Ontario

Ministry of Health
Vaccine Policy and Programs Branch

Vaccine Cold Chain Maintenance Inspection Report

For Routine (Annual) Inspections

Premises Information

Client ID (If applicable)	Name of Premises

Date of Inspection (yyyy/mm/dd)	Type of Inspection	Number of Refrigerators in this Premises	This Inspection is for Refrigerator no./ID
	☐Initial ☐Re-inspection no		

Premises Contact Information

Last Name	First Name

Address

Unit Number	Street Number	Street Name

P.O Box	City/Town	Province	Postal Code
		ON	

Telephone Number	Fax Number	Email Address

Temperature Monitoring Device

☐Max-min Thermometer ☐Data Logger ☐Other

Type of Refrigerator

☐Bar Style
- ☐Separate Freezer
- ☐Combined Freezer
- ☐Refrigerator Only

☐Domestic
- ☐Separate Freezer
- ☐Combined Freezer

☐Purpose-built

Age of Refrigerator

☐0 years to < 1year ☐1 year to < 5 years

☐5 years to <10 years ☐> 10 years

Premises Type

☐Physician Office (FP)	☐Long-Term Care Home	☐Occupational Health	☐Pharmacy
No. of Immunizers:	☐Hospital	☐Indigenous Organization	☐Other
☐Physician Office (PED)	☐Community Health Centre	☐Retirement Home	
No. of Immunizers:	☐Correctional Facility	☐Walk-in Clinic	
☐Family heath team	☐Addiction Treatment Centre	☐Public Health Unit	
No. of Immunizers:	☐Nursing Agency	☐School	

1. Vaccine Refrigerators Temperature and Readings	Compliant	Strategies/Actions Taken
a. Temperature monitoring device is present and is able to record current, maximum and minimum temperatures	☐Yes ☐No	☐Premises given a temperature monitoring device or advised to obtain a temperature monitoring device ☐Conducted a cold chain incident inspection ☐Implemented troubleshooting measures

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Client ID (If applicable)	Name of Premises	
b. Current temperature of refrigerator using premises' temperature monitoring device °C Current temperature of refrigerator using public health unit's temperature monitoring device °C	☐Yes ☐No	☐Temperature variance between public health unit's temperature monitoring device and premises' temperature monitoring device °C ☐Replaced premises' temperature monitoring device's battery ☐Accuracy of the premises' temperature monitoring device was checked using the slush test ☐Replaced premises' temperature monitoring device
c. Temperature variance between public health unit's temperature monitoring device and premises' temperature monitoring device is no greater than +/- 2ºC (**Note for public health units:** the degree of variability is dependent on the devices that are being checked for accuracy. Refer to pages 25-27 in the Vaccine Storage and Handling Guidance Document)	☐Yes ☐No	☐Conducted a cold chain incident inspection ☐Implemented troubleshooting measures ☐Instructed to change batteries every 6 months
d. Maximum-minimum thermometer sensor and/or data logger is properly located	☐Yes ☐No	☐Placed maximum-minimum thermometer sensor on the middle shelf inside an empty vaccine box ☐Labelled the vaccine box as empty ☐Placed data logger on the middle shelf ☐Conducted a cold chain incident inspection ☐Implemented troubleshooting measures
Rating for Section 1: ☐Pass ☐Conditional ☐Fail		

Comments

2. Log Book Review	**Compliant**	**Strategies/Actions Taken**
a. Temperature Log Book present	☐Yes ☐No	☐Given Temperature Log Book.
b. Current, maximum and minimum temperatures are checked twice daily and documented with initials and time in the Temperature Log Book	☐Yes ☐No	☐Instructed to record maximum, minimum and current temperatures twice daily (at the beginning and end of each business day) and the time that the temperatures were taken in Temperature Log Book ☐Instructed to view temperatures every time the refrigerator is opened ☐Conducted a cold chain incident inspection
c. Current, maximum and minimum temperatures are maintained between +2ºC to +8ºC	☐Yes ☐No	☐Instructed premises to notify the public health unit when temperatures are outside the required range ☐Conducted a cold chain incident inspection ☐Implemented troubleshooting measures ☐Suspended vaccine ordering for days

