



## **Barrier Isolation Technology: A Labor-Efficient Alternative To Cleanrooms**

**Paul Mosko, MS. FASHP and Hank Rahe, BSIM, MSE**

***Abstract** - Barrier isolation technology has been recognized by the Food and Drug Administration for a number of years as a safe and effective way to process parenteral products aseptically. Pharmaceutical companies have shown that this method of processing increases the sterility assurance level of their products and reduces manufacturing costs. Hospital pharmacies in Europe have used this technology for more than 10 years as a means of product and personnel protection. In the United States, the technology is becoming accepted because of its capital cost effectiveness and because it increases safety during the preparation of cytotoxic compounds. Some pharmacists, however, have expressed concerns about the efficiency of such systems in the pharmacy setting. Using work measurement techniques, the authors tested a barrier isolator system at the University of Cincinnati Hospital. The results are presented here.*

***Key Words** - barrier/isolator technology: cleanrooms: parenteral drugs*

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Providing a facility for the manipulation of parenteral drugs within the pharmacy is a significant concern for health care organizations because of the costs, space requirements, and potential lack of flexibility this preparation often entails. The American Society of Health-System Pharmacists (ASHP) has focused on quality working conditions in health system pharmacies by upgrading the guidelines for cleanliness in preparatory work environments.<sup>(1)</sup> Some have interpreted these guidelines simply to mean laminar flow hoods or "cleanrooms," because these have been the conventional particulate-control technology for more than 40 years.<sup>(2)</sup>

Some states have taken steps to upgrade the quality of the environment in which IV admixtures and cytotoxic compounds are prepared recognizing new technologies that can achieve this goal.<sup>(3)</sup> Since new regulations were enacted in June 1998, New Jersey is leading the way in requiring safe parenteral drug preparation.<sup>(4)</sup> A summary of New Jersey facility regulations is presented in Appendix A.

While health system pharmacies are considering a move to cleanroom technology, the



technology.<sup>(5,6)</sup> Increased quality assurance and cost reduction are the driving forces behind this move by pharmaceutical manufacturers. Studies have shown a reduction in both capital and operating costs for pharmaceutical manufacturing facilities using barrier/isolators.<sup>(7,8)</sup>

This article focuses on a study conducted at the University of Cincinnati Hospital that evaluated the ergonomics and productivity of barrier/isolation technology versus conventional biological safety cabinets and laminar flow hoods.

Barrier/isolation technology had its beginning with "glove boxes" developed for the nuclear industry. Current technology has made significant improvements in all phases of interaction between people and the barrier/isolator system. Improvements include such things as viewing ports slanted to a proper angle, allowing individuals to see inside the isolator, and the use of new material for gloves. A barrier/isolator is shown in Figure 1.

The supervisory pharmacy staff at the University of Cincinnati Hospital were skeptical about the level of productivity using a barrier/isolation system compared with conventional IV admixture preparation techniques. To address this concern, an industrial engineering work measurement technique, time and motion work study, was used to define methods and then the elements of the methods. These individual elements are described in Table 1.

Using the time and motion techniques of work measurement the individual elements that make up a total task can be studied separately. A number of measurements of the individual elements are taken, the data is compiled, and average times for the elements are determined.

Individual efforts were rated by comparison with an average person working at an average pace (100% effort). Only individuals operating the range of 80% to 120% efficiency were studied. The efficiency rating was used to adjust the time per element with the end goal being establishment of the time required for an average person working at an average pace to complete the task.

To ensure that the average time to perform the task was determined accurately, only times that fell within three standard deviations of the average were used to develop the



each element to establish an accurate time.

The methods define, step by step, how the sterile products were being prepared. Once this detailed description was completed, the time and motion study was used to determine the time required to perform each of the defined elements in the barrier/isolator and conventional laminar flow environments. More than 20 pharmacists and pharmacy technicians were involved, using biological safety cabinets and laminar flow hoods, as a baseline for defining the method for the conventional laminar flow equipment.

Background information for the study was gathered by observing the central pharmacy, the satellite pharmacy, and the ambulatory pharmacy facilities in operation. Each of these facilities was involved in the time and motion studies to determine times for the unit operations required to prepare admixtures and cytotoxic compounds. After observing the activities of pharmacists and pharmacy technicians preparing admixtures and cytotoxic compounds during a 2-day trial period, a protocol that defined the elements was developed (see Table 1).

