

AABB Standards

3.2.2 Operational Qualification

The functionality of each piece of equipment and each component of a computer system shall be verified before actual use, and shall meet the manufacturer's operational specifications.*

*FDA Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility (April 2013)

3.2.3 Performance Qualification

The BB/TS shall demonstrate that equipment performs as expected for its intended use. Performance specifications established by the manufacturer shall be met.

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G Thomas



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