Refrigeration Guidelines

Requirements for the Storage of Blood, Blood Products and Tissue for DHB Blood Banks

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NZBLOOD
Te Ratonga Toto O Aotearoa

Contents

Section 1 - Introduction

These 'Refrigeration Guidelines' were written in response to requests for help in understanding the requirements and routine application of **Australian Standard AS 3864 '*Medical refrigeration equipment – for the storage of blood and blood products*** and the NZBS requirements for storage of blood, blood products and tissue.

Whilst this document provides a summary of, and information supporting the interpretation of standard AS 3864 Part 2: User-related requirements for care, maintenance, performance verification and calibration, it is primarily intended as an educational tool and **should** not be used in isolation from the original standard which **should** be referred to when more detailed (or definitive) information is needed.

It is important to understand that AS 3864 is a standard for the construction, performance and maintenance of blood storage refrigerators and plasma storage freezers. It does not specify standards for platelet incubators or ultra-low freezers used for tissue storage. It does not set the standards for blood component and tissue storage temperatures. Blood component and tissue storage temperatures are specified in the NZBS Manufacturing Standards and are based on EDQM recommendations[1] [,2].

NZBS requires that blood and blood products provided to hospitals and other healthcare providers are stored in equipment (either standalone 'reach-in' cabinets or walk-in rooms) specifically designed for this purpose and which conform to standard AS 3864. This applies not only to all blood banks but also the external locations that they supply within their hospital campus(es), other DHB locations and private healthcare facilities. Please note that compliance with the standard is the responsibility of the organisation which owns the equipment.

There are no specific standards for tissue freezers and it is acknowledged that standards and specifications for -30°C freezers cannot always be applied to ultra-low freezers. However, where possible, NZBS applies the broad principles of AS3864 to freezers used to store tissue.

All new refrigeration equipment **shall** conform to the current version of AS 3864. At date of issue of these guidelines the current version is AS 3864:**2012**. When purchasing any new refrigeration equipment or making any significant changes the local NZBS Quality personnel (e.g. the regional NZBS Quality Systems Associate) **should** be approached for advice as to suitability and validation requirements.

NZBS welcomes feedback regarding the content or application of these guidelines and this **should** be sent to:

Director Quality and Regulatory Affairs
New Zealand Blood Service
Private Bag 92071
Victoria Street West
Auckland 1142

[1] Guide to the preparation, use and quality assurance of blood components. EDQM (Council of Europe Publishing). Published biennially.
[2]Guide to the quality and safety of tissues and cells for human application. EDQM (Council of Europe Publishing)

Section 2 - Terminology

For the purposes of these guidelines the following terminology is used:

- The term **shall** indicates a mandatory requirement as either explicitly stated in the original standard or arising from accepted NZBS practice when applying the standard.
- The term **should** implies a recommendation where guidance is intended and does not preclude other acceptable practices.
- The term **may** is used to indicate an acceptable alternative or addition to the prescribed practice.
- The term **Working Thermometer** refers to thermometers or temperature probes in regular use which have been calibrated against a reference thermometer and are therefore traceable to the National Standard.
- The term **Reference Thermometer** is more difficult to define. Reference thermometers have a higher degree of sensitivity and accuracy than working thermometers and will usually be calibrated at several points. The calibration must be traceable to a national standard. In general, the uncertainty of calibration of the reference thermometer **should** be a factor of 5 smaller that than the uncertainty of calibration required for the working thermometer. For example, if an uncertainty of the working thermometer is +/- 0.5°C, than the uncertainty of the reference thermometer **should** be +/- 0.1°C or better. Refer to the following publications for more detailed technical information:
    - IANZ technical guide on working thermometer calibration procedures available at www.ianz.govt.nz
    - *Traceable Temperatures* by JV Nicholas and DR White. 2nd ed, Wiley.

Section 3 - General Requirements

Blood, blood products and tissues **shall** be stored so that air can freely circulate throughout the refrigerator or freezer. Interiors **should** be clean, well organised and adequately lit.

