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About the Cover

The top picture shows an ultraviolet transilluminator that is commonly used to show DNA bands on gels stained with ethidium bromide. Unfortunately, a lab employee received skin and eye burns while using this transilluminator and an acrylic plastic shield thought to provide protection against UV. The lab did not realize that the shield had not been manufactured for this use or rated for protection against UV light; this incident underscores the importance of ensuring that safety equipment meets the shielding requirements for the intended use. In addition, hazard communication and training is vital to prevent inadvertent exposures as many laboratorians use UV to conduct data analysis or work near equipment housing UV lights.

The germicidal properties of UV light have been recognized for many years, as have concerns over its safety and factors influencing its efficacy. Articles by Paul J. Meechan et al. (pages 222-227) and Jyl Burgener (pages 228-230) provide a timely point/counterpoint discussion of the pros and cons of using UV light in the biosafety cabinet.


Bottom photo: UV region of the electromagnetic spectrum, courtesy of NASA.
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ABSA, the leader in the profession of biological safety.

Mission Statement

The American Biological Safety Association is dedicated to expanding biological safety awareness to prevent adverse occupational and environmental impact from biohazards.

Goals

• Expand professional and public awareness of biological safety through effective communication.
• Participate in the development of biological safety and biosecurity standards, guidelines, and regulations.
• Develop ABSA as the recognized resource for professional and scientific expertise in biological safety and biosecurity.
• Advance biological safety as a scientific discipline through education, research, and professional development.

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The 49th Annual Biological Safety Conference October meeting in Boston, Massachusetts was absolutely wonderful and educational! My personal and special thanks are extended to the Scientific Program Committee and the Local Arrangements Committee, and the ABSA Office personnel for organizing such an informative Conference. Arranging for an Annual Conference is not an easy task! Thanks again, Team! Of the 1,370 members in ABSA, 648 attended the Conference. In addition to our U.S. members, over 95 members attended from 27 countries. I am sure that many of you noticed the simultaneous translations that occurred during the main sessions. Their attendance presented a great opportunity to interact with our international colleagues.

It is truly an honor to have been elected to serve as your President during this next year and I humbly thank everyone for their support and confidence. As my predecessors will certainly agree, being President is quite a challenge. As your representative, I seek your continued support and encouragement towards meeting your individual and collective goals. We must continue to work together—communication is a very important criterion in the success of an organization. I have learned very much from my colleagues while serving on the Council as President-Elect. Listening to the concerns and interests of our membership during the many past years has directed me to the development of 8 specific goals that I am confident will benefit our Association. I wish to share these goals with you and, as always, seek your input towards achieving these goals.

1) Address member issues and concerns.

The membership has expressed a variety of concerns. One issue that continually arises is the meeting venues and associated costs. The ABSA Office and Council arrange for meetings at least 3-4 years into the future at a venue that will support all of the activities for our Annual Biological Safety Conference. This can be difficult, keeping in mind inflation and hotel rates increasing about 4-5% each year. My effort is to secure more affordable hotels and more rooms within the U.S. Government per diem rate. We are right on target now because our efforts have resulted in tentatively securing, pending signing of the contract during the November 20 site visit, 200 premium government rooms at the Denver Hyatt for the 2010 Conference.

To better address issues and concerns of the membership, the Executive Council, composed of the Past-President, President, and President-Elect, will continue to have a teleconference each week. We will also have a teleconference with members of the Council each month. I firmly believe these conversations will foster communications. I encourage you to contact one of the elected officers to address any issues or concerns you may have.

2) Explore innovative ways to increase membership.

I believe this may be accomplished through active marketing. Each member of ABSA should consider themselves a salesperson. Promote your organization and its purpose through the various meetings you attend and through interaction with your nonmember colleagues.

3) Expand outreach programs to universities promoting biological safety (biosafety) as a discipline.

A suggested approach is to foster the addition of a biosafety curriculum in life science undergraduate and graduate programs. I am sure that many of you have been invited to various academic institutes to discuss your career or to perhaps present a lecture on your current topic. Include your experiences and the challenges you encountered to address current issues involving biosafety and the programs that support your efforts.

I would like to promote the involvement of ABSA working towards the establishment of undergraduate and graduate degrees in the field of biological safety at various academic institutes. A starting point could be by providing the core competencies list that the Body of Knowledge Task Force is developing as a guide for development of course curricula. To the best of my knowledge, there are no academic institutes that offer concentration in the field of biosafety. However, Washington University, the University of Pittsburgh, and Colorado State University are beginning curricula. Perhaps the core curricula of biosafety could be integrated within institutes offering a degree in Environmental Health. Some of our members are more familiar with programs that are currently available. Let us know, so we can pursue this issue.
4) Ensure the preservation of the history of the biosafety profession and ABSA.

Members of the Historical Committee are attempting to establish an agreement with the U.S. Department of Agriculture (USDA) National Agricultural Library (NAL) to support the storage and maintenance of significant biosafety-related historical documents and equipment. The plan is to make these materials accessible to ABSA members and the general public.

5) Expand the current Mentorship Program by establishing programs at various facilities.

The mentorship program may be expanded through programs similar to Visiting Scientist or Apprenticeship programs. Another approach could be an externship program, funded by an organization, which would allow an individual to “shadow” a colleague at a host institute. A stipend would be provided for a 2-week to 1-month period.

6) Generate income through grants and gifts to support ABSA efforts.

External funding would help to support the ABSA historical collection at the USDA NAL, and the expanded mentorship program. Explore provision of a Travel Fellowship for a student member of ABSA to attend the ABSA Conference. Students would compete for the fellowship, provide a platform or poster presentation at the Conference, and publish their presentation in our Applied Biosafety journal. There is precedence for such a recognition and travel award within ABSA with the Robert L. Gross Award. The American Society for Microbiology also makes available an award enabling students to attend their annual conference.

Establishment of an ABSA Training Center would complement the training sessions provided by ABSA, other than those at the annual Conference. One approach would be through establishing a partnership with existing laboratories.

7) Make ABSA more international.

Biosafety is becoming increasingly important throughout the world because of recent events involving biological agents, and the concomitant concern for safety of the public and the environment. Many laboratories worldwide are adopting newly-developed diagnostic technologies. ABSA was founded to promote biosafety as a scientific discipline and serve the growing needs of biosafety professionals throughout the world. Our goals are to provide a professional association that represents the interests and needs of practitioners of biological safety, and to provide a forum for the continued and timely exchange of biosafety information. We have an opportunity to continue to share our information with colleagues from countries in the Former Soviet Union, Europe, the Middle East, Asia, and other areas throughout the world through interactions. We should also encourage them to become members of ABSA and apply for Affiliate status.

8) Explore consolidation of the number of committees.

Only the Bylaws, Finance, Membership, and Nominating Committees have permanent standing under the ABSA Bylaws. All other committees are temporary. ABSA currently has 6 teams that oversee 23 committees. The Council has integrated the Media and Public Relations Committee (Alliance Team) into the Marketing Committee (Management Team). Evaluating the purpose of each committee may direct a recommendation for integration into another committee to eliminate any potential overlap of responsibilities. I will ask the Council to continue to provide guidance, where needed, to refine the expectations and essential tasks for each committee. I will also ask the Council to establish a process whereby the Council periodically reviews the need of each temporary committee.

I wish to continue to use the “task force” approach to accomplish short-term goals.

Conclusion

What other suggestions should we address? We may wish to consider the pros and cons of establishing specialty subgroups within the Membership, Affiliate Relations, and Professional Development Committees. Should we encourage additional affiliation and membership activities along the line of job duties in addition to geographic affiliates? For example, the affiliate member grouping or affiliated organization might be comprised of university Biological Safety Officers (BSOs), government BSOs, etc.

My desire is to promote more interaction! The Association always needs your help. In this context, I encourage everyone to become more involved by volunteering for Committee(s) service and contributing an article(s) to our journal, Applied Biosafety. I also encourage you to consider applying for registration as a biosafety professional. With additional experience and qualifications, you may wish to consider applying to the National Registry of Microbiology (NRM) of the American Society for Microbiology for certification as a Specialist Microbiologist in Biological Safety Microbiology. Upon successful completion of NRM requirements, you may apply to ABSA for the designation of Certified Biological Safety Professional. Each of these designations will reward you in your further pursuits in the biological safety profession.

I encourage you to contact me at any time with issues or concerns you may have. Let us take the Teamwork approach and communicate with each other to further our Association!
International Sharps Injury Prevention Society (ISIPS)

According to its website, ISIPS was formed to reduce the number of accidental sharps injuries that occur globally by promoting the use of safety-engineered products and services. Links to resources from many countries are provided, as well as an excellent training course on the requirements of the U.S. Bloodborne Pathogen Standard. Many safety products are already featured, and ISIPS welcomes input on new products. See: www.isips.org/international_resources.html

Training Resource

The U.S. Department of Transportation provides a 36-slide Powerpoint training on “Transporting Infectious Substances Safely.” Changes in shipping regulations which took effect on October 1, 2006 are explained. The slides may be downloaded from http://hazmat.dot.gov/training/Transporting_Infectious_Substances_Safely.pdf

Biorisk Management: Laboratory Biosecurity Guidance—September 2006

WHO/CDS/EPR/2006.6
English - [pdf 221kb]

The concept of biosecurity was briefly described in the WHO’s “Laboratory Biosafety Manual” 3rd edition (2004). This latest document provides more detailed guidance on biosecurity within a biological laboratory and addresses its basic principles and best practices.

Readers are encouraged to provide comments on the document to labbiosec@who.int before the December 22, 2006 deadline.
Introduction to Applied Computational Fluid Dynamics for the Biological Safety Environment

Thomas Scott, David Banks, and Amit Mishra
CPP, Inc., Fort Collins, Colorado

Abstract

The basics of Computational Fluid Dynamics (CFD) are presented to allow the practicing biological safety professional to have a preliminary understanding of the use of CFD for airflow analysis and contaminant tracking. A discussion of result interpretation is provided to assist in communicating with the applied CFD engineer. Results from two actual buildings, a Biosafety Level 3 (BSL-3) facility and a hospital, provide examples of post-processed CFD data. An overview of the general costs associated with a CFD business unit is provided to facilitate budgeting. Next, a discussion of the ways CFD can add value to a design is provided. Finally, a short list of information required to model a generic space is provided to facilitate project initialization.

Definition of Terms

ACH air changes per hour
BSL-3 Biosafety Level 3
CAD Computer Aided Drafting/Design
CFD Computational Fluid Dynamics
RANS Reynolds Averaged Navier-Stokes
LES Large Eddy Simulation
\( \dot{m}_i \) Mass flow rate of species i
\( \rho_i \) Density of species i
\( D_{ij} \) Diffusion coefficient of species i with respect to species j
\( C_i \) Concentration of species i
\( n_i \) Coordinate direction

Introduction

The objective is to provide a high level technical overview of Computational Fluid Dynamics (CFD) followed by the background necessary to work with an applied CFD engineer. The background includes some basic information about interpreting results, costs of a CFD study, and the value this adds to a project.

CFD provides a numerical simulation of fluid flow based on the Navier-Stokes equations. Information at the boundaries is required to determine the flow conditions inside a space. Some boundaries require flow to be specified, examples would be ventilation system inlets and returns, biosafety cabinets, and biosafety hoods. Another common specification is heat leaving a boundary, such as a hot machine or computer. Boundaries may be inside the solution areas as well as at the edges. Internal boundaries could be tables and room partitions, while external boundaries are generally walls, doors, or windows. Boundary conditions can be very complicated depending on the model requirements. CFD provides information on the motion of air within a space. In addition to velocities, temperature and pressure are commonly available. Particles and individual gases can also be tracked.

Rather than focusing on equations, the technical discussion will be from a conceptual perspective. Next, a section on interpreting results is provided, followed by an examination of the results from the two cases. Sample results are provided for a simulation of a Biosafety Level 3 (BSL-3) environment and a hospital environment. An overview of the costs and computational equipment required to perform CFD simulations is provided. The cost-value of a CFD study is discussed. The final section focuses on the information required by an applied CFD engineer in order to create a model. While not exhaustive, this information should help both biosafety professionals and CFD professionals communicate.

Technical Discussion

The region to be modeled using CFD must first be divided up, or “discretized,” into cells. The combination of all cells is referred to as the grid or “computational domain.” Individual cells are usually hexahedral (six sides like a brick, [Figure 1]) or tetrahedral (4-sided like a pyramid, [Figure 2]). Depending on the methodology, solutions are obtained either at cell centers or at cell intersections, as shown in Figure 1. (Technical aside: For an equi...
spaced orthogonal grid [Figure 1], it has been shown there is no practical difference. For a more typical non-equidistant non-orthogonal grid [Figure 2], it has been proven that the finite volume methodology with the solution point in the middle of the cell is more robust, i.e., less likely to cause the solver to crash.

Numerous commercial CFD codes are available to solve the governing equations and obtain the airflow pattern. Also, software independent of the actual solver is often purchased; for example, the application used to create the grid. Additional software is sometimes used to set up complicated boundary conditions (pre-processors) and to provide enhanced visualization of the results (post-processors). In addition to the software, computational resources are required. A simple desktop computer is capable of running small solutions (under 500,000 cells) to steady solution in about a day, but cannot process large-scale problems. A distributed load (parallel) system is required.

The number of grid cells in any domain is a significant factor in determining what can be assessed. As a rule, one cannot "know" anything smaller than the cell size where information is sought. For example, if the cells near a chemical source are six inches away; stating the concentration at three inches from the source would be a violation of the rule. At a minimum, there should be a cell three inches from the source and, preferably, several cells between the source and the three-inch measurement point. For swirling flows, one generally needs at least three tetrahedral cells to capture the motion. Basically, more cells equal better results. However, as the cell count increases, so does the solution processing time. If the cell count is sufficiently high, the simulation can overwhelm computing resources. The number of cells that can be solved and the resolution obtainable are directly related to the computing resources available.

In CFD, a major decision is the type of model to use to simulate the airflow. Some models are best for getting an average snap-shot of the flowfield while extremely high value/risk situations may warrant the use of more expensive, fully time-varying or "transient" models. Steady-state RANS (Reynolds-Averaged Navier-Stokes) is often sufficient to resolve key information about the flowfield. A steady-state simulation provides a "snap-shot" of the average flowfield. Sometimes an unsteady RANS solution is used for particularly difficult problems in order to keep the solver stable as it progresses to the solution. An unsteady or time-varying solution would be required if the boundary conditions change with time. LES (Large Eddy Simulation) is an advanced unsteady solution method that can provide more data about transient operation, but is more computationally expensive. LES should be carefully considered in light of the information desired, the grid resolution, and the ability to model boundary conditions accurately. The limiting boundary conditions for internal airflow are usually the air inlets. The solution’s representation of the real-world situation is limited by the crudest component of the model. For many situations, a RANS model is adequate, but if accuracy is critical, the additional costs of LES would be justified.

