping the execution of the code.
- **Major change:** Modification in the source code that has an impact on the results and/or output produced by the macro. For instance, the addition of an input parameter or the addition of an output (new table, new graphs). A correction of a program defect is also considered as a major change.
- **Minor changes:** Modification in the source code that does not impact the result and/or output of the macro. For instance, adding or modifying a title or footnote. Changing the color of a graphs or modifying the name of some intermediate datasets is also considered as minor changes.
- **Working group:** a group of maximum 5 members of the statistical department, including the developer and the tester, chosen according to their expertise in the field of the macro.
- **Development testing:** All the tests performed by the developer when writing the macro in order to ensure the proper functioning of the macro code.
- **System Level testing:** a complete set of tests performed by the tester to assess
    - The substance: Check the correctness of results, the parameters, the error messages (defensive writing), and the outputs (layout and content), …
    - The form: checks the SAS source code, the log file, history of different versions.
- **User Acceptance Testing (UAT):** A formal means for users to evaluate a system against criteria that determines how a system behaves based on their interaction and the expected output and performance of the system.
- **Product description & requirements document:** Document that describes the aim and the needs for which the macro is being developed. Lists the requirements (parameters, desired output) of the macro.
- **Development document:** Document that reports all the actions taken during the writing of the macro. This document must clearly identify the SAS datasets that will be used to develop the SAS code and describe how these datasets will eventually be merged or transformed. It will also indicate the version of the macro that is being validated.
- **System level testing document:** A document that contains a list of all the tests performed by the tester, with an explanation of their purposes and the corresponding macro calls.

- **User Acceptance document:** Document to be filled in by each member of the working group after having tested the macro 'in real life' during a predefined period of time. This document should explain which data were used for the tests, how the macro was used and if the results were acceptable.
- **Macro documentation document:** User guide explaining in a simple way the functionalities of the macro and the way to use it. This document also contains examples of macro calls. It is written by the Developer, stored on the server (J:\UNIT\Stat\7. SAS and R\SAS Macros Documentation) and made available on the intranet in the list of macro currently in use.
- **Final validation report:** a compilation of all the documents created during the process of macro development and validation. It needs to be signed for approval by the (Associate) Head of Statistical Department.
- **Macro modification form:** After the official release of the macro some issues can be raised by the users or some new requests could be made. The macro modification form should be used to report those issues/requests to the Statistical Analyst.

3 INSTRUCTIONS

3.1 Process

3.1.1 Pre-Development phase

Before starting the development process the working group will be asked to complete a "Product description & requirements document" (ST-003-AF-03) summarizing all the functionalities. Once finalized this document will be presented to all statisticians of the department for review and/or questions. In case of relevant remark(s) the working group may update the product requirement document. The final document will then be signed for approval by the (Associate) Head of Statistics Department.

3.1.2 Development phase

3.1.2.1 Writing of macro and development testing

The developer writes and performs the development testing of the SAS macro. He/she completes the development document (ST-003-AF-04).

3.1.2.2 System Level testing

Once the developer releases the first version of the macro the tester validates the SAS macros by performing the System Level testing. In case of a program defect the tester will notify this in a System level testing document (ST-003-AF-05) and stop the level testing. The developer will correct the code and release a new testing version. This process will be repeated until no more program defects are identified, then the tester will release the System level testing document (ST-003-AF-05).

3.1.2.3 User acceptance testing

The user acceptance testing consists of a period of "real-life testing" by the working group. According to the scope and complexity of the macro being validated the deadline for User Acceptance can vary up to 2 months. If a major

change is required the developer will perform the revision and the validation process described in section 3.1.2.2 will be re-started. In case a minor change is required the developer will report it in the development document (ST-003-AF-04) and no further validation is needed. At the end of the user acceptance testing, the working group member will complete positively the “User Acceptance Document” (ST-003-AF-06).

