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Transport and Storage Coolers used in Blood Banks

Tips, Helpful Ideas & Reference Information

This is some information you may find helpful regarding cooler documentation and validation procedures in the blood bank. Those items not referenced are shared recommendations compiled from various online forums with blood bank professionals and customer feedback.

Equipment considerations

- Routine cleaning and inspection of coolers should be written into procedure and at the minimum be in accordance with manufacturer's instructions. For example, cleaning and visually inspecting a cooler each time it is returned to the blood bank.
- The use of a temperature recorder to collect temperature and time data during cooler validations is recommended because an electronic as well as a print record may be generated. Additionally, the use of a data logger makes cooler validation more efficient, eliminating the requirement for someone to take the time to manually record information during validation.
- Temperature recorder placement is somewhat variable in regards to how the units of blood are packed in the cooler (ie. Stacked or side by side). It is recommended, however that the temperature recorder be positioned in the outer most units for the validation. The method of temperature recorder placement needs to be consistent and written into the procedure accordingly.
- Recalibration of the temperature recorders should be performed annually following the manufacturer's instructions.
- If equipment performance (including validation) is in question, appropriate follow-up should be performed and documented (3.5.2 *Technical Manual*[1]) and remedied before being put back into service.
- Validation of every cooler should be done before its initial use.
- If using many coolers, a rotation for their validation will be helpful, such as a quarterly validation schedule for a set of coolers.
- Staff should be deemed "competent" to perform validation of a cooler having completed appropriate training.

Courtesy of William Laboratories, Inc. Manufacturer of *Safe-T-Vue®* & *Trans-Vue™* Non-Reversible Temperature Indicators.
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Documentation considerations

- Keeping up to date, accurate documentation is imperative and also a challenge in today's busy environment. Consider starting a QC manual which includes all the pertinent information necessary for various validations and procedures.
- Check back with www.williamlabs.com frequently for any updates in validation procedures and other helpful publications for blood bank professionals.

Listed below are Standards pertinent to this Validation procedure and the length of time recommended by the American Association of Blood Banks to keep the paperwork associated with each standard. The information comes from the Reference Standard 6.2C from AABB *Standards*[2].

[2]Standard	Record to be Maintained	Minimum Retention time (yrs)
3.3	Equipment Validation	10
3.4	Unique identification of equipment	5
3.5	Monitoring and maintenance of equipment	10
5.1.8.1.2	Records of storage temperatures for blood products	5
5.1.8.2.1	Container qualification and process validation records	5
6.1.3	Review and approval of new and revised documents prior to use	5

References

[1] *American Association of Blood Banks,* **Technical Manual** (16th ed.) *'Tech Man'*

[2] *American Association of Blood Banks,* **Standards for Blood Banks** (27th ed.) *'Standards'*