

Summary of changes to the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd Edition)

The following is my (Bernadette Heaphy) summary of the differences between the previous edition of the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 and the recently published 2nd edition (National Standards).

New or altered definitions:

Buffered probe
Calibration
CCA reviewer
CFA
Continuous monitoring services
Datalogger
Medicines Control
National Immunisation programme
Pharmaceutical refrigerator
Refrigerator technician
Validation

Throughout document updated sections and appendixes as required.

Throughout the document the word access has been added to download when discussing reviewing of the electronic temperature recording device, to be more inclusive to the use of continuous monitoring services, as these are accessed rather than taking the device to a port and downloading it.

Most references to NCCA have been removed and just wording around distributor logger left in the National Standards. One reference to NCCA in the Provider cold chain policy section was left in, this is an oversight.

Introduction:

Addition of detail regarding Medicines Control role.

Part 1: National Standards for Vaccine Storage and Transportation for Immunisation Providers

Standard 8 – added in that providers must *ensure that spatial logging of pharmaceutical refrigerators occurs at least every three years*. This not a new requirement, it was just not spelt out up front. Spatial logging occurs usually in line with CCA for non-community pharmacy providers and a 3 yearly (at least) for community pharmacy providers.

Inclusion of DHB 's Cold Chain Providers Non-Compliance Policy in note at end of page 3 and appropriate referral in event of non -compliance.

Part 2: Background.

2.1: Addition re Medicines Control audit responsibilities and removal of NCCA information.

2.2: inclusion of comment about temperatures at or below 0°C.

2.3: Changes to vaccine cost tables.

Part 3: Cold Chain Accreditation

Clarifying that all providers must meet CCA requirements at any time they are storing vaccines or offering an immunisation service (not just at the time of CCA assessment).

Additional information on community pharmacies and the requirement met standards as part of Licence to Operate and process for non-compliance.

All DHBs must have a Cold Chain Non-Compliance Policy, previous standards advised they would be required to create a process.

Part 4: Cold chain compliance

Some reordering of wording.

Where it is not possible for a coordinator to complete a CCC reviewer prior to a seasonal provider offering an immunisation service, the provider must complete and return the CCA self-assessment form to the coordinator for review before starting vaccinating.

Providers who have previously offered seasonal service would be expected to provide documentation from the year before.

Part 5: People

Addition of wording

All relevant clinical staff must review cold chain records prior to accessing any vaccine, to ensure vaccine thermostability.

This is to reinforce that all providers are responsible to ensure that daily checks are done and should check this prior to vaccinating.

5.1: some clarifying wording

5.2: Addition of wording in *italics*

The designated cold chain staff are responsible for:

- ensuring the daily and weekly temperature monitoring checks are undertaken and documented, *including ensuring the datalogger is rotated within the refrigerator*
- reviewing records at the end of each month to check for seasonal fluctuations and trends
- ensuring that any cold chain breaches, excursions or failures have been followed up
- ensuring all relevant clinical staff are trained on how to check and reset the minimum/maximum thermometer and how to record the minimum and maximum temperatures, and know what to do if the temperature is outside the +2°C to +8°C range
- following up privately purchased vaccine thermostability following a cold chain breach *(this should be discussed with the coordinator)*
- ensuring all relevant clinical staff know how to download/access and review the datalogger information and know the actions to take if the recordings are outside the required range
- *changing, when required, the refrigerator set point, only on advice from the pharmaceutical refrigerator technician, manufacturer or coordinator (this must be documented)*
- *ensuring the refrigerator performance and daily temperature monitoring equipment are checked for accuracy on an annual basis as part of the refrigerator service*
- *ensuring spatial logging of the provider's refrigerator occurs every three years by the coordinator.*

The final two points note the change in requirement of annual logging by coordinator to equipment accuracy being confirmed on annual basis as part of the refrigerator service and noting the minimum requirement by coordinator is the spatial log at least every three years. The annual validation at service, along with spatial log at CCA and the rotation of the datalogger through the fridge, should pick major issues with refrigerator performance.

5.3 Immunisation/cold chain coordinators new section outlining role and requirements under the National Standards for the immunisation coordinators.

Part 6:

Additional wording: *These systems and processes may also support cold chain management for the storage of other refrigerated medicines.*

6.1: Additional wording: *reviewed when the designated cold chain staff, vaccine equipment or processes change, a copy of the this should be supplied to the coordinator.*

Changes to wording but not intent to other parts of **6.1**.

6.2: Updated stock management tables. These will be updated following the schedule changes and made available via the RIAs, rather than updating the standards each time.

Change in wording. **Receiving vaccines:**

document the arrival date at the provider on the vaccine box
now

document the date the vaccines arrived at the provider on the vaccine box or have a documented system for identifying when vaccines were delivered

Wording around stock register updated. Also, requirement to log vaccines returned as a result of distribution cold chain events into providers stock system removed (as not possible in pharmacy electronic systems).

Wording changes but no intent changes in **Placing vaccine in a pharmaceutical refrigerator**.

6.3 additions of requirement to check and document refrigerator temperature in event of power failure and indication to use temperature of 7.5°C as the time to seek alternative storage to avoid breaches.

6.4 addition of Medicine Control to notes following flow chart.

Part 7

7.1 information re when fridge can be turned off.

7.2 advice re logging of new refrigerator, new minimum requirement if 24 hour log can't be done. Additional information around Continuous monitoring services and Cold room temperature monitoring (eg DHB hospital pharmacy sites).

7.3 re wording and ordering of section. Additional information about short term vaccine transport in hospital sites, single patient home visits and vaccine stored in chilly bins in clinical rooms. This is design to give flexibility to different clinical environments, while still maintaining the cold chain.

Bibliography

Updated.

Appendix updates

Appendix 1 is now Vaccine pharmaceutical refrigerator (NCCA appendix removed).

Appendix 2 is now Transporting or storing vaccine in chilly bins

Similar information and references COOL project on IMAC website.

Appendix 3 is now Dataloggers and digital minimum/maximum thermometers

Appendix 4 is now Key contacts

RIA email addresses updated, and Medicines Control contact details added.