Cold Chain Accreditation Review for Immunisation Services

Cold Chain Accreditation (CCA) is an audit tool used to assess an immunisation provider's (provider) cold chain management practices and ensure that they meet the required 10 standards as outlined in the *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition)* (National Standards) **AND** *2021 Addendum COVID-19 Vaccine Immunisation Programme* (Addendum). To achieve CCA, an immunisation provider must meet all the standards. The provider self-assessment tool must be completed prior to review to allow the immunisation provider with an opportunity to self-review their cold chain management, the self-assessment will confirm whether the provider is ready to go through the CCA process or requires further actions to meet the CCA requirements.

Notes to reviewers:

- All vaccines must be stored between +2°C and +8°C at all times to ensure vaccine effectiveness is not destroyed during storage. For the Pfizer/BioTech mRNA Comirnaty vaccine, the specific required temperature ranges are between -70°C to +8°C as detailed in the Addendum.
- All providers storing vaccines must achieve CCA or Cold Chain Compliance (CCC) or be working towards this through an agreed remedial plan before they offer an immunisation service. Providers include but are not limited general practices, public health units, community and hospital pharmacies, corrections facilities, outreach immunisation services, travel clinics, emergency medical services, hospital wards and departments and occupational health services.
- CCA cannot be achieved if the provider does not use a pharmaceutical refrigerator and/or an approved freezer to store vaccines.
- Should a provider not meet the minimum requirements for CCA/CCC, a remedial plan will be agreed by the CCA reviewer and the provider, while the provider works to meet the CCA/CCC requirements. The provider is still able to administer vaccines while this remedial plan is being achieved, if the recommended temperature range of +2°C and +8°C can be maintained at all times (or for the Pfizer/BioTech mRNA Comirnaty the specific required temperature ranges are met as detailed in the 2021 Addendum and the Medsafe data sheet), and the provider works within the agreed timeframes outlined in the plan.
- The maximum timeframe for completing the remedial plan is three months. If a provider is not willing to work on a remedial plan or does not keep to the agreed timeframes, discuss with your DHB, PHO, Medical Officer of Health and IMAC Regional Advisor, further actions to be taken, which may include the suspension of vaccine supply.
- Providers who do not store vaccines throughout the year, will need to meet all the other requirements for CCA, apart from the three months continuous electronic temperature monitoring (ie, data logger) downloads and will be awarded a CCC certificate. This will be valid for up to nine months. Providers will need to produce their records from previous years at their CCC visit (if applicable) and their initial monitoring information.

Name of provider:		Name of individual(s) completing the assessment:
Provider physical address:		Provider postal address:
Provider contact details:	Phone:	Email:
Name of PHO and DHB or other:		
Date of CCA/CCC assessment:		Provider type:

Provider name: _____ Assessment date: _____

Criteria 1: Vaccine reference information

	Met	Not met	N/A	Comments
The provider has access to the online or printed versions of the:				
• current *Immunisation Handbook*	☐	☐	☐	
• current *National Standards for Vaccine Storage and Transportation for Immunisation Providers* AND *2021 Addendum for National Standards: COVID-19 Vaccine Immunisation Programme*	☐	☐	☐	
• *Annual Cold Chain Management Record (for all pharmaceutical refrigerators and freezers)*	☐	☐	☐	
• Medsafe vaccine data sheets	☐	☐	☐	
	Yes	**No**	**N/A**	**Comments**
Is the provider able to access these documents and other immunisation information via the internet?	☐	☐	☐	

Criteria 2: Provider's cold chain policies

	Met	Not met	N/A	Comments
The provider has a documented cold chain management policy available for review. This policy includes the following provider specific information:				
a) names of the designated staff members responsible for cold chain management (ie, two or more staff, the cold chain lead should be an authorised vaccinator, GP or a pharmacist vaccinator)	☐	☐	☐	
b) vaccine stock requirements for their programme or clinic	☐	☐	☐	
c) vaccine ordering and stock keeping processes (including a vaccine register)	☐	☐	☐	
d) processes for receiving and storing standard vaccines	☐	☐	☐	
e) documented process for receiving Comirnaty vaccine including confirming in range status of datalogger and arrangement for returning same datalogger for downloading	☐	☐	☐	
f) action to be taken when they receive a vaccine distributor or National Cold Chain Audit data logger (including Comirnaty vaccine), can the provider describe what action to take	☐	☐	☐	
g) cold chain equipment maintenance plan and schedule (including refrigerator and/or freezer annual service as per the manufacturer's recommendations, and cleaning schedule)	☐	☐	☐	

