

New York State Vaccines for Children (NYS VFC) Program Job Aid: Monitoring Vaccine Expiration Dates

An important part of managing vaccine inventory is understanding and monitoring expiration dates. **Expired vaccine or diluent should never be used.** If expired vaccine is administered by mistake, contact the NYS VFC program for guidance (1-800-543-7468).

Vaccine stock should be rotated weekly, with the vaccine that is to expire soonest, moved to the front. **Any expired or non-viableⁱ vaccine should be removed from the storage unit(s) and clearly labeled "Do Not Use.**" All publicly-funded vaccine that becomes non-viable must be reported to the NYS VFC Program via the New York State Immunization Information System (NYSIIS)*.

Expiration dates vary by type of vaccine or diluentⁱⁱ and lot number and are printed on vials, manufacturer-filled syringesⁱⁱⁱ and packages. As long as a product is normal in appearance and has been stored and handled properly, follow the expiration dates given.

Images obtained from the CDC's Vaccine Storage and Handling Toolkit



Vaccine Expiration Date: 08/16/15 Use through August 16, 2015. Do NOT use on or after August 17, 2015.



Vaccine Expiration Date: 08/15 Use through August 31, 2015. Do NOT use on or after September 1, 2015.

Exceptions to Expiration Dates: Beyond Use Dates

Some vaccines must be used prior to the expiration date that is printed on the label. This is referred to as the *Beyond-Use Date* or *BUD*. Always **refer to the product's package insert** to determine if the vaccine has a BUD.

Examples of vaccines with BUDs:

- Reconstituted vaccine
 - Reconstitution refers to a process in which lyophilized or freeze-dried vaccine is mixed with a diluent prior to administration. Once a lyophilized or freeze-dried vaccine has been reconstituted, there is a limited time frame in which it can be used (BUD). The life of each reconstituted vaccine varies by product. Calculate the BUD using the time interval found in the vaccine's package insert. Label the vaccine with the correct beyond use date/time and your initials.
- Vaccine with a manufacturer-shortened expiration date
 - If vaccine has been exposed to inappropriate storage conditions, potency may be reduced before the expiration date. The manufacturer may shorten the expiration date.

Additional exceptions to expiration dates:

- Vaccine that has been exposed to inappropriate storage conditions
 - If you are unsure whether vaccine is still usable due to a temperature excursion^{iv}, do not use the product, clearly label it "Do Not Use" and contact the vaccine manufacturer to determine whether the product is still viable or useable.

*All publicly-funded vaccine that becomes nonviable must be reported to the NYS VFC Program via the New York State Immunization Information System (NYSIIS). For instructions and information on how to use NYSIIS to report/return nonviable, publicly-funded vaccine refer to the NYSIIS Returns/Wastage Training Handout and the NYS VFC Program Job Aid: Return or Discard.



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Additional exceptions to expiration dates (cntd.):

- Pre-drawn vaccine and single dose vials with caps removed or with a metal seal that is not intact
 - Any vaccine that has been pre-drawn and is unused by the end of the workday is considered non-viable and should be discarded*. The Centers for Disease Control and Prevention (CDC) recommends that providers draw up vaccines only at the time of administration and do not pre-draw vaccines.





- Do not open a single-dose vial until ready to use. A single-dose vial with the cap removed or with a metal seal that is not intact, that is unused by the end of the workday, is considered non-viable and should be discarded* as it is difficult to tell whether a syringe has entered the vial.
- Activated manufacturer-filled syringes
 - Manufacturer-filled syringes are prepared and sealed under sterile conditions by the manufacturer. Once a manufacturer-filled syringe is activated (i.e., syringe cap removed or needle attached), the sterile seal is broken. An activated manufacturer-filled syringe that is unused by the end of the workday is considered non-viable and should be discarded*.

Expiration Date Guidance		
Vial Type	Condition	What do I do?
Single-dose vials and manufacturer-filled syringes	Vial is opened or the syringe has been activated.	Use or discard by end of clinic day*
	Unopened, or inactivated	Use until expiration date indicated by manufacturer
Single-dose vials (reconstituted)	Vial has been reconstituted (opened)	Clearly label the vial with the date and time the vaccine was reconstituted and use only within the timeframe specified by the manufacturer (indicated in the package insert).
Multi-dose vials (not requiring reconstitution)	Vial has been opened/entered	May be used until expiration date printed on vial, unless contaminated ^v or manufacturer package insert specifies otherwise
	Unopened	May be used until expiration date printed on vial

Adapted from the Colorado Department of Public Health's Vaccines for Children Program Job Aid: Interpreting Vaccine Expiration Dates

Resources

New York State Vaccines for Children Program, 1-800-543-7468

nyvfc@health.ny.gov http://www.health.ny.gov/vfc

Centers for Disease Control and Prevention, Vaccine Storage and Handling Toolkit

http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

Centers for Disease Control and Prevention, Epidemiology and Prevention of Vaccine-Preventable Diseases. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C. Public Health Foundation, 2015.

http://www.cdc.gov/vaccines/pubs/pinkbook/index.html

Immunization Action Coalition, Vaccines with Diluents: How to Use Them

http://www.immunize.org/catg.d/p3040.pdf

Colorado Department of Public Health and Environment, Job Aid: Interpreting Vaccine Expiration Dates: When Do Vaccines Really Expire? <u>https://www.colorado.gov/pacific/cdphe/vaccines-children</u>

¹ Nonviable vaccine refers to vaccine that can no longer be used for any reason including: expiration, spoilage due to temperature excursion, vaccine that has been opened/damaged (e.g., broken syringe, vaccine that was drawn up but not administered, etc.).

[#] A diluent is a liquid that is mixed with a lyophilized (freeze-dried) vaccine prior to administration in a process called reconstitution.

A manufacturer-filled syringe is a vaccine product that is pre-filled and sealed by the manufacturer.

^v Multi-dose vials to be used for more than one patient should not be kept or accessed in the immediate patient treatment area to prevent inadvertent **contamination** from surfaces or equipment. If a multi-dose vial enters the immediate patient treatment area, it should be discarded after use.

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¹ A **temperature excursion** is an event in which vaccine is exposed to out-of-range temperatures. The acceptable temperature range for refrigerated vaccine: Between 35°-46° Fahrenheit or between 2°-8° Celsius. Acceptable temperature range for frozen vaccine: Between -58° and 5° Fahrenheit OR between -50° and -15° Celsius.