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PRINCIPAL INVESTIGATOR: James LeDuc, Ph.D.

CONTRACTING ORGANIZATION: University of Texas Medical Branch at GA
Galveston, TX 77555

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14. ABSTRACT The National Biocontainment Training Center (NBTC) provides standards-based theoretical and practical training to trainees and professionals preparing for work in biocontainment laboratories where especially dangerous pathogens will be handled. Training is staged and appropriately targeted to requirements for biological safety level 2 (BSL-2), BSL-3 and BSL-4. Structured coursework is designed to prepare trainees to safely manipulate pathogens, including growth, genetic and antigenic characterization, and molecular studies of pathogenesis. Coursework includes both theoretical training and supervised hands-on procedures tailored to meet the specific needs and requirements of the individual trainee.					
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INTRODUCTION

The **National Biocontainment Training Center (NBTC)** provides standards-based theoretical and practical training to students and professionals preparing for work in biocontainment laboratories where especially dangerous pathogens will be handled. Training is staged and appropriately targeted to requirements for biological safety level 2 (BSL-2), BSL-3 and BSL-4. Structured coursework is designed to prepare trainees to safely manipulate pathogens, including growth, genetic and antigenic characterization, and molecular studies of pathogenesis. Coursework includes both theoretical training and supervised hands-on procedures tailored to meet the specific needs and requirements of the individual trainee. Advanced coursework includes hands-on mentored training in the containment laboratories, including consecutive training at BSL-3 and BSL-4 levels of containment. Specialized training in the handling of laboratory animals is also offered. Sponsored mentored training is available to scientists embarking on a career focused on high hazard pathogens at the BSL-4 level through a dedicated fellowship. Fellows in this program work under the close supervision of an established mentor while addressing a research topic of their own choosing. Mentored scientists and fellows progress to full independent access to the BSL-4 laboratory only when the mentor and laboratory director are fully confident of the individual's skills and ability to work independently in this environment.

The NBTC also offers a unique training opportunity for facility operations specialists interested in pursuing a career as a biocontainment operations manager. To the best of our knowledge, this is the only such training program in the world. This program is designed as a series of modules which address specific aspects of the construction, maintenance and safe operation of a biocontainment laboratory. The coursework is tailored to the specific needs of the individual trainee and involves both didactic training and mentored hands-on work using the Galveston National Laboratory (GNL) as its classroom. Over the course of the training period, which is anticipated to require up to two years for completion, the fellow will be directly involved in the maintenance of the laboratory, decontamination of specific laboratories, monitoring and replacement of filters, and a wealth of other duties routinely seen in the operations of typical biocontainment facilities.

BODY

TATRC's financial support for the NBTC formally began on 22 May 2009 and this submission comprises our second annual report for this initiative. The Laboratory Biosafety Training Center was established and operational prior to receiving TATRC funding; consequently, the course structure and procedures were already in place and allowed the NBTC to implement enhanced training operations almost immediately. From inception to date, the NBTC has provided training to approximately 2,500 participants through the various courses offered. Below is a summary of the significant progress made over the preceding year (2010-2011) under TATRC support. Funding and accomplishments are organized by each specific aim as they were presented in our original proposal.

Staffing Report.

The NBTC relies on a cadre of highly skilled scientists, engineers and technicians to offer a robust portfolio of training opportunities to trainees and professionals working in the field of biocontainment. Below is a summary of these individuals and their roles in the operation and management of the NBTC.

Dr. Tom Ksiazek. Leadership of the overall NBTC program is provided by Dr. Tom Ksiazek, a veteran of nearly four decades of research and development addressing some of the most dangerous pathogens known to humankind, including the filoviruses, Ebola and Marburg, as well as other causes of viral hemorrhagic fevers such as Crimean-Congo hemorrhagic fever, yellow fever and dengue. Dr. Ksiazek also oversees the BSL-4 mentored fellowship program and is responsible for the selection of fellows and for monitoring their progress. As the director of the GNL BSL-4 laboratories, he has ultimate responsibility for the individuals working in this space and as such has final approval in determining when an individual has successfully mastered the essential skills needed to safely work independently in the BSL-4 environment.

Dr. Anne-Sophie Brocard. Classroom and laboratory training is directed by Dr. Anne-Sophie Brocard, an accomplished virologist and experienced trainer who has directed the training center courses since their inception. Dr. Brocard provides both theoretical and practical training to trainees and monitors their progress as they develop appropriate skills for work at each level of biocontainment.

