

CLEAN MANUFACTURING

C L E A N R O O M S

Human beings are the problem, — but also the solution.

HUMAN CONTAMINATION

Of the many potential sources of contamination in cleanrooms and other clean manufacturing environments, none is more persistent, pervasive, or pernicious than the human beings who occupy them.

There are many possible sources of contamination of the cleanroom environment. Equipment, structures, and surfaces can generate particles through friction, heat, exhaust, outgassing, and static electricity. Incoming production components may introduce contaminants. Still, it is the people working in the cleanroom that generate the most particles. Of the many elements of cleanroom operations and processes, humans are the easiest to control, yet contribute the most contamination.

While non-particulate contamination (nonvolatile residue or airborne molecular contamination, for example) is a concern in many applications, the fundamental aspect of the cleanroom environment is an effective cleanroom management program that keeps the environment free of airborne particles.

Particles that present a contamination hazard to the cleanroom environment are measured in *micrometers* (μm), one millionth of a meter. Common cleanroom contaminants and their sizes are shown in **Table 1**.

As cleanroom operators are working, they generate millions of particles with every movement. Schlieren thermal images (see **Photos**) show particles emitted from the human body. Particles migrate up through the cleanroom apparel toward the head

and fall down the legs during cleanroom activities. Examples of generation of particles 0.3 μm and greater per minute are shown in **Table 2**.

Bacteria, molds, and yeast are viable organisms which are chemically active. Byproducts of their growth and replication can cause a variety of contamination in the cleanroom, based on the nature of the chemicals released during generation. Humans also release elemental chemicals that can cause contamination:

- ▶ **Spittle:** potassium, chloride, phosphorus, magnesium, and sodium
- ▶ **Dandruff:** calcium, chloride, carbon, and nitrogen
- ▶ **Perspiration:** sodium, potassium, chloride, sulfur, aluminum, carbon, and nitrogen
- ▶ **Fingerprints:** sodium, potassium, chloride, and phosphorus

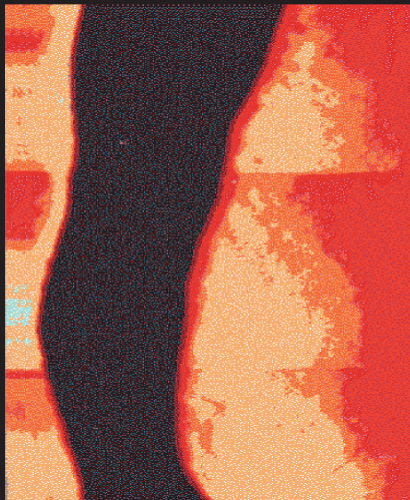
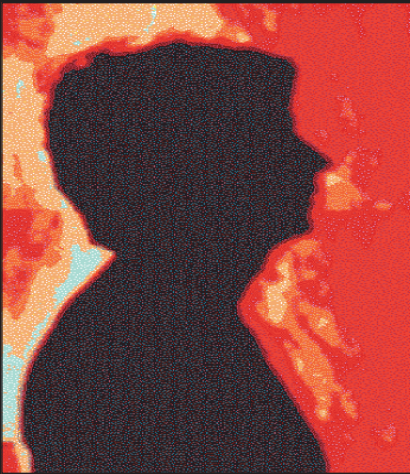
Consequently, a critical component of cleanroom management is strict adherence to protocol. Cosmetics are prohibited because in addition to their gross particle generation, cosmetics release iron, aluminum, silicone, carbon, titanium, magnesium, potassium, sulfur, and calcium.

Table 1. Common cleanroom contaminants.

Contaminant	Size (μm)
Human hair	70-100
Human skin flakes	0.4-10
Pollen	5-100
Mold	2-20
Smoke	0.01-1
Household dust	0.05-100
Bacteria	0.25-10

Table 2. Particle generation rate ($\geq 0.3 \mu\text{m}/\text{min.}$)

Motionless/sitting/standing	100,000
Head, arm, neck, leg motion	500,000
All of the above with foot motion	1,000,000
Standing to sitting position and vice-versa	2,500,000
Walking at 2.0 mph	5,000,000
Walking at 3.5 mph	7,500,000
Walking at 5.0 mph	10,000,000



Schlieren photographs graphically reveal the dissemination of particles from unprotected body parts and surfaces. (Photos courtesy of Micron Video International.)

Just as humans are the greatest potential contamination risk, they are also the greatest resource for contamination control. A thorough, comprehensive training program detailing all aspects of cleanroom management will empower the cleanroom operators to control the degree of contamination during the production process.

