Applied Biosafety: Journal of the American Biological Safety Association (ISSN 1355-6760) is published quarterly by the American Biological Safety Association (ABS). ABS members receive the journal as a benefit of membership. An additional annual subscription fee is $60. Nonmembers may subscribe at the annual rates of $92 and $122 respectively. Single issue rates are: members $18; nonmembers $28; and institutions/libraries $35.

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Vision

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 standards, guidelines, and regulations.
- Develop ABSA as the recognized resource for profession and scientific expertise in biological safety.
- Advance biological safety as a scientific discipline through education, research, and professional development.
- Develop and maintain standards for biological safety professionals.

About the Cover

The cover illustration shows the components of a package damaged somewhere in transit due to improper packaging and labeling. A tube of blood in the tan envelope had been placed in the Tyvek overpack envelope without appropriate labeling to indicate its contents and without protective absorbent packaging materials. As a result, the package was crushed somewhere in the transportation chain, resulting in the contamination of the entire shipment as well as adjacent envelopes and packages. A summary of the proceedings of the recent World Courier symposium on packaging and transporting of diagnostic specimens and infectious substances is one of the reports in this issue. In addition, as a companion article, this issue contains the Center for Disease Control and Prevention's recommendations on these same topics as contained at their web site, http://www.bt.cdc.gov/labIssues/packaginginfo.pdf.
What’s in a Name?

Debra L. Hunt
Duke University Medical Center, Durham, North Carolina

The co-chairman of my Institutional Biosafety Committee knows how to yank my chain: He laughs as he refers to me as Duke’s “Biological Safety Officer” (BSO). He knows I absolutely abhor that title. The term BSO undoubtedly originates from the NIH Recombinant DNA Guidelines, and probably as an outgrowth of the Radiation Safety Officer (RSO) whose job is to enforce the regulations of the Nuclear Regulatory Commission. But does it really apply to us?

I have been prompted to challenge the appropriateness of this title as we also change the name and format of our Journal. After all, what is ABSA’s vision? It is to be “the leader in the profession of biological safety,” not “the leader in the enforcement of biological safety!” Do we have the right to call ourselves professionals versus officers? Let’s look at who we are and what we do.

I recently reviewed this year’s ABSA directory and found that approximately 30% of the membership works in University or Research settings, 23% in Pharmaceutical or Biotechnology Industries, 12% in Testing or Technology Control Companies, 9% in Medical Centers, and <6% in a variety of other settings including government, public health departments, consulting, animal or veterinary services, architecture, firefighting, the American Red Cross, and even OSHA. Clearly, we are diverse in our workplaces, as well as in our responsibilities.

What topics or issues are we asked to address in our jobs? Are we responsible only for interpreting and enforcing existing regulations or guidelines? I think not. Issues for many of us include such diverse topics as bioterrorism response, responses to latex sensitivities, implementation of safer sharps devices, indoor air quality (bioaerosols), transgenic animals, facility design and containment, risk assessments, statistics, effective training methods, medical surveillance, performance improvement, program management, and customer service. Doesn’t this indicate that we have grown from quoting the exact Federal Register pages, CFRs, title, and verse to working with our customers as partners to evaluate the risks (perceived and real) of the workplace and develop rational, mutually acceptable, hazard prevention strategies?

Does ABSA help to foster this professionalism? Absolutely! Take a look at some of the topics that we study in our preconference courses and conference proceedings—toxins, genetic therapies, GMPs and GLPs, hazardous materials transportation, microbial contamination of buildings, arboviruses, containment for large-scale production of microorganisms, polio virus eradication, emerging pathogens, smallpox vaccine for bioterrorism threats, and the “art” of biosafety audits. Look at the publication you are holding. The Publications Committee has insured that we have a very practical source of state-of-the-art, information and diversity of biosafety issues to help us do our jobs, hence the name change to Applied Biosafety. As professionals, we should be contributing to the success of our Journal.

Our registration and certification programs are other ways we can document our professionalism. However, only about 15% of our membership has been registered as RBPs or certified as CBSPs. I challenge the rest of you to set this documentation as a personal goal. Take ABSA or ASM courses, or even take some more college courses to meet the requirements. If you are already registered or certified, be proud to use these credentials!

We have come a long way to gain respect and credibility and to partner with our renowned customers. Let us continue down this path of professionalism. Take courses on topics you know nothing about...you
may find you become the expert in your workplace! Enhance your CV by writing articles for the Journal! And, if you now have the title BSO, consider a name change—Biological Safety Specialist, Consultant, Advisor, etc. What we call ourselves is how we are perceived!

Call me enthusiastic about our newly formatted Journal, our organization, and our profession...just don’t call me a BSO!
Julia Hadar

Biological Safety and Toxins, Dept. of Safety and Occupational Health, The Hebrew University of Jerusalem, Israel

HEPA filters are an integral part of biological safety cabinets, providing a sterile work environment and protecting people from exposure to infectious or allergenic agents. Looking through an advertising brochure recently, I came across the term High Efficiency Particle Arrestor used to refer to HEPA filters.

According to the NSF International Standard 49, the term used is High Efficiency Particulate Air (HEPA) filter which is described as a throwaway, extended/pleated medium, dry-type filter with rigid casing enclosing the full depth of the pleats and minimum particulate removal of 99.97% for thermally generated monodisperse dioctylphthalate (DOP) smoke particles or equivalent with a diameter of 0.3 microns.

The VNR Dictionary of Environmental Health and Safety (Lisella, 1994) also defines HEPA filters as high-efficiency particulate air filters but states that they are also known as high-efficiency particulate arrestor filters and high-efficiency particulate absolute filters.

HEPA filters are rated 99.99% efficient on removal of all particulate matter 0.3 microns, with greater efficiency on larger and/or smaller particles. The word particulate is an adjective defined as "of, pertaining to, or formed of separate particles."

The phrase "particulate air" is somewhat strange nomenclature. My suggestion is that high-efficiency particle arrestor is more realistic and should become the general term used to define HEPA.

Reference

First U.S. Biomedical Seminar on the Transportation of Infectious and Diagnostic Substances

Co-Editor’s Note

The following summaries of the presentations from this meeting on the shipment of infectious and diagnostic substances were provided by World Courier, the company that hosted the seminar. As an attendee at this meeting, I believe that the summaries are accurate and will be interesting and useful to Association members.

Ira F. Salkin

Abstract

The globalization of the biopharmaceutical industry over the past 15 years has provided unprecedented opportunity for laboratories and research organizations to tap into new geographies and extend the scope of clinical trials and studies. At the same time, pressing biosafety issues that potentially put at risk both those handling the specimens and the public at large, has led to a profusion of directives—and sometimes conflicting information—from within the industry, governmental bodies, regulatory agencies, and transporters themselves.

Introduction

The first U.S. Biomedical Seminar on the Transportation of Infectious and Diagnostic Substances, hosted by World Courier, addressed many of the critical issues associated with this increasingly complex and critical aspect of clinical trial management.

Held in Miami Beach, Florida on April 20, 2001, the seminar brought together more than 200 industry practitioners from as far away as Japan with principals from the air transportation industry and various regulatory bodies.

Chairman and moderator for the event was Dr. Jonathan Y. Richmond, Director of the Office of Health and Safety at the Centers for Disease Control and Prevention in Atlanta and an internationally recognized consultant and educator in the field of biosafety and training. Dr. Richmond was joined on the podium by speakers representing the Centers for Disease Control, IATA, the FAA, U.S. Customs, the FDA, the Pan-American Health Organization, LabCorp and Bristol-Myers Squibb Pharmaceutical Research Institute (see Table 1), with each sharing his or her unique perspective and personal insight on the issues.

“The transportation of diagnostic samples is an extremely complex issue that relies on the knowledge and expertise of many different organizations and individuals in the course of even a single shipment,” says Wayne B. Heyland, president of World Courier Group. “Our objective in presenting these seminars is to educate and to examine all sides of the issue.”

By the conclusion of the conference, participants had a better understanding of: current transportation regulations and the reasons for their implementation; the need for an ongoing reassessment of this evolving area of legislation; each organization’s unique role in the transportation process; their organization’s need to comply with federal and international regulations as well as the liabilities and penalties for noncompliance; and the integral role that transportation can play in the success of a study.
Table 1
Seminar Agenda & Speakers’ Topics
U.S. Biomedical Seminar on the Transportation of Infectious and Diagnostic Substances
Wyndham Miami Beach Resort, Miami, Florida, Friday, April 20, 2001

<table>
<thead>
<tr>
<th>Morning Session</th>
<th>Afternoon Session</th>
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<tbody>
<tr>
<td>Mr. Mark Hemphill, Acting Chief, External Activities, Centers for Disease Control and Prevention…</td>
<td>Dr. José R. Cruz, Regional Advisor, Laboratory &amp; Blood Services, Pan-American Health Organization…</td>
</tr>
<tr>
<td>on regulatory activities of the CDC including Import Permits, Laboratory Registration, and the Select Agent Transfer Program</td>
<td>on the global perspectives and realities of transporting infectious and diagnostic substances, particularly with respect to the emerging nations of Latin America</td>
</tr>
<tr>
<td>Mr. William Wilkening, Manager, Dangerous Goods &amp; Cargo Security Division, Federal Aviation Administration…</td>
<td>Mr. Richard Rubio, Senior Customs Inspector, United States Customs Service, Office of Field Operations…</td>
</tr>
<tr>
<td>on the compliance enforcement trends of the FAA including inspections, incidents, and outreach programs</td>
<td>on the Code of Federal Regulations (CFR) governing the transport of infectious substances, preclearance inspection, enforcement and penalties</td>
</tr>
<tr>
<td>Mr. Jean Abouchaar, Assistant Director, Cargo Regulatory Industry Affairs, International Air Transport Association…</td>
<td>Ms. Christine Humphrey, Compliance Officer, U.S. Food and Drug Administration…</td>
</tr>
<tr>
<td>on the mandate and role of IATA, and new provisions affecting the transportation of diagnostic specimens scheduled for July 2001</td>
<td>on import and export procedures, laws, and regulations affecting the transportation of regulated products, including the implication of notices of sampling, failure to hold/redeliver, and the FDA’s Import Alert Authority</td>
</tr>
<tr>
<td>Mr. Remy A. Rodas, Esq., Attorney, Ivey Barnum &amp; O’Mara, LLC…</td>
<td>Mr. Jeff O’Connor, Managing Director, American Airlines—Safety, Security and Environmental Compliance…</td>
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<td>on the liability exposure faced by shippers of diagnostic specimens and key preventive measures</td>
<td>on reducing the potential of an airline’s refusal of a shipment and successfully transporting diagnostic specimens</td>
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<tr>
<td>Capt. Ed Sprengle, Member and representative for International Federation of Airline Pilots, Dangerous Goods Committee…</td>
<td>Mr. Steven J. Olsen, Senior Manager, Clinical Pharmacology/Experimental Medicine, Bristol-Myers Squibb Pharmaceutical Research Institute…</td>
</tr>
<tr>
<td>on the position of commercial pilots and airlines in handling and refusing diagnostic specimens; undeclared shipments and the “worst case” scenario for flight crews and passengers; and the potential impact of airborne pathogen leakage in new generation aircraft</td>
<td>on the need for stronger relationships between sponsors, CROs, investigator sites, labs, and service suppliers in meeting the demands of today’s competitive environment, and in recruiting subjects and managing studies in developing nations</td>
</tr>
<tr>
<td>Ms. Denise McFadden, Director, Business Development, Infectious Disease Clinical Trials, LabCorp…</td>
<td>Ms. Denise McFadden, Director, Business Development, Infectious Disease Clinical Trials, LabCorp…</td>
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<tr>
<td>on the challenges of conducting successful clinical trials in Central and Latin America, including the trends, the timing, and the logistics</td>
<td>on the challenges of conducting successful clinical trials in Central and Latin America, including the trends, the timing, and the logistics</td>
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Summaries of Presentations

Mark Hemphill, Acting Chief, External Activities, Centers for Disease Control and Prevention (CDC)

In this presentation, Mr. Hemphill outlined the fundamental criteria of the two key CDC initiatives most likely to impact biomedical practitioners—the need to obtain Import Permits and to properly package and label any infectious substances imported into or
transferred within the United States and the Select Agent Transfer Program. The latter program has been designed to identify, regulate, and track biological agents that may pose a threat to public safety and establishes guidelines and procedures for the registration, transferring, tracking, handling, and disposal of these agents. Underscoring the seriousness with which this program is regarded, Mr. Hemphill cautioned that non-compliance can result in organizational fines of up to $500,000 per event.