Ms. Je T'aime Newton. Dr. Brocard is ably assisted by Ms. Je T'aime Newton, a highly experienced instructor with extensive expertise in biocontainment. Ms. Newton provides specialized training at all levels of containment, but is specifically responsible for preparing trainees for BSL-4 investigations, focusing her efforts on the proper care, use and maintenance of the protective "space suits" used in the BSL-4 laboratory and other aspects of work in this highly specialized environment.

Ms. Vicki Jones. Ms. Jones is a critical member of the teaching faculty who assists as a trainer in both the theoretical and practical training modules.

Ms. Belinda Rivera. Ms. Rivera is a critical member of the teaching staff who assists as a trainer in both the theoretical and practical animal training modules.

Mr. Jason Hardcastle. Mr. Hardcastle is a trainer and assists Ms. Jones and Rivera with the training of students, specializing in *in-vitro* techniques.

Ms. Dee Zimmerman. Ms. Zimmerman is the director of the University's biosafety program and offers guidance in the regulatory requirements for operation of any biocontainment facility.

Mr. Lee Thompson and Mr. Miguel Grimaldo. The containment operations fellowship is coordinated through the efforts of Mr. Thompson and Mr. Grimaldo (currently funded

by other GNL and UTMB resources). They are responsible for the content development of each module of the containment operations fellowship and they also provide the dedicated instruction associated with each module. They serve as the primary mentors for the containment operations fellows.

Ms. Sharon Walters. Ms. Walters serves as the business coordinator for the NBTC and is involved in the outreach program as well as registration process for all external trainees, nationally and internationally.

Dr. Gavin Bowick. Dr. Bowick was a senior biocontainment fellow preparing for work in the BSL-4 laboratory during the first year of the TATRC contract. Dr. Bowick's training, which focused on preparing him to work on BSL-4 arenaviruses, was interrupted due to visa issues and he had to depart UTMB. His visa issues were subsequently resolved and he has now returned to UTMB as a faculty member with sponsorship from other funding sources. He has not received support from the NBTC fellowship during the current reporting period. However, involvement in the fellowship did allow him to transition into a permanent faculty position with sponsored funding directed at BSL-4 pathogens.

Dr. Janice Endsley. Dr. Endsley is an assistant professor on the UTMB faculty. She entered the BSL-4 fellowship program in 2010. Dr. Endsley is an expert in tuberculosis and is preparing for work with XDR-TB. We anticipate that Dr. Endsley will continue in the fellowship for much of the coming year as she gains critical experience and masters skills needed to work in this environment.

Ms. Joan Geisbert. Ms. Geisbert joined the NBTC in 2010 to assist in training at the BSL-4 level. Ms. Geisbert has over 30 years of experience in BSL-4 laboratories and has worked extensively with experimentally infected animals, including non-human primates, under containment conditions. As our animal handling in containment training module is developed, Ms. Geisbert plays a key role in leading this effort and is lending her practical skills to mentor users in the BSL-4 laboratory.

Additional Mentors. We anticipate expanding our cadre of skilled mentors to provide oversight and supervision of trainees as they complete their hands-on training under BSL-3 or BSL-4 laboratory conditions. Mentors will be existing faculty members who have earned independent access to the containment laboratories and they will incorporate this added duty into their existing activities.

Dr. James LeDuc. Dr. LeDuc serves as the principal investigator for the NBTC award and is responsible for programmatic oversight, budgetary issues and reporting requirements. Dr. LeDuc has nearly four decades of experience in the conduct and supervision of research and development activities under biocontainment conditions and he has been intimately involved in the development of national policy in the fields of emerging infectious diseases, bioterrorism preparedness and biocontainment.

To meet the growing demand for training opportunities offered through the NBTC, we are in the process of recruiting additional trainers and mentors. We are also in the

process of developing skilled trainers to assist in the education of trainees and fellows in the safe and appropriate handling of laboratory animals in the context of research under biocontainment conditions.

Teaching Laboratory Facilities.

The teaching laboratory is a critical asset of the NBTC and it is designed to offer trainees realistic exposure to the conditions and equipment they will typically encounter as they conduct their studies in the containment laboratory.