The Institute for Environmental Sciences and Technology (IEST) publishes recommended practices that contain information for developing a comprehensive cleanroom management program. *IEST-RP-CC027.1, Personnel and Practices and Procedures in Cleanrooms and Controlled Environments*¹ specifically addresses the control of human contamination in the cleanroom. Areas covered include hiring and training, health and hygiene, behavior, and monitoring and auditing the efficacy of the cleanroom management program.

Hiring practices include meticulous screening for physical characteristics such as body size, facial hair, sensitivity to heat, cold, and humidity; seasonal allergies and chemical sensitivity, and for behaviors such as smoking. When evaluating interpersonal and language skills, mental characteristics such as claustrophobia must be considered.

Training for Critical Environments

Just as all operators must be thoroughly trained in occupational skills, knowledge of the product, and all aspects of the production process, they must also be trained in the unique practices and behaviors required for working in the cleanroom environment. Testing and certification of cleanroom operators and subsequent observation of operators after training assures that the training has been implemented and is effective. Training is mandatory for *all* personnel (including Management), regardless of frequency of entry or job classification.

Personal health and hygiene begins at home with daily bathing or showering, shaving, brushing of teeth and hair, and application of silicone-free skin moisturizers to reduce skin flakes. Make-up, hair gels, hair sprays, aromatic after-shave lotions or body lotions are not cleanroom-compatible. While at work, all employees must wash hands after eating and/or using the toilet. Cleanroom-compatible hand cream may be applied prior to gowning.

*IEST-RP-CC003.3, Garment Systems Considerations for Cleanrooms and Other Controlled Environments*¹, addresses gowning requirements for all cleanroom classifications as well as additional requirements for aseptic gowning (See **Table 3**).

In conjunction with the recommended garment configurations, the appropriate cleanroom fabric, findings (i.e. snaps, zippers), and garment style must be determined. Fabric should be evaluated for small pore size to entrain particles, comfort to the wearer, durability and, if necessary, the presence of cleanroom-compatible, gamma-compatible carbon thread to impart static dissipative qualities, therefore minimizing the effects of triboelectric charging in the cleanroom. It is imperative that all operators be trained in proper donning and doffing techniques specific to the cleanroom classification and cleanroom manufacturing operations. Only approved cleanroom apparel is donned before entering the cleanroom. This apparel must be worn correctly to be effective in encapsulating contamination emanating from the cleanroom operator.

As mentioned earlier, any activity by the cleanroom operator generates millions of viable and non-viable particles. Consequently, it is imperative to limit talking and actions in the cleanroom to only those required for the manufacture of the product. Running, horseplay, and other non-professional activities are not permitted. Other behavioral requirements include, but are not limited to, the following:

- ▶ Smoking is not allowed inside the manufacturing facility including all cleanroom areas. Smokers release particles for at least one-half hour after smoking one cigarette.

TABLE 3. IEST recommended garment configurations by cleanroom class.
Legend: R = Required; NR = Not Required; AS = Application-Specific.

Apparel Type	ISO 8 M6.5 or 100,000	ISO 7 M5.5 or 10,000	ISO 6 M4.5 or 1000	ISO 5 M3.5 or 100	ISO 5 M3.5 or 100 (aseptic)	ISO 4 M2.2 or 10	ISO 3 M1.5 1	ISO 1 and 2
Inner Suit	AS	AS	AS	R	AS	E	R	R
Hair Cover (Bouffant)	R	R	R	R	R	R	R	AS
Woven Gloves	AS	AS	AS	AS	NR	NR	NR	NR
Barrier Gloves	AS	AS	AS	AS	R	R	R	R
Facial Cover	AS	AS	AS	R	R	R	R	AS
Hood	AS	AS	AS	R	R	R	R	AS
Powered Headgear	AS	AS	AS	AS	AS	AS	AS	R
Frock	R	R	AS	AS	NR	NR	NR	NR
Coverall	AS	AS	R	R	R	R	R	R
2-piece Suit	AS	AS	AS	AS	R	R	R	R
Shoe Cover	R	R	AS	AS	NR	NR	NR	NR
Boot	AS	AS	R	R	R	R	R	R
Special Footwear	AS	AS	AS	AS	AS	AS	AS	AS
Typical Frequency of Change*	2X/wk	2X/wk	3X/wk	1x/day	per entry	per entry	per entry	per entry

Nothing is allowed inside the cleanroom complex which is not required in the cleanroom manufacturing process. This includes personal items such as jewelry or keys, cosmetics, tobacco or matches in any form, and food or drink in any form. Hair may not be combed in the cleanroom gowning area.

Only cleanroom compatible ball-point pens are allowed inside the cleanroom for recording data on cleanroom compatible paper and clipboards.

While working in the cleanroom, mannerisms such as scratching or hand-rubbing. Cleanroom personnel may not access the inside of the cleanroom uniform.

