60th Annual Biological Safety Conference Platform Abstracts

SESSION: Behavior/Enhancing Compliance

LABORATORY ACQUIRED INFECTIONS
Monday, October 16, 2017, 9:30 AM - 9:50 AM

Karen B. Byers, Dana Farber Cancer Institute, Boston, MA

Objectives: The aggregated data from 3,260 laboratory acquired infections (LAIs) reported in the literature since 1979 will be analyzed. The objectives of this presentation are: to show the trends in what agents cause LAI: to show the LAI data available for settings (clinical, research, teaching, vivaria, vaccine production facilities, and field studies); to highlight how the summarized data illustrates key biosafety principles.

Method: Data summarized from more than 450 references is analyzed to discuss each of the objectives listed above. Primary and asymptomatic infections are tallied, and, in a few instances, secondary and tertiary infections are described. Trends in the types of exposures that led to LAI in each setting will be presented.

Results: LAI have been reported in all settings, with bacteria, viruses, parasites, and fungi. The LAI data explains concepts such as droplet vs. aerosol transmission and the importance of validating inactivation procedures, strain verification, preventing cross-contamination, and proper use of the biosafety cabinet.

Conclusion: Infections occur whenever the infectious dose is delivered by the agent's mode of transmission to a susceptible host. Understanding the small, but real risk of LAI can help biosafety professionals conducting risk assessments and training programs.

Outcomes: A greater understanding of LAI will lead to improved preventive efforts.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Behavior/Enhancing Compliance

A CHANGE IN CLIMATE CAN LEAD TO A BETTER SAFETY CULTURE
Monday, October 16, 2017, 9:50 AM - 10:10 AM

Kimberly DiGiandomenico, Erin Straley, MedImmune, Gaithersburg, MD
Jonathan Harris, Atrium Environmental Health & Safety Services, Gaithersburg, MD

Objectives: Laboratory animal research presents unique hazards pertaining to worker safety. Many times, unsafe conditions are not discovered until an injury occurs and in most cases, the injury could have been prevented had someone informed the staff or safety team of an at-risk condition or a near miss. Most observations go unspoken due to fears of repercussions. In an effort to cultivate the safety climate in the animal facility and encourage proactive, rather than reactive, reporting, the Laboratory Animal Resources (LAR) staff partnered with the Safety Health & Environment (SHE) group to take a behavioral-based approach to safety. A primary focus has been to measure the performance of culture, rather than the absence of injury.

Method: This partnership focuses on promoting safe behaviors within the working environment, increasing the reporting of near misses and at-risk conditions / behaviors, and encouraging employee participation in safety awareness while further evaluating technical and husbandry procedures. The initiative was further encouraged through participation and transparency of management and by incorporating safety components into the overall goals of the LAR group.

Results: While the program is still in its infancy, the facility has seen an increase in reporting, increased training and documentation, and incorporation of safety components into key communications and required trainings.

Conclusion: Through our partnership, we have found that a behavior-based safety approach to animal safety can strengthen the safety culture within a department, by empowering the employees and promoting a proactive approach to risk mitigation prior to near misses or at-risk conditions becoming incidents.

Outcomes: Increase in reporting; Empowerment to freely speak to others about unsafe conditions; Creative solutions to problems

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Behavior/Enhancing Compliance

A HOLISTIC RESEARCH SAFETY APPROACH IMPROVES LABORATORY SAFETY CULTURE
Monday, October 16, 2017, 10:10 AM - 10:30 AM

Esmeralda L. Meyer, Kalyn Jones, Kalpana Rengarajan, Patricia Olinger, Emory University, Atlanta, GA

Objectives: Analyze how the different areas of laboratory safety intersect. Discuss why the different areas of research should not be handled in silos. Illustrate how our institution is using an electronic platform to increase oversight of the research conducted in laboratories.

Method: How do we know that our research safety/biosafety program is working well? To answer this question, the biosafety team at Emory University set out to analyze the transition of biosafety protocols submission from paper format to electronic registration, after eighteen months of the implementation. Various strategies, including the laboratory annual inspection program and allocation of spaces, are being used to strengthen the oversight of the biosafety office and increase our relationships with investigators.

Results: The status of the research safety/biosafety program before and after the electronic platform was implemented will be presented. Current data on research laboratories, hazards, and assessments will be discussed in the context of offering tangible awareness to the research safety/biosafety office of existing and potential risks.

Conclusion: A holistic research safety approach including biological safety, chemical safety, radiation safety, and occupational health evaluations, for example, has improved the interactions between the research safety/biosafety office and investigators as demonstrated by the increase in laboratory registrations in the electronic platform.

Outcomes: The goal of the research safety/biosafety office is to acquire laboratories hazards assessments for all existing research spaces. A periodic review of these assessments will allow the biosafety office to prioritize areas of safety that need immediate attention and for which programs need to be developed.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: International Biosafety

DEVELOPING BIORISK MANAGEMENT SYSTEMS IN THE MIDDLE EAST AND AFRICA THROUGH PROJECT BASED MENTORING - THE TWINNING PROGRAM
Monday, October 16, 2017, 11:00 AM - 11:20 AM

Eric N. Cook, Sandia National Laboratories, Albuquerque, NM

Objectives: Biorisk management (BRM) concepts and principles are relatively new in the Middle East and Africa. Many lab workers in these countries have little knowledge of biosafety as a profession or biorisk management as a concept and very few institutions have dedicated biosafety officers or developed BRM programs. Networking, mentorship and learning from experienced biorisk management advisors (BRMAs) can help newly appointed, inexperienced BRMAs and their institutes and laboratories to develop programs, improve existing systems, increase awareness, and establish biorisk management as a professional pursuit. With funding from the US State Departments' Biosecurity Engagement Program (BEP), Sandia National Laboratories created a twinning program that seeks to pair a BRMA from one of these countries (Eastern twin) with an established (preferably credentialed (CBSP or RBP) BRMA (Western twin) to develop a partnership for education, problem-solving, and networking.

Method: Eastern twins were recruited from the countries that have established cooperative engagement agreements with BEP. Western twins are unpaid ABSA volunteers, selected through an application process. Prospective twins receive orientation, via an electronic session and written materials, on the responsibilities, expectations, resources, etc. for being in the program. Participants meet for orientation, they get to know each other, and are paired based on mutual interests. As a team, they plan a BRM related project that will benefit the Eastern twins' institution. Over a six-month period, twinned teams work to complete their project plans and at the end, teams reconvene at a wrap-up/graduation symposium. At this symposium, each team is assisted in developing a presentation (poster, course, or paper) based on their BRM project for delivery at a scientific conference or in an appropriate journal.

Results: Seven rounds of twinning have been held to date. Fifty-one Eastern twins from the following countries have participated: Kenya, Uganda, Mali, Jordan, Morocco, Tunisia, Algeria, Libya, Egypt, Somalia, Iraq, and Yemen. Twenty-two Western twins, all members of ABSA from the US, Canada and Great Britain have served as mentors. Overall, 45 projects have been completed related to biosafety and biosecurity, thus BRM practices have increased at their home institutions and countries. Six of these projects have been presented as posters at past ABSA conferences. Some examples include the introduction of BRM curriculum in several Universities throughout Libya; development of a library of training tools and BRM resources in Arabic and English through the Egyptian Biosafety Associations website; establishment of a BRM system with creation of 27 new biosafety officer positions who are now trained in BRM basics in all of the regional Ministry of Health laboratories in Egypt.

Conclusion: Project-based mentoring between established professionals and those who are developing as BRM professionals can provide a vehicle for creating life-long partnerships and networks that increase the knowledge, skills, abilities; enhance the profession; and create culturally relevant biosafety/biosecurity tools and resources. Western twins gain a new perspective of biorisk management implementation as they face unique barriers and challenges. Melissa Mørland past president of ABSA, who has participated in 6 rounds of twinning expressed "this program has been the most rewarding and educational experience in all my years in biosafety".

Outcomes: We plan to continue building a network of biosafety professionals through excellent volunteers who share their passion for biosafety, their time, knowledge and experience and serve as role models for best practices and professionalism. These partnerships will continue to improve the practice of biosafety and biosecurity throughout the world.

SESSION: International Biosafety

ESTABLISHMENT OF SAFETY CULTURE AWARENESS FOR FIELD VETERINARIANS AT THE ANIMAL HEALTH RESEARCH INSTITUTE, BENHA BRANCH

Monday, October 16, 2017, 11:20 AM - 11:40 AM

Ali M. Asy, Animal Health Research Institute, Benha, Egypt
Heather Blair, Colorado State University, Fort Collins, CO

Objectives: Avian influenza (AI) is a zoonotic disease with high morbidity and mortality. In Egypt, AI virus was first reported in 2006 and was declared to be enzootic in 2008. To date, there have been 358 human cases and 119 deaths due to AI infection and the virus has rapidly mutated in Egypt. The Egyptian authorities have used vaccination as the only strategy for the prevention of AI and ignored application of biosafety controls. Field veterinarians (FVs) from the Animal Health Research Institute (AHRI) in Egypt collect samples from the poultry farms for AI diagnosis. These FVs lack proper education regarding the need for and procedures to put on and remove personnel protective equipment (PPE) safely and they lack general poultry health and husbandry knowledge. Due to this lack of knowledge, the FVs were not wearing the proper PPE to protect themselves, their community and other poultry farms and they were not being trusted by the poultry farm owners and workers. The aims of our project, therefore, were to 1) protect the FVs, their communities and the other poultry farms from contamination and 2) build a relationship of trust between the field veterinarians and the farm owners and workers by applying PPE and increasing their scientific knowledge, respectively.

Method: FVs were provided pre- and post-questionnaires and were observed in the field before and after training was provided to them. Hands-on trainings were provided on how to put on and remove minimal PPE safely and five training sessions regarding five different biosafety topics were conducted to improve the FVs scientific knowledge and build a relationship of trust between the FVs and the farm owners and workers.

Results: Our results revealed that there was a statistically significant increase ($P \leq 0.01$) of all post-training evaluation percentages in comparison with the pre-training evaluation percentages.

Conclusion: By conducting our project, it could be inferred that most FVs used minimal PPE (gloves, over shoes & masks) as well as the training provided proper education for FVs.

