2003 ABSA Conference Abstracts

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The underlined name in these abstracts denotes the speaker.

The Scientific Program Committee would like to encourage everyone whose paper has been approved for poster or oral presentation to submit the paper to be considered for publication in Applied Biosafety: Journal of the American Biological Safety Association. For more information contact the ABSA National Office at 847-949-1517.

Microsphere Suspension Array Detection of Biological Warfare Agents: A Powerful Diagnostic and Surveillance Tool for Public Health Laboratories

Michael J. LaGier, PhD, New York Department of Health, New York, New York; Christina T. Egan, and Nick M. Cirino

A proficient response to a natural or intentional (e.g., bioterrorism) release of biological agents is largely dependent upon effective public health laboratory-based surveillance and diagnostics. A significant effort is being made throughout the public health laboratory infrastructure to develop and implement methods designed to rapidly identify select biological agents from clinical and environmental matrices. The current detection platforms are based on classical culture methods, polymerase chain reaction (PCR), or antibody capture immunoassays (e.g., ELISA). The use of fluorescent microspheres for the development of diagnostic assays is an exciting technique that has been gaining popularity in the public

Mousepox, Rabbitpox, and Monkeypox: Small Animal Models to Study Smallpox

R. Mark L. Buller, PhD, Saint Louis University, St. Louis, Missouri

Following the terrorist events of September and October 2001, there has been increased interest in enhancing the Biodefense capacity of the United States. This has been accomplished by identifying likely bioterrorist agents, providing funds for basic and applied research, developing public health and safety programs, and improving the infrastructure of the relevant agencies. Variola virus, the causative agent of smallpox, is a CDC/NIAID category A agent, but its study is hampered by the lack of good animal models. Ectromelia, rabbitpox, and monkeypox viruses are three orthopoxviruses that can be considered as surrogates for the study of variola virus in small animal models; however, each has a different set of strengths and weaknesses as a model virus, and each possesses a different set of problems for the Biosafety Officer. The relevant biological properties of each of these agents will be discussed in the context of the infrastructure and procedures required for biocontainment.
health arena. Part of this popularity is due to its flexibility, since either immunoassays or post-PCR hybridization assays can be performed. Fluorescent microsphere platforms utilize a dual-laser flow cytometer—one laser to discriminate between microsphere fluorescent tags (i.e., which analyte will be detected), and the second laser to excite a reporter fluorochrome (i.e., how much target analyte is present). Antibodies, antigens, or oligonucleotide primers can be coupled to the microspheres to create a suspension immunoassay or oligonucleotide hybridization assay, respectively. Theoretically, with 100 beads sets, 100 protein or nucleic acid analytes can be detected in a single sample.

We propose that fluorescent-based microsphere suspension arrays have the ability to rapidly detect and identify multiple select biological agents from a single, small-volume sample. As a proof of principle, we show that a microsphere suspension assay is capable of detecting the biotoxin ricin (CDC/NIAID Category B agent) from clinical and environmental samples with high sensitivity and specificity. The ricin microsphere suspension assay will be presented in the context of topics relevant to public health laboratory scientists and will include platform instrumentation, assay design and implementation, data interpretation, and the development of novel, multiplexed microsphere methods for the detection of other biological warfare agents.


**Tyrrel de Langley, DVM, Animal Care and Veterinary Services; Gillian Norton, RBP, CBSP, University of Western Ontario, London, Ontario, Canada**

The perinatal research group at Lawson Health Research Institute, an affiliate of the University of Western Ontario, is a high profile and internationally recognized centre of excellence. Suspicion of Q-fever in staff led to the discovery of *Coxiella burnetii* in a retroactive analysis of placental samples of sheep that had been used. Two issues were faced: the necessity to shut down and decontaminate the current facility, and the urgency to create a new facility so the research group could quickly resume their work. I will review the considerations faced when decontaminating an animal facility within a human hospital and discuss the challenges we faced in being the first institution to build a containment unit to meet Health Canada's new guidelines for sheep containment facilities. In addition, I will review the unique air handling, animal transport, and SOP development difficulties we faced by choosing to retrofit existing animal space. In conclusion, there are lessons learned by our experiences that I hope will facilitate the process for others.

**West Nile Virus Handling and Containment In Large and Small Animals at the University of Florida: Birds, Gators and Horses**

**Barbara Fox Nellis, RBP, CBSP, University of Florida, Gainesville, Florida**

West Nile Virus has emerged in the United States and taken on epidemic proportions. Research projects at the University of Florida vary from insects to birds, alligators, and horses. The zoonotic nature of the disease and potential for transmission to both warm- and cold-blooded animals as well as humans present significant challenges to conducting research safely. The objectives of this presentation are to review facilities, engineering controls, practices, and PPE required in laboratories, large and small animal containment facilities, and field environments to safely work with this agent. Actual current projects will be used as examples to demonstrate the principles for Biological Safety in this research. The planning, communications, and other key issues will be discussed to demonstrate the synergy between the Biological Safety Office, Animal Care Services, and the Principle Investigators involved in the design of both the experiments and the containment facilities. Results include readiness to safely conduct research on the various species affected by this agent in both wildlife and institutional settings.
Reactivity of Monoclonal Antibody Established Against PERV

Wang Shih-Rong, Chang Jen-Ting, and Lin Meng-Shiue, Division of Biotechnology, Animal Technology Institute Taiwan, ROC

The xenotransplantation of pig organs may be associated with a risk of the transmission of microorganisms. Porcine endogenous retroviruses (PERV) are a particular concern since in vitro experiments reveal that human cells are susceptible to such microorganisms. To monitor the transmission of PERV, highly sensitive and specific immunoassays must be developed for clinical surveillance. In this study, we generated and characterized a monoclonal antibody against recombinant protein Env and Gag of PERV. The 26, 63, and 65 kilodaltons of PERV translated proteins were recognized specifically by Gag mAb. The 15 and 83 kilodaltons of PERV translated proteins were recognized specifically by Env mAb. These mAb characterised were of IgG isotype. No cross-reactivity was shown with exogenous viral protein (HIV, HTLV, MuLV). Furthermore, these mAb could be applied to localize PERV particles by using immunohistochemical staining. Recombinant PERV Env and Gag protein and monoclonal antibody may be applicable for detecting the patient treated with xenotransplantation, or butchers with extensive contact to living porcine material to detect antibody against PERV.

