A Review of Medical Device Quality System Controls for Laboratory Testing Equipment

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Introduction:

The FDA's Medical device 21 CFR 820 Quality System Regulation has multiple parts, including a subpart dedicated solely to equipment and facilities controls. For example, equipment and facilities controls include machines such as universal mechanical testing equipment for validation testing of medical devices. For medical device manufacturers, it is imperative that laboratory controls for equipment validation, equipment maintenance, results management, and standard operating procedures (SOPs) are met and maintained. The purpose of this review is to discuss laboratory controls pertaining to materials testing equipment.

Laboratory Controls:

An overview of laboratory equipment controls for materials testing equipment can be broken down into the following categories: equipment validation, method validation, and results management.

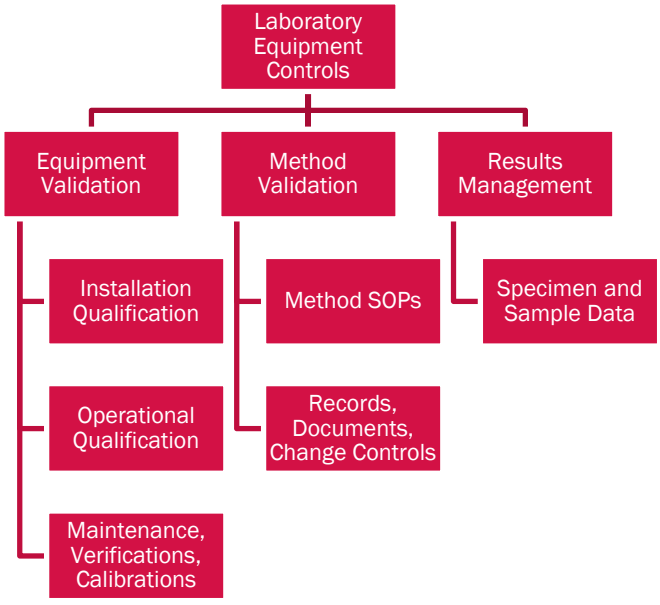

Figure 1: Outline of laboratory controls for universal materials testing equipment

Equipment Validation:

Equipment validation per FDA 21 CFR 820.72 is done to ensure that a particular piece of equipment is suitable for its intended purpose and is capable of producing a valid result.

Installation Qualification (IQ):

An installation qualification process is designed to establish that the system has been installed correctly. This documentation should include factual information such as installation conditions, operational safety features, all system manuals, environmental conditions, and all information on proper training and maintenance of the equipment.

Operation Qualification (OQ):

An operation qualification process is designed to verify the proper operation of the testing system and its ability to produce valid results. A validation plan should include a functional check of the software to validate all necessary measurements and calculations. Instron Professional Services group provide on-site support of IQ/OQ documentation for a variety of test types including tension, compression, and flexural testing and validation of a variety of calculations within Instron's Bluehill® 3 Software.

Maintenance, Verification, Calibration:

Equipment maintenance is typically outlined in a manual provided by the equipment supplier. Maintenance can be as simple as machine cleaning and proper equipment storage to more complex tasks such as transducer verification and calibration. Verification and calibration services are often available through the equipment supplier and can include force, strain, speed, displacement, etc. It is imperative that medical device companies perform routine verification and calibration in order to confirm the accuracy of the system's measurements. Typically verifications should be performed by the equipment supplier at least once a year. If the equipment is moved, the system should be re-verified. The main objective of preventive maintenance, verification, and

calibration is to ensure and maximize the performance of the testing equipment.

Method Validation:

After a materials testing machine is installed, IQ and OQ are completed, and all necessary verifications and calibrations are performed, many medical device companies assess the equipment's performance qualification (PQ). Performance qualification is often a specific qualification that requires identification of specific tests, calculations, and results. As part of the PQ and method validation, companies will create test method standard operating procedure (SOPs) and use a quality system to track revisions of this test method SOP.

Method SOPs:

Many medical device companies require their equipment operators to abide by a testing procedure that is clearly outlined in a SOP. While SOPs will vary, Instron has found that utilizing the security features and prompted test feature in Instron's Bluehill Software aids in the SOP process. Setting security features in the software enable a user to log into the software at the operator, manager, or administrator level. At the operator level, the user may not have the ability to delete or modify test specimens while an administrator has full control. Prompted test methods ensure that an operator performs a specific step before moving onto the next step in the testing procedure. For example, the operator could be prompted to enter specimen information such as dimensional measurements and batch identification before being instructed to load a specimen into a grip or fixture for testing. Instron offers guidance to customers regarding best practices but often writing SOPs and tracking revisions of SOPs is the responsibility of the medical devices quality system.