Outcomes: After the training sessions, and during the field visits, most of the FVs used at least the minimal PPE and the FVs began to interact with the farm owners and workers, informing them of the information they had learned in the training sessions.

SESSION: International Biosafety

BIOSAFETY OF WORK ENVIRONMENT IN NATIURAL FOCI OF ESPECIALLY DANGEROUS INFECTIONS IN KAZAKHSTAN

Monday, October 16, 2017, 11:40 AM - 12:00 PM

Svetlana Issayeva, Tolybek Alzhanov, Kolganat Konyratbayev, Aral Anti-Plague Station, Aralsk, Kazakhstan

Objectives: Biosafety analysis of field work in natural foci of especially dangerous infections in Kazakhstan.

Method: The subject of the study was the analysis of biosafety of field personnel work in the epicenters of especially dangerous infections in the northern and north-western regions of the Aral Sea in the period of 2011-2016. Fleas, mites, rodents and other small mammals were harvested for further study in the laboratory.

Results: The problem is the natural foci of the plague in Kazakhstan are very often combined with the epicenters of other dangerous and especially dangerous infections. This results in the need to implement biosafety methods that ensure the protection of field personnel, not only against the plague, but also against all other infections. However, standards that would regulate such work have not yet been developed. Under these conditions, an adequate assessment of the level of contamination risks of field personnel, with the subsequent development of a plan to reduce them, is a very effective method. An assessment of the risks of employee contamination using specially developed indicators for these purposes was conducted. Risk assessment took into account the specific nature of the collection of field material. To test for the plague, rodents were captured and their ectoparasites were examined. For Congo-Crimean hemorrhagic fever test, ectoparasites were taken from farm animals. Therefore, the factors and the level of risk varied significantly. Annual training was conducted to reduce the risk of infection of field personnel. An obligatory element in this case was the training of skills in the event of accidents (rodent and ectoparasites bites, ectoparasites' blood splatter during their removal from mammals for Congo-Crimean hemorrhagic fever test, open injuries of field personnel).

Conclusion: To reduce the risk of infection in work field, it is necessary to put field personnel, for each infection separately.

Outcomes: Our experience has shown that when working in combined foci of especially dangerous infections (plague, tularemia, Congo-Crimean hemorrhagic fever), it is reasonable to use a risk management system outside the laboratory (field conditions), where the important roles are an adequate assessment of the level of risks and proper training of personnel.

SESSION: Inactivation and Decontamination

SUMMARY OF VALIDATED AND VERIFIED VIRAL INACTIVATION METHODS
Monday, October 16, 2017, 1:30 PM - 1:50 PM

David Harbourt, United States Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, MD

Objectives: Determine acceptable scientific criteria to merit a successfully validated or verified inactivation method. Develop acceptable criteria for viability testing of viruses to confirm absence of live virus. Validate previously established viral inactivation methods for efficacy against both enveloped and non-enveloped viruses.

Method: Demonstration of a verified or validated method relied on viability testing data obtained using a minimum of two passages in cell culture followed by the use of a plaque assay, immunofluorescence or PCR to determine presence of live virus. Based upon a consensus of the scientists at USAMRIID, it was established that a validated method required three independent studies under equivalent conditions demonstrating efficacy while a verified method required only a single experiment, provided literature supported the efficacy of the method in question. Chemical inactivation of virus was accomplished through the use of Trizol LS, formalin, acetone, formic acid or SDS buffer.

Results: Trizol was successful up to 11 log reductions. SDS buffer, acetone, formic acid and Buffer AVL inactivation all resulted in a minimum of 6 log reductions of virus facilitating their safe removal from the biocontainment suites. Strategies such as desalting columns or dilution of chemicals used to remove toxins that could affect cell culture growth followed by concentration of diluted samples were still able to demonstrate efficacy of inactivation while achieving LOD below 10 pfu.

Conclusion: These efforts have allowed USAMRIID to continue to facilitate its vital research programs focusing on detection assays and vaccine development while ensuring that any manipulation of inactivated viruses can be done with the highest confidence of safety and security.

Outcomes: This research has allowed USAMRIID to continue its mission of generating detection assays, reagents, vaccines and other biological products with the highest safety and security. USAMRIID remains in compliance with both the latest CDC/DSAT requirements along with DoD and Army requirements with respect to Select Agent inactivation and disposition. USAMRIID has set a standard for burden of proof when validating and verifying inactivation methods for efficacy.

SESSION: Inactivation and Decontamination

USING THE HIGHLIGHT DISINFECTANT COLOR ADDITIVE TO CONFIRM COVERAGE AND CONTACT TIME FOR ANY DECONTAMINATION PROCESS

Monday, October 16, 2017, 1:50 PM - 2:10 PM

Jason Kang, Katherine Jin, Kevin Tyan, Kinnos Inc., Brooklyn, NY

Objectives: Surface decontamination is a critical part of infection prevention. While disinfectants such as bleach have been well-established to exhibit antimicrobial potency across a wide variety of pathogens, a lack of training and compliance renders most decontamination protocols ineffective. For context, 1 out of every 20 people who died during the Ebola crisis in West Africa was a healthcare worker, and the CDC estimates that healthcare-associated infections (HAIs) are responsible for 75,000 deaths and cost the U.S. healthcare system over $28bn each year. The problem is that current disinfectants are: 1) transparent, making it easy to miss spots; 2) form droplets on hydrophobic surfaces, leaving gaps in coverage; and 3) have no method for ensuring compliance, with end-users not waiting sufficient contact time to inactivate the pathogen. This means that surfaces could still be contaminated even after applying a disinfectant. Indeed, a recent report in *JAMA Internal Medicine* demonstrated that contamination of skin and clothing occurs in about 50% of glove and gown removal procedures without proper training and intervention, and Orenstein *et al*. previously demonstrated that improving compliance with contact times can reduce HAIs by more than 80%. The present innovation is a patent-pending additive combined with disinfectants at point-of-use that seeks to address these problems with coverage and compliance. The additive is designed to make the disinfectant colorized and highly visible, modifies the liquid properties to eliminate droplet formation and form a complete film on all surfaces, and fades in color to prevent staining and provide real-time visual feedback for when decontamination is complete. Here, we present data that quantitatively evaluates the effect of the additive on existing bleach and chlorine disinfectants and a qualitative assessment of its ease-of-use by healthcare workers.

Method: The disinfectants used in the quantitative tests comprised 0.2-0.5% solutions of sodium hypochlorite, calcium hypochlorite, and sodium dichloroisocyanurate. To determine the effect of the additive on coverage, a disinfectant was mixed with the additive or a soluble bleach-stable dye and sprayed on a hydrophobic polypropylene surface. Coverage was quantified by analyzing video of the sprayed areas across 10 minutes using a MATLAB script. By changing the ratio of the components of the additive's formula, the color-fading time was modified and the reaction rate was captured using a spectrometer. Third-party laboratories were also contracted to perform ISO-standard primary skin irritation tests to evaluate safety of the additive, and ASTM- and AOAC-standard germicidal tests were performed to compare the contact time and log kill of disinfectant alone vs. disinfectant with additive on various bacteria and viruses. The additive was field-tested with healthcare workers (n=75) working at Ebola treatment units, community health centers, and patient transport teams in Liberia (November 8-19, 2015) and Guinea (May 31-June 13, 2016). Healthcare workers were given a questionnaire to assess existing decontamination protocols, trained on using the additive, and subsequently given a follow-up questionnaire to evaluate adoptability and perceived efficacy.

Results: Across a period of 10 minutes, additive-enhanced disinfectants maintained >99.9% surface coverage, while disinfectant alone had an initial coverage of 32.6% which dropped to 14.8% surface coverage over time due to droplets rolling off vertical surfaces and evaporative effects ($p<0.01$). Modifying the ratio of the components in the additive resulted in changes in reaction rates of more than 6-fold ($p<0.01$). In practice, formulas with color-fading times ranging from 1-10 minutes were easily produced. Third-party laboratories determined that the additive was a negligible irritant (with the lowest possible score of 0 out of 4 on the Primary Irritation Index) and found no difference in contact time or log kill ($p<0.01$) when disinfectant alone and disinfectant with additive were tested on West Nile Virus, Influenza A, Ebola virus, human coronavirus, *S. aureus*, *P. aeruginosa*, and *V. cholerae*. During the initial survey of healthcare workers in Liberia and Guinea, 100% of respondents stated that improper disinfection with bleach is one of the primary reasons people get infected with Ebola and that they would feel more protected if they could see where disinfectant was being applied. When asked about appropriate contact times for disinfecting Ebola virus, responses ranged from not waiting at all to over 15 minutes, with 37.7% of respondents answering below 10 minutes. Following training and usage with the additive, 99% strongly agreed that the additive significantly improves coverage, 97%

found the additive easy-to-use, and 100% preferred using the additive over using disinfectant alone due largely to improved feelings of confidence and safety. Other feedback included that the additive's ability to better adhere to surfaces drastically reduced the smell of bleach, which was a health concern and respiratory irritant for many of the healthcare workers, and that the color-fading was a simple way to learn about contact times.

Conclusion: Current disinfectants are ineffective because of droplet formation on waterproof surfaces and the inability to visually confirm complete coverage and adhere to contact times. The novel additive presented here is added to existing bleach disinfectants to provide visual confirmation of coverage and enforces compliance through color-fading feedback. It is safe, maintains the antimicrobial potency of the disinfectant, and is easy-to-use. The additive can be used as a training tool and in everyday decontamination procedures to protect healthcare workers, patients, and the general public.