Mr. William Wilkening, Manager, Dangerous Goods & Cargo Security, Division, Federal Aviation Administration (FAA)

In this presentation, Mr. Wilkening drew on FAA statistics to reinforce industry's need to practice proper packaging procedures when preparing hazardous substances for shipment. Of almost 1,000 "incidents" involving dangerous goods shipments reported in 1999, the predominant reason for packaging failures was faulty closure/seal leakage.

With an estimated 75,000 dangerous goods shippers in the United States, the FAA supports the efforts of the federal government and the CDC in monitoring and maintaining a safe environment for the shipping of hazardous materials. The FAA's Dangerous Goods and Cargo Security (DG/CS) Program, an initiative currently administered by Mr. Wilkening, combines enforcement, trend analysis, and outreach programs to ensure that shipments comply with existing regulations. Under this program, the FAA investigated almost 3,000 cases last year, resulting in the collection of almost $8 million in fines.

Mr. Jean Abouchaar, Assistant Director, Cargo Regulatory Industry Affairs, International Air Transport Association (IATA)

With over 270 member airlines worldwide carrying 98% of all air cargo, IATA sets the standards for the shipping of dangerous goods. Its mandate is to work with governments and other international organizations to develop practical, yet economically sound, regulations that advance air safety.

In this presentation, Mr. Abouchaar previewed pending changes to IATA's Dangerous Goods Regula-

tions that impact the biomedical community—changes scheduled to come into effect on July 1, 2001 including the reassignment of diagnostic specimens to category UN 3373 and infectious or potentially infectious specimens to UN 2814 or UN 2900. Other changes include redefinition of infectious substances to encompass all body fluids without risk group 4 pathogens, an increase to 1 litre in the maximum quantity that may be carried (special provision A81), and new provisions related to certain sterilization devices (special provision 131).

Reinforcing the need for proper packaging and labelling, Mr. Abouchaar reviewed important changes to package marking and testing for infectious substances that came into effect January 1, 2001 (4G designation). He also fielded a variety of questions on the adoption of Packing Instruction 650 (minimum packaging for potentially biohazardous materials) by the International Civil Aviation Organization (ICAO), and the differences between it and Packing Instruction 6.2 for infectious substances.

Mr. Remy A. Rodas, Esq., Attorney, Ivey Barnum & O'Mara, LLC

Using a hypothetical case study, Mr. Rodas convincingly demonstrated the legal need for diligence, adequate training, and established procedures in the workplace to minimize the biomed's exposure to liability.

In his fictitious account of injuries suffered by an airline worker who is unwittingly contaminated by incorrectly packaged and labelled infectious specimens, Mr. Rodas vividly described the "four knocks on the door" that his shipper, a San Francisco hospital, would receive: the first from the FAA, the next from the media, the third from the airline's attorneys, and the last from the victim's personal injury lawyer—as well as the potentially weighty financial penalties and public relations nightmares to which the hospital would be subject.

He concluded with an overview of key preventive measures shippers should implement and enforce within their work environment including staff training, the development of an in-house "checks and balances" system, the preparation of adequate emergency response procedures, and consistent compliance with shipping protocols and regulations.
He further recommended that shippers maintain detailed in-house records of all employee training.

Capt. Ed Sprinkle, Member and representative for International Federation of Airline Pilots, Dangerous Goods Committee

In the final presentation of the morning, Captain Sprinkle provided an extremely informative and unique "cockpit" perspective on the need for safety and security when transporting potentially dangerous diagnostic specimens aboard commercial aircraft. He boldly suggested that fear, combined with a lack of adequate training and awareness by airline employees, often erroneously resulted in "refusal solutions" by pilots and cargo personnel who can and do reject shipments, sometimes without adequate reason.

In light of air tragedies such as the Valujet crash in Florida, caused by exploding—and undeclared—oxygen generators, he also called for better training for shippers, encouraging the health care industry to assume the lead in assuring compliance.

Captain Sprinkle concluded by elaborating on important technical concerns—including the ease with which airborne pathogens can be returned to the passenger cabin in new generation aircraft—that may have contributed to some airlines' refusal to carry specific types of dangerous goods. This, according to Captain Sprinkle, poses the most serious danger in the opinion of pilots—the increase in undeclared shipments as shippers knowingly attempt to circumvent airline policy.

Dr. José R. Cruz, Regional Advisor, Laboratory & Blood Services, Pan-American Health Organization

In keeping with a secondary theme of the seminar—the ongoing development of business opportunities within the Americas—Dr. Cruz painted a clear and concise picture of the realities of conducting biomedical research in Latin America and the Caribbean.

He detailed the primary constraints faced by biomedical organizations operating in these areas: national regulations and governmental awareness and involvement; lack of adequately trained lab personnel; lack of trained service personnel including couriers, airline personnel, customs officials, and customs brokers; difficulties in procuring appropriate laboratory and packaging materials; the considerably higher cost of services including transportation costs; and the lack of financial resources to rectify these situations.

Dr. Cruz also reiterated some of the key concerns articulated by other members of the panel, particularly the threat of bioterrorism and danger to personnel and public safety, that potentially can arise in a less regulated environment.

Mr. Richard Rubio, Senior Customs Inspector, United States Customs Service, Office of Field Operations

In this presentation, Mr. Rubio outlined the role of U.S. Customs in enforcing the provisions of the Code of Federal Regulations (CFR) that relate specifically to the transport of infectious substances on passenger or air cargo aircraft (Title 49, Parts 107-180, Subchapter C, Class 6, Division 6.2).

Mr. Rubio then walked participants through the importation and clearance process. He reinforced the need for correct paperwork that clearly and accurately describes the nature of the substances being imported, and for the correct packaging and labelling, without which shipments can be subjected to inspections, delays, and potential seizure by Customs.

He concluded with an overview of the civil penalties and monetary liability to which companies that knowingly violate federal hazardous materials transportation law are subject.

Ms. Christine Humphrey, Compliance Officer, U.S. Food and Drug Administration (FDA)

The focus of Ms. Humphrey's presentation was meeting compliance requirements for the importation of FDA-regulated products, notably biological products including blood/blood components, drugs, medical devices, food, and electronic products. She elaborated on the specific regulatory requirements that pertain to each product grouping, the conditions under which they are subject to licensure, the articles of law to which they are subject, and the data required for importation.

She then discussed legislation affecting substances imported for future export (such as drug and biologic components), the necessary steps to be taken by the
importer, and the ramifications of noncompliance with FDA requirements.

Ms. Humphrey concluded with an overview of the various mechanisms that the FDA and U.S. Customs have put in place to regulate the importation and transport of controlled articles. These include Notices of Sampling, Failure to Hold/Redeliver, Customs Entry Bond Conditions, and Import Alert Authority. In each case, she cautioned, noncompliance can result in serious repercussions of either a monetary or operational nature.

**Mr. Jeff O'Connor**, Managing Director, American Airlines—Safety, Security and Environmental Compliance

Mr. O'Connor's presentation addressed the keys to avoiding shipment refusal by airlines—adherence to proper packaging protocol, and the preparation of clear, correct, and accurate paperwork.

He explained that the best way to circumvent the airlines' "10,000 ways to refuse a shipment" was, plainly and simply, to "dot all the i's and cross all the t's" when completing the airline's air waybill and the Shipper's Declaration for Dangerous Goods. He also reinforced the need for appropriate packaging, marking, and labelling to help mitigate the fears and concerns of airline personnel.

In closing, Mr. O'Connor reiterated many of the conclusions drawn by other members of the panel, citing a need for better and more consistent training of everyone involved in the shipping process—from laboratory personnel to transportation and airline staff to customs officials.

**Mr. Steven J. Olsen**, Senior Manager, Clinical Pharmacology/Experimental Medicine, Bristol-Myers Squibb Pharmaceutical Research Institute

In his opening remarks, Mr. Olsen provided participants with an interesting juxtaposition between the "old" approach of containing a clinical trial within a single country, and the "new" and highly competitive business model which calls for shorter developmental time, the maximization of resources and intellectual capital, and a global perspective on the part of trial sponsors. He enumerated the many changes associated with this evolution, including governmental intervention and industry regulation designed to ensure uniform and acceptable practices on a worldwide level as well as the rise of more accurate laboratory testing methods and markers.

Mr. Olsen then offered a compelling argument that infectious disease trials require global coordination that can only be effected by strong communications between all parties associated with the study—the sponsor, the investigator sites, central lab, and the transportation providers—particularly in those emerging geographies where patient recruitment has been based on disease incidence.

**Ms. Denise McFadden**, Director, Business Development, Infectious Disease Clinical Trials, LabCorp

Speaking on the challenges of conducting successful clinical trials in Central and Latin America, Ms. McFadden opened her presentation with a discussion on the rationale behind sponsors' growing interest in these venues. The expansion of the company's global reach, the ability to fulfill the regulatory requirements of larger geographies with fewer trials, time and cost considerations, and the availability of naive subjects were key reasons cited.

Ms. McFadden then drew on her experiences in coordinating international studies in countries such as Brazil, Argentina, and Chile to describe the challenges faced by companies interested in conducting research in this region, and the many decisions that must be made in advance of the study.

She explained that issues such as country and site selection; cultural, time and temperature differences; airline schedules and transportation capabilities; import and export requirements; the selection of local versus central laboratories; study timelines; and data management issues are some of the considerations that can have a serious impact on the outcome of a study. She further cautioned that the logistics of initiating studies in Central and Latin America cannot typically be expedited as quickly as in other parts of the world.
Professional Specialty Cleaning: A Critical Element of Fungal Reservoir Control in Homes of the Immunocompromised and Hypersensitive

Eugene C. Cole
DynCorp Health Research Services, Morrisville, North Carolina

Abstract

As our population ages, and many persons with chronic diseases are living longer, threats to their health from biopollutant exposures in the home environment take on major importance. Opportunistic fungal infections are increasing, as are the number of individuals convalescing at home due to managed care and other factors. Individuals experiencing cancer chemotherapy, transplant recovery, and AIDS require clean living quarters to minimize the risk of opportunistic infections from undue exposures to environmental molds. A critical element of control will be provided by the trained, certified, professional specialty cleaner, who will meet the challenge of reducing fungal reservoirs by maximizing the cleaning of porous furnishings and hard surfaces, while minimizing dust resuspension and cleaning residues. With a working knowledge of indoor ecology and related pollutant reservoirs, and by using high performance equipment and effective cleaning products, the professional specialty cleaner becomes an essential component of the indoor environmental quality team.

