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Applied BioSafety
Journal of the American Biological Safety Association
Volume 7, Number 1, 2002

In Memoriam

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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

Richard C. Knudsen, PhD
March 23, 1939 — February 21, 2002
In Memory of Richard C. Knudsen

Jonathan Y. Richmond

Centers for Disease Control and Prevention, Atlanta, Georgia

Richard C. Knudsen died early in the morning on February 21, 2002 after a noble and heroic struggle with cancer. He is survived by his wife, Kathy, two children, and three sisters.

Rich earned his PhD in Microbiology in 1971 from the University of Arizona and then completed a 2-year National Research Council Postdoctoral Fellowship with the Naval Medical Research Institute (NMRI) in Bethesda. He held positions in research at NMRI and the Plum Island Animal Disease Center (PIADC) in New York. Rich then focused his attention on biological safety, first at PIADC and then at the Centers for Disease Control and Prevention in Atlanta, serving for 11 years as Chief, Laboratory Safety Branch and as Biological Safety Officer.

During his professional career, Dr. Knudsen published 40 scientific papers on foot-and-mouth disease and African swine fever research and an additional 20 papers of biological safety interest. He was a recognized national and international expert on biological safety and a highly sought-after speaker.

Dr. Knudsen was very involved with the American Biological Safety Association. He served in various capacities, including President and Editor of Applied Biosafety. He served as a guest editor for the 4th edition of the CDC/NIH publication, Biosafety in Microbiological and Biomedical Laboratories. Rich was also an active mentor to ABSA members and others who sought his advice on biological safety matters.

Rich had also been very involved with the Boy Scout program in Atlanta as well as on Long Island. He coached several soccer teams and was always available to support his team members off the field as well. He will be missed by many.

A memorial fund has been established by the American Biological Safety Association (ABSA) to recognize excellence in scientific publication by its members. Those wishing to make donations in Rich's memory should make their checks payable to "American Biological Safety Association—R. C. Knudsen" and send them to: 1202 Allanson Road, Mundelein, Illinois 60060-3808. This professional association was a fundamental component of Rich's career as it provides a forum for the exchange of biosafety information, expands biosafety awareness, and promotes biosafety as a scientific discipline.
Maureen Best
Health Canada, Ottawa, Ontario, Canada

The abstracts in this edition of *Applied Biosafety* are compiled from ABSA’s 44th Annual Biological Safety Conference, held October 21-24, 2001. Once again the conference served to inform us about current biosafety issues and regulatory initiatives. We learned about the diversity of biosafety programs in other countries, biosafety issues encountered in the design and commissioning of containment facilities, pathogen inventory tracking tools, new innovative training techniques, and current approaches to decontamination. Technical papers on testing of decontamination systems, the creation of aerosols, and other applied biosafety research studies were presented. This is in keeping with ABSA’s goal of exchanging scientific knowledge and advancing biosafety as a scientific discipline.

Roundtable sessions were also included in the scientific program and provided a forum for interactive discussion on emerging issues. We discussed the pros and cons of using risk groups vs. biosafety levels. Classification of organisms according to risk group has been used by some countries to categorize the relative hazards of infective organisms. The roundtable discussion centered on whether or not the classification of organisms according to risk group is appropriate for the handling of biological hazards in the laboratory setting. For example, does the risk group system take into account the procedures that are to be employed during the manipulation of a particular organism? Would a classification system based on laboratory biosafety levels be an acceptable alternative? In addition to the inherent characteristics of each organism, this system includes the engineering, operational, technical, and physical requirements for manipulating a particular pathogen.

A second roundtable session presented the proposed new shipping regulations for infectious materials. Those of us involved in the packaging and shipping of specimens know how problematic this issue is. Shipping infectious materials can be especially difficult for some of our international affiliates where the availability of approved packaging and carriers is severely limited. The UN Committee on the Transport of Dangerous Goods is currently reviewing the requirements in the Model Regulations. Some of the problems identified include the complexity of the requirements and the notion that some requirements are directed to perceived risk rather than real risk. ABSA has a consulting status with the UN Subcommittee of Experts and can be proactive in the modification of the regulations. Members wishing to become involved in our effort should send an email to Penny Holeman at pholeman@acdus.jnj.com.

The Scientific Program Committee has released the “Call for Papers” for our 45th Annual Biosafety Conference to be held October 20-23, 2002 in San Francisco. All topics related to biological safety are requested, with a special emphasis on original research. I encourage everyone whose paper is approved for poster or oral presentation to submit his or her paper to be considered for publication in our Journal.

Finally, on a personal note, it is with sadness that we are publishing notification to our members of the death of Rich Knudsen. Rich was a Past-President of ABSA, a former editor of the Journal, and mentor to many of us. It was his wish that donations be made to ABSA to award the best paper published and a memorial fund has been established for this purpose.
Laboratory-acquired Meningococcal Disease—United States, 2000

*Morbidity and Mortality Weekly Reports (MMWR)*
February 22, 2002 / 51(07):141-144

**Editorial Note:**
In the interest of keeping the Association’s members informed of recent reports relative to safety, we are reprinting a discussion of laboratory-acquired infections that appeared in the February 22, 2002 issue of the *Morbidity and Mortality Weekly Report* (http://www.cdc.gov/mmwr). The case studies point out that even bacteria that are routinely encountered in the clinical laboratory still “pose a risk for microbiologists and should be handled in a manner that minimizes risk for exposure to aerosols and droplets.” All of us involved in biological safety should find the report illuminating and of assistance in maintaining safe working conditions for staff members in our respective facilities.

Ira F. Salkin, PhD, F(AAM)
Editor

*Neisseria meningitidis* is a leading cause of bacterial meningitis and sepsis among older children and young adults in the United States. *N. meningitidis* usually is transmitted through close contact with aerosols or secretions from the human nasopharynx. Although *N. meningitidis* is regularly isolated in clinical laboratories, it has infrequently been reported as a cause of laboratory-acquired infection. This report describes two probable cases of fatal laboratory-acquired meningococcal disease and the results of an inquiry to identify previously unreported cases. The findings indicate that *N. meningitidis* isolates pose a risk for microbiologists and should be handled in a manner that minimizes risk for exposure to aerosols or droplets.

**Case Reports**

**Case 1**

On July 15, 2000, an Alabama microbiologist aged 35 years presented to the emergency department of Hospital A with acute onset of generalized malaise, fever, and diffuse myalgias. The patient was given a prescription for oral antibiotics and released. On July 16, the patient returned to Hospital A, became tachycardic and hypotensive, and died 3 hours later. Blood cultures were positive for *N. meningitidis* serogroup C. Three days before the onset of symptoms, the patient had prepared a Gram's stain from the blood culture of a patient who was subsequently shown to have meningococcal disease. He also had handled and subcultured agar plates containing cerebrospinal fluid (CSF) cultures of *N. meningitidis* serogroup C from the same patient. Coworkers reported that in the laboratory, aspiration of materials from blood culture bottles was performed at the open laboratory bench; biosafety cabinets, eye protection, or masks were not used routinely for this procedure. Results of pulsed-field gel electrophoresis (PFGE) and multilocus enzyme electrophoresis (MEE) testing at CDC indicated that the two isolates were indistinguishable. The laboratory at Hospital A infrequently processed isolates of *N. meningitidis* and had not processed another meningococcal isolate during the previous 4 years.

**Case 2**

On December 24, 2000, a Michigan microbiologist aged 52 years had acute onset of sore throat, vomiting, headache, and fever. By December 25, the patient had
developed a petechial rash on both legs, which quickly evolved to widespread purpura. The patient presented to the emergency department of Hospital B and died later that day of overwhelming sepsis. Blood cultures were positive for *N. meningitidis* serogroup C. The patient was a microbiologist in the state public health laboratory and had worked on several *N. meningitidis* serogroup C isolates during the 2 weeks before becoming ill. That laboratory had handled a median of four meningococcal isolates per month (range: 0–11) during the previous 4 years. Coworkers reported that the patient had performed slide agglutination testing and recorded colonial morphology using typical biosafety level 2 (BSL 2) precautions; this did not entail the use of a biosafety cabinet. PFGE was performed at the state public health laboratory and at CDC on all four specimens handled by the microbiologist. Results of this testing indicated that the isolates from the patient and from one of the recently handled laboratory samples were indistinguishable.

To detect additional cases, on November 11, 2000, a request for information was posted on selected electronic mail discussion groups (i.e., listservs) to members of several infectious disease, microbiology, and infection control professional organizations. A probable case of laboratory-acquired meningococcal disease was defined as confirmed or probable meningococcal disease (CDC, 1997a) in a laboratory scientist who had had occupational exposure to a *N. meningitidis* isolate during the 14 days before onset of illness and who had illness with a serogroup that matched the source isolate. In addition to the two cases described in this report, CDC received an additional 14 reports of probable laboratory-acquired meningococcal disease worldwide during the preceding 15 years; six cases occurred in the United States during 1996-2001. The source isolates from five of these six U.S. cases were from either blood or CSF; the source of the sixth isolate could not be definitively determined but was most likely CSF or middle ear fluid. Of these 16 previously unreported cases, nine (56%) were caused by *N. meningitidis* serogroup B, and seven (44%) were caused by serogroup C. Eight cases (50%) were fatal (three from serogroup B and five from serogroup C). Case-fatality rates did not differ significantly by serogroups (serogroup C: 71%; serogroup B: 33%; *p*=0.16). In the 10 cases for which data were available, a median of 4 days (range: 2–10 days) passed between handling the source isolate and symptom onset. Procedures performed on the 16 source isolates included reading plates (50%), making subcultures on agar plates (50%), and performing serogroup identification at the bench (38%). In 15 of the 16 cases, the laboratory reportedly did not perform procedures within a biosafety cabinet. All 16 cases occurred among workers in the microbiology section of the laboratory. No cases were reported among workers in hematology, chemistry, or pathology.

**Reported by:** J. Lofgren, MD, B. Whitley, MPH, Alabama Dept of Health. D. Johnson, MD, F. Downes, DrPH, State Public Health Laboratory. P. Somsel, DrPH, B. Robinson-Dunn, PhD, J. Massey, DrPH, G. Stoltman, PhD, M.G. Stobierski, DVM, S. Bidol, MPH, Michigan Dept of Community Health. C. Hahn, MD, L. Tengelson, DVM, Idaho Dept of Public Health. P. Murray, PhD, American Society for Microbiology, Washington, DC. The Infectious Diseases Committee of the American Public Health Laboratories Association, Washington, DC. The College of American Pathologists, Waukegan, Illinois. D. Sewell, PhD, National Committee for Clinical Laboratory Standards, Wayne, Pennsylvania. W. Schaffner, MD, Vanderbilt University School of Medicine, Nashville, Tennessee. D. Stephens, Division of Infectious Diseases, Emory University School of Medicine, Atlanta, Georgia. M. Miller, Division of Healthcare Quality Promotion; J. Sejvar, MD, T. Popovic, MD, B. Perkins, MD, N. Rosenstein, MD, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases; National Institute for Occupational Safety and Health; Division of Laboratory Systems; Office of Health and Safety, CDC.

**Editorial Note:** Although the risk for disease remains low (Collins & Kennedy, 1999), laboratory-acquired meningococcal disease represents an occupational hazard to microbiologists. The findings in this report were self-reported and required respondents to have access to electronic media. However, the identification of 14 previously unreported cases and the additional two cases reported to CDC in 2001 suggest that either cases of laboratory-acquired meningococcal
Laboratory-acquired Meningococcal Disease—United States, 2000

disease has increased. The case-fatality rate of 50% in this report is substantially higher than that observed among community-acquired cases. This might reflect underreporting of mild cases or might be a result of the highly virulent strains and high concentration of organisms encountered in the laboratory setting.

Each year in the United States, approximately 3,000 isolates of invasive N. meningitidis are cultured (Boutet & Stuart, 2000). On the basis of standard practices used for isolation and identification of N. meningitidis, each of the clinical samples and isolates is handled by an average of three microbiologists during the course of a laboratory investigation, resulting in an estimated 9,000 microbiologists exposed per year. During 1996–2000 in the United States, six cases of probable laboratory-acquired meningococcal disease were detected, for an attack rate of 13 per 100,000 population (95% confidence interval [CI] = 5-29) at risk per year, compared with approximately 0.2 per 100,000 population among adults aged 30-59 in the United States (CDC, unpublished data, 2001), the age group of most laboratory scientists. If the three cases from 2000 are excluded from this estimate, the attack rate is seven per 100,000 (95% CI = 1-19).

N. meningitidis is classified as a biosafety level 2 organism (CDC, 1999). Guidelines recommend the use of a biosafety cabinet for mechanical manipulations of samples that have a substantial risk for droplet formation or aerosolization such as centrifuging, grinding, and blending procedures (CDC, 1999; NCCLS, 2001). Less is known about the risk associated with routine isolate manipulation.

The exclusive occurrence of probable laboratory-acquired cases in microbiologists suggests that exposure to isolates of N. meningitidis, and not patient samples, increases the risk for infection. Nearly all the microbiologists in this report were manipulating isolates and performing subplating with an inoculation loop on an open laboratory bench. A recent study indicated that manipulating suspensions of N. meningitidis outside a biosafety cabinet is associated with a high risk for contracting disease (Boutet & Stuart, 2000). Isolates obtained from a respiratory source are, in general, less pathogenic and represent a lower risk for microbiologists.

Although the exact mechanism of transmission in the laboratory setting is unclear, use of a biosafety cabinet during manipulation of sterile site isolates of N. meningitidis would ensure protection. Alternative methods of protection (e.g., splash guards and masks) from droplets and aerosols require additional assessment. If a biosafety cabinet or other means of protection is not available, manipulation of these isolates should be minimized, and workers should consider sending specimens to laboratories possessing this equipment. Education of microbiologists and strict adherence to these safety precautions when manipulating meningococcal isolates should further minimize the risk of infection. To address these safety issues, the governing bodies of organizations responsible for setting policy for laboratory safety will be reassessing current guidelines about the handling of N. meningitidis.

Although primary prevention should focus on laboratory safety, laboratory workers also should make informed decisions about vaccination. The quadrivalent meningococcal polysaccharide vaccine, which includes serogroups A, C, Y, and W-135, will decrease but not eliminate the risk for infection (CDC, 2000). Research and industrial laboratory scientists who are exposed routinely to N. meningitidis in solutions that might be aerosolized also should consider vaccination (CDC, 1991, 1997b; 2000). In addition, vaccination might be used as an adjunctive measure by microbiologists in clinical laboratories.