Outcomes: Although disinfectant chemistry and concentration are important facets of infection prevention, proper coverage and contact time must be enforced as well. We demonstrate here that our additive is able to significantly raise coverage from <33% to >99.9%, while providing an intuitive way to visually confirm that coverage and comply with contact times. Unlike other training tools, the additive can be used in real-time with every decontamination process and is simple enough to use that even an untrained worker can immediately learn how to use a disinfectant effectively and conduct independent quality control. In effect, the additive retrains the worker every time it is used and empowers workers to be confident in their safety. Given the well-established link between compliance and infection rates, we expect the additive to improve the process of how disinfectants are used to reduce the rate of infection. This not only saves lives and reduces costs both for the patient and healthcare systems, but more thorough decontamination may also limit the spread of antimicrobial resistance.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Inactivation and Decontamination

IMPROVING PROCESSES FOR DECONTAMINATION OF LABORATORY WASTE DECONTAMINATION
Monday, October 16, 2017, 2:10 PM - 2:30 PM

Aufra C. Araujo, Centers for Disease Control and Prevention, Atlanta, GA

Objectives: Laboratory waste is autoclaved to inactivate pathogens and for compliant disposal in the landfill. For complete decontamination, the steam produced during the autoclave process must reach all infectious material. A risk assessment identified lack of standardization of current lab waste management practices and risk for thermal and biohazardous exposures. Our objectives were to evaluate: length and type of autoclave cycles; autoclave performance monitoring methods; requirement for water in autoclave bags and pans; use of X-linked polyethylene tubing (BagPipes) for standardizing autoclave bag closure; and loading configurations of autoclaves.

Method: All experiments were performed in triplicates with addition of 250 mL water and without water. Four autoclave bags containing 8 lbs of PPE each were used per run. Two of the bags in each run had openings closed by twisting and taping shut and in the other bags, BagPipes were held in place by securing the neck of the bag. Three biological indicators (BIs) (Accufast, Getinge) were placed at bottom, center and top inside each autoclave bag. All material was autoclaved in a Getinge machine, pre-vac cycle at 121^0C, 15 psi and 60 min exposure. Twelve metal autoclave pans per run and one BI was added in the center of each pan containing 3.5 lbs of PPE. Pans were closed with lids and closure was evaluated with and without a gap. After each autoclave run was completed, the BIs were incubated at 60^0C for 10 hours.

Results: All 12 autoclave bags taped closed exploded during the cycle and 5 failed the BI test. Of these, 3 had water added and 2 did not. In contrast, when the BagPipe was used, none of the 12 bags exploded and all BIs passed. Using the autoclave pans, all BIs passed whether or not water was added or pans were closed.

Conclusion: BagPipes are effective for standardizing the opening of autoclave bags prepared for autoclaving, allow for adequate decontamination of lab waste, and eliminate the risk of bags bursting in the autoclave. BagPipes diminish the risk of exposure to infectious agents and burns. Both autoclave bags and pans are effective containers for autoclaving biohazardous material and did not require addition of water.

Outcomes: We have developed scientific evidence to improve decontamination of biohazardous waste and inform best practices for CDC laboratories.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Biosafety Program Management

AGRICULTURAL AND PLANT BIOSAFETY PROGRAM MANAGEMENT AT RUTGERS UNIVERSITY
Monday, October 16, 2017, 2:30 PM - 2:50 PM

Aparupa Sengupta, Jessica McCormick-Ell, Rutgers University, Piscataway, NJ

Objectives: Plant and plant-related research includes different categories including traditional breeding, transgenic research, gene editing, and studying indigenous and exotic plant pathogens. Each type of research has different compliance requirements in terms of federal, state, and institutional regulations and guidelines. Unlike human pathogens and recombinant DNA materials, plant and plant-related research do not pose potential threats to human and animal health but do present other important concerns and risks to the environment and ecosystem. The ultimate goal of the 'Rutgers Agricultural and Plant Biosafety Program Management' is to have a robust program in place that is in compliance with various regulations, but that also provides resources and guidance to our faculty and staff.

Method: Rutgers University's agricultural and plant research program is extremely diverse in nature, and spread out in multiple locations around New Jersey. Recently, the biosafety group has spent significant time in improving the program compliance, oversight and resources available for Rutgers researchers. As such, the plant biosafety program management was re-evaluated and revamped to ensure compliance with applicable regulations.

Results: New resources and programs, such as 'Plant Specific Biosafety Training' (classroom and online), 'Greenhouse and Agricultural Farm Inspection Checklist' and, the 'Autoclave Validation Program' were created and implemented for all transgenic and non-transgenic research facilities. Also, we were able to get over 40 plant and plant-related protocols registered with Rutgers Institutional Biosafety Committee.

Conclusion: As a result of the improved program there are new resources and training materials available ensuring compliance with applicable regulations, and can be widely used by different plant and agricultural farm researchers.

Outcomes: These efforts have been very well received and appreciated by faculty, researchers, and green house and farm managers. This talk will discuss our program, the changes we have made and our plans moving forward.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Biosafety Program Management

LOOKING BEYOND THE RISK GROUP: RISK ASSESSMENT CHALLENGES IN MODELS OF EMERGING, RE-EMERGING, AND ZOONOTIC DISEASE
Monday, October 16, 2017, 2:50 PM - 3:10 PM

Molly S. Stitt-Fischer, University of Pittsburgh, Pittsburgh, PA

Objectives: The state of the art in biological research evolves at a very rapid pace. Likewise, public awareness and scrutiny of biological research programs have increased during recent years. Recognizing and mitigating potential risks to the public, environment, and personnel have long been the foundation of risk assessment. However, given the rapidly changing research environment are there additional risk factors that should be considered? How much weight should these additional factors have in our risk assessment process?

Method: Using examples from research studies at the University of Pittsburgh this presentation will demonstrate lessons learned from research with pathogens causing emerging disease; those that are re-emerging in our communities; and lessons learned while accommodating use of infectious pathogens as research tools.

Results: It is increasingly important to look beyond the risk group to consider the impact of intangible risk factors, (e.g. increased public scrutiny of research programs, emerging public health issues, institutional reputation and potential loss of public trust, etc.) on institutional risk assessment and communication processes.

Conclusion: Incorporating assessment of a variety of tangible and intangible risks into biosafety programs ensures safe conduct of research, demonstrates commitment to responsible research to the surrounding community, and protects the institution's reputation.

Outcomes: Attendees will be able to identify intangible risk factors (e.g. increased public scrutiny of research programs, emerging public health issues, institutional reputation and potential loss of public trust) that should be considered as part of the institution’s risk assessment and communication program. Attendees will be able to develop strategies to communicate the potential impact of these risks to researchers and other institutional stakeholders. Attendees will be able to apply lessons learned to continual improvement of institutional programs.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Biosafety Program Management

BSL-2 LABORATORIES ACCREDITATION PROGRAM IMMPLEMENTATION IN NU LABS
Monday, October 16, 2017, 3:10 PM - 3:30 PM

Iwona S. Spath, Rob Foreman, Andrea Hall, Michael Blayney, Northwestern University, Evanston, IL
Hongliang Yang, Houston Methodist Research Institute, Houston, Texas, United States

Objectives: The oversight of Biological Safety Level 2 (BSL-2) laboratories presents a number of challenges in research safety management in many large research institutions. The reasons for this may vary but are often some combination of lax oversight by the Principal Investigator, disorganization, poor housekeeping and the haphazard use of Personal Protective Equipment. On the other hand, there are some extraordinarily well managed BSL-2 labs that deserve special recognition and dispensation for their efforts. At Northwestern University, our BSL-2 Accreditation Program both encourages and recognizes those labs that demonstrate and maintenance of a culture of safety and responsibility. Specifically, the BSL-2 Accreditation Program: ensures the safety of laboratory workers, support staff and the community; assists laboratories in maintaining compliance with applicable NIH, OSHA, CDC, and EPA regulations as well as other relevant State and Local agencies (as applicable); reinforces and rewards a positive working relationship between the Office for Research Safety (ORS) and individual laboratories; and Grants special dispensation to accredited laboratories in the form of rewards and incentives including recognition, rewards and less frequent inspections.

Method: The primary structure of the Northwestern University BSL-2 Accreditation Program has been developed in a form of a rubric by which laboratories could be accredited in a standardized fashion. The rubric uses elements that had already existed as a part of the Office for Research Safety (ORS) Laboratory Safety Review (LSR), a safety checklist that Laboratory Safety Specialists (LSS) use to evaluate a laboratory. The rubric identifies several key safety elements in which laboratories must not be deficient in order to achieve accreditation. Additionally, two unannounced laboratory inspections will be conducted within a three month period prior to being considered for accreditation. The Associate Biosafety Officer and Biosafety Officer will make a determination and provide accreditation following careful consideration of the elements described. Upon achieving accreditation, a laboratory maintains that status for two years, during which time laboratory inspections will be waived. In order to implement the accreditation lab, ORS will evaluate all Northwestern Laboratories to determine eligibility for the program. All laboratories whose primary research interest is biology will be considered. The ABSO will work with LSS to determine which labs are likely candidates to achieve accreditation. The ABSO will reach out to these laboratories to determine their interest and enroll them in the program. Several incentives will be provided to encourage laboratories to achieve and maintain accreditation. Accredited laboratories will have their names published on the ORS website and receive a certificate signed by Vice President for Research, Jay Walsh. Additionally, members of accredited laboratories will receive a quarterly bagel and coffee hour or pizza party.

Results: This program has been planned and preparations are underway for implementation. We expect to have this program fully implemented by September 2017. We expect to have at least five laboratories accredited by September 2017.

Conclusion: We expect that this program will help laboratories to understand the importance of a culture of safety. We also hope to foster and/or improve a working relationship with biology-focused labs. Following successful implementation of the BSL-2 Accreditation Program, we hope to develop similar programs for chemistry-, physics-, and engineering-focused laboratories.