Although not recommended practice, it is accepted that equipment storing blood and blood products **may** also be being used to store (for example) donor samples, patient blood samples, blood testing reagents and other medicines. In doing so the following conditions **shall** be met:

Blood components, blood products and tissues **shall** be stored in a separate, clearly designated area.

- ✓ Samples, reagents and other materials **shall** be physically segregated from the blood, blood products and tissues to ensure that there is no possibility of adverse contact or interaction.
- ✓ Blood, blood products and tissue **shall** always be stored above any other items.
- ✓ Food or drink **shall** not be stored with therapeutic products.
- ✓ Other products e.g. anti-D, hepatitis B immunoglobulin **may** be stored in a blood refrigerator as long as the manufacturer's instructions allow for storage at 2 - 6°C.

Equipment used to store blood, blood products and tissues away from the blood bank e.g. in theatre, Emergency Department, satellite hospitals **shall** meet the same standards as those for blood bank.

Note: Some fractionated product **may** be stored in a validated storage system that meets Ministry of Health (MoH) requirements for vaccine storage. These systems are not covered by these guidelines. The MoH Immunisation Handbook provides details of cold chain storage management of vaccine fridges.

The NZBS Quality Team should be contacted about suitability of equipment prior to purchase. New equipment **shall** be validated before use to confirm it functions correctly. NZBS can provide validation protocols. All validations **shall** be reviewed for acceptance by the NZBS Quality Team prior to commencement of storage of blood, blood products or Tissues. The NZBS can be contacted for advice if required.

The NZBS **shall** be contacted via the local Quality personnel to inform of any significant change including equipment relocation and any significant maintenance/repair.

Location and Power Supply

Refrigeration equipment **shall** be located where it is not readily accessible to unauthorised persons and **shall** be secure from tampering.

The manufacturer's instructions regarding the placement of the equipment (e.g. distance from walls, adequate room ventilation) **shall** be followed.

Refrigeration equipment **should** be connected to the hospital's 'essential power supply' (e.g. with back-up generator) if it has one. If this is not available, a suitable uninterruptible power supply (UPS) **should** be used. This **should** ensure that the equipment continues to operate during a mains power outage.

Monitoring of Conformance

Conformance to the requirements of NZBS and the relevant standard(s) will be monitored through NZBS and/or IANZ audits and/or the shipping site. Where blood is on-shipped by a non-NZBS Blood Bank the responsibility for monitoring conformance with requirements rests with the shipping site. Refer Section 7.

Non-conforming Equipment

Any blood, blood products or tissue stored in nonconforming equipment or where there is any doubt regarding the conditions of storage or transport **shall not** be used for transfusion. Any such products **shall** be held in secure quarantine until a decision regarding their fate is made.

Maintenance, Calibration and Servicing

The owner of the refrigeration equipment is responsible for its maintenance and calibration and keeping records of these activities.

Equipment **shall** be regularly tested at appropriate intervals (as defined later in this document). Additional testing is required when equipment is moved, has had any repairs or maintenance work or has suffered a mechanical or electrical failure. Refer to section 5.

There **shall** be documentary evidence of temperature monitoring (including alarm systems), performance checks, calibration and maintenance programs. Any problems **shall** be promptly detected and dealt with in a timely fashion.

Calibration should be done by an accredited calibration provider or in-house using a reference thermometer traceable to a national standard of temperature and **shall** cover a temperature range appropriate for the temperature(s) being measured.

Older equipment **should** be monitored closely for signs of deterioration and replaced before failing completely. It should be noted that NZBS is not able to supply replacement refrigeration equipment and contingency plans for blood/tissue storage **should** be in place in the event of equipment failure.

