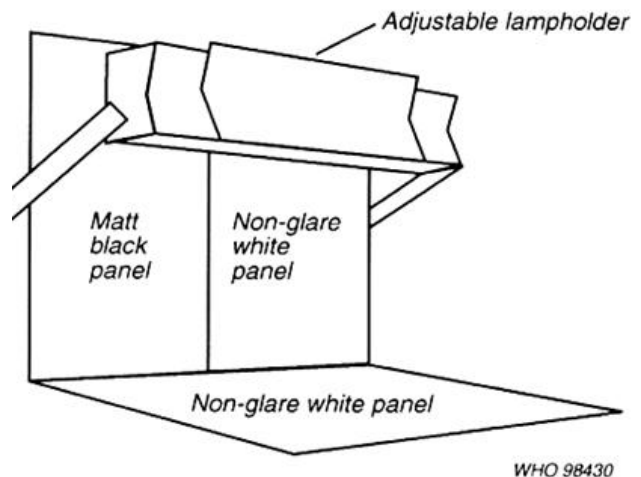


## Inspection station for examining sterility test, media fill trials or for visible particles in filled vials, ampoules or Prefilled Syringes (PFS)

### Apparatus<sup>1</sup>

- Vertical matte black panel
- Vertical non-glare white panel next to black panel
- Adjustable lamp holder with shaded, white “daylight” source and ...a diffuser (...two 13W fluorescent tubes, each 525 mm (20.7 in) in length is suitable). ...illumination at the viewing point is ...between 2,000 and 3,750 lux for clear glass ampoules or vials. Higher values are preferable for coloured glass and plastic containers.
- under a maintenance plan to check lux. (Note lamp output can drop 50% in 12months)



### Recommended procedure

- Gently swirl or invert each individual container, making sure that no air bubbles are introduced, and observe for about 5 seconds in front of the white panel. Repeat ...in front of the black panel.
- Record the presence of any particles or in the case of sterility testing or media fill trials, any turbidity. Repeat the procedure for all containers.

### Critical Inspection Parameters

#### • Lighting

##### Illumination Intensity

- JP - 1,000 lux
- WHO - 2,000-3,750 lux
- IESNA - “Difficult Inspection”, visual tasks of low contrast and small size - 1,000 lux, “Exacting Inspection”, visual tasks near threshold 3,000-10,000 lux

##### Intensity at container:

- 65-750 ft-candles / 215 ft-candles median
- 90-500 ft-candles / 225 ft-candles median
- 600-7,000 lux / 2,000 lux median
- 850-4,650 lux / 2,100 lux median

##### Uniformity

must have diffuser

##### Flicker

- Incandescent - No flicker

<sup>1</sup> <http://apps.who.int/phint/en/p/docf/>

- Fluorescent - Possible flicker, check HF Ballast,
  - Type
- Background
  - Black / White
  - 18% Gray (optional)
- Presentation and Manipulation
- Pace – pacing system for manual inspection, eg such as metronome
  - Molded Glass Vials - 1 to 10 mL – a) 0.7-4 sec / 2 sec median
  - Molded Glass Vials 11 to 100 mL - a) 1-28 sec / 6 sec median,
  - Molded Glass Vials >100 mL a) 1-4 sec / 3 sec median,
  - Tubing Glass Vials - 1 to 10 mL a) 0.7-60 sec / 8 sec median,
  - Tubing Glass Vials 11 to 100 mL a) 1-60 sec / 15 sec median,
  - Glass Ampoules - a) 4-42 sec / 4 sec median,
- Magnification optional but recommended
- Single or grouped up to 5 in group, but can be up to 15 for experienced operator
- Polarizer optional but recommended