Determining the Efficacy of a Common Laboratory Disinfectant on Bacillus Anthracis Sterne Spores Gives Rise to Questionable Swipe Technique

Mellisa L. Theodore, Huong Le, and Joany Jackman, Johns Hopkins University Applied Physics Laboratory, Laurel, Maryland

Proper decontamination of a laboratory and its instruments is critical in determining the validity of certain molecular assays and their results. A common and widely practiced method of laboratory de-

How a National Biocontainment Laboratory Impacts a University in the Northeastern United States

Rebecca L. Ryan, Boston University Medical Center, Boston, Massachusetts; Jon Crane, CUH2A, Atlanta, Georgia

There is a critical need for an increase in emerging infectious disease research. The National Institute of Allergy and Infectious Diseases (NIAID) issued an RFP to build a high-containment research facility as part of Project Bioshield. On February 10, 2003, Boston University Medical Center (BUMC)
applied for the NIAID grant for a National Biocontainment Laboratory (NBL). BUMC hopes to become a leader in the country for bioterrorism, biodefense, and emerging infectious disease research through the NBL. One of the greatest challenges in the application process was communicating with various publics (residents, elected officials, neighborhood associations, Boston residents, and media). It is crucial to address the concerns of these groups regarding safety and security. Initially, we identified the various groups with whom it would be necessary to interact, scheduled meetings, and addressed media inquiries and similar publics. The application was submitted with significant support from the Mayor of Boston, Boston City Councilors, community groups, and residents. Design planning committees are currently in place while the NIAID will officially award the grant later this fall.

How Clean is Clean—Following Microbial Remediation

M. C. Hull, Air Quality Sciences, San Diego, California

Colonization of fungi on cellulose materials found inside buildings can lead to degradation of indoor air quality (IAQ). Resolving these IAQ issues involves investigation and generally remediation of mold colonized areas.

Comparing two environmentally diverse buildings, the results of the initial investigation from Building A established spore concentrations of water indicator species (i.e., Penicillium/Aspergillus) in the range of $10^3$-$10^7$ spores/m³, which was approximately 2-10 times above background samples. In Building B, initial spore concentrations of indicator species were in the range of $10^2$-$10^3$ spores/m³, which is approximately 10-100 times above background samples. This is indicative of a potential exposure problem. In addition, the visible mold colonization on interior surfaces indicates the need for remediation.

Following proper containment and removal of contaminated materials, a clearance criteria program was implemented for each building to ensure proper remediation. Criteria included visual inspection of all areas, rank order of species found in indoor air samples compared to those found in outdoor samples, and elimination of all water sources that contribute to microbial colonization. Information included from each location consists of clearance criteria, mycological conditions contributing to colonization, and outdoor sample results for comparison. Data provided will confirm clearance in each building through sample results and through quality assurance by visual inspection of the clean-up process.

Implementing an Animal Biosafety Level 3 (ABSL3) Program

Lolly Robinson, MBA, Midwest Research Institute, Kansas City, Missouri

In 2002, Midwest Research Institute (MRI), a private, not-for-profit center for applied research and technology development, implemented an Animal Biosafety Program for the newly built ABSL-3 Containment Facility. The implementation plan included orientation of new staff members, initial training, a written proficiency test, and laboratory observations. The ABSL-3 Program has been successful in meeting the goals of developing a standardized program to be used for future employees.

BSL4 Autoclave Design Considerations in the CDC Building 18 Project

M. Randy Kray, CUH2A Smith Carter, Atlanta, Georgia

The BSL4 autoclave design for the CDC Building 18 project integrates unique biosafety features and operational considerations within the context of the overall facility containment system. Design considerations include effluent decontamination processes, gravity vs. vacuum cycles, pressure relief methods, decontamination of individual components for safe maintenance, and components’ vulnerability to gaseous decontamination. Diagramming the points of interface with related systems and their solution illustrates the interrelationship of the unit with other containment systems.
Use of Statistical Process Control for Quality Management of Biosafety Level 4 Wastewater Decontamination

Richard Henkel, PhD, and Robbin S. Weyant, PhD, Centers for Disease Control and Prevention, Atlanta, Georgia

Decontamination of Biosafety Level 4 (BSL4) laboratory wastewater is required to ensure the safety of BSL4 workers and the surrounding community. This process has been historically performed by thermal treatment of wastewater collected from the laboratory. Maintaining a high level of quality control of this process is necessary to ensure safety and public trust. Statistical Process Control (SPC) is a quality management approach that can significantly improve the ability to monitor many types of mechanical engineering systems. This approach, which relies on detecting shifts in the mean and/or variance of key process indicators to permit intervention before critical components in the system fail, has been widely used in many types of process monitoring applications. We have implemented use of SPC for quality management of the BSL4 Wastewater Decontamination System (WDS) at CDC. This approach has enabled system operators and safety managers to more closely monitor system stability and to more rapidly detect potential maintenance issues. In addition, this approach has resulted in improved documentation for all BSL4 WDS operations. The use of SPC to define specific troubleshooting indicators for WDS will be presented.

PI-101! A Safety Training Program for the Principal Investigator

Robert J. Hashimoto, Debora Van der Sluis, Marjorie Winkler, Genentech, Inc., South San Francisco, California

A key requirement of the California Injury Illness and Prevention Program is mandatory training of workplace hazards for at-risk employees. Genentech had existing biosafety training programs for laboratory workers but no programs designed to instruct the Principal Investigator (PI) on his or her supervisory responsibilities such as IBC application submission or regulatory compliance in areas such as CDC Select Agents.

The Biosafety Program and the Institutional Biosafety Committee (IBC) developed a series of training programs to teach the PI how to register biohazard and recombinant DNA experiments with the IBC. PIs learn the essentials of lab design and how to order biosafety cabinets and other safety equipment. Initial results are promising, as new investigators have had a high level of compliance with institutional policies. This poster describes the program elements and discusses the challenges of establishing this program in content and dissemination.

Safety Improvement Teams—A Proactive Safety Program

Jim Ragual, Marlene Kosinski, Robert J. Hashimoto; Genentech, Inc., South San Francisco, California

In 1998, Genentech created the inaugural Safety Improvement Team (SIT) to supplement and provide client-based EHS services to individual departments. However, the past year has seen a diversification of duties, including biosafety responsibilities for the SIT team. The team membership includes both EHS members and department scientists.

This poster describes the efforts to have a proactive safety structure within the company and demonstrate this concept’s effectiveness in safety as evidenced by a lowered accident rate and a safer workplace. Examples of biosafety issues resolved and other key team accomplishments are illustrated in detail. Forms and other administrative elements of this program are made available to the ABSA membership, and the audience is invited to comment on the approach and efficacy of similar safety programs.
Cleanliness Effect of New Float-type Barometric Damper in Changing Room of BSL3 Laboratory

Katsuaki Shinohara¹, Mitsuyuki Ohtani², Hideki Sato², Shinji Nakamura², Hirotaka Takagi¹, Kazuyoshi Sugiyama¹; ¹National Institute of Infectious Diseases Japan, ²Sanken Setsubi Kogyo Co., Ltd.