Client ID (If applicable)	Name of Premises

d. Maximum-minimum thermometer is being reset twice daily and/or the data logger's continuous temperature readings are being downloaded as required	☐Yes ☐No	☐Provided education regarding the importance of: ☐Resetting the maximum-minimum thermometer twice daily after recording minimum and maximum temperatures; and/or ☐Downloading the continuous temperature readings from the data logger ☐Conducted a cold chain incident inspection
e. Office staff demonstrates resetting and/or downloading data from the temperature monitoring device	☐Yes ☐No	☐Provided temperature monitoring device resetting/downloading instructions/demonstration ☐Conducted a cold chain incident inspection
f. Office staff demonstrates reading temperature monitoring device	☐Yes ☐No	☐Provided temperature monitoring device reading instructions/demonstration ☐Conducted a cold chain incident inspection

Rating for Section 2: ☐Pass ☐Conditional ☐Fail

Comments

3. Ministry Cold Chain Material	**Compliant**	**Strategies/Actions Taken**
a. How to monitor your refrigerator temperature sticker is mounted on exterior of vaccine refrigerator	☐Yes ☐No	☐Given How to monitor your refrigerator temperature sticker and placed on exterior of vaccine refrigerator
b. Protect your vaccines - Protect your patients poster is mounted on exterior of vaccine refrigerator	☐Yes ☐No	☐Given Protect your vaccines - Protect your patients poster and placed on exterior of vaccine refrigerator
c. Vaccine Storage and Handling Guidelines is on hand	☐Yes ☐No	☐Given Vaccine Storage and Handling Guidelines
d. Vaccine Refrigerator Maintenance Log Book is on hand	☐Yes ☐No	☐Given Vaccine Refrigerator Maintenance Log Book
e. Insulated vaccine container(s) with packing material and a temperature monitoring device is i. Present ii. Used when transporting vaccines	☐Yes ☐No ☐Yes ☐No	☐Given or advised to obtain insulated vaccine container(s) with packing material (i.e., ice packs) and temperature monitoring device(s)

Rating for Section 3: ☐Pass ☐Conditional ☐Fail

Comments

4. Organization of Refrigerator	**Compliant**	**Strategies/Actions Taken**
a. Publicly funded vaccines are stored in the middle of the refrigerator away from the walls, floors and cold air vents	☐Yes ☐No	☐Placed publicly funded vaccines in the middle shelves away from the floor, cold air vents and 2 to 3 inches from the walls of the refrigerator
b. Publicly funded vaccines are stored on internal shelves of the refrigerator (not stored in the door or in drawers)	☐Yes ☐No	☐Placed publicly funded vaccines in the middle shelves , away from the floor, cold air vents and 2 to 3 inches from the walls of the refrigerator
c. Publicly funded vaccines are organized by product	☐Yes ☐No	☐Organized publicly funded vaccines by product

Client ID (If applicable)	Name of Premises

d. Drugs (including privately purchased vaccines) that require refrigeration between +2ºC to +8ºC may be stored in the refrigerator with publicly funded vaccines. The refrigerator must have capacity to store the drugs without compromising the safe storage of publicly funded vaccines. No food, beverages and/or medical/laboratory specimens can be stored with publicly funded vaccines	☐Yes ☐No	☐ Removed food, beverages and/or medical/laboratory specimens from the vaccine refrigerator and instructed not to store these items in the refrigerator with publicly funded vaccines
e. Space is maintained between each publicly funded vaccine product	☐Yes ☐No	☐ Ensured space is maintained between publicly funded vaccine products to allow for air circulation ☐ Removed excess publicly funded vaccine ☐ Advised that refrigerator has exceeded capacity to safely accommodate required stock and instructed to: ☐ Obtain larger or additional refrigerator ☐ Obtain additional refrigerator to store publicly funded vaccines only ☐ Order and stock less publicly funded vaccines and if applicable, drugs
f. Publicly funded vaccines and diluents are stored in original packaging	☐Yes ☐No	☐ Ensured publicly funded vaccines and diluents are stored in original packaging to protect vaccines from light
g. Publicly funded vaccine with the longest expiry dates are placed behind shorter-dated publicly funded vaccines	☐Yes ☐No	☐ Instructed to rotate publicly funded vaccine supply by placing publicly funded vaccine with the longest expiry dates behind shorter-dated publicly funded vaccines
h. Use publicly funded vaccine that has been previously exposed to a cold chain incident first	☐Yes ☐No	☐ Instructed to use publicly funded vaccines that have been previously exposed to a cold chain incident first
i. Only current dated publicly funded vaccines present in refrigerator (no expired publicly funded vaccines)	☐Yes ☐No	☐ Removed expired publicly funded vaccine ☐ Instructed to return expired publicly funded vaccines to the public health unit or OGPMSS
j. Water bottles placed on empty shelves and in refrigerator door (not required for purpose-built refrigerators)	☐Yes ☐No	☐ Instructed to place or placed cooled water bottles in the refrigerator's empty shelves and doors
k. Refrigerator type and size is sufficient to accommodate required stock	☐Yes ☐No	☐ Advised that refrigerator has exceeded capacity to safely accommodate required stock. Instructed to: ☐ Obtain larger or additional refrigerator ☐ Obtain additional refrigerator to store publicly funded vaccine only ☐ Order and stock less publicly funded vaccines and if applicable, drugs
l. No more than a 1 month supply of publicly funded vaccines is in stock	☐Yes ☐No	☐ Inventory control measures have been taken by the public health unit