Outcomes: The success of the program (to enlist as many BSL-2 labs into the program) will make a difference in the daily operating routines of the labs, and it will provide safer environment for everyone. Furthermore, the accreditation program will improve the safety management system for ORS including safety inspections of biological laboratories.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Regulatory Issues

IMPLEMENTATION OF THE HUMAN PATHOGENS AND TOXINS ACT AND REGULATIONS: A YEAR OF TRANSITION
Monday, October 16, 2017, 4:00 PM - 4:20 PM

Cinthia Labrie, Public Health Agency of Canada, Ottawa, Ontario, Canada

Objectives: When the *Human Pathogens and Toxins Act* (HPTA) and the new *Human Pathogens and Toxins Regulations* (HPTR) came into force it marked the culmination of a 10-year effort within the Public Health Agency of Canada (the Agency) to reshape how biosafety and biosecurity are regulated across the country. The new regulatory regime brought significant changes to our role and responsibilities at the Centre for Biosecurity (the Centre). Before December 2015, we issued importation permits to individual importers of certain pathogens. Today we have a full range of responsibilities for administering and enforcing the Act and Regulations, delivering national programs for laboratory licensing, incident reporting, pathogen risk assessments, standards development, and more. Taking on this new scope of work required a substantial culture shift. Dealing with license-holding organizations instead of individual researchers — on a broader set of compliance points — has required an evolution of our procedures. Overseeing the new regulatory framework has demanded greater cross-functional collaboration as well. Reporting of laboratory incidents involving Risk Group 2, 3, and 4 human pathogens and toxins also became mandatory for regulated parties. Any incident involving a biological agent in a licensed facility in Canada must be reported. The primary objective is to ensure an early and appropriate response to an incident. This presentation will enable attendants to better understand the Canadian regulatory regime for human pathogens and toxins and to see how a risk-based approach can be applied to biosafety and biosecurity. Additionally, audience members will bring back to their organizations valuable lessons learned applicable in the areas of policy/regulation-making, project management, and client service.

Method: The new regulations are proportionate to risk ensuring regulated parties working with lower risk human pathogens (Risk Group 2 pathogens) or toxins are not subject to the more stringent regulatory requirements as those conducting controlled activities with higher risk agents, such as Security Sensitive Biological Agents (SSBA), Risk Group 3 and Risk Group 4 pathogens. Regulations include a licensing regime, mandatory reporting requirements, security clearances for select human pathogens and toxins, and describe specific exemptions from the licensing requirements. A risk-based approach is also applied to compliance monitoring, verification and enforcement, seeking to bring regulated parties into compliance using the most appropriate level of intervention. The Canadian Biosafety Standard (CBS) is a harmonized national standard for the handling and storing of human and terrestrial animal pathogens and toxins in Canada. The CBS sets out the physical containment, operational practice, and performance and verification testing requirements for the safe handling or storing of human and terrestrial animal pathogens and toxins. Its companion, the Canadian Biosafety Handbook (CBH) is a document that provides the core information and guidance on how the biosafety requirements outlined in the CBS can be achieved. An electronic Biosecurity Portal acts as a data management system housing information on license holders, licensing, biological agent management, risk assessment, compliance monitoring and verification, and incident reporting in one place. This allows the Centre to create a comprehensive and functional picture of the biosafety and biosecurity landscape in Canada.

Results: Hundreds of organizations in eight sectors migrated to the new regime. Currently, over 1000 Canadian organizations have registered through the Biosecurity Portal, which includes more than 858 biological safety officers. One hundred percent of license applications received during the transition (December 1st, 2015 to February 29th, 2016) were processed by January 2016. We have now issued over 1100 licenses for the following license types: - Risk Group 2 pathogens and toxins, - Security Sensitive Biological Agents (SSBA) toxins, - Risk Group 3 pathogens and toxins (may include SSBA microorganisms), and - Risk Group 4 pathogens and toxins (may include SSBA microorganisms). During the transition period, more than 390 HPTA Security Clearance Applications were received. Over 90% of them have been successfully granted so far. In the first year since data collection began, a total of 102 laboratory incidents were reported, 48 of which involved exposure or possible exposure including laboratory acquired infections, confirmed or suspected. Among laboratory incidents involving possible or confirmed exposure, the most common areas of error related to procedures or sharps, whereas the most common root causes identified were standards,

policies, and procedural or communication deficiencies. Feedback received from stakeholders has been positive. Many regulated parties are pleased with the new regulatory regime. Most have found the Biosecurity Portal to be a useful tool; some have proposed ways and ideas to improve end-user experience. They have appreciated the efforts the Centre has made to raise awareness and help them comply with the new legislation.

Conclusion: Going forward the Centre will continue to develop and refine its standard operating procedures for managing the new regime and respond to feedback from regulated parties. The aim is to give license holders the greatest possible clarity about how to manage risks within their operations. Communication with stakeholders will remain at the forefront of our priorities. We are also working on updating the Biosecurity Portal to improve the user interface, create new functionality, and increase business efficiency. With regard to incident reporting, the goal during the first few years of the implementation of the HPTA is to establish a baseline of incidents that will provide reliable comparisons for the establishment of trends and detection of patterns of concern, which can contribute to evidence-based decision making for the on-going improvement of biosafety and biosecurity practices.

Outcomes: This risk-based regulatory framework enables Canadian public health labs to continue responding to disease outbreaks and threats of unknown pathogens as efficiently as possible. It also enables Canadian companies to maintain a competitive edge and facilitate the best and most innovative science in our academic institutions, while ensuring activities are conducted in a manner that is as safe and secure as possible. Using the Biosecurity Portal, the Centre is able to use relevant data to inform evidence-based decision-making regarding biosafety and biosecurity. There is an ability to communicate in real time with the appropriate individuals through training programs, advisories, and reports. As the Centre continues to build a reliable evidence base, the accuracy and relevance of these findings will improve, facilitating appropriate responses to safeguard biosafety and public health.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Regulatory Issues

ESTABLISHING SAFETY STANDARDS ACROSS THE GROWING DIYBIO AND COMMUNITY BIOTECH LABORATORY LANDSCAPE
Monday, October 16, 2017, 4:20 PM - 4:40 PM

Todd Kuiken, North Carolina State University, Raleigh, NC
Daniel Grushkin, Genspace, Brooklyn, NY

Objectives: The purpose of this program is to further develop a set of standards and practices that are easily scalable and transferrable across shared, community, and home labs. Spurred by the convergence of economic and social forces, the pursuit of laboratory-based activities and access to biotechnology are no longer domains occupied exclusively by trained scientists working in academia, government, or industry. Low-cost technologies, access to funding and other reductions in barriers to entry have resulted in a broad range of people conducting sophisticated lab activities—including citizen scientists, hobbyists and entrepreneurs—often called Do-It-Yourself Biology or biohacking. This growing sector in biotech portends to open new avenues of entrepreneurship and scientific exploration. It also generates new risks associated with the mismanagement of biology and engineered organisms.

Method: At this early stage in DIYbio's development, it's imperative to develop a culture of safety so as to ingrain community safety standards in advance of biotechnology's increasing power to adversely affect health and the environment. Activities will focus around the development and promotion of accessible safety resources for the growing network of labs by: 1. Evaluating existing programs, protocols and resources to identify whether they are/will meet the technical capabilities and future trends of the community. 2. Raising awareness of, and recruiting for, new types of roles needed from the professional biosafety community (primarily through the American Biological Safety Association). Designing and implementing new biosafety protocols/systems that align with the evolving needs of the community.

Results: Site Visits**:** Qualitative interviews with community laboratories - Site visits with individual labs in order to qualify the state of the field in terms of capabilities, trends, and needs in relation to biosafety/biosecurity Biosafety Fellowship Program A pilot program embedding biosafety professionals inside three community biotech labs for 6-12 months in order to: • Better understand the capabilities, trends and biosafety needs of the lab. • Train members of the lab in order for them to serve as biosafety managers after the fellowship is completed. • Collect data to design/develop biosafety manuals for the lab(s). These data points will be collected across the fellowship program to design a broader biosafety program for the entire community. • Evaluate the fellowship program to see if it could be sustainably expanded/continued.

Conclusion: This talk is designed to better educate the ABSA community on the growing DIYBIO and community biotech landscape.

Outcomes: The goal of this talk is to garner interest in the program and recruit potential fellows.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Regulatory Issues

SURVIVING THE OSHA AUDIT!
Monday, October 16, 2017, 4:40 PM - 5:00 PM

David Casavant, Sustainable Workplace Alliance, Lake Wales, FL

Objectives: Understand how to proactively prepare for an OSHA visit. List key items OSHA will ask for during the opening conference. Learn how to effectively negotiate fine amounts down (and perhaps even get them removed). Discuss exactly what to expect during each of the three phases of an OSHA visit.

Method: By examining OSHA's safety audit protocols and procedures, we can accurately predict what an OSHA CSHO (Compliance Safety and Health Officer) will target during an onsite health and safety inspection.

Results: Once we understand what OSHA targets, the safety / compliance professional can easily put together a safety program that addresses OSHA inspections. The safety / compliance officer will also understand OSHA's fine and citation classifications and how to petition OSHA for reduction or elimination of these fines.

Conclusion: Last Year OSHA issued over 40,000 citations for safety violations in the workplace. The good news - many labs and healthcare related facilities organizations have learned to comply with OSHA regulations and have avoided fines and citations when audited by OSHA. The best solution is to proactively prepare for the OSHA audit and the solutions in this presentation will do just that - and help you protect your organization's most valuable asset, its employees.

Outcomes: By attending this presentation, participants will have a better understanding of OSHA's inspections protocols and how to better prepare for the "surprise" OSHA inspection.

SESSION: Training

DEVELOPMENT AND IMPLEMENTATION OF A CUSTOMIZED BSL-3 SAFETY TRAINING PROGRAM
Tuesday, October 17, 2017, 9:25 AM - 9:45 AM

Michele Edenfield, Hao Vu, Kristy Jennings, Booz Allen Hamilton, Atlanta, GA
Brandi Limbago, Centers for Disease Control and Prevention, Atlanta, GA

Effective and complete safety training of laboratory staff prior to the inception of work in BSL-3 environments is an essential component of a successful laboratory biosafety plan, and is a long-standing requirement for laboratory workers at the Centers for Disease Control and Prevention (CDC). Due to the recognition that laboratory staff were frequently traveling off-site to vendor-provided training to meet our BSL-3 safety training needs, the National Center for Immunization and Respiratory Diseases (NCIRD) at CDC created a customized BSL-3 Safety Training Program that met both the general CDC requirements and the specific needs of each program with BSL-3 laboratories. The NCIRD BSL-3 Safety Training Program includes online and hands-on modules. The training curriculum was developed from the specific procedures used in NCIRD BSL-3 laboratories, as well as competencies and guidance from internal and external laboratory safety and quality resources. The online module provides trainees with a foundational knowledge of BSL-3 facilities, operations, practices, and hazards, and includes a post-training assessment that must be completed in order for the trainee to move on to the hands-on modules. The hands-on modules address commonly-encountered and high-impact laboratory scenarios, and establish a baseline standardization of common procedures across NCIRD laboratories. Trainees are required to demonstrate the practices learned in order to complete post-training competency assessments. This training program is a self-sustained training designed to meet NCIRD specific needs, developed with minimal funding, and conducted in-house. After attending this training, trainees are prepared to work in NCIRD BSL-3 laboratories, have demonstrated competency in the identified areas, and are more comfortable working in the BSL-3 environment.