A changing room in a BSL3 laboratory is a very important facility to prevent contamination between the clean area and the dirty area. The main functions of the changing room are not only for putting on personal protective equipments but also for preventing leakage of any dirty air. Therefore, an inward air flow pass through the changing room from a clean corridor into a laboratory should be required in a BSL3 facility. The direction of air flow is usually controlled by the facility's ventilation system. A barometric damper is one of the convenient systems that can control the direction of air flow and stabilize the room pressure.

Now, we have developed a new float-type barometric damper that has performed very well in maintaining the stability of the room pressure and [has a little restriction for its installing position. In previous research, we confirmed the ventilation efficiency influenced by the installing position of the developed damper and the slide-type damper by using numerical simulation. In this study, we compared the performance of both dampers by measuring the room pressure, airflow distribution, ventilation efficiency, and cleanliness recovery characteristic. The ventilation system of the changing room had a supply air outlet in the upstream room of the damper, and exhaust air inlet in the downstream side.

We obtained the result as follows:
1. Regarding the pressure control stability: both the slide-type damper and float-type damper had equal control ability.
2. In the upstream room of the damper, the system with the float-type damper had a superior ventilation ability.
3. In the downstream room, the ventilation ability of the float-type damper system was better at the center of the room, while the slide-type damper system was better just above floor level.

Infectious Isolation Unit ABKL-3 Procedures & Training for Husbandry & Technical Staff at the University of Florida

Kelly L. Flint and Barbara Fox Nellis, RBP, CBSP; University of Florida, Gainesville, Florida

A newly renovated animal level 3 containment unit, at this large university, required the development of procedures and a training program suitable for both the husbandry personnel supporting the unit and the technical investigators and their staffs conducting level 3 research on various small animal models. Animal Care Services worked with the University of Florida Biological Safety department of Environmental Health and Safety to develop this program. Standard procedures were documented and incorporated into the training program with the development of both a PowerPoint presentation and a practical demonstration exam for the user. The multi-corridor design of the facility allows for multiple simultaneous users that require strict adherence to procedures and protocols. The vast variation in backgrounds and education of the potential users and support staff was taken into consideration in the design of the training presentation and the practical exam. The results were the successful start-up and operation of this critical unit within Animal Care Services.

Improving Responses to Bioterrorism: Lessons Learned from the Anthrax Attacks

Robert Curtis, USDOL/OSHA, Salt Lake City, Utah; John H. Bridges III, USPS, Washington, DC; David Ippolito, USDOL/OSHA, Washington, DC

OSHA Lessons Learned: IH Perspective (Robert Curtis). This presentation will describe the common problems identified in the Health and Safety Plans implemented for clean-up of the various anthrax-contaminated sites, including excessive PPE resulting in unnecessary heat stress, inappropriate sampling methods, poor containment, poor worker training
and experience, and unrealistic decontamination end-points.

Brentwood Facility Lessons Learned: Incident Commander’s (IC) Perspective (John H. Bridges III). Due to its complexity and size, the decontamination of the Brentwood postal facility took more than 16 months to complete. During this period, the IC had to deal with the demands of various Federal and local authorities as well as the workers and the community at large. The experience will be described along with suggestions to improve the support provided to other ICs.

NRT Reconciliation Committee Lessons Learned: Federal Response Plans Perspective (David IPPolito). The overlap of government agency jurisdictions and perceived conflicts among the various federal response plans caused unnecessary confusion and delays during the anthrax response activities. The NRT has commissioned a "Reconciliation Committee" to develop a strategy to resolve the apparent conflicts. A member of the Committee will describe its findings and the potential impact on responders to future incidents.

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**Historical Sources: Their Use and Application to the Present Day**

Emma Kerrod, Ray Gani, Steve Leach; Health Protection Agency, Centre for Applied Microbiology and Research, Salisbury, United Kingdom

Deliberate release of infectious agents (bioterrorism) is a small but feasible and increasingly recognized risk. One of the inherent problems in planning a response to such events is that often little is known of the epidemiology of these diseases, especially in contemporary contexts. Historical data sets can, however, provide valuable insights into the epidemiological, clinical, and dynamic aspects of potential outbreaks. Smallpox has been considered the greatest bioterrorism threat by virtue of its person-to-person transmissibility. Extrapolating information from historical sources to a modern population, however, has many limitations and has been the subject of much debate. Societal differences, waning immunity, contra-indications to vaccination, social networks, and expedited travel, all mean that historical data sets must be approached with care. Actions taken as a result of a deliberate release, both re-active and pro-active, must be timely and relevant. Analyzing past smallpox outbreaks—the dynamics of spread, clinical parameters, immunity levels, and the efficacy of intervention/control methods—helps us to construct model simulations upon which evidence-based risk assessments can be constructed. Two well documented UK smallpox outbreaks from the 20th century (Liverpool 1902-1903, Edinburgh 1942) are described along with the public health interventions used to control them. Here we show how they may be used, along with other historical records, to provide evidence for risk assessment work and what the limitations of these data sets may be. In both outbreaks, extensive contact tracing, quarantine, and staged vaccination campaigns were initiated and the outbreaks were brought under control within 11 months and 3 months, respectively. Of particular note, in Edinburgh the number of fatalities associated with vaccination exceeded the number of deaths from the disease, and in Liverpool, the large number of vaccine-modified cases resulted in problems for outbreak control because of frequent misdiagnoses as chickenpox.

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**A Functional and Interactive Local Emergency Planning Group**

Robert P. Ellis, PhD, CBSP, SM, Colorado State University, Fort Collins, Colorado; Erik Nilsson, Larimer County Office of Emergency Management, Fort Collins, Colorado; Mike Gress, Office of Emergency Management, City of Fort Collins, Colorado; and Earlie Thomas, Environmental Health Services, Colorado State University, Fort Collins, Colorado

Larimer County, Colorado (275,000 population and 2,640 square miles) is located in north-central Colorado. Larimer County extends east from the Continental Divide (at nearly 12,000 ft elevation) to the plains (at 4,500 ft elevation), and from the Wyoming border on the north to about halfway to Denver. The largest city in the county is Fort Collins (120,000 population). Many small towns and com-