Laboratory scientists with percutaneous exposure to an invasive N. meningitidis isolate from a sterile site should receive treatment with penicillin; those with known mucosal exposure should receive antimicrobial chemoprophylaxis (CDC, 2000) (Table 1). Microbiologists who manipulate invasive N. meningitidis isolates in a manner that could induce aerosolization or droplet formation (including plating, subculturing, and sero-grouping) on an open bench top and in the absence of effective protection from droplets or aerosols also should consider antimicrobial chemoprophylaxis.

CDC has instituted prospective surveillance for laboratory-acquired meningococcal disease. Hospitals, laboratories, and public health departments that are aware of suspected cases should report these cases through their state public health department to CDC, telephone 404-639-3158.
### Table 1
Schedule for Administering Chemoprophylaxis Against Meningococcal Disease

<table>
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<td>&lt;1 month</td>
<td>5 mg/kg every 12 hours</td>
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<td>&gt;1 month</td>
<td>10 mg/kg every 12 hours</td>
<td>2 days</td>
</tr>
<tr>
<td></td>
<td>Adults</td>
<td>600 mg every 12 hours</td>
<td>2 days</td>
</tr>
<tr>
<td>Ciprofloxacin ‡</td>
<td>Adults</td>
<td>500 mg</td>
<td>Single dose</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>&lt;15 years</td>
<td>125 mg</td>
<td>Single intramuscular dose</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>Adults</td>
<td>250 mg</td>
<td>Single intramuscular dose</td>
</tr>
</tbody>
</table>

* Oral administration unless otherwise indicated.
† Not recommended for pregnant women because the drug is teratogenic in laboratory animals. Because the reliability of oral contraceptives may be affected by rifampin therapy, consideration should be given to using alternative contraceptive measures while rifampin is being administered.
‡ Not generally recommended for persons aged <18 years or for pregnant and lactating women because the drug causes cartilage damage in immature laboratory animals. However, ciprofloxacin can be used for chemoprophylaxis of children when no acceptable alternative therapy is available.

### References


Biosafety at the Tropical Medicine Institute “Pedro Kouri” (IPK) of Havana

Roberto J. Fernández and Patricia M. Jiménez
Department of Safety and Occupational Health, IPK, Havana, Cuba

Abstract

The Tropical Medicine Institute “Pedro Kouri” of Havana (IPK) was founded in 1937. Formerly engaged in parasitology, it has evolved into one of the top institutions in the Cuban Public Health System.

IPK comprises a complex of research laboratories and a 170-bed hospital. It is devoted to infectious and parasitic diseases and involved in research, teaching, reference diagnostic and medical services, special medical care, and epidemiological surveillance of communicable diseases.

The Institute employs about 700 workers who could be potentially exposed to different kinds and levels of physical, chemical, and biological hazards, so we are strongly motivated to employ a group with enough skill and expertise to implement a program to guarantee personnel safety, health, and environmental protection.

Some aspects of the evolution of biosafety in Cuba are described, as biosafety-related activities developed at IPK in the last 15 years and the improvements achieved by the organization are summarized.

Overview of IPK

Founded in 1937 by Professor Pedro Kouri, the Tropical Medicine Institute of Havana occupied the facilities of an ancient city hospital. Formally engaged in parasitological studies, it achieved its pinnacle in the 1940s and 1950s, but for some reason its activity declined sharply by the 1960s. However, its mission was expanded in late 1970s to address the risk of the introduction of exotic diseases as a consequence of growing Cuban exchanges with many third-world countries from Africa and Latin America and to cooperate with these countries in controlling tropical diseases. At this time, the Tropical Medicine Institute took the name of its founder, who had died some years before after making outstanding contributions to the fields of parasitology and tropical diseases.

The Tropical Medicine Institute “Pedro Kouri” (IPK) is a public health institution devoted to infectious and parasitic diseases and involved in research, teaching, reference diagnostic and medical services, special medical care, and epidemiological surveillance of communicable diseases. It consists of two main areas: a complex of research laboratories and a 170-bed hospital.

The complex of research laboratories includes 1) the National Reference Microbiology Lab: virology, bacteriology-mycology, tissue culture, and general services, plus an adjoining building housing a BSL3+ lab for special diagnostic services (presently under construction) and 2) The National Reference Parasitology Lab: parasitology, vector control, animal house, and insectary.

The hospital also is a National Reference Service for AIDS diagnosis and treatment and has: 1) eight medical wards (166 beds) and an ICU (four beds); 2) diagnostic laboratories: clinical, microbiology, pathology, and pharmacology; 3) other diagnostic services such as radiology, endoscopy; and 4) outpatient services.

Many common services are provided to both the research laboratories and the hospital, e.g., energy supply, laundry, solid waste disposal, incinerator, liquid waste treatment plant, etc.

In general, IPK has about 700 workers and they,
like in most health care centers, are exposed to different kinds and levels of physical, chemical, and biological hazards (Gestal, 1993). Laboratory workers usually handle infectious substances and diagnostic specimens while performing research or diagnostic activities and can potentially be exposed to biological hazards. Hospital personnel and occasionally other workers from the Institute could be in contact with patients and/or clinical samples that may result in exposure to bloodborne pathogens (human immunodeficiency virus [HIV], hepatitis B virus [HBV], hepatitis C virus [HCV], etc.) and tuberculosis (mainly), but also to several more pathogens as a consequence of their jobs.

Additionally, the IPK participates in scientific and academic exchanges with national and international organizations. The institute receives many visitors, researchers, students, and trainees from countries all over the world. Its objective is to employ staff with enough skill and expertise to guarantee personnel safety, health, and environmental protection.

**Background of Biosafety in Cuba**

For many years, isolated scientific leaders in some microbiology laboratories were concerned about occupational biological hazards. They took some empirical safety measures to protect their own staff, but this did not occur in a comprehensive or organized manner.

In the mid-1960s Cuba experienced accelerated and intense scientific development, particularly in biomedical sciences. Hospitals increased in number and the variety of services and Cuba's public health laboratory network were expanded. New research centers were constructed and staffed, and a growing biotechnological and pharmaceutical industry was established. These advances and expansions in health care, research, and biotechnology also led to the potential for increased exposure to new or more biohazardous materials.

In the early 1980s, a very small group of researchers, representative of the Cuban scientific centres, formed the Biological Front, an organization under the Cuban Academy of Sciences and the progenitor of the present complex known as the Scientific Pole of Western Havana. They formed a taskforce to face the challenge of developing and implementing a comprehensive biosafety program.

In 1983, the Cuban Academy of Sciences conducted a survey to explore staff knowledge about biosafety in the 10 most representative research institutions. The results obtained were poor. Afterwards, the first biosafety courses were established to disseminate knowledge, sensitize people to the importance of biosafety, and create a culture regarding this subject. An exiguous group of novice biosafety specialists started looking at project designs for new investments from a biosafety perspective.

At the same time there was an attempt to develop laws and regulations regarding biological safety throughout the country. However, this effort was not successful and many initial efforts were marked with very few accomplishments and many difficulties. It was under these circumstances in the 1980s that the development of a national biosafety program began.

Recently, the importance of the discipline of biosafety has received additional support from high levels. Following a review of the comprehensive and coordinated knowledge in the area of biosafety, the Cuban government now appreciates its importance. As a state party, and having obligations to the Biological and Toxin Weapons Convention (Convention, 1992) and those derived from the BTWC Third Review Conference in 1990, the government has placed increased emphasis on the development of robust biosafety professionals in Cuba.

In the five-year period between 1991 and 1996, important results were achieved. In those years, specialists working in this field increased in number and diversity, forming true multidisciplinary groups, looking not only to issues of human safety but widening their scope to animal and plant biosafety.

In addition, national courses on biosafety have been implemented annually. At technical schools and universities, programs from different specialities have incorporated biosafety issues into their curriculum. We have been working to develop a national biosafety culture and trying to disseminate biosafety information and skills nationwide to occupations and activities where biological hazards are present.

The National Center for Biological Safety (NCBS) was created in 1996 (CITMA, 1996) to be a consultative scientific body and national authority that regulates and ensures compliance in all areas related to biological safety in Cuba. In addition, recently approved Cuban laws and regulations (CITMA, 1999 a, b; CITMA,
create a rational basis to organize biosafety issues throughout the country. We believe Ministries and institutions should work to accomplish this goal in a proper manner and a reasonable time frame.

In the last few years, relationships with other organizations have been established and are increasing. Some of our specialists have had the opportunity to participate in different organizations, conferences, and events. Moreover, biosafety has become influential in solving problems of biodiversity, quality control, medical care, and other activities and aspects of the social and economic life in the country.

**Main Achievements at IPK**

Our general objective was to develop a comprehensive safety and occupational health program at the Tropical Medicine Institute "Pedro Kouri." To achieve this goal we have worked in a variety of areas and tried different approaches.

Since for many years attempts to organize biosafety at IPK were unsuccessful, in early 1996 we visited the Office of Health and Safety at the CDC and discussed various aspects of biosafety. After returning to IPK we conducted studies to develop and implement a biosafety program there. We established a biosafety group that has evolved into the Department of Safety and Occupational Health, which is staffed by eight individuals:

- **Department Chief**
- **Physical/Chemical/Radiation/Fire and Environmental Safety Group:** two specialists
- **Biological Safety Group:** one MD/microbiologist, one technician in hygiene and epidemiology and one vector control worker
- **Occupational Medicine Group:** one physician and one nurse

**General Activities**

We initiated an aggressive teaching and training program with our instructors often rapidly learning new biosafety information and then teaching it. Although we have been organizing local biosafety courses since 1983, recently we have greatly expanded our initial training program to include many other teaching activities.

We offer many biosafety courses and training classes. Every year internal biosafety courses are provided for IPK personnel and are specific for requirements at IPK. Annually, an official course is offered to personnel from a wide array of outside institutions (public health laboratories, research institutions, production facilities, etc.), professionals who may work with biohazardous material (medical doctors, nurses, biochemists, biologists, engineers, etc.), and individuals who may have limited experience working with biohazards (technicians, undergraduate students, residents, postgraduates). In addition to providing technical information, the course curriculum also covers a wide variety of topics including program administration, development, and support as well as applications in health care and research settings. These courses are attended by national and international participants.

We also provide teaching modules required to earn a master's degree in biosafety. This graduate-level degree is sponsored by the NCBS. In addition, we provide annual infection control courses at IPK for microbiology residents and students involved in earning a master's degree in infectology. Finally, we provide training and tutorial classes and exercises for individuals earning diplomas and thesis of residence in microbiology. IPK is strongly committed to teaching and providing training to students seeking professions in biosafety and medicine.

The Department of Safety and Occupational Health is also responsible for conducting risk assessment in all areas of the facility. We review occupational incidents, accidents, and disease records in the institution and its different programs and make recommendations to prevent further incidents. Technical experts observe working conditions and practices, and conduct inspections, audits, and inquiries. The department is responsible for writing manuals, guidelines, and other safety-related documents.

We consider biosafety and infection control in many ways as being “two sides of the same coin.” We work very closely with the hospital epidemiologist and the infection control nurse, strengthening relationships between those activities and biosafety activities at IPK. We promote the development of similar work relationships and goals in other hospitals and medical care settings. Two people from our staff also belong to the Infection Control Committee for the IPK hospital. Together we have implemented Universal Precautions (Fernández, 1998) and a tuberculosis control plan for
the hospital (Boroto et al., 2000) to assess the ventilation modifications made in the ICU at the IPK hospital and to design and establish an inpatient isolation unit for cholera vaccine clinical trials, etc.

Currently we are preparing for the commissioning of a BSL3+ laboratory that is presently under construction. We are developing a number of programs that will be used in commissioning the facility and will be integral to facility operations and personnel work requirements. Several programs and protocols are focused on aspects of technical containment and personal and environmental protection. The certification program for biological safety cabinets and high efficiency particulate air filters has recently started.

We have also developed a program to control solid waste treatment and disposal as well as provide for environmental controls regarding the liquid waste treatment plant. Similarly, the vector control program has been implemented not only to provide better working conditions in the facility, but also to prevent the inadvertent egress of potentially contaminated vectors.

Some of our programs are directed at strengthening our existing personal protection programs. Individuals working with pathogens or in occupations that may place them at risk of exposure will participate in our newly established medical surveillance and vaccination program.

An Institutional Biosafety Committee was recently created to deal with the review and approval of research protocols and other biosafety issues.

The implementation of the safety and oHealth program at IPK has directly resulted in achieving a balance in providing adequate levels of personnel safety and health and environmental protection in the facility, while raising the performance in biosafety to a higher level in accordance with international standards (Richmond & McKinney, 1999; WHO, 1993). This has indirectly resulted in improving the quality of all services offered by IPK, and we hope this program serves as a model for similar institutions in other developing countries.

**Lessons Learned and Advice**

We have found that in order to grow and excel in biosafety it is important to interact with biosafety experts in other organizations. As such, we attend training and educational courses from several sources. In 1984, when present facilities were under design, we received a short advisory visit from two skilled and well-known specialists representing WHO's Special Program of Safety Measures in Microbiology. They made a number of valuable suggestions which we have tried to implement in our current program. Additionally, after many years of requesting budget funds, we have been successful in participating in biosafety courses in Canada/LCDC (1993) and U.S./Johns Hopkins (1994). At present, one of our biosafety specialists is pursuing a master's degree course in biosafety in Cuba.

To further strengthen national biosafety capabilities we have developed a robust collaboration program with other institutes in Cuba that includes:

- Teaching and attending regional and provincial courses for PHL in the country
- Participating in courses organized by the National Center for Biological Safety (CNSB), Faculty of Biology/Havana University, Genetic Engineering and Biotechnology Center (CIGB), National Center for Scientific Research (CNIC), pharmaceutical industries, and others
- Providing biosafety advisory activities to different national institutions

Our Department of Occupational Safety and Health provides service to our country at the highest levels. We participate as members of the following national groups:

- Technical Advisory Group on Biosafety for the National Center of Biological Safety, Ministry of Science, Technology & Environment (CITMA), Cuba
- National Commission on Biosafety for the Ministry of Public Health, Cuba
- National Technical Advisory Group for the Biological Warfare Convention under the Ministry of Foreign Affairs, Cuba

We are also involved in a number of international activities. These include:

- ABSA membership: One person since 1994. ABSA has become a personal source of inspiration, knowledge, friendship, and support.
- Attendance at the 4th and 6th National Symposia on Biosafety
• Participation in the meeting of the Biosafety Advisory Group, Washington, DC (PAHO/AMRO, 1997)
• Scientific visits to CDC/OHS and Harvard School of Public Health

Conclusion

Cuba's biomedical and biotechnical industries have grown and developed into diverse industries. The complexity of public health services has likewise grown rapidly. These changes and advances required us to regard subjects like safety, hygiene, and environmental health as first priority actions to guarantee the protection of our personnel, the community, and the environment.