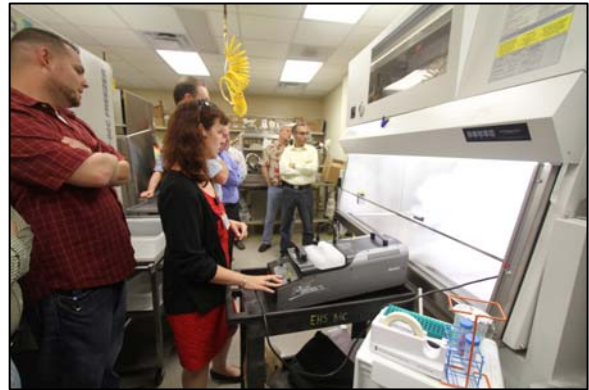
At the BSL-2 level, this typically includes a biological safety cabinet where handling of pathogens at all levels of containment takes place (*pictured*). It also includes limited specialized equipment, as well as facilities to manage laboratory waste and storage of pathogens. Training for individuals preparing for work in the BSL-3 laboratory includes a dedicated area where individuals master the donning and doffing of protective gear and its proper disposal.

Those trainees going on to prepare for work in the BSL-4 laboratory have specialized instruction in the care and use of the positive pressure encapsulating ensemble or “space suit” that is worn in the most common type of BSL-4 laboratory in use today (*pictured*). This includes inspection of the suit for any evidence of leaks prior to use, gaining experience and familiarity in the wearing of the suit, use of compressed air hoses, and training in emergency procedures. In order to provide this training under realistic conditions, the training facility has been outfitted with a breathing air compressor and a mock laboratory where trainees can experience wearing the suit and become familiar with working in this unique environment. Some people discover that they experience claustrophobic reactions when wearing a suit; and this practical, realistic suit training environment allows them to overcome any such reactions under well-controlled conditions, or decide that this work is not a good fit for them.



A key benefit of the support provided to the NBTC is the availability of resources that allowed for the renovation of our existing teaching laboratory facilities. We have completely refurbished the training facility to significantly expand the mock laboratory space available to us, and to enhance the breathing air compressor and suit training area.

Laboratory training is conducted in the mock training laboratory with authentic laboratory equipment utilizing non-infectious materials. Entry into the lab is through a double door anteroom with directional airflow and mock pressure monitors. The laboratory has three class II biological safety cabinets, two of which are constructed with see-through panels which allow the trainer to introduce smoke into the BSC to visualize air movement within the BSC (*pictured*). There is a third BSC class II cabinet on order which has see-through panels and BSL-4 air connections ports. Two of the BSC cabinets are equipped with cameras inside that allow us to perform remote demonstrations. The laboratory itself also has two cameras installed for remote demonstrations. The laboratory has two class III glove boxes, incubators, centrifuges, bench top autoclave, refrigerator, -80° freezer, dunk tank, and general laboratory equipment to allow for mock BSL-2 to BSL-3 and -4 laboratory work. The laboratory is equipped with a compressor and air lines for practice in the suit check examination and use of BSL-4 suits within that facility prior to the trainee entering the active BSL-4 laboratories. The laboratory also has multiple airline drops allowing the trainee to work throughout the laboratory with the ability to connect and disconnect airlines as needed.



Overview of NBTC Training.

The NBTC provides a series of training modules involving a mixture of didactic instruction and hands-on training to be carried out within an existing mock BSL-3/-4 training laboratory located within the Environmental Health and Safety Office space in the Materials Management Building on the UTMB campus. The intent of the NBTC is to promote good techniques and safe procedures to be used at all biosafety levels, and to provide consistency in research practices. The program is designed to ensure that all training attendees have the same general biosafety training at BLS-2 and -3, and if necessary BSL-4, prior to entering an active biocontainment laboratory, thus ensuring that safety standards are observed and good practice is pursued.

BSL-2 and BSL-3 Training.

The BSL-2 and -3 training provide a multi-phased approach:

- the assessment phase
- the training phase
 - theory
 - hands- on practicum
- final assessment

Each trainee begins with an **assessment phase** that includes a written test focusing on safety related topics, hands-on skills related to protocols based on their research using appropriate biosafety practices and procedures. During the assessment the trainer does not intervene as he/she notes both safety and scientific techniques employed by the trainee. This allows for the determination of experience and level of training that will be required for each trainee. Once the initial assessment is completed the results are reviewed with the trainee, the specific areas of training focus are identified. A written report is then sent to the trainee and their principal investigator or supervisor.

