Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine

Alberta Health

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Alberta Vaccine Cold Chain Policy for Provincially Funded Vaccine

https://open.alberta.ca/publications/alberta-vaccine-cold-chain-policy

For further information on the use of this policy contact:

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Health and Wellness Promotion Branch

Public Health and Compliance Division

Alberta Health

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PART 1

I. Introduction

Alberta Health purchases, stores and distributes provincially funded vaccine from the Provincial Vaccine Depot to vaccine depot sites across Alberta referred to as “Alberta Health Services (AHS) Vaccine Depots” in this document. AHS administers the vaccine to clients or provides it to some Community Providers to administer. Alberta Health distributes provincially funded vaccine to pharmacies through the Pharmacy Wholesale Distributors.

Cold Chain refers to the processes and procedures that maintain optimal temperature and light conditions during the transport, storage, and handling of vaccines. The temperature for most vaccine storage and handling is +2.0ºC to +8.0ºC. Some vaccines also need to be protected from exposure to light. Refer to the product monograph as posted on the Health Canada website for specific vaccine storage and handling information.

Vaccines are sensitive biological products that may become less effective or ineffective when exposed to temperatures outside the recommended range or inappropriate exposure to light. Exposure to temperatures outside the recommended range results in loss of potency with each episode of exposure. Repeated exposures to heat results in a cumulative loss of potency that is not reversible. Cold-sensitive vaccines experience an immediate loss of potency following freezing. Loss of potency may result in failure to stimulate an adequate immunologic response, leading to lower levels of protection against disease.

Sites must meet the requirements outlined in the Alberta Vaccine Storage and Handling Policy (The “Policy”) prior to receiving provincially funded vaccine and prior to immunization services being offered.

This Policy is based on National Vaccine Storage and Handling Guidelines healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-storage-entreposage-vaccins/index-eng.php as well as vaccine manufacturer recommendations.

II. Legislative Authority

The Alberta Vaccine Storage and Handling Policy is provided under the authority of the *Public Health Act Immunization Regulation* Part 3 – Maintenance of Vaccine Viability which outlines the requirements for the storage, handling and transportation of vaccines.

Questions related to the Policy may be directed to Alberta Health’s Immunization Team at: health.imm@gov.ab.ca

III. Definitions

(For the purposes of this document)

Alarmed Temperature Monitoring System	A continuously-monitored alarm system that monitors temperature in vaccine refrigerators 24 hours a day and seven days a week.
Alberta Health Services (AHS)	The regional health authority established under the *Regional Health Authorities Act.*
Alberta Health Services Province-wide Immunization (AHS Province-wide Immunization)	Alberta Health Services Province-wide Immunization Program Standards and Quality, Population, Public and Indigenous Health Division. This division of AHS is responsible for immunization program standards and quality within AHS.
Alberta Health Services Vaccine Depots (AHS Vaccine Depots)	AHS locations that receive vaccine from the Provincial Vaccine Depot and then distributes the vaccine to AHS sites and Community Providers.
Alberta Health Services Sites (AHS Sites)	Sites that report to and are governed by AHS. These include, but are not limited to, Public Health Centres, AHS Workplace Health and Safety, and Acute Care Pharmacy.
Audit	An independent evaluation that will include quantitative and qualitative analysis.
Bar Refrigerator	Small single-door fridge that is non-lab grade and intended for food storage.
Chart Recorders	A device in which the refrigerator temperature is marked by ink pens on graph paper continuously 24 hours a day.
Cold Chain	Refers to the process used to maintain optimal temperature and light conditions during the transport, storage, and handling of vaccines. This starts at the manufacturer and ends with the administration of the vaccine to the client.
Cold Chain Excursion	The vaccine has been exposed to light and/or to temperatures outside the recommended range as specified in the product monograph.
Cold Chain Monitors	The device that monitors environmental conditions during the transport, storage, and handling of vaccines, from the point of manufacture until such time as the vaccine is administered to a client. They are indicators that show when a temperature excursion has occurred above or below the recommended +2.0ºC to +8.0ºC.e.g., TempTale®, LogTag™
Community Provider	Community Providers are individuals or group of individuals who are authorized to provide immunizations in the community and are not employed directly by AHS. Community Providers could include; medical clinics, private occupational health services, and post-secondary institutions. Community providers may receive vaccine from AHS or from wholesale distributors contracted by Alberta Health (e.g. Accuristix). Some community providers may receive vaccine from both AHS and wholesale distributors.
Continuous Temperature Recording Devices	An electronic device that measures temperatures and records the results. This includes Chart Recorders and Data Loggers.
Data Loggers	Miniature, battery-powered, stand-alone temperature monitors that record hundreds of temperature readings. They can indicate when the exposure occurred and how long exposure to the temperatures lasted. Multiple-use digital data loggers are accompanied by software that is installed on a computer allowing the user to set the frequency of temperature readings, download data from the device, and calculate temperature averages, minimums, maximums, and the time spent at each temperature.