Two key questions in the design of a BSL-3 containment laboratory space are air changes per hour (ACH) and what happens in the case of a contaminant release. RANS can provide an overview of ACH that is more detailed than an analytical calculation by identifying areas of short-circuiting, re-circulation, and dead-air. Species transport is driven by two phenomena, the flow pattern (or streamlines) and Fickian Diffusion, driven by concentrations which is represented by the following formula:

$$\dot{m}_i = -\rho_i D_{ij} \frac{\partial C_i}{\partial n_j}$$
In Fickian diffusion, species move from regions of high concentration to regions of low concentration and they try to do this independent of the airflow. A third consideration is how the airflow behaves in various modes of operation (fume hood on/off, etc).

Room features include standard furnishings, as well as ventilation system components and heat sources (Figure 3). An empty room will not necessarily have the same airflow characteristics as a fully furnished room. Heat sources in a room can create convective currents that alter airflow patterns locally. Laboratory equipment can be re-circulating, partially venting, or fully venting and is an obvious contributor to the motion of air through a room. CFD can include all these effects, provided the vendors can supply information on the devices.

**Interpreting Results**

CFD is known for producing color pictures; it has sometimes been called colorized fluid dynamics. Unfortunately, the color pictures often mask the grid used. One cannot tell the grid density from a contour plot. This makes it very difficult for the novice (and sometimes the expert) to assess a CFD simulation on the basis of the images. Furthermore, the graphics can distract from the key points. CFD is being used to validate or to analyze a design. Therefore, there exist key deliverables. In a few cases, the pictures can show “uniform flow” or “a lack of significant recirculation or stagnation regions.”

Figure 4a provides an example of air moving over a block. The picture of velocity contours gives few hints about the grid used to obtain the solution. In Figure 4b, the 670-cell grid is now superimposed on the solution showing a very coarse representation of the domain. The flow as shown is not inaccurate; it is just insufficiently resolved to make any conclusions. If the number of cells is increased to 57,518, there is far greater resolution (Figure 4c). Specifically, the wake region behind the block is improved. Figure 4d shows the streamlines, or airflow pattern, around the block.

The graphics illustrating the anticipated airflow patterns can be useful for a developer or a review board, but the best value of CFD is in the expertise of the person performing the simulations and their skill in interpreting the results. An expert CFD consultant can help improve the design of a space before it is constructed. Valuable information on the actual performance of a facility can be obtained. For example, assume Design 1 has an average of 5 ACH with no region of less than 2 ACH, and Design 2 has an average of 4.5 ACH with no region of less than 3.5 ACH. These are useful quantitative numbers. Without an extensive database of testing, it is best to take the numerical values on a qualitative basis. Design 2 is better than Design 1, but 5 ACH versus 4.5 ACH is not significantly different while the 2 to 3.5 is large enough to be important. Obtaining quantitative data from qualitative pictures requires post-processing capabilities and adherence to good CFD practices. A skilled CFD provider will help interpret the accuracy of the results for a client. An example of this expertise would be knowledge that, based on the simulation parameters, 0.5 ACH is not significantly different. Because many people who know they need CFD are uncomfortable evaluating the results due to the lack of explicit published guidelines for modeling the indoor air environment, peer review can be a way of ensuring the results are reasonable. To ensure recommendations are valid, peer review can be required as an item in the request for proposal.

While finding a CFD practitioner is easy using the internet, finding a qualified individual is not. Some common criteria to consider, when contracting CFD services, are the academic credentials and personal biographical sketches of the people who will be doing the analysis. Additionally, the core business of the company is relevant. Hiring a company focused on gaseous dispersion in indoor and outdoor environments might be preferable to hiring an automobile, turbine, or rocket focused company to model a laboratory. Finally, requesting references from previous clients is generally a good practice. The authors work for CPP Wind Engineering, a firm experienced in providing CFD services.

**Results**

Sample results are provided for two facilities to familiarize the reader with typical output from simulations. Since the reader will have only limited information on the spaces being modeled, only one case is presented for each facility for demonstration purposes although more cases would typically be analyzed to compare different designs for a client.

An overview of the hospital space modeled is provided in Figure 3. The rooms contain a bed, light, equipment panels on two walls, a computer on a small desk, and some cabinets. The air inlet is colored green and the return is red. The grid cross-section is provided in Figure 5. A total of 76,503 cells were used for the domain. The largest cell size was 10 inches by 10 inches in the horizontal plane, by 5 inches in the vertical plane. Higher grid density (smaller cells) must be used close to heat sources and ventilation intakes and returns. Contour plots were made for temperature (Figure 6) and mean-age air (Figure 7). Temperature is an occupant comfort criterion and mean-age air correlates to ACH (600 sec = 6 ACH, 300 sec = 12 ACH). The temperature contour shows the effect of heat sources in the room. Mean-age air data can be used for occupancy criteria and also to determine areas with less circulation and lower velocities. Species contours are shown in Figure 8. In this example, a large amount of contaminant is released for visualization pur-
Figure 4

Figure 4a: Contour plot of velocity. Figure 4b: Contour plot of velocity with the 670-cell grid superimposed showing how little is actually “known.” Figure 4c: Velocity contours from a 57,518 cell grid for the same problem. Note the improvements the wake region (arrow) and the overall quality. Figure 4d: Example of streamlines colored by velocity magnitude showing how the flow enters the domain on the left and travels over the block.
**Figure 3**
Hospital room showing heat sources (patient light; dark yellow, illuminator panel; light yellow, and diagnostic set; purple), ventilation system (green inflow, red return) and room furnishings (teal).

**Figure 5**
Grid cross-section for the hospital room.
Figure 6
Hospital showing a horizontal cross-section colored by temperature. Note that air is warmer near the illuminator panel, diagnostic panel, and over the patient light.

Figure 7
Hospital showing a horizontal cross-section colored by mean-age-air (600 sec = 6 ACH). Note that air is circulating less in the corners and that small changes in room design can result in some significant difference in contours.

Figure 8
Hospital showing iso-lines of contaminant. In the left room the release point is on the floor near the center of the room, in the right room the release point is at the head of the patient bed.
poses. The contaminant is moved by the air currents and is also diffused from the high concentration where it is added to the low concentration in the room.

An overview of the BSL-3 space being modeled is provided in Figure 9. The space is very complicated containing equipment heat sources, recirculating biosafety cabinets, furniture, and even door undercuts so air can move between the spaces. For the BSL-3 facility, velocity vectors (Figure 10) show the magnitude and direction of air movement. Note that the high inflow vent in the middle “dumps” air in the room, creating vortices on either side. The space was also designed to have negative pressure so air moves between the rooms through the door undercuts. The mean-age air in the laboratory space is provided in Figure 11. The lowest ACH in the space is 12, with most areas seeing many more air changes per hour. Temperature contours in a vertical plane are shown in Figure 12. Note that the presence of high wattage equipment can result in relatively warm air spaces even with a high air-exchange rate.

If the spaces were being reviewed for construction or modification, many more pictures would be provided. Often there are specific objectives such as attaining a minimum ACH everywhere in a space or ensuring occupant comfort near external windows. This detailed discussion can have great value in the design phase, but generally overwhelms someone not familiar with the details of the space.

**Costs**

Some explanation of the costs involved in CFD is warranted for budget planning purposes. The costs can be broken down into three main categories: fixed, recurring, and personnel. The fixed costs include the computer hardware and configuration, initial software purchasing, and construction of an area to house the system (these computers can be noisy and generate a lot of heat). The yearly maintenance fees on the software dominate the recurring costs. One also has to consider routine maintenance on the hardware. There is quite a bit of variance from different vendors for both the software and hardware. Table 1 provides a rough estimate of the costs associated with setting up and maintaining a small system.

Personnel costs are most difficult to assess because of the variances in expertise and information provided to clients. Some companies have one person who does CAD (Computer-Aided Drafting/Design), grid-generation, and CFD; others have people assigned to each task. Engineering rates are researchable, keeping in mind that most CFD personnel and resources are applied in the Aerospace industry. The engineering costs should be compared relative to the services being provided.

Rather than setting up a computing facility for a short-term project, CFD is often subcontracted to firms who have invested significantly in specialized personnel and computing resources. Costs for CFD projects vary depending on simulation requirements. Small projects can often be completed for less than $10,000. Very large, complex projects can approach the hundreds of thousands of dollars associated with typical Aerospace projects.

**Value-Added**

CFD in a pure dollars view is not inexpensive, but from the perspective of the cost of a multi-million dollar facility and the cost of individual components of a facil-

<table>
<thead>
<tr>
<th>Software costs (per seat)</th>
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<td>CFD fluid dynamic solver</td>
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<td>10 CPU system, 2 solvers, 8 parallel licenses, 1 grid generator, 1 CAD</td>
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<td>Yearly maintenance costs (30 % of system)</td>
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**Figure 9**
BSL-3 laboratory overview where inlets are green and outlets are red. Door undercuts allow for negative pressure flow effects. Various recirculation and externally venting laboratory devices are included. Thermal effects are also considered for heat generating pieces of equipment.

**Figure 10**
BSL-3 velocity vectors. Note the high velocities near the inlets and under the doors. The high velocity vent “dumps” to the floor creating vortices (arrows) to the left and right.

**Figure 11**
BSL-3 vertical plane showing mean-age-air. In this facility the air is rapidly exchanged, the lowest ACH is 12.

**Figure 12**
BSL-3 showing temperature contours. Note the presence of high wattage equipment can create warm zones even with a low mean-age-air.
Conclusions

The objective of this paper is to provide the practicing biological safety professional a context for applied CFD. This background includes a discussion of the basic considerations of grids and their relationship to solution quality. The two modes of contaminant transport, flow pattern and Fickian Diffusion, are explained in lay-terms. The importance of having a skilled CFD expert interpret results is explained and an example is provided with a focus on ACH criterion. Results from a simulation of a hospital and a BSL-3 environment are provided. The costs associated with CFD and the potential value-added is explained. Finally, a list of key information needed to develop a CFD solution is provided to facilitate communication between the biological safety professional and the applied CFD engineer. For an indoor environment, CFD can provide more detailed information than analytical calculations and is the next best option to building a scale model to test a facility design.

Suggested Further Reading

In lieu of References, a Suggested Further Reading list in order of increasing technical complexity is provided.


Use of Computational Fluid Dynamics to Predict Airflow and Contamination Concentration Profiles Within Laboratory Floor Plan Environment

Alexy Kolesnikov
CD-adapco, Melville, New York

Abstract

Eliminating environmental or other airborne contaminants in medical, biological research and production facilities is critical to the success of their mission (Sansone & Losikoff, 1977; Walters & Ryan, 2001). In situ measurement of environmental conditions creates a potential for inhalation hazards. Use of computational fluid dynamics (CFD), allows for a non-intrusive way of determining the room air conditions without concern for operator safety. The goal of this study is to use CFD computer modeling to study a pharmaceutical clean-room environment in which there has been an accidental introduction of aerosolized contaminant. The concentration and distribution of the contaminant is determined throughout the room for a range of conditions, by computation using three mathematical models and also experimentally field determined. A comparison of best fit shows High Reynolds number k-ε model calculations are most practical from a computational and prediction standpoint.

Introduction

Increased safety awareness has lead to steady refinement of regulations and best practice standards (Bell et al., 2006) emphasizing the need to accurately perform risk assessment studies of human exposure to air pollutants in cases of their accidental release into indoor spaces. In addition, for a variety of building design applications, detailed knowledge of ventilation flowfield distribution within occupied spaces is needed to provide thermal comfort evaluation. Experimental tests are costly and supply only limited data. The goal of this study is to validate the use of Computational Fluid Dynamics (CFD) in providing reliable predictions of laboratory room airflow patterns and contaminant distributions. Many common laboratory practices involve dealing with gaseous or potentially aerosolized particles (virus, bacteria, fungi, powders, vapors), due to weighing, pipetting, transfer, handling, autoclaving, and incubating. While rare, accidents such as equipment malfunction, human errors and improper use of containment devices could all lead to the release and dispersion of airborne pollutants into the laboratory work area, thus creating inhalation or contamination hazard. A variety of studies have shown that small powders and particulates are easily aerosolized, entrapped and transported by room air currents during routine handling procedures (Sansone & Losikoff, 1977). Temperature and contaminant concentration distribution within a room is uniquely dictated by room airflow patterns, the air change rate, location and type of the contaminant source, as well as its weight, shape and size and different running ventilation conditions (heating/cooling). Inhalation or contamination risk assessment, therefore, requires detailed information concerning indoor airflow velocity distribution. Aided by rapid advances in the areas of turbulence modeling and parallel computing technology, CFD finds itself uniquely positioned to provide high fidelity numerical airflow distribution data as obtained by solving genuine conservation laws directly controlling airflow behavior. While the initial validation study presented in this paper establishes ability of a numerical simulation to adequately reproduce experimental results, following sections further focus on a real-life, full-scale production laboratory environment consisting of two laboratory rooms, corridors, equipment pass through and several auxiliary rooms. Several contaminant sources are placed within the floor plan and their locations are varied. CFD is used to numerically obtain airflow velocity and pollutant concentration distributions within the floor plan.