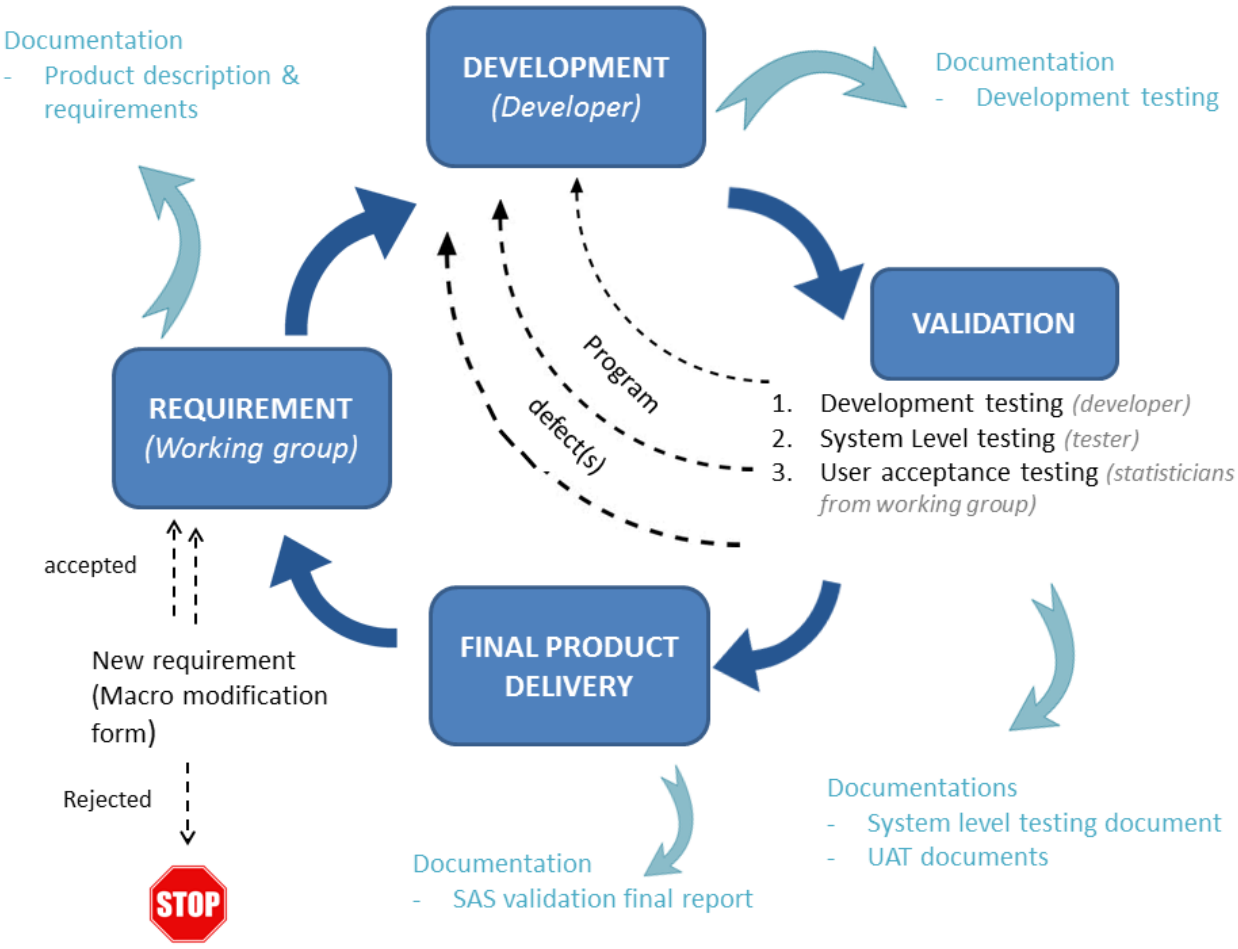
The statistical analyst prepares the Macro Documentation document (ST-003-AF-07) which describes the goal, the main functionalities and the parameters of the macro. As a tool for users, this document is put online on the intranet page “EORTC SAS macro Guide”.