Background

Infections from common indoor environmental molds such as Aspergillus, Penicillium, Alternaria, Fusarium, and Rhizopus, are increasing dramatically in HIV-infected and other immunodeficient persons (Ampel, 1996; Walsh, 1998). Those at increased risk for opportunistic fungal infections include those immunocompromised due to HIV infection, neoplasms, chemotherapy, transplantation, steroid therapy, and underlying lung disease (Nash et al., 1997; Teh et al., 1995). Children with neutropenia or prolonged antibiotic therapy are especially susceptible to infection (Shenep & Flynn, 1997). Species of Aspergillus, in particular, are recognized as significant emerging pathogens in persons with HIV/AIDS, causing invasive sinusitis and invasive pulmonary disease (Mylonakis et al., 1997; Nash et al., 1997). Many others are at risk for allergic hypersensitivity to inhaled microbes and animal proteins. And yet others are recognized as chemically hypersensitive, which makes the selection and use of cleaning chemicals a professional challenge.

Microbial Ecology

Each home environment supports a microbial ecology that can influence the quality of the indoor air. The indoor environment is an ecosystem comprised of an interrelated series of microenvironments, each of which can serve as a reservoir of microbial contamination, which if not controlled, can become a source of airborne pollution. Microbial reservoirs, such as wall-to-wall carpet, upholstery, mattresses, pet areas, and hard surfaces associated with moisture, allow pollutants such as mold spores and animal allergens to increase on a continual basis and potentially affect air quality. Recent research has shown that dusts from carpet, upholstered furniture, pet areas, and hard surfaces harbor more than 30 different types of fungi, representing the spectrum of potential opportunistic, allergic, and
toxigenic molds (Cole et al., 1999). Dusts from upholstered furniture averaged $4.2 \times 10^4$ fungal CFU/g, including *Aspergillus fumigatus, Aspergillus flavus, Fusarium, Alternaria*, and others. Similarly, dusts from pet areas averaged $5.0 \times 10^4$ fungal CFU/g, to include *A. fumigatus, Alternaria, Penicillium, Fusarium*, and others. Likewise, dusts from non-water-damaged carpets have been shown to exceed $1.0 \times 10^5$ fungal CFU/g (Cole et al., 1996). Critical in addressing the risks of opportunistic infection and respiratory hypersensitivity, in addition to moisture control, is the routine cleaning of carpet, upholstery, other porous materials, and hard surfaces by qualified individuals using high performance equipment and effective, nonpolluting cleaning products.

**Professional Specialty Cleaning**

Qualified individuals are those experienced in professional carpet and upholstery cleaning, who have received professional training and certifications, such as those of the Institute of Inspection, Cleaning, and Restoration Certification (IICRC). The IICRC (www.iicrc.org) is a nonprofit certifying and standard-setting body for the inspection, cleaning, and restoration industry, and has promulgated standards for Carpet Cleaning (IICRC, 1997), Upholstery Cleaning (IICRC, 2000), and Water Damage Restoration (IICRC, 1999). While technical training, certification, and experience in cleaning are mandatory, it is desirable that those cleaning the homes and other indoor environments of the immunocompromised and hypersensitive also have a working knowledge of indoor ecology and related pollutant reservoirs, including a basic understanding of the health conditions of concern and how effective, critical cleaning can reduce pollutant reservoirs and potential exposures.

High performance cleaning equipment is required. This equipment has been quality engineered using the finest materials, its performance has been rigorously tested and documented, and it is backed by the manufacturer's warranty and a strong user-support system. Effective, nonpolluting cleaning products are those that have been formulated and tested to provide maximum cleaning while protecting and preserving the materials to be cleaned, as well as minimizing residues and volatile organic compounds.

**Cleaning Practices and Recommendations**

Cleaning is the activity of removing contaminants, pollutants, and undesired substances from an environment or surface to reduce damage or harm to human health or valuable materials. Cleaning practices for residences of the immunocompromised and hypersensitive must:

1. Maximize the extraction of pollutants, while minimizing the introduction of moisture; and
2. Minimize the suspension of dusts and associated pollutants into the air, while maximizing their removal through the use of air-scrubbing HEPA filtration.

In regard to carpet, upholstery, and hard surface floor cleaning procedures, the following equipment is recommended in addition to the standard cleaning equipment:

1. A high efficiency vacuum cleaner for prevacuuming, with a new, double-walled disposable inner bag that retains fine particles down to 0.1 μm, in addition to a multiple filtration exhaust system that includes a final HEPA or ULPA filter; and
2. High-volume, portable, commercial HEPA filtration units, with a charcoal prefilter that can operate during the cleaning procedures to help minimize the airborne suspension of pollutants.

It is desirable that HEPA air filtration units be left running in the home after the cleaning is completed for at least 48 hours to maximize the removal of airborne pollutants and promote acceptable air quality. Recommended airflow for a HEPA unit, and the length of time the unit should optimally operate in each area of a home with or without use of air movers to enhance drying, requires an applied research study. It is essential to remember that all equipment, cleaners, and other materials brought into the indoor environment of an immunocompromised or hypersensitive person must be very clean, with no crossover contamination from other homes or cleaning jobs.

It is recommended that a professional home cleaning be carried out at least 1 week prior to the arrival of the immunocompromised individual. While cleaning may continue to be done on the basis of need or frequency (such as two or three times a year), it is crucial that other means of maintaining the indoor environ-
ment and controlling fungal reservoirs be implemented routinely by persons other than the convalescent. Comprehensive and practical recommendations for home moisture control and reservoir reduction, including topics such as relative humidity, water damage, heating and air-conditioning systems, building materials, track-in, hard surface cleaning, air filtration, and others, have been developed (Cook et al., 1999).

Effective Communication

It cannot be overemphasized that the most important point in conducting professional specialty cleaning in the home of an at-risk person is at the very beginning, when the cleaner and the customer communicate effectively. Each shares important information necessary for proper decision-making. The customer must discuss his or her cleaning needs, while the cleaner discusses his or her cleaning procedures, equipment, and chemicals, all within the context of the specific illness or sensitivity of concern. Appropriate decisions can then be made regarding the best cleaning approach and related options (use of antimicrobials, deodorizers, etc.). The cleaner must be very knowledgeable about product ingredients and be prepared to modify the carpet, upholstery, and hard surface cleaning procedures, if necessary, without compromising the overall cleaning goal.

Future of Professional Specialty Cleaning

As the elderly population increases, the parameters of managed care increase the number of home convalescents. Simultaneously, chronic and infectious diseases and therapies place more and more persons at risk for opportunistic infections and hypersensitivity reactions. The need for professional specialty cleaning in such indoor environments will continue to grow. In this regard, the professional cleaner becomes an essential component of the indoor environmental quality team.

Acknowledgement

This manuscript was presented, in part, at the Healthy Indoor Environments 2001 Conference in April 2001 in Philadelphia, Pennsylvania.

References


Positive Benefits Arise from Hospital Pollution Prevention Programs

Jack S. McGurk
California Department of Health Services, Sacramento, California

Introduction

In response to the memorandum of understanding between the American Hospital Association (AHA) and the United States Environmental Protection Agency (EPA), hospitals are beginning to initiate pollution prevention (P-2) programs. At the heart of this agreement is the goal to reduce solid and medical wastes generated by hospitals and eliminate all mercury from these facilities. Implementation of P-2 programs provides hospitals opportunities to realize positive benefits through system improvements. The infection control nurse must play a major role in the P-2 activities if the program is to be successful.

California Pilot Project

Through an EPA grant and funding from an inter-agency agreement with the California Department of Toxic Substances Control, the California Department of Health Services (DHS) has been able to implement a pilot P-2 project with six Bay Area hospitals. Many of the experiences and early lessons learned are included in this article. The six California hospitals participating in the P-2 project are:

- Eden Medical Center, Castro Valley
- Children’s Hospital, Oakland
- Kaiser Foundation Hospital, Walnut Creek
- John Muir Medical Center, Walnut Creek
- Sutter Delta Medical Center, Antioch
- University of California, San Francisco

The P-2 project includes a safe harbor provision under which regulators working on these activities will not cite the participating facility for violations observed while at the hospital, but do point them out for immediate corrective action. This provision has proven valuable in reducing the anxiety level of hospital staff while working with regulators and allowing candid conversations as to how best to separate the medical and solid waste streams.

Common to all participating hospitals is support from top administration for the project and designation by the administrator of a contact person to lead P-2 efforts for the facility. Managers of either environmental services or health and safety were most often tasked with overseeing implementation of the P-2 project. However, activities in the P-2 project not only took place within these units, but also cut across organizational boundaries and staffing hierarchy within hospitals. One incidental benefit of implementing P-2 activities is the team-building that takes place as participants from different disciplines within the hospital undertake project tasks together and work to design improved systems.

It is essential that the status of the systems operating within the hospital be documented during the initial implementation of P-2 activities. This baseline data can then be used to measure the outcomes from P-2 interventions. The documentation of solid and medical waste generation for a hospital is based on the amounts being produced over a specific period of time. In contrast, the baseline documentation for mercury is obtained through an inventory of bulk mercury and mercury-containing devices within the facility.
The Mercury Mission

The University of California, Los Angeles, is also working with DHS to build its new medical school hospital as a mercury-free facility. The decision to develop a mercury-free hospital was an outgrowth resulting from several costly mercury spills at the current medical school on the UCLA campus.

A small team conducted the mercury audit of the facility. A team of two or three persons, including a representative from environmental services/health and safety and the infection control nurse, was found to be the most effective and efficient. A team of that size and composition was not disruptive to ongoing operations, had familiarity with the layout of the facility, and was able to engage in dialogue with staff from the different areas surveyed. This approach often results in the discovery of mercury-containing devices that might have otherwise gone undetected.

Elimination of mercury as recognized by the EPA/AHA memorandum of understanding calls for the replacement of mercury-containing devices where non-mercury equivalents are available. However, where nonmercury replacements are not available or when mercury-containing devices or medicines are required for patient care, their use should continue. The P-2 project found that nonmercury alternatives are available for the types of equipment containing the highest quantities of mercury.

The P-2 project worked with participating facilities to inventory mercury-containing devices such as sphygmomanometers, thermometers, bougies, barometers, barostats, and thermostats could be replaced. They then developed a business plan with cost estimates for replacement. Calculations were also made for the amount of mercury contained in fluorescent tubes. The fluorescent tube calculations, as well as those for thimerosal used in pharmaceuticals, were included in the inventories although no substitutes are currently available. A new California regulation requires fluorescent tubes to be recycled when replaced.

A compound widely used in hospital laboratories is B-5 fixative. This mercury-containing fixative is used in histology to aid in identifying certain cell types. The tissue being examined is placed into a container with B-5 fixative, which penetrates the tissue. The tissue is next stained and placed on a slide for microscopic examination. During the rinse process, mercury may be discharged into the sewer system. However, several brands of B-5 fixative have been developed that use zinc chloride instead of mercury. Laboratory suppliers should be able to provide listings of these substitute brands.

Potentially overlooked sources of mercury in hospitals are cleaning products. Although many cleaning products contain low levels of mercury in parts per million or billion, the large amount of cleaners used in hospitals can result in mercury being placed in wastewater systems. Hospital purchasing departments should be aware of this situation and request mercury-free product verification from their suppliers.

Removing Mercury

When mercury-containing devices are changed-out at hospitals, they should have secondary containment to avoid spills, be transported to the hazardous waste storage area, and held there for recycling or disposal as a hazardous waste. Mercury devices must never be placed into red medical waste bags or sharps containers. It is important to have individuals at the facility who are trained and familiar with handling mercury spills available to respond.

Once mercury sources have been removed from the hospital, the next challenge is to prevent new sources of mercury from entering the facility. Personnel tasked with purchasing supplies and equipment serve as the first line of defense against mercury sources entering the hospital. They must continually update their familiarity with mercury-free alternatives. It should become common practice for departments that order materials or equipment that contain mercury, to provide justification that mercury-free alternatives are not available or applicable.

The California Department of Health Services has recently published a 79-page publication entitled, A Guide to Mercury Assessment and Elimination in Health Care Facilities. This document is available at the department's web site at: www.dhs.ca.gov.

