

# COLD CHAIN TOOLKIT FOR IMMUNISATION PROVIDERS

NSW Health
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## **Cold Chain Toolkit for Immunisation Providers**

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#### **Cold Chain Toolkit for Immunisation Providers**

This toolkit is to assist all immunisation providers, health care professionals and administration staff in the safe management of vaccines. All immunisation providers must have access to the National Vaccine Storage Guidelines, Strive for 5 (3<sup>rd</sup> edition) 2019, either online or hard copy version. The Guidelines are referenced along with the NSW Health cold chain resources throughout this document

#### 1 Why is Vaccine Management Important?

Vaccines are sensitive biological substances that can become less effective or even destroyed if they are frozen, or exposed to temperatures outside the recommended range of 2°C to 8°C, and/or exposed to direct sunlight or fluorescent light. The loss of vaccine effectiveness is cumulative and cannot be reversed.

#### 2 The Cold Chain



Refer to the National Vaccine Storage Guidelines: Strive for 5 (section 2), safe vaccine storage.

The 'cold chain' is the system of transporting and storing vaccines within the safe temperature range of +2°C to +8°C to ensure the vaccines remain potent and effective.

If vaccines are stored outside of these temperatures, as may occur during a power outage or refrigerator malfunction, immunisation providers must contact their local public health unit for advice. **Refer to Section 11: Managing a Cold Chain Breach** 

#### 3 Staff Education

Vaccine management is the responsibility of ALL staff with access to vaccines. All staff should be trained to manage the cold chain including recording twice daily temperatures and downloading the data logger report and reviewing it.



From July 31 2019 practices receiving government-funded vaccines must have at least one staff member who has successfully completed the NSW Health <u>Vaccine Storage and Cold Chain</u> <u>Management</u> on-line learning module to order vaccines. It is however recommended that ALL staff complete the online learning module.

The practice must keep record of the certificate of completion of all staff that have completed the on-line learning module.

The NSW Health <u>Vaccine Storage and Cold Chain Management</u> on-line learning module is available to support staff education at https://www.health.nsw.gov.au/immunisation/coldchain/story\_flash.html

#### 4 Vaccine Refrigerators



Refer to the National Vaccine Storage Guidelines: Strive for 5 (section 3, 6 and appendix 10) for information about purpose built vaccine refrigerators

Purpose-built vaccine refrigerators (PBVR) are specifically designed to store vaccines and temperature sensitive medications and must be used to store vaccines.

Domestic fridges and bar fridges are not built to store vaccines and MUST NOT be used for vaccine storage.

For outreach and mobile immunisation clinics, vaccines should be packed into a cooler and monitored during transport and while contained within the cooler. **Refer to Appendix 5: Vaccine Cooler Temperature Chart.** 

TIP: Purpose-built vaccine refrigerators do not have freezer compartments. An additional refrigerator with a freezer section will be required for storing ice packs and gel packs for use in an emergency or when packing a cooler for transport. Refer to section 12: Power outages.

### **5 Vaccine Storage**



Refer to the National Vaccine Storage Guidelines: Strive for 5 (section 5), key recommendations for effective vaccine storage management.

Vaccines MUST be stored in a Purpose-built vaccine refrigerator (PBVR).

Vaccines are sensitive to UV light and must be stored in their original packaging to protect them from light and temperature fluctuations.

DO NOT remove vaccines from their original packaging if your fridge is overcrowded.

You may need to source an additional Purpose-built vaccine refrigerator for additional storage space to maintain adequate vaccine stock during the flu program or if you have more vaccines than your PBVR can hold. Check with the manufacturer about your fridge's vaccine storage capacity.

#### It is best practice to:

- Store vaccines in open weaved baskets clearly labelled with the name(s) of the vaccine(s)
- Leave enough space between the vaccines and the walls of the refrigerator to ensure adequate air flow
- Store vaccines in their original packaging to protect them from light and temperature fluctuations.