3.1.2.4 Validation report and release of the macro

The validation process is documented in the final validation report (ST-003-AF-08) which is composed of all the different documents created from the beginning of the process:

- The product description and requirement document (ST-003-AF-03)
- The development document (ST-003-AF-04)
- The system level testing document (ST-003-AF-05)
- The user acceptance testing documents (ST-003-AF-06)
- The macro documentation document (ST-003-AF-07)

The final validation report is signed for approval by the (Associate) Head of Statistics Department. The final SAS macro is then made available to the EORTC SAS users through central EORTC SAS macros server (K:\SAS\EORTC macros).



3.2 Description of testing

3.2.1 Development testing

This is the main type of testing that a developer carries out while developing the macro: testing the macro to ensure its proper functioning. Check if the macro code gives expected results. The developer ensures that the comments and headers are clear: header may indicate the macro name, the version number, its version date, the author's name and brief description of the macro's goal. It is also advisable to create a complete list of macro's arguments and its parameter values.

In addition the developer should also keep track of history of versions.

3.2.2 System Level testing

The system level testing contains 5 mains steps:

3.2.2.1 White box testing

Testing the macro in the context it was meant for, using known data and results. It should be clear what the result of the macro should be in terms of output datasets or output listings from the "Product description and requirement document" (ST-003-AF-01). These should be verified for correctness.

3.2.2.2 Fool proof testing

This is the most important task of the macro validation: it explicitly should check all user specifications in order not to produce nonsense results. This fool proof testing includes:

- Testing with all variations of input parameters
- Testing with existing but known erroneous data and input parameters
- Checking for appropriate responses, error reports and their consistent layout and verify whether all parameters are being checked on validity (legal SAS names, …)

The tester should extensively check all the parameters and ensure that the macro is programmed to react to any inconsistency in a user friendly way, i.e. with clear error messages and without producing any results.

3.2.2.3 Source code checks

This part of the validation process should focus on the SAS code to check whether:

- It is optimally written: keep the code short and logical, not more complex than needed but neither more compressed than needed. No further validation is needed for the (small) changes performed at that step.
- There are enough comments and sufficient headers: check for descriptive heading and user documentation with examples, purposes and verify the presence of identifying information (programmer, SAS version, macro version, date, …).
- The SAS code is readable: respect the coding conventions (keywords in uppercase, macro parameters in uppercase, indent in the code, empty lines, …)
- The SAS variables and datasets created within the macro have unique names not interfering with others. The datasets created throughout the macro should have a name starting with one or two underscores (example: _data2, __patient2, …)
- All temporary datasets are deleted after use. They should also be deleted (as far as created yet) in case of unexpected SAS errors or macro generated errors.
- The titles and footnote of the produced output are sufficiently flexible, allowing the user to specify titles and footnotes outside the macro.

3.2.2.4 Output layout checks

The tester checks whether the layout of the output fits the requirements of the macro. The tester also checks for readability of tables and graphs.

3.2.2.5 Log files check

Especially in case of program defects the log of a macro should be intelligible and detailed enough to identify the problem.

3.3 Documentation

Each step of macro development must be properly documented.

Product description & requirements document Product description:

- describes the aim and the needs for which the macro is being developed
- explains the context in which the macro will be used.
- indicates the level of priority and deadlines (i.e: in case of a group meeting, a conference, …)

Requirements:

- a list of all computations that will be produced and validated (for macros that perform computations)
- an explanation of how the displayed output should look like (table or graph set up) and how it will be validated (for macros that produce display of results -in tables or figures-)
- a list and a description of all the macro parameters, making a clear distinction between optional and mandatory parameters.

3.3.1 Development document

Throughout the development process the developer will fill a template in to report all actions taken during the writing of the macro. This document must clearly identify the SAS datasets that will be used to develop the SAS code and describe how these datasets will eventually be merged or transformed. It will also indicate the version of the macro that is being validated.