Table 1 provides a composite of the P-2 project's findings for mercury at the six participating facilities. The P-2 project developed an assessment "toolkit" that summarizes findings for mercury and presents them on a Pareto chart. The assessment toolkit is also available at the department's web site.
Solid and Medical Wastes

Solid and medical waste audits have been performed at the six hospitals that had agreed to participate in this portion of the project. Most have initiated cardboard recycling and several are bailing substantial amounts of cardboard. This process requires expenditure of personnel resources to break down the cardboard containers and transport them to an area where bailing takes place. One hospital receives supplies and pharmaceuticals from its regional distribution center in reusable plastic containers and totes. This reduces the amount of cardboard waste at the hospital.

The cardboard recycling process provides an excellent example of how a system can be analyzed and improved. As a result, the P-2 project is encouraging other suppliers to send their supplies to the hospitals in reusable plastic containers and totes.

The hospitals have also initiated other strategies to reduce the amounts of solid waste being sent to their community landfills. Several are working with their solid waste authorities to implement recycling programs that allow all recyclable materials to be placed into a single container. This is possible when these materials are sent to a central materials recovery facility in the community for sorting. One strategy being implemented is to utilize a small solid waste receptacle for wet garbage and large, conveniently located receptacles for recyclable materials.

Efforts to reduce the medical waste stream most frequently focus on eliminating solid wastes that are being incorrectly placed into medical waste containers. This must be an ongoing effort and include training of the health care practitioners who generate this waste stream. The location of medical waste containers can determine whether nonmedical wastes are placed within them. A medical waste container located next to a hand-washing sink, for example, increases the likelihood that soiled paper towels will be errantly placed into the medical waste stream.

The P-2 project has been working on several interventions that hold promise for significantly reducing the medical waste stream. Several hospitals are in the process of converting to reusable sharps containers. These containers are more durably constructed than traditional sharps containers and are expected to last 5 years or longer. After being dumped by mechanical means, the empty sharps containers are washed and disinfected before being returned to the hospital for reuse. A 250-bed hospital participating in the P-2 project re-

<table>
<thead>
<tr>
<th>Device</th>
<th>Inventory</th>
<th>Weight (Kg)</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bougies</td>
<td>8</td>
<td>43.3</td>
<td></td>
</tr>
<tr>
<td>Other GI</td>
<td>6</td>
<td>0.1</td>
<td>Blakemore, Cantor tubes</td>
</tr>
<tr>
<td>Barometers</td>
<td>5</td>
<td>5.1</td>
<td></td>
</tr>
<tr>
<td>Sphygmomanometers</td>
<td>475</td>
<td>39.1</td>
<td></td>
</tr>
<tr>
<td>Bulk mercury</td>
<td>4.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flourescent tubes</td>
<td>39,843</td>
<td>0.9</td>
<td>Calculated as 4-foot tubes, based on lighted floor area</td>
</tr>
<tr>
<td>Switches</td>
<td>90</td>
<td>0.3</td>
<td>Switches from thermostats, barostats, boilers, X-ray tubes, and safety tip-over devices</td>
</tr>
<tr>
<td>Thermometers</td>
<td>254</td>
<td>0.6</td>
<td>Laboratory, fever, refrigerator, boiler</td>
</tr>
<tr>
<td>Total (Kg)</td>
<td></td>
<td>93.7</td>
<td>Sum of device totals</td>
</tr>
</tbody>
</table>

Source: Pollution Prevention Project, California Department of Health Services
viewed its 1999 purchase records and determined that approximately 18,000 sharps containers were used. The weight of each type of empty sharps container was recorded and calculations were completed that documented the hospital could divert 13 tons of medical waste annually by switching to reusable sharps containers. The department also recently approved a safety needle device as a single use sharps container that allows the device to be placed directly into the red bag waste stream. This device also eliminates the need for sharps containers.

**Conclusion**

Hospitals benefit in many ways by introducing pollution prevention programs. They reduce wastes, free their facilities from mercury, improve the environment, save money, and increase employee morale by demonstrating that the hospital is a responsible neighbor in the community. Additionally, as employees from across the spectrum of professions working within the hospital participate jointly on teams to study pollution prevention strategies, new ideas often surface for systems improvements that can strengthen the fiscal condition of the hospital while also improving working conditions.

Packaging Critical Biologic Agents

Co-Editor's Note

To complement the information provided in the summary from the World Courier Symposium, we are republishing below more specific instructions on the packaging and transport of infectious substances and diagnostic specimens. As you will note, the document contains information on numerous web sites where you can obtain the shipping requirements of several federal and international regulatory agencies. To directly access this information, go to http://www.bt.cdc.gov, then click on laboratory issues in the left-hand column. The first topic listed under “laboratory issues” will be this document.

Ira F. Salkin


1. Definitions
   a. Biological agents include infectious agents of humans, plants, and animals, as well as the toxins that may be produced by microbes and by genetic material potentially hazardous by itself or when introduced into a suitable vector. Biologic agents and infectious substances are closely related terms that are found in the transfer and transportation regulations. Biological agents may exist as purified and concentrated cultures but may also be present in a variety of materials such as body fluids, tissues, soil samples, etc.
   c. Transportation refers to the packaging and shipping of these materials by air, land, or sea, generally by a commercial conveyance.
   d. Transfer refers to the process of exchanging these materials between facilities.

2. General Packaging Requirements for Transport of Biological Agents and Clinical Specimens

The generalized “triple” (primary receptacle, watertight secondary packaging, durable outer packaging) packaging required for a biological agent of human disease or materials that are known or suspected of containing them requires an “Infectious Substance” label on the outside of the package. This packaging must be certified to meet rigorous performance tests as outlined in the Department of Transportation (DOT), United States Postal Service (USPS), Public Health Service (PHS), and International Air Transport Association (IATA) regulations.

Clinical specimens with a low probability of containing an infectious agent are also required to be “triple” packaged, but performance tests require only that the package not leak after a 4-foot drop test. DOT, PHS, and IATA require a “clinical specimen” label on the outside of the package.

For information regarding packaging and labeling of infectious substances and clinical specimens in volumes of less than 50 ml in accordance with the provisions of subparagraph 72.3(a) of the regulation on Interstate Shipment of Etiologic Agents (42 CFR, Part 72), consult the BMBL or visit: www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s1.htm

3. Transportation

Regulations on the transportation of biological agents are aimed at ensuring that the public and the workers in the transportation chain are protected from
exposure to any agent that might be in the package. Protection is achieved through:

a. The requirements for rigorous packaging that will withstand rough handling and contain all liquid material within the package without leakage to the outside;

b. Appropriate labeling of the package with the biohazard symbol and other labels to alert workers in the transportation chain to the hazardous contents of the package;

c. Documentation of the hazardous contents of the package should such information be necessary in an emergency situation; and

d. Training of workers in the transportation chain to familiarize them with the hazardous contents enabling response to emergency situations.

4. Regulations

Biological agents and the materials that are known or suspected to contain them are recognized by federal and state governments as hazardous materials, and their transportation and transfer are subject to regulatory control.

a. Interstate Transportation of Biologic Agents

Public Health Service: 42 CFR Part 72. This regulation is being revised so that it coordinates with other U.S. and international regulations. A copy of the current regulation may be obtained from the Internet at: http://www.cdc.gov/od/ohs.

b. Hazardous Materials Regulations

Department of Transportation: 49 CFR Parts 171-178. Applies to the shipment of both biological agents and clinical specimens. Information may be obtained from the Internet at: http://www.dot.gov/rules.html.

c. Ability to Mail Etiologic Agents


d. Occupational Exposure to Bloodborne Pathogens

Occupational Health and Safety Administration (OSHA): 29 CFR Part 1910.1030. Provides minimum packaging and labeling requirements for transport of blood and body fluids within the laboratory and outside of it. Information may be obtained from your local OSHA office or from the Internet at: http://osha.gov.

e. Dangerous Goods Regulations (DGR)

International Air Transport Association (IATA). These regulations provide packaging and labeling requirements for infectious substances and materials, as well as clinical specimens that have a low probability of containing an infectious substance. These are the regulations followed by the airlines and are derived from the Committee of Experts on the Transport of Dangerous Goods, United Nations Secretariat, and the Technical Instructions for the Transport of Dangerous Goods by air which is provided by the International Civil Aviation Organization (ICAO). A copy of the DGR may be obtained by calling 1-800-716-6326 or through the Internet at: http://www.iata.org, or http://www.who.org.

5. Other Regulations: Transfer

Regulations on the transfer of biological agents are aimed at ensuring that the change in possession of biological materials is in the best interests of the public and the nation. These regulations require documentation of the personnel and facilities, justification of need for the biological agent in the transfer process, and subsequent approval of the transfer process by a federal authority. The following regulations fit in this category:

a. Importation of Etiologic Agents of Human Disease

42 CFR Part 71 Foreign Quarantine. Part 71.54 Etiologic Agents, Hosts and Vectors. This regulation requires an import permit from the Centers for Disease Control and Prevention for importing etiologic agents of human disease and any materials, including live animals or insects, that may contain them. An application and information on importation permits may be obtained by calling 1-888-CDC-FAXX and enter document number 101000, or on the Internet at: http://www.cdc.gov/od/ohs/biosfry/impreper.html.

b. Importation of Biologic Agents of Livestock, Poultry, and Other Animal Diseases

9 CFR Parts 92, 94, 95 96, 122, and 130. These
regulations require an import permit from the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services to import or domestically transfer etiologic agents of livestock, poultry, other animals, and any materials that might contain these etiologic agents. Information may be obtained at 301-734-3277, or from the Internet at: http://aphisweb.aphis.usda.gov/ncie.

c. Importation of Plant Pests
7 CFR Part 330. Federal Plant Pest Regulations; General; Plant Pests; Soil; Stone and Quarry Products; Garbage. This regulation requires a permit to import or domestically transfer a plant pest, plant biological agent, or any material that might contain them. Information can be obtained by calling 301-734-3277, or through the Internet at: http://www.aphis.usda.gov/ppq/ppqpermits.html.

d. Transfer of Select Biological Agents of Human Disease
42 CFR Part 72.6 Additional Requirements for Facilities Transferring or Receiving Select Agents. Facilities transferring or receiving select agents must be registered with the CDC and each transfer of a select agent must be documented. Information may be obtained on the Internet at: http://www.cdc.gov/od/ohs/lrsat.

e. Export of Etiologic Agents of Humans, Animals, Plants, and Related Materials
Department of Commerce. 15 CFR Parts 730 to 799. This regulation requires that exporters of a wide variety of etiologic agents of human, plant, and animal diseases, including genetic material, and products that might be used for culture of large amounts of agents, will require an export license. Information may be obtained by calling the DoC Bureau of Export Administration at 202-482-4811, or through the Internet at: http://bxa.fedworld.gov or http://www.bxa.doc.gov.

For further information on any provision of transfer regulations contact: Centers for Disease Control and Prevention, Attn: External Activities Program, Mail Stop F-05, 1600 Clifton Road NE, Atlanta, GA 30333, phone 404-639-4418, fax 404-639-2294.

Note that the shipper's name, address, and telephone number must be on the outer and inner containers. The reader is also advised to refer to additional provisions of the Department of Transportation (49 CFR, Parts 171-180) Hazardous Materials Regulations.

Contact your state health department laboratory director if you represent a laboratory that would like to ship a biologic agent to an advanced capacity laboratory for presumptive or confirmatory identification. Inform the state health department laboratory director as to the identity of the suspected critical biologic agent.
Capsule—Protection of Health Care Workers on Two Fronts!