CFD Modeling Approach for Ventilation Class Airflows

CFD is the science of utilizing advanced computer modeling techniques to solve the Navier-Stokes equations governing fluid/gas flows (Baker, 1983). The Navier-Stokes system is derived by applying the principles of conservation of mass, momentum, and energy to a control volume of fluid. The resultant equations are extremely complex and possess no known analytical (exact) solution. Instead, their approximate computer-simulated solutions
are considered, with additional assumptions related to turbulence modeling and properties of the flow field being made based on the physics of the specific process. The solution is obtained using discretization techniques applicable upon division of the initial, continuous geometric domain into a finite number of non-overlapping discrete volumes that are referred to as computational mesh in technical literature. Consequently, numerical simulation results in velocity, pressure, and temperature values calculated for each of the individual volumes and whose combination provides a detailed airflow distribution inside the original geometry. Given the approximate nature of the numerical solution, the computational results need to be validated experimentally. The steady-state conservation of energy incorporating the Boussinesq approximation is shown for flows class characteristic of most ventilation-type flows and be validated experimentally. The steady-state conservation of the numerical solution, the computational results need to be validated experimentally. The steady-state conservation of energy incorporating the Boussinesq approximation is shown below (Baker, 1983; Emmerich, 1997).

\[
\frac{\partial u_i}{\partial x_i} = 0
\]

Conservation of momentum

\[
\frac{\partial u_i}{\partial t} + \frac{\partial u_i u_j}{\partial x_j} = -\frac{1}{\rho} \frac{\partial P}{\partial x_j} \left[ \nu \left( \frac{\partial u_i}{\partial x_j} + \frac{\partial u_j}{\partial x_i} \right) \right] - \beta g_i \theta
\]

Conservation of energy

\[
\frac{\partial \theta}{\partial t} + \frac{\partial \theta u_i}{\partial x_j} = \frac{\partial}{\partial x_j} \left( \kappa \frac{\partial \theta}{\partial x_j} \right) + H
\]

where \(i, j = \text{summation indices}\)

- \(g_i = \text{gravitational acceleration in } x_i \text{ direction}\)
- \(H = \text{volumetric heat source generation rate}\)
- \(P = \text{instantaneous static pressure difference}\)
- \(t = \text{time}\)
- \(u_i = \text{instantaneous velocity component in } x_i \text{ direction}\)
- \(x_i = \text{Cartesian coordinates}\)
- \(\beta = \text{volumetric coefficient of expansion}\)
- \(\kappa = \text{thermal diffusivity}\)
- \(\theta = \text{instantaneous temperature difference}\)
- \(\rho = \text{density}\)
- \(\nu = \text{kinematic viscosity}\)

Physically, room airflows combine several distinct modes of heat and mass transport (Nielsen, 1998), namely natural convection with buoyancy effects due to temperature gradients dominating the flow, forced convection for flows with high supply rates and negligible temperature gradients (clean room type flows) and mixed convection involving a combination of both. Most ventilation type flows are turbulent and characterized by velocity fluctuations with a number of irregular turbulent eddies forming within the flow structure as opposed to laminar stratified flows. Mathematically, the ability to accurately model and resolve these turbulent fluctuations within the “bulk” airflow pattern during computer simulation ultimately determines the accuracy of the overall numerical solution. Turbulence modeling and its applicability to indoor airflow prediction has been a subject of numerous research studies focused on benchmarking CFD-generated results against available experimental data. Chen (1995, 1996) studied application of various Reynolds-Averaged approaches, namely Reynolds-Stress and k-ε turbulence models for indoor flow modeling. Both model types were shown to provide satisfactory results for the mean velocity distributions, with Reynolds-Stress model better capturing secondary recirculation zones due to its inherent anisotropic (directional non-uniformity) turbulence modeling assumption. Application of Large Eddy Simulation modeling has been discussed among others by Zhang and Chen (2000) and Su et al. (2001) and was shown to provide good agreement with experimental results. Unlike Reynolds Averaging, which relies on ensemble-averaging in its mathematical formulation and calculates mean characteristics of the flow, Large Eddy Simulation models divide the overall flow structure into large-scale and small-scale motions (Su et al., 2001; Piomelli, 1999). The large-scale motion is directly calculated, while small-scale motion is modeled during the simulation. This approach can provide instantaneous flow information as well as mean properties of the flow, but is inherently more computationally expensive, since significantly finer grids and time-dependant calculations are required to directly resolve physically meaningful smaller-scale motions.

Rapid progress being made in the area of computing technology and its parallel implementation, coupled with continuous developments in advanced modeling research, ensures the ever-expanding role CFD modeling enjoys as a design tool of choice in both academic and industrial ventilation applications. Thus, simulations involving tens of millions of computational cells needed to adequately resolve ventilation flow characteristics in industrial scale facilities are now routinely performed at leading CFD industrial and research centers. As a result, high fidelity velocity, temperature and contaminant concentration data obtained during numerical simulations is now available for use during design phase implementations of real-life building projects. Towards this goal, Lin et al. (2005) investigated airborne pathogen transport in aircraft cabins, Yang et al. (2000) used numeric analysis to optimize ventilation and predict air quality in indoor skating areas, while Baker et al. (2000, 2001) studied airflow patterns...
within commercial aircraft cabins and industrial scale plant facilities. A comprehensive CFD study of laboratory hood performance outlining specific recommendations aimed at optimized containment for various laboratory settings was conducted by Memarzageh (1996). Design phase recommendations included optimized airflow rates and facility-specific geometrical configuration specifications.

**Forced Convection Validation Study**

A well documented forced convection benchmark study by Nielsen et al. (1978) is used herein to validate CFD flow field predictions. Geometrical arrangement used in the experiment is presented in Figure 1, where $H=3\text{m}$ (height in meters). The experiment was conducted in a room with a single slot inlet/single slot outlet configuration. The inlet velocity distribution was a uniform velocity profile with a magnitude of 0.455 m/s (meters/second). The inlet and outlet heights were 0.168 m and 0.48 m respectively. The air velocity was measured by a laser Doppler anemometer along the centerlines of the four cross sections as shown in Figure 2, namely $x/H = 1$, $x/H = 2$, $y/H = 0.028$, $y/H = 0.972$. Numerical computations were performed using commercially available software package STAR-CD developed by CD-adapco.

---

**Figure 1**
Experimental room geometry.

---

**Figure 2**
Computational mesh cross sectional representation.
Since the idea behind the outlined benchmarking strategy is to develop a general solution approach readily adaptable to industrial problems of arbitrary scale and geometric complexity, a fully unstructured hexahedral trimmed mesh comprised of approximately 500,000 cells was built using an automated mesh generator. This included a core mesh consisting of 160mm sized cells, which were refined to 40mm in the layer immediately following the surface as appropriate for subsurface boundary layer resolution. Inlet and outlet domains were sufficiently extended outwards from the main solution domain to provide a physically realistic flow configuration near the inlet and outlet areas. The four representative cross sections of the mesh are shown in Figure 2, with local mesh detail highlighted in Figure 3. The boundary conditions consisted of uniform velocity equal to that of the experiment specified at the inlet, zero pressure perturbation at the outlet and no-slip (zero normal velocity) condition applied at the walls. All solutions were obtained at isothermal conditions. Velocity, pressure and tracer gas mass fractions were obtained by solving Reynolds-Averaged Navier-Stokes equations. Several turbulence models were considered in the validation study including high and low Reynolds number $k$-$\overline{\omega}$ models and Gibson-Lauder Reynolds stress model (RSM). Wall functions were used to model flow distribution in the near wall region in conjunction with high Reynolds $k$-$\overline{\omega}$ and RSM models, while near wall mesh was modified to include 25 near wall layers (Figure 4), thus increasing the overall mesh size to 1.3 million cells when using low Reynolds number $k$-$\overline{\omega}$ model (Baker 1983).

A three-dimensional representation of the flow field solution obtained using high Reynolds number turbulence model is presented in Figure 5, while velocity distributions along the X-direction taken through the middle of the room are shown in Figure 6 for all considered turbulence models. Solution contours represent flow velocity component computed along the X axis (Figure 3) and are colored by its magnitude. As expected, the flow velocity magnitude diminishes upon incoming airflow propagating into the main room domain, from right to left (Figure 6). Airflow forms a large recirculation pattern inside the room, with the bulk-entering airflow moving from right to left along the ceiling, turning towards the floor, partially exiting the room at the outlet and partially proceeding from left to right along the floor completing the recirculation pattern by turning upwards at the right lower corner of the solution domain. An important characteristic of the flow confirmed by experimental results includes two secondary recirculation regions, one in the upper left and one in the lower right corners of solution domain. Normalized experimental and numerical results are shown in Figure 7 for the four measured cross sections. All numerical solutions show close adherence to experimental measurements except for the cross-sectional results taken along the floor of the room and shown in Figure 7D where all turbulence models significantly overpredict measured velocity magnitude. Overall, while the RSM model is able to better capture above-mentioned secondary recirculations, represented in Figures 7C and 7D by the changing sign of normalized velocity magnitude at $x/H \sim 2.95$ in Figure 7C and $x/H \sim 0.05$ in Figure 7D.
Figure 5
Velocity magnitude along the X axis. High Reynolds number turbulence model.

Horizontal Velocity Magnitude m/s

- 0.5500
- 0.5031
- 0.4563
- 0.4094
- 0.3625
- 0.3156
- 0.2688
- 0.2219
- 0.1750
- 0.1281
- 0.0750
- 0.5938E-01
- 0.1250E-01
- 0.3437E-01
- 0.8125E-01
- 0.1063
- 0.1531
- 0.2000
Use of Computational Fluid Dynamics to Predict Airflow and Contamination Concentration Profiles

**Figure 6**

Velocity magnitude along the X axis. Cross-sectional view.

Horizontal Velocity Magnitude m/s

<table>
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<th>Value</th>
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</table>

**Figure 6A.** High Reynolds number $k-\varepsilon$ model.

**Figure 6B.** Low Reynolds number $k-\varepsilon$ model.

**Figure 6C.** RSM Gibson-Launder model.

Figure 7D and low Reynolds $k-\varepsilon$ model trails closer to experimental results in some of the near wall sections (Figures 7A and 7B), they also evidence notable numerical as well as computational drawbacks. Low Reynolds number $k-\varepsilon$ model is the most computationally demanding of the three, with mesh size ballooning to 1.3 million cells for this simple geometry and its performance within the bulk of the solution domain being similar and in parts inferior to that of the high-Reynolds $k-\varepsilon$ model. While the RSM model is better suited for capturing secondary recirculation zones due to its ability to account for anisotropic nature of turbulence, it also requires solving a larger number of turbulence modeling equations and its performance in the bulk of the solution domain trails that of the high Reynolds number $k-\varepsilon$ model. Numerical results presented in Figure 7 are consistent with previously published results (Chen, 1995; Chen, 1996).

Since the stated goal is to develop a generally-viable strategy for resolving large-scale real-life ventilation flows within domains of arbitrary geometric complexity, High Reynolds number $k-\varepsilon$ model presents the best balance of the three, requiring the least amount of computing effort and providing the best overall correlation between numerical and experimental results inside the bulk of the solution domain. This model is therefore used in the next section to predict airflow distribution within laboratory floor plan environment.
Figure 7
Experimental results comparison.

Figure 7A. Section at $x/H = 1$

Figure 7B. Section at $x/H = 2$
Figure 7 (continued)
Experimental results comparison.

Figure 7C. Section at $y/H = 0.972$

Figure 7D. Section at $y/H = 0.028$
Laboratory Floor Plan Ventilation Prediction

The floor plan section considered in this study is shown in Figure 8 and the corresponding three-dimensional representation is shown in Figure 9. Overall, nine rooms and connecting corridors are considered, combining to represent an approximately 10,000 square foot facility. Six slot inlets and five outlets are used to facilitate ventilation airflow. The boundary conditions are uniform velocity inlets with corresponding values shown in Figure 8 and atmospheric pressure at outlets. No-slip boundary condition is used along the walls. Temperature boundary conditions were specified as 68°F supply air, 98°F on the side wall, and 75°F at the floor and ceiling levels. In accordance with the meshing strategy developed in the validation section above, a core mesh consisting of 160mm sized cells was built using automatic mesh generator. As before, the mesh was refined to 40mm in the layer immediately following the surface in order to provide near surface layer resolution required by the use of wall functions characteristic of the high Reynolds number k-ε turbulence model implementation. The final computational mesh consisted of 3.9 million cells. A cross-section of the mesh and its detail is shown in Figure 10. In addition to the general floor plan geometry and to emphasize the direct applicability of the method to a wide range of problems including those involving comfort study simulations, a person potentially representing a laboratory worker was somewhat randomly placed inside solution domain as illustrated in Figure 11.

Solution profiles are shown in Figures 12 and 13. Figures 12A and 13A show velocity magnitude and temperature contours along the walls of the building, while Figures 12B, 12C, and 13B show velocity magnitude and temperature distributions across some of the sections taken throughout the solution domain. The flow field is highly non-uniform and clearly exhibits three-dimensional stratification both in temperature and velocity within the entire building. Upon a brief inspection of the presented results, immediate recommendations on ventilation flowfield optimization can be made. Thus, area A in Figure 12A clearly evidences local velocities significantly lower than those in adjacent rooms, resulting in undesirably high temperatures (Figure 13A) indicating the need for an additional ventilation outlet. The airflow velocity in some of the corridor openings is sufficiently high (area B, Figure 12C) to warrant specific attention, a situation that could be resolved by placing additional outlets to redistribute the outflow. Velocity and temperature distribution profiles in the vicinity of the worker are shown in Figures 13, 14 illustrating benefits of potential

Figure 8
Laboratory floorplan.
**Figure 9**
Laboratory floorplan. Three dimensional representation and boundary conditions.

**Figure 10**
Laboratory floorplan. Mesh detail.
comfort study simulations. The temperature profile indicates lower temperatures near the floor that in turn results in a several degree difference between the head and feet areas of the worker.

A time-dependant numerical study was conducted to simulate transient tracer gas release from two of the supply inlets. Tracer gas modeled as a passive scalar not contributing to bulk air properties was continuously released for 10 seconds and its propagation was modeled during the simulation. Figures 14A, 14B, and 14C illustrate tracer gas concentrations at 12, 67, and 77 seconds, respectively. Figures 15A and 15B present numerically-predicted tracer gas concentrations attained upon release conducted from a different supply and show concentration profiles at 22 and 62 seconds. Again, three-dimensional and highly non-uniform nature of airflow and tracer gas concentration propagation is clearly visible in the presented results. It is clear that ability to estimate local concentration distributions and their time evolution throughout the floor plan allows for better engineering controls.

**Figure 11**
Laboratory personnel representation.
Use of Computational Fluid Dynamics to Predict Airflow and Contamination Concentration Profiles

**Figure 12**
Velocity magnitude distribution.

Velocity Magnitude m/s

- 0.5000
- 0.4688
- 0.4375
- 0.4063
- 0.3750
- 0.3438
- 0.3125
- 0.2813
- 0.2500
- 0.2188
- 0.1875
- 0.1563
- 0.1250
- 0.9375E-0
- 0.6250E-0
- 0.3125E-0
- 0.0000

**Figure 12A**

**Figure 12B**

**Figure 12C**
Figure 13
Temperature distribution.

Figure 13A

Figure 13B
Figure 13 (continued)
Comfort Simulation. Calculated Velocity magnitude distribution.

Figure 13 (continued)
Comfort Simulation. Calculated Temperature distribution.
Figure 14
Tracer gas concentration profiles.

Figure 14A. 12 sec.

Figure 14B. 67 sec.

Figure 14C. 77 sec.

Tracer Gas Mass Fraction

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Figure 15
Tracer gas concentration profiles.

Tracer Gas Mass Fraction

1.000
0.9375
0.8750
0.8125
0.7500
0.6875
0.6250
0.5625
0.5000
0.4375
0.3750
0.3125
0.2500
0.1875
0.1250
0.6250E-01
0.0000
Conclusions

The room validation study presented in the paper establishes the ability to closely predict ventilation airflow distribution profiles during CFD simulations. The multi-purpose applicability of CFD tools is further illustrated in the example of a large-scale, real-life generic laboratory floor plan. Design cycle optimization recommendations as well as risk assessment strategy development can be made in confidence based on the high density of data provided by the simulations. Table 1 shows computer resources that were required to perform the study. While transient tracer gas simulations required several days to complete in parallel implementation, steady-state velocity and temperature profiles were generated in under 10 hours, translating in a one-day turnaround design cycle. Thus, the necessary parametric changes comprising a comprehensive design optimization of an entire laboratory floor plan could be conducted in a one-week period. With an established mesh development strategy outlined and validated in the previous sections, a larger-scale problem would simply require a larger number of processors for parallel implementation, thus making it a “resource” problem readily resolvable with the capabilities available at leading academic and industrial CFD institutions. By providing high-fidelity data sets detailing airflow characteristics within built environments which are not available otherwise, Computational Fluid Dynamics has clearly matured into a design tool of choice at the forefront of building design applications.

