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Entry and Exit of Personnel

People can disperse millions of particles and thousands of microbe-carrying particles from their skin and clothing. It is therefore necessary for personnel working in a cleanroom to change into clothing that minimises this dispersion.

Cleanroom clothing is made from fabrics that do not break up and lint; they therefore disperse the minimum of fibres and particles. Cleanroom clothing also acts as a filter against particles dispersed from the person's skin and their indoor, or factory, clothing.

The type of cleanroom clothing used varies according to the type of cleanroom. In cleanrooms where contamination control is very important, personnel wear clothing that completely envelops them and prevent their contamination being dispersed, i.e. a coverall, hood, facemask, knee-length boots and gloves. In cleanrooms where contamination is not as important, less enveloping clothing such as a smock, cap and shoe covers may be quite sufficient. Information about cleanroom clothing is given in Chapter 19.

Whatever the choice of clothing, garments will have to be donned prior to entering the cleanroom, and they should be put on in such a way that the outside of the clothing is not contaminated. This chapter describes typical methods.

Some types of cleanroom garments are worn once before being thrown away; others are sent for cleaning and processing after being used once. However, garments are normally used more than once. It may therefore be necessary to devise a storage method to ensure that a minimum of contamination is deposited onto them. Possible methods are discussed at the end of this chapter.

17.1 Prior to Arriving at the Cleanroom

Poor personal cleanliness is not acceptable in a cleanroom. However it is not clear how often personnel should bathe or shower, there being little in the way of scientific investigations into this topic. Clearly a shower would be necessary if someone has just had a haircut and is likely to shed hair clippings. It is known that washing can remove the natural skin oils and, in some individuals, the dispersion of skin and skin bacteria can increase. People with dry skin may wish to use a skin lotion to replace the lost skin oils.

Consideration should be given to what clothing is best worn below cleanroom garments. Clothing made from artificial fibres, such as polyester, are better than those made from wool and cotton, because synthetic fabrics disperse much fewer particles and fibres. Close-woven fabrics are also an advantage, as these are more effective in filtering and controlling the particles and microbe-carrying particles dispersed from the

skin. This type of problem will be overcome if personnel are issued with factory undergarments. These should be made from a fabric that does not lint, and it should effectively filter particles dispersed from the person.

Personnel should consider whether applying cosmetics, hair spray, nail varnish, etc. at home is necessary, as these should be removed prior to entering the cleanroom. They should also consider what rings, watches and valuables they will bring to work, as they are likely to be removed and stored. These and other suggestions with regard to staff entering a cleanroom are discussed in Section 16.1.

17.2 Changing into Cleanroom Garments

The best method of changing into cleanroom garments is one that minimises contamination getting onto the outside of the garments. One such method is described below. Some of the suggested procedures may be unnecessary in poorer classes of cleanrooms, and further procedures can be introduced in cleanrooms that manufacture products very susceptible to contamination. It should also be noted that alternatives to the proposed method are successfully used in existing cleanrooms, and these are quite acceptable as long as they give a level of contamination control appropriate to the standard of the cleanroom.

The design of clothing change areas is discussed in Chapter 5 where it is explained that the change area is normally divided into zones. These may be rooms, or rooms divided by crossover benches. Change areas can vary in design, but it is common to find them divided into three zones:

- (1) Pre-change zone
- (2) Changing zone
- (3) Cleanroom entrance zone.

Personnel move through the zones in the following manner.

17.2.1. Approaching the pre-change zone

Figure 17.1 Cleanroom shoe cleaner

Before starting to change into cleanroom clothing, it is best that personnel blow their nose. It is impossible to do this correctly in a cleanroom, and if this is done it will save an unnecessary trip out of the cleanroom. They should also go to the toilet. If it is necessary to come out of the cleanroom to go to the toilet, it is likely to entail changing out and back into cleanroom clothing.

In cleanrooms where outdoor shoes are not removed, or effectively covered, shoe cleaners should be used. Cleanroom shoe cleaners are specially made to retain contamination dispersed from the shoe: use of one is illustrated in Figure 17.1.

Figure 17.2 Dycem cleanroom mat

Sticky cleanroom mats or flooring are often used in the approach to the change room. These are specially manufactured for use in cleanrooms. There are two general types. One type is laminated from layers of thin adhesive plastic film and the other from a thick resilient adhesive plastic. Both work by removing dirt from the soles of footwear as personnel walk over them (see Figure 17.2). After a while they become soiled. In the case of the plastic film version, the topmost layer is peeled off to expose a fresh layer. In the case of the resilient plastic type the surface is washed.