Ed Krisiunas

WNWN International, Burlington, Connecticut

(from the CDC Working Group on Safe Disposal of Needles and Syringes in the Community)

On July 17, 2001, OSHA began enforcement of the new requirements in its bloodborne pathogen standard. The new requirements direct employers to:

1. Involve frontline employees who provide direct patient care in identifying and choosing safety devices.
2. Maintain a log of injuries from contaminated sharps for employers with 11 or more employees. (Information must be recorded and maintained in a manner to protect the privacy of the injured employee.)
3. Select safer needle devices as they become available.

State and territories that operate their own OSHA-approved programs must adopt the revisions to the federal bloodborne pathogens standard, or a more stringent amendment to their own standard, by October 18, 2001. The following web sites are useful resources for information:

- OSHA web site on needlestick prevention:
  http://www.osha-slc.gov/SLTC/needlestick
- OSHA’s technical background and summary on the revised bloodborne pathogens standard:
  http://www.osha-slc.gov/needlesticks/needlefact.html
- OSHA’s frequently asked questions on the revised bloodborne pathogen standard:
  http://www.osha-slc.gov/needlesticks/needlefaq.html
- OSHA’s PowerPoint presentation on needlestick prevention:
- From the CDC’s National Institute for Occupational Safety and Health, the publication “Preventing Needlestick Injuries in Health Care Settings”:
  http://www.cdc.gov/acidad/hip/blood/blood.htm
- Exposure Prevention Information Network (EPINet) at the University of Virginia, including a directory of resources on complying with needlestick safety regulations:
  http://www.med.virginia.edu/medcntnr CENTERS/EPINET/
- The Safe Injection Global Network (SIGN) is an international organization dedicated to needle safety:
  http://www.injectionsafety.org
- The National Alliance for the Primary Prevention of Sharps Injuries:
  http://www.nappsi.org/needlestick.shtml

West Nile Virus on the Move—Increased Tracking Urged

An enhanced human and animal surveillance system (ArboNET) for West Nile Virus (WNV) in the United States has detected WNV activity in the District of Columbia as well as 12 states. WNV has now been detected as far south as Georgia and Florida. The finding of WNV in the southeastern states may indicate not only transmission by other types of mosquitoes but also longer transmission periods due to temperate climates. This report summarizes ArboNET data from January 1 through July 25, 2001, which documents epizootic WNV activity in the Southeast and indicates the need for widespread implementation of WNV prevention activities. See the following link: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5029a1.htm.
Ask the Experts

John H. Keene
Biohaztec Associates, Inc., Midlothian, Virginia

This is the second article in a series that we hope will be a continuing forum for ABSA members to obtain answers to questions of particular interest to professionals in biosafety. We will attempt to get expert advice on these topics and publish them in this column in each issue of Applied Biosafety: Journal of the American Biological Safety Association. We hope to have several pertinent questions and their answers in each issue. The success of this endeavor will be up to you, the membership. Please help yourself, your organization, and your fellow biosafety professionals by submitting your questions for publication.

Question:

Are there any guidelines in support of, or in opposition to, the use of fans in Biosafety Level 2 laboratories (clinical chemistry, hematology, immunology, and microbiology laboratories) when work is performed on an open bench? Is it appropriate to use electrical fans at a low setting, equivalent to the air velocity coming from a ceiling air vent?

Answer:
(John H. Keene, Biohaztec Associates, Inc.)

There are no guidelines in support of the use of floor or bench fans in Biosafety Level 2 laboratories. The ventilation of the laboratory is to be designed to take into account the health and comfort requirements of the laboratory personnel and to assure adequate removal of the heat load caused by equipment in the space. On the other hand, there are no guidelines that I could find which prohibit the use of such fans in laboratories.

It is well known that we “lab rats” tend to push the limits of our equipment and facilities and at times will overload our spaces with equipment and personnel without consideration of the consequences with regard to ventilation. Therefore, the solution to this perplexing problem may be left to the wiles of the biosafety professional to establish those times and places where such cooling/air movement may be used.

However, there are potential problems with the use of fans in laboratories. One must remember that even air movement “equivalent to the air velocity coming from a ceiling air vent” can cause disruption of the air curtain of a biosafety cabinet. Any cooling fans in the laboratory should not be in such a position that would result in an adverse effect on the containment devices in that laboratory. In addition, fans, when used, should not be directed at a hazardous work site or placed in a position that draws the potentially hazardous material towards personnel in the laboratory. Fans should also not be directed so that the directional airflow into the laboratory is compromised.

The use of fans for cooling in laboratories should be carefully evaluated and should be only a temporary measure until HVAC changes can be made to alleviate the problems encountered by excess heat in the labs.

This question has come from a biosafety professional who is required to audit laboratories for safety, which has raised concerns in my mind as well. I would appreciate any readers who have an opinion on this subject to e-mail me with comments (jkeene@biohaztec.com). I will attempt to consolidate the opinions and print them in a future edition of Applied Biosafety.
Question:

When shipping proficiency testing materials containing infectious agents, it is self-defeating if the outer package is labeled with the genus and species of the enclosed agents. Is there some way to avoid this?

Answer:

(Eileen Edmonson, Transportation Regulation Specialist, US DOT, Research and Special Programs Administration [RSPA])

US DOT’s Hazardous Materials Regulations, 49 CFR Part 171, Paragraph 171.8 states:

“Technical name means a recognized chemical name or microbiological name currently used in scientific and technical handbooks, journals, and texts. Generic descriptions are authorized for use as technical names provided they readily identify the general chemical group or microbiological group. Examples of acceptable generic chemical descriptions are organic phosphate compounds, petroleum aliphatic hydrocarbons, and tertiary amines. For proficiency testing only, generic microbiological descriptions such as bacteria, mycobacteria, fungus, and viral samples may be used.”
Regulatory Affairs—Summary: Management of Occupational Exposures to HBV, HCV, and HIV

Co-Editor’s Note

The Morbidity and Mortality Weekly Report recently published (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.html; June 29, 2001) an update on the management of occupational exposures to HBV, HCV, and HIV. Due to the length of the report, we are republishing only a summary of the document, as well as its three appendices. The latter documents provide the specific procedures for the management of exposure to these bloodborne pathogens.

Ira F. Salkin

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis.

Summary

This report updates and consolidates all previous U.S. Public Health Service recommendations for the management of health care personnel (HCP) who have occupational exposure to blood and other body fluids that might contain hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV).

Recommendations for HBV postexposure management include initiation of the hepatitis B vaccine series to any susceptible, unvaccinated person who sustains an occupational blood or body fluid exposure. Postexposure prophylaxis (PEP) with hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine series should be considered for occupational exposures after evaluation of the hepatitis B surface antigen status of the source and the vaccination and vaccine-response status of the exposed person. Guidance is provided to clinicians and exposed HCP for selecting the appropriate HBV PEP.

Immune globulin and antiviral agents (e.g., interferon with or without ribavirin) are not recommended for PEP of hepatitis C. For HCV postexposure management, the HCV status of the source and the exposed person should be determined, and for HCP exposed to an HCV positive source, follow-up HCV testing should be performed to determine if infection develops.

Recommendations for HIV PEP include a basic 4-week regimen of two drugs (zidovudine [ZDV] and lamivudine [3TC]; 3TC and stavudine [d4T]; or didanosine [ddI] and d4T) for most HIV exposures and an expanded regimen that includes the addition of a third drug for HIV exposures that pose an increased risk for transmission. When the source person’s virus is known or suspected to be resistant to one or more of the drugs considered for the PEP regimen, the selection of drugs to which the source person’s virus is unlikely to be resistant is recommended.

In addition, this report outlines several special circumstances (e.g., delayed exposure report, unknown source person, pregnancy in the exposed person, resistance of the source virus to antiretroviral agents, or toxicity of the PEP regimen) when consultation with local experts and/or the National Clinicians Postexposure Prophylaxis Hotline ([PEPline] 1-888-448-4911) is advised.

Occupational exposures should be considered urgent medical concerns to ensure timely postexposure management and administration of HBIG, hepatitis B vaccine, and/or HIV PEP.
### APPENDIX A
Practice Recommendations for Healthcare Facilities Implementing the U.S. Public Health Service Guidelines for Management of Occupational Exposures to Bloodborne Pathogens
June 29, 2001 / 50(RR11);43-4

<table>
<thead>
<tr>
<th>Practice Recommendation</th>
<th>Implementation Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish a bloodborne pathogen policy.</td>
<td>All institutions where health care personnel (HCP) might experience exposures should have a written policy for management of exposures.</td>
</tr>
<tr>
<td>Implement management policies.</td>
<td>The policy should be based on the U.S. Public Health Service (PHS) guidelines.</td>
</tr>
<tr>
<td>Establish laboratory capacity for bloodborne pathogen testing.</td>
<td>The policy should be reviewed periodically to ensure that it is consistent with PHS recommendations.</td>
</tr>
<tr>
<td>Select and use appropriate PEP regimens.</td>
<td>Health care facilities (HCF) should provide appropriate training to all personnel on the prevention of, and response to, occupational exposures.</td>
</tr>
<tr>
<td>Provide access to counseling for exposed HCP.</td>
<td>HCF should establish hepatitis B vaccination programs.</td>
</tr>
<tr>
<td></td>
<td>HCF should establish exposure-reporting systems.</td>
</tr>
<tr>
<td></td>
<td>HCF should have personnel who can manage an exposure readily available at all hours of the day.</td>
</tr>
<tr>
<td></td>
<td>HCF should have ready access to postexposure prophylaxis (PEP) for use by exposed personnel as necessary.</td>
</tr>
<tr>
<td></td>
<td>HCF should provide prompt processing of exposed person and source person specimens to guide management of occupational exposures.</td>
</tr>
<tr>
<td></td>
<td>HCF should develop a policy for the selection and use of PEP antiretroviral regimens for HIV exposures within their institution.</td>
</tr>
<tr>
<td></td>
<td>Hepatitis B vaccine and HBIG should be available for timely administration.</td>
</tr>
<tr>
<td></td>
<td>HCF should have access to resources with expertise in the selection and use of PEP.</td>
</tr>
<tr>
<td></td>
<td>HCF should provide counseling for HCP who might need help dealing with the emotional effect of an exposure.</td>
</tr>
<tr>
<td></td>
<td>HCF should provide medication adherence counseling to assist HCP in completing HIV PEP as necessary.</td>
</tr>
</tbody>
</table>
Monitor for adverse effects of PEP.  

HCP taking antiretroviral PEP should be monitored periodically for adverse effects of PEP through baseline testing (every 2 weeks) and clinical evaluation.

Monitor for seroconversion.  

HCF should develop a system to encourage exposed HCP to return for follow-up testing.

Exposed HCP should be tested for HCV and HIV.

Monitor exposure management programs.  

HCF should develop a system to monitor reporting and management of occupational exposures to ensure timely and appropriate response.

Evaluate 1) exposure reports for completeness and accuracy, 2) access to care (i.e., the time of exposure to the time of evaluation), and 3) laboratory result reporting time.

Review exposures to ensure that HCP exposed to sources not infected with bloodborne pathogens do not receive PEP or that PEP is stopped.

Monitor 1) completion rates of HBV vaccination and HIV PEP and 2) completion of exposure follow-up.

APPENDIX B  
Management of Occupational Blood Exposures  
June 29, 2001 / 50(RR11);45-6

Provide immediate care to the exposure site.  
- Wash wounds and skin with soap and water.
- Flush mucous membranes with water.

Determine risk associated with exposure by  
- Type of fluid (e.g., blood, visible bloody fluid, other potentially infectious fluid or tissue, and concentrated virus) and  
- Type of exposure (i.e., percutaneous injury, mucous membrane or nonintact skin exposure, and bites resulting in blood exposure).

Evaluate exposure source.  
- Assess the risk of infection using available information.
- Test known sources for HBsAg, anti-HCV, and HIV antibody (consider using rapid testing).
- For unknown sources, assess risk of exposure to HBV, HCV, or HIV infection.
- Do not test discarded needles or syringes for virus contamination.