The **training phase** includes a theoretical class which covers the following topics:

- BSL-1 through 4 standard microbiological practices, special practices, safety equipment and laboratory facilities.
- Personal protective equipment, types of respiratory protection, gloves, gowns, use and disposal.
- Proper use of the biological safety cabinet (BSC), how the cabinet functions, monitoring the BSC functions, setting up the work field, decontamination prior to and after work, and spill response in the BSC.
- Procedures with the potential for creating infectious aerosols, recognizing aerosol producing devices and learning how to mitigate and control aerosol production.
- Emergency procedures, spills in the laboratory, BSC, centrifuge, incident response, cleanup, first aid, reporting procedures, and medical emergencies in the lab.
- Waste management, types of disinfectants, types of waste generated, the differences in disinfection, decontamination and sterilization.
- Introduction to select agent rules and NIH-OBA guidelines.

The hands-on practicum during the training phase compliments and reinforces the theoretical class and allows the trainee to experience different scenarios in a non-hazardous environment. It also allows the trainer to observe, advise and correct the trainee's techniques in the laboratory relative to safety as well as scientific issues (e.g. contamination of cultures). The practicum is specific to biosafety and agents to be used (e.g. bacteria, parasites, viruses) by the trainee. This approach also allows the use of specific protocols or facility specific practices that the trainee brings with them. Emergency response and spill training allows the trainee to visualize and respond to spills and contamination with the use of florescent dye and breakable training lab ware.

The **final assessment** is identical to the initial assessment, with a written exam and hands-on skills assessment. Once the trainee has completed and passed the final assessment, the trainee is provided with a certificate of training for the biosafety level they completed. A report is sent to the principal investigator, trainee and laboratory director.

Animal BSL-2 and Animal BSL-3 Training.

An animal biosafety training program was developed and instituted based on the same concepts as the BSL-3 training program. Trainees must have completed BSL-3 training before commencing ABSL-3 training. All animal use is approved by our institutional animal care and use committee, and our animal holding facilities and procedures have been approved by AAALAC. All aspects of our ABSL-2 and ABSL-3 training program have been reviewed and approved by the USAMRMC Animal Care and Use Review Office (ACURO).

The ABSL training phase includes a theoretical class which covers the following topics:

- Personal protective equipment, types of respiratory protection, gloves, gowns, use and disposal.
- Proper use of the biological safety cabinet (BSC), how the cabinet functions, monitoring the BSC functions, setting up the work field, decontamination prior to and after work and spill response in the BSC.
- Procedures with the potential to create infectious aerosols, recognizing an aerosol producing devices and learning procedures to mitigate and control aerosol production.
- Emergency procedures, spills in the laboratory or in the BSC, incident response, first aid, reporting procedures, and medical emergencies in the lab.
- Waste management, types of disinfectants, types of waste generated, the differences in disinfection, decontamination and sterilization.
- The hands-on practicum compliments and reinforces the theoretical class and allows the trainee to experience different scenarios in a safe working environment. It also allows the trainer to observe, advise and correct the trainee's techniques in the laboratory relative to safety as well as animal handling. The practicum is specific to biosafety and animal species to be handled. This approach to training also allows the use of specific protocols or facility specific practices the trainee brings with them.

In the third phase, the final assessment includes a written exam and a hands-on skills assessment. Once the trainee has completed and passed the final assessment the trainee is provided with a certificate of training for the biosafety level they completed.

BSL-4 Training.

BSL-4 training rests upon a firm adherence to the principles and specific practices of safe BSL-3 research. This practice prevents an over-reliance on the BSL-4 suit as a primary means of personal protection, and makes the suit an operationally redundant means of personal protection, significantly enhancing overall containment. Accordingly, individuals who are selected for BSL-4 training will have completed training at BSL-3 and have been approved for independent access to the BSL-3 laboratories. These individuals would then complete the BSL-4 modular training.

Specific Aims.

Aim 1: To provide standards-based, high containment laboratory safety knowledge.

Standard training activities for UTMB staff, trainees and investigators from outside the University have been in place throughout the year. The number of individuals trained at each level is summarized in Table 1 below and the associated figures. As summarized above, the topics typically covered in this introductory training include the principles of basic safety precautions in the laboratory, routine rules and regulations designed to protect the individual and environment from accidental contamination by an infectious microbe, and the care and use of the biological safety cabinet. Also covered are the appropriate procedures of clean-up following a spill, decontamination procedures, principles of the care and use of autoclaves and other essential equipment.

