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VALIDATION OF COMPUTERISED SYSTEMS

ANNEX 3: VALIDATION OF COMPUTERS AS PART OF TEST EQUIPMENT

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**ANNEX 3 OF THE OMCL NETWORK GUIDELINE
“VALIDATION OF COMPUTERISED SYSTEMS”**

VALIDATION OF COMPUTERS AS PART OF TEST EQUIPMENT

INTRODUCTION

The present document is the 3rd Annex of the core document “Validation of Computerised Systems”, and it should be used in combination with it when planning, performing and documenting the validation steps of computerised systems.

The core document contains the Introduction, Scope and general requirements for the validation of different types of computerised systems.

This Annex contains additional recommendations, which are to be used in combination with the general recommendations given in the core document. It is addressed to software for controlling laboratory equipment and evaluation of analytical raw data.

This document should be considered as a guide to OMCLs for planning, performing and documenting the validation of their computerised systems. It should not be taken as a list of compulsory requirements. It is left to the professional judgement and background experience of each OMCL to decide on the most relevant procedures to be undertaken in order to give evidence that their computerised systems are working properly and are appropriate for their intended use.

Level I. Selection of Software and Computer Equipment

The selection and purchase of new software and the associated computer equipment should follow a conscious decision process based on the requirements for the intended use of the test equipment. Usually the first step is the selection of software which meets the analytical requirements of the intended applications. Typical requirements are listed in Table 1. In the second step, appropriate computer equipment is selected which meets all hardware requirements of the selected software. Typical requirements are listed in Table 2.

TABLE 1: ANALYTICAL REQUIREMENTS ON THE SOFTWARE

- Integration algorithms (Peak detection, identification, evaluation parameters, etc)
- Calibration algorithms
- System suitability functions (Symmetry factor, theoretical plates, resolution, etc)
- Statistical functions (mean, standard deviation, etc)
- Control of the analytical system
- User management, i.e. the administration of user accounts and the definition of user privileges.
- Electronic signature
- Compatibility to external software (LIMS, Excel, etc)

TABLE 2: HARDWARE REQUIREMENTS

- Hardware components
- Operating system
- Interfaces. Particular attention should be paid to the characteristics of the a/d converters, which may have an impact on the resolution, the accuracy, the linearity or the sampling rate.

For software and associated computer equipment already in use the user requirement specifications may be described retrospectively.

Level II. Installation Qualification

Once the software and the computer equipment are selected and purchased, the whole system should be installed and connected to the analytical instrument by appropriately trained personnel. After installation, the system should be adequately qualified. Typical parameters to be tested are listed in Table 3.

TABLE 3: INSTALLATION QUALIFICATION

- Verification that the correct operating system (incl. version and service package) is installed.
- Verification that the software controls the analytical instrument.
- Verification that the measuring signal(s) is (are) transferred to the software.
- Verification of the correct function of the user management.

Level III. Qualification of the software functionality

The proper function of the software should be checked by testing the performance of key functions like calibration and quantification (internal standards, external standards), peak identification, and calculation of system suitability parameters.

Ideally, a raw data set can be used for which the results are known. These raw data sets are often provided by the vendor of the software. These raw data sets are processed by the software and the results are then compared to the expected values.

If no such data sets are available, example raw data sets can be acquired by running typical samples. The results of the processed raw data sets should be verified by recalculating the key parameters (e.g. calibration curves from peak areas of standards) using standard spreadsheet software.

Level III Qualification should be repeated after installation of new software modules, new software versions, new service packs, patch updates, or after major changes in the software structure of the computer (e.g. new Anti-virus software). Analogous behaviour should be applied for every change in hardware platform.

Level IV. Suitability for specific test procedures

In connection with the validation of an analytical procedure, calculations performed by the software of the relevant computerised system should be checked. Special emphasis should be placed on grouping of data and statistical analysis of the results. In many new software programs it is possible to implement user-defined calculations and control fields. The proper function of these parameters has to be checked by example calculations. These user-defined calculations should be locked or password protected to prevent overwriting.