Evaluate the exposed person.  
- Assess immune status for HBV infection (i.e., by history of hepatitis B vaccination and vaccine response).

Give PEP for exposures posing risk of infection transmission.  
- HBV: See Table 3.
— HCV: PEP not recommended.
— HIV: See Table 4 and Table 5.
  — Initiate PEP as soon as possible, preferably within hours of exposure.
  — Offer pregnancy testing to all women of childbearing age not known to be pregnant.
  — Seek expert consultation if viral resistance is suspected.
  — Administer PEP for 4 weeks if tolerated.

Perform follow-up testing and provide counseling.
— Advise exposed persons to seek medical evaluation for any acute illness occurring during follow-up.

HBV exposures
— Perform follow-up anti-HBs testing in persons who receive hepatitis B vaccine.
  — Test for anti-HBs 1 to 2 months after last dose of vaccine.
  — Anti-HBs response to vaccine cannot be ascertained if HBIG was received in the previous 3 to 4 months.

HCV exposures
— Perform baseline and follow-up testing for anti-HCV and alanine amino-transferase (ALT) 4 to 6 months after exposures.
— Perform HCV RNA at 4 to 6 weeks if earlier diagnosis of HCV infection is desired.
— Confirm repeatedly reactive anti-HCV enzyme immunoassays (EIAs) with supplemental tests.

HIV exposures
— Perform HIV-antibody testing for at least 6 months post-exposure (e.g., at baseline, 6 weeks, 3 months, and 6 months).
— Perform HIV antibody testing if illness compatible with an acute retroviral syndrome occurs.
— Advise exposed persons to use precautions to prevent secondary transmission during the follow-up period.
— Evaluate exposed persons taking PEP within 72 hours after exposure and monitor for drug toxicity for at least 2 weeks.

APPENDIX C
Basic and Expanded HIV Postexposure Prophylaxis Regimens
June 29, 2001 / 50(RR11);47-52

BASIC REGIMEN
— Zidovudine (RETROVIR™; ZDV; AZT) + Lamivudine (EPIVIR™; 3TC); available as COMBIVIR™
  — ZDV: 600 mg per day, in two or three divided doses, and
  — 3TC: 150 mg twice daily
  Advantages
  — ZDV is associated with decreased risk of HIV transmission in the CDC case-control study of occupational HIV infection.
  — ZDV has been used more than the other drugs for PEP in HCP.
  — Serious toxicity is rare when used for PEP.
  — Side effects are predictable and manageable with antimitilaty and antiemetic agents.
  — Probably a safe regimen for pregnant HCP.
  — Can be given as a single tablet (COMBIVIR™) twice daily.
  Disadvantages
  — Side effects are common and might result in low adherence.
  — Source patient virus might have resistance to this regimen.
  — Potential for delayed toxicity (oncogenic/teratogenic) is unknown.
ALTERNATE BASIC REGIMENS

- Lamivudine (3TC) + Stavudine (ZERIT™; d4T)
  - 3TC: 150 mg twice daily, and
  - d4T: 40 mg (if body weight is <60 kg, 30 mg twice daily) twice daily
  **Advantages**
  - Well tolerated in patients with HIV infection, resulting in good adherence
  - Serious toxicity appears to be rare.
  - Twice daily dosing might improve adherence.
  **Disadvantages**
  - Source patient virus might be resistant to this regimen.
  - Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

- Didanosine (VIDEX™, chewable/dispersable buffered tablet; VIDEX™ EC, delayed-release capsule; ddl) + Stavudine (d4T)
  - ddl: 400 mg (if body weight is <60 kg, 125 mg twice daily) daily, on an empty stomach
  - d4T: 40 mg (if body weight is <60 kg, 30 mg twice daily) twice daily
  **Advantages**
  - Likely to be effective against HIV strains from source patients who are taking ZDV and 3TC
  **Disadvantages**
  - ddl is difficult to administer and unpalatable.
  - Chewable/dispersable buffered tablet formulation of ddl interferes with absorption of some drugs (e.g., quinolone antibiotics, and indinavir).
  - Serious toxicity (e.g., neuropathy, pancreatitis, or hepatitis) can occur. Fatal and nonfatal pancreatitis has occurred in HIV-positive, treatment-naïve patients. Patients taking ddl and d4T should be carefully assessed and closely monitored for pancreatitis, lactic acidosis, and hepatitis.
  - Side effects are common; anticipate diarrhea and low adherence.
  - Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

EXPANDED REGIMEN
Basic regimen plus one of the following:

- Indinavir (CRIXIVAN™; IDV)
  - 800 mg every 8 hours, on an empty stomach
  **Advantage**
  - Potent HIV inhibitor
  **Disadvantages**
  - Serious toxicity (e.g., nephrolithiasis) can occur; must take 8 glasses of fluid per day.
  - Hyperbilirubinemia common; must avoid this drug during late pregnancy.
  - Requires acid for absorption and cannot be taken simultaneously with ddl in chewable/dispersable buffered tablet formulation. (Doses must be separated by at least 1 hour.)
  - Concomitant use of astemizole, terfenadine, dihydroergotamine, ergotamine, ergonovine, methylergonovine, rifampin, cisapride, St. John's Wort, lovastatin, simvastatin, pimozide, midazolam, or triazolam is not recommended.
  - Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

- Nelfinavir (VIRACEPT™; NFV)
  - 750 mg three times daily, with meals or snack, or
  - 1,250 mg twice daily, with meals or snack
  **Advantages**
  - Potent HIV inhibitor
  - Twice dosing per day might improve adherence.
Disadvantages
— Concomitant use of astemizole, terfenadine, dihydroergotamine, ergotamine, ergonovine, methylergonovine, rifampin, cisapride, St. John’s Wort, lovastatin, simvastatin, pimozide, midazolam, or triazolam is not recommended.
— Might accelerate the clearance of certain drugs, including oral contraceptives (requiring alternative or additional contraceptive measures for women taking these drugs).
— Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

• Efavirenz (SUSTIVA™; EFV)
  — 600 mg daily, at bedtime

Advantages
— Does not require phosphorylation before activation and might be active earlier than other antiretroviral agents (Note: this might be only a theoretical advantage of no clinical benefit.)
— One dose daily might improve adherence.

Disadvantages
— Drug is associated with rash (early onset) that can be severe and might rarely progress to Stevens-Johnson syndrome.
— Differentiating between early drug-associated rash and acute seroconversion can be difficult and cause extraordinary concern for the exposed person.
— Nervous system side effects (e.g., dizziness, somnolence, insomnia, and/or abnormal dreaming) are common. Severe psychiatric symptoms are possible. (Dosing before bedtime might minimize these side effects.)
— Should not be used during pregnancy because of concerns about teratogenicity.
— Concomitant use of astemizole, cisapride, midazolam, triazolam, ergot derivatives, or St. John’s Wort is not recommended because inhibition of the metabolism of these drugs could create the potential for serious and/or life-threatening adverse events (e.g., cardiac arrhythmias, prolonged sedation, or respiratory depression).
— Potential for oncogenic toxicity is unknown.

• Abacavir (ZIAGEN™; ABC); available as TRIZIVIR™, a combination of ZDV, 3TC, and ABC
  — 300 mg twice daily

Advantages
— Potent HIV inhibitor
— Well tolerated in patients with HIV infection

Disadvantages
— Severe hypersensitivity reactions can occur, usually within the first 6 weeks of treatment.
— Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

ANTIRETROVIRAL AGENTS FOR USE AS PEP ONLY WITH EXPERT CONSULTATION

• Ritonavir (NORVIR™; RTV)
  Disadvantages
— Difficult to take (requires dose escalation)
— Poor tolerability
— Many drug interactions

• Saquinavir (FORTOVASE™, soft-gel formulation; SQV)
  Disadvantage
— Bioavailability is relatively poor, even with new formulation.

• Amprenavir (AGENERASE™; AMP)
  Disadvantages
— Dosage consists of eight large pills taken twice daily
— Many drug interactions
• Delavirdine (RESCRIPTOR™; DLV)
  Disadvantages
  — Drug is associated with a rash (early onset) that can be severe and progress to Stevens-Johnson syndrome.
  — Many drug interactions

• Lopinavir/Ritonavir (KALETRA™)
  — 400/100 mg twice daily
  Advantages
  — Potent HIV inhibitor
  — Well tolerated in patients with HIV infection
  Disadvantages
  — Concomitant use of flecainide, propafenone, astemizole, terfenadine, dihydroergotamine, ergotamine, ergonovine, methylergonovine, rifampin, cisapride, St. John’s Wort, lovastatin, simvastatin, pimozone, midazolam, or triazolam is not recommended because inhibition of the metabolism of these drugs could create the potential for serious and/or life-threatening adverse events (e.g., cardiac arrhythmias, prolonged sedation, or respiratory depression).
  — May accelerate the clearance of certain drugs, including oral contraceptives (requiring alternative or additional contraceptive measures for women taking these drugs).
  — Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

ANTIRETROVIRAL AGENTS GENERALLY NOT RECOMMENDED FOR USE AS PEP

• Nevirapine (VIRAMUNE™; NVP)
  — 200 mg daily for 2 weeks, then 200 mg twice daily
  Disadvantages
  — Associated with severe hepatotoxicity (including at least one case of liver failure requiring liver transplantation in an exposed person taking PEP).
  — Associated with rash (early onset) that can be severe and progress to Stevens-Johnson syndrome,
  — Differentiating between early drug-associated rash and acute seroconversion can be difficult and cause extraordinary concern for the exposed person.
  — Concomitant use of St. John’s Wort is not recommended because this might result in suboptimal antiretroviral drug concentrations.
Innovations—Rapid Test for West Nile Virus in Mosquito Vectors

Eugene C. Cole
DynCorp Health Research Services, Morrisville, North Carolina

A rapid immunochromatographic field assay for West Nile Virus (WNV) in vector mosquitoes has been developed and is presently commercially available. Medical Analysis Systems (MAS™), Inc. of Camarillo, California, has developed, evaluated, and now markets the monoclonal VecTest™ for detection of WNV antigen in Culex mosquitoes.

The VecTest™ West Nile Virus Antigen Assay is a rapid-wicking assay that identifies the presence or absence of viral antigen specific to WNV in infected mosquitoes. Rapid results, ambient storage, and no required or specialized equipment are the major advantages of the test over the ELISA. While growth of the virus in culture or detection by PCR-based molecular methods remains the standard for virus identification, the availability of a rapid, stable, sensitive, and specific diagnostic tool makes surveillance more expedient and cost-effective.

The use of the test kit appears extremely easy. First, up to 50 female mosquitoes are placed into the plastic culture tube provided in the kit, to which are also added 2.5 ml grinding solution and four copper-coated BBs. The capped tube is then vortexed for 1 minute at high speed or until the mosquito pool is homogenized into a slurry. Next, 250 µL of mosquito homogenate is transferred to a conical tube, also provided in the kit. The tube is positioned in a stand, and a test strip is added, with the indicated arrows on the strip facing down. After 15 minutes, the test strip is compared to the pictorial examples provided in the test kit. Results are interpreted as negative, WNV positive, or invalid.

In speaking with the company's technical director, I was informed that the test kit was recently evaluated in collaboration with the CDC, using samples from the 1999 New York City outbreak, and found to be specific for WNV detection with no false positives. I was told that the publication of those results would be forthcoming, and also that Fisher Scientific would soon be the major supplier.

The value, of course, of such a rapid assay is its aid in field epidemiology studies, particularly where time-sensitive decisions must be made to implement targeted vector control measures.