Despite some difficulties, many economic restraints, and lack of expertise in some areas, we have worked intensely and enthusiastically for more than 15 years to improve biosafety in Cuba. We have achieved a modest but important level of success in our facilities and are seeing some success nationwide. There is still too much work to be done in order to achieve the complete, harmonized, and integrated development of Biosafety in Cuba as a country, and particularly at IPK, but it can not wait longer. We believe: “Biosafety is not an option. It is a crucial need for the development of biological sciences that can not be postponed.”

References


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All opinions are those of the author and not of the American Biological Safety Association (ABSA) or endorsed thereby. The information contained in these abstracts do not constitute publication and should not be referenced as such in scientific literature. Data reported herein should be considered as tentative and subject to refinement or change prior to publication. Research findings communicated through the abstracts should be treated as “personal communication” from fellow investigators and receive credit as such in any situation where questions of priority may arise. The underlined name in these abstracts denotes the speaker who presented the studies.

Providing Biosafety Conditions in Research Work with Class I-IV Pathogenic Viruses at the SRC VB “Vector”

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The requirement to provide appropriate biosafety conditions in the research work with Class I-IV pathogenic viruses has become more and more important both nationally and internationally. This is demonstrated by the growing epidemiological significance of microorganisms that change their features, new pathogen discoveries, emerging and reemerging diseases, bioterrorism-related problems, military conflicts, ecological disasters, etc. For many years the SRC VB “VECTOR” has developed and implemented a comprehensive and integrated biosafety program for conducting research work with such highly dangerous viruses as Ebola, Marburg, Machupo, Lassa, Variola, and others. The biosafety program includes a complex of engineering, organizational, control, and biomedical measures. All the work is conducted in specially designed for virology studies facilities with the BSL3 and BSL4 containment laboratories and all the infrastructure of the biosafety engineering systems that are compatible with the Russian and the U.S. biosafety regulations and guidelines. The engineering biosafety systems include: ventilation systems of input and exhaust air flow with millipore filters, lock-chamber autoclaves and formalin steam chambers, liquid sewerage collecting and treatment system, system of disinfectants preparing and distributing, system of air supply to the pneumatic suits. Continuous functioning of the engineering biosafety systems and current control of their efficiency ensure safe conditions for viral research work. The programs for education and training of scientific and technical staff have been established. All the personnel working in the containment area are subject to obligatory instructions, training, and examination. Only those having basic medical or biological background, at least three years experience of work with highly dangerous viral pathogens, and special training courses are allowed to work on one’s own. Work in high-containment laboratories is compliant with national, international, and WHO requirements. Regulatory training-related methodological documentation has been elaborated. Plans of countermeasures in case of emergency situations or accident are foreseen. Taken together, these measures enable us to provide ensured and reliable biosafety conditions for the virology research.
Two Factors Influence Biological Safety: Human and Technical; Which is More Important?

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Research on the causative agents of especially dangerous infections (EDI) is always accompanied with the risk of infection. Two factors that strongly influence the medical and biological safety of the personnel are "human" and "technical" factors. In Russia, more than a 100 years of experience working with EDI under various conditions (both field or laboratory investigations) allows us to speak about the importance of the "human" factor and that of engineering systems. The "human" factor is dependent on each individual and directly depends on a skill of the researcher, his or her knowledge, experience, specialized training, health status, vaccination with specific vaccines, psychological state, and the preparedness of the employee for independent, optimum actions in case of unforeseen situations. The second factor, "technical" or engineering, represents a complex of engineering systems and their maintenance. These systems are integral to the requirements for providing medical and biological safety not only to the workers in the laboratory, but also to the surrounding population. Our experience and analysis of interrelation of the two factors indicate that for protection of man and the environment from microorganisms caused by especially dangerous infections, both factors should be considered as equivalently important in providing medical and biological safety when working with these pathogens.

We have found that there is some general confusion on the part of BSL2 laboratory personnel regarding when and when not to use a biological safety cabinet to minimize risk from aerosol formation when working with enteric pathogens. Although enteric organisms are not known to be infectious via inhalation, it was felt that a secondary route of infection, i.e. ingestion, may cause laboratory-acquired infection in workers from the ingestion of formerly aerosolized droplets containing microorganisms that may have been deposited around the work area. A literature search was conducted to assess the risk involved in performing some standard microbiological manipulations in the enterics laboratory. It was found that routine procedures such as centrifugation, opening screw-capped bottles and wet petri dish covers, improper use of a syringe, needle and septum, streaking plates, pipetting, slide agglutination, and microscopic preparations all have potential to cause aerosol formation. Over the years, laboratory manipulations with Salmonella, Shigella, E. coli 0157, and other E. coli have resulted in laboratory-acquired infection due to improper laboratory technique. It has been suggested in the literature that proper microbiological technique in combination with primary containment devices such as biological safety cabinets can reduce the risk of laboratory-acquired infections when working with enteric pathogens. It is the duty of the laboratory worker to ensure that he or she uses any means available by which to minimize the risks due to the infectious agent being manipulated.

Glanders: A Laboratory Infection Case Study

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On May 1, 2000, the first reported case of human glanders in the U.S. in over 50 years occurred in Frederick, Maryland. A civilian researcher working with Burkholderia mallei was infected during routine laboratory operations. During this presentation, a history of
glanders infections occurring in the United States will be reviewed, as well as symptomatology, incubation, types of infections, and treatment methods. This case study will address the employee's work habit, putative cause of exposure, course of illness, and subsequent recovery. We will comment on difficulties diagnosing the disease, the organizations that assisted USAMRRIID with the investigation, and the challenges and successes encountered. In conclusion, we will address the importance of evaluating the strengths and potential weaknesses of a biosafety program, as well as program preparations that may assist organizations in handling a similar event.

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The Biosafety Program at the World Health Organization

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The World Health Organization (WHO) promotes the use of safe practices in the handling of pathogenic microorganisms in different settings to keep the chances of unnecessary infection and all their consequences at the lowest possible level. An overview of biosafety activities within WHO will be given, with emphasis on the most recent developments within the context of transport of infectious substances.

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Immunological Prophylaxis of Dangerous Infections Within the System of Biosafety

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Specific immunization of personnel is one of the ways to augment medical and biological safety when conducting work with dangerous pathogens. To the present day, there is not a uniform consensus among international experts concerning which vaccines employees should receive when working with highly dangerous pathogens. In Russia, a system is in place regarding immunologic prophylaxis of individuals working in microbiological laboratories with dangerous pathogens. The efficiency of this system has been demonstrated by long-term experience working with different microorganisms. The underlying principle to provide maximum immunity involves the utilization of all available preparations and methods of fascination that have been proven to be safe, effective, and synergistic in preventing infection. In SRCAM, personnel are immunized against plague, anthrax, and tularemia in accordance with administration schedules and doses developed and proven effective for each vaccine. Revaccination against tularemia is performed every five years, and that against plague and anthrax is carried out annually. For specific protection against disease, measurements of antibody titers and other immunologic responses are important. Other measurements of immunogenicity are made by indirect immunological methods, such as reaction at the site of immunization (swelling, erythema). Efficiency of immunization against anthrax is indicated by measuring antibodies in blood serum, dermal response, and other parameters. Utilization of the direct and indirect tests for immunity allows for the measurement of immunologic prophylaxis and vaccine efficiency in people working in microbiological laboratories. It is an important component for decreasing the risk of infection of the personnel working with dangerous pathogens.

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Evaluation of Physiological Status of Virologists Working in Personal Protection Clothes

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The physiologic parameters of respiratory, cardiovascular, and thermoregulatory systems have been studied and monitored in male and female virologists with different experience of working with viruses (<1 year, 1-3 years, >3 years) in conditions of using the “Anti-protein-5” pneumatic suits, respirators ShB-1 “Lepestok—200” compared to the control group. The control group consisted of general biologists comparable with virologists by sex, age, and work experience. The specific technological procedures and work time breakdown of virologists have been preliminarily studied, as well as labor factors and physiological response in virologists working in personal protection clothes. Different conditions and operational variants of the personal protection means have been modeled in thermal box. The physiological parameters have been controlled and evaluated with instrument complex EOSPRINT (Germany), metabolism measuring complex MMC (“Beckman,” Austria), ECG BIOSET-6000 (Germany), hygrometer “Volna,” and other tools. The obtained data have been processed using “Statistica” software.

Regular overheating of virologists working in pneumatic suits has been shown to result in increased pulmonary ventilation: Those working in protection clothes during three-four years have had statistically proven (p<0.05) higher breath frequency and increased in-breathed volume per minute. These changes prove the decreased breathing efficacy. The virologists have been shown to have higher concentrations of carbonic acid in breathed out air (p<0.05).

Changes in thermoregulatory status of the experienced virologists have also been registered: They have higher core temperature in normal conditions and working hyperthermal level compared to the control group (p<0.05). Conditions of working in pneumatic suits affect the functions of the cardiovascular system. Statistically proven differences were observed in a group of virologists with three-four years work experience compared to the group with less than one year experience: The second group had higher diastolic blood pressure, peripheral vascular resistance, and lower rate for percussion blood volume (p<0.05). The labor activity of the virology labs personnel in personal protection clothes (“Anti-protein-5” pneumatic suits, respirators ShB-1 “Lepestok”) has been shown to cause the reduced energetic efficacy of the physiological functions and body reserve capabilities that is proven by the data on low-oxygen utilization in normal conditions, with higher breath frequency and increased in-breathed volume per minute, higher arterial blood pressure, and on the decreased efficacy of muscular activity. At standard labor load, the limit of body overheat is reached in two hours of continuous work in pneumatic suit “Anti-protein-5”; the change in body thermoregulatory status is explained by the decreased heat exchange in hermetic suit—higher normal core temperature, level of working hyperthermia, temperature level of sweating, and level of heat exchange through evaporation from the body skin.

The obtained results enabled to optimize working hours and labor conditions for virologists to provide safety as well as to improve the system of medical examination of the personnel to select those able to work in pneumatic suits.

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**Isolating Class III Biosafety Cabinet (4BP1, Unified Cabinet) for Microbiology Studies**


State Research Center of Virology and Biotechnology “Vector,” Koltsovo, Novosibirsk Region, Russia

The two types of isolating Class III biosafety cabinets have been developed at the State Research Center of Virology and Biotechnology “Vector” (SRC VB “Vector”). These designs have been successfully operated for several years and are referred to as isolating virology cabinet 4BP1 and unified cabinet for virology and microbiology studies. Both designs are for dual-side operation. The cases are made of noncorrosive stainless steel. They ensure complete isolation of the material on the inside from the environment by use of an hermetic case and units, high efficiency input and exhaust airflow filters, hydraulic locks, and hermetic fittings. They both are equipped with outside operated systems for disinfection and washing of the operational surface.
system of differential pressure control, and alarm with outside panel. Cabinet 4BP1 has two work places, detachable solid wastes collector, two lock-chambers for pass through of materials, filter elements FETO-60. Operational experience of using cabinet 4BP1 for virology research with Class III/IV pathogens has revealed a number of design shortcomings, such as insufficient working space and small sizes of pass-through devices. Taking these into account, the unified cabinet has been designed that has expanded operational space that allows to position portable equipment and devices and to work with small laboratory animals to include autopsy of small monkeys. The cabinet has four detachable gloves panels what makes it possible to make it Class II biosafety cabinet and equipped with FETO-750 filter elements. The experience in using these biosafety cabinets at the SRC VB “Vector” has proved high reliable performance and safety in virology research with Class III/IV pathogens.

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**Monitoring of Specific Contamination of Laboratory During Work with Filoviruses**

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One of the main actions during the scientific investigations with filoviruses is the maintenance of containment and monitoring for contamination of the air and surfaces inside the laboratory. Monitoring of air contamination is accomplished by sampling air through impingers MC-2, which effectively catch virus particles. Aerosol camera experiment showed the high ability of these impingers to collect virus in low concentration that is very important for controlling of air contamination. The volume of one air sample is 100 liters. Monitoring of laboratory surfaces is performed by sampling determined areas (100 cm²) comprising different surfaces with a moistened cotton swab. All samples were tested in three blind passages for specific activity in animal models and cell cultures. For Marburg virus guinea pigs and Vero cell culture were used; for Ebola virus we used newborn ICR mice and Vero cell culture. During the five-year period in infectious premises we collected and investigated 2,250 air samples and 2,500 surface samples from laboratories where work with highly dangerous pathogens is conducted. Virus has not been detected in any air sample. However, in surface samples the presence of live Marburg virus was detected twice. The first case was in the centrifuge rotor immediately after centrifugation of blood sera of infected animals. In the second case, virus was revealed on the light switch in the infectious vivarium. The analysis of contaminated places and thorough epidemiological study of these cases allowed us to modify procedures and produce additional training preventing repeated cases.

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**A Biotechnology Company’s Strategy for Biological Agent Inventory**

Robert J. Hashimoto and Heather Jutila

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Last year Genentech began a series of corporate audits designed to improve the health and safety status of the company. One area identified for improvement was the bloodborne pathogen exposure determination required for compliance to the Bloodborne Pathogen Standard.

In the past, Genentech maintained accountability of all Class 2 and Class 3 biological agents through its Institutional Biosafety Committee (IBC). However, Genentech did not have a mechanism to update IBC registrations and a recent inventory could not be verified for accuracy.

Consequently, the Biosafety Office prepared a survey to query the research community on the use of blood and other potentially infectious materials (OPIM). Since many of the bloodborne agents were
classified as Class 2 by the Centers for Disease Control and Prevention (CDC), the survey was expanded to include other biohazardous agents.

A secondary target of this survey now includes those agents regulated by the CDC Select Agents Standard, the standard designed to regulate the transfer and usage of certain biohazardous agents and toxins that have a potential for bioterrorism application.

Some concerns arose. Record-keeping, facilitation of response, and simplicity were discussed as potential complications of this project. Consequently, this poster demonstration will illustrate the information acquisition approach taken by Genentech and the mechanisms utilized to expedite a thorough and informed response by the research community.

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**A Risk Assessment of Biological Agents in a Medical Center in the Netherlands**

Edwin M. M. Hagelen and Annet Troelstra

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The European Community, through its directives, has obliged the member countries to identify biological hazards in the workplace and to assess the risk that those hazards could present. In the Netherlands, the Infection Control Department of the University Medical Center Utrecht developed and carried out a qualitative risk assessment to monitor the possible Laboratory Division employee exposure to the biological agents in use. Based on available literature, a questionnaire and checklist were developed. For all laboratories, the senior technician completed the questionnaire. All rooms of the 28 diagnostic and research laboratories were investigated by an occupational industrial hygienist. The results of the risk assessment were discussed with the personnel of the laboratories. We gained a good insight into the biological hazards that laboratory personnel face. Although workers were aware of the potential hazards present in their work areas, their practices were not always adequate for preventing exposure. The process of the risk assessment permitted discussion, optimization, and implementation of correct laboratory practices. This realization led to reduced exposure to infectious agents in the workplace.

