Figure 22-2 Manual visual inspections. *Source*: Courtesy of Baxter Healthcare Corporation.

A standard inspection booth contains an all-black interior except for the front entrance for the inspector (Fig. 22-2). A vertical screen in the back of the booth is half black and half white. Light usually is projected vertically with frontal blockage to protect the observer's eyes from direct illumination. A magnifying lens at 2.5× magnification may be set at eye level to aid the inspector in viewing the container in front of the white/black background. Excellent viewing is provided without distraction, and acuteness of vision is increased to improve the level of discrimination. It could be argued that the level of discrimination becomes too high, that is, containers are rejected that would not have been rejected had no magnification been used.

Inspection cabinets should have black sidewalls with a baffle to prevent the light source from impinging on the inspector's eye. Fluorescent lamps provide a better light source because these are more diffuse than incandescent lamps.

Standard operating procedures for inspection of parenteral containers depend on the kind of container inspected, that is, procedures will be slightly different for ampuls than for large-volume glass bottles, for amber vials than for flint vials, and for plastic bags than for glass containers. However, a basic procedure can be followed regardless of the type or size of container, and an example of such a procedure is given in Table 22-7.

Semiautomated to Automated Inspections

High technology strives for sophisticated automatic methodology to replace the dependency on human manual inspection. The area of technology that offers the greatest potential in replacing human examination in 100% container inspection requirements is the area of computer-controlled, automatic electro-optic systems. Such systems are rapid, nondestructive, and reproducible in their inspection of parenteral products.

Technology has made significant improvements in fully automated parenteral product inspection procedures. Disadvantages of earlier automated systems, such as lack of standardization of performance, separating marks on the outer container surface from particles inside, failures to detect underfills or empty containers, and machine variabilities, have largely been eliminated with the automated systems available today.

Video inspection employs one of two basic mechanisms for automated container inspection.

1. Using imaging optics in which the particles suspended in the solution are illuminated by a fiber optic light system and imaged on a video display. Brightwell's Micro-Flow Imaging technology is one of the most popular systems for counting, sizing, and classifying particles in liquids although at the time of this publication this technology was only being used as a research tool (7).
2. Using light scattering techniques where particles scatter light that is received by a detection system and projected onto a television camera system. The Eisai AIM system is the most widely used automated detection system (8,9).

The fact that the liquid contents are swirling while the container itself is motionless during the inspection process has a very important implication. The master picture is based on