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All communities are located throughout the county. Colorado State University is located in Fort Collins and has a student population of 25,000. The county Local Emergency Planning Committee meets at least quarterly. In addition to the quarterly meetings, we plan and conduct tabletop and onsite exercises (mock cyanide exposure, mock disease outbreak), and respond to emergencies including floods, blizzards, and wild fires. October 15, 2001, the Larimer County Office of Emergency Management notified by e-mail representatives of 24 agencies that a meeting would be held Tuesday, October 16 in the Larimer County Sheriff Department Conference room. The subject of the meeting was how to handle suspected anthrax incidents that may occur within the county. Over 70 representatives from federal, state, and local law enforcement, health agencies, emergency responders, and the postal service were present at the meeting. The discussion addressed the issue of the FBI definition of a "credible threat." If a "credible threat" existed, the FBI had jurisdiction and controlled the investigation. In the event a threat was not linked to the product, a process was required to address the jurisdiction, process, and control issues that would arise. It was the consensus of the group that a rapid and accurate answer was needed for each sample submitted in order to address the needs of the various agencies involved. Wednesday the 17th two of us met with the director of the Veterinary Diagnostic Laboratory and microbiologists within the Laboratory, to determine whether the Laboratory would analyze samples reported to be suspicious for anthrax or other biologic agents. The Diagnostic Laboratory agreed to analyze any samples that were reported to officials in Larimer County. The microbiology laboratory in Environmental Health Services agreed to analyze samples reported on Colorado State University property. Law enforcement entities designed a chain of custody form that was to accompany all samples, with instructions on how to handle and submit the samples. Thursday, October 18 all pieces were in place for the system to begin, and the first sample was submitted on Friday, October 19. Nearly 90 samples were submitted from October 19 to December 31. Over 70 of the samples were submitted from the Colorado State University campus. No samples were positive for anthrax or any other pathogen, and all who submitted samples were notified in a timely manner.

Lesson: Community- and county-wide cooperation can be accomplished if the structure is in place, the personnel involved know each other and have worked with each other, specific action is needed, and it is needed quickly. Hopefully, such cooperation will be forthcoming with future unforeseen incidents that may have a potential impact, real or imagined, of the magnitude of the anthrax incidents.

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**SARS “Outbreak” on a University Campus**

Ray Hackney, DPH, CBPS; Peter Reinhardt, University of North Carolina

In May 2003, the University of North Carolina developed travel guidance and policies to minimize the risk of Severe Acute Respiratory Syndrome (SARS) to students, faculty, and staff who travel internationally and study abroad, as well as those returning from high-risk international locations and visitors coming to Chapel Hill from those areas. Later that month, a contractor working at the University returned from Toronto and developed SARS.

This paper describes the University’s experience in SARS policymaking and its response to a confirmed SARS case of an individual who had worked at the University. Risk communications were critical to inform employees and address their concerns. Although no secondary transmissions of SARS have been reported in the United States, public health and employee concerns were compounded by a number of concurrent illnesses and two university employees designated by CDC as “Persons of Special Interest.” In conjunction with Public Health officials and UNC Hospitals, the University implemented a health questionnaire and a pre-work temperature monitoring procedure, and constructed a temporary screening facility. With many thousands of students returning to U.S. universities from SARS-affected areas, UNC’s experience can provide valuable insights into how to respond to a SARS “outbreak” and the many fears of students, employees, families, and the media.
Community-based Clinicians’ Response to Bioterrorism

Robyn R. M. Gershon, DrPH, Columbia University; Kristine Qureshi, RN, DNSc; Stephen S. Morse, PhD; Kent N. Sepkowitz, and Alejandra Gurtman

The Columbia University Center for Public Health Preparedness at the Mailman School of Public Health helped address an important gap in the greater New York City area by developing and administering a bioterrorism training program and assessment questionnaire for community-based clinicians. These healthcare providers were targeted for training because they might be reasonably expected to treat patients in early stages of bioterrorism-related illnesses, especially as many of these diseases present with symptoms similar to influenza. A pre- and post-test design was used to evaluate the effectiveness of the training in terms of knowledge, attitudes, fear and concern, and infection-control intentions. Over 500 healthcare workers participated in the program and evaluation. The results indicated at baseline that a significant portion of the participants lacked an understanding of the appropriate treatment, prevention, and reporting mechanisms of diseases caused by Class A agents. Participants’ confidence in their ability to recognize, diagnose, and report a case of suspected bioterrorism increased following the intervention. These types of targeted programs may be important adjuncts to improving the readiness of clinicians with respect to bioterrorism response.

Health Care Workers’ Ability and Willingness to Report to Duty During Disasters

Kristine Qureshi, RN, DNSc, Columbia University; Robyn R. M. Gershon, DrPH, MHS; Erin Hogan, BS

It is important to assess the ability and willingness of healthcare workers to report to duty in response to a terrorist event that involves biological or chemical agents, mass casualties, and nuclear and radiological weapons. A well-prepared workforce that is both willing and able to report to duty during times of crisis is an essential element of an effective public health response capacity. Our understanding of this issue is extremely limited. To improve our understanding of this issue, we recently studied this issue in a range of healthcare worker populations, including community-based clinicians, dentists, hospital workers, and EMS workers. This paper presents the results of these studies conducted by researchers from the Columbia University Center for Public Health Preparedness at the Mailman School of Public Health. Surveys were administered to identify the ability and willingness of personnel in various sectors of the healthcare system to respond to duty during different types of disaster situations. Facilitators and barriers for reporting to work were also identified. This information is valuable as part of the overall public health preparedness and response planning.

EMS Preparedness for Response to Chemical and Biological Terrorism

Erin Hogan, BS, Columbia University, New York, New York; Kristine Qureshi, DNSc; Robyn R. M. Gershon, DrPH; Lorraine Giordano, MD, NYC HHC, New York, New York; James Soto, NYS DOH, BEMS, Albany, New York

The objectives of this study were to: a) demonstrate the effectiveness of an educational intervention on workers’ knowledge of diseases of bioterrorism, including the role of EMS in the public health response to these agents; and b) to assess the ability and willingness of EMS workers to respond to duty in the face of terrorist incidents. A 3-hour course on recognition and response to bioterrorism was conducted for New York City EMS workers. Pre- and post-tests were administered, as well as a survey questionnaire to assess attitudes to both chemical and bioterrorist incidents. A total of 125 EMS workers completed the program. Results showed a statistically significant improvement in the knowledge of bioterrorism, as well as their role in the public health response. As first responders, EMS workers play a critical role in the response to terrorism. As such, it is essential that they receive effective preparedness training.
Implementation of the New Select Agent Regulation: Fine-tuning Your Program

Stephen A. Morse, MSPH, PhD, Centers for Disease Control and Prevention, Atlanta, Georgia; Philip Hauck, MS, RBP, CBSP, Mt. Sinai School of Medicine, New York, New York; USDA Representative: TBA

The final compliance requirements for Select Agent Regulation need to be in place by November 12, 2003. How does your program stack-up? This roundtable includes a quick overview of the requirements. Representatives from public institutions and industry discuss how they approached the implementation of the new regulations. This is an opportunity for you to compare your program with that of your colleagues and to discuss compliance issues with the speakers and the audience.

Ethical Issues in Confinement of Genetically Engineered Organisms

David Magnus, MD, Stanford Center for Biomedical Ethics, Stanford University, Stanford, California

ABSTRACT NOT PROVIDED.