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**Environmental Impacts of Treating Carcass Waste by Alkaline Hydrolysis; Characteristics of Treatability of Process Effluent**

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¹Biosafety Engineer, Cornell University, Ithaca, NY, ²Malcolm Pirnie, Inc., Buffalo, NY, ³Director, City of Ithaca Environmental Laboratories, Ithaca, NY

The College of Veterinary Medicine at Cornell University is developing a new facility to manage pathological waste (including infectious carcasses and bedding) and conventional regulated medical waste. Alkaline hydrolysis, a relatively new technology, will replace incineration to dispose of more than half a million pounds of carcass waste annually at the facility. The technology's disinfection efficacy has been well investigated, and its ability to inactivate prions (the causative agents of "Mad Cow Disease" and other transmissible spongiform encephalopathies) is currently being verified. In contrast to incineration, however, little has been published to date about the technology's environmental emissions. Specifically, the chemical characteristics of the technology's liquid effluent and air emissions as well as the treatability of the effluent in certain wastewater treatment processes have only recently been investigated. This presentation will highlight the results of the authors' investigations in these three important areas and provide a comparison to the environmental impacts of incineration.
Levels of Airborne Mold Spores During Cold-Room Cleaning

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During the planning for the renovation of one of our oldest building at the School of Medicine, it was noted the cold-rooms would need to be cleared of all hazards prior to turning them over to the contractors performing the renovation. Cold-rooms within this institution are generally shared among a number of groups and, consequently, are difficult to keep free of mold. We decided to take this opportunity to initiate an investigation to determine employee exposure to mold before and during clean up of these cold-rooms. Air sampling was conducted with an Aerotech sampling pump and Air-O-Cell cassettes and was analyzed by Aerotech Laboratories in Phoenix, Arizona. One baseline sample was taken a week before the scheduled cleaning and then again the day cleaning was to take place. Baseline spore counts ranged from 60 to 3,116 CFU/M³. Multiple samples were taken during the cleaning process and the resulting spore counts ranged from 98,000 to 1,201,320 CFU/M³. Though the air samples during quiet sampling (baseline) are in the range of outside levels, the species are predominately Aspergillus and Penicillium, species capable of aggravating symptoms in atopic individuals. An aggressive cleaning process can release sufficient quantities of spores and their associated mycotoxins to affect even nonatopic individuals. Proper PPE is essential to prevent respiratory injury and/or infection in immuno-compromised workers.

Put the “Power of Wow” back into your training! This session will exam why and how game show training formats can work to deliver biosafety training with real impact. Using case studies and learning theory, participants will learn about this exciting format while taking part in an actual game. Using popular game show formats can make a significant difference in participation, enthusiasm, and retention in biosafety training programs.

This program will cover how to: educate employees about key aspects of both biosafety and operational knowledge; create a competency-based learning tool to improve safety performance; encourage employees to share their knowledge and skill by contributing to game show content; identify gaps in biosafety systems and job tasks to promote consistency of knowledge and application of skills; contribute to maintaining excellence in biosafety performance criteria as established by world-class auditing systems; and encourage friendly competition between lab teams, resulting in a high level of interest and motivation among employees.

Presentation attendees will get a brief review on what current research is telling us about the impact of televised game shows on popular culture; understand the psychology of why game show formats appeal to people in general and employees specifically; learn which types of content lend themselves to being delivered through game show formats and limitations of game show formats; and learn the key steps in developing and implementing a successful game show program at their institution.

Effective Use of Game Show Formats for Biosafety Training

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Importance of Individual Training for the Observance of Medical and Biological Safety Requirements on Working with Especially Dangerous Infection Causative Agents In SRCAM

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Medical and biological safety regulations for working with especially dangerous infection causative agents in BSL3 laboratories (CII 1.2.011-94, COII 1.2.036-95) are authorized by the Ministry of Public Health of RF. These rules strictly regulate the training requirements of microbiologists and bacteriologists who have graduated from various educational institutions (specialized schools, institutes, universities) and are involved in work with especially dangerous pathogens. In order to obtain approval to work independently with microorganisms that are causative agents of especially dangerous infections in BSL3 laboratories, all employees of SRCAM must complete specialized training and earn the corresponding "admission certificate." The complete course of training takes from three to six months. Topics covered in the training program include theoretical manipulation of pathogenic material (simulants are used), knowledge of the biosafety regulations, good and safe microbiological practices and techniques, and "anti-epidemic" measures to maintain containment and prevent the release of organisms. The state certificate that is earned is respected throughout Russia. The training program allows the experts in the field of microbiology and bacteriology of especially dangerous infections to get a comprehensive knowledge of medical and biological safety requirements and to observe them when studying dangerous pathogens and other microorganisms, cell fragments, and genetic materials. A long-term practical experience in working with dangerous pathogens in SRCAM confirms the necessity of individual training in order to meet the requirements of medical and biological safety.

It has been shown that a HEPA membrane will allow 10³ PFU of viruses in the effluent stream in relation to a positive control of 10⁶ PFU, while creating severe pressure drop. A low-pressure drop, biocidal air filtering membrane was developed in view of individual and collective protection applications required in laboratory settings. The objective was to assess the biocidal filtration efficacy, self-sterilization capacity, and pressure drop values of these novel membranes. A bioaerosol was generated using a collision nebulizer. Filtration time was 30 minutes at 6 LPM for a 47 mm diameter sample. The filtered air was collected using AGI-30 and assayed. Two hours after filtration, membranes were sampled and assayed for evaluation of self-sterilization capacity. Against MS2 phage, the performance of the VF-56 membrane was beyond detection level (>99,99992%) compared with 72.88% for untreated material. Self-sterilization capacity of VF-81 averaged between 96.78% and 99.64%. Pressure drop values measured at 12 LPM for 47 mm VF-56, and VF-81 prototypes were 1.5 mm H₂O as opposed to 36-38 for HEPA material. The Tricosynation of low-quality, low-pressure drop membranes conveys to the treated material the ability of devitalizing microorganisms from an air stream without creating additional pressure drop. Tricysynated membranes demonstrated excellent self-sterilization properties that may prove useful when it comes to providing enhanced antiviral protection, handling, and disposal of filtering material.

Research on a Biocidal Membrane for Use in Individual and Collective Air Filtration

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Time Course Study of Inflow Velocity in Biological Safety Cabinet in National Institute of Infectious Diseases Japan

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The Class II Biological Safety Cabinet (BSC) is designed to minimize hazards to workers and to protect samples from cross-contamination. To maintain the good performance of BSC, regular monitoring of inflow velocity (IV) and downflow velocity (DV) is very important. At the National Institute of Infectious Diseases Japan (NIID Japan), more than 100 Class II BSCs are operating in Biological Safety level 2 (BSL2) and BSL3 laboratories. All BSCs are annually inspected by specialists. In most manufacturers’ specifications in Japan, the IV should be more than 0.5 m/sec. In this report we directly measured IV and DV of Class II BSCs that were actually in use in BSL2 laboratories in NIID Japan for several years. At the inspection in 1998, the mean IV of well conditioned BSCs was 0.64±0.07 m/sec, while that of poorly conditioned BSCs was 0.44±0.03 m/sec (mean±SD). BSCs that showed IV above 0.50 m/sec kept good performance in the following year. On the other hand, once IV fell below 0.50 m/sec, the IV never recovered and became unacceptable conditions within a year, despite the slight shortage of IV at the time of inspection. These BSC failures were mainly due to the clogged HEPA filters. From these results, we considered that mean value of 0.50 m/sec is appropriate, as the threshold value of IV, for the acceptable BSC condition.

Biosafety Organization in Spain

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The Act for the Prevention of Labour Risks, of November 8, 1995, produced other mandatory regulations, such as the Act for the Prevention Devices (January 17, 1997), the Act for the Protection of Workers from Risks Related to Biological Contaminants (May 12, 1997), the Act for the Minimal Safety and Health Requirements Related to the Use of Protective Equipment by the Workers (May 30, 1997), etc. Generally speaking, all these acts are not very different from those established by the European Law. The authority in charge of the implementation of these acts is the Ministry of Work.

In the field of biosafety, the May 12, 1997 Act provides a classification of human pathogens in four groups, as well as four different levels of containment, with more stringent requirements for industrial production.

Regarding genetically modified organisms, the last Act is from June 20, 1997, promulgated by the Ministry of Environment. There is a Biosafety National Commission responsible for the surveillance of the implementation of this normative, as well as for the authorization of any kind of genetic manipulation.

In Spain, there is no specific regulation for the containment of animal pathogens other than zoonotic agents, although institutions and private companies follow international rules, such as those published by the OIE, and especially the European Commission Security Standards for Foot-and-Mouth Laboratories (its last edition was published in 1996).

Design of a Room Pass-Through Using a Dual-Access Biological Safety Cabinet

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Nuaire Inc., Plymouth, MN

Pass-throughs between rooms have been used for many years as a means of moving material from dirty rooms to clean rooms. Traditional pass-throughs consist of a sealed chamber installed into a common wall between rooms. The doors are interlocked to prevent both doors being open at the same time, minimizing the spread of contamination between rooms. These traditional types of pass-throughs present many limiting factors in terms of size and function.

The use of a dual-access Biological Safety Cabinet (BSC) as a room pass-through offers many advantages over traditional room pass-throughs. The dual-access BSC provides both personnel and product protection.
from either side of the cabinet (i.e., clean side or dirty side). Other improvements include process techniques, communication, and quality assurance.

The use of a dual-access BSC, however, does present several unique installation considerations for proper operation: mechanical closure panels are required for room seals; room pressurization; supply/exhaust requirements; and normal room operations and their interaction within the larger facility. Even with these installation issues, using a dual-access BSC offers many benefits over traditional room pass-throughs.

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**Current Plague Epidemiology Issues in Kazakhstan**

Bakhtiyar M. Suleimenov, Bakyt B. Atshabar, and Larisa E. Nekrasova

Kazakh Research Institute for Plague Control, Almaty, Kazakhstan

Plague natural foci in Kazakhstan are located in different landscape zones: mountain, steppe, semi-desert and desert and occupy about 40% of the territory. The most dangerous in epidemic respect, acute local plague epizootics, are registered annually. In the year 2000, square kilometers of acute epizootics increased twice as much in comparison with 1999 when the area of acute epizootics was more than 40,000 km². Current peculiarities of plague epidemiology are closely connected with qualitative and quantitative changes of natural and man-made factors.

The most important natural factors:
- _R. opimus_ penetration in landscapes, formerly occupied by other species of rodents
- _R. opimus_ settlement of zones highways, oil and gas mains and railways
- _R. norvegicus_ penetration in zone of natural plague foci
- _Pirritans_ number increasing in houses

The most important factors attributed to human activity include:
- Introduction and expansion of agricultural activity by humans in the zone of natural plague foci
- Reduction of epizootic process control
- Reduction of the health monitoring and maintenance of health of camels
- Technical complications in the processing and relating of information and the transportation of patients

Strains of _Y. pestis_ with high virulence circulate in plague natural foci. The basic mechanism of human infection is transmission, through fleas bites, and during manipulations of infected camel meat. The main clinic forms of plague in people are bubonic and septic-bubonic. The existing system of epidemiological surveillance allows for the control of epidemiological situations of plague in Kazakhstan.

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**Canopy Exhaust System Performance**

Daniel Ghidoni

The Baker Company, Sanford, ME

Proposed revisions to NSF International Standard 49 define cabinet types that require canopy exhaust connections (CEC). The proposed standard calls for smoke testing as a means of verifying performance. Industry standards do not exist for design or for quantifiable performance testing of CECs. This research identifies performance variables that influence the safe operation of the biological safety cabinet (BSC) and its associated exhaust system. Methods for quantifying containment of the CEC air gap, effects of exhaust system fluctuations, and exhaust failure are identified and performance data are presented. The results show that CEC geometry affects the level of each performance variable. In order to define system operational performance levels, CEC test methods are required. In addition, CEC design affects the exhaust system's ability to maintain room pressurization and ventilation rate, especially during the BSC decontamination procedure. System design approaches utilizing CECs are offered and discussed. CEC design is critical to the safe operation of the laboratory, thus methods to assure proper operation and building integration are essential.
Working with Infectious Bacterial Agents: Procedures Used at Kazakhstan Plague Control Facilities

Ladsa E. Nekrasova, Bachtiyar M. Suleimenov, Bakyt B. Atshabar, and Tatyana V. Meka-Mechenko

Kazakh Research Institute for Plague Control, Almaty, Kazakhstan

The system of plague control facilities of Kazakhstan includes a plague control institute (Kazakh Research Institute for Plague Control-KRIPC), 8 regional plague control stations (PCS), 15 plague control departments (PCD), and more than 20 temporary epidemiological squads (ES). Their functions include detection and identification of infecting agent strains, including plague and other yersiniosis-type infections, tularemia, anthrax, brucellosis, cholera, pasteurellosis, and listeriosis that occur in Kazakhstan. Only plague control facilities can test samples for plague. Plague-enzootic area of Kazakhstan is 800,000 km² with acute epizootics occurring annually on the area of 20,000-30,000 km² where 300-400 strains are detected in the mountains, prairie, semiprairie, and desert locations. Strains of other infectious agents are detected in plague control laboratories, veterinary stations, and sanitation/epidemiological laboratories.

Detected strains undergo initial identification by epidemiological squads, plague control departments to plague control stations. As many as 800 strains may be transferred annually to a collection of live cultures at KIRPC. The final identification and selection of strains to be maintained as part of the live culture collection depends upon their scientific and practical value. The remaining strains are destroyed according to the appropriate directive. Periodically, bacteria strains are passed through laboratory animals, nutrient media and replaced for storage. Thus, the collection of bacteria strains in the museum is not constant but variable in quantity and quality relations.

Infectious strains are of great interest as most objective and useful indicators of epizootic and epidemiological processes. There is a need to develop an effective system of strain selection for our collection of microorganisms based on genetic and functional criteria.

