# Cold Chain Accreditation Provider Self-Assessment Form

Cold Chain Accreditation (CCA) is an audit tool used to assess an immunisation provider's 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 external review is conducted by an approved reviewer to ensure that the immunisation provider meets all the standards. Prior to the review, the immunisation provider is required to complete the self-assessment tool to ensure that they are ready for CCA. CCA is valid for up to three years and must be renewed after that time in order for vaccine supply to be continued.

**Notes to providers:**

- All vaccines must be stored between +2°C and +8°C at all times to ensure vaccine effectiveness is not damaged during storage. For the Pfizer/BioTech mRNA Comirnaty 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.
- Providers who do not store vaccines throughout the year and/or new providers, who do not have three months of temperature monitoring information must meet all the other requirements for CCA, to be awarded a CCC certificate. This will be valid for up to nine months.
- All immunisation providers must use a pharmaceutical refrigerator/freezer to store vaccines to achieve CCA. All pharmaceutical refrigerators/freezers must be replaced every 10 years.
- 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 ranges can be maintained at all times, 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.
- Please complete and return this form to your CCA reviewer before your review. If you are unsure about any questions on this form, contact your CCA reviewer or leave the questions blank to discuss during your CCA review. If you answer 'no' to any questions, your CCA reviewer will discuss these with you before the CCA appointment.

## Immunisation provider details

| | | |
|---|---|---|
| Name of provider: | | Name of individual(s) completing the self-assessment: |
| Provider physical address: | | Provider postal address: |
| Provider contact details: | Phone: | Email: |
| Name of PHO and DHB or other: | | |
| Date of CCA/CCC assessment: | | Preferred appointment days/times: |

## Vaccine reference information

| Do you have copies of or access to the online versions of the following: | Yes | No |
|---|---|---|
| • the current *Immunisation Handbook* (available on the Ministry of Health website at: **www.health.govt.nz**) | ☐ | ☐ |
| • current *National Standards for Vaccine Storage and Transportation for Immunisation Providers* AND *2021 Addendum for National Standards: COVID-19 Vaccine Immunisation Programme* (available on the Ministry of Health website at: **www.health.govt.nz/coldchain)** | ☐ | ☐ |
| • *Annual Cold Chain Management Record* (soft copies available on the Ministry of Health website at: **www.health.govt.nz/coldchain)** | ☐ | ☐ |
| • Medsafe vaccine data sheets (available from the Medsafe website at: **www.medsafe.govt.nz/Medicines/infoSearch.asp**) | ☐ | ☐ |
| Are you able to access the intranet/internet at your workplace to access these documents and other immunisation information? | ☐ | ☐ |

## Provider's cold chain policies

All immunisation providers are required to have a documented cold chain policy that is reviewed annually. The Ministry of Health has developed a cold chain policy template covering all the areas of cold chain management required to achieve CCA. The template can be found on the Ministry of Health website at **www.health.govt.nz/coldchain**. The template can be altered to fit your clinical area and immunisation clinic/services. Contact your local immunisation coordinator or CCA reviewer if you have any questions about the template or your own policy. More information about the provider cold chain policy requirements can be found in the Standards.

| Does the cold chain management policy include the following information: | | Yes | No | N/A |
|---|---|---|---|---|
| a) | names of the designated staff members responsible for your 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 specific to your workplace | ☐ | ☐ | ☐ |
| c) | vaccine ordering and stock keeping processes (including a vaccine register) | ☐ | ☐ | ☐ |
| d) | receipt and storage of standard vaccines processes | ☐ | ☐ | ☐ |
| 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 if you receive a vaccine distributor or National Cold Chain Audit data logger (including Comirnaty vaccine) | ☐ | ☐ | ☐ |
| g) | operation and annual maintenance plan and schedule for all your cold chain equipment | ☐ | ☐ | ☐ |
| h) | refrigerator and/or freezer temperature monitoring processes (including instruction on data logger use) | ☐ | ☐ | ☐ |
| i) | actions if your temperature recordings are outside the +2°C to +8°C range | ☐ | ☐ | ☐ |
| j) | emergency plans and equipment for use in the event of refrigerator and/or freezer failure and/or power outage, including a nominated back-up provider | ☐ | ☐ | ☐ |
| k) | 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 | ☐ | ☐ | ☐ |
| l) | process for temperature monitoring while vaccines (including Comirnaty vaccine) are being stored in chilly bin(s) for offsite immunisation clinics | ☐ | ☐ | ☐ |
| m) | action to be taken when the refrigerator/chilly bin(s) temperature recordings are outside the +2°C to +8°C range | ☐ | ☐ | ☐ |
| n) | 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) | ☐ | ☐ | ☐ |
| o) | process for the disposal of vaccines | ☐ | ☐ | ☐ |
| p) | date of next planned annual review of your cold chain policy | ☐ | ☐ | ☐ |
| q) | an orientation process for new staff to cold chain management practices | ☐ | ☐ | ☐ |
| r) | a cold chain equipment replacement plan, including replacement of refrigerator/freezer every 10 years | ☐ | ☐ | ☐ |
| s) | the cold chain policy is signed by all relevant staff. | ☐ | ☐ | ☐ |

Note: If you answered 'no' to any of these questions, please ensure you update your cold chain management policy to include the relevant information. Ensure your cold chain management policy has been updated before your CCA review. If you have any questions, please contact your local immunisation coordinator or CCA reviewer.