<table>
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References


Select Agents Diagnostic Test Reporting Requirements—Exemptions and Implications to Biosecurity

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Abstract

New regulations on the possession, transfer, and use of biological agents and toxins have provided the regulatory premise to introduce institutional-level biosecurity practices at research laboratories handling Select Agents and other infectious materials. However, clinical and public health laboratories licensed under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) that do diagnostic testing, verification, or proficiency testing are generally exempted from the regulations. Although a CLIA laboratory director is required to notify the Department of Health and Human Services immediately upon identifying specific Select Agents, a prevailing opinion is that there is no reporting mechanism for diagnostic test results. CLIA Laboratories are required to adhere to established biosafety guidelines, but face fewer biosecurity-driven restrictions on their behavior, and are often more vulnerable compared to research laboratories to diversion of Select Agents and other agents of public health concern for malevolent uses. International laboratories involved in proficiency testing programs routinely receive agents of public health concern, and lack biosecurity status and reporting mechanism. This applies also to international shipping companies involved in transport of agents of public health concern under the proficiency testing programs. This paper reviews the emerging consensus on whether CLIA exemption fundamentally compromises on the biosecurity goals of the new regulations, and options for addressing biosecurity of Select Agents and other agents of public health concern for international CLIA Laboratories and shipping companies.

Keywords
Biosecurity, Select Agents, Biosafety, CLIA Laboratories, Risk Assessment, Bioterrorism, Public Health, Proficiency Testing Programs

Introduction

The scientific community and regulatory agencies are beginning to place considerable importance on laboratory biosecurity with a focus on improving security at microbiological research facilities, clinical laboratories, and ancillary laboratory services such as biological material storage and distribution facilities. A key element of this growing awareness requires a clear delineation of the concepts of biosafety and biosecurity in the context of new regulations. Whereas biosafety refers to institutional level measures to prevent and mitigate the accidental release of biologic agents and toxins, biosecurity refers to instructional measures that guard against the deliberate release of pathogens for malicious purposes (including bioterrorism). Thus far, existing U.S. and international regulations and guidelines have focused on biosafety rather than biosecurity.

In the aftermath of the 9/11 terrorist attacks, followed in the same year by a string of Anthrax attacks on the United States, the U.S. Congress passed two significant pieces of legislation. First, the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001 established criminal penalties for possession, shipping and receiving of certain biological agents, known as Select Agents and toxins (SA), if used as a weapon or for any reason not plausibly justified for prophylactic, protective, bona fide research or other peaceful purposes. Second, the Public Health Security and Bioterrorism Preparedness and Response Act (PHSBPRA) of 2002 greatly expanded controls over dangerous pathogens and toxins stored, used and transferred between laboratory and ancillary facilities within the U.S. These legislations establish the regulatory premise to introduce biosecurity practices at research laboratories handling dangerous etiologic agents and toxins as part of an overall national security program.

Although clinical laboratories licensed under the Clinical Laboratory Improvement Amendments of 1988 (CLIA Labs) are required to report diagnostic, verification and proficiency test results for SA to the Department of Health and Human Services (DHHS), they typically do not report diagnostic test results, as there is no reporting mechanism under the new regulations.

As new regulations mandate expanded control on the use and transfer of SA, it is unclear if the guiding ration-
ale for CLIA exemption from reporting requirements, under 42CFR 73.6, is an acceptable level of biosecurity risk for clinical laboratories, local community and the country at large. Regardless, scientists and members of the biosafety community have pointed out that clinical laboratories face fewer laboratory-imposed restrictions on their behavior and therefore are often in the best position to divert a SA for malicious use (Malakoff, 2003).

To our knowledge, there is no comprehensive review of CLIA Labs for biosecurity risks posed by SA and other agents of public health concern from routine operations. Agents of public health concern, which are not listed under the SA Rule, introduce yet another dimension to biosecurity risks. This paper will review whether CLIA exemption is unwarranted, considering the broader implications to biosecurity risk and goals of the new regulations and options for addressing biosecurity for international CLIA Labs and shipping companies involved in proficiency testing programs.

**Regulatory Context for CLIA Exemption**

During the 1999 Congressional review of both the regulatory regime governing the possession of SA and the adequacy of the Centers for Disease Control and Prevention (CDC) regulations in preventing unauthorized access to SA for malicious activities, members of the scientific community and law enforcement officials expressed concern that the existing CDC guidelines (42 CFR 73) exempted CLIA Labs from SA Final Rule reporting requirements. These investigations indicated a need to expand CDC regulations to cover all testing laboratory categories on the possession as well as transfer of SA. With over 150,000 CLIA Labs in the U.S., the PHSBPRA has in effect granted 150,000 exemptions to the CDC rule.

Although the enactment of the PHSBPRA greatly expanded controls over the possession, transport and use of SA, CLIA Labs retained their exempt status, but are required to be registered with CDC if they choose to retain SA at the facility. CLIA Labs are required under the regulation (42 CFR 73.6 [a], [b]) to report SA if detected in clinical specimens to DHHS and destroy within seven days, or transfer to a registered facility.

Perhaps the exemption is based on the premise that registration of over 150,000 diagnostic laboratories would pose a formidable logistical problem for both the regulators and the labs themselves. Moreover, since CLIA Labs perform routine diagnostic tests on a vast array of clinical specimens accompanied with limited microbiological information, it is not always possible to define appropriate facility-level biosafety requirements.

During the course of a routine test, a CLIA lab may isolate common microbes found in clinical specimens or highly-contagious agents of public health concern such as Mycobacterium tuberculosis or Influenza A H2N2 strain. In most cases, CLIA Labs do not perform the confirmatory identification test; normally the procedure is carried out by a designated public health lab or by the CDC. As a result, CLIA Labs cannot claim, with absolute certainty during the registration, it was not in possession of SA given the receipt of multiple clinical samples for diagnostic work from various hospital and healthcare providers.

**CLIA Exemptions and Biosecurity Challenges**

Biosecurity challenges arising from the CLIA exemption regarding diagnosis, verification and proficiency testing related reporting requirements is five fold.

First, potentials for biosecurity risks exist with CLIA Labs in the U.S. and foreign countries participating in the laboratory proficiency testing programs to evaluate the accuracy in the performance of diagnostic tests, not essentially on SA, but agents of public health concern of national and global significance, such as AIDS, Tuberculosis, and Influenza A. Administered as a single-blind study involving multiple rounds of testing and reporting cycles, these studies allow labs to receive, possess, and manipulate potential highly-contagious test specimens. Unlike routine clinical specimens of unknown analytes, CLIA Labs in the proficiency testing program are aware that test slants may contain infectious agents of high public health concern, although the actual etiologic entity and composition of test samples remains unknown, except for employees assigned to work on the task. As CLIA Labs constitute the bulk of the participating laboratories with a growing number of international participants, reporting mechanisms verifying compliance under prevailing regulations remain unclear.

Potentials for biosecurity risks from proficiency testing program on agents of high public health concern were recently illustrated in the Influenza virus proficiency testing study (CDIRAP, 2005). Briefly, the performance evaluation study of the Influenza A testing kits included, among a variety of samples of pathogens and viruses, Influenza A H2N2, a viral strain linked to between one and four million deaths during the flu pandemic of 1957 and 1958 (Kaye, 2005). Inclusion of H2N2 was not known to public health officials until a routine clinical test in a Canadian public health laboratory revealed an accidental cross-contamination of a test sample with H2N2 from a proficiency test specimen elsewhere. Following this revelation, CDC and the World Health Organization (WHO) issued orders to the participating labs to destroy all test specimens (Shute, 2005). In such instances, beyond issue of orders to destroy dangerous specimens, regulatory agencies have no mechanism to ensure that all test specimens were destroyed, except relying on the responsible behavior of the laboratories participating in the testing program. There are no published data on the CLIA re-
porting under Form 4, on how test specimens were destroyed.

Second, there is no mechanism in place to track CLIA Lab notification related to SA to DHHS. Exemption under current regulations applies to CLIA Labs involved only in diagnostic, verification and proficiency testing, although the lab is required to notify DHHS upon identifying SA and the entity must be transferred to a registered facility or destroyed within seven days after agent identification (42 CFR 73. 6(a) (i)). There is no published data to verify reporting status of CLIA Labs.

A serious shortcoming is that confirmatory tests are performed at a reference laboratory, and not the CLIA facility. Since the current reporting mechanism is cumbersome, it is often difficult to track follow-up activities at the CLIA lab to ensure that stored specimens and cultures are transferred to the reference lab or destroyed. The current regulation does not require a separate audit trail for tracking the work of CLIA Labs related to SA and no requirement for third-party audit of the laboratory records.

Third, no biosecurity-driven guidance is available for the biologics shipping companies involved in the transport of SA and infectious materials of public health concern between research facilities and CLIA Labs. Although biologics shipping companies follow the biosafety level containment guidelines for the packaging and shipping containers as outlined in 42 CFR, Section 72.25, there are no explicit biosecurity-related guidelines currently available to this industry sector (DHHS, 2005).

At present, biologics shipping companies involved in temperature-sensitive and infectious diagnostic samples have various (i.e., non-standardized) operating procedures for handling, shipping and management of transport to international destinations. Some shipping companies forward samples that may be considered biosecurity-sensitive only up to the international port of arrival, leaving it up to the local (foreign) lab to clear the shipment from Customs.

Currently, there is no mechanism to verify the bona fides of the individuals at international Customs clearing the specimen. A confirmation of receipt from the recipient lab is the only mechanism to verify that the shipment was received by the designated point of contact at the laboratory participating in the study. Our proficiency testing support follows an in-house standard operating procedure for sample/specimen tracking process and matrix for coordinating with the biologics shipping company. We have described this approach briefly in the next section.

Fourth, the CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines are less explicit about CLIA on safeguarding of dangerous pathogens and other biosecurity-related problems. There are no studies in the literature on biosecurity lapses in CLIA Labs, although some published reports erroneously cite lapses in biosafety as those of biosecurity, such as the reported incidence of laboratory worker’s occupational exposure to SA (Hecht et al., 2005; WHO, 2003).

Until recently, the safeguarding of dangerous pathogens was viewed primarily as a matter of biosafety rather than biosecurity. Nevertheless, there are documented studies reporting biosecurity lapses at major national laboratories working on infectious agents. The 2002 U.S. Department of Agriculture (USDA) audit report found that several of the 124 USDA laboratories were vulnerable to theft and could not accurately account for stocks of animal and plant pathogens (Tucker, 2003; USDA 2003). Several institutions funded by the USDA Labs grant access to visiting scientists, including foreign nationals, with very limited or no background security investigations. Several publicized incidents of security lapses at government laboratories and academia were traced to poor internal controls and record keeping on dangerous human pathogens (Tucker, 2003). Although similar security violations cannot be ruled out at CLIA Labs, we could not locate any report in the published literature on security lapses at these laboratories.

Fifth, biosecurity related measures are inadequate under the existing national and international biosecurity guidelines for clinical, microbiological or biomedical laboratories. Following the 2002 GAO report on the shortcomings in the existing CDC SA program (GAO, 2002), a revision of the BMBL was issued by DHHS to include requirements to maintain up-to-date inventories and develop transfer and shipping procedures. A subsequent CDC response to the PHSBPR resulted in a more biosecurity-directed interim final rule on the potential misuse of SA and toxins as bioterrorism agents against the U.S. (CDC, 2002). Similarly, the National Institutes of Health (NIH)/CDC have outlined plans to make additions to the forthcoming 5th edition of the BMBL on biosecurity-related measures. Use of risk management-based methods is a key biosecurity-related directive under the new NIH/CDC guidance.

Finally, the international dimensions of the biosecurity problems of microbiological and biomedical laboratories remain poorly defined. No global standards for laboratory security currently exist providing a conceptual framework to formulate national legislation and regulatory structures (Tucker, 2003). This lack of international harmonization of biosafety and biosecurity has created gaps and vulnerabilities that must be addressed as part of a coordinated global strategy to improve biosecurity at clinical laboratory facilities.

**Options for Moving Forward**

Options for moving forward must address two separate, but interrelated issues related to biosecurity affairs at
The first set of issues address the need for biosecurity guidance for microbiological and biomedical laboratories by systematically integrating emerging biosecurity requirements within the existing biosafety practices. An ideal biosecurity plan should integrate biosafety requirements into a unified set of facility-level SOPs; CLIA Labs should have a formalized reporting mechanism to DHHS; and revised BMBL biosafety guidelines including a more explicit requirement for third-party audits made as part of laboratory biosecurity program.

Regulators must take additional care to refine aspects of biosafety regulations that violate biosecurity standards without compromising their protective intent. For example, since entry to and exit from a laboratory during an emergency could supersede biosecurity protocol, a system must be incorporated into emergency response planning that prevents potential for theft of SA. Suggestions include previously-screened emergency personnel being able to override access controls with the assistance of an escort, preferably laboratory personnel, and creating protocol for the relocation of SA in case of an emergency (Rivera, 2005; Richmond & Nesby-O'Dell, 2002).

In addition to operational impediments, reasons for the hesitancy of the scientific community to accept biosecurity guidelines include increased restrictions on programs funded by the federal government, inconvenience of increased security (such as the additional time it takes for staff to comply with security regulations), the use of research funding on required security upgrades, a decrease in the number of qualified researchers due to increased personnel security, and concern that scientists will be held criminally responsible for violations of biosecurity guidelines, both for themselves and for their overseas collaborators (Rivera, 2005; Malakoff, 2004; Stone, 2004).

The second set of issues more specifically address biosecurity implications of CLIA exemptions and options to narrow the security-related gaps with minimal disruption to the routine functions of clinical laboratories. Options for integrating effective biosecurity requirements into clinical laboratories include improving CLIA Lab participation in proficiency testing programs involving SA and agents of public health concern, tracking SA via pathogen inventory and accountability protocol, third-party audits similar to annual biosafety inspections, creating biosecurity-related guidelines for the transport of SA, implementing CLIA facility-specific biosecurity plans that utilize threat analysis and a tiered agent-based risk assessment, and adopting international standards for laboratory security.

**Improving CLIA Lab Biosecurity in Proficiency Testing Program:** Public health agencies working with the CLIA facilities in proficiency testing programs involving agents of public health concern are required to follow biosafety measures having biosecurity implications. For example, clinical laboratories participating in the CDC’s global Mycobacterium tuberculosis/NTM drug susceptibility proficiency testing program (Mtb-PE) have proactively instituted infectious agents’ access and transportation procedures aimed at improved biosafety and biosecurity.