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SESSION: Training

DEVELOPING A SITUATION-BASED TRAINING
Tuesday, October 17, 2017, 9:45 AM - 10:05 AM

Gabriel Ó Riordain, CeMM Research Center for Molecular Medicine of the Austrian Academy of Sciences, Vienna, Austria

Objectives: We developed situation-based lab safety training at CeMM. The objective was to supplement existing safety manuals, risk assessment processes and lectures with a practical exercise in the labs. It was considered vital that any training exercise had to deliver memorable impact within a limited time frame and the exercise had to focus on behavioral skills. A key consideration was the diversity of staff from many different countries with different levels of experience. Hence our learning objectives included imparting vital local knowledge, building awareness of the location of emergency safety equipment, and providing trainees with opportunities to practice their own behavior in, and management of, various situations.

Method: The exercise is interactive and challenging with the use of on-site role playing. A number of "stations" are set up in various lab environments within which realistic incident and accident scenarios were created. Images and role-plays were employed to present trainees with a situation to which they were compelled to react. Teams were encouraged to assess the situation, the possible courses of action, and, the potential consequences if they took the right or wrong action, all under a degree of time pressure.

Results: The clear advantages of the training exercise were: the realism in terms of situation and setting; the development of automatic risk assessment skills under time pressure; the enhancement of rapid and confident decision-making; and the testing of trainees' behavioral application of factual safety knowledge.

Conclusion: This interactive training approach was enthusiastically received and showed improved analysis, evaluation and retention of safety information. Weaknesses exposed by the training exercise have led to the development of focused, corrective improvements in the ongoing training effort.

Outcomes: In conjunction with lectures and printed materials, we have permanently integrated this style of training session into the CeMM Safety Program.

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SESSION: Training

BIOSAFETY TRAINING FOR IGEM STUDENTS
Tuesday, October 17, 2017, 10:05 AM - 10:25 AM

Claudia Gentry-Weeks, Colorado State University, Fort Collins, CO

Objectives: Students engaged in iGEM (International Genetically Engineered Machines) research projects come from a variety of backgrounds, including molecular biology, microbiology, computer science, and engineering. To ensure biosafety of the students and their environment, a training event was developed to specifically introduce iGEM students to basic microbiology skills and biosafety techniques.

Method: 'Hands-on' training was developed which included BSL1/2 biosafety training on use, donning and doffing PPE with GloGerm, spill response, aseptic technique, methods to reduce aerosols, and waste decontamination and verification. In addition, basic microbiology techniques were addressed including pipetting, aseptic technique, pouring agar media, streaking bacterial colonies for isolation, preparing serial dilutions, staining bacteria, and recording data. A pre- and post-evaluation was provided to each student to assess their knowledge before and after the training.

Results: An average increase of 30% in awareness and understanding of the need for training and introduction of biosafety and safe microbiology practices was observed among iGEM students. Areas that showed most improvement among the students included use of PPE and aseptic technique.

Conclusion: This study highlights the effectiveness of implementing biosafety and microbiology training early in scientists' careers to enhance understanding of the biosafety practices and increase safety among novice scientists.

Outcomes: A significant increase in biosafety awareness and microbiology skills were acquired by iGEM students following the training sessions, many of whom had never had training in these areas.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Dual Use Research of Concern (DURC)

BEYOND THE 15 AGENTS, SHOULD YOUR INSTITUTION REVIEW LIFE SCIENCE RESEARCH FOR POTENTIAL DURC?
Tuesday, October 17, 2017, 2:00 PM - 2:30 PM

Rebecca Moritz, MS, CBSP, SM(NRCM), University of Wisconsin—Madison, Madison, WI
Robert Ellis, PhD, CBSP, Colorado State University, Fort Collins, CO

Objectives: Dual Use Research of Concern (DURC) is a concept that has been discussed by the National Science Advisory Board for Biosecurity (NSABB) since its inaugural meeting in 2005. Although it was not a new or novel concept, it was not discussed regularly in scientific circles. However, in 2011/2012, media coverage of the potential publication of gain-of-function (GOF) research involving H5N1, a highly pathogenic avian influenza virus, brought the concept of DURC into the mainstream. We will highlight the approaches taken by two different academic institutions in reviewing life sciences research for potential DURC and whether or not to review life sciences research not required by the current DURC Policies.

Method: We will explore the methods and rationale behind how Colorado State University (CSU) and the University of Wisconsin-Madison (UW-M) review life science research for potential DURC using the requirements listed in the March 2012 United States Policy for Oversight of Life Sciences Dual Use Research of Concern and the September 2014 United States Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. We will also look at how both institutions debated whether or not to include life sciences research not covered by the list of agents and toxin in their review and plans to adapt to future changes as needed.

Results: CSU and the UW-M have thoroughly debated and evaluated the best method of reviewing potential DURC research at their institutions. Both have considered whether or not to proactively review research not covered by the current DURC policies in order to meet the requirements of the current DURC policies and to ensure expandability and proactivity as life sciences research evolves. CSU determined that their current Institutional Biosafety Committee (IBC) will be their Institutional Review Entity (IRE). The IRE convenes a separate meeting to deliberate matters of DURC. At this time, CSU has decided to not expand their review process beyond the 15 agents and toxin in the DURC Policies. All protocols submitted to the IBC are reviewed by the IBC Coordinator for the 15 agents/toxin listed in the DURC Policies. Any research involving any of those agents is then forwarded to the IRE to determine if any of the seven experimental effects listed in the DURC Policy. If any of the seven effects are determined by any member of the IRE to apply, the research is discussed at the next IRE meeting. All Principal Investigators conducting research with an agent/toxin listed in the DURC Policy are notified that immediate notification to the IRE is mandatory should they determine their research has led to potential DURC. During a review of all of the submitted new or renewal protocols, the IRE Coordinator or any member of the IRE may cite research outside the 15 agents/toxins for IRE discussion. The UW-M created a permanent subcommittee of their IBC that meets separately to review potential DURC research and serve as the IRE. This subcommittee is chaired by the Institutional Contact for Dual Use Research (ICDUR) and has two virologists, a bacteriologist/infectious disease physician, and the Director of the Communicable Disease Division of the Wisconsin State Laboratory of Hygiene. These members review all research covered by the DURC Policies as well as any life sciences research that has DURC potential that has been flagged by various institutional resources. The results of DURC reviews are presented to the IBC and Biosecurity Task Force if deemed to be potential DURC.

Conclusion: It is essential to remember that DURC is not bad research and the label does not mean that the research should not be conducted. There are no one-size-fits all models for reviewing potential DURC at institutions. In addition, each institution must decide whether or not to proactively review life science research not covered by the current DURC Policies. Whichever model is chosen, it should be thorough and expandable as life sciences research evolves while promoting a culture of awareness, safety, and responsible communication.

Outcomes: Participants will receive an overview of the review process for life science research potentially containing DURC conducted by the two institutions; the thought process behind whether or not to limit the review procedure to the 15 agents and toxins listed in the DURC policies or to expand the review to

all life sciences research. Examples of both possibilities will be given as well as the types of research that could potentially be DURC beyond the 15 agents and toxin. This will be a thought provoking discussion that ABSA Conference attendees can take back to their institutions to develop a DURC review process or tweak their existing structure if warranted.

SESSION: Emergency Response

BROADENING PERSPECTIVES: INTERAGENCY EMERGENCY RESPONSE EXERCISES BETWEEN THE NATIONAL GUARD, CIVILIAN AGENCIES, AND ACADEMIC INSTITUTIONS

Tuesday, October 17, 2017, 3:30 PM - 3:50 PM

Marcia C. Finucane, Ethan Carter, University of Colorado—Denver, Aurora, CO
Christian M. Gonzales, Daniel R. Meade, Charles Q. Beatty, Colorado Army National Guard, Aurora, CO
Holger M. Peters, Colorado Air Force National Guard, Aurora, CO

Objectives: The mission of the National Guard's Civil Support Teams (CST) is to support Civil Authorities at a domestic Chemical, Biological, Radiological, Nuclear or Explosive (CBRNE) incident or disaster site. This includes intentional or unintentional release of CBRNE and natural or man-made disasters in the United States that result, or could result, in the catastrophic loss of life or property. They do this by identifying CBRNE agents/substances, assessing current and projected consequences, advising on response measures, and assisting with appropriate requests for additional state support. To maintain these capabilities, CSTs regularly conduct practical, hands-on exercises with local agencies. There is at least one CST located in every state and the 8th CST of Colorado contacted the University of Colorado Denver | Anschutz Medical Campus to request our participation in two series of exercises pertaining to chemical, radiological and biological agents. Exercise and test the capabilities of the local CST, other local agencies (such as law enforcement and public health), and the University's departments involved in emergency response.

Method: The University's executive leadership endorsed the participation of the University's police, security forces, and Environmental Health and Safety (EHS) in these exercises. Some of the exercises were conducted on the University's Anschutz Medical Campus and some on the base where the CST is located. EHS helped to secure resources such as appropriate space and "potential" CBRNE agents for the mock incident scenes. EHS personnel used their relationships and connections with researchers to obtain materials such as bacterial cultures, microscopes, short lived radiological materials and other laboratory materials to simulate a "do-it-yourself" laboratory of a person with ill intent. Researchers enthusiastically offered to prepare cultures and gather supplies. University emergency responders were consulted on the development of the scenarios for the exercises, supplied the scenarios of each exercise, allowed to observe the deployment and response by the CST, and then disposed of materials (as needed) after the exercise ended.

Results: Not only was the 8th CST able to test their procedures, equipment and overall response to a civilian incident, but the University and other civilian agencies were able to identify potential gaps or areas for improvement in procedures and communication during an incident response.

Conclusion: While exercising University emergency response procedures internally is always useful, in a serious event external agencies would also likely be involved. Developing communication channels and trust between individuals in those agencies is invaluable in preventing disputes over jurisdiction and delays in effective response.