Provider name: _____ Assessment date: _____

		Met	Not met	N/A	Comments
h)	vaccine refrigerator and/or freezer temperature monitoring processes, including instructions on data logger use	☐	☐	☐	
i)	emergency plans and equipment for use in the event of refrigerator and/or power outage, including a nominated back-up provider	☐	☐	☐	
j)	details of equipment to be used for offsite vaccination clinics (delivering both standard and Comirnaty vaccine), including chilly bin(s), insulation material and temperature monitoring equipment	☐	☐	☐	
k)	process for temperature monitoring while vaccines are being stored in chilly bin(s) for offsite immunisation clinics	☐	☐	☐	
l)	action to be taken when the refrigerator/chilly bin(s) temperature recordings are outside the +2°C to +8°C range	☐	☐	☐	
m)	action to be taken when the refrigerator/freezer/chilly bin(s) temperature recordings are outside the required range for Comirnaty vaccine (-25°C to -15°C, or -90°C to -60°C, or +2°C to +8°C)	☐	☐	☐	
n)	process for vaccine disposal	☐	☐	☐	
o)	a documented cold chain orientation process for new staff, including how to download and read the data logger	☐	☐	☐	
p)	cold chain equipment replacement plan, including replacement of refrigerator/freezer every 10 years	☐	☐	☐	
q)	all relevant staff have read and signed the cold chain policy	☐	☐	☐	
r)	date of next annual cold chain policy review	☐	☐	☐	

Note: If the provider's cold chain policy does not include all the information listed above, they will need to update this and send it through to the reviewer before CCA can be issued.

Providers are expected to update their cold chain policy when there is a change in staff responsible for cold chain management; change in location of the refrigerator or purchase of new cold chain equipment including chilly bins (in conjunction with their immunisation coordinator).

Provider name: _____ Assessment date: _____

Criteria 3: Vaccine stock management

		Met	Not met	N/A	Comments
The provider understands the importance of vaccine stock management and:					
a)	can explain the importance of vaccine stock management (ie, to ensure vaccines are protected from thermal insult, maintain vaccine effectiveness, minimise vaccine wastage due to cold chain failure and to allow air to circulate in the refrigerator)	☐	☐	☐	
b)	can produce their current vaccine register (logbook) or equivalent	☐	☐	☐	
c)	orders vaccines at appropriate frequencies to maintain their stock levels for either a two- or four-week vaccine supply, and this is reflected in their vaccine register	☐	☐	☐	
d)	ensures their vaccine stock does not exceed the refrigerator/freezer manufacturer's recommendations for maximum storage capacity	☐	☐	☐	
e)	can describe the appropriate process for the receipt of standard vaccines	☐	☐	☐	
f)	can describe the appropriate process for the receipt of Comirnaty vaccine	☐	☐	☐	
g)	rotates vaccine stock on receipt of a vaccine order to ensure the shortest expiry dates are used first	☐	☐	☐	
h)	Refrigerators: maintains a 2–3cm space between: each vaccine package and the vaccine boxes and the back and sides of the refrigerator and the shelf above	☐	☐	☐	
i)	Freezers: Ultra-cold = refer to manufacturer's requirements a. Spark-free = vaccine <u>does not</u> require airflow gaps b. Fan-assisted = vaccine <u>does</u> require an airflow gap (same as refrigerator)	☐	☐	☐	
j)	all vaccines are stored in their original packaging/boxes	☐	☐	☐	
k)	expiry dates are visible and shortest expiry dates are up front	☐	☐	☐	
l)	no more than 90% of the refrigerator/freezer storage space is in use	☐	☐	☐	

Provider name: _____ Assessment date: _____

Criteria 4: Temperature monitoring and refrigerator performance

		Met	Not met	N/A	Comments
The provider is aware of the requirements for temperature monitoring and refrigeration performance and:					
a)	is aware of the temperature ranges for all vaccines stored eg +2°C to +8°C for NIS and -25°C to -15°C, or -90°C to -60°C, or +2°C to +8°C for Comirnaty vaccine (site dependant)	☐	☐	☐	
b)	can describe their processes to identify a deviation from the required temperature range and their actions if the temperature falls outside this range, including who to contact	☐	☐	☐	
c)	has the last three months of daily minimum and maximum refrigerator temperatures for each vaccine storage appliance available at their CCA review	☐	☐	☐	
d)	has an electronic temperature recording device* (eg, data logger or external monitoring) that is separate from the daily minimum/maximum device in each vaccine storage appliance.	☐	☐	☐	
e)	What type of device(s) does the provider use?				
f)	Does the device(s) record the temperature at the required parameters?	☐	☐	☐	
g)	If the battery in the device can be changed, has this been done as per the manufacturer's instructions?	☐	☐	☐	
h)	If the device requires calibration, is this done as per the manufacturer's instructions?	☐	☐	☐	
i)	Has the last three months of weekly data logger/external monitoring downloads available at their CCA review?	☐	☐	☐	