Domestic Refrigerator	Combination refrigerator and freezer units. Also referred to as kitchen-style refrigerators.
Immunizer	A health practitioner who meets the following requirement and is eligible to administer vaccine as part of the Alberta Immunization Program: • A regulated member of a health profession body under the *Health Professions Act* and *Government Organization Act* authorized to administer a vaccine.
Laboratory Grade Refrigerator	Also referred to as pharmacy, purpose-built, laboratory, lab-style or industrial-quality refrigerators.
Manually Recorded	A paper-based temperature log or record keeping system completed manually.
Minimum and Maximum Thermometers	Thermometers that show the current temperature and the minimum and maximum temperatures that have been reached since the last time the thermometer was reset.
Pharmacies	Pharmacies are community pharmacies **that receive vaccine from Alberta Health via wholesale distributors** and are not employed by and/or under the governance of AHS. The community pharmacy has signed the Alberta Blue Cross Pharmaceutical Services Provider Agreement and is a proprietorship, partnership, corporation, business organization or other legal entity which is legally authorized by license, permit, registration or other lawful authority to provide pharmaceutical services, and is compliant with the applicable policies of the Alberta Immunization Policy.
Pharmacy Wholesale Distributors	Refers to a pharmacy wholesale distributor who has a signed vaccine distribution contract with Alberta Health.
Phase-Change Material	Phase-change materials are substances that absorb and release thermal energy during the process of melting and freezing. This includes gel packs and shipping containers that maintain temperature for longer periods.
Qualified Insulated Container/Package	Purpose-designated container that has been qualified by the manufacturer to transport vaccine. There should be a high degree of assurance that the container will maintain the vaccine at between +2.0ºC to +8.0ºC or as specified in the product monograph.
Staff	Persons who direct the storage/ or who have employment duties respecting the storage, handling and transportation of vaccine.
Vaccine Bags	Purpose-designated insulated bags used to transport vaccine.
Vaccine Controller	A staff member who is trained in vaccine storage, handling and transportation protocols, and in procedures for managing cold chain excursions.
Vaccine Suspension	Withholding of provincially funded vaccine **due to Cold Chain requirements not being met**.

IV. Policy Scope and Objectives

The Alberta Vaccine Storage and Handling Policy applies to all provincially funded vaccines.

The Policy outlines the accountabilities, roles and responsibilities for staff and immunizers in maintaining vaccine viability for provincially funded vaccines.

The Policy sets out cold chain (storage, transport, and handling) requirements for staff and immunizers in order to maintain the safety and efficacy of provincially funded vaccine.

Objectives of the Policy are to:

- Protect vaccine safety and efficacy;
- Ensure a potent and safe vaccine is administered;
- Minimize and reduce the cost of vaccine wastage due to cold chain excursions;
- Strengthen quality assurance activities related to vaccine cold chain storage, handling and transportation; and
- Improve knowledge of vaccine handlers regarding vaccine cold chain maintenance.

PART 2

1. ROLES AND RESPONSIBILITIES for Vaccine Storage, Handling and Transportation

All providers must comply with the requirements of the Policy	
Vaccine Cold Chain Protocols	Each site storing vaccine must have detailed, written, and easily accessible vaccine cold chain standard operating procedures in accordance with the Policy including: • Routine day to day operations; • Vaccine handling during transport; • Urgent situations including refrigerator malfunctions, power failures, natural disasters or other emergencies that might compromise vaccine storage conditions; and • Quality assurance plan.
Staff Education See Section 2	All staff, who handle vaccine in any way, must be orientated in vaccine storage, handling, and transportation according to the Policy.
Vaccine Controller	Each site where vaccine is stored must have a designated vaccine controller and another staff member as a back-up. The designated person is responsible for ensuring vaccines are handled and stored correctly and that procedures are followed and documented.
Vaccine Storage Requirements See Section 3	Sites must have vaccine storage equipment and back-up power in place as per the Policy.
Temperature Monitoring/Alarms See Section 4	Sites must have temperature monitoring equipment and alarms in place as per the Policy.
Vaccine Transportation See Section 5	Sites must have standard operating procedures for vaccine transportation as per the Policy.
Cold Chain Excursion See Section 6	Staff who handle vaccine must immediately label and return any vaccine exposed to a cold chain excursion to storage between +2.0°C and +8.0°C or as specified in the product monograph and report the incident.
Quality Assurance See Section 7	Sites must have a quality assurance plan for vaccine storage and handling (cold chain) practices.
Vaccine Supply	Sites should maintain no more than a one month supply of vaccine at any time.

AHS
Must designate a senior executive with accountability for the Alberta Vaccine Storage and Handling Policy.

AHS Province-wide Immunization
Must develop, implement and monitor vaccine storage, handling, and transport in accordance with the Policy including: providing vaccine cold chain standards, an education component, and a quality assurance plan.
May distribute Alberta's vaccine directly or through another Community Provider in conjunction with Public Health as applicable.
May withhold distribution of vaccine to AHS sites and Community Providers where there is inadequate vaccine storage, temperature monitoring, or unsatisfactory cold chain excursion reporting until these are corrected and in compliance with the Policy.
Must contact the manufacturer within 5 days to request a viability assessment and determination respecting the vaccine for AHS distributed product. Must provide the viability determination to all impacted sites.

AHS Sites and Community Providers
Sites that have been given the authority to further distribute vaccine within their facility/program assume accountability to ensure the sites they are distributing to are compliant with all aspects of vaccine storage, handling and transportation as per the policy.
Refer to the AHS Standard on Vaccine Storage and Handling for additional information www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf.

2. INFORMATION AND EDUCATION

Staff orientation and annual review to include the following elements	
Routine Vaccine Storage and Handling	Routine vaccine storage and handling for day-to-day operations including: • Importance of cold chain and the implications of cold chain excursions; • Recommended vaccine storage and handling practices; • Equipment maintenance and repair procedures; • Ensure contingency plans are in place in the event of premises closure during staff vacation, equipment failure and/or electrical disruptions; • Vaccine storage unit temperature monitoring; • Vaccine storage equipment maintenance; • Placement of vaccine within storage units; • Response to vaccine storage and handling problems, including off-site clinics; • Proper use and packing of vaccine bags/coolers (can be off-site or on-site); • Vaccine inventory management; • Packaging, transporting, and receiving vaccine shipments; and • Disposal of vaccines and diluents as directed by site specific policy.
Urgent Vaccine Storage and Handling	Urgent vaccine storage and handling in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions.
Management of Inappropriate Vaccine Storage Conditions	Immediate and appropriate action to be taken in the event of a vaccine exposure to temperatures outside the recommended storage conditions as specified in the product monograph.

3. VACCINE STORAGE REQUIREMENTS

Vaccines that require storage between +2.0°C and +8.0°C must remain in the refrigerator, except when being administered (see Cold Chain Maintenance and Vaccine Bags below) or transported (see Vaccine Transport section).

In the case of a power failure, refrigerator failure, or refrigerator maintenance, alternate storage that has the capacity to monitor Cold Chain is acceptable.

Laboratory Grade Refrigerators	Required for vaccine storage at sites with $5,000 or greater of vaccine. Advantages: – A digital feedback system that ensures narrow tolerances with internal temperatures; – Ongoing air circulation that ensures that the temperature distribution is even; – System for vaccine storage; – A set-point temperature is kept within the range specified in the product monograph; – Temperature recovery system is appropriate; and – Built to handle ambient temperature changes.
Domestic Refrigerators	• May be used for storage of vaccine less than $5,000. • Acceptable domestic combination refrigerator and freezer units must have separate external doors for the freezer and fridge. • Manual and cyclic defrost refrigerators should not be used due to the significant temperature variations and the risk of vaccines freezing. • Some domestic frost free refrigerators can be used but may require adjustments to how and where the vaccine is stored. That is, vaccines should only be stored in certain areas of the refrigerator, depending on the temperature zone. Vaccines should be stored in the middle of the compartment away from the coils, walls, floor, and cold-air vent. Precautions should be taken, as temperatures may fluctuate in different compartments of the refrigerator. Vaccines should never be stored in the bins or doors.
Bar Refrigerator units	Must **NOT** be used for continuous vaccine storage (eight hours or longer).
Vaccine Use Only	• Refrigerators are “Vaccine Use Only”. Do not store other items such as food, beverages, and/or clinical specimens in vaccine refrigerators to prevent unnecessary opening of the refrigerator. • For refrigerators where vaccines share space with other cold chain medications, consideration must be given to the frequency of access to these medications. Frequent access may compromise the temperature stability of that storage unit.
Refrigerator Maintenance	• Refrigerators must have regular maintenance checks (e.g., cleaning coils, checking door seals). • At a minimum, maintenance should be performed annually and records (e.g., a log book) retained for the period of time as determined by site specific records management standards. • Infection Prevention and Control measures should be in place as per current organizational requirements.

Power Supply	• All refrigerators must be connected to a dedicated circuit, that is, have nothing else plugged into the circuit. • Steps must be taken to protect the power supply (e.g., safety-lock plug, warning signals, warning signs, labeling fuses and circuit breakers).
Back-up Power	• On-site power back-up is required for sites with $20,000 or greater of vaccine; OR • Written agreement with an alternate storage facility with back-up power that can provide storage units to maintain the recommended storage temperatures.
Cold Chain Maintenance	• Cold Chain must be maintained when vaccine is not stored in the refrigerator (e.g., vaccine bag usage in clinic). • Appropriately pack vaccine in vaccine bags including a temperature-monitoring device unless using a container with phase-changing material to ensure the cold chain is not broken.
Vaccine Bags/Qualified Insulated Container	• Must be inspected for integrity prior to each use and an appropriate temperature monitoring device must be used to transport vaccine. If the vaccine bag is showing signs of wear due to material break down or damage, it must not be used. • Must be tested for their ability to maintain a stable temperature between +2.0ºC and +8.0ºC or at temperature specified in product monograph. • Vaccine bags must be replaced periodically (e.g. every 2 years), due to material break down and decreased effectiveness of ability to maintain temperature. • Infection Prevention and Control measures should be in place as per current organizational requirements.

4. TEMPERATURE MONITORING

The minimum, maximum, and current temperature of all refrigerators where vaccine is stored must be monitored and recorded.	
Temperature Monitoring Devices	The only thermometers and temperature recording devices that are acceptable for monitoring the temperature within vaccine storage units are: • **Minimum and Maximum Thermometer**. • **Data Logger** - must function like a min/max device and therefore the minimum, maximum, and current temperatures need to be downloaded twice a day. • **Alarmed Temperature Monitoring System** - must function like a min/max device and therefore the minimum, maximum, and current temperatures need to be downloaded twice a day. • **Chart Recorder in combination with a min/max thermometer** Note: Chart recorders can be hard to interpret, inaccurate, and difficult to ascertain minimum and maximum temperatures. In addition, if chart recorders are on the same power supply as the fridge (and do not have back-up power) and the power goes out – there is not enough data to make a decision on vaccine viability. Fluid-filled bio-safe liquid (bottle) thermometers, bi-metal stem thermometers, and household thermometers are NOT acceptable.
Continuous Temperature Recording Devices	Sites where $5,000 or more of vaccine is stored at any time must have a Continuous Temperature Recording Device. These include: • Chart Recorders (in combination with a min/max thermometer); OR • Data Loggers (downloaded twice a day); OR • Alarmed Temperature Monitoring System (downloaded twice a day)
Maintenance	• Thermometers should be checked annually to ensure the temperature measurement is accurate: ○ Temperature calibration is accurate - within at least ± 1.0ºC. This can be done by having the temperature monitoring device calibrated (contact the manufacturer for instruction) OR replacing the device. ○ Batteries are functioning. ○ Cables or probes are not damaged. • If applicable, there is an adequate supply of graph paper and ink pens for Chart Recorders.
Temperature Recording	At **minimum**, the temperature must be recorded and reviewed at the beginning and end of each business day (separated by at least 8 hours) for each refrigerator storing vaccine: • The current, minimum, and maximum temperatures need to be recorded; and • Minimum/Maximum thermometers need to be reset after recording the temperature.

Temperature Logs	• All temperature logs that are manually recorded must be verified by trained staff each business day to ensure appropriate vaccine storage temperature. • All alarmed temperature monitoring system logs need to be verified by trained staff each business day. • Temperature logs and Alarmed Temperature Monitoring System logs must be retained for one year.
Alarm Monitoring	• Sites where $20,000 or more of vaccine is stored at a time are required to have alarms that are monitored 24 hours a day, seven days a week and the capacity to respond quickly to the alarm. • In the event of an equipment malfunction that occurs outside of regular working hours, an alarm temperature monitoring system can prevent substantial vaccine and financial loss.
Alarm Setting	• Alberta Health recommends the following programming for alarm settings: ○ Storage between +2.0ºC to +8.0ºC. ○ Low +3.5°C ○ High +6.5°C • Freezer setting ○ -15°C

5. VACCINE TRANSPORT

Cold Chain must be maintained during transport to another location.	
Written protocols	Each site must have written standard operating procedures in accordance with the Policy, which must include providing instructions to the person(s) who has duties in the transportation of the vaccine to ensure that the temperature conditions are maintained.
Packing Vaccines	Vaccines must be packed for transport taking into account: • Type of transport; • Amount of vaccine to be transported; • External air temperature; and • Length of time the vaccine will be in a Qualified Insulated Container/Package. Packing configurations will vary on a seasonal basis.
Container	A Qualified Insulated Container or Vaccine Bag must be used to transport Vaccine.
Temperature Monitoring	An appropriate temperature monitoring device must be used to transport vaccine unless utilizing a pre-qualified container with phase-changing technology.
Receiving Vaccine	• When a vaccine shipment is received, it must be examined and stored as specified in the product monograph. • Check for evidence of physical damage, freezing or excessive heat. • Read and/or stop the recording of the temperature monitoring device upon receipt to determine if it has been activated or alarmed.
Cold Chain Excursions	In the case of a suspected cold chain excursion, see cold chain excursions section.
Staff training	Staff responsible for packing vaccine for transport must receive appropriate training in accordance with the Policy.

6. COLD CHAIN EXCURSIONS

All known exposures of vaccine to temperatures outside temperature or light requirements as specified in the product monograph must be reported.	
Quarantine Vaccine	• Affected vaccines must be isolated and marked as "DO NOT USE" until viability has been assessed. • Affected vaccines must be stored under the temperature conditions as specified in the product monograph as soon as possible following a cold chain excursion. • Affected vaccine must remain in quarantine until the viability of the vaccine has been assessed.
Exposed to second cold chain excursion	When vaccines are involved in more than one cold chain excursion, the cold chain excursion report must include the dates and locations of the previous cold chain excursions, in order to accurately assess the time out of refrigeration and/or exposure to light, which can have a cumulative effect on vaccine potency.
Reporting Cold Chain Excursions (Contraventions)	**AHS Sites** • AHS Province-wide Immunization will provide direction on the reporting of cold chain excursions • Must report cold chain excursions to AHS Province-wide Immunization as soon as possible. • AHS Province-wide Immunization must contact the manufacturer of the vaccine to request a viability assessment and determination of all reports of cold chain excursions within 5 days of receiving a report. • AHS Province-wide Immunization must provide viability determination of any vaccine to AHS sites • Refer to AHS Standard www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf • Vaccine Cold Chain Break Reporting Form can be found on the AHS website www.albertahealthservices.ca/frm-20322.doc **Community Providers** 1. Receiving AHS distributed vaccine – AHS Province-wide Immunization will provide direction on the reporting of cold chain excursions – Must report cold chain excursions to AHS Province-wide Immunization as soon as possible. – AHS Province-wide Immunization must contact the manufacturer of the vaccine to request a viability assessment and determination of all reports of cold chain excursions within 5 days of receiving a report. – AHS Province-wide Immunization must provide viability determination of any vaccine to AHS sites – Refer to AHS Standard www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf – Vaccine Cold Chain Break Reporting Form can be found on the AHS website www.albertahealthservices.ca/frm-20322.doc

	2. Receiving wholesale distributor vaccine – Report cold chain excursions to the vaccine manufacturer within 5 days for viability determination. – Notify wholesale distributor if vaccine received from them experiences a cold chain excursion. **Pharmacists** • Report cold chain excursions to the vaccine manufacturer within 5 days for viability determination. **Pharmacy Wholesale Distributors** • Cold chain excursions must be reported to Alberta Health within 24 hours. • Report cold chain excursions to the vaccine manufacturer within 5 days for viability determination. • Manufacturer recommendations must be shared with Alberta Health and approval is required prior to releasing product from quarantine.
Viability assessment and determination (Stability recommendation)	• Viability determination are for a specific incident and must not be applied to other similar exposures since viability information may change. • Each separate cold chain exposure requires the submission of an individual cold chain report.
Documentation and record keeping re: Cold Chain Excursions (temperature conditions contraventions)	• Documentation must include: ○ date and time that the cold chain excursion was identified; ○ date and time the vaccine was quarantined; ○ minimum and maximum temperatures recorded during the cold chain excursions; ○ duration of the cold chain excursion or the maximum possible duration if the actual duration is unknown; ○ date that the viability determination was provided; ○ viability determination (that is, viable or non viable); ○ statement of whether any non viable vaccines were administered to clients; ○ vaccine code of the vaccine(s) (see Vaccine Codes) that was(were) exposed; ○ manufacturer of the vaccine that was exposed; and ○ lot number of the vaccine that was exposed. • A copy of the documentation must be kept with the vaccine and sent with the vaccine. This is required in order to document time of exposure should this vaccine experience another cold chain excursion. • This record must be retained for at least 7 years.
Non-viable vaccine	• Ensure non-viable vaccine is not administered to clients. ○ AHS sites and Community Providers receiving AHS distributed vaccine refer to AHS Standard for management of non-viable vaccine www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf ○ Pharmacists and Community Providers receiving vaccine from wholesale distributors - non-viable vaccine is to be disposed of or returned to the manufacturer. • In the event that non-viable vaccine was administered to client(s), the client(s) will be notified by a health practitioner at the site within 5 days.

QUALITY ASSURANCE

Alberta Health and **AHS Province-wide Immunization (in conjunction with Public Health where applicable)**
Vaccine suspension May withhold distribution of vaccine to sites where vaccine handling equipment or practice is not in accordance with this policy, until these are corrected.
Audits/Onsite inspections Periodic Audits and/or onsite on-site inspections may be conducted to assess cold chain practices.

AHS Province-wide Immunization (in conjunction with Public Health where applicable)
Must conduct, at minimum, annual on-site inspections of all AHS depot sites to assess cold chain.
Must provide on-site inspections of new AHS Public Health sites prior to distributing and storing vaccine.
Must review cold chain management plans of new Community Providers receiving AHS distributed vaccine prior to providing them with vaccine.
Must conduct periodic audits, which may include on-site inspections, as determined by AHS, of AHS sites to assess cold chain practices.
May conduct on-site inspections of Community Providers to assess cold chain standards.

Pharmacists
Process for Pharmacy audits is through the Alberta College of Pharmacy.

References

Communicable Diseases Regulation, AR 238/1985, ss. 2 and 2.1.

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Additional Resources

CDC resources

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