Hemorrhagic Fevers in Kazakhstan

Bakyt B. Atshabar, Alim A. Aikimbaev, Alfarid O. Baitanaev, Seidym A. Aubakirov, Bakytały K. Jetybaev¹, Nursulu N. Tasmagambetova², Kandarat R. Rakhimov³, Seidigapbar M. Mamadaliev⁴, Alexandr K. Graidjanov⁵, and Erslan N. Kuandykov⁶

Kazakh Institute for Research on Plague Control, Almaty, ¹Jambyl Sanitary Station, ²Shimkent Sanitary Station, ³Shimkent Plague Control Station, ⁴Science Agriculture Institute Gvardeskii, ⁵Ural Plague Control Station, ⁶Kyzylorda Sanitary Station, Kazakhstan

There are natural epicenters for Congo-Crimean Hemorrhagic Fever (CCHF) virus in the three southern districts of Zhambyl, South Kazakhstan, and Kyzylorda in Kazakhstan. The infectious agent is the RNA-containing Nairovirus that belongs to the Bunyaviridae family. The natural vector for this virus is the Ixodes tick (Hyalomma asiaticum). In their adult stage, ticks parasitize farm animals; in their larva and nymphal stages they parasitize gerbils and other rodents. According to research data, ticks are found on 100% of farm animals in the center of contagion. In southern Kazakhstan 48 CCHF cases were reported in 1999 and 40 cases in 2000. The vast majority of the infected were farm workers. The differential diagnosis was made on the basis of clinical symptoms—fever, hemorrhagic syndrome, etc. and was also confirmed by serological diagnostics (indirect hemagglutination response and complementary typing against other similar infectious agents). Infected patients were injected with immunoglobulin and treated with proper therapeutic measures.

In 2000, four cases of hemorrhagic fever with nephrotic syndrome were detected in Western Kazakhstan. This viral infection has natural centers of contagion and is accompanied by fever and general toxicity complicated by a severe nephrosis/nephritis. The natural hosts for this virus are various rodents (field mice, voles, etc.). Food, dust, and possibly water may be contaminated by rodent excrements and may become a source of contagion. The virus cannot be transmitted through direct physical contact from one person to another. This outbreak in 2000 in Western Kazakhstan has demonstrated our inability to diagnose this disease. The data on the cases cited above are far from com-
plete. Due to insufficient funding, epidemiological control and the study of hemorrhagic fevers and epizootic conditions in Kazakhstan were not possible. We are applying through the ISTC for grants to develop diagnostic capabilities for this and other endemic diseases.

Plague Strain Infectivity in Kazakhstan

Alim A. Aikimbayev, Bakyt B. Atshabar, Seidym A. Aubakirov, Bakhtiyar M. Suleimenov, Tatiana V. Meka-Mechenko, Gulnaz S. Stbyayeva, Larisa E. Nekrasova, Kairat Tuganbayev

Kazakh Institute for Research on Plague Control, Almaty, Kazakhstan

Objectives: In Kazakhstan, when people are infected in the natural epicenter of an outbreak with Bubonic plague, it is almost always associated with septic complications. This indicates a high rate of pathogenicity associated with these plague strains. However, the infection is not transmitted every year or in all autonomous centers of contagion. In 1999, nine people were infected with plague, whereas in 2000 during the height of epizootics, a great number of infectious cultures where collected and propagated yet there were no humans infected. Lower infectivity was found in 95% of cultures present in laboratory animals. This indicates that infectivity and pathogenicity for humans may fluctuate from year to year. No cases of plague were reported in the Moiyncumskiy center of contagion and in the recently discovered enzootic areas: Talas, Betpakdala, Saksauldala.

Methods: Tests conducted using human cells, which are a more reliable model than laboratory animals, provided an opportunity to study strains of plague taken from infected patients and cadavers. We were able to study infectivity and virulence comparing strain samples from epidemics, vaccine EV strains, nonepidemic strains, and strains from Moiynnevskiy at the center of one particular epidemic.

Results: Strains taken from infected patients and cadavers were found to destroy cells, whereas EV strains and those taken from Moiyncumskiy epidemic did not.

Conclusions: Noninfectivity or lack of pathogenicity of plague strains from the Moiyncumskiy epidemic strain was demonstrated. Research on strain infectivity using molecular epidemiologic methods has begun. Results can be used for planning plague prophylaxis, forecasting severity of disease associated with epidemics, and better understanding the interactions between infectivity and pathogenicity.

Safety Training at the Centers for Disease Control and Prevention: From the Classroom to the Webroom

Richard J. Green, Patricia W. Galloway, Robert H. Hill, and Jonathan Y. Richmond, PhD, RBP

Centers for Disease Control and Prevention, Atlanta, GA

In 1999, the Centers for Disease Control and Prevention (CDC) implemented a new safety training policy which required all of its workers (17,000 today) to receive annual safety training. To accomplish this, the Office of Health and Safety developed a three-part course in both classroom-based and web-based venues entitled “Safety Survival Skills” (S3). Part I of the course covers “General Safety Responsibilities,” Part II, “Laboratory Safety,” and Part III, “Supervisory Safety Responsibilities.” Each classroom-based course is approximately two hours in length. Web-based courses each require from 30 minutes (Parts I and III) to 1-1/2 hours (Part II) to complete and are located behind the CDC firewall. Both classroom-based and Web-based courses require the successful completion of a final exam to receive full credit. New CDC workers must present a certificate of completion before being issued a permanent CDC ID/entry badge.

Now in its third year of implementation, many pitfalls have been overcome, but many more lurk just beneath the surface. As usage has increased each year, new problems have arisen, i.e., use of multiple plat-
forms, access from remote field sites, world-wide access, Web-master priorities, tracking and worker verification. This presentation will describe the difficulties encountered during the development and implementation of S3 and offer advice for future course developers.

**Challenges in Controlling Potential Agents of Bioterrorism: An Overview of the Select Agent Rule**

Mark L. Hemphill, MS, Shanna Nesby, and Jonathan Y. Richmond, PhD, RBP

Centers for Disease Control and Prevention, Atlanta, GA

The Antiterrorism and Effective Death Penalty Act of 1996 (Pub. L.104-132) authorizes the Secretary of Health and Human Services (HHS) to regulate the transfer of certain biological agents ("select agents") that have the potential to pose a severe threat to public health and are of potential use by terrorists. The Centers for Disease Control and Prevention (CDC) is the agency within the Department responsible for promulgating this regulation under 42 CFR 72.6, "Additional Requirements for Facilities Transferring or Receiving Select Agents." This regulation went into effect on April 15, 1997 and is designed to ensure that select agents are not shipped to parties within the United States who are not equipped to handle them appropriately, or who otherwise lack proper authorization for their requests. Under this regulation, facilities wishing to transfer select agents are required to register with CDC. CDC is required to (1) maintain data on registered facilities, (2) inspect those facilities to ensure that they are capable of safely working with and transferring select agents, (3) maintain data on shipments of select agents between registered facilities, and (4) work with law enforcement agencies when violations of the regulation occur or are suspected of having occurred. As of June 2001, 235 facilities have registered with CDC to transfer or receive select agents. Four years after the implementation of this novel regulation, we provide a status on the regulation and some of the issues and challenges that have been encountered during the implementation of this regulation.

**Commissioning a BSL3 Vaccine Production Facility**

Danielle Caucheteux

GlaxoSmithKline Biologicals s.a., Rixensart, Belgium

This paper will describe how we turned a BSL2 into a BSL3 in order to meet the production needs.

In other words, we will detail how the hazards were identified; how the risks were assessed; how the containment/control levels required were defined, on the basis of both corporate standards and European/national regulations. Further, we will explain how a team made up of engineers, production, safety, and QA people/managers materialized the project, taking into account both GMP rules in order to protect the product and safety requirements with regard to exposure/pollution control and process safety.

This experience illustrates how GMP and (bio)safety can supplement each other, provided we remain vigilant because if we don't, they might counteract each other.

**A Biological Way for Destruction of Illegal Papaver Somniferum L. Crops**

L. A. Glukhova and A. Abdulkadmov

Institute of Genetics and Plant Experimental Biology, Academy of Science, Republic of Uzbekistan

The Institute of Genetics and Plant Experimental Biology, Academy of Science, Republic of Uzbekistan is unique, having no analogues in the world. We have developed an environmentally safe method of biocon-
control and destruction of *Papaver somniferum* plants, specifically illegal narcotic plants using strains of the mycoherbicide, *Pleospora papaveracea* fungus, isolated and identified in 1991 by L. A. Glukhova. *Pleospora papaveracea*, according to numerous scientific publications, is the most harmful for opium-producing poppy plants in all the countries where it is grown. This naturally occurring opium poppy pathogen was discovered in Central Asia (Uzbekistan). Thirty-one strains of the pathogen have been separated. A high degree of susceptibility of 13 opium poppy biotypes from Afghanistan, Burma, Russia, and Central Asia region to the mycoherbicide has been established by testing.

By investigations of the fungus persistence in natural conditions in different soil stratifications, it has been determined that the fungus keeps its viability through 14 months of observation. By testing the pathogen on the wide range of plant species (198) from 58 families, we have established that the fungus is specifically pathogenic to opium poppy plants.

The fungus did not exert a toxic effect on rat liver cells. It does not propagate itself in warm-blooded organisms. On the basis of these data we recognize the mycoherbicide *Pleospora papaveracea* fungus as an environmentally safe agent for *Pleospora papaveracea* opium poppy crop control and eradication. The Project is supported by State Committee on Science and Techniques of Uzbekistan, USDA-ARS, and UNDCP.

Investigations on environment safety, separation of the fungus toxic component, determination of chemical structure of toxic compounds, and genetic stability of *Pleospora papaveracea* are in progress.

**Antibacterial Action of Yeasty Microorganism Rhodotorula Rubra (TG-1) on a Number of Human Infectious Agents**

N. I. Akhtyamova and A. A. Abdurkarimov

Institute of Genetics and Plant Experimental Biology, Academy of Science, Republic of Uzbekistan

A strain of *Rhodotorula rubra* TG-1 (TG-1) has been separated by N. I. Akhtyamova from rice plant endothelium. It moves through plants’ vascular systems, but does not adversely affect the plant. This strain exerts a pronounced antibacterial effect on a group of enteropathogenic colibacilla, which are common causative agents of colitenteritis in children. We have isolated and tested the effect of TG-1 in 215 cultures of Shigelia sonnei, Salmonella typhi, and 24 cultures of Vibrio cholerae, obtained from human clinical samples, drinking water, hydrobiotes, and other sources. The strain TG-1 has inhibited effectively all the cultures tested. It is especially effective in inhibiting the growth and propagation of *V. cholerae* cultures, separated from ill individuals and carriers of the organism.

Tests of TG-1 strain on the polyresistant cultures of *Pseudomonas aeruginosa* and on cultures, obtained from sick patients (with purulent-septic complications, otitis, osteomyelitis), show a high efficiency of TG-1 against *Ps. aeruginosa* isolated from various sources. The strain of *Rhodotorula rubra* TG-1 is not pathogen for mammals and does not persist in the blood or tissue. Production of the biomass TG-1 is not expensive, and it does not require additional complementary factors to nutrient medium for its growth. Currently, investigations are underway on separation, purification, and study of the structure of antibacterial toxic substances, produced by the strain *Rhodotorula rubra* TG-1. These investigations are financed by “Geninmae” Fund of State Committee of Republic of Uzbekistan on Science and Techniques and Academy of Sciences of Uzbekistan.

**Room Decontamination with Vapor Hydrogen Peroxide (VHP) for Environmental Control of Parvovirus**

Gerald E. McDonnell1, PhD, James Hartling2, Stephanie Armige3, Bezi Belete1, and Claire Fritz1

1STERIS Corporation, Mentor, OH, 2Fort Dodge Animal Health, Fort Dodge, IA

Vaporized hydrogen peroxide biodecontamination has been widely used due to its rapid action and safety in use, as it can be easily broken down into environmentally safe byproducts of water vapor and oxygen at
the end of a cycle. The VHP$^2$ 1000 is a self-contained hydrogen peroxide vapor generator used for the decontamination of clean, hard, dry surfaces. This report describes the successful decontamination of a laboratory animal facility room (>5,500 ft$^3$) using this system. The efficacy of room decontamination was studied using bacterial spores and parvovirus, as indicators of process effectiveness. Parvoviridae are recognized as the most resistant viral family to disinfectants and sterilants, and, due to their ability to survive adverse environmental conditions, they are particularly contagious and difficult to eradicate from critical environments. A 5,600 ft rectangular room consisting of 30 individual animal cages and a general purpose area was shown to be successfully decontaminated in just over three hours (total cycle time), with no adverse material compatibility observed. Triplicate cycles were evaluated with VHPD biological (Bacillus stearothermophilus spores) and chemical indicators randomly distributed around the room, on the walls, ceiling, and floor. In addition, mouse parvovirus carriers ($10^3$ viable virus particles dried onto the surface of plastic petri plates) were randomly positioned around the room. A total of 60 biological indicators, 30 chemical indicators, and seven parvovirus carriers were evaluated for each cycle evaluated. All chemical indicators (90) indicated the presence of VHP$^2$ following each decontamination cycle. Similarly, all biological indicators (180) and recovered virus samples (21) demonstrated no growth following decontamination. Vaporized hydrogen peroxide offers a significant saving in time and expense in comparison to manual room decontamination methods.

The proliferation of infectious diseases transmitted by vectors throughout the world including the emergence of West Nile Virus in North America has led to a resurgence in applied research in this field. In addition to the standard containment requirements, specialized facilities, equipment, and practices are required to ensure the safety of research personnel, other employees, and the surrounding community when working with these agents or infected vectors. This Roundtable will outline information on Insectary design, protocol review, and safe working practices for containment and collection of agents classified at BSL2 and BSL3. Proposed Guidelines on arthropod containment will be reviewed and relevant applications of vector containment for biolabor control will be provided. Finally, Biosafety practices for field research and elements of a vector control program for public health will be presented.

Arthropod Containment Levels and Insectary Design: Overview of the development of arthropod containment levels and their practical application in design and use strategies in a multidisciplinary university setting. Arthropod containment levels meet the challenge of vector control to provide safe use and handling of vectors in research while protecting the researcher, the institution, and the surrounding community.