Note: Until a provider has an electronic temperature recording device in place and can produce the last three months of continuous temperature monitoring data, they cannot achieve CCA. CCC may be awarded for new or short-term provider providers. If the provider only uses a pharmaceutical refrigerator for a short period of time, eg, three months during the seasonal influenza immunisation programme, they cannot achieve CCA. They must demonstrate that they meet all the other CCA requirements as part of their cold chain management, and if they provided an immunisation service in the year proceeding, they must produce their temperature recordings from that year. Providers who meet all the criteria for CCA other than continuous temperature monitoring data will be considered Cold Chain Compliant (CCC) and issued with a CCC certificate valid for up to nine months only.

Provider name: _____ Assessment date: _____

Criteria 4: Temperature monitoring and refrigeration performance continued		Met	Not met	N/A	Comments
j)	reviews their refrigerator(s) daily minimum/maximum temperature recordings weekly in conjunction with electronic temperature monitoring device (eg. data logger or external monitoring) to check for inconsistencies or temperature changes and documents the results and the actions taken	☐	☐	☐	
k)	documents their actions following any cold chain breach and their response reflects that appropriate action was taken.	☐	☐	☐	

Note: If the provider has had a cold chain breach and has not acted in an appropriate manner, eg, has not notified their immunisation coordinator or cold chain coordinator then a remedial plan (eg, staff education/training) should be put in place, which may mean that CCA can still be awarded but should be reviewed within 12 months.

Criteria 4: Temperature monitoring and refrigeration performance continued

l) The provider retains all temperature monitoring documentation for at least 10 years.

a. How is this information accessed?

b. Where is this information stored/backed up?

		Met	Not met	N/A	Comments
m)	The provider can describe their vaccine storage plan in the event of an equipment and/or power failure?	☐	☐	☐	
n)	Does the provider have sufficient portable vaccine storage equipment for storing their vaccine(s) in the event of an equipment and/or power failure?	☐	☐	☐	

Note: This includes the appropriate number and sized chilly bins, digital minimum/maximum thermometers with audible alarm or electronic temperature recording device (eg, data logger) with a display that is visible without opening the chilly bin, ice packs and insulation material. There must be a temperature monitoring device for the refrigerator/s and one for each chilly bin.

Criteria 4: Temperature monitoring and refrigeration performance continued		Met	Not met	N/A	Comments
o)	The provider can describe their vaccine storage plan for offsite vaccination clinics.	☐	☐	☐	
p)	Does the provider have equipment for the running of offsite vaccination clinics?	☐	☐	☐	
q)	Does the provider have evidence that their equipment is able to maintain the required +2°C to +8°C temperature range?				

Note: This includes the appropriate number and sized chilly bins, electronic temperature recording device (eg, data logger) with a display that is visible without opening the chilly bin, ice packs and insulation material.

Provider name: _____ Assessment date: _____

Provider pharmaceutical refrigerator details

	Refrigerator 1	Refrigerator 2	Refrigerator 3	Refrigerator 4
Brand				
Model				
Year purchased				
The provider has a long-term replacement plan in place as their pharmaceutical refrigerator ages	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Expected replacement date for refrigerator:				

Criteria 5: Pharmaceutical refrigerator/freezer requirements	**Met** 1 2 3 4	**Not met** 1 2 3 4	**Comments**
Refrigerator(s)			
a) Does the provider use a pharmaceutical refrigerator to store vaccines? ☐ Yes ☐ No	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	If no, outline plan in place to purchase one:
b) Is the refrigerator used to store vaccines and medicines only?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
c) Is the provider's refrigerator placed in a well-ventilated room (ie, on an internal wall, away from direct sunlight or sources of heat)?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
d) Is there a space of at least 4 to 10 cm from the back and sides of the refrigerator's surfaces (to allow for circulation around the condenser)? – refer to the manufacturer's instructions.	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
e) Is the refrigerator connected to the power via an independent power point?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
f) Does the refrigerator's power source have a surge protector in place (if required by manufacturer)?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
g) Is the refrigerator connection labelled as 'do not disconnect/unplug' (if not wired in)?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
h) Is the refrigerator serviced annually as per the manufacturer's recommendations?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	Date of last service:
i) Is the daily minimum/maximum thermometer externally validated on an annual basis?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	