Figure 1 illustrates the categories of global CLIA laboratories participating in the Mtb-PE program during 2002-2005. Among the clinical lab categories, public health laboratories and hospital-based clinical testing facilities accounted for over 87 percent of the total complying with the prescribed safety and security requirements of the testing program.

Figure 2 illustrates that, during the study period 2002-2005, the majority of CLIA in the program, representing about 54 percent of the total laboratories, were Biosafety Level-3 (BSL-3) facilities, while about 34 percent identified as BSL-2 facility, which is the minimum BSL requirement to participate in the testing program. The Mtb-PE program over the years has assured adherence to BSL-3 containment during shipment and end-to-end tracking of the samples from the point of origin to destinations all over the world.

As Mtb-PE program coordinators, we have developed a series of program-level measures aimed at tracking the nature, type and geographic (international) location of the laboratory in the program to ensure biosafety containment requirements and biosecurity of shipments across the supply chain. We perform a preliminary background evaluation of the self-declared CLIA status of the international laboratory and to ensure the facility is a privately-owned, regional health, or national reference laboratory.

Transportation of test samples to participants is closely monitored such that samples shipped to domestic and international laboratories are tracked for receipt door-to-door from the point of origin to final destination. Safe and secure transport of infectious agents is one of the key parts in guaranteeing delivery of an intact shipment to the testing facility. Without any clear international biosecurity-driven regulations governing transport of infectious materials, public health programs and participating entities are attempting to establish guidelines for sample preparation for shipment, selection of shipping company, and tracking methodology to ensure integrity of the test specimen, biosafety, and biosecurity of the supply chain.

**Better Pathogen Inventory and Accountability:** A crucial obstacle in the SA inventory is that there is no feasible way to precisely quantify pathogens since infectious material can be found in storage freezers, incubators, living animals, animal excrement or carcasses (Salerno, 2002). Thus, pathogen inventory control must rely on accountability: cataloging what materials exist in the facility, where they are, and who is responsible, or
**Figure 1**
Primary Classification of the CLIA Laboratories Participating in the Mtb/NTM Proficiency Testing Program (2002-2005)

**Figure 2**
Self-reported Biosafety Levels of CLA Laboratories Participating in the Mtb/NTM Proficiency Testing Program (2002-2005)
who has access to them (SNL, 2003). An example of pathogen accountability is the establishment of a CLIA Lab record keeping protocol for SA, including mechanisms to account for pathogens that are being stored, storage location, storage method, pathogens used during experiments or destroyed (Richmond & Nesby-O’Dell, 2002). CLIA Lab director notification upon identification of SA, given the large number of these labs, may require a record keeping protocol as part of reporting requirements verified by an audit process, either self-driven or administered by a federal government agency (e.g., CDC, NIH), of the laboratory records of a random sample of CLIA Labs.

**Tracking Transport of SA:** Some headway has been made in creating security guidelines for the shipment of SA, most notably by the Department of Transportation (DOT). In March 2003, DOT amended 49 CFR 172 with the inclusion of a security component to employee training and requiring development and implementation of company-specific security plans (DOT, 2002).

Our in-house process for the Mtb-PE program operationalized partial elements of a biosecurity-oriented international shipping process, namely by adopting a more stringent tracking process and selecting a shipping agent for international destinations that minimize misuse at potentially vulnerable transit locations during shipment. One component of the shipping process involves a precautionary measure of sending a pre-shipment letter to participating laboratories reminding them of the shipment, providing instructions in the event the package does not arrive, and verifying address information.

Additional tracking measures involve a project shipping log, quality assurance list (a list of participating laboratories for the specimen provider to track the shipping process), and ensuring that each program participant is sent a sample specimen panel using generated listings.

**Develop Facility-Specific Biosecurity Plans:** According to the BMBL 4th Edition, the procedure for developing a facility-level biosecurity plan must begin with a threat assessment followed by a facility-level risk assessment. Threats are defined at facility-level as the capability of an adversary to undertake malevolent actions while risk is a measure of the potential loss involved with the theft or diversion of the SA (Richmond & Nesby O’Dell, 2002). Since security resources are finite and must be distributed realistically to address the most high-consequence and high-probability events, biosecurity plans should be, (1) facility-specific depending on the SA under study, and (2) tiered according to agent-based protection system, ranking the security measures needed to protect an agent based on the nature and extent of risk.

Although existing regulation requires security assessment and surveys, additional measures are required to better integrate governance and program oversight at the facility level. The creation of both internal and third-party security evaluations are also necessary, such as a security program audit process, annual inspections, and security breach drills to evaluate program effectiveness. Third-party security evaluations would be better facilitated by the mandatory registration and licensing of laboratories that work with SA.

A CLIA facility biosecurity plan also requires physical protection measures to deter, detect and respond to unauthorized attempts to acquire pathogens (SNL, 2003). In general, laboratory biosecurity measures are based on physical protection, such as perimeter fences and armed guards—what security specialists often refer to as the “guns, gates, and guards” approach. Excessive perimeter controls are not a financially- and operationally-feasible option for CLIA Labs, rendering them vulnerable to unauthorized intrusion. However, a measure of physical protection could be implemented through reengineering of floor design to consolidate work spaces and graded protection areas designated by an agent-based risk assessment.

Perhaps the biggest threat to biosecurity lies with the integrity of laboratory personnel. Hence, the most fundamental laboratory biosecurity measure is the implementation of a screening process that would involve background checks for all personnel: full and part-time employees, short-term employees, contractors, even a screening process for one-time visitations by emergency and maintenance personnel and visitors. Additional personnel security measures consist of briefings and training on biosafety and biosecurity, interaction procedures for one-time visitations, establish procedures to escort visitors by screened and approved employees, and mechanisms to report suspicious activity.

CLIA Labs could proactively initiate biosecurity practices through a combination of floor space engineering and administrative mechanisms, and integrate biosecurity with existing biosafety practices for greater efficiencies and facility protection.

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Use of Ultraviolet Lights in Biological Safety Cabinets: A Contrarian View

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Abstract

In the U.S., the use of ultraviolet lights (UV) has been a source of friction between the research community, who desire them in their biosafety cabinets (BSCs), and the biosafety community, who have largely been agnostic or openly hostile to their use. This paper examines some of the claims on both sides of the issue, provides data regarding the actual irradiance inside and near BSCs at a large pharmaceutical research and development site, and makes recommendations that both protects users from the adverse effects of UV as well as supports its continued use as a useful adjunct to good laboratory hygiene.

Introduction

The use of ultraviolet (UV) lights in biological safety cabinets (BSCs) has enjoyed a long history, although it would be difficult to tell from the biosafety literature. The current version of the NSF International Standard 49 dismisses the use of UV in a BSC. The current standard, as have previous versions, states that the use of UV lights in cabinets, according to Section 5.25.2, is not recommended, although a purchaser could request it. The CDC and NIH, in their joint pamphlet “Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, 2nd Ed.” have taken a similar stand. Regarding the use of UV lights in a BSC, the pamphlet states:

“Ultraviolet (UV) lamps are not required in BSCs. If installed, UV lamps must be cleaned weekly to remove any dust and dirt that may block the germicidal effectiveness of the ultraviolet light. The lamps should be checked periodically with a meter to ensure that the appropriate intensity of UV light is being emitted. UV lamps must be turned off when the room is occupied to protect eyes and skin from UV exposure, which can burn the cornea and cause skin cancer.”

ABSA has, to date, made no official pronouncement. Curiously, researchers continue to request their cabinets be outfitted with the lights and the major manufacturers offer them as an option in nearly all cabinets. This suggests a disconnect in the risk/benefit analysis made by both researchers and biosafety professionals.

To start the analysis, one needs to understand the physical properties of UV light, the effects of UV light on biological organisms, including humans, and the current limits of exposure of humans to UV light. One also needs to know the limitations of UV as a disinfectant, as well as its ability to exert its effect outside the desired area, e.g., the ability to be transmitted through the BSC glass or be reflected off the work surface and pass through the opening in the cabinet. Only after a thorough analysis of these items may one compare UV light to chemical disinfectants and determine the relative value of UV light as part of a total strategy of good laboratory hygiene.

Properties of Ultraviolet Light

Physical Properties of Ultraviolet Light

Ultraviolet light is, by definition, light with shorter wavelengths than may be observed by the human eye. Physicists and photobiologists generally break the region into three distinct subgroups: UVA, consisting of light with a wavelength between 400 and 320 nm; UVB, consisting of wavelengths between 320 and 290 nm; and UVC, with wavelengths between 290 and 200 nm, although other groups have slightly different division points (www.merckmedicus.com/pp/us/hcp/thcp_dorlands_content.jsp?pg=/ppdocs/us/common/dorlands/dorland/dmd-u-002.htm#1135839, www.gelighting.com/na/home_lighting/ask_us/pop_glos sary.html#U). For disinfection purposes, the optimal wavelengths reside within the UVC range and low pressure mercury lamps provide a nearly monochromatic 254.6 nm output (for representative spectra, see www.gelighting.com/na/business_lighting/education_res ources/literature_library/product_brochures/specialty/d ownloads/germicidal/germicidal_tech_sheets.pdf). For the remainder of this paper, the term “UV” shall represent only wavelengths within the UVC band.
UV Effects on Biological Molecules and Microorganisms

DNA appears to be the critical target for killing by UV, although the debate concerning the “lethal lesion” has existed for decades. Two major adducts are formed by UV light, both of which are bimolecular adducts of pyrimidine bases. The most common adduct is the (cis-syn) (5-6) cyclobutane pyrimidine dimer, although a “minor” adduct, known as the (6-4) or PyC dimer, may actually be the lethal lesion in vegetative cells. It has, however, been known for more than three decades that either lesion is a block to DNA and RNA polymerases that inhibits both replication on either DNA strand and transcription on the antisense strand (for a review, see Friedman, Walker and Siede, 1995).

Ultraviolet light has been used in the research laboratory as an effective germicide and virucide. UV inactivation doses have been determined for a variety of organisms and UV is a fairly efficient disinfectant for most vegetative organisms and viruses. Even at the minimum acceptable irradiance in a biosafety cabinet of 40 μW/cm² (U.S. Department of Health and Human Services et al., 2000), it takes 12.5 minutes to reach 30,000 µl/cm² (1 W = 1 J/sec), which has been listed as germicidal for spore forming organisms by one UV manufacturer (www.uvp.com/pdf/ab-115.pdf). UV does not penetrate well. Although UV can disinfect an empty biosafety cabinet (BSC), it will only disinfect the outer surface of any material stored in a BSC.

UV Damage to Humans and Current Limits of Exposure to UV

The American Conference of Governmental Industrial Hygienists (ACGIH) has set a threshold limit value (TLV) of 6.0 ml/cm², which is based on the only observed acute effect: erythema to a “fair skinned” individual (ACGIH, 2005). Damage to the eye or skin is significantly affected by the UV wavelength utilized. Penetration into the dermis does not occur until wavelengths of greater than 300 nm have been reached; for wavelengths within the UV-C band, penetration of no more than approximately 50 μm into the epidermal layer occurs (Jagger, 1985; Suess, 1982). In contrast to the data known for UV-B and UV-A, the link between erythema and the most severe long-term stochastic effect, skin cancer, has not been quantitated and there is no current link between UV and the most severe form of skin cancer, melanoma (Gilchrest, Eller, Geller and Yaar, 1999; Alam and Ratner, 2001; Rubin, Chen, and Ratner, 2005). It must be noted, however, in their 11th Report on Carcinogens the National Toxicology Program (NTP), classifies UV-C as a probable (reasonably anticipated to be) human carcinogen. It should also be noted that a TLV is defined as “...conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, over a working lifetime, without adverse health effects.” suggesting that adherence to the TLV should preclude any adverse effects, stochastic or deterministic (ACGIH, 2005).

Although not included in any regulatory framework, in terms of human risk, the risk of keratoconjunctivitis (“corneal burn”) would be considered to be a risk to a worker and his or her ability to perform their daily routine, since UV-C band wavelengths are capable of only penetrating the cornea (Jagger, 1985). Although the data are fragmentary, the threshold for keratoconjunctivitis from UV in humans, according to one web site, is approximately 70 ml/cm² (www.med-physik.vu-wien.ac.at/uv/actionspectra/as_eye/eye.htm). The damage is usually noticed within six to 12 hours after exposure and recovery is essentially complete within seven days (Jagger, 1985).

It must be acknowledged that skin cancer, including the potential for melanoma, must be considered as part of the risk from exposure to UV. However, no reputable studies have been reported regarding the risk to humans from UV, as it is not currently possible to separate the effect of workplace exposure to 254 nm radiation from solar spectrum UV, which causes an estimated one million cases of skin cancer annually in the U.S. alone (CDC, 2006).

Current Objections

A series of objections have been raised to the use of UV bulbs in a BSC in a paper submitted to ABSA for consideration as an ABSA position paper (Burgener, personal communication). It has been argued that in addition to putting researchers at risk from ocular damage and cancer, which has been discussed previously in this paper, the light generates ozone that can damage materials in the cabinet, is ineffective at high humidity levels and must be cleaned on a weekly basis to prevent a drop in output. Each is briefly explored below:

The risk of ozone potentially generated from the use of UV-C bulbs has not been quantitated in a biosafety cabinet. Since the standard low-pressure mercury, quartz-enveloped bulbs emit 95% of their energy at 254 nm and less than 3% of the energy at an ozone-generating wavelength, 149 nm (www.gelighting.com/na/business_lighting/education_resources/literature_library/product_brochures/specialty/downloads/germicidal/germicidal_tech_sheets.pdf), the potential ozone hazard to materials within the cabinet is small, especially if the length of time the UV bulb is energized is minimized. Moreover, if the cabinet blower is active during UV disinfection of the work area, any potential ozone within the cabinet would be exhausted. Although the data are not shown, GE
claims that their bulbs do not generate ozone which, if correct, makes the entire discussion moot. The authors acknowledge that 254 nm radiation can directly interact with plastics and cause crazing and potential weakening, but these are direct events and can be eliminated by good biosafety cabinet practices, specifically, by minimizing the amount of material left in a cabinet.

Since the CDC/NIH measurement protocol (U.S. Department of Health and Human Services et al., 2000) allows one to measure the irradiance in the center of the cabinet at ambient relative humidity, temperature and air flow, this irradiance should be the major determinant in deciding whether the UV is capable of killing the agents introduced into the cabinet. It is recognized that bulb cleanliness and temperature affects UV bulb output, but the actual measurement in the cabinet accommodates these factors. Data that suggest killing is reduced at high relative humidity need to take into account two factors:

1. Most laboratories in this country are air conditioned and the relative humidity is unlikely to be significantly above 70% most of the year; and
2. I. L. Shechmeister, in his chapter on UV irradiation, states "There are also inconsistent results in the attempted correlation of susceptibility of airborne bacteria to UV at different relative humidities." (Shechmeister, 1991), suggesting that the data are not beyond dispute.

