

CLEANROOM MANAGEMENT & GOWNING PEST CONTROL EXTREME PIPETTING III

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A Blueprint for Cleanroom Design

Avoid
headaches by
designing
efficiency and
ease of use
into your new
cleanroom

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A BLUEPRINT FOR CLEANROOM DESIGN

Avoid headaches by designing efficiency and ease
of use into your new cleanroom

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Cleanrooms are among the things that people in industry don't think much about, that they tend to take for granted. All too often, not much thought goes into the design of a cleanroom, but once the room becomes operational, the Monday morning quarterbacking begins. Nagging doubts begin to surface. In the design stage, was everything considered for my specific application? Was it built properly? Am I doing everything I can to operate my room at optimum efficiency? Often, this is when many discover the big difference between the purchase price of a cleanroom and the cost of maintaining one. The stories an ill-conceived cleanroom generates can seem humorous—that is, as long as the room in question is not your headache.

To optimize the money invested in a cleanroom, you must keep many things in mind as you design, realizing, at the same time, that a cleanroom is not a panacea. Before the final design is approved, there are a number of items to consider—in the design as well as the operational stages—that can be tailored to your specific application.

Prior to contacting a firm that specializes in designing and building cleanrooms, seek out a seasoned cleanroom certifier to discuss some of the pros and cons of different cleanroom designs. These people have seen the good, the bad, and the ugly in the many cleanrooms they have serviced over the years. Talking to them can save you a lot of time, money, and aggravation, both before and after your cleanroom is up and running.

Allow for plenty of window space for marketing purposes—yes, the cleanroom is also a marketing tool. Ample window space also helps keep non-essential personnel out of the cleanroom and helps to minimize feelings of claustrophobia for those working in the room. Make a plan for installing electrical conduits and compressed air lines, as well as piping throughout the walls for equipment fit-up. If you have to do this after the cleanroom is built, install these below the space where you believe the work area will be.

Put together a product or process flow chart that outlines how your product or process will be coming into and leaving the cleanroom. In addition, determine the best configuration for placing high efficiency particulate air (HEPA) filters in the ceiling

matrix for good airflow management and maximum effectiveness. It is also crucial to not place a laminar flow bench with a top intake below a ceiling-mounted HEPA filter. Locate this bench to ensure effective use of the clean air produced elsewhere in the cleanroom in a manner conducive to your product and process flow.

Lastly, take the ongoing expense of garmenting, wipes, cleaning supplies, and custodial costs into account to get a true analysis of your overall operational costs. When it comes to garments, you can determine your requirements by asking a few simple questions: Will you be using a cleanroom laundry service or disposable garments? Will you need anti-static garments or not? Will garment color be a concern?

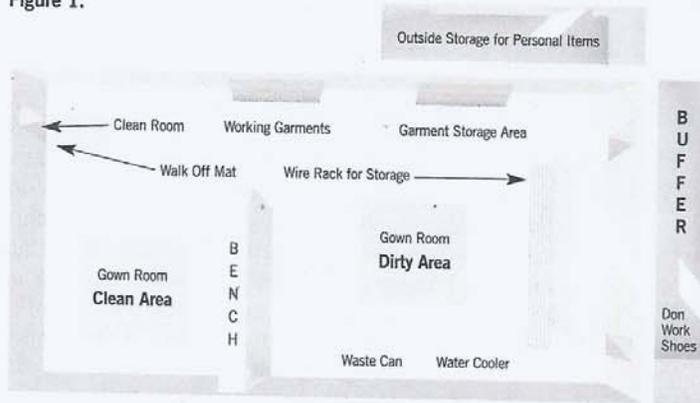
A CLEANROOM CHECKLIST

Once you have selected a firm to design and build your cleanroom, there are a number of items that must be discussed. Number one on the list: the cleanliness classification requirements for your specific application. It is also important to figure out what the ongoing operational costs will be by projecting the costs of kilowatt versus cubic foot per minute of compressed air.

Also, remember that over-design of the air handling system is just as bad as under-design when it comes to ongoing operational costs. You do not want to find out after the fact that you have an ISO 5 (class 100) in an operational mode when the room was designed as an ISO 7 (class 10,000) in an as-built mode. It is also im-

(Continued on p. 16)

Figure 1.