Provider name: _____ Assessment date: _____

Criteria 5: Pharmaceutical refrigerator/freezer requirements	Met 1 2 3 4	Not met 1 2 3 4	Comments
j) Results available from last external validation. Note: This may be done as part of the annual refrigerator service or by the local immunisation coordinator using calibrated logger/s.	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	Date: By whom: Frequency:
k) Does the provider undertake regular checks of the door seals and ensure that the door closes automatically if left ajar?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	

Provider pharmaceutical freezer details

	Freezer 1	Freezer 2	Freezer 3	Freezer 4
Brand				
Model				
Year purchased				
The provider has a long-term replacement plan in place as their pharmaceutical freezer ages	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Expected replacement date for freezer:				

Criteria 5: Pharmaceutical freezer requirements	Met 1 2 3 4	Not met 1 2 3 4	Comments
Freezer(s)			
a) Does the provider use a pharmaceutical freezer to store Comirnaty vaccines? ☐ Yes ☐ No	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	If no, outline plan in place to purchase one:
b) Is the freezer used to store Comirnaty vaccines and medicines only?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
c) Is the provider's freezer placed in a well-ventilated room (ie, on an internal wall, away from direct sunlight or sources of heat)? Is the room temperature monitored and recorded daily?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
d) Dependent of the type of freezer (ultra-cold, spark-free or fan assisted) vaccines are stored as per to the manufacturer's instructions.	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
e) Is the freezer connected to the power via an independent power point?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	

Provider name: _____ Assessment date: _____

Criteria 5: Pharmaceutical freezer requirements		Met				Not met				Comments
		1	2	3	4	1	2	3	4	
f)	Does the freezer's power source have a surge protector in place (if required by manufacturer)?	☐	☐	☐	☐	☐	☐	☐	☐	
g)	Is the freezer's connection labelled as 'do not disconnect/unplug' (if not wired in)?	☐	☐	☐	☐	☐	☐	☐	☐	
h)	Is the freezer serviced annually as per the manufacturer's recommendations?	☐	☐	☐	☐	☐	☐	☐	☐	Date of last service:
i)	Is the daily minimum/maximum thermometer externally validated on an annual basis?	☐	☐	☐	☐	☐	☐	☐	☐	
j)	Results available from last external validation. Note: This may be done as part of the annual freezer service or by the local immunisation coordinator using calibrated logger/s.	☐	☐	☐	☐	☐	☐	☐	☐	Date: By whom: Frequency:
k)	Is the freezer connected to a 24-hour-a-day monitoring/alarm system via either a datalogger or an external monitoring (cloud-based) system that allows daily minimum and maximum recordings to be downloaded weekly and reviewed?	☐	☐	☐	☐	☐	☐	☐	☐	
l)	Does the provider undertake regular checks of the door/lid seals and ensure that the door closes automatically if left ajar?	☐	☐	☐	☐	☐	☐	☐	☐	

Provider name: _____ Assessment date: _____

Provider CCA summary

	Met	Not met	N/A	Timeframe / completion date / notes
Vaccine reference information	☐	☐	☐	
Cold chain policy	☐	☐	☐	
Vaccine stock management	☐	☐	☐	
Temperature monitoring and refrigerator performance	☐	☐	☐	
Pharmaceutical refrigerator requirements:				
• Refrigerator 1	☐	☐	☐	
• Refrigerator 2	☐	☐	☐	
• Refrigerator 3	☐	☐	☐	
• Refrigerator 4	☐	☐	☐	
Pharmaceutical freezer requirements:				
• Freezer 1	☐	☐	☐	
• Freezer 2	☐	☐	☐	
• Freezer 3	☐	☐	☐	
• Freezer 4	☐	☐	☐	

Provider name: _____ Assessment date: _____

Temperature validation at the time of CCA review

Note: A minimum of 24 hours continuous logging (over a working period) of the refrigerator temperature, using independent calibrated loggers is required at time of CCA. These readings should be compared with the provider's electronic temperature recording device (eg, data logger) data and the daily minimum/maximum recordings for the same time period.

The table below should be copied and pasted as many times as needed, depending on number of refrigerators and freezers logged.

	Shelf 1	Shelf 2	Shelf 3	Internal thermometer
Minimum				
Maximum				
Current average				

Provider has achieved CCA

☐ Yes ☐ No

Provider has achieved CCC

☐ Yes ☐ No

If not, outline the remedial plan and action required by the provider to improve their cold chain management and achieve CCA/CCC.

Action:

By when:

Duration of CCA/CCC:

Next CCA review date:

_____ _____

Signature: Date:

Provider name: _____ Assessment date: _____