Aim 2: To provide standards-based, high containment laboratory hands-on training.

Training offered under this aim is directed at providing trainees with practical, real-world training in the laboratory setting. Course content is tailored to include those procedures and the use of specific equipment likely to be encountered by the trainee in their routine work. Thus, those destined to work in a virology laboratory may focus on those protocols most appropriate for use in a virology laboratory as opposed to those typically used when working with bacteria. There are, of course, common practices used in any BSL-2 laboratory and training on the safe conduct of these procedures is the foundation of this course. Training typically is undertaken in small groups of only one or two individuals, allowing for intense interaction between the instructor and trainees. By actually doing the procedures essential to their day-to-day laboratory work under the close supervision an instructor (with the use of indicator dyes that allow clear recognition of contamination), the trainee quickly grasps the key teaching points and rapidly masters safe laboratory practices. Training is offered in the newly renovated training laboratory described above.

The numbers of individuals trained under Aim 2 for the NBTC is summarized in **Table 1**.

Aim 3: To provide topic-specific training.

Autoclave Operations. A routine requirement for all persons working in containment laboratories is the need to be able to properly operate autoclaves. A dedicated training session is offered to all individuals as a separate element of their orientation to the GNL, and this training is offered to individuals working in other laboratories using the same or similar equipment. During the first year of support we trained 26 individuals in the proper care, use and operations of autoclaves. As new hiring actions within the GNL occur routinely, we anticipate ongoing demand for this training through coming years.

Aerobiology. The GNL contains aerobiology laboratories at both the BSL-3 and BSL-4 levels of containment. The BSL-3 facilities were fully commissioned and approved for use by the CDC and USDA during the year just completed; however, the GNL BSL-4

facilities were approved for full operations in May 2010 and operations began in September of 2010. These facilities are highly complex and require specialized training not only in the operation of this sophisticated equipment, but also in the proper care and handling of the laboratory animals that will be experimentally infected. During the course of the year we have trained 42 individuals for work in the BSL-3 facility, and during the coming year we anticipate that many of these same persons will acquire training in the BSL-4 facility as well.

External Training: As highlighted later in this report, the Kenya Medical Research Institute (KEMRI) in Nairobi, Kenya requested that we provide BSL-3 training for their staff prior to opening their new BSL-3 facility. Subsequently 19 trainees received external theoretical BSL-3 training of which 10 trainees also received hands-on training. Trainers also travelled to the University of Texas El Paso (UTEP) to provide BSL-3 and ABSL-3 training in laboratory operations prior to the opening of their research facilities. The topics discussed included biocontainment operations, BSL-3 facility maintenance, the Select Agent registration process, record keeping, the benefits for annual biocontainment maintenance validations, and an extensive tour of BSL-3 laboratories and support spaces. Additionally, the World Health Organization (WHO) sent 18 of their worldwide BSL3 facilities staff to the NBTC for training.

Gamma Irradiator Training. BSL-4 laboratories utilize a number of techniques to inactivate biological materials prior to removal from the containment laboratory. One of the most frequently utilized means of removing materials from the BSL-4 laboratory is inactivation by gamma irradiation. In an effort to provide training of individuals that use gamma irradiation at UTMB, a module providing background on radiation biology, radiological and biological safety training, select agent and radiological security training, introductory training on dosage determination and method validation, and practical instruction on the use of the devices used for gamma bombardment was assembled and offered to staff. Instructors included members of the Radiation Safety Office and Biological Safety Office of UTMB's Environmental Health and Safety Office and Faculty and Staff from the Galveston National Lab.

High Through-Put Screening. We continue to work to develop a systematic training program focused on the safety concerns associated with high through-put screening. Four of the original 8 trainees introduced to the program are continuing personalized training on this unique equipment, and we anticipate an additional 2 trainees to start during the next quarter. In addition, we purchased a major piece of equipment, a pyrosequencer, to augment the existing robotics and PCR equipment already in use in the laboratory. All of this equipment was used to assist the Texas Department of State Health Services and other collaborating laboratories in response to the emergence of Influenza A H1N1 that recently occurred. We will continue to develop this capability in future years as it represents the cutting-edge interface between technology and biological sciences and as such potentially creates new challenges for biological safety.