TIP: Vaccine fridge stickers are available to order via the Better Health Centre <a href="NSLHD-BHC@health.nsw.gov.au">NSLHD-BHC@health.nsw.gov.au</a>, please include the practice mailing address, contact number, quantity required and product required i.e. NIP vaccine fridge labels.

## **6 Vaccine Temperature Monitoring Devices**



Refer to the National Vaccine Storage Guidelines: Strive for 5 (section 4), vaccine temperature monitoring devices.

To ensure vaccines are stored within the recommended temperature range, immunisation providers must, at a minimum have:

- A data logger
- A minimum/maximum thermometer (inbuilt or portable) with an easy to read digital display to manually monitor the temperature of the refrigerator
- A supplementary portable minimum/maximum thermometer that is available for use in vaccine transportation or emergency Purpose-built vaccine refrigerator failure situations

## 7 Temperature Monitoring



Refer to the National Vaccine Storage Guidelines: Strive for 5 (section 5), monitoring and recording fridge temperatures.

Vaccines must be stored between +2°C and +8°C, the optimal storage temperature for vaccines is +5°C. To ensure your PBVR is running within the recommended temperature follow the temperature monitoring guide below.

How often	Action required
Before removing vaccines for administration	Check the vaccine fridge temperature before removing vaccines to ensure the temperature is in range.
Twice daily (every day the practice is	<ul> <li>Manually record current, minimum and maximum temperature of the vaccine refrigerator on the Strive for 5 - Vaccine Fridge Temperature Chart (Refer to Appendix 2)</li> </ul>

open, including weekends)	<ul> <li>Record in the morning and in the evening, at opening and closing of practice</li> <li>Check that temperatures have remained between the +2°C to +8°C range, if out of range download the data logger.</li> <li>Reset thermometer after recording each reading</li> </ul>
Once a week  Annually	<ul> <li>Download data logger (for practices which are not open daily, the data logger must be downloaded and reviewed prior to using vaccines).</li> <li>Save downloaded data to computer, and review data</li> <li>Check that temperatures have remained between the +2°C to +8°C range</li> <li>Relaunch data logger</li> <li>Ensure the logger is set to record at 5 minute intervals</li> <li>Perform vaccine storage self-audit (Appendix 2 of National Vaccine Storage Guidelines - Strive for 5).</li> <li>Service vaccine refrigerator— contact manufacturer</li> </ul>
•	<ul> <li>Calibrate thermometers/data loggers and change batteries</li> </ul>
If a potential breach is identified	<ul> <li>Report temperatures outside the +2°C to +8°C range to your Public Health Unit (Refer to section 11: Managing a cold chain breach).</li> <li>Do not use and do not discard vaccines until advice is received from your local Public Health Unit.</li> </ul>

#### Purchasing a new fridge?

 All new vaccine fridges must be stabilised and 72 hours of stable data logging submitted to the local public health unit before vaccine orders will be accepted by the NSW Vaccine Centre.

#### Moving address?

 Following a change of address the fridge must be stabilised and 24 hours of stable data logging submitted to the local public health unit before vaccine orders will be accepted by the NSW Vaccine Centre.

#### 8 Vaccine Expiry

Immunisation providers must check the vaccine expiry to ensure expired vaccines are not administered to patients. The inadvertent administration of expired vaccines may require recall and revaccination of affected patients. To ensure expired vaccines are not administered to patients:

- Check all vaccine expiry dates when taking the vaccine out of the fridge and prior to administration
- Regularly review vaccine stock and expiry dates including prior to ordering vaccines and discard expired vaccines

 When reviewing stock and receiving a vaccine delivery bring vaccines with the shortest dates to the front of the refrigerator so they are used first

Contact your local public health unit on 1300 066 055 for advice if you inadvertently administer an expired government funded vaccine to a patient.

The public health unit will require the de-identified Patient (s) details including name (patient initials) and date of birth, vaccine name, dose number, batch number, expiry date and date of administration.

Contact the vaccine manufacturer for advice if expired private vaccines have been administered.

