

***Sample SOP for Vaccine Management  
(YOUR PROVIDER SITE NAME)***

**Please Post on or near your vaccine storage unit(s)**

**Purpose**

To ensure the safe storage and handling of vaccines in order to maintain optimum potency.

*(Designated Person)* is the Vaccine Manager and will be responsible for oversight of all vaccine storage and handling and *(Designated Person)* will be the backup Vaccine Manager.

**Vaccine Ordering and Inventory Control**

- *(Designated Person)* will complete and fax the *Vaccine Order Form, Usage Form* and current **temperature logs** for all vaccine storage refrigerators to (617) 983-6924.
- *(Designated Person)* will complete a physical inventory of all vaccines in the refrigerator before placing an order.
- Orders should be placed when vaccine inventories reach about a 4 week supply.
- Establish a routine, so that orders are placed no more than once per month.
- Vaccines will be delivered directly to the office based on shipping information given by the provider.
- Contact the Vaccine Management Unit (617) 983-6828 to update any changes regarding shipping information.

**Documentation**

- Enroll annually in the MDPH Immunization Program/Vaccine for Children (VFC) program.
- *(Designated Person)* will review and update the provider SOP on an annual basis.
- Maintain a record of vaccines received and returned; including type of vaccine, manufacturer, lot number, expiration date and number of doses.
- Retain the order form for reference when the vaccine shipment arrives.
- Maintain temperature logs for a minimum of 3 years
- Offer the appropriate Vaccine Information Statement (VIS) with each dose of vaccine administered. Subscribe to the CDC's e-mail update for VIS at: (<http://www.cdc.gov/vaccines/pubs/vis>)
- Record vaccine administration information in the patient's chart including: administration date, type of vaccine, manufacturer, lot number, date on VIS, and date VIS is given.
- Record all doses administered on the Vaccine Usage Aggregate Report.

**Vaccine Receiving**

- Upon arrival at *(your site)*, open box of vaccines immediately. Check the two transit temperature monitors. *(Designated Person)* must contact the Vaccine Management Unit @ 617-983-6828 within 2 hours of receipt of vaccine if temperature monitors indicate a possible temperature variation. Vaccines will then be counted and compared with packing list and original order form making sure the order and delivery is correct, with all expiration dates and lot numbers matching.
- Ensure that all containers noted on the packing list have been delivered.
- If there are any concerns or inaccuracies with the vaccine order or cold chain monitors *(Designated Person)* will contact the MDPH Vaccine Management Unit (617) 983-6828 immediately for guidance.
- Once an inventory is completed, the vaccine is immediately placed in the refrigerator/freezer designated for vaccine storage only.
- *(Designated Person)* will contact McKesson Specialty Customer Care at (877) 822-7746, to arrange for shipping box return.
- Always keep 1 box on hand to use when returning any lost or expired vaccine.

**Vaccine Storage**

- All refrigerated vaccines must be stored within the temperature range of 2° C to 8° C, or 35° F to 46° F, in a refrigerator designated for vaccine storage only.
- Varicella and MMRV vaccine must be stored in a frost-free freezer with a separate, insulated door that maintains a temperature of -15° C (+5° F) or colder.
- All refrigerators/freezers designated for vaccine storage will be set to maintain the proper temperature using a calibrated product temperature thermometer, certified by an appropriate agency (eg: National Institute of Standards and Technology).

### **Vaccine Storage continued**

- *(Designated Person)* will rotate stock ensuring that short-dated vaccine is used first.
- Inventory will be clearly marked or identified so that you can differentiate between state-supplied and private purchased vaccine.
- The thermometers should be placed in a central area of the refrigerator and freezer unit adjacent to the vaccine.
- Food or beverage should not be stored in the vaccine storage units.
- Vaccines should be stored centrally in the refrigerator or freezer, not on the door or on the bottom of the storage unit, and sufficiently away from walls to allow for proper air circulation.
- Bottles of water should be placed in the refrigerator and ice packs in the freezer, if space allows, maintaining the internal temperatures of the storage unit.
- A “DO NOT UNPLUG” sign is posted next to the refrigeration units electrical outlet and a “DO NOT DISCONNECT” sign is posted next to the circuit breaker for the refrigerator.

### **Temperature Monitoring**

- Refrigerator/Freezer temperatures will be monitored and recorded at least twice daily on temperature logs attached to each unit, one time at the start of the workday and one time at the end of the workday.
- Temperature logs must be maintained for at least 3 years.
- *(Designated Person)* must review temperature logs at least once a week for completeness and any deviations from recommended temperature ranges.
- Around-the-clock monitoring systems might be considered to alert staff to after-hours emergencies, particularly if large vaccine inventories are maintained.

### **Temperature Out of Range**

- Any out of range temperatures should prompt immediate action by contacting the MDPH Vaccine Management Unit at 1-617-983-6828 for guidance. When a problem is discovered, the exposed vaccine is maintained at proper temperature and marked “Do Not Use”. Vaccine Management Unit staff will determine if the vaccine is still viable for use.
- If a freezer temperature is out of range, contact the MDPH Vaccine Management Unit immediately at (1-617-983-6828). If necessary, the manufacturer of varicella and MMRV vaccine might have to be contacted (1-800-672-6372). Please have available the lot number of the vaccine affected, the temperature the vaccine was exposed to, and the duration of time the vaccine was stored out of range.
- All out of range temperatures require immediate reporting to the Vaccine Management Unit with actions and results of these actions documented on the temperature logs.

### **Power Failure/Refrigerator Failure**

- In the event of an extended building power failure or refrigerator failure, vaccines will be packed in insulated containers with cool packs and transported to secure refrigerators located at a pre-arranged site. This site location is *(indicating site address, phone number and contact person/s here)*. The above temperature ranges and monitoring procedures will be followed at the back up site. The MDPH Vaccine Management Unit will be notified immediately at (1-617-983-6828). Varicella and MMRV vaccine should only be transported in an insulated container with dry ice.
- *(Designated person)* will review and update the practice emergency plan on an annual basis.

### **Vaccine Returns**

- All vaccines that cannot be used due to expiration or exposure to unsafe temperatures must be reported to the Vaccine Management Unit and appropriately coded on an *Expired/Damaged Vaccine Return Form*.  
***Loss of efficacy due to exposure can only be determined by Vaccine Management Unit***
- *(Designated Person)* will fax completed *Expired/Damaged Vaccine Return Form* to Vaccine Management Unit (617)983-6924 for review. Once reviewed, the Vaccine Management Unit will fax back the approved form for shipping.
- Pack Vaccine in a McKesson shipping box with the return form and return shipping label provided and the Vaccine Management Unit will arrange to have the non-viable vaccine picked up.