Clinical Production of Gene Therapy Vectors

Philip J. Cross, Deputy Director, Harvard Gene Therapy Initiative, Boston and President, Philip J. Cross & Associates, Wilmington, Delaware

Production of gene therapy viral vectors for early phase clinical trials presents unique challenges with respect to GMP compliance, biosafety, and cost. FDA has presented examples of the "GMP Continuum" and the "Spirit of GMP." These analogies are often misunderstood, resulting in clinical manufacturing facilities and operations that often don’t meet basic GMP standards. The design of two types of clinical manufacturing laboratories (concurrent multi-use and campaign) is illustrated as well as the engineering and operational controls needed for each. The minimum elements needed to operate clinical production facilities in a safe, compliant manner and achieve the "Spirit of GMP" are discussed. These include SOPs, training, adequate records, environmental monitoring, cleaning/changeover procedures, critical equipment validation, and other items. Additional FDA reporting requirements concerning the production and testing of viral vectors and cell banks in INDs and annual reports are discussed.

Comprehensive Gene Transfer Protocol Review and Training

Susan J. Weekly, University of California, Irvine, California

The University of California, Irvine initiated the first gene transfer protocol for the campus in January 2003. The gene transfer protocol involved the use of an Adenoviral Vector administered through direct intra-tumoral injection to treat pancreatic cancer. The presentation addresses the entire protocol review, risk assessment, and training components for this protocol. Many complex issues were addressed including the facility design requirements, risk assessment with selection of personal protective equipment, and development of task-specific gene transfer training for Pharmacy, Gastroenterology, Oncology and Radiation personnel. Since the protocol was initiated under the College of Medicine but was performed at the Medical Center, additional partnering was required in order to have the process go smoothly. The presentation includes the UCI video of hands-on training performed for the Pharmacy Staff, which involves complete reconstitution of the vector in a biosafety cabinet. As a result of the comprehensive gene transfer protocol review and training, inexperienced personnel gained confidence through hands-on training, and the protocol proceeded without incident.
Occupational Health and Safety in the Care and Use of Nonhuman Primates

Jack Geissert, Wyeth BioPharma, Andover, Massachusetts; Joanne Zurlo, PhD, Institute for Laboratory Animal Research; Elizabeth Gilman Duane, Wyeth Research, Cambridge, Massachusetts

The Committee on Occupational Health and Safety in the Care and Use of Nonhuman Primates was appointed by the National Research Council (NRC) in response to requests from the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration to address the risks associated with occupational exposure to nonhuman primates and suggest practical and efficacious ways of minimizing these risks.

The Committee identified and assessed numerous risks, infectious and noninfectious, of working with nonhuman primates or their blood or tissues. The Committee determined that the most effective way to manage these hazards is through the development and implementation of an institutionally specific occupational health and safety plan (OHSP). The Committee report provides a listing and discussion of the necessary features of an effective OHSP, including organization and administrative procedures, engineering controls, work practice controls, use of personal protective equipment, and preventive and postexposure medical management.

OSHA’s eTool on Legionnaires Disease: Is the Information Accurate, Current, and Complete?

Janet Macher, California Department of Health Services, Environmental Health Laboratory, Berkeley, California; Richard Danielson, BioVir Laboratories, Inc., Benicia, California

Inform ABSA members of the information available at the Occupational Safety and Health’s (OSHA’s) web site on legionellosis (http://www.osha-cd.gov/SLTC/etools/legionnaires/index.html). The eTool is designed to assist industrial hygienists in the assessment of worksites for potential Legionnaires’ disease. It provides information on disease recognition, investigation procedures to identify probable water sources, and control strategies.

As part of the OSHA/ABSA collaboration in their common mission to protect health and prevent workplace illness and injury from biological hazards, a committee was formed to review eTool material on Legionnaires’ disease and suggest improvements to its format and content. A computer is available for meeting participants to access the site and submit additional comments by completing a short ques-
Molecular Characterization of Tetracycline-resistant Bacteria from a Concentrated Hog Feeding Operation (CAFO)

Kellie L. Perry; J. Tigno; J. A. Johnson; J. G. Morris, and O. Colin Stine, The University of Maryland, Baltimore, School of Medicine, Baltimore, Maryland, The Applied Physics Laboratory, Johns Hopkins University, Laurel, Maryland, The Veterans Affairs Hospital, Baltimore, Maryland

Antibiotic resistance (AR) in bacteria is a growing problem. Although antibiotics are used in CAFO for hogs at subtherapeutic levels, there is little understanding of the distribution of AR bacteria and AR genes. We surveyed the bacteria from a single CAFO. Samples were collected from the feed, fresh feces of starter pigs and market hog, the waste pit in the hog house, the waste lagoon, the soil, and the well and stream water. Bacteria were isolated on media containing tetracycline. Genomic DNA was extracted. PCR amplification of gene fragments from 16S, and tet—A, B, C, E, H, L, M, was performed and the products were sequenced. Bacteria isolates were identified to species based on comparison of 16S to those in Genbank. The tet genes were aligned and compared. TR bacteria were found in the feed and well water and throughout the rest of the samples. Different species of bacteria that contain the identical alleles of the same TR genes (e.g., E. coli Pseudomonas and Bacillus all have tetM allele #1). We conclude that the identical TR gene may be present in multiple bacterial species and at multiple sites/samples. Thus, feed may be the route that TR genes are introduced to the CAFO. TR is widespread throughout the CAFO even though tetracycline is used at subtherapeutic levels.

Microbiology: Friend or Foe—The Challenge to Identify a Balanced Approach to Biosafety, Biosecurity, and Public Health

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One of the two subjects that will be addressed at the 2003 Meeting of Experts (Geneva, August 18-19, 2003) and meeting of States Parties (Geneva, November 10-15, 2003) is on “national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins.” This subject is of relevance to WHO and the entire public health community, including clinical and research laboratories, the pharmaceutical industry, and the biosafety community-at-large. The WHO Biosafety Programme has been asked to participate in the Meeting of Experts in August 2003.

This presentation focuses on the implications to find the correct balance between biosafety, biosecurity, and public health, while aiming at reducing to the extent possible the spread of disease caused by accidents or inappropriate handling or usage of pathogenic microorganisms, in an era of increasing bioterroristic threats.


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One of the most significant challenges facing both biosafety professionals and the community they serve is the ability to provide a working laboratory environment that is both safe and not negatively impacted by security measures. It was not too long ago when biosecurity was synonymous with safety; in today’s world, however, the term has taken on new meaning and is filled with subtleties and nuance. The objective of this presentation is to compare how various institutions (academia, government facilities, private labs, and the corporate sector: biotech and pharmaceutical companies) have approached and implemented security arrangements, their rationale for sometimes going beyond regulatory requirements, their impact on the conduct of science, and implications for the future way in which biological research is conducted. Interviews and discussions with biosafety professionals, scientists, administrators, research directors, and compliance personnel form the basis on the information that is presented. The results, to date, indicate there is a wide range of variability in the types of security measures being implemented: ranging from modest, after-hours only building lockdowns to security cameras that are able to detect suspicious movements of lab personnel. Conclusions suggest that despite the fact that all are working with the same agents and/or organisms and at the same risk and biosafety levels, there is a difference in perception of security and vulnerability risk.