If a laminated mat is used, shoes should be applied to a mat three times to ensure the removal of practically all of the footwear contamination. If the resilient-type cleanroom flooring is used it can cover a floor surface area large enough to ensure that sufficient steps are placed on it to ensure effective dirt removal. This is a minimum of three per foot i.e. six in all.

17.2.2 Pre-change zone

Within the pre-change zone the following tasks may be carried out:

1. Personnel should remove sufficient street or factory clothes to feel comfortable in the cleanroom. If the company provides dedicated clothing to wear under the cleanroom garments, then all street clothing should be removed and replaced with factory garments.
2. Watches and rings should be removed. They can harbour dirt, produce chemical and particle contamination, and are liable to tear gloves. Wedding rings that are smooth may be kept on if the ring (and under the ring) is kept clean. Rings that are not smooth can be taped over. Items such as cigarettes and lighters, wallets and other valuables should be securely stored.
3. Remove cosmetics and, if required, apply a suitable skin moisturiser. The composition of any moisturiser should be considered to ensure that no chemicals used in the formulation cause contamination problems in the product being manufactured.
4. Don a disposable bouffant hat, or hairnet. This ensures that hair does not stick out from under the cleanroom hood.
5. Put on a beard cover, if appropriate.
6. Put on a pair of disposable footwear coverings, or change into dedicated cleanroom shoes.
7. If a hand washing system is located in this area then wash the hands, dry them and, if necessary, apply a suitable hand lotion. However, it is probably best if hands are washed within the change area just before the clean garments are put on (see below). If gloves are used to put on cleanroom clothing, then hand washing can be done here. In bioclean areas, it will be necessary to wash the hands in a suitable skin disinfectant. Hands can be dried with a non-linting towel or a hand drier. If a hand drier is used then the best type is one that does not disturb the dirt on the floor.
8. Cross over from the pre-entry area into the change zone. The demarcation between these two zones may be a door or a crossover bench, or both. A sit-on transfer bench may be built across the zones to ensure that personnel cannot walk round but must cross over it. If a bench is used footwear should be attended to as it is crossed. If a bench is not used, then a cleanroom mat or flooring should be used. Personnel should stop at the mat and put their footwear three times to the mat to make certain that it is clean and the minimum of contamination is tracked into the next zone.

17.2.3 Changing zone

The garments used in the cleanroom are put on in this area. Several methods can be used but the following is suggested. This uses a method assumes that a facemask, hood, coverall and overboots are used, but it can be adapted for use with a cap, gown and overshoes. It requires that the garments are put on from the top down.

1. The garments to be worn are selected. If a fresh garment is used, then it should be checked for size and the packaging checked to ensure that it is free from tears and faulty heat seals. The packaging is then opened.
2. A facemask and hood (or cap) is put on. It appears to make little difference whether the mask is put under, or over, the hood. Choose which method is the most comfortable. If a hood is put on, the hair must be tucked in and the studs (snaps) or ties at the back of the hood adjusted for comfort.
3. If a hand washing system is installed in this area then the hands should now be washed (and disinfected if required). This is possibly the best time for personnel to wash their hands as clean garments will now be handled and contaminated parts of the body, such as the hair and face, should not be touched again.
4. Temporary gloves known as 'donning gloves' are sometimes used to prevent the outside of the cleanroom garment being contaminated. Use of these gloves is confined to the higher quality of cleanroom. These should, if required, be put on.

5. The coverall (or gown) should be removed from its packaging and unfolded without touching the floor. It is sometimes possible to get the cleanroom laundry to fold the garment in a way that will minimise both the chance of the garment touching the floor and the outside surface being contaminated by the personnel's hands. If this is not done, then the following can be considered.

If a coverall is used, it should be removed from its packing and allowed to unfold without touching the floor. It should be unzipped and turned so that the zip is to the side away from the person.

There are now several methods of putting on the garment to ensure that it does not touch the floor. These are as follows:

- The coverall can be gathered together at the 4 corners i.e. the two wrists and the two ankles. It should then be possible to put first one leg and then the other into the garment without the trouser legs touching the floor.
- The garment can be held in the inside at waist level, some of the material gathered up and one leg and then the other put in to the trouser legs. The top of the coverall can then be slipped over the shoulders, or,
- The left cuff and left zipper can be taken in the left hand and the right zipper and right cuff taken in the right hand. The coverall can then be gathered up at the waist and one leg placed into the garment, and then the other leg placed into the other garment leg. By releasing one cuff at a time, first one arm and then the other can be placed into the garment.

The last two methods will work better if the trouser legs are folded back on themselves so that they are shorter and less likely to touch the floor. The garment should then be zipped all the way up to the top, ensuring that all of the hood (if used) is tucked under the collar. A mirror is useful at this stage. If the garment has press studs (snaps) at the ankles and wrists, then these should be snapped shut.

