Annex 11 Gap Analysis

MALVERN MASTERSIZER 3000
Annex 11 – Computerised Systems - Gap Analysis

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1.1   Regulatory Requirements computerised systems (Annex 11)

Annex 11 Section	Possible Interpretation	Is this met?	Comment
1	Personnel: Appropriate training should be provided to people in responsible positions who manage computerized systems	N - User Procedure Required	The user must put in place appropriate training procedures for Mastersizer 3000. Guides are available from Malvern explaining the security and electronic signature functions available in the Mastersizer 3000 software. In addition, training courses covering the general use of the Mastersizer 3000 system are available.
2	Validation: required as part of the lifecycle of the computerized system.	N - User Procedure Required	It is the customer's responsibility to assess the requirements for validation based on the intended use of the Mastersizer 3000 system. However, Support from Malvern is provided through the provision of Mastersizer 3000 system Installation (IQ) and Operational Qualification (OQ) procedures. Test scripts are also available to aid validation of the system's security and electronic signature functions.
3	System: Attention should be paid to the siting of equipment	N - User Procedure Required	Malvern provides a site requirements summary for the Mastersizer 3000 system. However, the system user needs to consider the risks associated with the siting of the computer equipment used to operate the system.
4	A written detailed description of the system should be produced (including diagrams as appropriate) and kept up to date. It should describe the principles, objectives, security measures and scope of the system and the main features of the way in which the computer is used and how it interacts with other systems and procedures.	Y	Regularly updated manuals describing the Mastersizer 3000 system, accessories and software are available. In addition, guides are available from Malvern explaining the security and electronic signature features included within the Mastersizer 3000 software.
5	The system software should be produced in accordance with a system of Quality Assurance.	Y	Malvern operate a ISO9001:2000 business management system. This includes a Software Codes of Practice guide which describes the requirements for software development, testing and deployment.

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6	The system should include, where appropriate, built-in checks of the correct entry and processing of data.	Y	The Mastersizer 3000's measurement SOPs enforce a robust record creation sequence, ensuring data is collected following the correct process.
7	Before a system using a computer is brought into use, it should be thoroughly tested and confirmed as being capable of achieving the desired results.	Y	IQ / OQ procedures are available to validate that the Mastersizer 3000 system performs as designed following installation. In addition, test scripts are available to aid validation of the system's security and electronic signature functions.
8	Data should only be entered or amended by persons authorized to do so.	Y	The Mastersizer 3000 software is provided with a security layer which can be used to assign Windows users to different roles within the software. The roles can be set to ensure only authorized users have the ability create. edit or delete records. Role definitions are configured using the Malvern Access Configurator (MAC) application, which is provided with the Mastersizer 3000 software.
9	When critical data are being entered manually (for example the weight and batch number of an ingredient during dispensing), there should be an additional check on the accuracy of the record which is made. This check may be done by a second operator or by validated electronic means.	Y (see note)	Primary data collection and analysis is carried out without user intervention within the Mastersizer 3000 analysis. Analysis and other method parameters can be stored electronically with Mastersizer SOPs, ensuring accurate recall during the creation of new records. The software's security system can also be configured to ensure that only authorized users can change these SOPs. However, the entry of sample identifiers, such as sample names and batch numbers, is the user's responsibility. Malvern do not currently provide any electronic means in the to cross validate such data entries. Validation by a second operation may be deemed necessary, dependent on the criticality of this data.
10	The system should record the identity of operators entering or confirming critical data.	Y	The name of the user / operator is stored against any electronic record created within the Mastersizer 3000 software. In addition, an audit trail tracks the identity of any users who change records.
10	Authority to amend entered data should be restricted to nominated persons.	Y	The Mastersizer 3000 software is provided with a security layer which can be used to assign specific Windows users to different roles. Role definitions are configured using the Malvern Access Configurator (MAC) application, which is provided with the Mastersizer 3000 software.
10	Any alteration to an entry of critical data should be authorized and recorded with the reason for the change. Consideration should be given to building into the system the creation of a complete record of all entries and amendments (an "audit trail").	Y	The Mastersizer 3000's security system can be configured to ensure that only authorized users can enter critical data. In addition, any changes made to electronic records are audited, with a reason for the change being requested when a change is applied.

