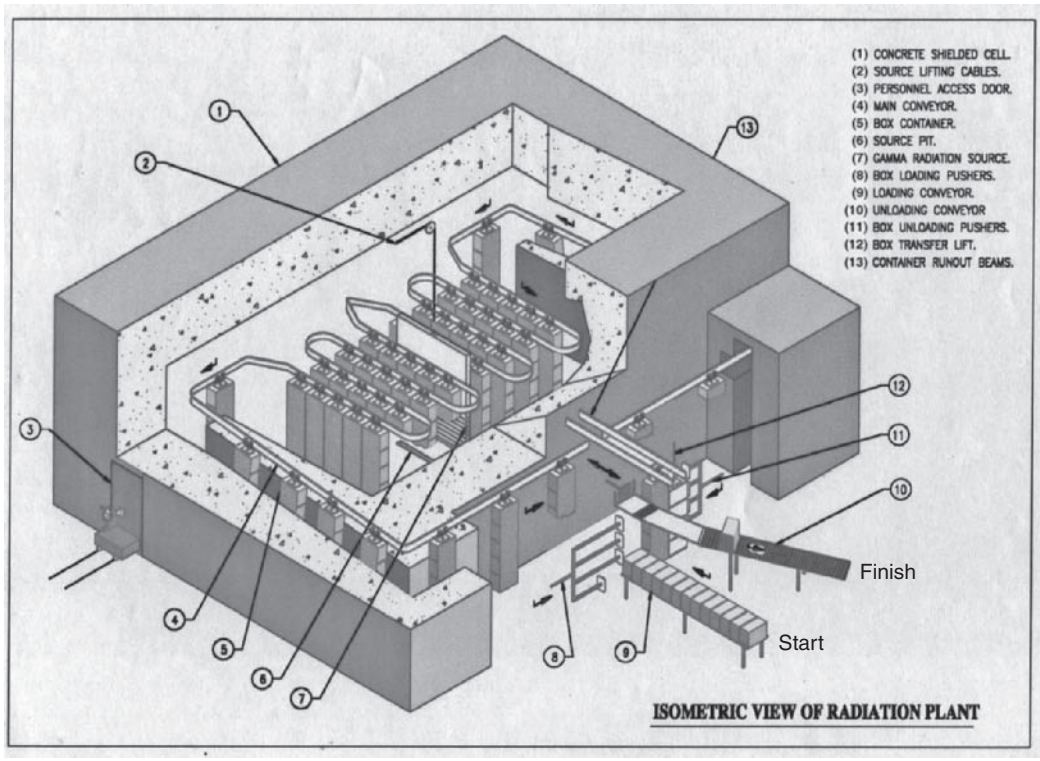

Figure 17-10 Schematic of radiation sterilization conveyor. Percentage of total radiation dose is distributed in varying amounts as items being sterilized are conveyed from start to finish. Percentages of total dose are greatest along conveyor closest to the source of gamma radiation (#7). *Source*: Courtesy of Dr. AK Kohli of BRIT/BARC Vashi Complex, Mumbai, India.

flash of pulsed light at 1 to 2 J/cm^2 will kill greater than one million colony-forming units of bacterial spores. Such brief light exposure does not affect the temperature of the product. Pulsed light can sterilize products in containers that can transmit light–polyethylene, polypropylene, nylon, and ethylene vinyl acetate. Polyvinyl chloride and polystyrene are examples of plastics that will not readily transmit pulsed light. Pulsed light is readily transmitted through water and most pharmaceutical solutions.

Filtration Sterilization

Filtration sterilization is covered in chapter 18.

TERMINAL STERILIZATION

Whenever possible, the parenteral product should be sterilized after being sealed in its final container (terminal sterilization) and within as short a time as possible after the filling and sealing have been completed. Since this usually involves a thermal process (although there is a trend in applying radiation sterilization to finished products), due consideration must be given to the effect of the elevated temperature upon the stability of the product. Many products, both pharmaceutical and biological, will be affected adversely by the elevated temperatures required for thermal sterilization. Heat-labile products must, therefore, be sterilized by a nonthermal method, usually by filtration through bacteria-retaining filters. Subsequently, all operations must be carried out in an aseptic manner so that contamination will not be introduced into the filtrate. Colloids, oleaginous solutions, suspensions, and emulsions that are thermolabile may require a process in which each component is sterilized separately and the product is formulated and processed under aseptic conditions.