Section 4 - Storage Temperatures

Blood Product/Tissue Storage Temperature and Alarm System Requirements

It is important that blood, blood products and tissues are stored at the temperature specified on the product label or packaging. The required storage temperatures are as follows:

Product	Storage Temperature
Red Cells	2°C to 6°C
Platelets	20°C to 24°C (with gentle continuous agitation)
Fresh Frozen Plasma	- 25°C or below
Cryoprecipitate	- 25°C or below
Serum Eye Drops	- 25°C or below
Tissue	- 20 to -40 (Max 6 months), -40°C or below (5 years).
Cryopreserved Platelets	- 65°C or below
Manufactured Products	According to manufacturer's instructions

Platelets **may** be stored in any room with the appropriate ambient temperature (20°C to 24°C). However, where platelets are being regularly stored as inventory it is preferable that they be stored in platelet 'incubators' which provide a controlled temperature environment (20°C to 24°C with gentle continuous agitation) and a temperature recording chart.

If during storage any blood, blood product or tissue reaches a temperature outside of specification it **should** not normally be used for transfusion. Any such occurrences **shall** be clearly documented and the product held in quarantine until a decision is made regarding its fate.

Temperature Recorders

To ensure correct storage temperatures are maintained equipment temperatures **shall** be monitored by a temperature recorder (either a chart recorder or a digital recorder). This **may** be integral to the equipment cabinet or remotely located and **shall** be secure from tampering.

Recorders requiring mains power **should** be linked to a secure power supply or alternatively be able to operate for 24 hours without mains power.

Temperature Recorder Chart

- ✓ **Shall** have continuous temperature recording with 7 days of recording externally visible. Circular charts are recommended. Fan fold charts **shall** not be used as these are known to be unreliable, difficult to read and are not compliant with AS3864.
- ✓ **Shall** have a temperature span and accuracy as follows:

Equipment Type	Chart Temperature Span	Accuracy
Refrigerator / Walk-in type coolrooms	- 5°C to + 20°C	± 0.5°C
Freezer/ Walk-in type freezer rooms	- 45°C to -20°C	± 1.0°C

Platelet incubator	As per chart supplied with recorder	± 0.5°C
Ultra-Low Freezer	-90 °C to -50°C	± 2.0°C

- ✓ Charts **shall** be scaled at not less than 1mm/°C, with increments of no more than 2°C.
- ✓ Charts **should** have an identifying band or strip for the applicable temperature range

Electronic Temperature Monitoring Systems

Where an electronic temperature monitoring system is used:

- ✓ It **shall** be capable of producing electronic records at the rate of at least one reading per minute for the required range of operation.
- ✓ The recorded data **shall** include date and time of each reading.
- ✓ If an alarm state occurs the record **shall** include the date and time at which it occurred and when it is subsequently cleared.
- ✓ The system **shall** maintain an electronic audit trail of all manual interactions associated with it.
- ✓ The system **shall** also include a hierarchical password control to manage technical changes, management and operational use.
- ✓ The temperature recordings **may** be stored on secure electronic media e.g. magnetic tape, CD etc. and a hard copy printed when required.

Thermal Lagging of Temperature Recording Probes

Temperature recording sensors **shall** be 'thermally lagged' to simulate the thermal response of stored products. This can be achieved either by immersing the temperature probe in a suitable volume of fluid (a volume similar to, but not greater than, that of the main product being stored) or by inserting the probe into a solid aluminum cylinder (as described in AS 3864).

The response time of the probe can be made shorter by decreasing the volume of lagging used. However, delaying response time by increasing the amount of lagging used to more than the volume of the main product being stored is not acceptable.

The device that activates the compressor **shall** act independently of the temperature recorder and alarm sensors over the acceptable temperature range and **should** not be lagged.

Alarm Systems

Equipment **shall** have an alarm system which activates if the temperature falls outside the required range or if the power to the cabinet is interrupted. This can be as part of a central monitoring system or, if not, the equipment **should** have a battery-operated audible and flashing visual alarm which **shall** be audible/visible to staff at all times.

The alarm's temperature-sensing probe **should** be thermally lagged similar to temperature recording probes.

