

**CHANGES TO AATB STANDARDS FOR TISSUE BANKING**  
**14<sup>th</sup> Edition**

**SECTION J**  
**GENERAL OPERATIONS**

*Current (14<sup>th</sup> Edition)*

**J5.000 Equipment and Instruments**

**J5.300 Qualification and Maintenance**

Equipment, instruments, apparatus, gauges, and recording devices *shall* be *qualified* and routinely calibrated, maintained, inspected, monitored, cleaned, *decontaminated, sterilized* (when applicable), and repaired at appropriate intervals in accordance with the *SOPM* and established equipment schedules. Calibration procedures *shall* include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there *shall* be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on *quality*. Where appropriate, *tolerance limits shall* be specified.

**J5.310 Requalification/Recalibration**

Following repairs and system upgrades, equipment *should* be requalified or recalibrated according to procedures in the *SOPM* that have been designed to be in compliance with the manufacturer's requirements and recommendations.

*With Amendments*

**J5.000 Equipment and Instruments**

**J5.300 Qualification and Maintenance**

~~Equipment,~~ Instruments, apparatus, gauges, and recording devices *shall* be ~~qualified~~ *calibrated or verified* and routinely ~~calibrated,~~ maintained, inspected, monitored, cleaned, *decontaminated, sterilized* (when applicable), and repaired ~~at appropriate intervals in accordance with the SOPM and established equipment schedules~~ *per the manufacturer's requirements and recommendations*. ~~Calibration procedures shall include specific directions and limits for accuracy and precision.~~ When ~~equipment, instruments, apparatus, gauges, and recording devices~~ *accuracy and precision limits* are ~~not met~~ *found out of tolerance*, there *shall* be provisions for remedial action ~~to reestablish the limits and~~ to evaluate whether there was any adverse effect on *quality*. ~~Where appropriate, tolerance limits shall be specified.~~

**J5.310 Requalification/Recalibration**

Following repairs and system upgrades, equipment *should* be ~~requalified or~~ *recalibrated or verified* according to procedures in the *SOPM* that have been designed to be in compliance with the manufacturer's requirements and recommendations.

*As Amended*

**J5.000 Equipment and Instruments**

**J5.300 Qualification and Maintenance**

Instruments, apparatus, gauges, and recording devices *shall* be *calibrated or verified* and routinely maintained, inspected, monitored, cleaned, *decontaminated, sterilized* (when applicable), and repaired per the manufacturer's requirements and recommendations. When equipment, instruments, apparatus, gauges, and recording devices are found out of tolerance, there *shall* be provisions for remedial action to evaluate whether there was any adverse effect on *quality*.

**J5.310 Requalification/Recalibration**

Following repairs and system upgrades, equipment *should* be recalibrated or *verified* according to procedures in the *SOPM* that have been designed to be in compliance with the manufacturer's requirements and recommendations.

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