Health New Zealand Te Whatu Ora

Lifespan of pharmaceutical fridges for vaccine storage

Frequently Asked Questions

Question	Response
Definition of continuous real-time monitoring services	Continuous monitoring is done by a device that can record, securely store and report temperatures at set time periods - no more than 10 minutes, ideally for a shorter time frame. Full definition is included in the National standards for vaccine storage and transportation for Immunisation providers 2017 (2nd Edition) (updated September 2019), section 7.2, clause 2b. See definition next page
Specificity on acceptable follow-up action for out-of-hours alarms.	Each provider will already have a cold chain breach management section in their Cold Chain policy. Those implementing continuous monitoring for the first time will need to ensure this section is updated to reflect who will receive any "out of range messages" and the actions expected from staff.
If Cold Chain Accreditation (CCA) granted for 2yrs as fridge was turning 10yrs before 3yr CCA. Does CCA need to be done, or will it extend automatically to 3yrs?	 1.Fridges 10 years of age, issued with a time limited CCA [due to age of fridge] where continuous monitoring services are already in place: The cold chain assessor may choose to extend a CCA, if they are confident about the continuous monitoring and that they have the relevant local policies documenting process for managing out of hours breaches. The length of a CCA continues to be at the discretion of the assessor or District/Regional Policy. It is recommended that three-month continuous monitoring records would be reviewed by their CCA reviewer and/or coordinator 2.Fridges 10 years of age, issued with a time limited CCA [due to age of fridge] where other types of temperature monitoring are in place: If a provider chooses to implement continuous monitoring services for a fridge reaching 10 years old, they will engage with their CCA assessor and/or coordinator, if they have implemented continuous monitoring, and have the relevant local policies documenting process for managing out of hours breaches, the CCA can be extended [up to max 3 years post last CCA] at the discretion of the assessor as an alternative to full assessment. It is recommended that three-month continuous monitoring records would be reviewed by their CCA
Can a 3- year CCA be awarded on a new fridge when they have continuous monitoring services in place on their old fridge. Can a 3-year CCA be awarded to a fridge	Compliance is required with all other aspects of the CCA review including 3 months of data for their continuous monitoring for the fridge or fridges being assessed. If this is in place the length of the CCA can be up to 3 years at the Immunisation coordinator discretion or District/Regional Policy. As above, plus 3 months of data for their new continuous
that is 10 yrs old, or do they have a shortened timeframe?	monitoring. Once this is in place the length of the CCA can up to 3 years at the Immunisation coordinator discretion.

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Is there a maximum age for fridges?	This guidance only applies to fridges that are in use when reaching 10 years of age. This means only 11-year-old fridges will be in use in the next 12 months. The need for setting maximum age requirement in future, will be assessed based on the data gathered from older fridges over time.
Service engineers not commenting on fridges working condition but "resale" condition. What are the parameters for "good working condition"	Fridges of any age can be deemed not fit for purpose, and the decision must be determined by the advice provided by the technician.
Need non-compliant or complaints process for providers or Coordinators who are appealing technician note as not fit.	As above plus if you disagree with guidance given it may be appropriate to request a second opinion from a different technician.
Is the statement temporary?	No, this new information will be included in the updated standards when they are released.
If a Provider has an old fridge and wants to "re-instate it to CCA" what is the requirement?	Statement applies to fridges with current CCA. Old fridges that have been decommissioned are not eligible.
How to seek support with queries.	The Interim statement provides the link to the IMAC website with contact details for regional advisors and local coordinators. Queries can be forwarded to the regional advisors for support from IMAC and Health NZ where required.

2b. Continuous monitoring services

A number of suppliers offer online (external or cloud storage-based) temperature monitoring and alerting services. These devices record refrigerator temperature and store/send the resulting recordings at set intervals (not more than 10 minutes; a five-minute interval is recommended). Providers can set up these services to send SMS or email alerts if the system picks up recordings outside the preset range.

The service should offer:

- detailed and accurate records of temperature history that the provider can access
- the ability for the provider to download/access and review the data every week and compare it with daily minimum and maximum recordings, to allow them to check for any unexplained variations in temperature
- an indicator for when the battery in the monitoring device needs replacing, if applicable
- a monitoring device powered separately from the refrigerator and the minimum/maximum thermometer (or have a back-up power system)
- back-up of information for at least 10 years.

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Information for immunisation providers including pharmacies, clinics and hospital services

Interim Statement

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October 2024

Effective Immediately

Health New Zealand | Te Whatu Ora (Health NZ) is reviewing the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition) and the 2021 COVID-19 Vaccine Addendum.

Whilst this review progresses, Health NZ is releasing the following interim guidelines on the lifespan of pharmaceutical fridges used to store vaccines.

Pharmaceutical fridges 10 years or older used to store vaccines can be used, provided continuous real-time temperature monitoring services with out-of-hours alarming and notification processes are in place.¹

All providers are required to comply with the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition) including and not limited to:

- Up to date policies and processes are in place to reflect the use of continuous temperature monitoring services
- Ongoing annual fridge service plans are in place
- Fridges are in good working condition based on the service reports
- The site has current Cold Chain Accreditation or Licence to Operate Pharmacy

Regional advisors and local coordinators can be contacted <u>here</u>

¹ For further guidance see the <u>National standards or vaccine storage and transportation for immunisation providers</u> <u>2017 (2nd Edition) (updated September 2019)</u>, section 7.2, clause 2b. Continuous monitoring services.