The alarm limits **should** be set as follows:

Equipment Type	Alarm Limit(s)*
Refrigerator / Walk-in type coolrooms	Lower limit: 2.5°C Upper limit: 5.5°C
Freezer / Walk-in type freezer rooms	Upper limit: -27°C

Platelet incubator	Lower limit: 20.5°C Upper limit: 23.5°C
Ultra-Low Freezer	Upper limit: -67°C

* The above limits assume uncertainty of the alarm systems to be ± 0.5°C for refrigerators / platelet incubators and ± 2°C for freezers. The uncertainty **may** however vary for individual equipment and this **shall** be considered when determining the actual limits required.

Written instructions **shall** be available explaining what to do in the event of alarm activation i.e.

- ✓ How to determine the immediate cause of the alarm. For example, the door has been left open, or the unit has recently been accessed.
- ✓ How to handle either a temporary or prolonged failure.
- ✓ A list of the key people to contact.
- ✓ How to ensure that the proper storage temperature is maintained for all products. There **should** be contingency plans available that cover alternative storage options in the event of a prolonged storage breakdown.

Platelet agitators **should** have a motion alarm that is activated should the agitator cease to operate for a period of 5 minutes or more.

Alarm systems that can be muted **shall** automatically reactivate between 15 minutes and 30 minutes (after muting) if the alarm condition still prevails.

Where the alarm system can be inactivated using a keyed switch such that it won't reactivate, the key **shall** not be left in the switch and **should** be available only to senior staff responsible for the management of the refrigerator.

Monitoring Room Temperature

If storing platelets (or other products at room temperature 20°C to 24°C) the room's temperature **shall** be continuously recorded e.g. the use of a data logger is recommended.

Temperature Fluctuations outside Specified Range

Any temperature fluctuation outside of the specified storage temperature range **shall** be recorded with a note specifying the cause of the fall or rise in temperature.

If as a result of these fluctuations any blood, blood product or tissue reaches a temperature outside of specification it **should** be held in quarantine and reported to the local NZBS logistics site. It **shall** not be used for transfusion unless authorised by an NZBS Transfusion Medicine Specialist or Medical officer.

Section 5 - Maintenance, Calibration and Servicing

Routine maintenance and calibration **should** ensure that the equipment continues to operate according to specification.

The frequencies specified below are minimum requirements but can be carried out more often especially for older equipment. Similarly, they **should** be repeated when the equipment is moved, has had any repairs or maintenance work or has suffered a mechanical or electrical failure.

Because of the work involved, maintenance and calibration of refrigeration equipment **may** be contracted (all or in part) to external refrigeration contractors or hospital service engineers. It is important that whoever undertakes these tasks is familiar with the detailed requirements of AS 3864 and that the maintenance and calibration requirements are clearly specified.

One problem that may be experienced, particularly with older equipment, is that of difficulty in accessing the temperature recording probes for the chart recorders or alarm systems. An electrical modification cited by Wenz and Owens (see references) may solve this problem.

Accuracy of Temperature Recorders

The accuracy of temperature recorders **shall** be checked on a 6-monthly basis against a calibrated working thermometer or a reference thermometer, with the aim of showing that, between (annual) probe calibrations, the chart and/or any digital readout is operating correctly. Similarly, 6-monthly alarm accuracy checks **shall** be performed.

When performing accuracy checks the temperature shown by the temperature recorder and/or alarm readout **shall** be within:

- ✓ ± 1°C of each other (refrigerator / walk-in type coolrooms / platelet incubator) if using a calibrated working thermometer. Note: this range is based on the fact that if both thermometers have an uncertainty of ± 0.5°C, one could be reading - 0.5°C and the other + 0.5°C, from the true temperature.
- ✓ ± 0.5°C of each other (refrigerator / walk-in type coolrooms / platelet incubator) if using a reference thermometer.
- ✓ ± 2°C of each other (freezers including ultra-low) if using a reference thermometer or calibrated working thermometer.