#### 9 Ordering Vaccines

Vaccines can be ordered on the NSW Vaccine Centre vaccine online ordering system at <a href="https://nsw.tollhealthcare.com/">https://nsw.tollhealthcare.com/</a>

To apply for a vaccine account, contact your public health unit on 1300 066 055.

Immunisation providers are responsible for:

- Ordering vaccines and maintaining appropriate levels of stock to meet practice immunisation program requirements while not exceeding the capacity of the refrigerator.
- Ensuring that stock is rotated when receiving new stock to prevent wastage of vaccines nearing expiry.

Aim for one routine vaccine order per practice per month

#### **Authorised provider declaration**

When placing a vaccine order, immunisation providers are required to electronically sign a declaration under the **authorised providers AHPRA registration** declaring that they:

- will notify any vaccine doses administered to the Australian Immunisation Register
- comply with cold chain requirements in the National Vaccine Storage Guidelines, Strive for 5 (current edition)
- monitor and record twice daily vaccine fridge temperatures
- continuously data log their vaccine fridge and download and review the data logging report weekly
- have maintained the vaccine cold chain since their last vaccine order and will report any cold chain breaches to their local PHU
- at least one staff member must have successfully completed the NSW Health Vaccine Storage and Cold Chain Management on-line learning module

It is the responsibility of the authorised practice provider to ensure that the signed declaration is true and the practice is compliant with mandatory vaccine storage and cold chain management requirements.

TIP: Online ordering system messaging: Messages regarding changes to vaccine stock availability, particularly during the flu season, and any ordering restrictions will be regularly posted on the online vaccine ordering system. It is important to regularly check for new messages and keep your contact details up to date

TIP: Moving address? Update your details on the online vaccine ordering system and submit 24 hours stable data logging to your local public health unit to continue to order vaccines. Refer to The National Vaccine Storage Guidelines: Strive for 5 (Appendix 8), checklist for emergency storage of vaccines, to ensure your vaccines are transported within the recommended temperature range.

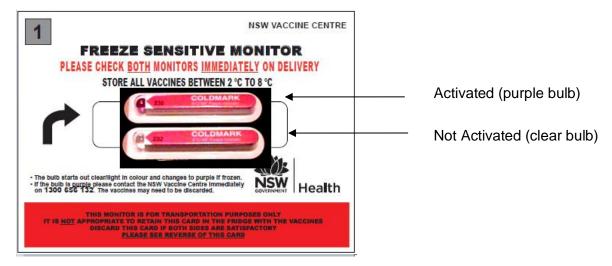
#### 10 Vaccine Deliveries

When receiving a vaccine delivery, it is important to confirm that the cold chain has been maintained during transport and the integrity of the vaccines has not been compromised.

Before accepting the delivery and transferring the vaccines to a dedicated vaccine refrigerator, check the cold chain monitors and record the check on the back of the vaccine minimum/maximum temperature chart. There are two types of cold chain monitors the Coldmark monitor and heat indicator.

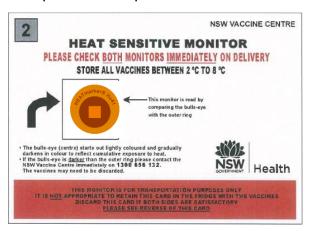
#### 1. Freeze indicators

If the bulb on the Coldmark monitor is purple you must <u>not</u> use the vaccines as they will have been exposed to temperatures  $\leq 0$ °C.



#### 2. Heat indicators

This bioCSL Time Temperature Indicator changes from "satisfactory" to "unsatisfactory" as vaccines are exposed to temperatures over 8°C





If the cold chain monitor(s) has activated contact the NSW Vaccine Centre immediately on 1300 656 132.

While awaiting advice, the vaccines **MUST** be:

- placed in the refrigerator
- isolated and
- labelled 'DO NOT USE'
- Record the breach on the back of the vaccine temperature chart

Note: For privately purchased vaccines, any concerns identified during transport should be directed to the manufacturer.

