VAISALA / APPLICATION NOTE

How to create a compliant validation program for your blood bank

All blood banks need to perform thermal mapping as part of a quality management system that adheres to ICH Q8, ICH Q9, ICH Q10, GAMP_ 5 and PIC/S. So that your validation standards comply with the relevant regulatory requirements, this application note will cover the basic steps to ensuring that your validation records are always ready for close scrutiny by state and nation regulatory and accreditation bodies.

Objective-based Validation

It is important to understand the basics of good validation before you create a validation plan/ policy for your blood bank. A true validation method is more involved than a verification of the temperatures in a given area. Validation needs to:

- Identify the operating conditions of an area or equipment
- Demonstrate repeatable results
- Understand the entire environment or process being validated
- Establish protocols for re-validation, including methods, personnel that will execute, and equipment used

Types of Validation

There are three types of validation; the Installation Qualification (IQ), the Operational Qualification (OQ), and the Performance Qualification (PQ). The IQ shows verifies correct installation. Basic objectives and elements of IQ testing include:

- hardware and software installation;
- installation conditions (wiring, utilities, network, UPS, etc.);
- sensor calibration, preventative maintenance;
- supplier documentation such as device specifications, calibration certificates, user guides and administration manuals;
- software and hardware documentation;
- compliance with regulatory requirements such as 21CFR part 11

To ensure that a newly installed refrigerator stays within the acceptable temperature range— 1...6º C—it must be mapped before use with sensors placed throughout. Test runs can go from 24-72 hours but should show that the refrigerator will maintain acceptable, uniform temperatures at all times. As an example, many blood banks perform an installation qualification over 72 hours, then revalidate every 6 months over 24 hours.

For the OQ phase of validation, you will test your fully deployed system to ensure that your storage area operates within anticipated conditions. You should include a “worst case scenario” in these tests, such as power outage or network interruptions during an alarm. Other OQ considerations include:

- alarm functions via different notification modes (visual, audible, email, phone) if applicable;
- environmental threshold and limits;
- configuration of sensors;
- training for users and administrators and system access/permissions;
- device maintenance and calibration and/or software updates;

- backup and recovery of records for compliance/audit trail.

performance qualification considerations include:

- testing the software within the parameters established during the OQ;
- confirming all OQ processes;
- confirming repeatability of results in mapping studies.

Creating a Master Validation Plan

Your master validation plan needs to include all documents connected to the validation equipment, including user and administration guides, protocols, (if provided), and calibration certificates and plans. Also include documentation of the training completed by any staff that will perform validation. Ensure that you that have a system for identifying each unit – refrigerators, coolers, freezers – to make your re-validation records consistent.

Temperature records must be backed up and gap-free to ensure that GxP relevant documentation on conditions is always available. Ideally, your system will guarantee data integrity with redundancy by storing data in multiple locations to make it immune to network or power failures. In a "worst case" part of your validation protocol, include a restoration procedure for data. In the event that data recovery is required, document the process and include maintain a record.

An effective validation study will help you determine the maximum number of products your storage units can hold and maintain acceptable temperatures. (IE: minimal load, maximal load without withdrawal and Maximal load with withdrawals every two hours). For transport equipment, you need to determine maximum duration of storage, according to the number of stored units. Note that coolers are considered "storage" rather than transport devices, (see 21 CFR 600.15-a); therefore, a recommended maximum temperature for each type of component should be set and an appropriate amount of coolant should be determined for each possible number of components.

Basic Validation/Mapping

When creating a validation protocol, consider how the equipment will be used. For instance, will the container be opened often during certain times and not at others? You'll need to validate under all operating conditions. The number of sensors you use to validate the refrigerator, freezer or cooler will depend on its dimensions and intended use. At a minimum, you should have a sensor at all four corners of the unit, top and bottom levels, as well as at the centers of each shelving row (where applicable). For long-term storage units, place sensors at areas of concern, such as cool air delivery points, near seals and any areas with restricted air flow, etc.

A data collection interval of every 5 minutes should be sufficient. After the study is complete, download the loggers to a PC to create graphs and tabular reports. Once your initial validation is completed, a careful analysis of the data will help to determine any hot or cold spots where you should place static sensors for continual monitoring. Record where sensors are placed to ensure that future validations are consistent.

Your written procedures should specify the frequency of re-validation for all equipment, and include worst case scenarios (failures such as coolants melting to quickly) with corrective actions, methods for storing and backing up records, and all required documentation, including calibration plans for equipment and training details for personnel who will execute validation.

References and Further Reading

International Society for Blood Transfusion "ISBT Guidelines for Validation of Automated Systems in Blood Establishments" published February 2010; accessed online September 15, 2010 http://onlinelibrary.wiley.com/doi/10.1111/j.1423-0410.2009.01287.x/pdf

"New York State Council on Human Blood and Transfusion Services: Guidelines for Remote Blood Storage" accessed online September 15, 2010 http://www.wadsworth.org/labcert/blood_tissue/pdf/GuidelinesRemoteBloodStorage.pdf

FDA Blood Proposed & Final Rules http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ActsRulesRegulations/BloodProposedFinalRules/default.htm

See also: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/default.htm

Draft Guidance for Industry - Part 11, Electronic Records; Electronic Signatures — Scope and Application http://www.veriteq.com/download/fda_guidance-for-industry_Part11.pdf

Summary (merged document) of 21 CFR and CLIA regulations: http://www.veriteq.com/download/21CFR_FDA_CLIA_Regs.pdf

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