Aim 4: To provide a mentorship program for scientists working in BSL-3/ABLS-3 or BSL4/ABSL4 facilities.

A total of 93 trainees and staff were enrolled in ongoing mentored guidance in the BSL-3 laboratory suites during the year just completed, while 16 participated in supervised training at the BSL-4 level. Mentored training typically extends beyond a given reporting quarter. A more extensive listing of the number of individuals trained during the year can be found in **Table 1**.

Aim 5: To establish a fellowship program for scientists and facility operations professionals working in BSL-3/ABSL-3 or BSL-4/ABSL-4 facilities.

The high and maximum containment fellowship program for scientists is in place and we have two fellows now in training. Dr Gavin Bowick, the first NBTC fellow, has transitioned from the NBTC fellowship to a permanent UTMB faculty position involving BSL4 pathogen research. Dr. Janice Endsley is the second fellow sponsored by the program. As indicated above, Dr. Endsley is an expert in tuberculosis and is preparing for work with XDR-TB. We anticipate that Dr. Endsley will continue in the fellowship for much of the coming year as she gains critical experience and masters skills needed to work in this environment. As the GNL BSL-4 laboratories have become operational and expand to a full scope of operations, we anticipate the possibility of expanding the number of fellows.

The laboratory containment operations fellowship is unique and is, to the best of our knowledge the only one of its kind. The program promises to set a new standard for preparation of individuals working in this highly specialized environment. Unlike the fellowship for scientists, where the candidate is likely to already have solid technical skills and will be applying them in the containment environment, most entering facility operators will require a more structured course of study. Consequently, we have identified fourteen distinct modules to be covered over the course of the fellowship. These structured modules will cover basic microbiology, provide an overview of biosafety and biocontainment principles, construction methodologies specific for each level of containment, risk assessments, select agent regulations, formal Good Laboratory Practices, annual certification of laboratories, testing of HEPA filter housing and filters, air balancing procedures, building automated systems and engineering controls, effluent treatment systems, autoclaves care and use, decontamination procedures, biosafety cabinet certification, and laboratory operations SOP development and record keeping. During the course of their training, fellows will directly participate in each of these activities, as well as be personally involved in the planned shut down and decontamination of containment suites, validate decontamination, and conduct and oversee maintenance activities. Plans are being developed to allow fellows to visit other high and maximum containment laboratories across the nation during the second year of their fellowship to better understand the diversity of facilities and variations in containment practices.

At the current time, our first biocontainment operations fellow is in-processing and we anticipate that he will begin formal training within the next 60 days. This individual comes from the construction industry and was directly involved in the construction of the GNL, so he is especially well qualified to participate in the fellowship. We are designing his course of study to be flexible to allow him to participate in the fellowship while retaining some of his duties with his current employer.

Aim 6: To provide training in Biosurety and Biosecurity for both leaders of biocontainment laboratories and for staff working in such facilities.

Over this past year of support we have actively participated in the national dialogue over the critical elements necessary for an effective program in biosurety and biosecurity of biocontainment laboratories. This remains an evolving field, with guidelines still being developed and a legal foundation yet to be established. As these issues are being debated nationally, we have continued to provide our expert opinion through the American Society of Microbiology and other organizations at the fore of these discussions. We have also participated in ongoing discussions on these topics hosted by the National Science Advisory Board for Biosecurity (NSABB) and the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight.

Biosurety and biosecurity are currently covered in our theoretical training sessions, and we are in the process of developing a structured course to more specifically address biosurety and biosecurity in depth. We anticipate posting this course on our internal website as an educational tool to augment our more formal training opportunities and to complement lectures already offered. Depending upon the success of this internal posting, we will then consider posting the course on our general website where it would be available to the general public.

As part of our participation in the national dialogue on biosecurity – and as a service to the research community – we also established a distinguished speaker series. Our *Topics in Biosecurity Symposia Series* has been offered twice thus far – in November 2010 and February 2011. Both sessions were attended by large crowds and drew positive attention and feedback.

Summary of Biosurety and Biosecurity training activities this past year:

Topics in Biosecurity Symposia Series – Session I.

A symposium on biosecurity policy was held at the Galveston National Laboratory on November 9, 2010. This was the inaugural symposium in the Topics in Biosecurity Symposia Series included as speakers the Honorable Judge Susan A. Ehrlich, a current member of the National Science Advisory



Board on Biosecurity, and Dr. Victoria Sutton, a Professor of Law and Director of the Center for Biodefense, Law and Public Policy at Texas Tech University School of Law. The symposium was open to the public and to students and faculty from across the UTMB campus.