#### 11 Managing a Cold Chain Breach



Refer to Section 9 of *The National Vaccine Storage Guidelines, Strive for 5*, for advice on how to pack a cooler.

A cold chain breach occurs when vaccine storage temperatures have been outside of the recommended range of +2°C to +8°C during storage or transport. This excludes excursions of >+8°C to up to +12°C for no longer than 15 minutes which may occur whilst restocking the refrigerator.

Immunisation providers must report all cold chain breaches to their local public health unit.

- 1. Refer to the NSW Cold Chain Breach Protocol (Appendix 3)
- 2. Isolate vaccines and place a 'DO NOT USE' sign on the fridge.

- **3.** Continue to store vaccines between +2°C to +8°C. The vaccines may need to be transferred to an alternate purpose built vaccine refrigerator or cooler if available, **see point 7 below**.
- **4. Do not discard** any vaccines.
- **5.** Download and review the data logging report to assess the duration of the breach and temperature the refrigerator reached.
- **6.** Complete the <u>Cold Chain Breach Reporting Form</u> (Appendix 4) and contact your local public health unit on **1300 066 055** as soon as possible during business hours to report the breach. If the breach occurs after hours, keep vaccines isolated and contact the public health unit on the next business day.
- 7. If transferring vaccines to a vaccine cooler (e.g. Esky), record temperatures on the <u>Vaccine Cooler Temperature Chart</u> (Appendix 5)

For more information and to download the cold chain breach reporting form, vaccine cooler temperature chart and cold chain protocol visit the NSW Health webpage at: <a href="https://www.health.nsw.gov.au/immunisation/Pages/cold-chain-management">https://www.health.nsw.gov.au/immunisation/Pages/cold-chain-management</a>

TIP: For privately purchased vaccines and medications contact the manufacturer for advice

**8.** Vaccines subject to cold chain breaches that are assessed by your local PHU as safe and effective to administer within their expiry date will need to be marked with the NSW Health Cold Chain Breach Label.



- Labels should be dated with the date of the breach and placed on the vaccine box. The label should not conceal the name of the vaccine or the expiry date.
- Any future cold chain breaches must be reported to your PHU as each breach is assessed on a case by case basis.
- Additional labels can be ordered from the Better Health Centre via email
   NSLHD-BHC@health.nsw.gov.au. Include the name, address and contact
   number of your practice and the quantity of cold chain labels required.

#### 12 Managing a Power Outage



Refer to The National Vaccine Storage Guidelines: Strive for 5 (Appendix 9), checklist for managing a power failure.

In the event of a power outage or refrigerator failure, ensure you have:

- a back-up plan available and staff are trained to manage power failures
- cooler, ice bricks and bubble wrap or an alternative purpose built vaccine refrigerator to store vaccines
- a portable minimum/maximum digital thermometer

In the event of a power failure:

- DO NOT transport vaccines to another unmonitored vaccine refrigerator or cooler. Alternative vaccine storage MUST have a minimum/maximum thermometer and/or data logger to monitor the temperature. Data loggers must have a visual display of minimum/maximum temperatures.
- **DO NOT** transfer vaccines to a domestic refrigerator (including bar fridges)
- DO NOT put yourself or your staff in danger. If there is a power failure outside normal business hours, such as during a storm, the safety, health and wellbeing of staff should be the main priority.

TIP: If there is no suitable alternative monitored storage option, isolate the vaccines and leave them in the refrigerator with the door closed for the duration of the power outage and follow the NSW Cold Chain Breach Protocol (Appendix 2).

## 13 Annual Vaccine Storage Self-Audits



Refer to The National Vaccine Storage Guidelines: Strive for 5 (section 5.9 and Appendix 2), vaccine storage self-audits.

A vaccine storage self-audit must be completed every 12 months and more frequently where there have been problems with:

- equipment or
- cold chain breaches

The results of the audit must be reviewed by the person responsible for vaccine storage and cold chain management. If the audit identifies any concerns or questions arise, contact the local public health unit on 1300 066 055.