Required Tasks

It is recommended that there is a simple, general check, performed daily that equipment is operating satisfactorily e.g. check the temperature at a regular time each day and check that the temperature recording has been stable.

Similarly, the following routine maintenance, calibration and servicing tasks **should** also be performed

Immediately or as Necessary

Perform the following as soon as the need arises.

- Immediately wipe clean all spillage (of blood) and decontaminate the surface with a suitable disinfectant. After decontamination, rinse the surface clean.
- Defrost freezers in accordance with manufacturer's instructions. When manually defrosting do not use sharp instruments to remove built-up ice.

Daily

a) Inspect the visual temperature display to ensure since the last daily review that the following apply:

- The recording chart shows a clear continuous trace
- Readings reflect the correct date and time
- Readings are within the acceptable range with no unexplained spikes or dips
- Where a cabinet/room has two independent temperature sensors the readings shall be within the alarm set points. See page 8.
- There is no unexplained upward or downward trend in the temperature readings

b) Verify that any temperature deviations have been appropriately dealt with.

Weekly

Change the temperature recording chart when completed. Ensure the following are recorded on the chart

- The equipment identification
- Initials, time and date of the person changing the chart on both the old and newly replaced charts.

After changing the chart check the pen is aligned with the current day/date and time.

Monthly

All internal surfaces and door seals should be checked for cleanliness and cleaned if necessary.

Where applicable the status of the chart recorder back up battery shall be checked and replaced where necessary.

Check alarm system function and back up battery.

6-Monthly

Perform Mechanical checks as follows.

- Review temperature on monitoring system to ensure that since the last review there are no unexplained upward/downward trends.
- Chart Recorders
- Battery voltages and change as required
- Alarm and power off buttons
- Rust & corrosion
- Lights
- Clean condenser fan, coils and filter
- Evaporator – drains, fan and cleanliness
- Compressor running satisfactorily
- No visible oil leaks
- Hinges and door seals for deterioration/air leakage

It **may** be beneficial for this to be done by external refrigeration contractors (or hospital engineers if used) as part of the regular maintenance contract.

Check accuracy of temperature recorders and alarm system (see pg10).

Check the activation temperature of high and low alarm points.

Check the alarm activates when equipment power is switched off. Note: If the equipment is hard wired to the power supply, with a back-up generator, then a 6-monthly power off check is not required. However, yearly checks **should** be performed if possible.

Check the activation of internal and external alarms.

Annually

Perform a two-point calibration of the temperature recorder and alarm system e.g. at 0°C (Ice-point) and 10°C for blood fridges, -30°C and 0°C for freezer, -80°C and 0°C for ultra-low freezers. The calibration **shall** be performed against a reference thermometer traceable to national standards. The probes **should** agree within 0.5°C with a reference thermometer for refrigerators and incubators, and within 2°C for freezers

A manual activation of the alarm is required for all equipment. If the alarm can be muted, check that it reactivates within 15-30 minutes.

Check the spatial temperature distribution of the equipment's interior. This **should** be done with a product load equivalent to the maximum number of items routinely stored, using probes that are thermally lagged in a volume similar to the smallest volume of product routinely stored in the equipment.

All Spatial checks must run for a minimum period of 24 hours, within which a period of at least 8 hours of minimal disturbance must be achieved. For freezers, at least one defrost cycle should be included.
During the period of minimal disturbance *(minimum 8 hours)*, the temperature at any measuring position must be within the applicable operating temperature.

A general clean **should** be performed annually for fridges or, for freezers, when defrosted.

Any area of the equipment not meeting performance specifications **shall** not be used for storage**.**

The above list is not exhaustive. Refrigeration contractors will normally have a standard checklist for routine maintenance that includes other tasks, e.g. checking for gas leaks.

Section 6 - Record Keeping

All completed records of temperatures, maintenance and calibrations **shall** be retained for a period of time as defined by the organisation's general disposal authority.