17.2.4 Cleanroom entrance zone

1. If a crossover bench is available, it should be crossed over now. This bench is used to demarcate the slightly soiled changing-zone from the cleaner entrance zone, and allows cleanroom footwear (overshoes or overboots) to be correctly put on.
2. Personnel should sit on the bench. One leg should be raised, the cleanroom footwear put on, the leg transferred over the bench and placed on the floor of the entrance zone. Then the other leg should be raised, the cleanroom footwear put on and the leg taken over the bench. While still sitting on the bench, the legs of the cleanroom garment and the footwear should be adjusted for comfort and security. Personnel should now stand up.
3. If required, protective goggles of the type shown in Figure 17.3 can be put on. These are used not only for safety reasons but to prevent eyelashes and eyebrow hair falling onto the product.

Figure 17.3 Protective goggles

4. The garments should be checked in a full-length mirror to see that they are worn correctly. Check that the hood is tucked in and there are no gaps between it and the coverall (or gown). Check that no hair can be seen.
5. If donning gloves have been used they can be dispensed with now. They can, however, be kept on and a pair of clean working gloves put on top. Two pairs of gloves can be used as a precaution against punctures, although sensitivity of touch is lost.
6. If deemed necessary, the hands can again be washed. Gloves can also be washed. In a biocleanroom it is beneficial to decontaminate the hands by applying an alcohol solution containing a skin disinfectant. Apart from being more efficient, the use of an alcohol solution overcomes the problem of having a washhand basin in the room, with its attendant risk of microbial growth.

7. Low particle (and if required, sterile) working gloves should now be put on, without the outside of them becoming contaminated. In some cleanrooms this task is left until the personnel is within the production cleanroom. If they are latex gloves, which are wrapped in pairs with the cuffs rolled back (in the style used by surgeons), then the gloves can be put on without being contaminated. In this case, the first glove is taken out of the exposed package by gripping the fold of the rolled-over cuff with the one hand and inserting the other hand into it. Two fingers of the gloved hand are then passed under the rolled-over cuff of the second glove and it is lifted from the package. The hand is then put into the second glove, the fingers being slotted into the correct fingers of the glove, and the cuff lifted over the cuff of the cleanroom garment. It is now possible to pull back the cuff of the first glove, making sure that it is completely over the garment's cuff.
8. Most cleanroom gloves are not packed in a way that will allow gloves to be put on without contaminating the glove surface. These gloves must be gripped at the edge of the cuff and put on in a similar way to that described above. Gloves packed in pairs will be contaminated less than those packed in 50s or 100s, as it is difficult to remove a glove from a large pack without contaminating those that are left. If considered necessary, the gloves can now be washed or disinfected.
9. Personnel may now proceed into the cleanroom. This may be over a cleanroom mat.

17.3 Exit Changing Procedures

When leaving a cleanroom, personnel will either (i) discard all their garments and on re-entry use a new set of garments (this is normally only employed in an aseptic pharmaceutical cleanroom), or (ii) discard their disposable items, such as masks and gloves, but reuse their coverall, smock, etc. on re-entry.

If a complete change of clothing is required on re-entry, then the disposable items such as bouffant hats, gloves, facemask and disposable overshoes are placed in a container for disposal. If the remainder of the garments are not disposable then they should be placed in a separate container for dispatch to the cleanroom laundry for processing.

If the garments are to be used again on re-entry, they should be removed so that the outside of the garment is contaminated as little as possible. The cleanroom footwear should be removed, one at a time, at a cross-over bench, as each leg is taken over the bench. The coverall should then be unzipped and removed using the hands within the garment to remove it over the shoulder and down to the waist. In a sitting position, one leg is now removed the garment. The empty arm and leg of the garment should be held so that they do not touch the floor. The other leg can now be removed. The facemask and hood can now be removed.

Garments to be used again on re-entry should be stored to prevent contamination. This can be done in several ways, as follows:

- Each item of clothing can be rolled up. In the case of cleanroom footwear this should be done so that the dirty soles are to the outside. The footwear can now be placed in separate pigeon holes and the hood and coverall (or cap and gown) in another. If thought necessary, the items of clothing can be placed into bags before being put into the pigeon holes.
- The hood (or cap) can be attached to the outside of the coverall (or gown) by means of a snap (stud) and hung up, preferably in a cabinet. The cleanroom footwear can be placed at the bottom of the cabinet. It is best that their garments should not touch the wall, or each other. In higher grade cleanrooms, clothing is often hung up in unidirectional flow cabinets (see Figure 5.7 in Chapter 5), specifically designed to ensure that garments are not contaminated.
- Garment bags can be used. These will have separate pockets for the various clothing items and should be regularly laundered.

Acknowledgements

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