When planning a gown room, remember that there must be a demarcation between clean and dirty areas.

(Continued from p. 15)

portant to remember the temperature and humidity requirements for your specific application and to ask if the construction process is to be validated.

You will want to talk to your firm about the advantages of a "build clean" approach and what that entails in the construction of your cleanroom. You must remember that a "build clean" construction plan is an investment and not simply money spent. Another thing to consult your firm about is the acceptable level of clean for your specific application during the design stages. There are also the questions of who will clean the cleanroom during the construction process and to what levels of acceptability, and who will do the final precision clean prior to certification and to what levels of acceptability. Finally, how will this cleaning process be verified, and by whom?

It is important to remember that proper installation of a cleanroom is only one part of the equation. Other key parts include efficient operation of the cleanroom in conjunction with the documented, ongoing support of housekeeping, custodial, and maintenance programs.

Additionally, you will have to determine the approved sealant for your specific application; obviously, you can't just go down to the local hardware store and buy some caulk. You also need to think about wall systems. The idea of using drywall for the construction of a cleanroom is becoming less appealing due to the ease of installation and flexibility of the demountable wall systems on the market. And don't forget the floor. You need to think about whether you will need electrostatic discharge flooring or not. You may want to use a no-wax sheet vinyl flooring with welded seams and a rolled cover base or epoxy flooring with a standard or rolled cover base. The use of block linoleum tiles is not recommended, because dirt will get in the

cracks. A few other questions to ask: Will you need static control for your process? Will you have a need for visible alarms in conjunction with audible alarms? Lastly, what will your fire protection requirements be?

THE GOWN ROOM

While you may consider saving money by skimping on the size of the gown room, resist that temptation. Remember that you will need this space for garment storage and other dedicated cleanroom items. You also need to think about how many persons will be using the gowning area at one time. A gown room has two sides, a dirty side, which is the one that you enter from the plant, and a

clean side. This is where the gowning process takes place; after it is complete, you enter the cleanroom, or you first move into the air shower and then the cleanroom. There must be some sort of demarcation line signifying the divide between these two areas of the gown room (see Figure 1, above left).

Table 1. Recommended data for a filter information sticker for laminar flow benches

- Company name and address
- Pre-filter size: 2- 20 x 20 x 1 pleated
- HEPA filter size: 3- 24 x 36 x 3—Middle one replaced 12/1/07
- HEPA filter initial pressure drop: .47 Wg @ 600 CFM
- HEPA filter manufacturer and filter model number

It is important to include an area—before the buffer area—that is outside the gown room. This is the place to store personal items like hats, coats, lunches, newspapers, and magazines. This is also where the bulletin board is located—not in the gown room. Place a buffer area just outside the gown room as a semi-clean area for those approaching the gown room. Identify this area by marking it off with a mat that only persons entering the gown room are authorized to use. This is a good place to put on disposable shoe covers before entering the gown room. Lastly, consider whether you will need an air shower between the gown room and the cleanroom.

FANS AND FILTERS

If you are going to use a plenum system with fan-powered HEPA filters, make sure the units have a variable speed control, rather than just an on/off-high/low switch. This will allow you to better control the airflow, especially in more critical areas. Consider a remote fan speed-control system for easier adjustment of air velocity and motor efficiency, instead of removing the ceiling tile when you need to adjust fan speed or change the pre-filter. Removing a blank ceiling tile to change a pre-filter or adjust the speed on fan-powered HEPA filters (FFUs) violates the integrity of the cleanroom; therefore, the placement of these FFUs in the ceiling matrix and the location of speed controllers on these units are critical. In other

words, you want to remove only one blank ceiling tile to service two or more FFUs.

This remote fan-speed control system approach can also be used on a regular terminal HEPA filter system with the use of direct drive controllers incorporated into the main air-handling system or systems. FFU pre-filters with a slide-out or pull-out holding frame will save you labor when it's time to change them. Foam pre-filters that are fastened to a pre-filter holding frame with self-tapping screws take longer to change. Though this doesn't seem to be much of an issue, it will be once you have changed enough pre-filters.