Outcomes: The first set of exercises between the University teams and the 8th CST were so successful that when a regional CST series of exercises were being developed for six months later, the University teams were contacted again for their participation. These exercises present a unique opportunity for the University to strive toward its mission of community engagement and collaboration.

SESSION: Emergency Response

CONDUCTING A MULTI-AGENCY, MULTI-JURISDICTIONAL, FULL-SCALE EXERCISE AT A BIOFACILITY
Tuesday, October 17, 2017, 3:50 PM - 4:10 PM

Brian O'Shea, Battelle Memorial Institute, Columbus, OH

Objectives: The purpose of this project is to present the process, implementation and improvement areas from a multi-agency/jurisdictional emergency response exercise conducted in West Jefferson, OH on October 30, 2015. Full-Scale Exercises provide the platform to validate current plans and procedures, identify response/recovery challenges, explore new technologies, familiarize personnel with roles and responsibilities and provides a forum for ideas, and inoculation to emergency response stress. A multi-agency and jurisdiction exercise was conducted that provided an opportunity for emergency responders at Battelle Memorial Institute, a private sector research organization, and surrounding communities to practice their response duties in a realistic setting in real-time. The planning and response outcome identified lessons learned for exercise planners and responders that anyone is the industry can utilize. The problem with multi-agency/jurisdictional exercises is their resource requirement. This thesis provides a basis to overcome those resource issues by fostering lasting relationships and implementing an exercise that will engage and enhance the capabilities of all stakeholders. Using Homeland Security's Exercise and Evaluation Program (HSEEP) as the basis for planning and execution allowed planners to meet their goals and objectives, while keeping the exercise flexible and fluid. Using HSEEP enabled planners to harness all of the lessons learned which are critical to enhancing capabilities. The lessons learned from the exercise are not limited to those involved. They can be used by anyone planning for or responding to large-scale incidents. In the FEMA National Preparedness Report (NPR), practitioners identified overarching findings on national issues. The intent of the NPR is to provide the nation with practical insights on preparedness that can influence decisions about program priorities, resource allocations, and community actions. One of the three overarching findings included "Response Coordination Challenges for Events that do not receive Robert T. Stafford Disaster Relief and Emergency Assistance Act funds." Recent events, including the Ebola epidemic, highlight challenges in coordinating the response to and recovery of complex incidents that do not receive Stafford Act declarations. By definition, emergency response becomes dramatically more complex when multiple jurisdictions are involved. Experience highlights obvious common themes; as more agencies respond, accountability, systematic processes, communications efficacy and effectiveness begin to diminish (FEMA, ICS 100, 2013). Common issues resurface when Local Emergency Preparedness Committee (LEPC) try to meet federal and state requirements every four years, making it very difficult for local jurisdictions to build meaningful continuity.

Method: A multi-agency and jurisdiction exercise was conducted that provided an opportunity for Battelle emergency responders and surrounding communities to practice their response duties in a realistic setting in real-time. One of the overarching goals emphasizes relationship building between response agencies throughout the planning process. The full-scale exercise offers realistic community related problems that require critical thinking and rapid problem solving. Emergency exercise practitioners recognize that full-scale exercises expedite capability development (Peterson & Perry, 1999). Our exercise not only enhanced the overall emergency response capability of the agencies involved, but as the host, Battelle personnel also gained significant insight on how to better plan, respond and implement these exercises, by challenging our own assumptions in the process. An added component to our exercises is the private-public sector integration. The Battelle West Jefferson Ohio facility is a large research laboratory complex. It is similar to research and development facilities found at universities and government installations. As a private entity, Battelle and the public sector response agencies must collaborate seamlessly to support any major incident involving our facility. While we have a robust and comprehensive emergency management program, we challenge our capabilities and those of the public sector on a regular basis. The outcome of this exercise includes an after action report identifying lessons learned and insights gained from a full-scale exercise involving multiple agencies and jurisdictions that any organization can utilize. The focus is not limited to the perspective of exercise participants, but to anyone involved in a large-scale incident. The focus was on multi-agency response operations and areas for improvements. The exercise involved private, local, state and federal agencies, providing an all perspectives approach, covering a range of skillsets from novice to experienced practitioner for enhanced learning opportunity. Given the geography/location of the exercise, not everyone was physically able to attend the exercise. To help bridge that gap, we developed a web-stream

of the Incident Command Post, as well as incident scenes. Furthermore, we also made available the Master Sequence of Events List (MSEL) for those in attendance at remote locations. Students and faculty from Philadelphia University's Disaster Medicine and Management Program, Executive Leadership from Battelle Memorial Institute, City of Columbus, Franklin County Health Departments, and the Columbus Regional Airport Authority viewed the exercise in real-time. The multi-agency and jurisdictional exercise involved 24 separate agencies, covering village, city, township, state and federal jurisdictions. The exercise encompassed two main sites, Battelle Memorial Institute's West Jefferson location at 1425 Plain City-Georgesville Road NE, West Jefferson, Ohio, and Bolton Field Airport, managed by Columbus Regional Airport Authority located at 2000 Norton Road, Columbus, Ohio. The two sites are eleven miles apart. The Columbus Regional Airport Authority developed its own documentation and communications plan relative to their portion of the exercise. The Ohio State University Wexner Medical Center provided medical support for each aforementioned location, receiving patients by air transport.

Results: Key components of integrated emergency planning and response are: establishing and institutionalizing the Incident Command System (ICS); establishing communications interoperability and disseminating concise hazards communications; providing continual training to staff and public sector responders; collaborating with community response organizations to develop common response strategies and conducting routine exercises. This year's R&R exercise objectives were based on these key components. The 2015 Battelle Recapture and Recovery (R&R) exercise complied with AR-50-6 and Memorandum of Understanding (MOU) commitments with public sector stakeholders. Recapture and Recovery is the immediate response to attempted or actual theft or seizure of chemical agents (CA) and/or biological select agents and toxins (BSAT) incidents. Battelle Physical Security and Public Sector Responders minimized the hazardous materials facilities intruder threat in an expedited manner. However, communications issues existed because of the rapid influx of responding units, strike teams and task forces. These communications issues resulted in emergency response organizations being unable to make response decisions and take mitigating actions quickly and/or accurately enough to protect emergency responders from possible adverse health consequences of a CA/BSAT incident.

Conclusion: Full-Scale, multi-jurisdictional/agency exercises provide a unique learning environment that a classroom cannot provide. The benefits far outweigh the time and effort invested. The mission is simple, provide for the public safety and the communities, as well as each other anywhere at any time. To do that, agencies and organizations, private or public, must enhance their capabilities through training, and most importantly, training together. This project demonstrates how the challenges of executing a full-scale, multi-jurisdictional/agency exercise can be overcome and should not be identified as disqualifiers for full-scale exercises, as is so often the case. Full-scale exercises can be executed efficiently and effectively to provide value, while fostering long-lasting relationships to enable future improvements to the response community.

Outcomes: Create additional reference information, tools, and decision-making aids needed for individuals who have initial decision-making authority to implement response objectives promptly and effectively (e.g., accurate hazards information, emergency action levels) and communications processes). Train and drill Battelle Security personnel vested with initial decision-making authority in the full scope of their emergency response duties. Improve and maintain the competency of initial decision-makers in executing time-urgent response decisions as demonstrated through ongoing performance-based, objectively evaluated, exercises

SESSION: Emergency Response

THE DEPARTMENT OF DEFENSE RESPONSE TO SHIPMENTS OF INCOMPLETELY INACTIVATED BACILLUS ANTHRACIS SPORES

Tuesday, October 17, 2017, 4:10 PM - 4:30 PM

Michael D. Chute, Neal E. Woollen, Department of Defense, Frederick, MD

Objectives: In May of 2015, a Department of Defense (DoD) laboratory shipped inactivated *Bacillus anthracis* spores to 194 laboratories, including 9 overseas facilities. Analysis of these samples determined that some of the samples contained residual live spores from an incomplete irradiation inactivation.

Method: The DoD, and Federal Select Agent Program in conjunction with the FBI conducted investigations into the event, however the DOD's investigations were unique; in addition to looking at root cause analysis, the DoD also sought to identify programmatic and procedural contributing factors and made recommendations to address those factors.

Results: Recommendations from two DoD reports were organized into five categories: quality assurance, peer review, program management, scientific, and institutional. The DoD established a Biosafety Task Force to consider report recommendations and develop a framework for BSAT biosafety program improvements.

Conclusion: The results of the investigations and the Biosafety Task Force were a re-organization of biosafety in the DoD and the designation of an Executive Agent Responsible Official for the DoD Biological Select Agents and Toxins (BSAT) Biosafety Program. The DoD also created the DoD BSAT Biosafety Program Office to improve oversight and implementation of BSAT biosafety across the DoD.

Outcomes: The DoD response to this incident has resulted in an improved BSAT biological safety posture across the DoD.

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SESSION: Human Gene Transfer

DEVELOPMENT OF RESOURCES FOR HUMAN GENE TRANSFER (HGT) CLINICAL TRIALS IN RESPONSE TO 2016 NIH GUIDELINES REVISION
Wednesday, October 18, 2017, 10:20 AM - 10:35 AM

Andrew B. Maksymowych, Shirly Mildiner-Earley, University of Pennsylvania, Philadelphia, PA

Objectives: On April 27, 2016 a revision of the NIH Guidelines went into effect assigning responsibility to institutional review entities for evaluation as to whether Human Gene Transfer (HGT) Protocols required public Recombinant DNA Advisory Committee (RAC) review. The development and implementation of an Institutional Biosafety Committee (IBC) work-flow to support compliance with this change coincided with several new initiatives towards supporting HGT trials at our institution. The initiatives included: additional administrative support for human trials, receipt of new funding to support HGT trials at Penn, Vice President Joe Biden announcing the "Cancer Moonshot" at Penn Medicine, and continuing successes at the Center for Cellular Immunotherapies: *ex vivo* T-cell engineering for cancer and HIV cell based therapies. It was evident that additional resources must be provided to support HGT research.

