Indiana Department of Health-Immunization Division

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| **Policy & Procedure Title** | Storage and Handling-Emergency Plans | **Issuing Date** | 07/17/2012 |
| **Policy & Procedure Number** | 10 | **Revision Date** | 02/05/2020 |
| **Policy & Procedure Approval Authority** | Dave McCormick | | |

**Policy Statement**

Every clinic that receives publicly funded vaccine should have an Emergency Management Plan in the event of inclement weather, power outages, and/or storage unit failures. All staff members should be trained on the policies and procedures of the Emergency Management plan.

All provider vaccine storage and handling plans must be reviewed and updated annually, or more frequently if changes to any information within the plan occur, such as new staff members who have responsibilities specified in the plan.

Written emergency storage and handling plans must be developed and maintained by every facility and/or clinic. A template form should be used and posted on the vaccine storage unit which includes details of the Emergency Management of Vaccines plan, containing instructions and emergency contact information. An Emergency Management Plan is necessary so that vaccine can be transported to another location if situations occur that make it so vaccines can no longer be safely stored at the facility. Such situations may include:

- A power outage that lasts more than 1 hour
- A malfunction of your vaccine storage unit
- A natural disaster
- A building maintenance issue such as a burst water pipe that results in standing water
- Even if your facility has a back-up generator, there may be a time when you will not be able to keep your vaccine storage unit plugged in and operational.

***Note: Immediately contact the Indiana Immunization Division in the event of an emergency. NEVER discard vaccine that has been exposed to a temperature excursion unless directed to by the vaccine manufacturer or the Immunization Division.***

**Calibrated digital data loggers with continuous monitoring and recording capabilities are required for all Emergency transfers**. Before providers transfer vaccine offsite during an emergency situation, they should contact, preferably by phone, the Regional Quality Assurance Specialist. If the RQAS is not available, they should contact the Immunization Division, at 1-800-701-0704. If contacted via email, please put *Emergency Pack-out* in the Subject line. If the emergency happens after hours, they should still notify the RQAS and follow the checklist and procedures in the most current Vaccine Management Plan.

A digital data logger report is required upon return of the vaccine to ensure all temperatures have been maintained in transit and stored properly at the alternative facility.

If temperatures are not monitored during transport/temporary storage, the vaccine could be deemed wasted because there is no proof that temperatures remained within acceptable ranges, regardless of duration.

**Failure to properly follow the pack-out procedures and provide documentation of proper temperatures could result in restitution of the vaccine loss - See restitution policy.**

When initiating emergency procedures, vaccines should never be in the trunk or bed of a vehicle and the temperature should be maintained before placing vaccines in the vehicle.

Every clinic should also have an emergency vaccine retrieval and storage plan. The plan should be easily accessible to staff and identify a backup location where the vaccine can be stored. Considerations when choosing this site include appropriate storage units, temperature monitoring capability, and a backup generator. Potential backup locations might include a local hospital, pharmacy, long-term care facility, or the Red Cross.

Providers should keep an adequate supply of packing materials (i.e. coolers/insulated shipping containers, cardboard, bubble wrap, and frozen water bottles) and calibrated temperature monitoring device(s) to accommodate the facility's vaccine supply, if transport is needed.

All providers should follow the following steps in the event of an emergency to ensure the viability of all publicly funded vaccines.

*Step 1) Provider notifies the emergency contact person for the site*

*Step 2) Provider determines if a generator or alternate power source is available. If so, ensure that all steps are followed to maintain the vaccines within the required temperature range for each storage unit.*

*Step 3) If the power failure will be temporary (less than 2 hours), providers should do the following:*

a. Ensure that the refrigerator and freezer doors remain closed for the duration of the outage.

b. Document the time of the power outage and the duration of the outage.

c. Document the room temperature during the outage.

d. Monitor the temperatures during this time.

Under these conditions, it is not necessary to remove the vaccines from the storage unit since the rise in temperature could be only slight or insignificant.

*Step 4) If the power or equipment failure is expected to last longer than 2 hours, follow these steps:*

a. Maintain use of generator or alternate power source and ensure that vaccines continue to be stored at appropriate temperatures.

b. If an alternate power source or equipment is not available, the provider should begin making arrangements to transfer the vaccine to a predetermined emergency storage facility.

c. The provider should begin packing the vaccine for transfer to the alternate location

1) The vaccine should be placed in insulated transport containers or shipping boxes with conditioned water bottles, cardboard, bubble wrap, and a continuous temperature monitoring device. Please refer to the **packing order diagram** for further guidance.

i. All refrigerated vaccines should be transported at 36° to 46°F (2° to 8°C)

ii. All varicella-containing or frozen vaccines should be transported at 5°F (-15°C) or colder. Use of dry ice is not recommended, even for temporary storage or emergency transport.

*The CDC and vaccine manufacturer do not recommend transporting varicella-containing vaccines. If these vaccines must be transported, CDC recommends transport with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). If varicella-containing vaccines must be transported and a portable freezer unit is unavailable, the vaccine MAY be transported at refrigerator temperature 36° to 46°F (2° to 8°C) for up to 72 continuous hours prior to being reconstituted. Please see the Special Instructions for Transport of Varicella-Containing Vaccines located in the References and Resources section of the policy manual.*

iii. Measles, mumps, and rubella vaccine (M-M-R-II) may be transported in a refrigerated or frozen state.

iv. Diluent does not need refrigeration and cannot be frozen.

d. If at any time during the power outage or equipment failure, the temperature is recorded **above** or **below** the recommended range, **DO NOT USE** the vaccine until the following steps are taken and the viability of the vaccine has been determined.