Therefore, humidity in most laboratories is not a significant issue and killing at high relative humidity may not actually be drastically curtailed.

Cleanliness has been raised as an issue, including the requirement in the NIH/CDC pamphlet that the bulb be cleaned weekly with ethanol to remove dust and dirt, although no citation is given demonstrating the need in a BSC (U.S. Department of Health and Human Services et al., 2000). Considering that the bulbs reside in, effectively, a Class 100 atmosphere, the source and amount of any such dust remains an open issue and one not further addressed in this paper. As a physical agent, it must be conceded that areas hidden from the light are not disinfected. Boxes of pipette tips left in a BSC will not have the tip disinfected through the case, will not have the area under them disinfected, nor will areas in shadows cast by the boxes be adequately disinfected. It must also be recognized that UV light will damage many materials which may be used within a biosafety cabinet, including many plastics and rubber-based materials, which could result in other hazards (e.g., leak in aspirator tubing or gas burner tubing). However, the NIH/CDC pamphlet on the selection and use of biosafety cabinets strongly discourages the storage of any materials within the cabinet and thus should not be a major concern in a lab which adheres to good laboratory practices.

Results

Three major cabinet manufacturers were contacted and asked what percentage of the 254 nm radiation escaped through the glass. None could provide documented data. Therefore, a calibrated UV photometer (UVP UVX radiometer, with a 254 nm probe [UVX-25]) was used to determine the irradiance through the glass. After measuring 45 cabinets from three major cabinet manufacturers onsite (NuAire, Baker, and Forma), the irradiance observed through the glass was found to be 0.9 +/- 0.8 μW/cm² (mean +/- 2 SD), with a range of 0.2 to 1.8 μW/cm². With the sash closed, it would take, on average, over 6667 seconds (111 minutes) for uncovered skin in contact with the BSC glass to reach the ACGIH TLV. Even at the worst performing cabinet, it would take 3333 seconds (55.6 minutes) of direct contact to reach the TLV.

However, the open area below the sash provides no glass to attenuate the radiation. During the survey, it was observed whether the cabinet was interlocked and the irradiance at the center of the open area, in the plane of the sash, was measured for the cabinets without interlocks. Thirty-five of the 45 were not interlocked and the mean flux at the center of the open area for these cabinets was 118.2 +/- 93.8 μW/cm². This allowed only an average of 50 seconds before reaching the TLV. With a 8-12 inch opening and 4 to 6 foot length, the irradiance could be expected to decrease in a roughly linear fashion with increasing distance at the same height as the opening, anticipating that the open area functioned as a plane source. However, data obtained from three different cabinets did not agree with that approximation (Figure 1). Within 15 cm of the opening, a significant irradiance was obtained (>90 μW/cm²). However, by 30 cm in two cabinets, and 45 cm in the other, the irradiance was approximately 4 μW/cm². At that distance, one could have bare skin exposed for 1500 seconds (25 minutes). At the top of the glass (142 and 136 cm), the maximum irradiance (3.1 and 4.1 μW/cm²), respectively) was observed 45.7 cm (18") from the plane of the sash. This would allow a person to stand 18" from the cabinet, facing the cabinet and not reach the TLV at the eyes for at least 1460 seconds (>24 minutes). Moving in either direction lowered the irradiance. Taller individuals would receive, as expected, lower doses to the eyes.

The use of PPE also plays a role in dose reduction. The publication of the data provided below are intended to demonstrate the degree of conservatism to one of the objections, and should not be construed as furnishing an excuse for an individual to intentionally expose themselves to UV radiation. Entry into any research laboratory at our facility requires the use of safety glasses. As shown in Table 1, placing commercially-available (UVEX) poly-
carbonate safety glasses in front of the UVX-25 probe while the probe was held in the center of the open face of a BSC reduced the irradiance by 97%, from 179 to 5.6 μW/cm². This reduction in irradiance would allow an individual to place their face in the opening and protect their face for over 1000 seconds (17.9 minutes). Although not recommended as a UV protection device, a single thickness of either nitrile or latex gloves wrapped around the UV-25 probe and placed in the center of a BSC reduced the irradiance to background (Table 1). Use of Tyvek® arm shields or coveralls, or lab coats, disposable or reusable, did not reduce the exposures to background. Moreover, a disposable lab coat allowed a significant leakage of UV through it, allowing only a 114 second exposure to an otherwise bare arm in the center of a BSC.

Discussion

The unpublished and unsubstantiated claim by some biosafety professionals that researchers do not need and do not use UV is undercut at our site by finding that during our survey, we only found 4 of 45 biosafety cabinets not equipped with UV lights (8.8%). The vast majority of our UV-equipped cabinets were using the light to assist with disinfecting their cabinets. Users of these BSCs also used chemical disinfectants, with isopropanol being the most common disinfectant in our tissue culture areas (data not shown).

The results are similar to results obtained by Noll (Noll, 1995), although, in this study, the time needed to reach the TLV was longer. Without knowing additional experimental details used by Noll, there can be no discussion of why there was relatively good agreement regarding the time to reach the TLV (0.83 minutes in this study vs. 0.47 to 0.73 in the Noll study) at hand level, and in the “room center” (34 to 83 minutes in this study at 91 cm from the cabinet vs. 32 to 84 minutes in the Noll study), with poorer agreement at eye level (24 to 32 minutes in this study at 45.7 cm from the cabinet vs. 13 to 24 minutes at an unknown distance in the Noll study).

There are also specific advantages to the use of 254 nm radiation as an adjunct to disinfection. They include:

1. Neither major lesion generated by UV allows polymers used in PCR to “read through” and amplify the damaged template. This makes it an ideal disinfectant to prevent cross contamination of PCR samples. Researchers performing PCR would be precluded from using biosafety cabinets to prepare samples if UV lights were banned.

2. Unlike most disinfectants, use of a physical disinfectant leaves no residue. The disinfecting action stops upon de-energizing the bulb.

3. Mutation to a fully-resistant phenotype is virtually impossible. Unlike chemical disinfectants, it is not possible to activate an efflux pump or degrade the active agent biochemically. Vegetative organisms do possess effective DNA repair processes, including photoreactivation, exci-
sion and recombination processes, but they are the wild type organisms and the doses required to inactivate many of them have been determined experimentally (www.uvp.com/pdf/ab-115.pdf).

4. Ultraviolet light is an effective germicide and virucide for organisms directly exposed to the UV light. As stated in the Background section, the UV inactivation doses have been determined for a variety of organisms. Compared to the data used to support listing by the EPA as a virucide, UV is more efficient for most vegetative organisms and viruses. Even using the NIH/CDC criterion of the minimum acceptable irradiance in a biosafety cabinet of 40 μW/cm², it takes 12.5 minutes to reach the 30,000 μJ/cm² found to inactivate spore forming organisms. Use of a UV light in excess of an hour or overnight is massive overkill. However, use of UV to disinfect the interior surface or contents of a container is likely to be futile, as UV has little penetrating power.

We do not, however, intend to discourage the use of chemical disinfectants even though they have several limitations of their own. It is not uncommon to find:

1. The incorrect disinfectant being used, such as isopropanol against adenovirus; and
2. Inadequate disinfection time for the agent, agent load, or organic material present.

It is extremely uncommon to find a biosafety cabinet wetted for 10 minutes, as is done in the Association of Official Analytical Chemists (AOAC) disinfection tests (5). Inadequate disinfection time or failure to wipe beneath pipette boxes or other materials left in a biosafety cabinet results in the same false sense of security as relying solely on UV as a disinfecting agent.

One may choose to argue that a ban on the use UV light should be viewed as part of an “ALARA” (As Low as Reasonably Achievable) program for non-ionizing radiation. If one accepts a linear, no-threshold approach to the stochastic effects (e.g., skin cancer), then this is not a difficult decision. However, this needs to be explicitly stated as a goal and balanced against the benefits of UV and the risks involved in using flammable (ethanol or isopropanol) or oxidizing chemicals (bleach).

Rather than simply eliminate the use of ultraviolet light, a more useful approach is to recognize the benefits and risks of the radiation. Since the only significant leakage of UV from a biosafety cabinet is from the front opening, taking steps to eliminate that leakage is the key to eliminating exposure. Requesting the manufacturer to interlock the light with the sash is a simple technical fix to the problem. ABSA could also request that such an interlock be included in the revision to NSF 49. For those cabinets with fixed sashes, an opaque covering could be provided that allowed air flow while minimizing UV exposure. Some cabinetmakers do manufacture retrofit kits to interlock the sash and UV bulb. An additional precaution would be the addition of a timer to the UV light, a feature recently added by at least one of the major manufacturers to their “digital” model. This would allow adequate time for disinfection without the potential for a person in the same room to reach the TLV for 254 nm radiation under any circumstances.

Even the most ardent supporters of the use of UV must also be willing to concede that UV lights in BSCs with open sashes are potential hazards and staff members must be informed of those risks and advised not to loiter.

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### Table 1

<table>
<thead>
<tr>
<th>Type of glove</th>
<th>μW/cm²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latex</td>
<td>background</td>
</tr>
<tr>
<td>Nitrile (blue)</td>
<td>background</td>
</tr>
<tr>
<td>Nitrile (green)</td>
<td>background</td>
</tr>
<tr>
<td>Nitrile (teal)</td>
<td>background</td>
</tr>
<tr>
<td>Nitrile (purple)</td>
<td>background</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other PPE</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Tyvek® arm shield</td>
<td>background</td>
</tr>
<tr>
<td>Tyvek® coverall</td>
<td>1.1</td>
</tr>
<tr>
<td>Disposable lab coat</td>
<td>52.5</td>
</tr>
<tr>
<td>Lab coat</td>
<td>2</td>
</tr>
<tr>
<td>Unshielded fluence rate</td>
<td>282 μW/cm²</td>
</tr>
<tr>
<td>Polycarbonate safety glasses</td>
<td>5.6</td>
</tr>
<tr>
<td>Unshielded fluence rate</td>
<td>179.3 μW/cm²</td>
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</table>
near the cabinets. Nearly all biosafety professionals can recall episodes during which a researcher has shown ignorance or complete indifference to the immediate and long-term risk from UV exposure, or the limitations of UV radiation. Attempting to culture cells while UV lights are on, attempting to sterilize the inside of a container by irradiating the exterior of the container with UV, or leaving the UV on all night are only a few examples of abuse of UV. However, an absolute prohibition of their operation in the presence of staff, is, however, equally not supported by the data. The prohibition for the operation of UV lights in cabinets with interlocks and no open areas while staff is present can also no longer be supported by experimental data and should be eliminated. Limited use of UV in BSCs with required safety features such as interlocks and timers is a reasonable compromise.

Acknowledgements

The authors wish to thank Mr. Brian Petuch, RBP and Mr. Joseph Gyuris, RBP for their assistance and expert advice during the review of this manuscript. The expert reviewers are thanked for their constructive criticisms.

References

American Conference of Governmental Industrial Hygienists (ACGIH). (2005). TLVs and BEIs based on the documentation of the threshold limit values for chemical substances and physical agents and biological exposure indices. Cincinnati: Author.


Position Paper on the Use of Ultraviolet Lights in Biological Safety Cabinets

Jyl Burgener
Eli Lilly and Company, Indianapolis, Indiana

Purpose

The purpose of this paper is to review information available on the use, risks and benefits of using Ultraviolet (UV) lights in Biological Safety Cabinets (BSC) and set forth a position based on the risk and benefits.

Background

Ultraviolet (UV) radiation is a form of nonionizing radiation and behaves in accordance with the laws and principles of geometric optics. Electromagnetic radiation can be described as a “wave” that consists of an electric field and a magnetic field. Electromagnetic radiation is usually characterized by wavelength and frequency or photon energy. The term wavelength refers to a distance in a line of advance of a wave from any point to a like point on the next wave; it corresponds to the distance traveled by the wave during one cycle. A wavelength is usually measured in angstroms or nanometers (nm).

The International Commission on Illumination (CIE) has divided the UV spectrum into three wavelength bands, primarily due to biological effects. The 315-400 nm wavelength band is designated as UV-A, 280-315 nm is designated as UV-B, and 100-280 nm as UV-C. Wavelengths below 320 nm are actinic, meaning they are capable of causing chemical reactions. The mechanism of the germicidal effect involves these chemical reactions and so effectiveness varies by composition of the target organism in addition to physical variables.

Effects of Overexposure to Humans

Biological effects from UV radiation vary with wavelength, photon energy, and duration of exposure. In general, adverse effects are limited to the skin and eyes. Erythema (e.g., reddening of the skin in sunburn) is the most commonly observed effect on the skin. Erythema is a phototoxic chemical response to the skin normally resulting from overexposure to wavelengths in the UV-C and UV-B bands. Exposure to UVA alone can produce erythema, but only at very high radiant exposures. Chronic exposure to UV radiation may accelerate the skin aging process and increase the risk of developing skin cancer. The National Toxicology Program’s (NTP’s) Report on Carcinogens classifies broad-spectrum UVR as a known human carcinogen and UVA, UVB, and UVC individually as probable (reasonably anticipated to be) human carcinogens. (http://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s183uvrr.pdf).

Elevated exposure of UV-B and UV-C radiation may adversely affect the eye and cause photokeratitis and/or conjunctivitis. A sensation of “sand in the eyes” and reddening of facial skin usually occurs within 6-12 hours of the exposure, with the symptoms and discomfort lasting up to 48 hours. UV radiation exposure rarely results in permanent ocular injury, although cataracts have been produced in animals by exposure to UV radiation in the UV-B and UV-A bands.

UV radiation exposure to eyes and skin is typically quantified in terms of an irradiance E (Watts/meter²) for continuous exposure, or in terms of a radiation exposure H (Joules/meter²) for time-limited exposure.

Regulations and Guidelines

The Occupational Safety and Health Administration (OSHA) do not have a permissible exposure limit for UV radiation. Guidelines on UV radiation exposure have been established by the International Radiation Protection Association (IRPA) and adopted by the American Conference of Governmental Industrial Hygienists (ACGIH). The ACGIH does have a threshold limit value (TLV) table for UV radiation and relative spectral effectiveness, which is published in the Threshold Limit Values (TLV) booklet annually. Refer to the most current “Threshold Limit Values for Chemical Substances and Physical Agents” published by ACGIH for values.

Using the current guidelines, it is expected that repeated exposure at or below the current guideline would not cause adverse health effects. However, it should be
emphasized that UV radiation is implicated in both skin cancer and cataracts in humans. These values apply to all UV radiation sources except UV lasers. These values do not apply to UV radiation exposure of photosensitive individuals or individuals concomitantly exposed to photosensitizing agents. It should be emphasized that many individuals who are exposed to photosensitizing agents (ingested e.g., aspirin or topically applied chemicals) probably will not be aware of their heightened sensitivity.