## Temperature monitoring and refrigerator performance

| | Yes | No | N/A |
|---|---|---|---|
| Do you use a pharmaceutical refrigerator/approved freezer to store vaccines?<br>If not, you will not be able to achieve CCA and must work with the reviewer to purchase one within an agreed timeframe. | ☐ | ☐ | ☐ |
| Do you have the last three months of your pharmaceutical refrigerator(s)/approved freezer(s) daily minimum/maximum temperature recordings available to discuss at the time of your CCA review? | ☐ | ☐ | ☐ |
| Do you have the last three months of your electronic temperature recording device (eg. data logger or external monitoring) recordings available to discuss at the time of your CCA review? | ☐ | ☐ | ☐ |
| Have the electronic temperature recordings been used to validate the daily minimum/maximum temperature recording every week? | ☐ | ☐ | ☐ |
| Where do you store your daily temperature recordings in the short (<3 months) and long (>3 months) term?<br>• <3 months:<br>• >3 months: | | | |
| Has your refrigerator temperature been outside the +2°C to +8°C range in the last 3 months?<br>If **yes**, please attach the documentation to this form. | ☐ | ☐ | ☐ |
| **Providers storing Comirnaty vaccine:** do you have a 24-hour-a-day alarm monitoring systems for your refrigerator/freezer?<br>This is required for distributors/wholesalers and recommended for providers. | ☐ | ☐ | ☐ |
| Do you have enough portable vaccine storage equipment (chilly bins, digital minimum/maximum thermometers with audible alarm, ice packs and insulation material) should you have an equipment and/or power failure? | ☐ | ☐ | ☐ |
| Do you have appropriate equipment for the running of off-site vaccination clinics including chilly bin(s), insulation material and a data logger for temperature monitoring? | ☐ | ☐ | ☐ |
| Have you trialled your offsite equipment and have evidence that it maintains the required+2°C to +8°C temperature range? | ☐ | ☐ | ☐ |
| When was your refrigerator's/approved freezer last annual independent temperature monitoring validation (including the minimum/maximum thermometer)?<br>Who undertook this independent valuation? | Date: | | |
| When the refrigerator/approved freezer was last serviced as per the manufacturer's recommendations? | Date: | | |
| If your electronic temperature recording device (ie, data logger) require calibration, when was this last done?<br>By whom? | Date: | | |

## Pharmaceutical refrigerator details (enter information for each refrigerator where vaccine is stored)

| | Refrigerator 1 | Refrigerator 2 | Refrigerator 3 | Refrigerator 4 |
|---|---|---|---|---|
| Brand | | | | |
| Model number | | | | |
| Year purchased | | | | |
| Age of refrigerator, if it was not new in year purchased | | | | |
| Is the top of the refrigerator kept clear of all other equipment? | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No |

## Approved freezer details (enter information for each freezer where Comirnaty vaccine is stored)

| | Freezer 1 | Freezer 2 | Freezer 3 | Freezer 4 |
|---|---|---|---|---|
| Brand | | | | |
| Model number | | | | |
| Year purchased | | | | |
| Age of freezer, if it was not new in year purchased | | | | |
| Anticipated replacement date for current freezer | | | | |
| Is a 24-hour-a-day temperature alarm monitoring system in place? | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No |

## Checklist (please tick as appropriate)

| | Tick |
|---|---|
| Fax or email your CCA reviewer your: | |
| • completed CCA Provider Self-Assessment Form | ☐ |
| • Cold Chain Management Policy | ☐ |
| • documentation of any cold chain breaches, temperatures outside the +2°C to +8°C range | ☐ |
| • documentation of any cold change breaches for Comirnaty vaccine outside the required range (-25°C to -15°C, or -90°C to -60°C, or +2°C to +8°C) | ☐ |
| • copy of your last annual service record. | ☐ |

## Have ready for your review

| | Tick |
|---|---|
| • The designated person(s) responsible for your cold chain management | ☐ |
| • Cold chain orientation checklist | ☐ |
| • The last three months of vaccine refrigerator/approved freezer temperature charts (both the daily minimum/maximum and weekly electronic temperature recording device, eg, data logger) | ☐ |
| • The documentation related to your off-site vaccination temperature monitoring (if applicable) | ☐ |
| • The documented actions taken if your refrigerator temperature recordings have been outside the +2°C to +8°C range | ☐ |
| • The documented actions taken if there is a deviation from the Comirnaty vaccine required range (-25°C to -15°C, or -90°C to -60°C, or +2°C to +8°C) | ☐ |
| • Your vaccine stock register | ☐ |
| • Your portable vaccine storage equipment. | ☐ |

## Don’t forget to make an appointment for your review.

Signature: Date:

Comments: