

Vaccine Storage & Handling Guide



Rhode Island Department of Health
Office of Immunization

RHODE
ISLAND

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Vaccine Cold Chain

The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines under optimal conditions. The cold chain relies on three main elements:

- Well-trained personnel
- Reliable transportation and storage equipment
- Efficient management procedures

Practices enrolled in the Rhode Island State-Supplied Vaccine (SSV) program are required to have an assigned primary coordinator and a back-up coordinator to manage storage and handling responsibilities. All staff assigned to vaccine storage and handling responsibilities must complete the You Call the Shots Vaccine Storage and Handling [training modules](#).

Vaccine Storage Unit Requirements

Note: Purpose-built or pharmaceutical-grade storage units (units specifically designed for storing biologics, including vaccines) may have different storage and handling requirements than those outlined below. If your practice has a purpose-built unit, **save any user guides or manufacturer information insert for guidance on unit-specific storage requirements.**

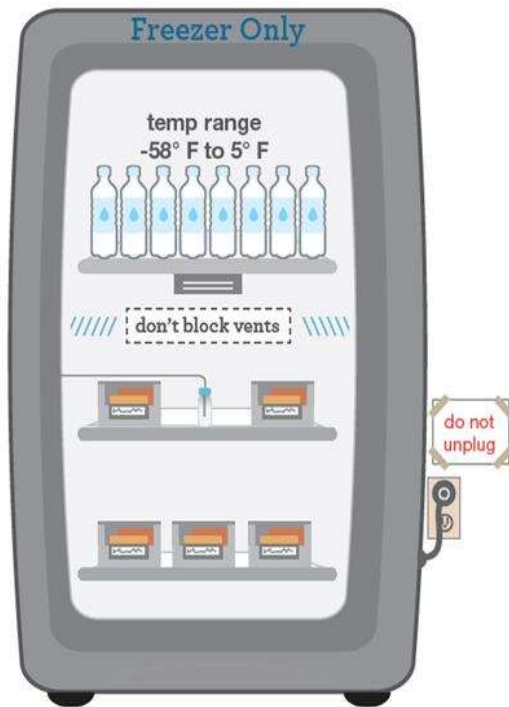
- **Stand-alone** refrigerator and freezer units are required for all vaccines.
 - If your unit is a combination (household) unit, only use the refrigerator portion. If you need to store both frozen and refrigerated vaccines, you will need to purchase a separate, stand-alone freezer unit.
- The vaccine storage unit must be large enough to store the year's largest vaccine inventory (usually flu season).
- Vaccine storage units must be dedicated to vaccines only. No food, beverages, or bodily fluids for laboratory testing can be stored with vaccines.
- Dorm-style refrigerators are **not** acceptable for vaccine storage.
 - A dorm-style refrigerator is classified as any size refrigerator with one external door and a freezer within the refrigerator compartment. Per the Centers for Disease Control and Prevention (CDC), all vaccines stored in a dorm-style unit will be deemed non-viable and must be returned.
- Avoid storing other medications and medical supplies with vaccines. If you do not have a separate refrigerator for other medicines and supplies, store these items **below** vaccines on a different shelf.

CDC Vaccine Storage Recommendations

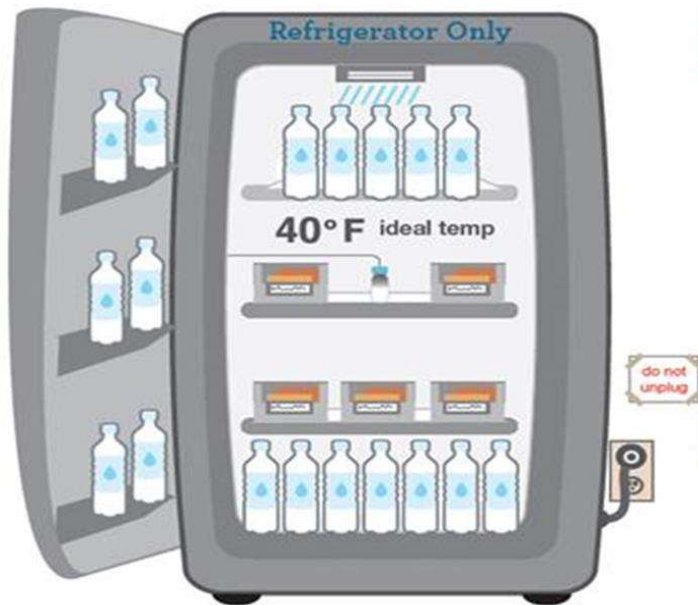
The CDC recommends the following for vaccine storage units:

- Use pharmaceutical-grade or purpose-built units designed to either refrigerate or freeze. These can be compact, under-the-counter styles or larger units.
- If a pharmaceutical-grade, built-in unit is not available, use a stand-alone household-grade unit.
- If you must use a combined refrigerator/freezer unit, use only the refrigerator compartment to store vaccines. You must then use a separate, stand-alone freezer to store frozen vaccines. **Using the freezer compartment of a household combination unit is not allowed.**

CDC Vaccine Storage Recommendations



CDC Vaccine Storage Recommendations



DO

- ✓ Do make sure the refrigerator door is closed!
- ✓ Do replace crisper bins with water bottles to help maintain consistent temperature.
- ✓ Do label water bottles "Do Not Drink."
- ✓ Do leave 2 to 3 inches between vaccine containers and refrigerator walls.
- ✓ Do post "Do Not Unplug" signs on refrigerator and near electrical outlet.

DON'T

- ✗ Don't use dormitory-style refrigerator.
- ✗ Don't use top shelf for vaccine storage.
- ✗ Don't put food or beverages in refrigerator.
- ✗ Don't put vaccines on door shelves or on floor of refrigerator.
- ✗ Don't drink from or remove water bottles.

Temperature Ranges

- Store **refrigerated** vaccines between 36°F and 46°F (2°C and 8°C).
- Store **frozen** vaccines between -58°F and 5°F (-50°C and -15°C).
- Never store vaccines against recommendations. For example, do not place vaccines meant to be refrigerated in the freezer.
- Set refrigerator or freezer thermostats at the factory-set or midpoint temperature. Consult the storage unit owner's manual for instructions on how to operate the thermostat.

Vaccine Placement

- Clearly label the designated space for each vaccine.
- Keep all vaccines in their original boxes and not loose in bins.
- Keep vaccines 2-3 inches away from walls and other boxes.
- Do not store vaccines in the door, at the bottom, or in drawers of refrigerators or freezers.
- Store water bottles or blocks in each of the vaccine units, if applicable.
- Post "Do not unplug" stickers above, near, or next to electrical outlets.
- If you must move the digital data logger probe, place the probe in the center of the unit.

Vaccine Inventory Control

- Conduct a vaccine inventory at least once a week and whenever vaccine is delivered.
- Avoid stocking excessive vaccine supplies. Limit inventory to a 60-day supply for monthly vaccines and 2-4 weeks for flu and COVID-19 vaccines.
- Monitor expiration dates and rotate stock. Use vaccines that expire sooner first.
- If vaccines will expire before use:
 - Locate another SSV-enrolled provider willing to accept vaccines transferred for use. Do not transfer opened, multi-dose vials to another practice.
 - Record transfer information in OSMOSSIS **before** removing vaccines from the practice. Do not transfer vaccines to any practice not listed in OSMOSSIS.
 - Use vaccine transport protocols when transferring vaccines.
- Never use expired vaccine or diluent.
- Immediately report expired or wasted vaccines through OSMOSSIS (read OSMOSSIS instructions to help choose the correct option). **Return labels will be emailed directly from McKesson.** Check your junk, spam, or clutter folders if you do not see an email from McKesson in your inbox.

Certified Calibrated Thermometers

- The CDC requires vaccine providers to use continuous temperature monitoring devices (data loggers) to monitor vaccine temperatures onsite, during transport, and at mass/community clinics. All SSV providers are eligible to receive a LASCAR state-supplied continuous temperature monitoring system from RIDOH.
- Practices are not required to use the state-supplied temperature monitoring device. However, any practice that purchases its own device must ensure it's a 24/7 continuous monitoring device that meets CDC guidelines for certified thermometers. Data logger criteria are outlined on the RIDOH [Office of Immunization website](#).

Temperature Monitoring Requirements

For RIDOH-issued data loggers, practices are responsible for completing the following temperature monitoring steps during each day of business operations:

- Log into the EasyLog Cloud temperature monitoring system to assess temperature records.
- Conduct an audit check on the data logger twice a day, at the start and end of business hours.
- After review of temperatures, enter initials into the *Comment* section under the *Table View* once a day.
- If approved to temporarily use a paper temperature monitoring log, record the minimum and maximum temperature on the paper log.

[Full instructions](#) on how to complete audit checks and initials in EasyLog Cloud are posted on the RIDOH Office of Immunization website.

Temperature Monitoring: Out of Range Temperatures

If the temperature of a vaccine storage unit goes outside of the recommended range:

1. Do not use vaccines in the affected unit.
2. Contact your Immunization Program Representative immediately.
3. Your Immunization Program Representative will review the EasyLog Cloud to determine if the out-of-range temperatures meet the criteria for an excursion.
4. If they do, your Immunization Program Representative will email you the *Temperature Excursion Response Worksheet*. Complete and return the worksheet to your Representative within 48 hours of the temperature excursion.
5. Your Immunization Program Representative will review manufacturer guidance to determine viability of the vaccines. Upon review, your they will contact you with further instructions on addressing the excursion and affected vaccines.

If vaccines are determined to be viable, place a mark or sticker on each box. Vaccines with an excursion history will need to be identified in the event of additional excursions.

Temperature Monitoring: Extended Practice Closures

If your practice is planning to be closed for an extended period, such as for a vacation or leave, and practice staff will not have access to the unit where your state-supplied vaccines are stored, your practice must:

1. Contact your Immunization Program Representative immediately to alert them to the extended closure dates.
2. All state-supplied vaccines must remain monitored and not go longer than 4 days without an audit being performed. Log into the EasyLog Cloud to assess temperature records every 4 days during your extended closure. After reviewing temperatures, enter your initials into the *Comment* section under the *Table View* once every 4 days during the extended closure.

The *Extended Practice Closure Temperature Monitoring* policy does not replace daily monitoring requirements. This exception will only be granted upon notification to an Immunization Program Representative. Practices that do not notify their Immunization Program Representative and have an extended lapse in their temperature monitoring will have their vaccine orders placed on hold. If a temperature excursion occurs during a lapse of monitoring, a practice may be held liable for the cost of the impacted vaccine due to negligence per the [Vaccine Replacement Policy](#).

Vaccine Management Plan

The CDC requires all SSV practices to create and maintain a Vaccine Management Plan with the following fields:

- Vaccine coordinator name and contact information
- Back-up vaccine coordinator name and contact information
- Description of roles and responsibilities for coordinators
- Procedures for vaccine ordering
- Procedures for receiving vaccine shipments or transfers
- Procedures for vaccine inventory control
- Procedures for temperature monitoring of vaccine storage units
- Procedures for handling of SSV vaccine waste and returns
- Procedures for transporting vaccine off-site
- Procedures for addressing out-of-range temperatures in the vaccine storage units

A [Vaccine Management Plan template](#) is available on the RIDOH Office of Immunization website.

Vaccine Storage Emergency Preparedness Plan

Emergency procedures may be necessary for:

- Equipment failure
- Impending or anticipated emergency, such as inclement weather
- Power outages

Practices should create and keep a current Vaccine Storage Emergency Preparedness Plan. The plan should include the identification of a back-up site with a generator, where the practice will store its vaccines should it experience equipment failure or a power outage. This plan can be combined with the Vaccine Management Plan, or practices can create a separate plan.

An [Emergency Preparedness plan template](#) is available on the RIDOH Office of Immunization website.

Emergency Vaccine Packing and Transport

If power loss is short-term (usually 2 hours or less), you can usually maintain storage temperatures during the time of outage with pre-chilled water bottles in the refrigerator and frozen coolant packs in the freezer. This depends on the room temperature. To help ensure safe temperatures during an outage:

- **Do not open the storage unit** until power is restored.
- Continue to monitor the temperatures of each unit.
- When power is restored, if temperatures are outside of recommended ranges, document the duration of inappropriate temperature exposure and follow procedures to report any loss to the Office of Immunization.

Do not allow vaccines to remain in a non-functioning unit for an extended period. If you are unsure how long the power interruption will last, activate your practice's Vaccine Storage Emergency Preparedness Plan.

Receiving Vaccines Deliveries

It's important to establish routine, systematic procedures to handle vaccine deliveries. Arrange for vaccine deliveries to occur only when the vaccine coordinator or alternate coordinator is in the office. Consider holidays, vacations, staff schedules, and changes in hours of operation.

All staff members, including non-medical staff, must be aware of the importance of maintaining the vaccine cold chain and need to immediately notify the vaccine coordinator when vaccines arrive so they can be properly handled and stored.

Check the Condition of the Deliveries

- Examine the shipping container and its contents for any signs of physical damage.
- Cross-check the contents with the packing slip to make sure they match.
- Check the vaccine lot numbers and expiration dates to be sure you have not received any vaccines or diluents that have already expired or will expire within 4 months.
- Check that the correct amount and type of diluents were shipped.
- Check the hot/cold temperature strips to determine if vaccines or diluents have been exposed to temperatures outside the recommended range.
- Ensure the vaccines were properly stacked. There should be an insulating barrier (bubble wrap or Styrofoam pellets) between the vaccines and the refrigerated or frozen coolant packs.

Receiving Vaccines Deliveries

Vaccines that require diluents will arrive in the same shipping container as the diluents. For varicella-containing vaccines, the diluents should arrive in a separate compartment of the same container.

Immediately store vaccines in the proper vaccine storage unit and do the following:

1. Rotate vaccines. Use vaccines that will expire sooner first.
2. Label vaccines (e.g., Pedi/State, Adult/State, or Adult/Private).
3. Be sure there is enough space between boxes of vaccines for adequate airflow.

If there are any discrepancies with the packing slip or concerns about the shipment:

- Mark or label the vaccines in question. Separate them from the other vaccines.
- Store the vaccines under appropriate conditions.
- Do not use the vaccines.
- Call the RIDOH Office of Immunization for guidance within 4 hours of delivery.

Vaccine Transfer

Vaccines may need to be transported for three reasons: emergency, transfer, or for off-site clinics.

If a practice is experiencing an emergency, such as a storage issue or power outage:

1. Notify the transfer site (identified in the Vaccine Management Plan and/or Emergency Plan) when and how much vaccine you will need to store.
2. Provide a list of all vaccine quantities, lot numbers, and expiration dates to the receiving practice and keep a copy at the transferring practice.
3. Follow appropriate pack-out procedures.
4. Do not retrieve vaccines from the transfer site until power is restored (if applicable) and your storage unit is operating under proper temperatures.

Vaccine Pack-Out Procedures

Pack-out materials:

- 2-inch-thick (Styrofoam or hard-sided) vaccine shipping container. CDC vaccine shipping containers are acceptable if intact. Do not use if there are tears or cracks in the cooler walls. Routinely check for damage.
- Conditioned frozen water bottles or conditioned frozen re-useable gel packs. CDC reusable gel packs used to ship vaccines are acceptable.
- Insulating material: corrugated cardboard cut to fit snugly against sides of cooler.
- Insulating cushioning material: 1-inch-thick bubble wrap or packing foam.
- Digital data logger (DDL) temperature monitoring device that is calibrated, has a digital display, has continuous temperature recording, and generates a detailed report.
- A vaccine inventory list form.

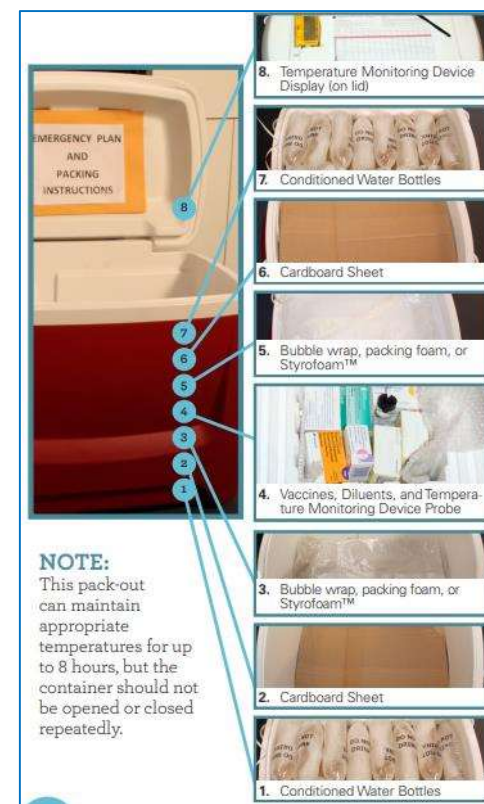
Vaccine Pack-Out Procedures

For emergency pack out, you can use conditioned water bottles or conditioned gel packs. For vaccine transfer or off-site clinic pack out, you can only use conditioned gel packs.

To condition water bottles and gel packs:

- Hold frozen water bottle under warm water until you see a water layer forming at the bottle surface. The bottle is conditioned when the ice block inside spins freely when rotated by hand.
- Hold the frozen gel pack under warm water until you feel the iced surface of the pack turn to water. The gel pack is now conditioned.

Example of emergency pack-out



Additional Resources

- CDC's [Vaccine Storage and Handling Toolkit](#)
- [RIDOH Immunization Resource Manual](#)
 - [Auditing Data Loggers](#)
 - [Stand-Alone Refrigerators and Freezers](#)
 - [Vaccine Storage and Transport Pack-Out](#)
- CDC's [Emergency Transport Guide](#)