Boettich performed a study evaluating UV light exposure from six biological safety cabinets. He evaluated permissible exposure times using a research radiometer photometer equipped with a UV actinic band sensor. Permissible exposure times were established within:

1. Thirty-two minutes to 1.4 hours at general eye level in the center of the room;
2. Thirteen to 24 minutes for eye level exposures while seated at the cabinet; and
3. Twenty-eight to 44 seconds for hand level exposures at the cabinet face.

Boettich also evaluated potential exposures around biological safety cabinets with 253.7 nm UV bulbs. Overexposures at the face of the cabinets (outside sash) could occur within 1.3-6.7 minutes.

**Performance Standards for UV Light in Biological Safety Cabinets**

The National Sanitation Foundation (NSF) Standard 49, the U.S. industry testing standard for all biohazard cabinetry, does not provide performance criteria for UV lighting and specifically states in section 5.25.2 “UV lighting is not recommended in class II (laminar flow) biohazard cabinetry.”

As it is possible to produce ozone levels from UV wavelengths below 250 nm sufficient to affect rubber or other polymer made materials, low or no ozone UV light bulbs are commercially available.

**Recommendations**

Due to the short time for UV overexposure to occur, it is recommended that neither laboratory nor maintenance personnel work in a room where UV lights are on. The CDC, NIH, and NSF agree that UV lamps are neither recommended nor required in Biological Safety Cabinets (BSC). There are no criteria available from NSF to evaluate the performance of the UV lights within a biological safety cabinet. Numerous factors affect the activity of the germicidal effect of UV light, which require regular cleaning, maintenance, and monitoring to ensure germicidal activity.

Retrofitting any equipment (e.g., UV lights) into a biological safety cabinet may alter the air flow characteristics of the cabinet and invalidate the manufacturer warranty and is not recommended.

This author agrees with the NSF that UV lights are not recommended for use in Biological Safety Cabinetry. Furthermore, expenses required to test and establish consistent UV germicidal performance for the agents in question may prove prohibitive to resolving this issue given that less expensive high-level disinfectants are in common use with good results. In the opinion of this author, the risks of using UV lights outweigh the benefits and effective alternative methods of disinfection are available and in common use.
References

American Conference of Governmental Industrial Hygienists. (2000). Threshold Limit Values for Chemical Substances and Physical Agents and Biologic Exposure Indices (TLVs and BEIs) ACGIH Worldwide, Cincinnati, OH.


ABSA ITEMS FOR SALE

- Polo Shirt $35.00  ○ S  ○ M  ○ L  ○ XL  ○ XXL
- Fleece Pullover (Men’s) $45.00  ○ M  ○ L  ○ XL  ○ XXL
- Fleece Pullover (Women’s) $45.00  ○ S  ○ M  ○ L  ○ XL
- Watch $30.00  ○ Men’s  ○ Women’s
- Pin $5.00

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Phone_________________________________________________________

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Signature________________________________________________________________ OR  ○ Check enclosed

Mail or fax this order form to: American Biological Safety Association (ABSA), 1200 Allanson Road, Mundelein, Illinois 60060-3808, phone 847-949-1517, fax 847-566-4580. Please allow 2-3 weeks for delivery. If using a credit card, please mail or fax the form as we will need a signature on file—the shipping and handling charge will be added to your order. If mailing a check, please call for the shipping and handling charge. We do not accept purchase orders.
Capsule

Ed Krisiunas

WNWN International, Burlington, Connecticut

What’s new? What’s hot? What’s timely? If you don’t have time to search the Internet for the latest developments that might impact your work environment, you just might find some of this information in the “Capsule” column. Please e-mail any comments or suggestions to ekrisiunas@aol.com or to Co-Editor Barbara Johnson at barbara_johnson@verizon.net or Co-Editor Karen B. Byers at karen_byers@dfci.harvard.edu.

Revised Recommendations for HIV Testing

The CDC has revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. This “Reports and Recommendations” was issued September 22, 2006.

The major revisions from previously published guidelines are as follows.

For patients in all healthcare settings:
• HIV screening is recommended for patients in all healthcare settings after the patient is notified that testing will be performed, unless the patient declines (opt-out screening);
• Persons at high risk for HIV infection should be screened for HIV at least annually;
• Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing; and
• Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in healthcare settings.

Additional information can be found at: www.cdc.gov/hiv/topics/testing/resources/reports/pdf/rr5514.pdf

Review of Aerosol Transmission of Influenza A Virus—Emerging Infectious Diseases—November 2006

There continues to be a growing concern regarding an influenza pandemic. This publication discusses the personal protective recommendation of various public health authorities that may contradict the existing body of knowledge. Surgical masks or N95 respirators? Review this publication to better understand the author’s perspective. Tellier, R. Review of aerosol transmission of influenza A virus in Emerging Infectious Disease—November 2006. Available from www.cdc.gov/ncidod/EID/vol12no11/06-0426.htm

Training and Education

The CDC’s Emergency Preparedness and Response web site provides a link for some interesting web-based training and education. Recent topics include:
• Training: “Radiological Terrorism: Medical Response to Mass Casualties”;
• Video Webcast: Learning from Katrina;
• Video Webcast: Preparing for Radiological Population Monitoring & Decontamination; and
• Video Webcast: “Mass Antibiotic Dispensing: Using Public Information to Enhance POD Flow.”

The Emergency Preparedness and Response web site is: www.bt.cdc.gov/
The training link is: www.bt.cdc.gov/training/

Biosafety via the ABSA Web Site

The ABSA web site is an excellent resource for links to various organizations and information relative to biosafety. Links to the following sites are available on the ABSA web site:
• www.absa.org/resinternet.html
• Belgian Biosafety Server (European Biosafety Topics)
• Office of Biosafety, LCDC (Canada)
• OHASIS, Office of Health and Safety Information Systems (CDC)
• Select Agent Web Site
• International Veterinary Biosafety Workgroup
• European Biosafety Association
Do you have a biosafety question and you’re not sure who to ask? Send your questions to the “Ask the Experts” column and I’ll get them answered for you. Drawing from my own experience or that of other experts in the field, we’ll try to compile a thorough and comprehensive answer to your question. Please e-mail your questions to jkeene@biohaztec.com or to Co-Editor Barbara Johnson at barbara_johnson@verizon.net or Co-Editor Karen B. Byers at karen_byers@dfci.harvard.edu.

The Musings of a Biosafety Professional on Containment Facilities

I have been pondering all of the perceived problems, questions and concerns that continually are voiced regarding biocontainment laboratories. Many of these have been addressed in this column, but they continue to surface. Others are pretty much common sense, but, for some reason, we tend to want confirmation of our common sense from our peers. In this column, the first of two on this subject, I’d like to simply comment on those questions that appear to arise most often and hopefully to encourage those of you who read this to try to educate your peers.

Zero Risk

The public and, most likely your administrative personnel, would like us to engineer biocontainment laboratories so that there is “Zero Risk,” i.e., no possibility of potential environmental release of the agents contained in the laboratory. No level of engineering or safety procedures alone will ever absolutely insure that release from any biocontainment lab will be prevented. We are at the mercy of mechanical devices that fail and personnel that, even though they are well intentioned, don’t always follow procedure, or who, for whatever reason, have an accident and cause a release. What we are attempting to do is to MINIMIZE risk. This is why it is so important to ensure appropriate design, construction, operations oversight, training, preventive maintenance, and periodic review of the facility.

Understanding Your Facility

No two containment facilities are alike. They may be designed by the same architect and built by the same construction contractor, but each has its own unique properties. HVAC systems differ in design, containment equipment is different, and construction details are not the same. Biosafety professionals must understand the nuances of the particular design of the facility and provide personnel with an understanding of the “inner workings” of the facility. You cannot rely on what your colleague in another facility tells you about how to operate your facility unless you know what the differences are. You must develop a facility-specific plan for training, operation, and maintenance.

Reliance on Your Architects and Engineers

Because many of us are not architects or engineers, we try to obtain the services of people who have done this before. A word of warning, “just because I’ve done it before, doesn’t mean it was done right.” We, as biosafety professionals, have a wealth of information that architects and engineers don’t have and we need to carefully review their prepared documents and communicate our concerns about any problems we observe. I have found over the years that a good engineer can provide me with great solutions to problems, if I can communicate to him/her exactly what the problems are. Unfortunately, left to their own devices, they will come up with a solution, but it may not be either appropriate or practical for the requirements of laboratory research and containment. Reliance on expertise is fine, but the Biosafety Professional must be involved in the development of plans. I have seen too many containment laboratories with excellent engineering and design fail because that engineering and design was not appropriate for the project. Don’t be intimidated by the credentials of the people you hire. You are the client. They are the suppliers of services and they should be listening to your comments and developing a facility which will meet your needs.
Reliance on Your Colleagues

We all are in this game together and we have to assist one another when problems arise. However, what works for your colleague may not be appropriate for you. Again, I emphasize that each biocontainment facility is unique and we must not rely on what someone else is doing unless we have performed the appropriate risk assessments and are satisfied that the advice we received actually applies to our facility as well as to the facility of the person giving the advice. Your colleagues may have the best intentions, but they may have made an incorrect decision. I would hate to go to court with the statement, “I did it this way because my colleague did it this way” as my only defense. Every decision must be based on the risk assessment of how that decision will affect your facility.

Clean Room Equipment

It seems that the Clean Room construction boom is over and Clean Room builders are using their expertise to build containment laboratories. While on the surface, this may seem to be an appropriate thing to do, it is wrought with problems. The most important thing to consider is that the ventilation of clean rooms results in a room under positive pressure. This means that all clean room devices, panels, ceilings, light fixtures, pressure monitors, etc. are built to function best when the room is under positive pressure. Containment laboratories operate under negative pressure, which means that a containment lab fitted out with clean room devices is continually pulling against the seal of the device. In general, the only clean room device that is really appropriate for containment spaces is the pressure monitors that have a diaphragm in their operating system to minimize the potential for contamination to either come in to the clean room, or get out of the containment laboratory. This diaphragm is also particularly useful when a containment laboratory must be gas decontaminated.

If you hire clean-room professionals to design and build your containment facility, then you will have to ensure they understand the requirements for containment and you must ensure the devices installed will continue to operate for safe maintenance of the containment.

Pressurization of Containment Laboratories

Can a containment laboratory ever be allowed to go positive to the outside environment? Theoretically, the answer to that question is NO. Is this practical? NO. It is obvious that when we are dealing with mechanical devices and human error, there is always a possibility that there will be failure. Our job as Biosafety Professionals is to minimize the potential for that failure. The BMBL does not require absolutes and, in the case of BSL-3 containment laboratory pressurization, it requires that “no sustained pressurization” of the laboratory exists. It does not even define “sustained.” We could imagine all kinds of scenarios that would allow for release of agents, should a spill occur outside of a Biosafety Cabinet at the moment that the laboratory went positive to the outside world. Having agreed to that possibility, it is up to the individual facility operator to do the risk assessment and determine how far they want to push the envelope with regard to pressurization. This risk assessment should be based on the effectiveness of the operation of the HVAC system and the perceived or actual hazard associated with release of the agent being used within the laboratory. In addition, appropriate testing of the systems and determination of the potential deficiencies, as well as an aggressive preventive maintenance program, warning systems and training of personnel, will minimize the potential for pressure shift and accidental release. The integrity of the containment must be maintained to the highest level possible.

To be continued...

Join a Committee

Have you ever considered joining a committee? When you choose to serve on a volunteer committee, you open up a world of possibilities for networking, professional growth, and career opportunities while serving your profession. Volunteer member groups are the backbone of the association because they: serve as a forum for exchange of information; advance the science in all specialties of biosafety; develop guidelines and standards; provide education and training; and link ABSA to many other institutions.

You should explore committees in areas of the profession where you are active or have an interest. There is a great variety; you can be sure to find one of interest to you. Please review the list of committees and identify those areas in which you would like to participate or contact the chair of the committee (www.absa.org/abocommittees.html) that interests you to find out more information about the committee’s goals. You are also invited to attend the committee’s meeting during our annual conference or at any other time (all committee meetings are open).
ABSA News

Tony Della-Porta knows there is no such thing as a perfect biocontainment facility. He also knows the importance of improving standards, increasing safety, and enhancing staff training at BSL-3 and BSL-4 laboratories throughout the world. The bird flu virus and the SARS virus, both potentially fatal infectious agents handled by high-containment microbiology labs, present a compelling case about the need for more stringent standards.

“We have looked at facilities in numerous countries, including the United States, Australia, New Zealand, Russia and China,” says Della-Porta, managing director of Biosecurity & Biocontainment International Consultants Pty Ltd (Bio2ic) in Geelong, Australia. “The only common thread between the countries is that every facility has issues to address.”

Della-Porta led the World Health Organization (WHO)/Centers for Disease Control (CDC) team that investigated the SARS laboratory infection in Singapore three years ago, and he advised the WHO regarding the 2004 SARS case in Taiwan.

During the investigation of the Singapore SARS incident, numerous lab deficiencies were deemed to be contributing factors to the infection. The problems included laboratory contamination, insufficient record keeping procedures, a lack of security, inadequate staff training, and a host of structural shortcomings such as improper equipment to monitor air pressure differentials. These are precisely the type of problems that Della-Porta believes must be corrected in order to avoid future infections and the release of agents into the community.

Citing the Issues

The lack of a uniform standard for the design, construction, and operation of biocontainment facilities is noticeable throughout the world. In order to properly design and operate a facility, it is critical to understand the type of viruses that will be handled, the specific characteristics of each virus, and the routes of infection that may occur.

Della-Porta believes all countries should create guidelines for certifying labs and monitoring the structural integrity and operating procedures within BSL-3 and BSL-4 labs. The varying designs and biocontainment standards make it very difficult to monitor issues.

Concerns regarding the following issues are noted at numerous facilities around the world:

- Penetrations and finishes
- Adoption of cleanroom principles instead of containment principles
- Lack of definition of containment requirements, such as air pressure, air flow, and changes in air rates
- Safety signage
- Dangerous situations with inert gasses and chemicals
- HEPA filter housings
- Construction materials
- Training and documentation
- Security
- Emergency exits
- Hand wash sinks and gowns

“There should be an openness in discussing safety concerns, reporting incidents, and viewing safety as a culture rather than an imposed obligation,” says Della-Porta.

Confronting the Issues

Penetrations and Finishes

“It does not matter how well a facility is designed if the penetrations are not done properly,” explains Della-Porta. “All services need to be brought in through airtight, sealed penetrations.”

Power, communication, and gas services can be surface-mounted in moduline ducts. Ordinary power points and electrical fittings should not be mounted in walls because they will leak. Instead, special airtight plugs are necessary, unless a moduline fitting is used. Rubber gaskets for doors and pass boxes must be mounted correctly and be airtight when the door is sealed.

