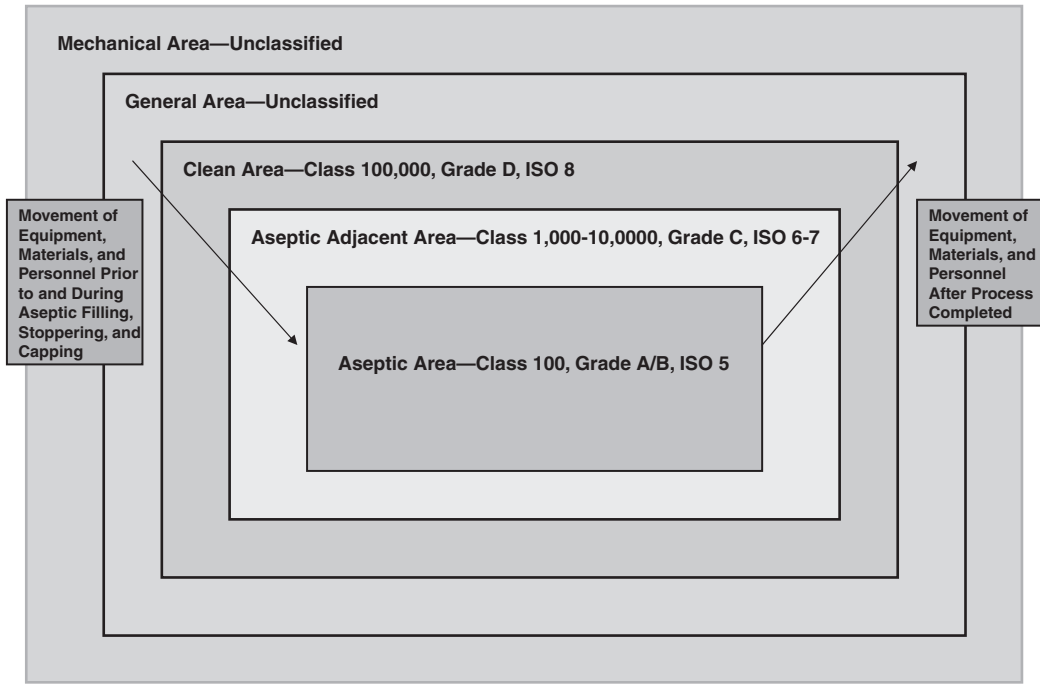

Figure 14-3 Generic floor plan of a sterile dosage form manufacturing facility (refer to Fig. 12-2 for typical activities that take place in each area).

minimizing back and forth movement from uncontrolled to controlled environments (Fig. 14-3). One example of a typical floor plan for sterile manufacturing is shown in Figure 14-4. Note the room classifications and the various entrances for personnel and equipment from lower classified rooms to higher ones.

Appropriate design of a sterile product manufacturing facility and flow of equipment, materials, and people should have the following characteristics (2):

- The exclusion of the surrounding environment (no possibility of surrounding room environment contaminants entering the cleaner environment).
- The removal or dilution of contamination generated during the manufacturing processes, especially potential contamination from personnel.
- A mechanism by which personnel (production operators) are protected from the product and product protected against environmental contamination.
- Optimal working conditions for personnel.
- Achievement of effective monitoring of room conditions at predefined time intervals.

MATERIALS OF CONSTRUCTION

As indicated above, materials of construction for sterile product production facilities must be "smooth, cleanable, and impervious to moisture and other damage" (Table 14-3). Floors start with a concrete slab coated with epoxy terrazzo, urethane, or solid vinyl. Walls are made of solid vinyl or cement plaster with an acrylic–polyvinyl chloride thermoplastic cover (Kydex®) applied for greater durability with the lower sections of the walls. Ceilings are also made of solid vinyl or cement plastic while curtains are typically composed of vinyl or Lexan® (Table 14-4).

Lights in clean rooms should be designed to offer little if any disturbance in airflow and be easily cleaned. In a laminar flow setting, lighting fixtures come in two varieties: the first is called a teardrop and mounts to the "T" grid. Its lens is shaped like an airfoil and contributes to the laminar flow in the room. The second, called a "flowthru," mounts under the high efficiency particulate air (HEPA) filter and allows the clean air to pass through it.