

Helpful Tips:

Transport and Storage Coolers used in Blood Banks

Ideas & Reference Information Regarding Cooler Validation and Documentation

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.
- Recalibration of temperature recorders (dataloggers) shall be performed annually following the manufacturer's instructions.
- If equipment performance (including validation) is in question, appropriate follow-up should be performed and documented (Technical Manual¹) 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 may be helpful (validate a set of coolers quarterly).
- Staff should be deemed "competent" to perform validation of a cooler having completed appropriate training.

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.zebra.com/valasure frequently for any updates in validation procedures and other helpful publications for blood bank professionals.
- Validation protocols found on www.zebra.com/valasure can be modified to fit your facility's needs simply 'cut and paste' into your SOP specifications.

Listed below is a listing of 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 from AABB Standards².

Standard	Record to be Maintained	Minimum Retention Time (years)
3.3	Equipment Validation	10
3.4	Unique identification of equipment	5
3.5	Monitoring and maintenance of equipment	10
5.1.8.2	Records of storage temperature 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

¹American Association of Blood Banks, Technical Manual ‘Tech Man’

²American Association of Blood Banks, Standards for Blood Banks ‘Standards’