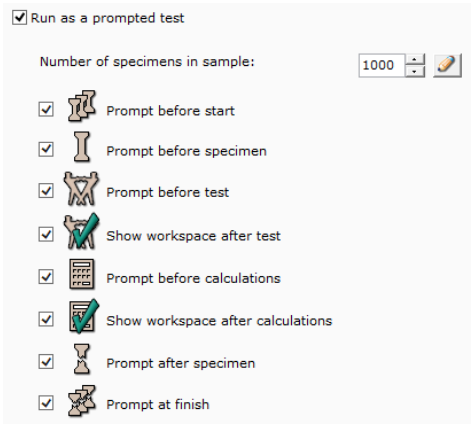

Figure 2: Example of a prompted test sequence that can be incorporated into any test sequence

Records, Documents, and Change Controls:

While it is critical to have established SOPs for documenting an operator's process to acquire data, it is also critical to maintain all records and changes associated with data to produce an audit trail. Most data obtained using materials testing equipment is stored electronically and thus must comply with FDA Title 21 CFR Part 11 on electronic records and electronic signatures. Instron partners with a third-party company to provide users with either a stand-alone or network solution for managing electronic records that is integrated with Bluehill Software. Using this tool, previous versions of Instron data, sample or method files can be restored and an audit report can be generated with all file modifications. For example, a lab manager can prove to an FDA auditor that a method for testing specimens has not been modified outside of the SOP by pulling up a trail of all additions, modifications, and deletions occurring since the method was first created. If a change does need to be made, the tool enables users to add a note to describe why the change was made along with their electronic signature.

Results Management:

Medical companies may use test data for a variety of different applications, i.e. pass/fail criteria or to ensure that a product is within a measurement range. Often companies export data from their materials testing machine into Excel or Minitab to perform data analysis. In addition to exporting data for post-test analysis, many companies use control charts built into Bluehill Software to examine a particular result throughout a test. This is helpful to get a picture of product variation and alert the operator if a material is out of a lower or upper acceptance range.

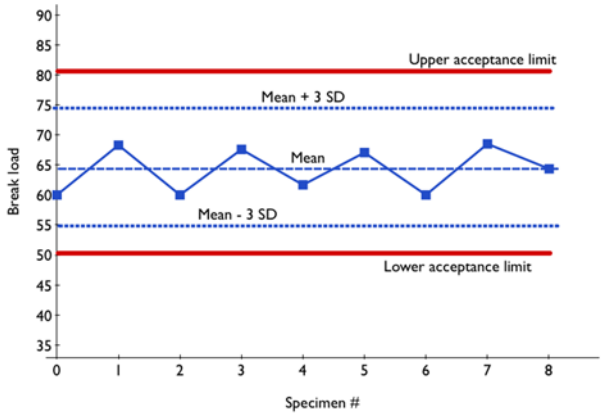

Figure 3: Example of a control chart in Bluehill 3

In addition to exporting data for post-test analysis, many labs will generate reports to track product quality over time. This

is key for medical device companies to ensure all sources of error such as lab environment, equipment, operators, and product variability are properly understood. Over the years, Instron has witnessed a variety of different ways medical device companies' share and report data internally. When one product needs to undergo multiple tests, one of the most common approaches is to use Bluehill's Application Programming Interface (API) to program an automatic export of results from Bluehill to the company's own LIMS database. Doing this enables labs to compare data acquired from materials testing equipment with data obtained from other laboratory equipment.

Another approach commonly used when product batches are tested between multiple labs or multiple operators is to use Bluehill's built-in database, TrendTracker™. Using TrendTracker, users can export Bluehill data from one or multiple materials testing machines to a company SQL Server maintained by the IT department. Using the TrendTracker viewer, companies can track sources of error in data and product variability across multiple materials testing machines and labs.

Conclusion:

In summary, laboratory controls for materials testing equipment can generally be broken down into equipment validation, method validation, and results management. For medical device manufacturers, it is imperative that laboratory controls for equipment validation, equipment maintenance, results management, and standard operating procedures (SOPs) are met and maintained.