Cold Chain Accreditation 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* (the Standards). 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.. All immunisation providers who store and/or offer vaccines must achieve CCA (or Cold Chain Compliance* (CCC) if appropriate), including but not limited to 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 before they offer an immunisation service. The accreditation 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.
- All immunisation providers must use a pharmaceutical refrigerator to store vaccines to achieve CCA. All pharmaceutical refrigerators **must** be replaced every 10 years.
- Should an immunisation provider not meet the minimum requirements for CCA, a remedial plan will be put in place in conjunction with the CCA reviewer, while the provider works to meet the CCA requirements. The maximum timeframe for completing the remedial plan is three months. 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 and the provider works within the agreed timeframes outlined in the plan. If a provider is not willing to work on a remedial plan or does not keep to the agreed timeframes, the DHB, PHO, medical officer of health and IMAC regional advisor will be notified and further action taken, which may include 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.

Fax or email the completed form to: to arrange an appointment for your CCA review by:

*CCC is issued when the provider meets all of the requirements for CCA but is unable to show the three month continuous temperature records due to being a new provider or offering a short-term vaccination service.

Immunisation provider details

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

Vaccine reference information

Do you have copies of or access to the online versions of the:	Yes	No
• 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* (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
a)	names of the designated staff members responsible for your cold chain management (i.e., 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 vaccines processes	☐	☐
e)	action to be taken if you receive a vaccine distributor or National Cold Chain Audit data logger	☐	☐
f)	operation and annual maintenance plan and schedule for all your cold chain equipment	☐	☐
g)	refrigerator temperature monitoring processes (including instruction on data logger use)	☐	☐
h)	actions if your temperature recordings are outside the +2°C to +8°C range	☐	☐
i)	emergency plans and equipment for use in the event of refrigerator failure and/or power outage, including a nominated back –up provider	☐	☐

Provider's cold chain policies continued

j)	details of equipment to be used for offsite vaccination clinics, including chilly bin(s), insulation material and temperature monitoring equipment	☐	☐	☐ N/A
k)	process for temperature monitoring while vaccines are being stored in chilly bin(s) for offsite immunisation clinics	☐	☐	☐ N/A
l)	action to be taken when the refrigerator/chilly bin(s) temperature recordings are outside the + 2°C to + 8°C range	☐	☐	
m)	process for the disposal of vaccines	☐	☐	
n)	date of next planned annual review of your cold chain policy	☐	☐	
o)	an orientation process for new staff to cold chain management practices	☐	☐	
p)	a cold chain equipment replacement plan, including replacement of refrigerator every 10 years	☐	☐	
q)	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

Do you use a pharmaceutical refrigerator to store vaccines?	☐ Yes	☐ No	
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) daily minimum/maximum temperature recordings available to discuss at the time of your CCA review?	☐ Yes	☐ No	
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?	☐ Yes	☐ No	
Have the electronic temperature recordings been used to validate the daily minimum/maximum temperature recording every week?	☐ Yes	☐ No	
Where do you store your daily temperature recordings in the short (<3 months) and long (>3 months) term?	<3months	>3months	
Has your refrigerator temperature been outside the +2°C to +8°C range in the last 3 months?	☐ Yes	☐ No	
If yes, what action was taken and was that action documented? Please attach the documentation to this form.			
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?	☐ Yes	☐ No	
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?	☐ Yes	☐ No	☐ N/A
Have you trialled your offsite equipment and have evidence that it maintains the required+2°C to +8°C temperature range?	☐ Yes	☐ No	☐ N/A
When was your refrigerator's last annual independent validation (including the minimum/maximum thermometer)?	Date:		
Who undertook this independent validation?	Who:		
When the refrigerator was last serviced as per the manufacturer's recommendations?	Date:		
Does your electronic temperature recording device (i.e. data logger) require calibration? If yes, when was the last calibration done and by who? Date: Who:	☐ Yes	☐ No	

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 was not new in year purchased				
Anticipated replacement date for current refrigerator				
Is the top of the refrigerator kept clear of all other equipment?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

Checklist (please tick as appropriate)

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 ☐
- copy of your last annual service record. ☐

Have available for your review:

- the designated person(s) responsible for your cold chain management ☐
- cold chain orientation checklist ☐
- the last three months of vaccine refrigerator 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 ☐
- your vaccine stock register ☐
- your portable vaccine storage equipment. ☐

Arrange an appointment for your CCA review. ☐

Signature: Date:

Comments:

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