**Integrating Biosecurity in the Design of a BSL3 National Laboratory**

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The Los Alamos National Laboratory is constructing a Biosafety Level 3 (BSL3) research facility that will be used for a wide range of activities in support of biological threat reduction. The facility was designed to support the following broad mission areas: (i) characterization of biochemical and pathogenic properties of infectious microbes; (ii) production of biochemical reagents (e.g., ligands, probes, proteins); (iii) attribution and forensic analysis; (iv) support of detector and technology development; and (v) collection and storage of samples for a national culture archive. This is the first biocontainment lab planned for the Department of Energy. A primary challenge for the BSL3 project team was the appropriate grading of the nuclear-oriented start-up requirements.

The 3,202 sq. ft. stand-alone building houses a 600 sq. ft. BSL-2 lab and two 312 sq. ft. BSL3 suites.
The facility meets or exceeds all CDC/NIH biosafety and occupational health guidelines that describe work with microorganisms and toxins requiring BSL3 containment. Facility staff will conduct work safely in one of the 5 Class II biosafety cabinets or the one Class III glove box. Additional protection of the environment and public will be achieved by HEPA-filtered exhaust air from the BSL3 suites. The facility’s security plan addresses both physical protection and human reliability. The building is surrounded by an industrial security fence and monitored by interior motion sensors; access is controlled by a combination of PIN codes and biometric (hand geometry) sensors. A human reliability program based on the requirements described in 42CFR, Part 73 (Use of Select Agents) will ensure that only non-restricted personnel conduct work in the facility.

**Laboratory Planning Considerations and Related Biosafety Issues Focused on a Biodefense Research Agenda**

M. Randy Kray, CUH2A Smith Carter, Atlanta, Georgia

Recent initiatives and funding opportunities to develop containment facilities that address a biodefense research agenda have generated several innovative design features. These features make these projects different from any existing biocontainment facility and are based on the mission to effectively develop therapeutic and prophylactic compounds specific to bioterrorism and emerging infectious diseases. Features include innovative laboratory-to-animal space relationships, increased flexibility of protocols, and the emergence of new analytical technologies in containment. While facilitating these new features, the laboratories must also maintain good microbiological practice, manageable protocols, and sound containment construction principles.

**Applied Biosafety: Legal Framework In Switzerland and Implications for Clinical Laboratories**

Felix K. Gmünder, Basler & Hofmann Consulting Engineers, Zurich, Switzerland; and Thomas Binz, Swiss Federal Office of Public Health, Biosafety Unit, Berne, Switzerland

In Switzerland the use of genetically modified and pathogenic microorganisms is regulated by the federal law relating to the Protection of the Environment. Principles and practices of biosafety on the level of enforcement such as risk assessment, general safety measures for all installations, and specific safety measures for individual types of research and development laboratories, growth rooms and greenhouses, animal units, and production plants are given by the “Swiss Ordinance on the Contained Use of Organisms.” The paper presents the ordnance and the background of the public health situation in Switzerland and what this implies for clinical laboratories (BSL2 and BSL3). Design, construction, and operation of clinical laboratories are presented in the form of two case studies (BSL2 and BSL3). The ordinance provides a practicable framework to protect people and the environment.

**Task-specific Ventilated Robotic Enclosures for Product and Worker Protection Against Biological Hazards in High-throughput Laboratories**

Alexy Kolesnikov, PhD, Ray Ryan, Flow Sciences, Inc., Wilmington, North Carolina; Douglas B. Walters PhD, KCP, Inc., Cary, North Carolina

Today’s laboratories have changed significantly. Synthesis-based R&D has moved into the new millennium and been replaced with advanced analysis/discovery processes utilizing sophisticated computer and high-throughput robotic technology. Many automated laboratory practices produce aerosols and par-
ticulates, e.g., weighing, pipetting, transfer, handling, autoclaving, and incubating. The laboratory use of high-throughput technology with hazardous solvents (e.g., DMSO, methanol), biological agents (e.g., HIV, TB, hepatitis), and novel compounds of unknown potency (e.g., drugs) is rapidly expanding. Enclosure, containment, and ventilation are frequently overlooked when automated and robotic laboratory equipment is used with potentially hazardous materials. Containment of these operations is further complicated if clean environments are required for sample and worker protection because incoming and exhaust air may require HEPA filtering. This presentation addresses the development and testing of a task-specific ventilated robotic enclosure designed and optimized for operator and product protection. Computational fluid dynamics (CFD) (i.e., computer modeling of airflows) is used to analyze airflow distributions inside the enclosure to optimize equipment and enclosure layouts and to promote stable containment performance of the entire airflow system. Results presented for a high-throughput system configuration validate the performance of a newly designed, ventilated robotic enclosure.

The Open Laboratory Design Concept in 2003—How Well Does This Design Concept Work?

Moderator: Lynn Harding, MPH, CBSP; Architect: Janet S. Baum, AIA; HERA, Inc; Ventilation Engineer: William T. Freeman, PE; CUH2A; Safety: Douglas Walters, PhD; KCP, Inc.; Scientist/User: James C. Alwine, PhD; University of Pennsylvania, Department of Cancer Biology

In the mid-20th century the basic biology or chemistry laboratory was a discrete room, entered through a door off a central corridor, where work activities were relatively self-contained and the research activity was reasonably homogeneous. In the 1970s, a combination of forces evolved that lead to the development of the larger open laboratory design, some of which now occupy entire floors in research facilities. The driving forces behind the increasing use of such laboratories were: 1) scientists and administrators who felt that scientific creativity and productivity would be enhanced by better interaction among the laboratory scientists; 2) the economics of construction that made larger open laboratories cheaper to build; and 3) increasing regulatory demands that required meeting more stringent fire protection and building codes and increased emphasis on air quality coupled with the availability of improved ventilation technology including the biosafety cabinet and other local exhaust capabilities. Today many of these open labs handle multiple hazards including physical, chemical, biological, and radiation sources. How well do these laboratories meet the needs of the scientific and safety community and what do the architects and engineers who design them think about their functionality in the light of such diverse usage?

This presentation focuses on the reasons for the development and popularity of the open laboratory design. The strengths and weaknesses of this design concept are discussed by each speaker from his or her particular viewpoint (architect, engineer, safety, and scientist/user).