Although it may seem obvious, it is important to remember that the cleanroom is a controlled, pressurized vessel. Using the approved sealant, seal the wall/ceiling angle on the cleanroom side to show that the seam is sealed. Also, seal all penetrations in the wall and ceiling panels. If you are considering regular terminal type HEPA filters, make sure there is an accessible balancing damper in each duct that serves each HEPA filter. Mark these on the "as-built" drawings. Finally, install balancing dampers in all return air ducts and/or registers so you can properly balance the room pressure. Mark these on the "as-built" drawings as well.

MEASURE EFFICIENCY

In order to measure HEPA filter efficiency, all laminar flow benches should have a pressure differential gauge installed or an accessible upstream port to measure the upstream pressure. This gauge should be calibrated on a routine basis or should have a sticker on it stating that it is for reference only. The recommendation that all laminar flow benches have a filter information sticker that is placed adjacent to the current certification sticker on the face of each bench is meant to help maintenance personnel when it's time to re-order pre-filters and HEPA filters (see Table 1, p. 16).

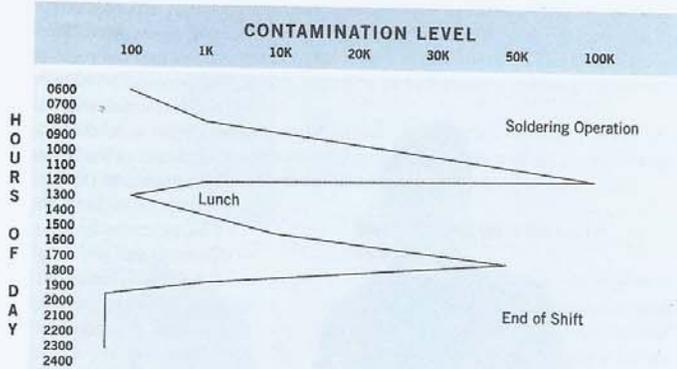
Have a pressure differential gauge panel placed in a conspicuous area where all can see it, and use it to monitor the following room pressure differentials on a daily basis:

- Cleanroom to ambient (0-.25 Wg gauge);
- Cleanroom to gown room (0-.25 Wg gauge);
- Gown room to ambient (0-.25 Wg gauge); and
- HEPA filter status (0-1.0 Wg gauge).

Mark each of these gauges with the high and low limits you have established in accordance with your standard operating procedures. Have these gauges calibrated as part of the certification process. If they are not calibrated, put a sticker on them that states "for reference only."

It is also important to develop ongoing viable and non-viable monitoring programs that are run either daily or weekly. Prior to and following particle counting, always "zero count" your particle counter, isokinetic probe, and hose together underneath a working HEPA filter for at least three one-minute samples or until you are certain that these items are clean. This

Figure 2.



Contamination levels can vary over the course of the day. Conducting quarterly or semi-annual particle counts can help benchmark cleanroom characteristics.

information should be included in the monitoring report (see Table 2, below).

Here are a few other tips that will help you maintain the integrity of your new cleanroom. Create a grid map of the area being tested; the map should show test locations that coincide with the certification report. Develop periodic and routine housekeeping and custodial programs. Conduct a 24-hour particle count of your cleanroom to benchmark its characteristics (see Figure 2, above). This can be done on a quarterly or semi-annual basis to track trends.

Table 2. Particle count monitoring report

Room designation: _____
 Room status at test time: () Operational () At rest
 Number of personnel in room at test time: _____
 Date of test: _____ Time of test: _____
 Test elev: _____ inches above floor Sampled by: _____
 _____ .05 Micron _____ 5.0 Micron _____ Loc 1 _____ Loc 2

Finally, develop preventive maintenance programs and check-off lists. These should include:

- A pre-filter change log on the heating, ventilating, and air-conditioning system and/or the fan-powered HEPA filter modules and laminar flow benches;
- A production equipment maintenance log; and
- Point-of-use filters on the compressed air and nitrogen blow-off guns and the in-line cartridge filters.

Although some of the steps noted above are economical to implement, others may seem too costly to undertake when making the initial investment in your cleanroom. They all warrant investigation, however. It is important to remember that proper installation of a cleanroom is only one part of the equation. Other key parts include efficient operation of the cleanroom in conjunction with the documented, ongoing support of housekeeping, custodial, and maintenance programs. ■

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