### Break Out Session

**Arthropod Risks and Safety Considerations**

Moderator: Robert Shope, PhD, Stephen Higgs$^1$, PhD; Scott Weaver$^1$, PhD; Durland Fish$^2$, PhD; Gregg J. Hunt$^3$, PhD; Dawn Wesson$^4$, PhD; Janet McAllister$^5$, PhD

$^1$University of Texas Medical Branch, Galveston, TX; $^2$Yale School of Medicine, New Haven, CT; $^3$Agriculture Research Service, Anthopod-Borne Animal Diseases Research Laboratory, Laramie, WY; $^4$Department of Tropical Medicine, Tulane School of Public Health, New Orleans, LA; $^5$New Orleans Mosquito and Termite Control Board, New Orleans, LA

### Break Out Session

Field Collection of Arbovirus Vectors: Biological Safety Implications

Scott Weaver, PhD

Associate Professor, Department of Pathology and Center for Tropical Diseases, University of Texas Medical Branch, Galveston, TX
Elucidation of arbovirus transmission cycles requires field studies to incriminate vector species. Traditional criteria for vector incrimination include: (1) demonstration of feeding or other effective contact with pathogen's host; (2) association in time and space of the vector and pathogen; (3) repeated demonstration of natural infection of the vector; and (4) experimental transmission of the pathogen by the vector. Fulfillment of these criteria usually requires the capture of very large numbers of arthropods for virus isolation, followed by experimental laboratory transmission studies to ensure that species found infected in nature are competent vectors. Both of these activities, especially the latter, are accompanied by biological safety risks. Some mosquitoes readily enter light and CO₂-baited traps (e.g., CDC traps) and therefore can be collected without much risk to the investigator. However, some mosquitoes are not attracted to most traps, and some bite only humans and nonhuman primates. These species have traditionally been collected using human landing collections, which may increase the risk of infection by vector-borne pathogens to the investigator. This risk should be evaluated on an individual basis to assess the increased risk to the investigator associated with the collections. For viruses transmitted to rodents or other small reservoir hosts, we combine collection and transmission detection using animal-baited traps (e.g., hamster for Venezuelan equine encephalitis [VEE] virus). This method simplifies the vector incrimination process in several ways: (1) hamster-baited traps attract and capture only arthropod species that are attracted to rodents, the natural reservoir hosts of the enzootic VEE viruses, minimizing collection efforts; (2) there is no need to sort arthropod collections from traps when no transmission occurs, greatly reducing a laborious step in the vector incrimination process; (3) only a small number of arthropod pools must be tested for virus, eliminating much of the cost and biological safety risk associated with traditional approaches. In addition, the hamster-baited traps serve as sentinels for detection of active virus circulation in a forest and sometimes reveal the presence of other viruses in a focus. However, unlike other sentinel enclosures that allow arthropods to escape after biting a viremic bait animal and thereby initiate artificial amplification, the hamster-baited traps capture the arthropods that bite the viremic host and prevent most or all artificial amplification.

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**Break Out Session**

**Biosafety Considerations for Tick-Borne Pathogen Studies in the Laboratory and Field**

Durand Fish, PhD

Yale School of Medicine, Department of Epidemiology and Public Health, New Haven, CT

The unique biological attributes of ticks and other aracnines pose special problems for studies of transmissible agents both in the laboratory and field. Research on tick-borne pathogens in the Department of Epidemiology and Public Health involves the maintenance of laboratory colonies of two tick species (*Ixodes scapularis* and *Rhipicephalus sanguineus*) and transmissible BSL2 spirochetes (*Borrelia burgdorferi*, and a new species of *Borrelia*), a BSL2+ rickettsial agent (*Ehrlichia phagocytophila*), and BSL3 spotted fever rickettsial agents (*Rickettsia conori*, *Rickettsia rickettsii*, *Rickettsia africa*, etc.), and flaviviral agents (Powassan virus and West Nile virus). Specific protocols have been adopted for feeding pathogen-infected ticks on rams, mice, rabbits, and guinea pigs for the isolation and propagation of tick-borne pathogens in culture and through continuous tick/host propagation cycles. Biosafety procedures involve containment of pathogen-infected ticks under laboratory conditions, containment of pathogen-infected farm and laboratory animals, and experimental pathogen transmission studies and culture of pathogens from infected animals in the laboratory. Protocols have also been adopted for field studies and field courses involving naturally occurring tick-borne pathogens in endemic areas. Biosafety procedures for tick collecting include protective clothing, monitoring for attached ticks, and recognition of clinical symptoms, and respiratory protection is required for collecting and handling wild mice. Detailed written Standard Operating Procedures are prepared by the investigators for each
protocol and approved by the Yale Biological Safety Committee and the Yale Animal Care and Use Committee. All personnel are trained in the required safety procedures and authorized for these experiments. Start-up meetings are held with research staff, biosafety staff, and Animal Care personnel to finalize procedures before initiation of projects. Finally, in accord with a unique State regulation, the proposed research facilities are evaluated by a representative from the State of Connecticut Department of Public Health.

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**Break Out Session**

**Biosafety Level 3 Containment Facility: Handling West Nile Virus-Exposed Insects Safely and Securely**

Gregg J. Hunt, MS, MPH

USDA, Agricultural Research Service, Arthropod-Borne Animal Diseases Research Laboratory, Laramie, WY

The understanding of pathogen-vector-host interactions is essential to control arthropod-borne animal diseases. One such contagion that is being studied at the Arthropod-borne Animal Diseases Research Laboratory (ABADRRL) of the Agricultural Research Service, U.S. Department of Agriculture, is the West Nile virus (WNV). Our BSL3 agricultural containment facility represents the only laboratory within the USDA research program that is authorized to study the WNV, potential insect vectors, and large animal hosts simultaneously. Combinations of containment (e.g., laboratory practices and techniques, safety equipment, and facility design and construction), if used correctly, prevent the exposure of laboratory personnel to zoonotic pathogens and hematophagous insects, and prevent the escape of these hazardous disease agents or infected insects into the environment that may endanger domestic livestock, wildlife, or human populations.

A succinct review of the various equipment and protocols used to handle WNV-exposed biting midges (e.g., Culicoides sp.) and mosquitoes (e.g., Aedes sp., Culex sp., Culiseta sp., and Psorophora sp.) safely and securely during studies conducted in our BSL3 containment facility will be presented.

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**Break Out Session**

**Laboratory Design and Biosafety Considerations for Mosquito-Borne Pathogen Studies**

Dawn M. Wesson, PhD

Associate Professor, Department of Tropical Medicine, Tulane School of Public Health and Tropical Medicine, New Orleans, LA

(Abstract not provided.)

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**Break Out Session**

**Vector-Borne Disease Surveillance in a Working Mosquito Control District**

Janet McAllister, PhD, BCE

Senior Entomologist, New Orleans Mosquito and Termite Control Board, New Orleans, LA

Surveillance for vector-borne diseases in New Orleans is done on a yearly basis. Early warning of virus activity in an area through the use of sentinel flocks and mosquito pools is an essential part of mosquito control operations. This surveillance translates into weekly collections of mosquitoes and blood from the field. How these samples are collected and handled will be described. What happens when virus activity is detected will be discussed.
Break Out Session  
Risk Groups V Biosafety Levels: Pros and Cons  
Moderator: Stefan Wagener, PhD, CBSP, Nicoletta Previsani, Marianne Heisz, Diane Fleming, and Richard Knudsen  

(Abstract not provided.)

The Vanderbilt University Human Gene Transfer Advisory Group—One Model for Monitoring Human Gene Transfer Research  
LouAnn C. Burnett and Kenneth L. Brigham  
Vanderbilt University, Nashville, TN

Based on the events surrounding the highly publicized death in a human gene transfer trial, our own experiences, and discussions with peer institutions, the Vanderbilt Institutional Biosafety Committee (IBC) recognized the need for more comprehensive, cooperative review of human gene transfer research at Vanderbilt and recommended the formation of an advisory group to initiate such a review. Thus was born Vanderbilt’s Human Gene Transfer Advisory Group (HGTAG). The core membership of the HGTAG includes representatives from the IBC, Institutional Review Boards (IRB), Pharmacy, Legal Counsel, General Clinical Research Center, Clinical Trials Center, Infection Control Committee, and the Occupational Health Clinic, in addition to investigators conducting human gene transfer trials. The purpose of the HGTAG is: 1) to facilitate the approval processes required for human gene transfer research; 2) to advise the IBC, IRB, investigators, and others in matters relevant to human gene transfer; 3) to compile and maintain a list of all human gene transfer protocols; and 4) to be aware of and to communicate current compliance issues in human gene transfer to the Vanderbilt community. This presentation will provide more detail about the creation, implementation, and continuing function of the Vanderbilt HGTAG, with specific cases of successes, false starts, and lessons learned.

Security Considerations for Microbiological and Biomedical Facilities  
Chris Royse and Barbara Johnson, PhD, RBP

Science Applications International Corporation

In the past years, increased concerns have been raised regarding the adequacy and implementation of security programs in biomedical institutes and facilities working with and storing pathogens. The perceived need for increased security requirements has been codified as a result of: 1) criminal activity by animal rights activists; 2) the necessity to protect intellectual rights/information, patent material/processes, and business sensitive information; and 3) recognition of the potential for terrorists or individuals to obtain biological pathogens for criminal/terrorist use.

The objective of this presentation is to provide information regarding components of a security program and the tools for developing a decision matrix to determine the security needs at a facility. In an attempt to develop a systematic and rational approach to defining a successful, cost-effective security program we will review: 1) security risk assessment and management; 2) methods for administrative and technical control at the facility and material level; 3) identification and nature of assets; 4) vulnerabilities and threats; 5) countermeasures to prevent security breeches; and 6) balancing the need for security with other programmatic requirements.
The Art of Biosafety Auditing in Industry

Richard Rebar, MS, RBP, CBSP
GlaxoSmithKline, King of Prussia, PA

The goals of biosafety in the workplace are: 1) to prevent employees and their families from acquiring laboratory-associated infectious diseases; 2) to prevent contamination of the environment and promote environmental quality; and 3) to comply with all national, international, and local regulations for the use of biohazards.

In order to achieve these goals, the biosafety professional needs to establish a quality biosafety program. This program should consist of the appointment of competent individuals to coordinate the program, conducting risk assessments to identify and control the biohazards, establishing training and communication programs, developing and implementing standard operating procedures for the use, emergency response, and disposal of biohazards, and finally developing a method to ensure that the programs and procedures are operating effectively.

There are several ways to ensure that the procedures and practices that have been developed are, in fact, being implemented. Site inspections can be conducted by site personnel to monitor compliance and routine site operations. These inspections can be conducted by department staff, site Safety Committee members, site safety professionals, or site management. Inspections generally cover the physical aspects of the biosafety program and provide an indication as to how well biosafety procedures are being followed. An inspection, though, is not the same as an audit. An audit is an in-depth analysis of how well the program is operating. Site inspections are included in an audit, but the audit looks at the site’s management procedures. Inspections provide a snapshot of how a site is performing at a given point in time, while an audit provides an analysis of how you ensure that the site’s policies and procedures are carried out consistently and whether the site’s procedures are effectively controlling the hazards and risks. Auditing a program consists of conducting a physical inspection of the site’s facilities, reviewing written procedures for the use and control of biohazards, and reviewing all documentation concerning the site’s biosafety program (e.g., training records, site risk assessments, medical records, disposal records, self-inspection documents, etc.). A follow-up system is also needed to ensure that corrective actions are taken to eliminate identified deficiencies that are noted during the audit and to prevent recurrences of the specified problem.

Status and Effect of Polio Virus Eradication on Laboratories Storing and Working with Virus

Jonathan Y. Richmond, PhD, RBP
Centers for Disease Control and Prevention, Atlanta, GA

As the effort to eradicate wild poliovirus continues towards reaching its goal in the next few years, several activities affecting the biosafety community and some of its laboratories are underway. Identification of all laboratories that may have samples containing wild poliovirus is becoming a higher priority. Humans are the only reservoir for wild poliovirus. When there no longer is wild poliovirus circulating among humans, the only remaining source of the virus will be frozen laboratory samples. Identification of such laboratories in the U.S. is proceeding in several stages. A pilot program was rolled out at two of the nation’s largest and most diverse federal institutions, CDC and NIH. The plan was successfully implemented in the spring of 2001. With input from the laboratorians, adjustments to the electronic communications materials were made. A second pilot beta testing was done during the summer of 2001 at several universities. The implementation plan for Phase I of the national laboratory survey initiative will be previewed; roll-out will begin during the winter of 2002.

The WHO Biosafety Advisory Group has been revisiting the recommendations for working safely with samples known to contain, or potentially containing,
wild poliovirus. A matrix for selecting the appropriate biosafety level based on the risk assessment for the samples to be manipulated will be presented at this conference.

Gene Therapy Biosafety

Larry Kowal, CSP, CBSP, CHO, CHMM
Genetic Therapy, Inc., Gaithersburg, MD

The number of laboratories performing gene therapy studies or generating DNA vectors from viral-based organisms is extensive and increasing every day. The potential benefits offered by this therapy are revolutionary. However, with multiple hurdles still requiring resolution, the number of final products remains minimal. These hurdles require the research scientist to become increasingly creative with his or her approaches and experiments. Trying to maintain laboratory biosafety throughout this research stage remains an art in balancing creative policy enforcement, regulatory interpretation, scientifically prudent practices, as well as conventional biosafety. This presentation will summarize some of the innovative approaches scientists are using to generate the gene therapy constructs, and then review the regulatory directives that currently exist. The presentation will conclude with some of the approaches used by private companies and institutions to control hazardous biosafety issues.

Assessing Laboratory Animal Containment Systems

Allan M. Bennett and Simon R. Parks
Centre for Applied Microbiology and Research (CAMR), Porton Down, UK

Under UK governmental regulations, wherever possible, laboratory animals infected with BSL3 agents must be housed and handled inside containment equipment in order to provide optimal protection to the operator and the environment. In practice, small laboratory animals are housed either in isolators or in individually ventilated cage racks. The UK Health and Safety Executive has funded a research program carried out by CAMR to investigate the performance of this equipment. Pressure hold testing and dispersed oil particle filter testing methods have been used to carry out leak tests of the following containment systems: 1) individually ventilated cage racks; 2) flexible film isolators (1.5 m³ volume); and 3) flexible film isolators with half suits (4m³ volume).

Biological aerosol testing has also been carried out on this apparatus under in-use conditions. Procedures such as transfer of material in and out of the isolators through a pass box and waste removal have been studied. The units were also tested under accident scenarios such as large leaks in the isolator canopy and glove punctures. The performance of the equipment was measured using the operator protection factor concept (OPF). The OPF is the ratio of the microbial aerosol inside the containment to outside the containment. It was found that the large half-suit isolator gave the best general performance. The IVCs were found to perform well when the cages were attached to the ventilation unit, but upon cage removal from the rack, negative pressure was lost and so material was found to leak from the cages. All systems were shown to create more manual handling problems than conventional equipment.

Microbiological Testing and Performance Characteristics of a “Walk-In” Biological Safety Cabinet

Cliff Colby, David Stuart, and Eugene Lockhart
The Baker Company, Sanford, ME

As part of the development of a large “walk-in” Biological Safety Cabinet, The Baker Company performed performance testing and microbiological aerosol
testing. The purpose of these tests was to insure the health and safety of laboratorians and to document the level of product protection. The Baker Company performed these tests per NSF 49 and modified the tests to address the unique features of this large cabinet. Further, testing was conducted in art "as used" condition to reflect actual laboratory conditions. The results of Baker's testing confirm that this unique Biological Safety Cabinet meets the performance criteria for Class II Biological Safety Cabinets with respect to personnel and product protection from bioaerosols. The Baker Company presents these data as an aid to biosafety officers to help in approving equipment for its facilities.

