Massachusetts Department of Public Health Immunization Division State Vaccine Program

MA Vaccine Program Guidelines for Reporting Out of Range Temperatures

This policy outlines the guidelines for reporting out-of-range (OOR) temperatures for refrigerators, freezers, and ultra-cold freezers storing state-supplied vaccines. The guidelines specifying when immediate or cumulative reports are required based on temperature deviations. If an OOR temperature lasts a cumulative 30 minutes (within a 24-hour period) sites must contact the Vaccine Program immediately via the submission of a TempX form in the MIIS, as this is considered a temperature excursion. Shorter out-of-range temperatures do not require reporting to the Vaccine Program, as viability data indicates that the vaccines will remain viable, as described in the tables below.

1. Definitions

Terminology	Definition
1.1 Normal Daily Operating Range (NDOR)	The temperature range within which vaccines are safely stored during routine operations in a refrigerator or freezer. Refrigerators should maintain temperatures between 2° C and 8° C (36° F and 46° F). Freezers should maintain temperatures between -50° C and -15° C (-58° F and +5° F). Ultra-Cold Freezers should maintain temperatures below -50° C (-58° F).
1.2 Out of Range (OOR) Temperature	Out of range temperatures refer to any instance where storage unit temperatures are outside of the normal daily operating range. Depending on the temperature reached and the time out of range, vaccine viability may not be impacted. Please note that not all out-of-range temperatures are considered temperature excursions.
1.3 Temperature Excursion	Excursions occur when storage unit temperatures deviate outside of the normal daily operating range to a point where vaccine viability could be impacted due to the temperature reached or the duration of the temperature deviation.

2. Reporting Requirements

Unit Type	Report Frequency	Temperature Range
2.1 Refrigerator OOR	Immediate	1.Temperature reaches +25°C or above, regardless of duration.2. Temperature drops to 0°C, regardless of duration.
	Cumulative	1. Temperature is above +8°C or below +2°C for a cumulative duration of 30 minutes or more within a 24-hour period. * Open MDV are non-viable after falling below +2°C for any duration or above +8°C for over 30 minutes cumulatively *
2.2 Freezer OOR	Immediate	 Temperature reaches 0°C or above, regardless of duration. Temperature drops below -50°C, regardless of duration.
	Cumulative	Temperature is above -15°C for a cumulative duration of 30 minutes or more within a 24-hour period.
2.3 Ultra-Cold Freezer OOR	Immediate	Temperature reaches -50°C or above, regardless of duration.