Section 7 – Remote Refrigerators

A remote refrigerator is a blood fridge used to store red blood cells in a hospital with no on-site blood banking function. This includes hospitals where there is a small laboratory, but no blood banking is performed on site. The blood stored in these fridges is supplied by a blood bank at another hospital.

The hospital or laboratory that owns the fridge is responsible for ensuring that all the care and maintenance requirements listed in this guide are carried out.

The blood bank that supplies blood to the fridge is responsible for monitoring compliance of the fridge with AS3864 and these Refrigeration Guidelines. In addition, it is an IANZ and NZBS requirement that copies of temperature charts are obtained by the supplying blood bank to verify ongoing compliance of the fridge with the storage temperature specification.

Section 8 - References

1. AS 3864-2012: *Medical refrigeration equipment – for the storage of blood and blood products* Standards Australia
2. NZBS '*Manufacturing Standards*'
3. NZBS '*Clinical Compendium*'
4. NZBS 'Records Management Policy' (108P025)
5. *Standards for Blood Banks and Transfusion Services*
   American Association Of Blood Banks (AABB)
6. *Technical Manual*
   American Association of Blood Banks (AABB)
7. *A simplified method for monitoring and calibrating refrigerator alarm systems*.
   Wenz B, Owens RT. Transfusion 1980; **20**: 75-8.
8. *Guidelines for Pretransfusion Testing*
   Australian And New Zealand Society of Blood Transfusion (ANZSBT)
9. *Requirements for Retention of Laboratory Records and Diagnostic Material*
   National Pathology Accreditation Advisory Council (NPAAC; Australia).
10. *Guidance Notes on AS 3864 –Medical Refrigeration Equipment for The Storage of Blood and Blood Products* (*BloodSafe-IM-LR-006)*
    BloodSafe Project, ARCBS-Southern Region (Adelaide)
11. G*uide to The Preparation, Use and Quality Assurance of Blood Components*
    EDQM (Council of Europe)
12. *Thermometers Calibration Procedures (Technical Guide)*
    International Accreditation New Zealand
13. *The Blood Cold Chain. Guide to the selection and procurement of equipment and accessories.* Department of Blood Safety and Clinical Technology, World Health Organisation, Geneva

Section 9 - Summary of Quality Control, Care and Maintenance Requirements

Activity	Frequency	AS 3864 Reference(s)
Cleaning		
• Spills	• Immediately	3.8.4
• Defrost	• As necessary	3.8.5
• Internal surfaces	• Monthly – check (clean as needed)	3.5.2
• Door seals	• Monthly – check (clean as needed)	3.5.2
	6 monthly (check for deterioration/air leakage – repair/replace as necessary)	3.6.4
• Heat exchanger coils	• 6 monthly	3.6.4
• General Clean	• Annually	3.7.4
Temperature Recorder		
• Change temperature chart (If used)	• Weekly	3.4
• Check chart recorder battery (If used)	• Monthly (Change as required)	3.5.1
• Download electronic data record into archive (where required)	• Monthly (As required by system/organization)	3.8.2
• Check accuracy of temperature monitoring system (Single point calibration)	• 6 monthly	3.6.1
• Perform 2-point calibration of temperature sensor	• Annually (or when equipment is moved or receives significant repair)	3.7.2
Alarm Systems		
• Check alarm system function and back-up battery	• Monthly (change battery as required)	3.5.1
• Check alarm sensor accuracy and activation temperature(s)	• 6 monthly (or when equipment is moved or repaired)	3.6.2
• Power failure test and alarm activation	• 6 monthly	3.6.3
• Check alarm re-activation	• Annually	3.7.3
• Perform 2-point calibration of temperature sensor (if separate sensor is used)	• Annually (or when equipment is moved or receives significant repair.)	3.7.2
Operating Temperature		
• Check spatial temperature distribution	• Yearly (or when equipment is moved or receives significant repair.)	3.8.3

Notes