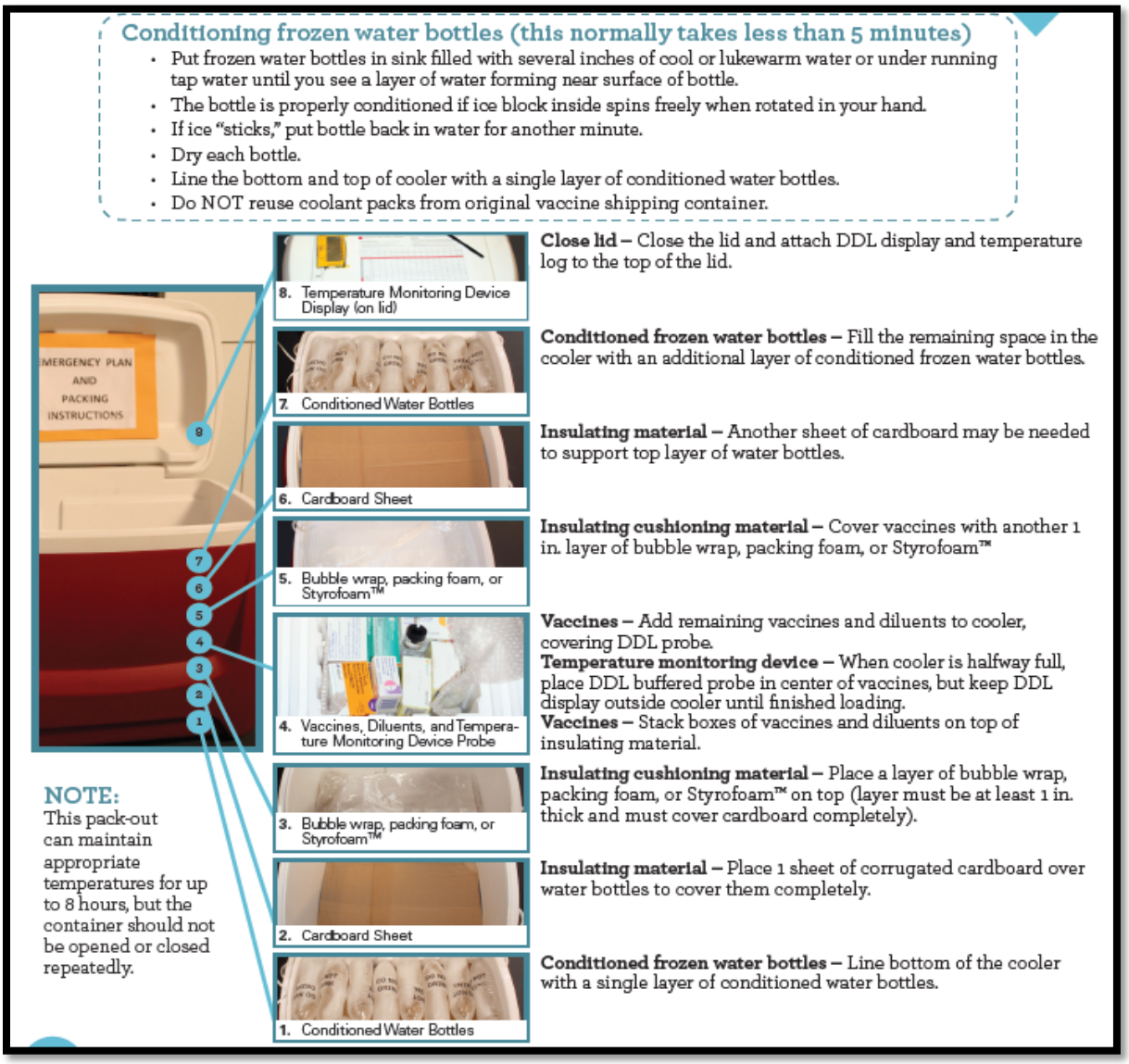
i. Immediately check the continuous temperature monitoring device for correct placement and operation.

ii. Contact the Indiana Immunization Division at (800) 701-0704.

iii. Contact the manufacturer of each affected vaccine.

e. In the event of an outage or equipment failure or if temperatures are **above** or **below** the recommended temperature for an extended period of time **AND** the vaccine was not relocated, immediately contact the manufacturer and your designated Regional Quality Assurance Specialist.

**Packing Order Diagram**



**References & Resources**

Centers for Disease Control and Prevention. (2020) Vaccine Storage and Handling Toolkit, Revised January 2020. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit-2020.pdf

Centers for Disease Control and Prevention. (13th Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2015. http://www.cdc.gov/vaccines/pubs/pinkbook/index.html

Emergency Response Worksheet, Immunization Action Coalition. http://www.immunize.org/catg.d/p3051.pdf

**Revision History**

07/17/2012, Created
11/19/2014, Revised
02/25/2016, Revised
04/01/2017, Revised