

WAC 246-871-030 Physical requirements. (1) Space. The pharmacy shall have a designated area with entry restricted to designated personnel for preparing compounded parenteral products. This area shall be designed to minimize traffic and airflow disturbances. It shall be used only for the preparation of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(2) Equipment. The pharmacy preparing parenteral products shall have:

(a) Appropriate environmental control devices capable of maintaining at least a Class 100 environment condition in the workspace where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 environment conditions during normal activity;

(b) Clean room and laminar flow hood certification shall be conducted annually by an independent contractor according to Federal Standard 209B or National Sanitation Foundation 49 for operational efficiency. These reports shall be maintained for at least two years;

(c) Prefilters. Prefilters for the clean air source shall be replaced on a regular basis and the replacement date documented;

(d) Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;

(e) Appropriate disposal containers for used needles, syringes, etc., and if applicable, antineoplastic agents;

(f) Refrigerator/freezer with thermometer;

(g) Temperature controlled delivery container, if appropriate;

(h) Infusion devices, if appropriate.

(3) Reference library. The pharmacy shall have current reference materials related to parenteral products. These reference materials will contain information on stability, incompatibilities, mixing guidelines, and the handling of antineoplastic products.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-871-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), § 360-16A-040, filed 1/17/90, effective 2/17/90.]