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**Temperature Stratification Testing of a Biowaste Cooker Without Agitation**

Les Wittmeier\(^1\), Gilles Tremblay\(^2\), PWGSC, CSCHAH, and Lee H. Thompson\(^3\)

\(^1\)Public Works and Government Services Canada, Winnipeg, Manitoba, Canada, \(^2\)Canadian Science Centre for Human and Animal Health (CSCHAH), Winnipeg, Manitoba, Canada, \(^3\)Health Canada, CSCHAH, Winnipeg, Manitoba, Canada

The CSCHAH uses a steam-heated batch processing system for secondary treatment of liquid from its agricultural BSL3 and combined BSL4 laboratories. Each tank is capable of processing up to 4,500 litres of waste and was designed to be heated indirectly via a steam jacket and an internal agitator. Problems were encountered with the mechanical seals on the agitator shaft with high consumption of barrier fluid. This problem created concerns for the integrity of the systems and also was the source of significant pressures on limited operations resources. As a possible solution to the problem, the removal of the paddles and shafts was recommended. The first step was a biological validation with the agitator and internal steam shut off. Results indicated no negative effect on the sterilization capability of the system. Temperature stratification of the load was the next concern. To test the temperature stratification, one of the biowaste cookers at the CSCHAH had a calibrated multipoint temperature probe inserted vertically to test temperatures at 10-inch intervals, the agitator was disabled (motion and steam). Ten clean loads were processed with temperatures recorded every two minutes during the sterilization phase. Results indicated that stratification was not a problem. The only operational impact was the increase in time to bring the load up to sterilization temperature. The shaft was removed from one biowaste cooker and the temperature tests were conducted and previous results were confirmed. The shafts will be removed on the two remaining biowaste cookers. A properly designed jacketed system can decrease processing time as well as eliminate concerns of temperature stratification.

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**Microbial Aerosols in Dental Surgery**

Allan M. Bennett, Martin Fulford\(^1\), Jimmy Walker, David Bradshaw, Mike Martin\(^2\), and Philip Marsh

\(^1\)Centre for Applied Microbiology and Research, Porton Down, UK, \(^2\)Shepton Mallet and University of Liverpool, UK

Microbial aerosols in dental surgeries have been regarded as a potential source of infection by bloodborne pathogens such as HIV and HBV, and with respiratory pathogens such as *Mycobacterium tuberculosis*. Previous surveys of dental aerosols have been carried out in dental hospitals, often with inappropriate air sampling equipment. In this study, sampling for both airborne micro-organisms and aerosolized blood has been carried out continuously during 13 treatment sessions in general dental practices in the South West of England. The findings were as follows.

The microbial aerosol concentration in treatment rooms was generally less than \(10^3\) colony forming units per cubic metre (CFU/M\(^3\)). However, in 7 out of the 13 visits, at least one peak concentration with much higher CFU/M\(^3\) was detected. The peak concentrations were associated with increased recoveries of oral streptococci, strongly suggesting their origin from the
mouth. The aerosol peaks dissipated within 30 minutes. Peak microbial aerosol concentrations were detected following mechanical scaling procedures (47% of procedures) and to a lesser extent following cavity preparation (11%). No aerosolized blood was detected. No dispersal of microbial aerosol into adjoining areas was detected. A risk assessment carried out on the data suggests that dentists and their assistants may have a slightly higher risk of exposure to *Mycobacterium tuberculosis* than the general public. This risk could be reduced by the use of appropriate respiratory protection by the dentists and their assistants.

This work was funded by the NHS R&D Primary Dental Care Programme.

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**Break Out Session**

**Federal Regulations: All of Your Answers and POCOS**

Moderator: Paul Mcchan⁴, PhD, RBP, Melody Sands⁵, James Wagner⁶, Richard Knudsen⁷, PhD; Art Rutledge⁸, and E. Mazzullo⁹

⁴Merck Research Laboratory, West Point, PA, ⁵Director, Office of Health Compliance Assistance, OSHA, DOL, ⁶President, MicroClean (Member, NSF49 Committee), ⁷Chief, Laboratory Safety Branch, Office of Health and Safety, CDC, ⁸Saf-T-Pak

The regulatory panel covers a myriad of regulatory agencies on both the U.S. Federal level and International corporate standard level. Biosafety professionals will have an opportunity to hear from people uniquely suited to discuss upcoming and existing regulations that impact our work. Specifically, representatives of OSHA, CDC, IATA, DOT, and NSF will present material as listed below.

Melody Sands, Director, Office of Health Compliance Assistance, OSHA, DOL: This presentation will describe OSHA's Occupational Exposure to Bloodborne Pathogens Rule and the recent changes to it resulting from the Congressionally-mandated Needlestick Safety and Prevention Act. Information will be provided on how to implement the new provisions in all health care settings, as well as what OSHA will be looking for regarding employer compliance. New requirements include the use of sharps with engineered sharps injury protectors (ESIs), the involvement of employees in the selection of safer devices, and the new needlestick log/record-keeping requirements.

Richard Knudsen, Chief, Laboratory Safety Branch, Office of Health and Safety, CDC: Proposed changes to the CDC regulations regarding the shipment of infectious agents/etiologic agents and application of the Select Agents regulations will be discussed in this segment of the session.

Art Rutledge, Saf-T-Pak (Reporting on IATA): There are several changes coming in IATA regulations, including major changes to Diagnostic Specimens. These changes will be discussed as well as the significant increase in spills and training violations.

Eileen Edmonson, Transportation Regulation Specialist, Office of Hazardous Materials Standards, Office of Hazardous Materials Safety, RSPA, DOT: The Department has recently solicited comments on a proposed revision to the shipping regulations for potentially hazardous biological materials and diagnostic specimens. The proposed revisions improve harmonization between the U.S. and IACO regulations while providing flexibility in domestic shipments via surface transport. The proposed regulations and the changes they represent are the focus of this talk.

James Wagner, President, MicroClean (Member, NSF49 Committee): NSF standard 49 is the industry standard for construction, installation, and testing of Biological Safety Cabinets. It is currently in the process of being updated. The most recent version of the standard is from 1992. We are still hopeful a new standard will be out by the beginning of next year. Some of the likely changes include: 1) cabinet classification; 2) venting and installation requirements; 3) alarm/interlock requirements; 4) Annex F will be a normative part of standard—there will be clearly defined mandatory field tests; and 5) guidelines for developing alternative face velocity measurement techniques.

The new standard will likely trigger changes for most facilities. At a minimum, there will be changes to how new installations are designed. In some cases, the new standard even suggests existing facilities consider
changes. The challenge to the Safety community will also include training the users, especially about the new cabinet classifications.

Break Out Session  
Global Considerations Shaping New Shipping Regulations

Moderator: Penny Holeman¹, RBP, CBSP,  
Participants: Stephen M. Nash², CHMM; Nicoletta Previsani³, PhD, David J. Cocker⁴, Linda Hume-Sastre⁵

¹Johnson & Johnson, Raritan, NJ, ²Hazardous Materials/Dangerous Goods Consultant, Corporate Environmental Affairs, Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN, ³Epidemic Disease Control, Department of Communicable Diseases Surveillance and Response, World Health Organization, Geneva, Switzerland, ⁴Chair, Transportation Working Group, European Biosafety Association, Brussels, Belgium, ⁵Director Legislation and Regulations, Transport Dangerous Goods Directorate Transport Canada, Ottawa, Canada

Current trends in the infectious substance transportation environment include: 1) increased reliance of biomedical activities on air transportation; 2) heightened regulatory enforcement activities; 3) reduced numbers of transportation carriers that accept dangerous goods; 4) more stringent requirements of carriers that do transport dangerous goods; and 5) expanded regulatory restrictions. This situation has caused the World Health Organization (WHO) to express “…concern how current regulatory development may have an adverse effect on public health services.” In addition, the WHO and the U.S. Centers for Disease Control and Prevention have no recorded evidence of an infection resulting from a transportation accident. Deepening concerns of professionals throughout the transportation chain are driving a movement for regulatory change.

This Roundtable will review how the current regulations for the transport of infectious and other biological substances were developed. The presentations will include examples of how the current transportation environment interferes with prompt patient diagnoses, impairs the development of new pharmaceuticals and medical treatments, and impedes the ability of public health professionals to address outbreak situations. The WHO’s position on the use of Risk Groups for transportation purposes and alternative solutions will be discussed. Finally, ideas about how the transportation of infectious and other biological substances might be regulated in the future will be presented.

Break Out Session  
How We Arrived Here: A History of the Infectious Substance Transportation Regulations

Stephen M. Nash, CHMM  
Hazardous Materials/Dangerous Goods Consultant, Corporate Environmental Affairs, Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN

(Abstract not provided.)

Break Out Session  
From Third-World to First-World: The Practicalities of Infectious Disease Control; The World Health Organization’s Alternatives to the Use of Risk Groups for Transportation Purposes

Nicoletta Previsani, PhD  
Epidemic Disease Control, Department of Communicable Diseases Surveillance and Response, World Health Organization, Geneva, Switzerland

(Abstract not provided.)
Designing to be Commissioned

Jim Orzechowski

Architect, Smith Carter, Atlanta, Georgia and Winnipeg, Manitoba, Canada

Commissioning is proving to be the single most important closing activity in the delivery of a successful, functioning laboratory. It continues to be the least understood and underutilized activity in the design and construction of more complex buildings. This presentation will deal with two laboratory facilities and will endeavor to put forth the important factors for success and demonstrate that commissioning as an integrated process beginning in design. We will hopefully bury and dispel those beliefs held so dear to many hearts—commissioning is more than air balance or controls verification. It is a strategy to achieve excellence in a facility that is functional and provides a safe environment.

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Getting the Most Out of Design—Flexible Solutions for BSL4 Labs

Scott Stirton

Architect, Smith Carter, Atlanta, GA

This extension to an historic campus building and one of the first BSL4 labs to be constructed in an academic setting in support of World Health Organization programs presented a challenge of how to design a small yet diverse and flexible BSL4 lab that would operate as one large integrated BSL4 lab, two smaller BSL4 labs or one BSL4 and BSL3 lab. Flexibility was the foundation. A “thinking-outside-the-box” approach to design provided new and better ideas for developing “inside-the-box” containment systems for this BSL4 laboratory at the University of Texas Medical Branch Galveston that are safe, simple, and affordable. Operational, planning, and HVAC systems were designed with flexibility in mind that would allow the scientific program the versatility to use the lab in a number of configurations, ensuring maximum use. Costly downtime for routine recertification, maintenance, and/or program changes associated with previous generation BSL4 labs will be minimized or eliminated through strategic planning. The strategic placement for personal and equipment access/egress coupled with flexible equipment and integrated HVAC zoning can ensure that you will get the most out of design. Implementation and operation of this small but versatile BSL4 lab will be delivered by an informed and integrated scientific, biosafety, and operations and maintenance team who understands this unique and critical flexibility.

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Ingegard Kalling, Fredrik Elgh, and Renee Norberg

Swedish Institute for Infectious Disease Control, Solna, Sweden

The Swedish government in early 1995 gave its approval of plans for a BSL4 laboratory, the only one of its kind in the Nordic countries. It was decided to create a new building housing both BSL3 and BSL4 laboratories. The suit principle was adopted for the BSL4 laboratory. During a three-year period, the planning team paid several visits to established BSL4 laboratories to seek advice on site: CDC, Winnipeg, USAMRIID, Lyon.

The four-level building is a reinforced concrete construction on rock with steel doors, high security windows, and a tinned roof. The area of each level is 550 M², the BSL4 laboratory space is 125 M², one large and two smaller rooms. The smaller rooms can be operated independently of the large room. An adjacent BSL3 laboratory has a glove box which can be used as support to the BSL4 laboratories. There is a dunk-tank to the BSL3 lab. The BSL4 laboratory is a welded steel box
within the building, with walls, floors, and ceiling coated with epoxy. Doors to passageway/chemical shower are of stainless steel with inflatable seals. Negative air pressure (-35, -70, -140 Pa) and directional airflow are maintained by mechanical dampers. Supply and exhaust air is HEPA-filtered, duplicated in the exhaust system. Exhaust ducts are of welded stainless steel with two exhaust fans in parallel. There are two pass-through autoclaves with incinerators for waste water. Effluent is heat treated in a 70 L cooker, duplicated. One pass through can be used as a fumigation chamber large enough to house a safety cabinet and as chemical shower. A commissioning procedure took place with an external expert early this year. The laboratory is expected to be authorized soon.

Part II: Commissioning a Swedish BSL4 Laboratory

Heather Sheeley

Head of Safety, Centre for Applied Microbiology and Research (CAMR), Porton Down, Salisbury Wiltshire, England

The laboratory was the first BSL4 in Scandinavia and thus there was an absence of established protocols at this level for the laboratory to meet. It was thus necessary to develop a working protocol for acceptance by the National authorizing body. In Europe, the regulation and harmonization of biosafety across member states are through laws on worker protection—in this case, protection from hazardous substances and biological agents in particular. These directives are enshrined in National legislation.

The approach taken at commissioning was that the protection principles had been met in the design, that best practice from other BSL4 laboratories was incorporated, that the built structures and fittings meet containment criteria, that systems were validated by appropriate tests, and that working practices were consistent with the contained systems. Critical areas explored in this presentation are leak-tightness, alarm and monitoring systems, security, waste treatment, sample operation, reliability of systems, and filter mounting and maintenance.

The final step was the establishment of acceptance criteria with the National regulatory body where no protocol existed within the framework of the European Directives.

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BioWISE: Development of a Web-based Inventory and Safety Evaluation for Research Use of Potentially Hazardous and Regulated Biological Materials

LouAnn C. Burnett and Robert F. Wheaton

Vanderbilt University, Nashville, TN

Designed to replace paper registration with the Vanderbilt Institutional Biosafety Committee (IBC), BioWISE features researcher-friendly Web screens for input of inventories of recombinant DNA materials, microorganisms, body fluids, cells, tissues, and biologically derived toxins. BioWISE also presents the researcher with a self-audit of research facilities and containment based on Biosafety Levels 1, 2, or 3. “While-you-click” education is provided through a glossary, pop-up boxes, and links to relevant individuals, institutions, or documents. In addition to the inventory, a customized biosafety plan is generated by BioWISE by combining lab-specific information with standard biosafety procedures. The inventory and biosafety plan are then reviewed by the IBC, with approval of those documents valid for three years. The researcher may, however, view his or her submission at any time and submit updates online as changes occur. We anticipate that full implementation of BioWISE will result in: 1) less frequent but more detailed IBC review; 2) more complete tracking of research involving biological materials; 3) comprehensive inventory (current and archival) of potentially hazardous and regulated biological materials at Vanderbilt; 4) more efficient information sharing with other regulatory committees; and 5) better informed researchers.
Inventory Tracking and Reporting at a Large Academic Research Institution—Wishful Thinking or Practical Reality?