Compliance with the NIH Guidelines: Questions Answered by the NIH Office of Biotechnology Staff

Allan C. Shipp; NIH Office of Biotec Activity, Bethesda, Maryland; Stephen Rose, PhD; Eugene Rosenthal, PhD, Biotechnology Program Advisor

This session provides a brief overview of the NIH system of oversight of recombinant DNA (rDNA) research, which is managed by the NIH Office of Biotechnology Activities (OBA). OBA employs various tools to fulfill its oversight responsibilities. These include the NIH Guidelines for Research involving Recombinant DNA Molecules (NIH Guidelines) and the Recombinant DNA Advisory Committee. OBA also undertakes special initiatives to promote the analysis and dissemination of information key to our understanding of recombinant DNA, and in particular, human gene transfer re-
search. These include a new query-capable database on human gene transfer trials and conferences and symposia on timely scientific, safety, and policy issues. Finally, Institutional Biosafety Committees (IBCs) are a critical partner with OBA in promoting the safe conduct of basic and clinical rDNA research. Speakers describe each of these elements of the NIH rDNA oversight system, focusing in particular on requirements that pertain to IBCs, and then address questions from the audience.

Biocontainment (BSL3) Design: Organizing the Design Team and the Facility

Olaf Schneewind, MD, PhD, University of Chicago, Chicago, Illinois; Dr. Harvey Drucker, Argonne National Laboratory, Batavia, Illinois; Jim Gazvoda, AIA, and Steve Freson, AIA, Flad & Associates, Madison, Wisconsin

A well organized project team is critical to the successful implementation of a biocontainment facility. The University of Chicago, Argonne National Labs, and Flad & Associates will share their insights into how they developed a highly functional BSL3 and BSL3A facility. This presentation focuses both on the owners/user perspective and the consultant perspective. It demonstrates how the synergy created by an integrated team can lead to a facility where biological safety is not an afterthought but embedded in the building design. The process-planning model will illustrate how the pathogens and protocols associated with their management will influence the design of the facility, its process flows, containment strategies, and associated equipment and systems. Design issues for this project include safety of the building and the users, redundancy for MEP systems, operation effectiveness, project reliability, and flexibility for adapting to future needs while maximizing interaction and collaboration of the scientist users from a number of academic and research institutions in the Midwest. The presentation describes how these impacted the design of BSL2, BSL3 and BSL2A, BSL3A facility.

Maintaining Contamination Control of Containment Spaces Intransition Using a Combination of Pressurization and Airflow Differential Control

J. Patrick Carpenter, P. E. Kling, Philadelphia, Pennsylvania

Most standards and conventional wisdom dictate that contamination control across containment barriers requires airflow to prevent contamination migration. This requires that pressure differentials be established to propagate those airflows. Some believe airflow differentials cause pressure gradients; others believe pressure differentials cause airflows. But almost everyone agrees that with little or no airflow migrating across an enclosed volume, pressure control is problematic when the barrier changes (i.e., doors open). The dynamics of barrier changes resulting from doors can be understood and designed so as to create stable and effective contamination migration control through the use of a combination of pressure and airflow sensing and control.

To develop a reliable and consistent method of controlling pressure and airflow differentials between spaces during transient periods that integrates with airlock concepts, decontamination requirements and reasonable operation by users to create effective contamination control. This is especially important in small spaces or in tightly sealed spaces requiring pressure decay testing.

Through theory and CFD modeling, contamination control concepts are formulated and demonstrated that incorporate the realistic constraints of relative air volumes, control device response, and acceptable transition times.

The weakness of space pressurization control concepts that depend upon long transition times to clear airlocks of contamination can be significantly reduced with a combination pressure/volume differential control scheme.
Using Cost/Benefit Analysis and Quantification of Risk to Determine Cost-effective, Reliable Infrastructure Systems

Raymond F. Millea, PE, CUH2A, Atlanta, Georgia

The challenge in designing and constructing reliable infrastructure systems to support the latest technologies used in research applications is weighing the costs and risks of outages against the costs and benefits of increasingly reliable mechanical and electrical systems. In this series, some of the metrics and methods used to determine facility risk and vulnerability are demonstrated and a quantification of these is presented. These risks and vulnerabilities are weighed against the escalating cost of highly reliable distribution systems. The study assists in determining the factors available in weighing the marginal costs on increased reliability against the associated offset risk. Several benchmarks are presented and some tools used in determining cost-effective design are evaluated.

Walkabout for Biosafety Excellence: A Case Study in Administrative Leadership

Mark J. Grushka, MS, University of Arizona, Tucson, Arizona

In the spring of 2001, the Vice President for Research at the University of Arizona initiated the Walkabout for Biosafety Excellence Program. The program is based upon five premises:

- Health and Safety are a Management Function.
- Health and Safety are Best Served by Management by Walking Around.
- Excellence in Health and Safety are Part of Running a Successful Organization.
- Demonstration of Leadership Often Means Listening and Learning.
- To Facilitate a Healthy University Culture, We Must Continually Find Ways to Connect as Human Beings.

Health and safety program development, implementation, and monitoring have often been characterized by compliance-oriented drivers. The oversight requirements from various regulatory entities often dominate the allocation of resources of health and safety support staff including biosafety professionals, leaving little or no time for more strategic approaches. Integrating effective health and safety into the academic research institution is also challenging because of decentralized management structures, unrelenting budgetary pressures, and autonomous faculty relationships. This can result in a less than effective approach to managing risk in a complex environment such as a research university.
At the University of Arizona, a novel program was started in 2001 to recognize individuals and organizations that consistently integrate health and safety values into their work. Through the leadership of the Vice President for Research and Graduate Studies, Dr. Richard C. Powell, the program has recognized how Good Science is achieved through health and safety performance.

The presentation covers how the program works, what has been learned in the process, and how it fits into the larger challenges and opportunities facing research universities. Should a platform presentation be selected, Dr. Richard C. Powell will be invited to present his perspective to the ABSA conference.

The Newly Revised American National Standards Institute (ANSI) Z 9.5 Laboratory Ventilation Standard

Douglas B. Walters, KCP, Inc.; Louis DiBerardinis, Massachusetts Institute of Technology, Cambridge Massachusetts

The 1992 ANSI Laboratory Ventilation Standard established minimum requirements for laboratory ventilation systems used to prevent overexposure of personnel to chemical contaminants generated in laboratories. The Standard has just been completely revised and reflects the significant advances made in laboratory ventilation design during the last 10 years. Key issues include establishment of a Laboratory Ventilation Management Program and designation of a cognizant person to coordinate and monitor the program. Emphasis is on use of laboratory hoods and local exhaust instead of specifying an air exchange rate, which is considered inappropriate for contamination control. Recommendations are provided for directional airflow with respect to hazards and minimum hood volume flow. The use of ductless hoods is discouraged unless there are tight controls over their use. Recirculation of hood exhaust and laboratory room air is also strongly discouraged. Recommendations are given for stack discharge, record keeping, maintenance, and monitoring, and a new section is included on hood exhaust diversity. The American Industrial Hygiene Association in Fairfax, Virginia serves as the Secretariat for this ANSI Committee.