Method: Development of Penn-specific guidance detailing the 'new' registration process elicited concern from clinical research coordinators (in response to questions from internal/external monitors and auditors), as well as from an increasing number of pharmaceutical sponsors regarding what the IBC will review, approve, and what IBC letters (approvals) will be provided for audit compliance. Finally, the procedure for registration of protocols with the NIH Office of Science Policy, as detailed in the revised Appendix M, needed to be addressed. Personal interactions with study teams uncovered the need for additional guidance and resources to support HGT trials.

Results: This presentation will detail development of two resource documents and will consider the rationale for an ongoing effort to enhance compliance awareness within our clinical research base. Furthermore, we will highlight how this development effort (outreach) motivated planning for IBC program enhancement.

Conclusion: Our efforts confirm that robust, ongoing, personal outreach contributes to enhanced safety and compliance for all clients that are supported by the IBC. This interaction is not only recommended but essential for safety and regulatory compliance.

Outcomes: Ongoing.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Human Gene Transfer

BIOSAFETY CONCERNS FOR HUMAN GENE TRANSFER STUDIES
Wednesday, October 18, 2017, 10:35 AM - 10:50 AM

Peili Zhu, Jonathan Koolpe, Yong Bai, Mei-Chuan Huang, University of California—San Francisco, San Francisco, CA

Objectives: An emerging field involving human gene transfer (HGT) clinical trials (such as targeted immunotherapy for cancer, etc.) is being promoted and is changing the paradigm for how we treat patients with cancer, neurodegenerative, AIDS, etc. This rapidly *changing field* presents a significant challenge to the biosafety professional who must determine: how to monitor all HGT studies at large medical research institution; how to conduct risk assessments on various viral vectors, and/or modified infectious agents used in HGT studies; and how to ensure preparation, storage, usage and disposal of the bio-agent is done safely. In addition, recent revised NIH Guidelines regarding the process for reviewing HGT protocols has put an increased burden on local Institutional Biosafety Committees (IBC) and Institutional Review Boards (IRB). This presentation will examine how to design and implement a campus HGT program to ensure proper compliance with all applicable regulations.

Method: Design and implement a campus HGT program to monitor all HGT protocols at University of California, San Francisco (UCSF) and ensure protocols will be reviewed and approved by the UCSF's IBC and IRB. Use an online Biological Use Authorization (BUA) application system to contain detailed information regarding various vectors, genes, hosts, modified infectious agents, and human materials for HGT studies as provided by Principal Investigators. BUAs for HGT studies are reviewed for risk assessments at monthly IBC meetings. Additional information is also reviewed including Informed Consent forms, completed Appendix M submitted to the NIH RAC, Clinical Protocols, Investigator's Brochures, etc. Conduct a site visit by the Biosafety Officer to ensure preparation, storage, usage, and disposal of bio-agent is done safely. Conduct safety training for investigators, pharmacists, and nurses on how to conduct HGT studies safely. Generate and implement a health surveillance program if necessary. Establish a system for reporting any *serious adverse events (SAEs).*

Results: By working closely with various programs at UCSF, we monitor all HGT protocols and ensure each meets all regulatory requirements. By using the online BUA system, conducting careful risk assessments, providing safety training(s), conducting site visits/reviews, and implementing health surveillance programs (when deemed appropriate), we ensure preparation, storage, usage, and disposal of the bio-agent is done safely.

Conclusion: By design and implementation of a campus HGT program that incorporates the methods listed above, we now monitor all HGT protocols at UCSF to ensure each meets all applicable regulatory requirements. The teamwork between the UCSF IBC and IRB, the biosafety professional, and the laboratory and clinical researchers ensures that HGT studies are conducted safely at UCSF and will lead to more effective and safer treatments in the future.

Outcomes: This presentation will examine how to design and implement a campus HGT program to ensure proper compliance with all applicable regulations.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Human Gene Transfer

THE IBC'S ROLE IN FACILITATING HUMAN GENE TRANSFER IN MULTICENTER CLINICAL TRIALS
Wednesday, October 18, 2017, 10:50 AM - 11:05 AM

Daniel G. Kavanagh, WCG Biosafety, Brookline, MA

Objectives: Understanding new requirements for Human Gene Transfer (HGT) protocol registration with the NIH Office of Science Policy (OSP), especially with reference to industry-sponsored trials; identifying points to consider for implementation of studies involving new experimental therapies at inexperienced sites; and understanding best practices for biosafety staff on site to interact with industry sponsors.

Method: Using a case study format, the work flow process for providing required and best-practice biosafety support for HGT trials will be described.

Results: Compliance with the requirements specified by the NIH OSP can be challenging, particularly for community hospitals and clinics where resources may not be readily available.

Conclusion: The advent of gene editing, molecular vaccines, CAR-T cell therapy, oncolytic viruses, and new experimental interventions for rare diseases have all contributed to a rapid growth in HGT trials both at academic medical centers, and at community hospitals and clinics. This presentation will address the process for registration of new HGT studies with the NIH OSP, as well as best practices for communicating with industry sponsors, clinical investigators, and biosafety personnel at each dosing site.

Outcomes: A well-informed approach to industry-sponsored trials can enhance efficient clinical trial startup while maintaining safety and compliance as the primary objectives of biosafety operations.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Facility Biosafety

KEEP IT SIMPLE - BSL-3 LABORATORY VENTILATION SYSTEMS
Wednesday, October 18, 2017, 2:00 PM - 2:20 PM

Daniel Cook, Cornerstone Commissioning, Boxford, MA

Objectives: Understanding the factors that affect the installation, operation and maintenance of BSL-3 laboratory ventilation systems. Communicate the requirements of a BSL-3 ventilation system to constituents. List the reasons why a BSL-3 Laboratory ventilation system should be simple.

Method: In the early days, the ventilation systems serving BSL-3 laboratories were simple. As times changed, the HVAC industry started to rely on technology and computers more. This naturally led to the use of new ventilation components to more accurately control BSL-3 laboratories. Implementation has not always gone smoothly and, in some cases, made the labs function worse than the simple design. Another reason that ventilation systems have sometimes become more sophisticated than necessary is because designers and owners may misunderstand or misinterpret the system or facility performance requirements. They believe that the system serving a BSL-3 lab has to be able to respond to every imaginable event, which is not the case. There are certainly places in the overall operation of a BSL-3 lab where technology has greatly improved performance. However, just because we can make something more complicated or add all kinds of "bells and whistles", doesn't mean that we should. We need to resist the urge to add features or perceived enhancements that are assumed to be capable of improving system or facility performance at the expense of the operation or use of the lab. Ventilation system features need to enhance day-to-day operation and use. Multiple factors affect the installation, operation and maintenance of BSL-3 laboratory ventilation systems. Facility location, layout, equipment, personnel, etc. should be considered in determining ventilation system selection and design. Working in an organization that has been involved with turning over more than 100 BSL-3 and higher containment projects in the last 16 years has shown us more than 100 unique variations of controlling the airflows and ultimately the pressurization of the spaces. Some have been simple and some have been exceedingly complex, all with the same focus for ventilation system operation: to maintain correct airflow direction.

Results: BSL-3 laboratories must be negatively pressurized relative to adjacent non-containment spaces as defined in guidelines like the BMBL. By keeping the components and control sequences simple, it has proven that reliability and long term stability performance are improved. This presentation will focus on the requirements of a BSL-3 ventilation system. The Ventilation system can be broken down into the following categories: a) Infrastructure systems: Supply air handling units and exhaust fans b) Zone level - Air terminal units or hard balanced or mixture of the two c) Building automation system - Computer based system with electronic controllers used to control and monitor equipment status and operation, including room pressures, with alarming and trend logging. The way this directional airflow and negative pressure is accomplished is by pulling more air out of the BSL-3 laboratory spaces than the amount of air that is put into the BSL-3 laboratory spaces. Maintaining inward directional airflow is the key, so that when doors are opened, as personnel enter and exit the laboratory, airflow direction is maintained from the "clean" areas to the "potentially contaminated" areas. The top 5 reasons why a BSL-3 Laboratory ventilation system should be simple: lower initial design and construction cost; lower number of components and systems to break or fail during operations (Less variables in the risk assessment); simpler standard operating procedure, less time spent writing them, less time spent training; less time for commissioning and inspections by third party agencies; and less down time during maintenance shutdowns and annual performance verification testing.

There are enhancements that can be made while still retaining a simple approach to the Ventilation system. Here are some ideas and items to focus on to meet the no reversal of airflow requirements: controls should focus on steady pressure control for the air handler and exhaust fan, this will result in steady room pressures. We have found that it is better to address the no reversal of airflow requirement at the main equipment level (AHU and EF) rather than at the zone level. We recommend not doing critical control over building automation networks, instead hard wiring these systems for critical control. Redundant AHU, EF and HEPA filter housing; each sized for the full load. Zone level control devices, combining the air terminal unit with similar capabilities of the bioseal damper. Energy recovery systems.

Conclusion: This is not to say that the more complicated systems cannot work. New technologies and sophisticated systems are some of the best assets we have in making labs function better and provide critically important data. As commissioning authorities advocating for facility owners, we prefer to see the simplest solutions applied to deliver BSL-3 labs that can be used safely with ease, stability and reasonable budgets for time and expense. Too much complexity adds time and expense to operations. Whether you are an owner (biosafety professional, researcher, facility manager, building operator, etc), design professional, contractor, or third party consultant, you should be an advocate for a simple BSL-3 ventilation system.

SESSION: Facility Biosafety

DECONTAMINATION WITH COLD PLASMA ACTIVATED IONIZED HYDROGEN PEROXIDE - DOES IT BEHAVE LIKE A GAS?

Wednesday, October 18, 2017, 2:20 PM - 2:40 PM

Miguel A. Grimaldo, MEng, University of Texas Medical Branch—Galveston, Galveston, TX

Objectives: To present the findings of decontamination studies performed on laboratory rooms spaces using atmospheric cold plasma-activation of a solution of hydrogen peroxide that generates Reactive Oxygen Species (ROS) and Hydroxyl Ions.

Method: An atmospheric cold plasma-activated system using SteraMist™ BIT™ solution (~7.5% hydrogen peroxide) for space decontamination was tested for its capability to diffuse the resultant product of the activation process in or during a laboratory decontamination activity. The decontamination effectiveness was verified with the use of biological indicators of *Bacillus atropheaus* and *Geobacillus stearothermophilus*.