NSW Health will be conducting random audits of practice compliance.

This will include checking that all vaccine doses administered in the practice are notified to the Australian Immunisation Register, as well as verification of the vaccine storage and staff training requirements

### **Appendix 1: Safe Vaccine Storage Checklist**

Remember to follow the principles of safe vaccine storage management to ensure safe and effective vaccines are given to your patients. Strive for 5°C and report ALL cold chain breaches to your local public health unit on 1300 066 055.

# Vaccine refrigerators

Purpose-built vaccine refrigerators (PBVR) are the only suitable option for vaccine storage.

- •If your practice does not have a PBVR you will be required to order a new PBVR.
- Domestic fridges and bar fridges are not built to store vaccines and must not be used for vaccine storage.

# Vaccine Storage

## Vaccines MUST be stored in their original packaging

- •Store vaccines in their original cardboard packaging as they are sensitive to UV light and temperature fluctuations.
- Vaccines must not touch the sides of the fridge
- ·Vaccines must not be stored on the floor of the fridge
- Annual vaccine storage self-audit completed and up to date.

# Temperature monitoring

# Vaccine fridge temperatures MUST be continuously monitored using a data logger

- Data loggers **MUST** be set at 5 minute intervals with a report downloaded weekly and when a potential cold chain breach has been identified.
- •Current, minimum and maximum temperatures **MUST** be manually recorded twice daily, every day the practice is open. Thermometer to be reset after temperatures are recorded.
- •Review temperature of fridge before removing vaccines for administration.

# Vaccine expiry

# Rotate stock and discard expired vaccines

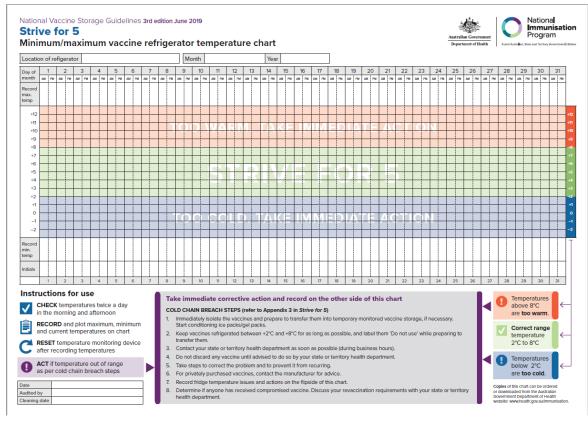
- Check the vaccine expiry before administering vaccines.
- •Regularly review stock and bring vaccines with the shortest dates to the front of the refrigerator so they are used first.

# Staff education

# Ensure ALL staff are trained in vaccine management

- Provide regular vaccine management orientation and education training sessions for all staff.
- •Ensure one member of staff is responsible for vaccine management and a back up person.
- •The NSW Health Vaccine Storage and Cold Chain Management online training module may be used to train all staff that are responsible for vaccine storage and monitoring, visit https://www.health.nsw.gov.au/immunisation/coldchain/story\_flash.html.

## **Appendix 2: Strive for 5 — Vaccine Fridge Temperature Chart**



Strive for 5
3rd edition

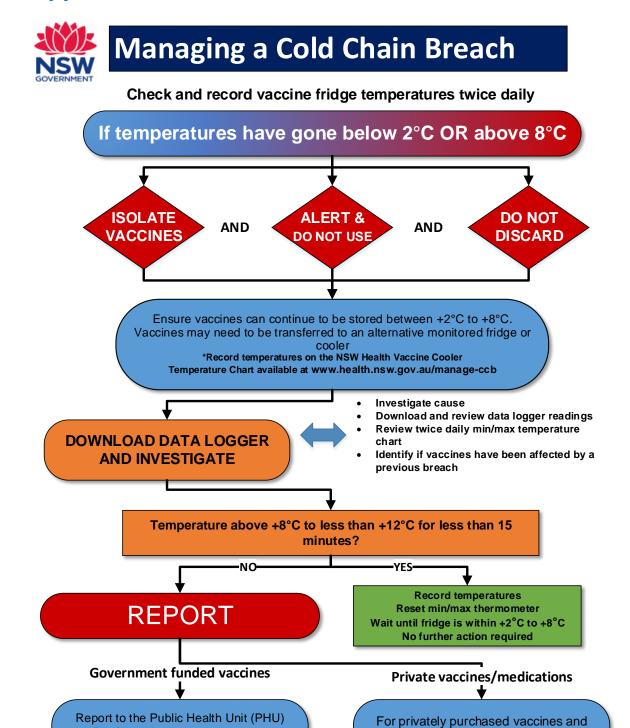
Refer to the National Vaccine Storage Guidelines: Strive for 5 (section 5.6) for information about monitoring and recording fridge temperatures.