Rating for Section 4: ☐Pass ☐Conditional ☐Fail

Comments

5. Vaccine Handling Review	Compliant	Strategies/Actions Taken

Client ID (If applicable)	Name of Premises

a. Office staff know to remove publicly funded vaccines from refrigerator for immediate use only	☐Yes ☐No	☐Instructed to only remove publicly funded vaccines from the refrigerator for immediate use
b. Multidose publicly funded vaccine vials (if present in refrigerator) are marked with the date opened and discarded as per manufacturer's instructions or within 28 days, whichever is shorter.	☐Yes ☐No	☐Instructed to mark multidose publicly funded vaccine vials with the date opened and disposed as per manufacturer's instructions or within 28 days, whichever is shorter.

Rating for Section 5: ☐Pass ☐Conditional ☐Fail

Comments

6. General	Compliant	Strategies/Actions Taken
a. Refrigerator should be optimally placed:	☐Yes ☐No	☐Instructed to relocate refrigerator:
i. In an area that is well ventilated	☐Yes ☐No	☐To an area that is well ventilated
ii. Away from direct sunlight	☐Yes ☐No	☐Out from direct sunlight
iii. Away from external walls		☐Away from external walls
b. Refrigerator door OR refrigerator room is locked at the end of the day	☐Yes ☐No	☐Instructed to install lock on vaccine refrigerator or refrigerator room door
c. Refrigerator electrical outlet is:	☐Yes ☐No	☐Ensured refrigerator's electrical outlet is covered by metal cage or is not easily accessible
i. Covered by metal cage; OR	☐Yes ☐No	
ii. Not easily accessible; OR	☐Yes ☐No	☐Given 'do not unplug' sticker and placed beside refrigerator electrical outlet
iii. Accessible but the **Do not unplug** sticker sign is posted beside refrigerator electrical outlet		
d. Refrigerator maintenance is performed:		☐Instructed to:
i. If applicable, freezer has been defrosted and ice is < 1 cm thick	☐Yes ☐No	☐Defrost refrigerator and move publicly funded vaccines to a monitored and insulated container while defrosting
ii. Back (including the coils, if necessary), top and sides are cleaned and dusted	☐Yes ☐No	☐Dust and clean the back (including the coils, if necessary), top and sides of the refrigerator
iii. Door is sealed tightly and properly and has:		
• Adequate door seals	☐Yes ☐No	☐Replace door seals
• Velcro door latch installed (if required)	☐Yes ☐No	☐Install Velcro door latch
• Tight door hinges	☐Yes ☐No	☐Tighten door hinges
e. One office staff member and a backup person is responsible for vaccine management	☐Yes ☐No	☐Assigned one office member and a backup person the responsibility of vaccine management
f. Office staff know to review existing publicly funded vaccine stock prior to each vaccine order	☐Yes ☐No	☐Instructed to review existing publicly funded vaccine stock prior to each vaccine order
g. If applicable: Stocks of private and publicly funded vaccine should be clearly marked and/or separated	☐Yes ☐No	☐Private and publicly funded vaccine supply is clearly marked and/or separated
h. Office staff know to contact public health unit immediately when publicly funded vaccines are exposed to temperatures below +2°C or above +8°C	☐Yes ☐No	☐Instructed to: ☐Report cold chain incidents to the public health unit ☐Place publicly funded vaccine involved in a cold chain incident in a bag marked 'Do Not Use' ☐Keep labeled bag of publicly funded vaccines in a monitored refrigerator or monitored insulated container until evaluated by the public health unit