We enjoyed excellent attendance with standing room only for the presentations and following discussions. Members of the greater Galveston County participated in the symposium, and included in the audience was at least one member of the UTMB Community Advisory Board and the Galveston National Laboratory Community Liaison Committee. Also present was the editor of the local newspaper, the Galveston County Daily News, and a reporter from the Houston affiliate of National Public Radio (NPR). The presentations and subsequent discussion focused on the yet to be released report from the Federal Experts Security Advisory Panel and their draft recommendations concerning the Select Agent Program. One of the topics of most interest to symposium participants was the issue of personnel reliability and how organizations handling Select Agents might best reduce the risk of insider misuse of Select Agents.



Following the symposium, the Galveston County Daily News published an editorial based on the presentations and discussions made during the symposium, “Unique Opportunities at Galveston National Laboratory, 14 November 2010 (www.galvestondailynews.com).

Topics in Biosecurity Symposia Series – Session II.

On February 28, 2011, the NBTC and the GNL hosted the second symposium in our series. Our guest speakers for this second session were: 1) RADM Kenneth Bernard, MD, USPHS (Ret.), a noted expert on biodefense who has influenced national and international biosecurity policy during stints, among others, as Special Assistant to the President for Biodefense, Assistant Surgeon General, Senior Advisor for Security and Health on President Clinton’s National Security Council staff, and with former U.S. Senator Bill Frist on assignment by the U.S. Surgeon General; and 2) Robert Kadlec, MD, a homeland security veteran with more than three decades of experience shaping, executing and championing public health and bioterrorism policies and preparedness. Dr. Kadlec



served as a career officer and physician in the United States Air Force with placements in several senior positions in the White House, the U.S. Senate and the Department of Defense. He served as the Special Assistant to the President and Senior Director for Biodefense Policy on the Homeland Security Council and as staff director for the congressional Subcommittee on Bioterrorism and Public Health under its chairman Senator Richard Burr. He was responsible for conducting the biodefense end-to-end assessment, which culminated in drafting the National Biodefense Policy for the 21st Century and is currently with global management consulting firm PRTM as a vice president in its Global Public Sector business, based in Washington, DC.

These distinguished speakers provided symposium attendees an “insiders” understanding on the current state of policy and legislation concerning biosecurity and biodefense issues. During their presentations they provided key insight as to the legislative process, the thinking behind some of the policy decisions made, and future challenges yet to be addressed. The symposia series is open to the public and to students and faculty from across the UTMB campus.



At both Session I and Session II we enjoyed excellent attendance with standing room only for the presentations and following discussions. Community members from greater Galveston County participated in the symposium, and included in the audience were also members of the UTMB Community Advisory Board and the Galveston National Laboratory Community Liaison Committee. The presentations and subsequent discussion focused on the mechanisms of federal policy regarding biosecurity and biodefense, particularly from the international perspective

Session III in the series is planned for Fall 2011.

NBTC Website.

Over the past reporting year, the new NBTC website was created and published - www.utmb.edu/nbtc. We will continue to add content to the site over the course of the coming year. The site serves as a hub of information regarding the Center, our goals, and the resources that the NBTC makes available to the biosafety and research communities. We are currently developing a dedicated section focused on biosecurity which will offer a comprehensive review of the topic and practical guidance.



External Onsite Training - KEMRI, Nairobi, Kenya.

The NBTC was invited to provide BSL3 training for a new facility in the process of opening at the Kenya Medical Research Institute (KEMRI) in Nairobi, Kenya. In this capacity two NBTC trainers travelled to the institution in February 2011 and provided biosafety training onsite to ten individuals (*pictured*). This trip was sponsored by a UTMB principal investigator who is in the process of establishing a formal collaboration with the institution.



2nd Annual African Biosafety Association meeting.

In February 2011, the NBTC was invited to attend the 2nd Annual African Biosafety Association meeting held in Accra, Ghana. At this meeting a number of different African countries were represented and each highlighted their biosafety efforts. Meeting attendees agreed to work together in an effort to improve training and biosafety knowledge of all laboratorians working in biosafety level laboratories in the different countries. The training program also received significant attention during the conference as an exhibitor and during a formal presentation on biosafety training provided to attendees by Dr. Brocard (*pictured*). The NBTC has already been invited to return to next year's conference.



