Controlled Clean Environment Enclosures

A Cost-Effective Alternative to Cleanrooms

Richard Matthews

Controlled clean environments, commonly referred to as cleanrooms, can be expensive spaces — potentially more than $5,000 per square foot. Such expense has driven industry to look for better ways to enclose critical process areas into smaller spaces. Why classify an entire room as a cleanroom when only a small portion of the space is critical? Why not just treat the critical area with clean air and tight temperature and relative humidity control, leaving the rest of the space to lesser environmental criteria? A self-contained, controlled, clean environment enclosure around a critical core process area is an economical alternative to a full-size cleanroom.

Controlled clean environment enclosures can be as simple as a clean bench in a hospital pharmacy or laboratory or as complicated as a totally enclosed, pressurized, stainless steel containment unit with an inert atmosphere. The common denominator is that all are controlled clean environments without people in them. The microelectronics industry calls these spaces minienvironments. The life sciences industry calls them isolators or barrier technologies. No matter what they are called or where they are used, these are the common benefits: They protect product from people contamination and people from product contamination; they protect product from product cross-contamination; they assure protection by reducing or eliminating outside influences; and they provide an enclosed process environment for quality-level achievement.

End-use applications include compounding IV solutions, sterility testing, preparing live vaccines, high-accuracy powder weighing, plant tissue laboratory research, robotic sampling, cell culture operations, ampule filling, nuclear medicine compounding, handling of toxic substances, micromechanical work, and microchip processing.

The International Organization for Standardization (ISO) is currently developing an international standard, ISO 14644-7, entitled "Cleanrooms and Associated Controlled Environments — Separative Devices (Clean Air Hoods, Glove Boxes, Isolators, Minienvironments)." This activity is under the auspices of ISO Technical Committee ISO/TC209 Working Group #7. Both ISO/TC209 and its Working Group #7 are chaired by the United States. ISO 14644-7 passed the crucial Draft International Standard (DIS) vote in 2001 by the member nations of the ISO. It goes out for a Final Draft International Standard (FDIS) vote in the third quarter of 2002 and is expected to become a formal ISO standard by the end of 2002.

Separative device is a generic term defined as "equipment using constructional and dynamic means to create assured levels of separation between the inside and outside of a defined volume." Filtration Technology Inc. has designed and built several such process isolation enclosures called Q/PECS units. Each unit is designed for the process it encloses and can be either fixed or portable. The end result is control of air cleanliness, air flow speed and direction, temperature, relative humidity, exhaust flow, sterilization and neutralization, inert atmosphere, and so forth.

Such units have enclosed laboratory experiments, pilot plant processes, and fully integrated manufacturing processes — all without people inside. Operators interact through air curtains, glove ports, transfer devices, half suits, and remote manipulators. The keys to successful use of such a unit involve a fail-safe design for the process being enclosed and properly trained operators. Effective cost management dictates that noncritical components of the particular process be placed outside the enclosure for easy access and service.

Annex A of ISO 14644-7, entitled "Separation Continuum Concept," describes

the variety of engineering techniques available for creating separative enclosures. I recommend that anyone considering separative enclosures become familiar with this document.

Interestingly, separative devices are the fastest-growing item in the cleanroom sector. In 2001, the pharmaceutical industry spent an estimated $66 million on separative devices. Automation permits isolation of product from workers and thereby attains cleaner environments. Biotech companies purchase a significant portion of the pharmaceutical industry investment in separative enclosures.

If you have a development or manufacturing process that requires isolation from personnel, particles, chemicals, gases, or microbes, you should seriously consider using a clean enclosure device. In the final cost-benefit analysis, you could be much better off using separative enclosures than traditional cleanrooms.

Richard Matthews *is technical director for Filtration Technology Inc., PO Box 18168, Greensboro, NC 27419, 336.294.5655, fax 336.854.0454, ram@filtrationtechnology.com, www.filtrationtechnology.com.*