Finally the developer will answer some general questions like:

- Were the deadlines of the project met?

- Are all the requirements fulfilled?

- Were there changes to the pre-specified functionalities?

- Indicates the version of the macro that will be pursuing validation process with the date of the former version(s).

The developer keeps track of history of previous versions and modifications in the SAS code.

3.3.2 System level testing document

This document must clearly identify the SAS datasets that will be used to perform the validation, and describe how these datasets will eventually be merged or transformed. All the tests that will be part of the SAS macro validation will be listed, with an explanation of their purpose and the corresponding macro call.

This validation will contain 5 chapters:

1. White box testing: List of tests being performed and their corresponding results. List of action taken in case of program defects if any. Main conclusion on the white box testing.
   The White box testing document also contains a description of the White box validation tests:
   - Compilation, calling and execution of the macro with the dataset of interest.
   - Programming of the same purpose with only a SAS Base Program without the macro.
   - Comparison of the two outputs obtained with and without using the SAS macro (PROC COMPARE)
   - Conclusion on the correctness of results
2. Fool proof testing:
   - List of all datasets and /or variables to check for validity, existence, etc.
   - List of all parameters to be tested and description of their corresponding tests or macro call and results.
3. Source code checks: the tester checks the code and attests that it has been optimally developed.
4. Output layout checks: the tester attests that the layout of output fits the objectives of the macro.
5. Log files check: the tester attests that the log file is well documented without being too voluminous.

3.3.3 User acceptance document

After the macro has passed the first two steps of validation (development testing and System Level Testing) the working group will be asked to perform a “real-life” validation. According to the scope and complexity of the macro being validated the deadline for User Acceptance can vary up to 2 months (between 1 week and 2 months). Each member of the working group will be asked to fill in a user acceptance document explaining which data were used for the tests, how the macro was used and if the results were acceptable.

In case of negative results, the members of the working group will discuss whether the reported program defect needs to be solved in this version of the macro of in later versions. The working group will also assess the importance of the required change. In case of major change the validation process re-starts at the point 3.1.2.1. In case of minor changes the developer will notify this in the Development testing form and no further validation will be required. The members of the working group will sign the User Acceptance document.

3.3.4 Final validation report

The final validation report is a compilation of all the documents created during the complete process of macro development and validation. It needs to be signed for approval by the (Associate) Head of Statistics Department.

3.4 Modification of a macro

After validation and release of the macro, a macro modification form should be filled in

- in case a program defect is identified to the macro

- in case a user would have a new request regarding the functionalities

This form will be sent by email to the statistical analyst. The working group will estimate the level of priority of the raised program defect or request and start the all process from the beginning if needed.

4 FILING AND ARCHIVING

The documentation related to the macro development and validation process will be managed by the Developer and will be stored on Statistical department page of the EORTC SharePoint Portal.
(http://portal.eortc.be/UNITs/Statistics_Department/default.aspx)

5 REFERENCES

Jim Groeneveld, OCS Consulting, Rosmalen, “SAS macro validation criteria”, PhUSE2016, Paper RA04.

Steven A. Wilson, Gilead Sciences, Inc. Foster City, CA, “The validator: A macro to validate parameters”, SAS global Forum 2011, Paper 015-2011.

6 ASSOCIATED DOCUMENTS

Document title	Reference (file name or path)
Product description & requirements document	ST-003-AF-03
Development document	ST-003-AF-04
System level testing document	ST-003-AF-05
User acceptance document	ST-003-AF-06
Macro Documentation	ST-003-AF-07
Final validation Report	ST-003-AF-08
Macro modification form	ST-003-AF-09

7 DOCUMENT HISTORY

Version N°	Brief description of change	Author	Effective date
1.00	Initial release	Jérôme Rapion	19 Apr 2010
1.1	Update in section 2.1 “signed for approval”	Jérôme Rapion	21 Jun 2013
2.0	Complete review of the process and reinforcement of validation process	Gaëlle Isaac	28 Jul 2017