WAC 246-339-010 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Allogeneic transfusion" means a blood transfusion where the donated blood comes from an individual other than the recipient.

(2) "Autologous donation" means the infusion or transfer of human blood cells back into the individual from whom the cells were recovered.

(3) "Blood establishment" means a blood-collecting or distributing blood establishment or organization that collects or distributes blood for allogeneic transfusion in Washington state. This chapter does not apply to a hospital licensed under chapter 70.41 or 71.12 RCW unless the hospital collects blood directly from donors for the purpose of allogeneic transfusions. For the purposes of this chapter, blood establishment does not include organizations that collect source plasma as defined in this section.

(4) "Change in standing" means that a blood establishment is the subject of titled letters, fines, suspensions, or revocations of its United States Food and Drug Administration (FDA) license, or judicial consent decrees.

(5) "Department" means the Washington state department of health.

(6) "Directed donation" means a donation of blood or blood products to a specific recipient who is personally known by the donor before donation.

(7) "FDA" means United States Food and Drug Administration.

(8) "Judicial consent decree" means an agreement between the FDA and a blood establishment that outlines steps that a blood establishment must take in order to return to full, independent production. The consent decree mandates that a blood establishment initiate change, and that change is usually associated with the way the blood establishment is manufacturing a product in order to bring it into compliance with the FDA's requirements.

(9) "Source plasma" means the fluid portion of human blood collected and intended as source material for further manufacturing use. The definition excludes single donor plasma products intended for intravenous use.

(10) "Titled letter" or "warning letter" means an FDA-issued correspondence that notifies blood establishments about violations that the FDA has documented during its inspections or investigations. Typically, a warning letter notifies a responsible individual or firm that the FDA considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the act), its regulations, and other federal statutes.

[Statutory Authority: RCW 43.70.040 and chapter 70.335 RCW. WSR 17-14-026, § 246-339-010, filed 6/23/17, effective 7/24/17.]