The 'Strive for 5' - Vaccine Fridge
Temperature Chart should be used to record
the current, minimum and maximum fridge
temperature twice daily.

The chart can be ordered or downloaded from the Australian Government Department of Health website: <a href="http://www.health.gov.au/immunisation">http://www.health.gov.au/immunisation</a>



## **Appendix 3: NSW Cold Chain Breach Protocol**



For more information visit www.health.nsw.gov.au/manage-ccb

medications, contact the manufacturer for

advice

**Business hours**: 1300 066 055

After hours: Isolate vaccines & contact PHU

next business day

Complete and return the \*Cold Chain Breach Reporting Form to the PHU and await advice Download the CCB form at www.health.nsw.gov.au/ccb

## **Appendix 4: Cold Chain Breach Reporting Form**

**\*SECTION 1: IMMUNISATION PROVIDER DETAILS** 

#### **COLD CHAIN BREACH REPORTING FORM**



**Facility Name** 

NSW GOVERNMENT	Health

**Vaccine Account Number** 

Address	Phone	Phone			
Number of GPs in the practice	Person Reporting	the breach			
Email					
*SECTION 2: DETAILS OF COLD	CHAIN BREACH	I (CCB)			
1. Type of refrigerator	☐ Vaccine Specific	refrigerator			
Type of refrigerator	☐ Domestic refriger	rator			
2. Date of cold chain breach					
3. Date CCB identified					
4. Select the reason for the CCB	☐ Refrigerator malf	unction			
	☐ Power outage				
	□ planned	□ unplanned			
	☐ Human error				
	☐ Unknown/Other				
5. Additional information about the CCB					
6. Data logger temperature	Min	Max			
7. Duration outside 2° C to 8° C (hrs/mins)	1				
8. Is this the first CCB for these vaccines?	P ☐ Yes				
	☐ No, what is the o	date of the previous			
	CCB?	·			
9. Was anyone vaccinated with potentially affected vaccines?	(	alth Unit to provide			
andica facilities:	advice) □ No				
10. Select current vaccine management		mont protocol /refer t-			
policies and procedures in place	_	☐ Vaccine management protocol (refer to 'Strive for 5' Guidelines)			
		☐ Accessible Cold Chain Breach Protocol			
		Shan Broadin rolood			

	☐ Completion of the NSW Health Cold
	Chain Training Module by all staff
	☐ Annual vaccine storage self-audits
	Date of last audit:
SECTION 3: FRIDGE AND COI	LD CHAIN MONITORING DETAILS
the cold cha	is been a refrigerator malfunction or the cause of in breach is unknown
3.1 Refrigerator details	
Date of refrigerator purchase	
Date of last refrigerator service	
3.2 Data logger details	
Type of data logger	☐ Inbuilt ☐ Portable
Date of purchase	
Date of last battery change	
Date of last calibration/ service	
3.3 Minimum/maximum thermometer de	tails
Type of min/max thermometer	☐ Inbuilt ☐Battery operated
Date of purchase	
Date of last battery change	
Date of last accuracy check i.e. ice	
slurry	
3.4 Alternative vaccine storage details	
Is there an alternative fridge for	□ Yes
vaccine storage?	□ No
Type of alternative fridge used for	☐ Vaccine specific refrigerator
back up vaccine storage	□ Domestic refrigerator