L. Gibbs

Stanford University, Stanford, CA

Tracking chemical and other hazardous materials inventory is necessary for business compliance and is especially challenging for laboratories and research organizations. Safety, emergency preparedness, and facility planning benefit from knowing what materials are on site, who is responsible for them, and where they are located. Stanford developed a Web-based application for hazardous materials inventory information management throughout its research and service support operations. This application includes reference hazard data matched to the specific chemicals in the inventory. Output includes reports on regulated carcinogens and other select toxins, local hazardous materials plan submittals, and fire and building code classification for compliance and permitting, as well as ad hoc hazard reporting. To achieve this outcome, Stanford conducted an extensive and thorough business process assessment of its chemical management and information program and operations. This presentation will demonstrate the functionality of the developed system and review the evaluation techniques used, lessons learned, and other potentially valuable strategies being developed.

The Road to Compliance: The NCI-Frederick’s Hazardous Materials Packaging and Shipping Program

Susan E. Smith

Sr. Biosafety Specialist, SAIC-Frederick, NCI-Frederick, Frederick, MD

Noncompliance with domestic (49 CFR) and international (International Aviation Transport Association—IATA) regulations can incur in the assessment of civil or criminal penalties, resulting in the delay of transporting vital research material. Proper classification, packaging, marking, labeling, and documentation are the key to avoiding such penalties. This presentation is the approach currently used at the NCI-Frederick to ensure compliance with all applicable hazardous material shipping regulations. This includes the new hazardous materials packaging and shipping courier service between the NCI-Frederick and the NIH.
Capsule

Ed Krisiunas
WNWN International, Burlington, Connecticut

BBC Presents Docudrama on Smallpox

On February 5, the BBC broadcast “Smallpox 2002,” a fictionalized account of the spread of the killer virus. It covered the first deaths in contemporary New York to an eventual global pandemic killing 60 million people.

Some of the world’s leading experts on bioterrorism, such as Dr. D. A. Henderson of the Centers for Disease Control, were closely involved in the making of the drama. Set in 2005, the drama contains fictional interviews with those involved in controlling the outbreak and news reports of the disaster.

http://www.bbc.co.uk/drama/smallpox2002

President Boosts Nation’s “Biodefense” Budget

President George Bush announced on February 5, 2002 that he is requesting $6 billion for domestic defense against the threat of bioterrorism.

The goal, the President said, is to make “America as safe as it can possibly be.” His fiscal 2003 budget request to Congress on February 4 included $5.9 billion for biodefense, an increase of $4.5 billion from the 2002 level. White House officials say the increase is intended to improve infrastructure, response efforts, and scientific research and development.

The additional funds also include $2.4 billion to develop new test protocols and new treatments for bioterror weapons, the President said. He noted that the University of Pittsburgh and the Carnegie Mellon Institute have launched the Biomedical Security Institute to help protect the nation from “the insidious biological attack.”


Lessons Learned from Fire at UC-Santa Cruz Lab

On January 11, 2002 a fire ravaged two labs at the University of California, Santa Cruz, knocking out power and shutting down multiple buildings. The Sin-shheimer building where the fire occurred remains closed, displacing approximately 150 researchers who are now scrambling to assess the damage, find new lab space, and salvage whatever is possible.

“The upper floor, where the real devastation occurred, is not likely to be back to normal use for 6 to 8 months,” says Elizabeth Irwin, Director of the UC-Santa Cruz Public Information Office.

David Silberman, Director of the Health and Safety Programs at Stanford University School of Medicine, is quoted: “In order to prevent losses, the first thing researchers can do is take a look at how they back up existing data, whether it is electronic or biological. Backing up electronic data does not mean just copying it onto a disk and storing it in your drawer. It really needs to be off site and that is pretty easy—you can take it home or there are companies that store data. With biological materials, it is a little trickier. People have been known to work out arrangements [to store biological materials] with colleagues on the East Coast or in the Midwest, especially if there is a collaboration going on.” He added that “unlike electronic data, it might be unwise for researchers to store infectious material at home.”

OSHA Reopens Tuberculosis Rulemaking Record

Limited reopening will focus on final risk assessment

WASHINGTON—The Occupational Safety and Health Administration on January 24, 2002 reopened for 60 days the tuberculosis (TB) rulemaking record to give interested persons the opportunity to review and comment on the agency’s final risk assessment and the Institute of Medicine’s (IOM) report, “Tuberculosis in the Workplace.”

Persons wishing to comment should send two copies of comments, postmarked no later than March 25, 2002, to: Docket Office, Docket H-371, Room N-2625, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210.

The notice soliciting comment is published in the January 24, 2002 Federal Register.

http://www.osha.gov/media/oshnews/jan02/trade-20020124.html

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Ask the Experts

John H. Keene

Biohaztec Associates, Inc., Midlothian, Virginia

In spite of all the good information available on the operation and use of biological safety cabinets (BSCs), it is evident that many who use them, regardless of their level of experience, simply do not understand either how they work or how to work in them. These are safety devices and it is our job as Biosafety Professionals to ensure that people who use them do so correctly. The question below seems to raise its ugly head over and over again. It recently appeared on BIO-SAFETY (a biosafety discussion list) and, in my opinion, the answer provided by Judy Pointer from M. D. Anderson Cancer Center (reprinted here with Judy’s permission) hits the nail on the head.

Question:

A researcher claims that the use of a flame in the “tissue culture hood” (BSC) is necessary because the storage of trypsin/EDTA solution in plastic tubes has led to contamination in cultures. Consequently, the lab group uses glass bottles and flames the neck of the bottle before pouring trypsin into the tissue culture flask. A bottle of trypsin/EDTA is used repeatedly and stored in the freezer after each use. What methods should be used to ensure that the neck of the bottle is sterile?

Answer:

Tell the principal investigator (PI) that first of all, the contamination is probably coming from the multiple use of the trypsin—not the plastic or glass tubes. Once the contents of the tube/bottle are contaminated (glass or plastic), using that same vessel repeatedly only spreads the contamination. Preventing the container from being contaminated in the first place should be the objective. How to do that without flaming the lips? Use good sterile technique!

First, the lab group should assess its system and the skills of those performing the work. The personnel may need more training, plus closer supervision. Second, they should run a test of their system. Select some sterile throwaway cell cultures. Remove the antibiotics in them and have each person in the lab carry the cultures for three weeks on routine maintenance (splitting, spinning, and replating). If they can’t do this without contamination, they have one of two problems, 1) the cultures were seeded with low levels of contaminants from the start or 2) they are introducing them while working.

In my experience, low levels of antibiotic-resistant common microbes (like Pseudomonas, yeast, and molds) were present in my cultures from the beginning. They were suppressed but never completely killed by the antibiotics. If this is the case, they need to figure out where the source is by isolating each step. My contaminants originally came from the incubator, the water bath, and a faulty Sweeney filtration apparatus I used for adding supplements. There were five different contaminants and each one was introduced a different way. None of the introductions was caused by “not flaming the lip of the bottle.”

If, after finding the source, it is determined that contaminated bottle lips are the problem, the solution is easy. Don’t touch the lip of the bottles with the pipette, and don’t use the same, supposedly sterile, pipette repeatedly. If you do touch the lip, either throw the contents away and don’t use it or carefully touch the drip on the lip with a sterile alcohol-soaked gauze pad. If you drop a lid, have sterile, prepacked ones available as replacements. If they are pouring the tryp-
sin out (bad technique in my opinion), they should be certain no media are on the lip before they pour.

What your tissue culturist doesn’t realize is that laminar flow sterile cabinets are designed to work best when the airflow turbulence is at a minimum. That means, minimum movement, minimum temperature variations (heat from flames), and minimum introduction of contaminated fluids into the workspace. The introduction of wet media bottles from a contaminated water bath, or wet flasks or plates from a contaminated incubator can result in contamination of the cultures. The bottom line is—no amount of flaming the lips of glass bottles will compensate for poor sterile technique.

Note:

Trypsin is notorious for carrying contaminants. It is turbid and cannot be filter sterilized. Growth in the trypsin may not be seen because of its turbidity. Double-check the trypsin source, dilute, and streak appropriate media with the trypsin to determine whether or not it is contaminated. It may be appropriate to check for mycoplasma. Trypsin is derived from pig pancreas and can be contaminated with low levels of swine mycoplasma.

Editorial Note:

Judy’s points are well taken. I once read that the best managers are those who follow the principle of “management by wandering around.” Perhaps that applies to biosafety professionals as well. Consider wandering into laboratories where biological safety cabinets are being used, evaluate the work practices, make constructive suggestions, and take the opportunity to do some “on the spot” training. It just might help the researchers and improve your relationships with them at the same time.

Errata

The Announcement “New NRM Registrants 2001” that appeared in Applied Biosafety (Volume 6, Number 3, 2001) on page 143 was incorrect. Robert P. Ellis, PhD, a new 2001 NRM Registant, was mistakenly listed as being affiliated with South Dakota State University; rather, Dr. Ellis is affiliated with Colorado State University in Fort Collins, Colorado.
Anthology I: Perspectives on Laboratory Design — Contents include, in part: Management of Biosafety; Design Issues at the Management/Facility Interface; Primary Biocontainment Devices; HVAC Issues in Secondary Biocontainment; Open BSL-2 Laboratories; Safety Guidelines for BSL-2 and BSL-3 Biological Laboratories; Design of BSL-3 Laboratories; Building a Maximum Containment Laboratory; Designing the BSL-4 Laboratory; Role of the Class III Cabinet in Achieving BSL-4: Containment Design Concepts for Extraterrestrial Sample Return; Biosafety Considerations for Design of Large Scale Facilities; Small Animal Research Facilities and Equipment; Small Animal Research Facility Management; Large Animal Research Facilities; and Waste Management Considerations.

Anthology II: Facility Design Considerations — Contents include, in part: Working Safely with Live Microorganisms; Biocontainment of Highly Pathogenic Avian Influenza Viruses; Management of Facilities for Researchers Exposed to Bacillus Subtilis; Modular Mobile BSL-2/3 Laboratories; Facility Maintenance Operations (Skilled Trades) for Biological Containment Laboratories; Construction and Commissioning Guidelines for Biosafety Level 4 (BSL-4) Facilities; Safety and Health Considerations for Conducting Work with Toxic Substances; Primary Containment Devices for Toxicological Research and Chemical Process Laboratories; Toxicology Laboratories; and Medical and Infectious Waste Management.

Anthology III: Application of Principles — Contents include, in part: Risk Assessment for Working with Infectious Agents in the Biological Laboratory; Biosafety Considerations in rDNA: Viral Gene Transfer Vectors, DNA-based Vaccines and Xenotransplantation; Biological Safety and the Academic Environment; Biosafety Issues in Hospital Settings: An Overview; Biological Safety from a Global Perspective; Beyond Compliance: Global Biological Safety at Johnson & Johnson; Twenty Years of Global Biosafety Programs; Ergonomic Considerations in Biomedical Research Laboratories; and Applied Safety Training in the Biomedical Facility.

Anthology IV: Issues in Public Health — Contents include, in part: Autopsy Autopsy Biosafety; Bioterrorism: Public Health Preparedness; Biological I Chemical Terrorism and the University; Global Perspectives on Infectious Substance Transportation; Biosafety Needs in Laboratories in Developing Countries; Understanding, Assessing, and Communicating Topics Related to Risk in Biomedical Research Activities; Biosafety in Public Health Laboratories; Biological Safety and Public Health Laboratory Design; Design Issues for Insectaries; and Investigations of Emerging Zoonotic Diseases.

BSA/CDC 5th National Symposium Proceedings: Rational Basis for Biocontainment
Apers presented during the 4-day conference jointly sponsored by BSA and CDC from January 17-20, 1998 in Atlanta, Georgia.

BSA/CDC 6th National Symposium Proceedings: Prudent Practices for the New Millennium
Apers presented during the 4-day conference jointly sponsored by BSA and CDC from February 6-9, 2000 in Atlanta, Georgia.

Both of these proceedings provide detailed information for biological safety professionals, architects, engineers, and attorneys in the development, design, and operation of containment laboratories of all sizes. This is a must-read for those involved in the operation and development of a containment laboratory.

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Guidelines for Submissions

All submissions will be acknowledged by the ABSA National Office. Applied Biosafety: Journal of the American Biological Safety Association uses a blind peer review procedure for articles, brief reports, and viewpoints. Final decisions regarding publication are made by the reviewers, Editor, and Associate Editor. The following are the guidelines for submissions. Submissions that do not conform to these guidelines will be returned to the author without review.

Submission Categories

Articles—Full-length articles may focus on the theory, practice, and research in biological safety or related areas. Articles must include an abstract of approximately 100-150 words summarizing the major point of the article.

Brief Reports—Short articles which focus on the results of research are appropriate for this section. Brief reports should include information on the research design, methods, and results. An abstract of approximately 100-150 words must also be included.

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Commentaries—Brief comments on submissions published in Applied Biosafety, issues critical to the profession and practice of biological safety, or letters to the Editor may be submitted to this section and should conform to the style of all other submissions.

Other Requirements

1. Send five (5) typeset copies of each submission to: Editor, Applied Biosafety: Journal of the American Biological Safety Association, c/o ABSA, 1202 Allanson Road, Mundelein, IL 60060-3808, USA. Neither ABSA nor the Editor can be responsible for submissions sent to any other address. Only original submissions that are not under consideration by another periodical or publisher are acceptable.

2. Submissions should be typeset on 8-1/2" x 11" paper using 1" margins, double-spacing, and full-justification. Indent paragraphs five (5) spaces. References, footnotes, table captions, and quotations should be single-spaced. Acceptable fonts are Times New Roman, Arial, AvantGarde, Helvetica, and Universal in 12 point. Avoid dot matrix printing. Primary headings should be flush left, bolded, and have the first letter of all main words capitalized throughout the submission. Secondary headings should be flush left, italicized, and have the first letter of all main words capitalized.

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5. A cover sheet should be prepared to include the full name(s) and degree(s) of the author(s), professional affiliations, and the return mailing address of the author to whom correspondence can be sent. Authors’ names, positions, titles, and places of employment should not appear in the body of the paper to assure anonymity and to facilitate the blind review process.

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