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11	Alterations to a system or to a computer program should only be made in accordance with a defined procedure which should include provision for validating, checking, approving and implementing the change. Such an alteration should only be implemented with the agreement of the person responsible for the part of the system concerned, and the alteration should be recorded. Every significant modification should be validated.	N - User Procedure Required	Control of the installation and update of the Mastersizer 3000 software is the responsibility of the user. However, Malvern apply standard Windows authorization rules, such that the software can only be installed by users who are recognized to hold local administrator rights on the host PC.
12	For quality auditing purposes, it should be possible to obtain clear printed copies of electronically stored data.	Y	The data held in electronic records within the Mastersizer 3000 software can be printed using user-defined reports. In addition, data held in the software's audit trails can be printed for review.
13	Data should be secured by physical or electronic means against wilful or accidental damage.	N - User Procedure Required	The Mastersizer 3000's security system can be configured to prevent record deletion from within the application. However, the user's local IT department needs to secure the host computer operating system against wilful damage to electronic records. Other controls against physical damage are also the responsibility of the user.
13	Stored data should be checked for accessibility, durability and accuracy. If changes are proposed to the computer equipment or its programs, the above mentioned checks should be performed at a frequency appropriate to the storage medium being used.	N	All stored data can be reviewed using the Mastersizer 3000 software. This includes backward compatibility for viewing of electronic data created using older software versions. The validity of any data, including audit trail data, is also tested using checksums, such that any unauthorised modification of records can be tracked. However, Malvern does not provide an archiving system. The requirements for long-term data storage therefore need to be met by the user's IT department.
14	Data should be protected by backing-up at regular intervals. Back-up data should be stored as long as necessary at a separate and secure location.	N	Malvern does not provide an archiving system. This requirement needs to be met by the user's IT department.
15	There should be available adequate alternative arrangements for systems which need to be operated in the event of a breakdown. The time required to bring the alternative arrangements into use should be related to the possible urgency of the need to use them. For example, information required to effect a recall must be available at short notice.	N - User Procedure Required	This is the user's responsibility. However, the Mastersizer 3000 software is configured such that the measurement procedures / SOPs developed using one system can be used on another system if required. This aids users in putting in place coverage for breakdowns. In addition, service contracts are available from Malvern to help with maintenance planning and timely fault resolution.
16	The procedures to be followed if the system fails or breaks down should be defined and validated. Any failures and remedial action taken should be recorded.	N - User Procedure Required	As for (15) above.

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17	A procedure should be established to record and analyze errors and to enable corrective action to be taken.	Y	The Mastersizer 3000 software includes error logging and data quality assessment tools, to aid with fault resolution and the definition of corrective actions.
18	When outside agencies are used to provide a computer service, there should be a formal agreement including a clear statement of the responsibilities of that outside agency.	Y	Malvern's responsibilities in providing the Mastersizer 3000 software are outlined in the software End User License Agreement. This is provided on the software CD-ROM. In addition, details for Malvern's responsibilities are provided within the conditions of sale for the Mastersizer 3000 system. The management of the computer system upon which the software is operated is the responsibility of the user and their IT department. However, Malvern offers guidance as to how the system can be best configured, including the provision of guides relating to the use of the electronic records and signatures control functions within the Mastersizer 3000 software.
19	When the release of batches for sale or supply is carried out using a computerized system, the system should allow for only a Qualified Person to release the batches and it should clearly identify and record the person releasing the batches.	Y	The Mastersizer 3000 software provides an electronic signature function, which may be used to track the reviewing and sign-off of electronic records. When a signature is requested, the user is prompted to authenticate and the time & time is recorded. Users can provide a reason for a signature as a free text string. Authorized users (set up within the Malvern Access Controller application) can lock a record following the application of their signature.