(c) Samples and Protocols for licensed biological products regulated by CBER or CDER. (1) Biological product samples and/or protocols, other than radioactive biological product samples and protocols, required under §§600.13, 600.22, 601.15, 610.2, 660.6, 660.36, or 660.46 of this chapter must be sent by courier service to: Sample Custodian (ATTN: HFM–672), Food and Drug Administration, Center for Biologics Evaluation and Research, Bidg: NLRC–B, rm. 113, 5516 Nicholson Lane, Kensington, MD 20895. The protocol(s) may be placed in the box used to ship the samples to CBER. A cover letter should not be included when submitting the protocol with the sample unless it contains pertinent information affecting the release of the lot.

(2) Radioactive biological products required under §610.2 of this chapter must be sent by courier service to: Sample Custodian (ATTN: HFM–672), Food and Drug Administration, Center for Biologics Evaluation and Research, Nicholson Lane Research Center, c/o Radiation Safety Office, National Institutes of Health, 21 Wilson Dr., rm. 107, Bethesda, MD 20892–6780.

(d) Vaccine Adverse Event Reporting System (VAERS). All VAERS reports as specified in §600.80(c) must be sent to: Vaccine Adverse Event Reporting System (VAERS), P.O. Box 1100, Rockville, MD 20849–1100.

(e) Address information for submissions to CBER and CDER other than those listed in parts 600 through 680 of this chapter are included directly in the applicable regulations.


§ 600.3 Definitions.

As used in this subchapter:

(a) Act means the Public Health Service Act (58 Stat. 682), approved July 1, 1944.

(b) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) Commissioner of Food and Drugs means the Commissioner of the Food and Drug Administration.

(d) Center for Biologics Evaluation and Research means Center for Biologics Evaluation and Research of the Food and Drug Administration.

(e) State means a State or the District of Columbia, Puerto Rico, or the Virgin Islands.

(f) Possession includes among other possessions, Puerto Rico and the Virgin Islands.

(g) Products includes biological products and trivalent organic arsenicals.

(h) Biological product means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man:

(1) A virus is interpreted to be a product containing the minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozoa.

(2) A therapeutic serum is a product obtained from blood by removing the clot or clot components and the blood cells.

(3) A toxin is a product containing a soluble substance poisonous to laboratory animals or to man in doses of 1 milliliter or less (or equivalent in weight) of the product, and having the property, following the injection of non-fatal doses into an animal, of causing to be produced therein another soluble substance which specifically neutralizes the poisonous substance and which is demonstrable in the serum of the animal thus immunized.

(4) An antitoxin is a product containing the soluble substance in serum or other body fluid of an immunized animal which specifically neutralizes the toxin against which the animal is immune.

(5) A product is analogous:

(i) To a virus if prepared from or with a virus or agent actually or potentially infectious, without regard to the degree of virulence or toxicogenicity of the specific strain used.
(i) To a therapeutic serum, if composed of whole blood or plasma or containing some organic constituent or product other than a hormone or an amino acid, derived from whole blood, plasma, or serum.

(ii) To a toxin or antitoxin, if intended, irrespective of its source of origin, to be applicable to the prevention, treatment, or cure of disease or injuries of man through a specific immune process.

(i) Trivalent organic arsenicals means arsphenamine and its derivatives (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of diseases or injuries of man.

(j) A product is deemed applicable to the prevention, treatment, or cure of diseases or injuries of man irrespective of the mode of administration or application recommended, including use when intended through administration or application to a person as an aid in diagnosis, or in evaluating the degree of susceptibility or immunity possessed by a person, and including also any other use for purposes of diagnosis if the diagnostic substance so used is prepared from or with the aid of a biological product.

(k) Proper name, as applied to a product, means the name designated in the license for use upon each package of the product.

(l) Dating period means the period beyond which the product cannot be expected beyond reasonable doubt to yield its specific results.

(m) Expiration date means the calendar month and year, and where applicable, the day and hour, that the dating period ends.

(n) The word standards means specifications and procedures applicable to an establishment or to the manufacture or release of products, which are prescribed in this subchapter or established in the biologics license application designed to insure the continued safety, purity, and potency of such products.

(o) The word continued as applied to the safety, purity and potency of products is interpreted to apply to the dating period.

(p) The word safety means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

(q) The word sterility is interpreted to mean freedom from viable contaminating microorganisms, as determined by the tests prescribed in §610.12 of this chapter.

(r) Purity means relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product. Purity includes but is not limited to relative freedom from residual moisture or other volatile substances and pyrogenic substances.

(s) The word potency is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.

(t) Manufacturer means any legal person or entity engaged in the manufacture of a product subject to license under the act; “Manufacturer” also includes any legal person or entity who is an applicant for a license where the applicant assumes responsibility for compliance with the applicable product and establishment standards.

(u) Manufacture means all steps in propagation or manufacture and preparation of products and includes but is not limited to filling, testing, labeling, packaging, and storage by the manufacturer.

(v) Location includes all buildings, appurtenances, equipment and animals used, and personnel engaged by a manufacturer within a particular area designated by an address adequate for identification.

(w) Establishment has the same meaning as “facility” in section 351 of the Public Health Service Act and includes all locations.

(x) Lot means that quantity of uniform material identified by the manufacturer as having been thoroughly mixed in a single vessel.

(y) A filling refers to a group of final containers identical in all respects, which have been filled with the same
§ 600.10 Personnel.

(a) [Reserved]

(b) Personnel. Personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing operations which they perform, the necessary training and experience relating to individual products, and adequate information concerning the application for a license.

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§ 600.10 Personnel.

(a) [Reserved]

(b) Personnel. Personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing operations which they perform, the necessary training and experience relating to individual products, and adequate information concerning the application for a license.

Subpart B—Establishment Standards

§ 600.10 Personnel.

(a) [Reserved]

(b) Personnel. Personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing operations which they perform, the necessary training and experience relating to individual products, and adequate information concerning the application for a license.