Results: The use of the atmospheric cold plasma activation process of the SteraMist™ BIT™ solution on complexed laboratory decontamination setups achieved an efficiency of inactivation of 100% in biological indicators of *Bacillus atropheaus* packaged in Tyvek/Tyvek envelops and after multiple trials from 94% to 100% of biological indicators of *Geobacillus stearothermophilus* in metal strips, both without the need of circulation fans.

Conclusion: The utilization of the atmospheric cold plasma-activation technology of the SteraMist™ BIT™ solution generating Reactive Oxygen Species (ROS) and Hydroxyl Ions presents a viable alternative for decontamination applications in the laboratory setting.

Outcomes: Learn about the results of ongoing testing with this technology as a possible replacement of formaldehyde gas decontamination. Learn about the possible usages of the ionization technology in a laboratory setting.

SESSION: Facility Biosafety

COLOMBIAN NATIONAL INSTITUTE OF HEALTH - BSL2/ABSL2 LABORATORY AND SPECIFIC PATHOGEN FREE FACILITY COMMISSIONING PROCESS

Wednesday, October 18, 2017, 2:40 PM - 3:00 PM

Ricardo Vanegas R, Alejandra M. Muñoz S, Carlos M. Agudelo, Lía Vizzotti, Néstor F. Mondragón, William Pérez, Instituto Nacional de Salud, Bogotá, Colombia

Objectives: To describe the commissioning process of the new Biosafety Level 2 laboratory (BSL-2 / ABSL-2) facilities of the Instituto Nacional de Salud (INS).

Method: Colombia, through INS, is the first country in the region to use a commissioning plan for its new facilities, This commissioning process is focused on reviewing and verifying critical support systems so that their operation and performance are planned, designed, installed, tested, operated and maintained according to the requirements of INS and in compliance with the international standards established for the design and construction of Biosafety Level 2 laboratories as well as for the welfare, care and use of laboratory animals.

Results: The new facilities were commissioned by functional tests using strict protocols in more than 700 different failure scenarios. This resulted in the optimal performance of the laboratory in terms of flexibility, sustainability, safety, quality and operational reliability of the facility, (BSL-2 / ABSL-2), requiring maintenance of barrier conditions for the Specific Pathogen-Free Animals (SPF) that we hosted.

Conclusion: The commissioning of the Biosafety Level 2 laboratory animal facility at the INS was a vital exercise that ensured a high degree of reliability in the engineering controls developed for scenarios including efficient routine operation as well as response to various failures.

Outcomes: This work shows that the management of facilities, as a direct responsibility to its institutional policies of biosafety, welfare, care and use of animals, results in a more efficient implementation.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Biosafety Promotion and Development

BUILDING A USER FRIENDLY BIOSAFETY PROGRAM FROM SCRATCH
Wednesday, October 18, 2017, 4:00 PM - 4:20 PM

Ray Scheetz, Penn State University College of Medicine, Hershey, PA

Objectives: Biosafety is recognized as a blending of many scientific, compliance, IT, mechanical and facilities components. Each overlapping in many defined, undefined and even yet some to be determined ways at a later date. The Penn State College of Medicine, in Hershey, Pa. has recently redefined the approach and makeup of the compliance and biosafety components on its campus. The main objective of the presentation will be to use our recent experience at the Penn State College of Medicine in the development of a unique Biosafety Management Program. Our current system can serve as a welcome blueprint for the establishment of sound biosafety program, encompassing all the many aspects of biosafety

Method: Beginning in 2010, the Research Quality Assurance Office was developed. The RQA office was structured in such a way to have interaction between top administration, biosafety, IACUC, IRB , chemical safety and most importantly, increased overview and training components for the 160 faculty and 350 research laboratories on campus. The biosafety component was removed from the historically located EHS office so the focus could be on the closing of the committee approved protocols and SOP's, as well as the important scheduling of lab surveys and subsequent biosafety approval.

Results: A model biosafety program was developed consisting of a unique blending of interaction between all the important parts of a successful medical school. A user based "home grown " lab specific database system, Lab Manager was also developed to increase the all-important timing of lab compliance , PI renewal of protocols and SOP's, equipment tracking , biological agents, Biosafety levels, and training. A sound Asset Management system was also initiated over the last 7 years resulting in properly calibrated equipment across the campus. This initiative as resulted in reduced non routine equipment repairs across the board substantially.

Conclusion: Our established biosafety program has resulted in increased compliance on our campus as we have effectively closed the loop with all our committee approved protocols. The newly established office of Research Quality Assurance has successfully driven the change which includes timely interaction between all our approval processes including the IBC, IACUC, and IRB

Outcomes: The sometimes myriad of complexity between approval committees and the proper management of biosafety and compliance has been addressed and has developed into a very manageable pattern on our campus.

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Biosafety Promotion and Development

DISSEMINATING BIOSAFETY INFORMATION TO THE NON-SCIENTIST
Wednesday, October 18, 2017, 4:20 PM - 4:40 PM

Lolly Gardiner, Sharon Altmann, MRIGlobal, Gaithersburg, MD

Objectives: Training requests that the author gets most often is, can you train our maintenance staff? Can you train our warehouse staff? Can you train our non-scientists? Non-scientists often rely heavily on pop culture, tv/movies, and the internet for information about viruses and bacteria. Often times these sources depict incomplete or inaccurate safety precautions/measures and inaccurate details about the biological materials being represented, which can negatively influence the perceptions non-scientists to have the safety of their work environments. These perceptions of risk can cause tension between non-scientists and biosafety and laboratory personnel, leading to strained working relationships and less than optimal working practices. The objective of this work is to develop a strategy for understanding the level of comprehension and specific concerns of particular audiences of non-scientists in order to create and disseminate information tailored specifically to address their needs.

Method: Meetings will be held with the job site managers to identify the concerns of their non-scientist personnel, assess the risks at the job site, and inform the development of tailored training materials. Questionnaires will be given pre- and post- training to evaluate the effectiveness of the training at addressing concerns and conveying key biosafety information.

Results: The presentation of biosafety information and training specifically tailored to address the concerns of the non-scientists at a job site can help improve relations between the non-scientists and the biosafety staff, and improve non-scientist understanding of and engagement in good biosafety practices.

Conclusion: Knowing your audience, and the concerns of your audience, allows for more effective and relevant information and training to the non-scientists.

Outcomes: Better training and more informed staff!

60th Annual Biological Safety Conference Platform Abstracts

SESSION: Biosafety Promotion and Development

FROM SCRATCH TO THE ESTABLISHMENT OF CENTER OF EXCELLENCE FOR TRAINING OF BIOSAFETY AND BIOSECURITY IN PAKISTAN: THINGS CAN BE DONE
Wednesday, October 18, 2017, 4:40 PM - 5:00 PM

Saeed Khan, Bilal Ahmed Khan, Anwar Ali, Mohsin Wahid, Dow University of Health Sciences, Karachi, Pakistan

Objectives: The emergence of new infectious diseases & re-emergence of pathogens pose the serious global health security threats. Around 36 newly emerging diseases have been reported between 1973 and 2003. These communicable diseases are responsible for at least a quarter of world deaths. Therefore, research and diagnostics of these deadly pathogens have been significantly increased. However, if these pathogens are not dealt in accordance with proper biosafety and biosecurity sops they pose a substantial health security concern especially in the developed world which is the new hotspot for emerging & re-emerging infectious diseases. Even with all the sophisticated SOPs many safety and security incidents had to occur over the past years at so called advanced facilities, which indicate that the conventional biosafety and biosecurity systems alone are not sufficient. Therefore a new approach "Biorisk Management" has been developed to manage the risk while working with biological agents. The Dow Diagnostic Reference and Research Laboratory (DDRRL) at Dow University of Health Sciences is the largest public sector diagnostic and research facility of Sindh, Pakistan established in 2007, working on No Profit No Loss basis to provide reliable, high quality diagnostic services of international standards for routine and specialized tests at very economical rates for all socio-economic segments of population. Till date, 38 collection units within Sindh have been established and much more are in progress. The DDRRL has now been ISO 15189 accredited, certified with ISO 9000-2001, and recognized by the College of American Pathologist (CAP) 89764-25-01. The DDRRL operates 24 hours a day, 7 days a week. When we started there was hardly any awareness of biosafety and biosecurity and our objective was to learn about the subject of biosafety and then implement not only in own institution rather also train people from other intuition.

Method: We attended a series of conferences, workshops, training courses on biosafety to educate ourselves. We participated in a 4-day workshop on "preparing for ISO Certification in Biorisk Management" where we had learned about the principles of Biorisk Management & strategies for implementation of the CWA:16793 Biorisk Management System which is based on the paradigm of Plan, DO, Check, Act/Adapt. After the workshop, we have done the gap analysis of our laboratory and found that most of the shortcoming can be fulfilled by continual learning through workshops and seminars which will not only benefit our institution but ultimately help the laboratory worker of different clinical labs of Sindh to get trained and implement the system in their respective facilities.

Results: Therefore after the meetings and approval from the competent authority. We have been successful in establishing the "Dow Center of Excellence for Biosafety and Biosecurity" (DUHS-COE) at Dow University of Health Sciences with the mission to conduct biosafety and biosecurity training programs and capacity building for risk assessment, risk management, and risk communication. Under this DUHS-COE we have successfully organized three workshops and trained more than 100 participants. The first workshop was on "Basic Principles of Biosafety and Biosecurity", the second workshop was on "Waste Management and Disposal" and the last workshop was on "Biosafety in the New Era of Emerging and Re-Emerging Infectious Disease". The hallmark of this event was the informative lecture from an international expert. We will organize the "National Biosafety Officers Training Program" as our next DUHS-COE event. During the workshops, we have conducted the pre and post survey through a structured questionnaire.

Conclusion: The results show that these training program significantly improves the knowledge and practices of laboratory workers. This effort was the first step towards the implementation of Biorisk management system in our institution.

Outcomes: With all these trainings and workshops we not only improved the biosafety and security at our own institution but with the training courses that we have offered, we have been successful to spread the slogan of "no one is safe until everyone is safe" and implementation of biosafety and biosecurity in the region which its self is a big achievement.