The use of facial tissues is prohibited in the cleanroom. If one must use a cleanroom compatible non-linting tissue, it must be used only in the gowning area and disposed appropriately in waste receptacle.

All doors must remain closed when not entering or

exiting. Emergency doors may be alarmed with a visual and audible alarm to enforce compliance.

Cleaning The Cleanroom

An integral piece of the cleanroom management program is cleaning of the cleanroom. *IEST-RP-CC018.3, Cleanroom Housekeeping¹* details aspects of proper cleaning of the cleanroom, selection of cleaning materials, equipment, and cleaning agents as well as auditing the cleaning of the cleanroom. A documented and controlled cleanroom cleaning program should be established and maintained to ensure the integrity of the cleanroom environment. Selection of cleanroom cleaning materials, equipment and cleaning agents should be appropriate to the type of cleaning required (i.e. aseptic versus non-aseptic cleanrooms). All cleaning agents and subsequent cleaning protocols should be validated to assure efficacy of cleaning.

TABLE 4.
Sample housekeeping audit evaluation form.

GOWN ROOM

- Baseboards clean
- Benches clean
- Corners clean
- Doors and doorframes clean
- Floors mopped
- Floors vacuumed
- Glass clean
- Horizontal surfaces clean
- Supplies stocked in shelves
- Rack and legs clean
- Adhesive mats cleaned
- Adhesive mats placed properly
- Trash cans clean, liners replaced
- Return air vents clean
- Walls clean
- Tables and legs clean
- Light fixtures clean

EXTERIOR CORRIDOR

- Baseboards clean
- Corners clean
- Doors and doorframes clean
- Floor swept/mopped
- Horizontal surfaces clean
- Light fixtures clean
- Overhead piping clean and labeled
- Adhesive mats clean
- Adhesive mats placed properly
- Trash cans clean, liners replaced
- Washers clean
- Windows clean

CLEANROOM AREA 1

- Baseboards clean
- Work tables clean
- Corners clean
- Doors and doorframes clean
- Pass-through clean
- Floor free of debris
- Floors mopped
- Floors vacuumed
- Garments on hangers
- Glass clean
- Gown racks clean
- Garment carts clean
- Horizontal surfaces clean
- Return air vents clean
- Supplies stocked
- Trash cans clean, liners replaced
- Floor vacuumed
- Supplies stocked

PROTOCOL ADHERENCE

- Bouffants cover all hair
- Employees mop properly
- Facial in proper place
- Gowned/gloved properly
- No candy, gum, drinks, etc.
- No make-up
- No spraymakers/aerosols
- No tobacco products
- Cleanroom-approved paper only
- Cleanroom-approved pens only

Date Performed:
Performed by:
Reviewed by:
Date Reviewed:

CLEANROOM AREA 2

- Baseboards clean
- Carts clean
- Corners clean
- Doors and doorframes clean
- Floor mopped
- Washer surface clean
- Washer trough clean
- Dryer surface clean
- Glass clean
- Walls clean
- Return air vents clean

CLEANROOM AREA 3

- Baseboards clean
- Floor appearance good
- Floor mopped

FINAL PACKAGING AREA

- Tables and legs clean
- Return air vents clean

HOUSEKEEPING SUPPLIES

- All containers labeled
- Cleanroom chemicals approved
- Equipment clean
- Equipment in good condition
- Equipment stored properly
- Used mops bagged

Key:
1 = Not present
2 = Poor
3 = Fair
4 = Good
5 = Excellent

Monitoring and auditing the cleanroom management program assures that the documented procedures and protocols are understood, implemented and effective at all levels within the cleanroom manufacturing process. The audit program should provide documented and impartial evidence that the cleanroom management program is robust and reproducible. Tracking and trending this data will show shifts in the program which can be addressed prior to compromising the entire cleanroom management program.

IEST's recommended practices enable the manufacturer to create a comprehensive cleanroom management program. In summary, the key to controlling human contamination within a balanced cleanroom management program lies in the combination of knowledgeable, empowered employees, working in a meticulously controlled cleanroom environment, using

quality-assured processes. When such a system is in place, manufacturers can expect a substantial decrease in product rejects and a corresponding increase in profitability.

† Documents cited are available from the Institute of Environmental Sciences and Technology (IEST), 5005 Newport Drive, Suite 506, Rolling Meadows, IL 60008-3841; 847-255-1561; fax: 847-255-1699; iest@iest.org. See www.iest.org.

Jan Eudy is Corporate Quality Assurance Manager, Cintas Cleanroom Resources, 1605 Route 300, Newburgh, NY 12550. Contact Jan at 845-564-6550; fax, 845-566-1302; eudyj@cintas.com. Cintas Cleanroom Services provides cleanroom supplies, equipment, and services.