#### \*SECTION 4: VACCINE DETAILS

Enter the number of doses of each vaccine brand on hand at the time of the cold chain breach

Vaccines exposed to a second breach should be recorded as follows:

Total number of doses exposed to first breach (total number of doses exposed to second breach), example:

Vaccine	*Doses	PHU advice	Vaccine	*Doses	PHU advice	
MMRII	5 (5)	Retain 5 (Discard 5)	Infanrix	13 (2)	Retain 13 (Discard 2)	

Vaccine	*Doses	PHU advice	Vaccine	*Doses	PHU advice
Act-HIB			IPOL		
Adacel			Menactra		
Afluria Quad			Menitorix		
Boostrix			MMR II		
Boostrix IPV			Neis-Vac C		
Energix B (adult)			Nimenrix		
Energix B (paed)			Pneumovax 23		
Fluad			Prevenar 13		
Fluarix Tetra			Priorix		
Fluquadri			Priorix Tetra		
Fluquadri Jnr			Proquad		
Fluzone			Quadracel		
Gardasil			Rabies		
Gardasil 9			Rotarix		
Havrix 1440			Tripacel		
Hep B VaxII - adult			Vaqta Adult		
Hep B VaxII - paed			Vaqta Paed		
Infanrix – Hexa			Varilrix		
Infanrix IPV			Varivax		
Infanrix			Zostavax		
Additional advice					

Vaccines that can be retained, should be clearly labelled. Any further cold chain breaches should be reported to your local public health unit as each breach is assessed on a case by case basis.

# Attachments required All providers are required to provide the following items on the checklist Data logging for the duration of the cold chain breach (graph and temp log required) Vaccine refrigerator twice daily min/max temperature chart Min/max temperature chart used during transfer of vaccines e.g. cooler (if applicable) Last refrigerator service report (required if there has been a fridge malfunction) Certificates of completion of all staff that have completed the NSW Health Vaccine Storage and Cold Chain Management online training module

Public Health Unit Use Only
PHU Contact person:
Action(s) taken:
Vaccines Quarantined: ☐ Yes ☐ No
Fridge service requested: ☐ Yes ☐ No
Service report received: ☐ Yes ☐ No
HETI module recommended: ☐ Yes ☐ No
Certificates received: ☐ Yes ☐ No
Stop placed on vaccine account: ☐ Yes - Date: ☐ No
Comments:

This form should be completed and returned to your local public health unit in the event of a cold chain breach. Your local public health unit will provide advice on cold chain management and vaccine efficacy.

Please email or fax this form to your local public health unit.

## **Appendix 5: Vaccine Cooler Temperature Chart**



					VACCI	NE COC	DLER TE	MPERA	TURE C	HART		
Facility	name:						Vaccine Account Number:					
							JRE RANGE					
	If 1	the cooler	r temperat	ure is outsi	de +2°C to	+8°C plea	se contact	your local	public hea	alth unit	on 1300 066 055 for further advice	
If the ice packs HAVE been *conditioned and the cooler has been pre-chilled							If the ice p	acks have	NOT bee	en *conditioned and the cooler has <b>N</b> C	T been pre-chille	
	and record										minutes for the first 30 mins then	
	ırly (provide										en hourly (provided the temperatu	
minim	um/maximu			ind reset th r accuracy	e thermon	neter atte	reach	using a			minimum/maximum or data logge ter after each reading for accuracy	
DATE:			reading to	1 accuracy					uie	mome	ter after each reading for accuracy	<u>:                                    </u>
	С	OOLER	1	С	OOLER	2	C	OOLER	3			T
TIME	Current	Min	Max	Current	Min	Max	Current	Min	Max	]	COMMENT/ACTION	SIGNATURE
ANY COLE	CHAIN BRE	ACHES	Y/N	ANY ACTIO	ON REQUIRE	ED	Y/N	DATE:			SIGNATURE:	