

GOWNING FOR USP <797>

People

People are a major source of contamination in the cleanroom.

Notice the number of particles produced per minute during these activities.

* A Basic Introduction to Clean Rooms By Roger McFadden, Technical Director, Coastwide Laboratories

ACTIVITY	PARTICLES/MINUTE (0.3 microns and larger)
Motionless (Standing or Seated)	100,000
Walking about 2 mph	5,000,000
Walking about 3.5 mph	7,000,000
Walking about 5 mph	10,000,000
Horseplay	100,000,000

Proper Gowning

Procedure

Healthy State

Avoid Excess Items

People

Makeup, jewelry, excessive clothing, open toe or open back shoes, heels, artificial nails, long hair, cleanliness of personnel can all be contributing factors in cleanroom contamination.

All makeup, jewelry and excessive clothing must be removed. Long hair should be secured before entering the cleanroom.

Prevent personnel from entering if they have sunburn, skin irritations, open sores, or respiratory infections, these personnel should be reassigned to non-cleanroom duties.

Gowning

Proper gowning is critical in reducing contamination in the cleanroom.

An SOP describing the proper gowning procedure must be drafted and followed. It should describe in detail the proper steps to be taken when gowning.

All employees must be trained on the procedure and have documentation that they are proficient in the procedure.

Gowning

Proper fitting gowning materials are essential. Gowning materials that are too large or too small are unable to contain the microbes within the gown.

Gowns should not be reused throughout the day or week. Once a gown is removed it should be disposed of or sent to be cleaned.

The extent of gowning will depend on the required cleanliness level of the cleanroom.

Gowning

It is helpful to have a picture of a properly gowned person in the gowning room as well a mirror for personal inspection before entering the cleanroom.

The number of people gowning or degowning at the same time should be limited.

Everyone who enters the cleanroom must be trained in the gowning procedure. This includes certifiers, maintenance, contractors and housekeeping personnel.

Gowning

Dedicated shoes for use only in the cleanroom can help prevent contamination from the outside being brought into the cleanroom.

Smokers should not be allowed to enter the cleanroom for a minimum of 30 minutes after smoking.

No personal items such as cell phones, keys, food, drinks, gum or mints are permitted in the cleanroom.

Gowning

Personnel should be encouraged to inspect others gowning attire while in the cleanroom and comment if they notice improper gowning or tears in the materials.

Full cleanroom attire is always required whenever entering the cleanroom.

Degowning should occur in the exact reverse order of the gowning.

Gowning

Gown from dirtiest to cleanest

Place one shoe cover completely over shoe. Place this foot down on the clean side of the line of demarcation. Place a shoe cover over the other shoe and place this foot down on the clean side of the line of demarcation.

Shoe covers should never touch the dirty side of the line of demarcation.

Gowning

Don a cleanroom hair bouffant completely covering all hair. A hair cover must be worn even if the person is bald.

Don a beard cover if necessary. Do not substitute a beard cover for a mask or vice versa.

Place a mask over the face and mouth. The metal band bends over the nose. Usually the colored side is facing away and the white side touches your face.

Gowning

Place the loops over the ears or tie the mask.

Wash and dry your hands and forearms.

Don a lab coat or gown. Avoid touching the outside of the gown as much as possible. Do not allow the gown or lab coat to come in contact with the floor.

Use the alcohol cleanse and don sterile gloves.