

WAC 246-895-040 Buildings or facilities. Buildings shall be maintained in a clean and orderly manner and shall be of suitable size, construction, and location to facilitate adequate cleaning, maintenance, and proper operations in the manufacturing, processing, packing, repacking, labeling, or holding of a drug. The buildings shall:

- (1) Provide adequate space for:
 - (a) Orderly placement of equipment and materials to minimize any risk of mixups between different drugs, drug components, drug products, in-process materials, packaging materials, or labeling, and to minimize the possibility of contamination.
 - (b) The receipt, storage, and withholding from use of components pending sampling, identification, and testing prior to release by the quality control unit for manufacturing or packaging.
 - (c) The holding of rejected components prior to disposition to preclude the possibility of their use in manufacturing or packaging procedures for which they are unsuitable.
 - (d) The storage of components, containers, packaging materials, and labeling.
 - (e) Any manufacturing and processing operations performed.
 - (f) Any packaging or labeling operations.
 - (g) Storage of finished products.
 - (h) Control and production-laboratory operations.
- (2) Provide adequate lighting, ventilation, and screening and, when necessary for the intended production or control purposes, provide facilities for adequate air-pressure, microbiological, dust humidity, and temperature controls to:
 - (a) Minimize contamination of products by extraneous adulterants, including cross-contamination of one product by dust or particles of ingredients arising from the manufacture, storage, or handling of another product.
 - (b) Minimize dissemination of micro-organisms from one area to another.
 - (c) Provide suitable storage conditions for drug components, in-process materials, and finished drugs in conformance with stability information as derived under WAC 246-895-110.
- (3) Provide adequate locker facilities and hot and cold water washing facilities, including soap or detergent, air drier or single service towels, and clean toilet facilities near working areas.
- (4) Provide an adequate supply of potable water under continuous positive pressure in a plumbing system free of defects that could cause or contribute to contamination of any drug. Drains shall be of adequate size and, where connected directly to a sewer, shall be equipped with traps to prevent back-siphonage.
- (5) Provide suitable housing and space for the care of all laboratory animals.
- (6) Provide for safe and sanitary disposal of sewage, trash, and other refuse within and from the buildings and immediate premises.
- (7) Be maintained in a clean, orderly, and sanitary condition. There shall be written procedures assigning responsibility for sanitation and describing the cleaning schedule and methods.

[Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-895-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-895-040, filed 8/30/91, effective 9/30/91. Statutory

Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), § 360-46-040,
filed 10/10/88; Order 133, § 360-46-040, filed 8/4/77.]