These elements were observed, their times were recorded and performances were evaluated. Operators were rated, and any unusual activities were eliminated from the study. (A typical example of unusual activity would be a disruption by a fellow worker, telephone call, or other distraction that would lead to inaccurate data). The times collected for the individual elements were used to determine the total time required to prepare IV admixture or cytotoxic compound by each individual in the study. This became the baseline for biological safety cabinet and laminar flow hood productivity study.

Several weeks later, the barrier/isolator was brought into the central pharmacy and set up for evaluation. In order to familiarize personnel with the workstation, a 10-minute, hands-on training program was conducted. An area of interest to the authors was the rapid conversion time of the operating personnel to the new methods and operating philosophy. It took less than 30 minutes of training for the individual to adapt to the new methodology of the barrier/isolator.

This new methodology involved the use of trays, which were placed on a work counter outside the barrier/isolator and filled with the orders to be processed. All of the required materials to complete the order were assembled and checked before being transferred to



number of entries and texts from the barrier/isolator workstation.

Next, the operator, using the glove ports, opened the internal airlock door, removed a tray, and performed the required manipulation. The operation sequence, which was developed with suggestions from the individuals being trained, is summarized in Table 1. This previously agreed-upon method used in the study provided overall organization and significantly reduced the time spend in preparation.

The ergonomic configuration of the barrier/isolator, conducting manipulations between the glove port, and keeping a proper angle on viewing surfaces. Suggestions that would enhance the functionality of the barrier/isolator were encouraged from the study workers. A number of significant improvements were identified and incorporated into the production model of the barrier/isolator. Examples of these improvements are operator-controlled height adjustment (allowing individuals to work at their most comfortable position); angling of the internal bar, which is used for hanging IV bags and relocation of the trash and sharps disposal ports to the end panel, which allowed for additional floor space inside the barrier/isolator.

The time studies were conducted based upon the elements defined in Table 1. Data from the 2-day study was summarized by element. Standard deviation from average was calculated and measures exceeding the standard deviation were eliminated. Once the data was summarized, the barrier isolator and hoods were compared by unit operation. The result of this summary is shown in Table 1 and indicates that individuals are as productive when working with the barrier/isolator workstations as with the horizontal/vertical laminar flow hoods. Comparisons to biological safety cabinets show that individuals take less time and therefore are more productive working at the barrier/isolator workstations.

The study did not include a direct labor efficiency comparison with Class 100 or class 1000 cleanrooms. However, labor efficiency information on a comparison of the operating expenses of isolators and conventional cleanrooms indicates a loss of 45 minutes or 9.5% of available time per employee per shift, for those working in a cleanroom.

This loss of available time has been documented in other studies and is caused by the time required to gown and degowning each time the individual enters or leaves the



study which indicate that barrier/isolators are as efficient as laminar-flow hoods, has convinced the authors that barrier/isolators workstations are much more labor efficient than clean rooms.

Observations and interviews made it apparent that the study workers made a rapid transition to the barrier/isolation technology, and insight was gained about what is important to people working in the pharmacy. The quietness of the barrier/isolator workstation, compared with laminar flow hoods is one quality that was important to pharmacists and technicians. The decrease in the noise level enhanced communication and resulted in perceived decline in stress levels. The personal comfort level in the area was also increased because, compared with the hoods, significantly less heat was generated by the workstation.

The speed with which technicians manipulated materials was increased with the barrier/isolator, because they were not restricted by placement of these materials within the environment. This is reflected by the reduced time for Element 3 (operation in unit - see Table 1) for the barrier/isolator, compared with the corresponding times for laminar flow, where placement and hand movement techniques are critical for providing product protection.

Long-term sterility assurance levels may be increased with the use of barrier/isolators.<sup>(9)</sup> This benefit may be related to the elimination of people from the critical environment, therefore reducing procedural errors. By reducing procedural concerns, personnel can focus on proper sanitization of the work environment, consistent with recommendations outlined in a recent article on preparing sterile products in the pharmacy.<sup>(10)</sup>

## **Conclusion**

Health system pharmacies are rethinking their methods of preparing parenteral drugs as they respond to rapid change in the health care delivery system and initiate the re-engineering of critical processes. During this period of change, they must ensure a safe environment for both patients and health care providers. New barrier/isolation technology offers a safe, high-quality, cost effective, and flexible alternative for the preparation of parenteral products.

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