Currently, the kit comes equipped with materials necessary to make 50 determinations, at a cost of approximately $10.00 per test. Information on the VecTest™ West Nile Virus Antigen Assay can be found on the MAS™ web site: www.mas-inc.com, as can information on the company's VecTest™ Malaria Panel Assay for detection of Plasmodium parasites in vectoring mosquitoes.

I look forward to reviewing published data on the WNV VecTest™ and hopefully reporting back to you with updated developments, as well as information on related products, such as the company's Dengue Panel Assay, currently under development.
Position Paper—NCCLS M29-2A

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Jennifer K. Geary, MT (ASCP), MSHA
National Committee of Clinical Laboratory Standards
940 West Valley Road, Suite 1400
Wayne, PA 19087-1898

RE: NCCLS M29-2A

August 29, 2001

Dear Ms. Geary,

The American Biological Safety Association (ABSA) is an organization of biological safety practitioners who work in a variety of academic, governmental, health care, and private work environments. We have many members in the United States, Canada, and in other countries. We are recognized as a leading authority in the field of biological safety. We appreciate the invitation to review your most recent revision to your guideline M29-A2, Protection of Laboratory Workers from Occupationally-Acquired Infections.

Please consider these general comments: Your practice of keeping these documents active through a 3-year review process is evident with the inclusion of current information on prions and latex allergy issues.

The Occupational Safety and Health Administration (OSHA) issued a number of new requirements regarding needles and sharps safety earlier this year. The Centers for Disease Control and Prevention (CDC) also issued a safety alert on this subject in 1999. These changes are reflected in sections in your document. To provide proper focus on these major changes, it may be helpful to describe them in a section or preamble early in the document, with a note that further details are to follow in the text of the document.

There are a number of references for the need to post items with the universal biohazard symbol. These references should also reference the need to include the word “Biohazard” in order to provide full communication of the hazard present and to better address the applicable labeling requirements.

Our specific comments follow the sections of your guideline.

3. Definitions
You provide definitions of an “aerosol” and “airborne transmission” in this section. You note that an aerosol is “a system of particles dispersed in a gas, smoke, or fog.”

*Mycobacterium tuberculosis* (TB) cultures are tested in clinical laboratories, and they pose the risk of airborne infections through the inhalation of respirable aerosols. In this context, the aerosol definition should reflect that aerosols are respirable particles that can be retained in the lungs.

You note that airborne transmission involves “infectious agents...carried by or through the air, usually in small droplets.” However, later in section 5.2.4, you note that aerosols are invisible particles, which are typically less than 10 microns in diameter. Small droplets are generally not considered to be respirable. The airborne transmission definition should be reflective of infectious agents that can be transmitted through retention in the lungs of a respirable infectious aerosol. May we suggest rewording this definition to define airborne transmission as “the spread of infection by inhalation of respirable size particles containing infectious agents.” This would provide the consistency and clarity needed for the development of information to follow in the document.

You have good definitions for “needleless system” and “sharps with engineered sharps injury protections.”
It shows early on that you have a document with current pertinent information from OSHA and the CDC.

The definition of “medical waste” is inclusive of “infectious waste” (well defined in these definitions) and of “non-medical waste.” To better make this distinction, the use of the term “regulated medical waste” is suggested. It would be defined as “Materials generated as a result of diagnosis and treatment of patients that require special handling. This may include ‘Infectious Wastes.’”

5.2 Lab Transmission

There is a statement regarding the types of fluids from which HIV has been isolated. We recommend adding to the next statement, “Only blood, bloody body fluids, or concentrated virus solutions have been implicated in the laboratory transmission of HIV to date.”

You also may want to mention that although the OSHA Bloodborne Pathogen Standard identifies only certain fluids that have been epidemiologically linked to HIV transmission, it also includes any body fluid that contains blood. The CDC Standard Precautions recommend precautions with all body fluids except sweat.

Tables 2 and 4: The data are those recorded through June, 2000, not June, 1999.

6. Protection Techniques

In the text following this heading, the hierarchy of controls identified in the original OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) is listed. The listing includes standard precautions. The reference should be to “universal precautions.” In the text of the OSHA Bloodborne Pathogens Standard, there is no definition for standard precautions. There is no reference to it in the text of the standard itself that follows the definitions section. We appreciate the later definitions of both Universal Precautions and Standard Precautions.

6.1 Handwashing

When water is not available, proper guidance is given regarding alternative means of cleaning hands on an interim basis. It needs to be clear that these interim measures do not substitute for washing of hands in soap and water. This must still be done as soon as possible in these situations when soap and water become available.

6.2.1 Gloves

Your document indicates that gloves are meant to help prevent exposures to health care providers who procure specimens. Employees who collect blood specimens from patients are to wear gloves that are recognized as medical devices by the Food and Drug Administration (FDA). FDA issues a 510(k) number to glove manufacturers, which enables them to label their product “patient examination gloves.” Gloves, which meet this requirement, would be the appropriate standard of care for the gloves used by employees who handle and test specimens from patients. This should be noted in your document.

Also consider adding to the list of appropriate glove use (6.2.1.3) the correct protective measures to be taken for ensuring that a health care provider’s hands are adequately protected if they have a cut or if their skin is otherwise compromised, such as with dermatitis. The cut or broken skin should be covered with a water-resistant bandage and gloves worn while handling clinical specimens.

The NCCLS draft document states, “It is the opinion of this subcommittee that used gloves should be discarded as biohazardous wastes.” Minimally contaminated materials such as gloves, gauze, or band-aids are not always designated as regulated medical wastes by state regulations or by OSHA, and pose almost no risk of bloodborne pathogen transmission. We would ask that a general statement about proper disposal of all disposables in laboratories be referred to the local state medical waste regulations.

6.2.1.1 Latex Hypersensitivity

The American Society of Testing and Materials (ASTM) in ASTM D 3578-00a recommends that latex gloves should contain no more than 200 micrograms/decimeter squared of water extractable protein in order to be considered ‘low protein. This limit should be noted in the recommendation for the selection of low protein gloves.

6.2.2 Facial Protection

The first paragraph states, “Facial barrier protection should be used if there is a reasonably anticipated potential for spattering or splashing blood or body substances.” We suggest that a biological safety cabinet, splashguard, or other engineering control be the preferred method of facial protection. If these are not
available, then a full “plastic face shield best provides facial protection unless there is the potential for respirable aerosols containing airborne pathogens.” Then the statement, “Splashguards may serve as an acceptable alternative to plastic face shields,” can be deleted.

Paragraph 3 states, “If face shields are not used, a personal respirator and eye protection should be used.” The preceding commentary in this section deals with protection against splashes and spattering of facial mucous membrane surfaces. A personal respirator is meant primarily to provide protection against respirable infectious aerosols. Its reference here could cause some confusion, especially since readers are being referred to Section 10 for further information regarding protection against airborne pathogens such as TB. The sentence should reference the use of a face covering that protects the facial mucous membrane surfaces, such as a fluid-resistant surgeon’s mask.

The last statement, “The prevention of transmission of Mycobacterium tuberculosis is discussed in detail in Section 10,” is an unnecessary statement under the facial protection section.

6.4.1.1 Disinfectants and Sterilants
A useful example under the FDA-approved chemicals for the laboratory would be the antiseptics or antimicrobial handwashing agents.

Table 7: Please complete the right-hand side of the table (“Activity Level”) for the Sterilants, or fill in as N/A.

6.4.2 Procedures and Products
In paragraph 5 of this section, there is the statement, “...It is the opinion of the committee that germicides of the intermediate-level category (i.e., have a tuberculocidal claim) be used for surface decontamination in laboratory areas as a safe minimum.” We suggest adding a statement regarding attention to the contact time recommended by the manufacturer in order to achieve tuberculocidal activity.

Footnote “g” in Table 7 makes some statements regarding the efficacy of alcohols as intermediate-level germicides. It would be helpful to also note that alcohol solutions are not sporidical.

7.2.3 Mask, Eye Protection, Face Shield
A short statement indicating that respirators should only be worn when there is a risk of exposure to a respirable, infectious aerosol or droplet nuclei (such as cleaning a spill of TB cultures or drawing blood from TB patients) should be added.

Again, we would suggest adding a statement that biological safety cabinets or splashguards are the preferred methods for protection when splashes are anticipated.

8.1 Facilities and Practices
Facilities for handwashing are described in this section. We recommend that foot-, knee-, or other automatic faucets be used in laboratories for washing hands to avoid contamination of handles.

7th bullet: Should read PPE, not PEP

8.2 Blood Collection
When using a hypodermic needle and syringe for transferring blood, consider using a safer blood transfer device to avoid the need for attaching a needle to puncture the vacuum tube stopper.

8.2.1 Blood Collection Equipment and Safety Devices
The second sentence in the first paragraph indicates that Federal Needlestick Safety and Prevention Act authorized OSHA to revise its Bloodborne Pathogens standard. Under this act, OSHA was required to amend the standard; it was not an optional action that could be considered by OSHA. The use of the word “mandated” would be more appropriate.

An important point is that the revised OSHA Bloodborne Pathogens standard requirements are applicable to any sharps that may be contaminated with blood and other potentially infectious materials. There has been much discussion in many forums about needle safety, but scalpels are also covered under the revised standard if they are used in procedures such as autopsies. A reference should be made here to this extent. Or, this should be noted as part of Section 8.11 that deals with autopsies.

It was good to see that you have referenced the state-specific needle safety requirements. At the time of the preparation of these comments, at least 20 states have passed such laws. You have referenced web sites earlier for information regarding disinfectants and germicides. The University of Virginia Health Care
Worker Safety Center has a web site that tracks these state needle safety laws, and it provides a wealth of information that would be of value to someone performing a risk assessment for their needle safety program. That address is: http://www.med.Virginia.EDU/medcntr/centers/epinet/.

8.2.3 Skin Puncture

OSHA may allow gauze pads with minimal blood to be discarded with the hospital waste stream as long as it is properly handled. (Although OSHA designates regulated wastes by definition to minimize employee handling or exposure, it does not regulate the disposal of state-regulated medical waste). As with gloves above, the disposal of items minimally contaminated with blood and other potentially infectious materials is an environmental issue that is regulated in many states. Their proper disposition, as per any applicable state environmental agency requirements, also needs to be referenced. Consideration of moving the edited sentence to Section 8.10 should be given.

The last paragraph regarding packaging of specimens belongs under 8.3, Specimen Collection, Handling, and Transportation.

This same paragraph is very confusing. The collection device is...“frequently contaminated on the outside.” Is this a capillary tube? The example of a secondary, leak-proof container (e.g., screw-top test tube) seems to indicate this. OSHA does not require labeling of secondary containers with “biohazard” symbol and verbiage if the specimen is visible and recognizable as a blood or body fluid container, and if the exposure control plan indicates that ALL blood and body fluids are handled with Universal Precautions.

8.3.2 Laboratory Requisition Slips

The best practices indicated in the document are good. However, the way contaminated requisitions are managed can vary considerably. This can be due to the testing performed at the site. For example, a facility that is accredited by the Substance Abuse and Mental Health Administration (SAMSHA) must retain original test requisitions as part of its accredited procedures. Contaminated requisitions may need to be placed into biohazard bags, photocopied, and then archived with a requisition photocopy processed with the specimen.

Institutions need to establish internal procedures for the proper management of contaminated requisitions. These need to be communicated to employees and followed by workers.

8.7 Shipping Specimens

A laboratory that may have to ship specimens off-site for testing should be referred to the CDC requirements for ground shipment of those specimens or the most current version of the Dangerous Goods Regulations of the International Air Transport Association (IATA) for air shipment of specimens.

8.8.2 Microbiology Laboratories

There is a reference to the need to perform some procedures in a biological safety cabinet (BSC) or behind a shield. More specific guidance needs to be provided as to which tasks need to be done in the BSC and which need to be done behind the shield. If specific tasks are not given, then criteria for making this determination need to be provided.