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i. Office staff know to return wasted publicly funded vaccines to the public health unit (or to OGPMSS if premises is in the City of Toronto) for disposal	☐Yes ☐No	☐Instructed to return wasted publicly funded vaccines to the public health unit or OGPMSS for disposal
j. Contingency (emergency) plan developed in the event of a vaccine refrigerator malfunction, power failure or other emergencies	☐Yes ☐No	☐Discussed a contingency plan ☐Premises instructed to establish a contingency plan
k. Health care providers are knowledgeable regarding reporting adverse events following immunization (AEFIs) to the public health unit	☐Yes ☐No	☐Given Public Health Ontario's AEFI reporting fact sheet for health care providers ☐Informed of Public Health Ontario's vaccine safety website (https://www.publichealthontario.ca/en/health- ☐Given ministry's parent vaccine safety information sheet to distribute to parents (if applicable)
l. Office staff are aware that only publicly funded vaccines that are: • ordered by the premises are stored in the premises • administered within the geographic boundaries of the public health unit.	☐Yes ☐No	☐Instructed to only store publicly funded vaccines that was received by the premises. ☐Instructed to not store publicly funded vaccine that the premises did not order. ☐Instructed to administer publicly funded vaccines within the geographic boundaries of the public health unit.

Rating for Section 6: ☐Pass ☐Conditional ☐Fail

Comments

7. Inventory

Publicly Funded Vaccines	Cost per Dose	# of Expired Doses	# of Doses Not Expired	Total Value of Expired Doses	Total Value of Non Expired Doses
Abrysvo					
Act-Hib®					
Adacel®					
Adacel®-Polio					
Arexvy					
Bexsero®					
Beyfortus					
Boostrix®					
Boostrix®-Polio					
Engerix B® Adolescent/Adult					
Engerix B® Pediatric					
Gardasil® 9					
Havrix® Adult					
Havrix® Pediatric					
Imovax® Polio					

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Imovax® Rabies					
Menactra®					
Menjugate®					
Menveo®					
Nimenrix®					
M-M-R® II					
NeisVac-C®					
Pentacel®					
Prevnar® 20					
Priorix®					
Priorix Tetra™					
ProQuad®					
RabAvert®					
Recombivax HB® Adolescent/Adult					
Recombivax HB® Paediatric					
Recombivax HB® Renal					
Rotarix™					
Shingrix®					
Td Adsorbed					
Tubersol®					
Varilrix®					
Varivax® III					
Vaxneuvance					
Fluad®					
Flucelvax					
FluLaval Tetra					
Fluzone® Quadrivalent					
Fluzone® Quadrivalent HD					
Moderna					
Novavax					
Pfizer: 6 months to 4 years					
Pfizer: 5 to 11 years					
Pfizer: 12 years+					
Subtotal in this refrigerator					
Grand total in this refrigerator					

Client ID (If applicable)	Name of Premises

Recommendations

Final Results of Inspection (Final Rating)

☐Pass ☐Conditional ☐Fail

Client ID (If applicable)	Name of Premises

Sign and Certify - Public Health Unit

Name of Public Health Unit

By signing this form, I certify the following:

- I have examined this form and, to the best of my knowledge and belief, the information provided in this form is true and accurate.
- I understand and acknowledge that if I proceed to sign this document electronically, this document will be valid and enforced in the same manner as a hand-signed document that exists in a physical form and that a record or my signature may not be denied legal effect or enforceability under law solely because it is electronic.

Authorized Electronic Signature:

Last Name	First Name	Date (yyyy/mm/dd)

☐Check box to certify by electronic signature

Sign and Certify - Premises

Name of Premises

By signing this form, I certify the following:

- I have examined this form and, to the best of my knowledge and belief, the information provided in this form is true and accurate.
- If any of the information listed above changes, I understand that it is my responsibility to notify my public health unit of any changes as soon as possible.
- I understand that my inspection information will be shared with authorized public health unit staff to support provincial vaccine storage and handling activities within my public health unit and indicate my acceptance and delivery of this information to authorized public health unit staff.
- I understand and acknowledge that if I proceed to sign this document electronically, this document will be valid and enforced in the same manner as a hand-signed document that exists in a physical form and that a record or my signature may not be denied legal effect or enforceability under law solely because it is electronic.

Authorized Electronic Signature:

Last Name	First Name	Date (yyyy/mm/dd)

☐Check box to certify by electronic signature