“One of the facilities we looked at in China appeared to be perfect on the outside. However, we discovered gaps in the pass box rubber seals where you could feel the air coming through,” says Della-Porta. “What we saw at a facility in Taiwan demonstrates why special care must be taken when retrofitting. We saw electrical fittings where holes were drilled to make penetrations when a retrofit was done and this is totally unsuitable.”
The 2003 SARS laboratory infection in Taiwan stemmed from a lack of management controls on the operation of the laboratory and training of staff. In this case, a principal investigator in a BSL-4 lab used 70 percent ethanol to decontaminate a spill in an isolator chamber. He opened the Class III biological safety cabinet without wearing a respirator and contracted the SARS virus.

**Lack of Definition of Containment Requirements**

Problems occur when an approach based on cleanroom design is applied to biocontainment. Cleanroom design has a very small pressure differential and mounting the HEPA filters in the walls as terminal filters makes it difficult to decontaminate and test them.

Pressure differentials are extremely important for maintaining containment of infectious diseases. Air pressure reversals were noted in high-security facilities where air was flowing in the wrong direction. There are also concerns about insufficient changes of air, especially since one particular facility had three changes per hour. The inability to control pressure differentials has caused walls to crack and ceilings to collapse. Pressure differentials must be adequate enough to ensure that a reversal of pressures cannot occur and that a sufficient differential is maintained even when the air lock is opened.

“We have also seen instances where the building monitoring systems are unable to respond quickly enough when a supply or exhaust fan fails,” says Della-Porta. “There must be a way to actually stop the fans instantaneously rather than waiting for the process to go through a computer system. Biocontainment facilities should also use building materials that can withstand at least double negative air pressure.”

The areas of highest risk, such as animal laboratories, should be at the lowest possible pressure to prevent pathogens from escaping into surrounding areas of lower risk. Della-Porta is currently providing consulting services to a BSL-3 lab in Thailand that is handling the avian flu. Pressure in the animal laboratory is at -120 pascals, while the pressure in the labs is at -90 pascals, the decontamination chamber is at -75, the showers are at -30, and the surrounding service corridor is at 0 pascals. Della-Porta explains that 100 pascals is equal to 0.4 inches of water.

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**Safety Signage**

“I was appalled that even in the most advanced laboratories in the world safety signage was either absent or incorrect,” says Della-Porta. “A lot of these labs have hazardous chemicals and inert gasses, yet the proper safety signage is missing.”

There are two types of general signs, including the red, black, and white ones which display the word “Danger” to alert individuals about potentially fatal situations, and specialized signs to warn of microbiological hazards. The specialized signs feature the biohazard symbol inside a triangle and are typically yellow throughout the world, except in the United States where they are orange.

Blue signs signal the need to wear certain personal protective equipment, such as safety glasses, a gown, solid shoes, or hearing protection. Red signs indicate the presence of flammable materials and the location of fire extinguishers. A white circle outlined in red with a diagonal red line denotes that items, such as food or sharp tools, are not permitted in certain areas. Emergency exits, eye wash stations and first aid availability should be visible with the proper signage. Informative signs should also be displayed to provide an emergency telephone number and the name of the laboratory manager.

**Inert Gasses and Chemicals**

Oxygen levels need to be maintained above 19.5 percent in order to provide a safe environment. Inert gasses, such as liquid nitrogen, should only be used in well ventilated areas, which can be difficult to achieve in high-containment facilities.

“Some people only think about liquid nitrogen as a substance that is freezing in properties, but if the oxygen in a room has been replaced with nitrogen, that creates a deadly situation,” says Della-Porta.

One major lab examined by Della-Porta contained a large supply of liquid nitrogen and the two oxygen meters were reading 0.2 percent and zero percent. The meters were inside the lab, instead of on the outside where they could serve as a warning of low oxygen levels. If the meters had been accurate, members of the inspection team would have been overcome by deadly gasses. The meters had actually failed and were never repaired. Oxygen levels must be continually monitored and audible and visible alarms must activate when there is an insufficient supply.

**HEPA Filter Housing**

Most standards require HEPA filtration of exhaust air from a BSL-3 lab. In the United States, however, this requirement only applies to ABSL-3 and BSL-4; BSL-3 is subject to risk assessment.

“Following a risk assessment, non-aerosol transmitted diseases can be used in U.S. labs that don’t have HEPA filtration, but that is not permitted anywhere else in the world,” says Della-Porta. “I encourage people to build laboratories to the highest level of standard rather than the lowest because if you want to work with avian flu, the facility will not meet the new containment requirements.”

Problems are also common with HEPA filter canisters, which are difficult to decontaminate, and it is difficult to scan test the filters. The location of the canisters is important, as well. They should not be located at floor level and they should not be close to an animal area where they can become contaminated.

HEPA filter canisters must be designed for biological...
work and not the radiochemical industry. They should include ports that can be opened along with a pre-filter. There is an ability to have damper valves for fumigation and ports for injection of substances used for scanning the filters and the ability to scan the surface of the filter rather than doing a complete test. Pinpoint holes in filters are not detected by doing a total test because of the dilution factor. Filters should be scanned after they are put into place to ensure there is no damage.

Construction Materials
Sandwich panel walls and ceilings are airtight and can resist pressures up to 400 pascals. They can contain fire-retardant polystyrene or rock wall fillings and the surfaces can be steel, aluminium, enamel, or other suitable coating. They can be pre-coated to suit a facility’s needs. The system for installing and sealing is similar to construction used for cold rooms, and it is easy to retrofit the panels in any building. Glass panels and windows can be mounted in the structure.

“I encourage having as much natural light as possible because it has a positive impact on staff,” says Della-Porta.

Documentation and Training
“This seems to be a forgotten thing. Training the staff that will work in facilities and the engineering team that will maintain them is not usually taken into consideration until after facilities are completed,” notes Della-Porta. “The problem is, especially with the engineering staff, that they will have trouble learning how to operate a facility if they have not been part of the entire development process.”

The lack of staff training is cited by Della-Porta as a leading cause of safety-related accidents within labs. Therefore, every lab should create the appropriate, competency-based training standards.

Laboratories must also have suitable record keeping to document specifics about who is working in the facility, the type of research taking place, and the kind of agents being handled.

Security
“With the number of facilities coming online, there is a major safety and security risk that we are about to face,” warns Della-Porta.

The lack of proper security is a safety issue in many BSL-3 and BSL-4 labs, prompting the need for a thorough evaluation of security concerns. Biometric devices, such as finger, iris, or palm scanners, should be used for entry into high-risk labs, as well as using access cards. Access to these labs should be properly documented and monitored. In addition, inventory records should be computerized and regularly monitored, long work hours in the labs should be discouraged, and an emergency response plan should be developed to address laboratory incidents.

Emergency Exits
Depending on the size of a facility, fire regulations may require alternate emergency exits. Break glass panels may provide such an exit as they are cheaper than airtight doors and they work well. The panels are easy to seal, can be replaced quickly, and break into small pieces (safety glass). The staff can safely exit, and is protected by a fire door.

Hand Wash Sinks and Gowns
Hand wash sinks are often placed in the wrong position by being located in the airlock just outside the door going into the lab, rather than being inside the lab. Staff members have to touch the door handle and, therefore, everyone who enters the lab is contaminated. The sink should be located just before the door going out as staff leaves the lab. Light-activated, hands-free sinks are reliable and prevent contamination.

Laboratory coats also present concerns because of the problems of contamination of staff, if there is a biological spill. Back-fastening, solid fronted gowns are strongly recommended because they can readily be removed when contaminated and are not a status symbol to be worn outside the laboratories.

“All of these are issues that need to be addressed and if we don’t address them, we are going to have significant problems in the future,” says Della-Porta.

Biography
Tony Della-Porta, managing director of Biosecurity & Biocontainment International Consultants in Geelong, Australia, is an internationally renowned expert in biosecurity, biocontainment, and biological safety. He led the World Health Organization/Centers for Disease Control team that investigated the SARS laboratory infection in Singapore in 2003, and assisted the WHO with its investigation of the SARS infection case in Taiwan in 2004. Della-Porta has served as a consultant to the health departments in New Zealand and Australia regarding biosecurity needs and laboratory capacity to respond to disease emergencies. He is providing advice to Hong Kong University about the construction and operation of a biocontainment facility to handle high-virulence influenza. He served as a member of the WHO Smallpox Team that recently inspected the CDC in Atlanta and VECTOR in Novosibirsk. Prior to becoming managing director of the consulting firm, he worked at the Australian Animal Health Laboratory from 1972 until 2003.

This report is based on a presentation given by Tony Della-Porta at Tradeline’s International Conference on Biocontainment Facilities in March 2006.

For more information, please contact: Tony Della-Porta, Managing Director, Biosecurity & Biocontainment International Consultants, P.O. Box 531, Geelong,
BSL-3
PRESSURE ZONE
-120 Pa
-90 Pa
-75 Pa
-60 Pa
-30 Pa
0 Pa

Figure 1
Pressure differentials should ensure that a reversal of pressures cannot occur. The areas of highest risk, such as animal laboratories, should be at the lowest possible pressure to prevent pathogens from escaping into surrounding areas of lower risk. Pressure in the animal laboratory is at -120 pascals. One hundred pascals is equal to 0.4 inches of water. (Image courtesy of Tony Della-Porta.)

Figure 2
HEPA filters in biocontainment facilities are often incorrectly mounted beneath biological safety cabinets. In this instance, air cannot reach the filter in a proper manner. (Photo courtesy of Tony Della-Porta.)

Figure 3
The SARS laboratory infection in Taiwan occurred because the person did not use a vaporized hydrogen peroxide generator like this one to clean up a spill. Instead, he used 70 percent alcohol and put his head in a BSL-3 biological safety cabinet without using a respirator. This room is not airtight because ordinary power points are mounted on the wall. (Photo courtesy of Tony Della-Porta.)
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Principles & Practices of Biosafety
Embassy Suites Hotel, Portland, Oregon
Contact: Phone: 847-949-1517, Fax: 847-566-4580, E-mail: absa@absa.org, Web Site: www.absa.org

March 12-13, 2007
San Diego, California
Contact: www.tradelineinc.com/conferences/

April 10-11, 2007
Animal Lab News “The 2007 TurnKey Conference”
Boston, Massachusetts
Contact: www.animallab.com/turnkey

May 14-18, 2007
“Guidelines for Laboratory Design: Health and Safety Considerations” Conference
Harvard School of Public Health, Boston, Massachusetts
Contact: Phone: 617-384-8692, Fax: 617-384-8690, E-mail: contedu@hsph.harvard.edu,
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October 7-10, 2007
American Biological Safety Association (ABSA) 50th Annual Conference
Opryland Hotel, Nashville, Tennessee
Contact: Phone: 847-949-1517, Fax: 847-566-4580, E-mail: absa@absa.org, Web Site: www.absa.org

October 19-22, 2008
American Biological Safety Association (ABSA) 51st Annual Conference
John Ascuaga’s Nugget, Reno, Nevada
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October 18-21, 2009
American Biological Safety Association (ABSA) 52nd Annual Conference
Hyatt Regency Miami, Miami, Florida
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Japanese Biological Safety Association (JBSA) affiliate status is in process. Contact: ksugi@nih.go.jp
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Viewpoints—Short articles focusing on personal experiences may be submitted to this section. Articles vary in length.

Book and Video Reviews—Reviews of books and media (videos/CD/other) of interest to biological safety or biosecurity may be submitted at any time. Reviews typically do not exceed 1-2 pages in length. Books or media which authors wish to have considered for review may be sent directly to the ABSA Office.

Commentary/Editorial—Brief comments on submissions published in Applied Biosafety, issues critical to the profession and practice of biological safety, or letters to the Editor may be submitted to this section. Individuals may be invited by the Editors to submit a guest editorial article.

Presentations—Articles that recount or summarize information relevant to the field of biological or biosecurity that has been presented at a conference. Presentation articles vary in length.

Other Requirements

1. Send an electronic submission or one (1) typeset copy with a disk of each submission to: Editor, Applied Biosafety: Journal of the American Biological Safety Association, c/o ABSA, 1200 Allanson Road, Mundelein, IL 60060-3808, USA. Submissions that are under consideration by another periodical or publisher or submissions that have been previously published must be identified as such, and previous citing must be disclosed.

2. Submission guidance:
   - Format for 8-1/2” x 11” paper using 1” margins, double-spacing, and full-justification.
   - References, footnotes, table captions, and quotations should be single-spaced, a guide to references can be found at www.absa.org.
   - Use Times New Roman, Arial, AvantGarde, Helvetica, or Universal font in 12 point.
   - Use high resolution laser printing if submission is made in hard copy media.
   - Primary headings should be flush left, bolded, and have the first letter of all main words capitalized throughout the submission.
   - Secondary headings should be flush left, italicized, and have the first letter of all main words capitalized.


4. The Attention Authors Form may serve as a cover sheet with the full name(s) and degree(s) of the author(s), professional affiliations, and the return mailing address of the author to whom correspondence can be sent. Authors’ names, positions, titles, and places of employment should not appear in the body of the paper to facilitate the blind review process.

5. Tables, charts, photographs (at least 3-1/2” x 5”) or diagrams must be computer-generated or professional quality and submitted as camera ready artwork. Tables, charts, or diagrams should be submitted on a separate page, referenced back to the text in a vertical (portrait) format including any legend, label, or number associated with them. Refer to each as Table 1, Table 2, etc., centered above the table. Captions should be single-spaced.

6. It is the author’s responsibility to secure written permission from the original copyright holder to use quotations of over 300 words from one source or use adaptation of tables or figures from copyrighted sources. A copy of the copyright holder’s written permission must be provided to the Editor immediately upon acceptance of the submission for publication. The author(s) bear full responsibility for the accuracy of all results, references, quotations, and materials accompanying their submissions.

7. In the event a diskette it used, it should be prepared on either an IBM or IBM-compatible computer. All submissions should be formatted using either: Microsoft Word, Microsoft Publisher, or WordPerfect. ASCII files are also acceptable.
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Checklist

☐ Electronic submission or one (1) hard copy (typeset using 8-1/2” x 11” paper with 1” margins).

☐ Electronic submission or one (1) hard copy original of tables, figures, and/or illustrations.

☐ Submission follows ASM guidelines regarding fundamental style and ethics.

☐ Abstract of approximately 250 words (for Articles, Reviews, and Summary Articles only).

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Please send the completed form along with your submission to: Editor, Applied Biosafety: Journal of the American Biological Safety Association, 1200 Allanson Road, Mundelein, IL 60060-3808, USA. Electronic submissions may be e-mailed to: Production Editor, Karen D. Savage, at ksavage@covad.net. If you have formatting, processing, or general questions, please contact Ms. Savage at the ABSA Office Monday through Friday between 9:00 a.m. and 5:00 p.m. Central Time at 847-949-1517.
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