Monitoring Contaminations with Hazardous Microorganisms of Laboratories During Biosafety Inspections

Guido Vogel, Claudia Baguti, Monica Alt, Urs Vögeli, André Herrmann; Kantonales Laboratorium Basel-Stadt, Kontrollstelle für Chemie-und Biosicherheit (Biological and Chemical Safety Administration), Basel, Switzerland

Compliance with guidelines for the work in enclosed systems and a “good laboratory practice” are prerequisites for occupationally and environmentally safe handling of pathogenic and genetically modified microorganisms. As an enforcement authority we are developing methods to take samples on laboratory surfaces during routine biosafety inspections as well as to subsequently detect and quantify specific microorganisms. Procedures based on “in culture” real-time PCR were developed and validated for the identification of Vaccinia- and Adeno viruses or bacteria, such as Campylobacter sp., Salmonella sp., Streptococcus pneumoniae, or Staphylococcus aureus. These methods not only detect specific DNA sequences in individual swabs. By measuring the increase of these target DNA sequences during an incubation period, they can also be used to identify the presence of living microorganisms. Furthermore, these methods can easily be adapted to different types of viruses and bacteria by changing the primers and probes and, if necessary, by modifying the cell culture and/or the growth conditions.

Experiences from routine inspections showed that the presented methods are a potent instrument for monitoring contaminations and controlling the handling of pathogenic and genetically modified microorganisms in laboratories. We could identify critical areas within the laboratories which recurrently showed high levels of contaminations.
U.S. National Inventory of Wild Poliovirus Materials

Walter Dowdle, Kim Koper, and Sandra Browning, Poliovirus Laboratory Containment Preparedness, Atlanta, Georgia

In October 2002, the U.S. Department of Health and Human Services mailed forms to all biomedical institutions/laboratories to alert them to the approaching eradication of polio, encourage destruction of all unneeded wild poliovirus materials, and to create an inventory of those institutions/laboratories that wished to retain such materials. As of May 2003, reports have been received from over 26,000 institutions representing nearly 90,000 laboratories in academic, federal government, hospital, industry, private, and state and local government facilities. Nearly 200 laboratories reported having wild poliovirus materials. Institution/laboratory cooperation, involving many ABSA members, has been excellent. The interim National Inventory for Phase I is anticipated to be complete in October 2003. The Inventory will be assessed for quality and completeness, and the information gained during this process will be utilized for the final inventory (Phase II) to be submitted after polio eradication has been achieved.

A Canadian DNA Traceability Trail to Enhance the Biosafety Control and Identity Preservation of Transgenic Livestock

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The development and production of transgenic animals are increasing with developments in the technology. In particular, the creation of livestock animals has become more prevalent and now includes cattle, sheep, goats, and pigs. The biotechnology/pharming industry, regulatory agencies, and the public alike all have a vested interest in seeing that such transgenic livestock are properly monitored and contained. However, the unapproved release of novel animals into the public food/feed chain has already occurred on at least three occasions in recent years. Such erroneous releases threaten not only the public confidence in the emerging transgenic biotechnologies but can also damage trust in the regulatory authorities that oversee such novel genetic applications. In the world's first publicly funded study to strengthen the biosafety control, traceability, and operational capacity in monitoring such novel livestock, the Canadian Food Inspection Agency (CFIA), a federal government agency in Canada, trialed a DNA traceability application on 300 conventional pigs within a real-time food production system. By using specialized DNA sampling Biotags™ and sampling at various critical points in the production and distribution chain, we demonstrated tracking target animals from field to fork. Retail samples were successfully traced back to specific individual animals, thus adding an unprecedented enhanced level of biosafety and risk mitigation. The results determine the efficacy and suitability of such a DNA traceability-based tool to enhance the CFIA's operational capacity to track and monitor transgenic animal stock that are considered high risk or are unapproved for food/feed use.

International Shipments of Clinical Trial Samples, Diagnostic Specimen, and Infectious Substances—Strategies for Compliance

Joyce Beerbower, Safety & Compliance Services, Inc., Kulpsville, Pennsylvania; Nicholas Mohr, PeterEast Associates, Ltd., London, United Kingdom

Effective on February 13, 2003, the United States implemented new regulations for the transportation of infectious substances and diagnostic
Formaldehyde as a Gaseous Disinfectant of Rooms

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Formaldehyde fumigation is the traditional method used to decontaminate microbiology laboratories. However, the fumigation methodology used varies internationally. In the United States, formaldehyde vapor is generated from para-formaldehyde powder after a prior humidification step. The formula used is 300g of paraformaldehyde vaporized per 1,000 ft³. In the UK, formaldehyde vapor is generated by boiling aqueous solutions of Formalin using the formula 100ml of Formalin (ca 40% formaldehyde) in 1,000ml of water per 1,000 ft³. The boiling humidifies the area and increases the temperature in the room thus allowing effective fumigation to be undertaken using approximately an eighth of the formaldehyde used in the U.S. method (<40g per 1,000 ft³).

An experimental fumigation using the United Kingdom method showed that the air concentration of formaldehyde never exceeded 214ppm though the theoretical concentration was 8,650ppm. Formaldehyde was mainly present in condensation layers on the surfaces of the room. When the room was ventilated using a recirculating purifier with 90% efficiency to reduce the air concentration, it took 30 minutes to halve the air concentration instead of the calculated 3 minutes. This was due to formaldehyde being released from the condensation layer as the vapor concentration decreased. This indicates that the United Kingdom method of fumigation forms a condensing layer of formaldehyde on surfaces. Its effectiveness is not a function of vapor concentration.

Disposals of TSE-Infected Materials—Risks and Effectiveness

Paul J. Huntley, DNV Consulting, London, United Kingdom

Transmissible spongiform encephalopathies (TSEs) include conditions such as variant Creutzfeldt-Jakob disease (vCJD) in humans, BSE in cattle (mad cow disease), and chronic wasting disease in deer. The causative agent of these conditions is widely considered to be a form of protein known as a prion, which is highly resistant to many traditional forms of microbial inactivation. This paper reviews the various options available for disposal of material that may be contaminated with a TSE and the known effectiveness of the methods used to destroy the infective agent. The paper reviews traditional methods (e.g., incineration, burning, burial, and rendering) and new or emerging technologies (e.g., alkaline hydrolysis and biosphere). The strengths, weaknesses, and practicality of each of the options is described in terms of their potential applicability to laboratory and industrial situations. The paper also considers the possible exposure risks to the external population from some of the disposal options, drawing on a case study carried out during the 2001 foot and mouth epidemic in the United Kingdom.