Standard 3.7 - Management of Storage Excursions

Preamble:

Vaccines are very sensitive products that can lose their effectiveness if subjected to less than optimum temperature and light conditions (hereafter referred to as *excursions*). Each vaccine is different, and the impact of the excursions varies depending on the type of excursion, the length of time the vaccine was exposed and the extent of the exposure (e.g., maximum temperature).

In the event that an excursion occurs, prompt and appropriate action is required to prevent further exposure and to assess the impact of the excursion.

The best way to prevent storage excursions is to ensure that recommended handling and storage guidelines are followed. Refer to *Standard 3.4 – Vaccine Storage and Handling* for additional information.

Procedures:

In the event that a storage excursion is identified:

- 1. Involve the vaccine co-ordinator or his or her back-up.
- 2. Assess the potential for continued risk to the product and take immediate steps to protect the vaccine. This may require moving the vaccine to an alternate storage location or packing the vaccine in coolers.
- 3. Identify, label (DO NOT USE) and quarantine *all* vaccines that have potentially been compromised by the storage excursion. Keep the vaccine in ideal storage conditions (2°C to 8°C) or as otherwise noted in the product monograph while investigating the excursion. Do not assume that exposed vaccines can or cannot be used; you must complete an investigation.
- 4. Once the vaccine has been secured, determine the details of the excursion:
 - a. Determine the nature of the excursion excessive heat, freezing or exposure to light;
 - b. Determine the duration of the exposure how long was the vaccine subject to less than ideal conditions; and
 - c. Determine the degree of the exposure what was the minimum or maximum temperature to which the vaccine was exposed.
- 5. For a first-time excursion, refer to the product monograph for each vaccine involved in the excursion. Product stability information may be included in the product monograph and should be used by the vaccine co-ordinator to determine if the vaccine can be used. It is important to ensure the most current product monograph is followed. If the product monograph does not contain information, it is necessary for the vaccine co-ordinator to contact the product manufacturer for guidance. Please note that stability data are NOT to be used as a guide for regular storage conditions. Vaccines must be stored in conditions as recommended by the manufacturer.
- 6. For subsequent excursions, on a previously exposed vaccine, the vaccine co-ordinator must consult with the manufacturer for guidance on whether the product can be used.
- 7. If vaccines are deemed usable, they should be labeled to indicate that they have been exposed to an excursion (include the date of the excursion) and used before vaccines not exposed to a storage excursion.
- 8. The Vaccine and Biologics Loss Summary Report Appendix 4.1.4, must be completed for all excursions, regardless of the outcome. The completed form is to be faxed to the Central Serum Depot (CSD), 506-648-6477.
- 9. Vaccine deemed unusable should be returned to the CSD directly or through a local sub depot along with a copy of the *Vaccine and Biologics Loss Summary Report*.

References:

- 1. National Vaccine Storage and Handling Guidelines for Immunization Providers, 2015. https://www.canada.ca/en/public-health/services/publications/healthy-living/national-vaccine-storage-handling-guidelines-immunization-providers-2015.html.
- 2. CDC Manual, Immunization Section, BCCDC, http://www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm.
- 3. Vaccine Storage and Handling Guide, Ontario Ministry of Health and Long-Term Care http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/reference/vaccine%20_storage_handling_guidelines_en.pdf.
- 4. Vaccine Storage and Handling Guide, Protect your vaccine Protect your patients, US Center for Disease Control, October 2011 https://www.cdc.gov/vaccines/hcp/admin/storage/index.html.