8.9.3 One-handed Technique

“A one-handed technique may be used to remove the needle…” needs to be changed to “A one-handed technique may be used to remove the needle, such as with a sharps container that has an integral device that enables one to remove the needle without having to touch it. Alternatively, a holder with a button-release for one-handed needle removal may be used for needle removal.”

8.9.4 Manual Removal of Needles

The picture shown properly demonstrates this procedure when a vacutainer needle and standard needle holder are in use. Currently, there is no shortage of needle safety devices that can be used to collect specimens in vacuum tubes using a needle holder. For most employers, the situation demonstrated will not occur with these specific materials. Some specimen collections, such as for arterial blood gases, may need to use the technique demonstrated, since the collected specimen must be injected into a test instrument after collection. If you have a sketch that shows this technique with a standard needle and syringe, consider using it since this may be more representative of an actual situation encountered by the users of your document.
8.9.1 Sharps Containers

Sharps containers should not be filled above the fill lines on the sides of the container. The container must not require shaking in order to seal the container.

8.10 Medical Waste Management

Throughout this section, attention needs to be given to the distinction between medical waste and regulated medical waste (i.e., infectious waste).

The implementation of a medical waste volume reduction program should be a recommended best practice. This program is an environmentally favorable practice, some state environmental agencies mandate this activity, and it reduces the risk of infection to employees and the public. (We have not reviewed GP5, the NCCLS document on the management of medical waste, so it is possible that you may have addressed this in that guide.)

8.10.5 Transport

Regulated medical waste is a hazardous material regulated by the U.S. Department of Transportation (DOT). Containers used to ship medical waste to offsite treatment facilities need to meet the (DOT) performance testing requirements and specific state regulations.

8.10.6 Treatment and Disposal

Generators of regulated medical waste are responsible for its proper treatment. On-site treatment by the generator affords the best opportunity for addressing this concern. In many cases, treatment by an offsite medical waste contractor is needed. In these situations, it is strongly suggested that the medical waste treatment site be audited to ensure that treatment is done effectively and in accordance with the terms of the site's operating permit(s).

8.10.7 Radioactive Biohazards

We recommend changing the term “sterilization” to “decontamination” when discussing treatment of wastes.

8.11 Autopsy and 8.11.1 General

There are conflicting statements in this section: “The guidelines that follow should be used for all cases and are considered suitable for autopsies on individuals infected with HIV, HCV, or HBV.” vs. “In established or suspected cases of serious bloodborne infections such as HIV, HCV, or HBV, the prossector may wish to apply more stringent precautions than those recommended herein.” Using Standard Precautions, as listed in the following sections, is appropriate, and no more stringent precautions are necessary, unless you mean to address CJD instead of HIV, HCV, or HBV.

In the recommendation of “airflow of 12 air changes per hour,” should read “at least 12 air changes per hour.”

8.11.5 Personal Protective Equipment

In the NCCLS draft document, wearing a N95 respirator or a HEPA-filtered respirator under the face shields of persons participating in an autopsy is recommended. Some pathologists will balk at wearing a respirator because they claim it interferes with their ability to accurately record their descriptions on the autopsy audio recording. The document, as written, could be interpreted as requiring the use of a respirator during any autopsy. The October 28, 1994 CDC Recommendations, “Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities,” indicate that these respirators are to be worn by personnel while performing autopsies on deceased persons who may have TB at the time of death. This qualification should be placed with the respirator recommendation in the document. Providing this focus will increase the likelihood that employees will wear face shields during any autopsy and respirators when a determination has been made that their use is warranted. See also 10.5 Autopsy Rooms.

8.11.6 Autopsy Procedures

The discussion of scalpel and/or needle and syringe use should include the requirement to evaluate and implement safer devices such as sheathing scalpel blades or safety needles.

A respirator use issue also exists in the section dealing with bone cutting. The N95 respirator is needed only with suspected M. tb cases.

8.11.7 Decontamination

Again, emphasize the use of safety scalpels and discourage the removal of scalpel blades from the holders for disposal.
8.12.1 Personal Protective Equipment

Emphasize the use of biological safety cabinets (BSCs) or splashshields when processing unfixed, large specimens where splatter would be expected.

9.1.1 Exposure Report

The investigation of bloodborne pathogen exposures has been an OSHA mandate for years. The 2001 OSHA Bloodborne Pathogen Standard revision now requires that a sharps injury log be prepared to record the circumstances of exposures that involve a sharp. The second bullet implies that a medical device is involved in any bloodborne pathogen exposure. It should note that prompt identification of any sharps involved in the injury is needed and that the name, type, and brand of any sharp involved needs to be recorded.

9.1.4 Postexposure Prophylaxis (PEP)

On June 29, 2001, the CDC released its consolidated PEP recommendations for exposure to HIV, HBV, and HCV. This document should be specifically referenced.

9.2 Postexposure to HBV

It was good to see that specific sites for the HBV vaccination and specific needle lengths are recommended. Both of these items are factors that may affect the immune response to the inoculation.

It is good to see that prompt administration of the HBV immunoglobulin within 24 hours is noted. This gives added incentive to provide a prompt medical evaluation for the exposed worker so he or she may benefit from this treatment.

9.4 Potential Postexposure to HIV

The second paragraph is timely, good guidance. Laboratories need to make arrangements with a medical provider that has access to HIV PEP drugs before an exposure occurs. Many physicians do not routinely administer these drugs and therefore are unfamiliar with their appropriate dosages, indications, and contraindications, as well as the side effects associated with these medicines. These steps are important to provide an effective, beneficial medical evaluation to the exposed worker. These considerations are echoed in Section 9.4.2.

10 Mycobacterium tuberculosis in the Health Care Setting

The tasks that need to be performed at Biosafety Level (BSL) 3 should be identified. The tasks that are to be performed at BSL-2 need to be identified. If these tasks are not detailed here, then readers should be referred to the most current version of Biosafety in Microbiological and Biomedical Laboratories (BMBL) or the CDC Guidelines for Working with TB in Laboratories for guidance.

10.1.2 and 10.2 Transmission and Pathogenesis, Risk of Transmission in Heath Care Facilities

You are correct in characterizing droplet nuclei as potential sources of airborne TB from TB patients. The risk of infections from respirable aerosols generated during the testing of specimens and cultures from TB patients is less clear and needs to be more distinct. Although TB can be present in many body fluids from TB patients, it should be noted that TB is found primarily in sputums and other respiratory specimens so that special care is taken when testing these types of specimens.

There is a statement in the first paragraph (10.1.2) which states, “Infection occurs when a susceptible person inhales droplet nuclei...” Please delete the word “susceptible” since all people are susceptible. This same type of situation is found in 10.3, Fundamentals of Infection Control in the first bullet, “…intended to reduce the risk of exposing susceptible individuals.” Please delete the word “susceptible.”

10.3 Fundamentals of Infection Control

When engineering controls are described, it should be noted that a written preventive maintenance program needs to be prepared and implemented to verify these controls are providing their intended protection (i.e., work within a routinely certified biological safety cabinet). In addition, a written plan needs to be prepared, posted, and implemented for dealing with spills of TB specimens and TB cultures. UV light is recognized as an engineering control, but should be used only as a secondary engineering control to augment other engineering controls. This should be noted in this section.
10.4 Respiratory Protection

The scope of your document includes workers who acquire specimens, and respirators are required for the collection of specimens from TB patients in respiratory isolation. Respirators are also needed for TB spill responders and laboratory workers in TB labs at the BSL-3 level. Also note that a Respiratory Protection Program is required per the OSHA Respiratory Protection Standard, and lab workers need to be medically cleared and fit-tested to wear the N95 respirators.

11.5 Storage and Retention of Specimens and Microorganisms

The sentence that indicates that food should not be stored with specimens in refrigeration units should also indicate that beverages should not be stored in this manner.

11.8.3 Flow Cytometry

There is a reference to the generation of aerosols from cell sorters in this section. Please revise to read, “if the fluid being sorted potentially contains organisms that are transmitted by the airborne route, and the cell sorter produces respirable size aerosols, a personal respirator should be worn.”

11.10 Policies

“Dirty” work surfaces and items where the use of gloves is mandatory must also be posted with the universal biohazard symbol and the word, “Biohazard.” Labeling alone and noting this practice in a policy manual are not sufficient. Employees must be trained to recognize and understand this posting in their work areas.

12.1 Initial Training

Please include in the list of references the January, 18, 2001 issue of the Federal Register (Volume 66, Number 12) that announced the revisions to the OSHA Bloodborne Pathogen Standard Revision.

On page 73, there is a statement, “Employees must be trained to report and carefully log each sharps injury with a minimum of information including 1) the identification of the device...,” Please include not only the identification of the type of device, but also the brand of the device as well (required by the OSHA Bloodborne Pathogen Standard for the sharps injury log).

To the statement, “The training program should be developed in cooperation with the infection control department of the institution,” please add “...safety office, or other professional group knowledgeable in bloodborne pathogens and other biological safety issues.”

Appendix B: Biological Safety Cabinets (BSCs)

There should be a statement noting that horizontal laminar flow cabinets are not recommended for use with infectious agents. This containment device was designed for work protection, not employee protection.

BSCs should also be placed away from high traffic areas in order to minimize airflow disruption inside the BSC. The need for at least annual certification of the BSC as per the most recent version of National Sanitation Foundation (NSF) Standard No. 49 or manufacturer’s specifications needs to be noted.

B.2.2 Preparation of Work Space

It was good to see the recommendation of a post-disinfection wipe of the BSC work surfaces with sterile water after decontamination with diluted bleach. It should be noted that 70% ethanol solutions are not sporicidal and may or may not be effective against fungal or bacterial spores. The reference to the “reduction in mold spores and thereby minimizing contamination of cultures” should be dropped.

B.2.3 Material Placement

Work materials should be manipulated at least 4 inches away from the air intake grille in order to take optimal advantage of the laminar sterile airflow within the BSC. It was good to see that the role of the BSC in room air balancing was noted.

B.4.3 Gas Decontamination

The NSF currently recognizes only gaseous formaldehyde as a decontamination agent. NSF is still reviewing efficacy data regarding the use of gaseous hydrogen peroxide.

Thank you for the opportunity to review this document. We look forward to similar opportunities in the future.

Sincerely,

Debra L. Hunt, MT (ASCP), DrPH, RBP, CBSP
President, American Biological Safety Association
Position Paper—Federal Register

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RE: Federal Register: August 13, 2001 (Volume 66, Number 156) (Proposal to amend Appendix B-I of the Guidelines to establish criteria for designating strains of E. coli as risk group 1 agents)

September 10, 2001

Dear Sirs,

The phrasing "and has a 'rough' colony morphology" is not informative. Colony morphology is a phenotypic property dependent on growth conditions—temperature, media, etc.—as well as underlying genotype. For instance, many of the K-12 derived strains, such as E. coli JM109 constructed by J. Messing, do not have a "rough" colony morphology due to production of colanic acid and other exopolysaccharides. We would like to suggest that the phrase "and has a 'rough' colony morphology" be deleted from the proposed Appendix B revisions. Also, the phrase, "does not carry any genes," may be overly restrictive. In the Florida case, the investigator may have inactivated virulence factors by partial deletion of sequences. Reversion would be extremely unlikely, yet probes may detect presence of sequences not deleted from the host. Your committee may wish to consider modifying the last sentence of Appendix B to say, "does not carry any [functional genes] or [complete genes] encoding these factors."

Thank you for the opportunity to have provided these comments. Your efforts to keep these guidelines active and current are appreciated.

Sincerely,

Debra L. Hunt, MT (ASCP), DrPH, RBP, CBSP
President, American Biological Safety Association
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