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the identity and integrity of the product. Samples retained as required in this section shall be in addition to samples of specific products required to be submitted to the Center for Biologics Evaluation and Research. Exceptions may be authorized by the Director, Center for Biologics Evaluation and Research, when the lot yields relatively few final containers and when such lots are prepared by the same method in large number and in close succession.

[41 FR 10428, Mar. 11, 1976, as amended at 49 FR 23833, June 8, 1984; 50 FR 4133, Jan. 29, 1985; 55 FR 11013, Mar. 26, 1990]

§ 600.14 Reporting of errors.

(a) The Director, Office of Compliance, Center for Biologics Evaluation and Research (HFB–100), 8800 Rockville Pike, Bethesda, MD 20892, shall be notified promptly of errors or accidents in the manufacture of products that may affect the safety, purity, or potency of any product.

(b) Manufacturers of licensed in vitro diagnostic products, and manufacturers of unlicensed in vitro diagnostic products which are required to be registered under part 607 of this chapter, shall notify the Director in accordance with paragraph (a) of this section. Manufacturers of other in vitro diagnostic products which are required to be registered under part 807 of this chapter, shall report in accordance with part 803 of this chapter.

[38 FR 32048, Nov. 20, 1973, as amended at 49 FR 23833, June 8, 1984; 49 FR 36348, Sept. 14, 1984; 55 FR 11014, Mar. 26, 1990]

§ 600.15 Temperatures during shipment.

The following products shall be maintained during shipment at the specified temperatures:

(a) *Products.*

Product	Temperature
Cryoprecipitated AHF	−18 °C or colder.
Measles and Rubella Virus Vaccine Live.	10 °C or colder.
Measles Live and Smallpox Vaccine.	Do.
Measles, Mumps, and Rubella Virus Vaccine Live.	Do.
Measles and Mumps Virus Vaccine Live.	Do.
Measles Virus Vaccine Live	Do.
Mumps Virus Vaccine Live	Do.
Fresh Frozen Plasma	−18 °C or colder.
Liquid Plasma	1 to 10 °C.
Plasma	−18 °C or colder.
Platelet Rich Plasma	Between 1 and 10 °C if the label indicates storage between 1 and 6 °C, or all reasonable methods to maintain the temperature as close as possible to a range between 20 and 24 °C, if the label indicates storage between 20 and 24 °C.
Platelets	Between 1 and 10 °C if the label indicates storage between 1 and 6 °C, or all reasonable methods to maintain the temperature as close as possible to a range between 20 to 24 °C, if the label indicates storage between 20 and 24 °C.
Poliovirus Vaccine Live Oral Trivalent.	0 °C or colder.
Poliovirus Vaccine Live Oral Type I.	Do.
Poliovirus Vaccine Live Oral Type II.	Do.
Poliovirus Vaccine Live Oral Type III.	Do.
Red Blood Cells (liquid product).	Between 1 and 10 °C.
Red Blood Cells Frozen	−65 °C or colder.
Rubella and Mumps Virus Vaccine Live.	10 °C or colder.
Rubella Virus Vaccine Live	Do.
Smallpox Vaccine (Liquid Product).	0 °C or colder.
Source Plasma	−5 °C or colder.
Source Plasma Liquid	10 °C or colder.
Whole Blood	Blood that is transported from the collecting facility to the processing facility shall be transported in an environment capable of continuously cooling the blood toward a temperature range of 1 to 10 °C, or at a temperature as close as possible to 20 to 24 °C for a period not to exceed 6 hours. Blood transported from the storage facility shall be placed in an appropriate environment to maintain a temperature range between 1 to 10 °C during shipment.
Yellow Fever Vaccine	0 °C or colder.