NASA's Johnson Space Center.

The trainers from the NBTC were invited to NASA's Johnson Space Center in Houston to provide BSL2 training to ten of their laboratory workers. The training was very well received and members of our team were invited back to the center to present on biosafety topics at a meeting of environmental health and safety professionals in May 2011 (*pictured*).



Table 1.

Summary of training courses offered and number of participants in each course, May 2009 through May 2011.

Module	May-Dec 2009	Jan-March 2010	April-June 2010	July-Sept 2010	Oct-Dec 2010	Jan-March 2011	April-June 2011	Total
BSL-4	9	2	6	2	24	5	26	74
BSL-3	45	14	28	27	18	31	11	174
BSL-2 Theoretical	107	30	62	38	26	44	56	363
BSL-2	64	11	18	28	16	33	26	196
ABSL-3 Theoretical	29	8	16	13	18	12	11	107
ABSL-3 hands-on	29	7	9	12	8	14	10	89
ABSL-2 Theoretical	N/A	N/A	N/A	N/A	N/A	20	32	52
ABSL-2 hands on	N/A	N/A	N/A	N/A	N/A	3	13	16
Comprehensive Facility Training for External Trainees <i>(new 2011)</i>	N/A	N/A	N/A	N/A	N/A	N/A	1	1
Graduate Program	48	N/A	N/A	N/A	35	N/A	N/A	83
Aerobiology	19	0	3	0	2	0		24
Autoclave	195	0	0	21	6	9	5	236
Annual Autoclave Retraining of ARC staff	N/A	N/A	N/A	N/A	N/A	N/A	15	15
High Through-put Safety training	8	0	9	0	3	0		20
Theoretical non human primate	16	0	0	0	15	20	62	123
Non-human primate hands-on						6	44	50
BSL-3 mentorship	36	26	7	5	3	4	2	93
ABSL-4 sign-off						6		6
ABSL-3 mentorship						9	8	15
Specialized training (Assay Development)	18	0	0	0	0	0		18
Total trained	623	98	158	146	174	216	322	1755

Figure 1: Total number of trainee from 2005-2011. As expected the number of trainees has continuously been increasing as indicated by the percentage noted atop each year.

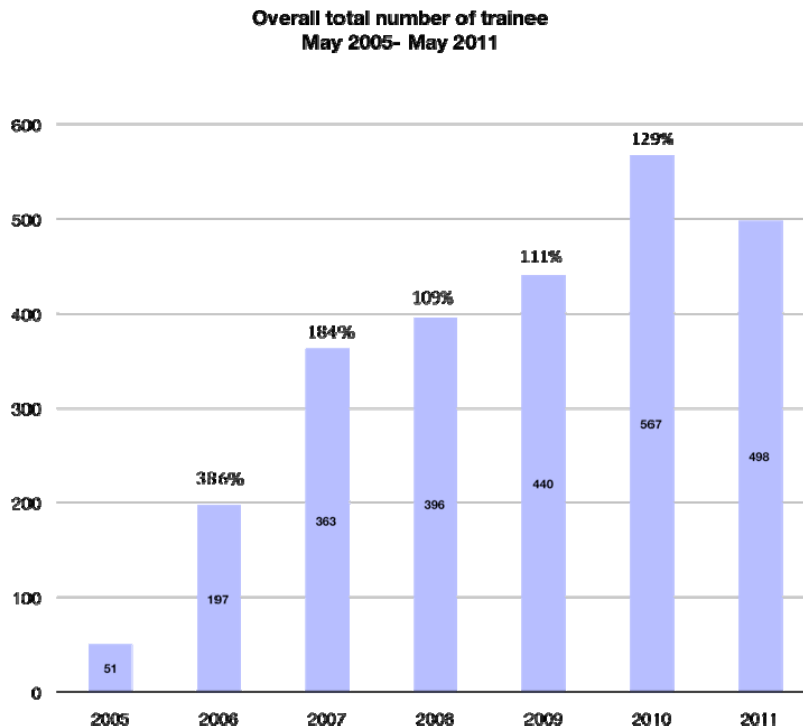


Figure 2: Distribution of trainees based on the courses taken. As expected the number of trainees follows the normal biosafety level pyramid with a large amount of BSL-2 trainees and then fewer as the biosafety level increases.

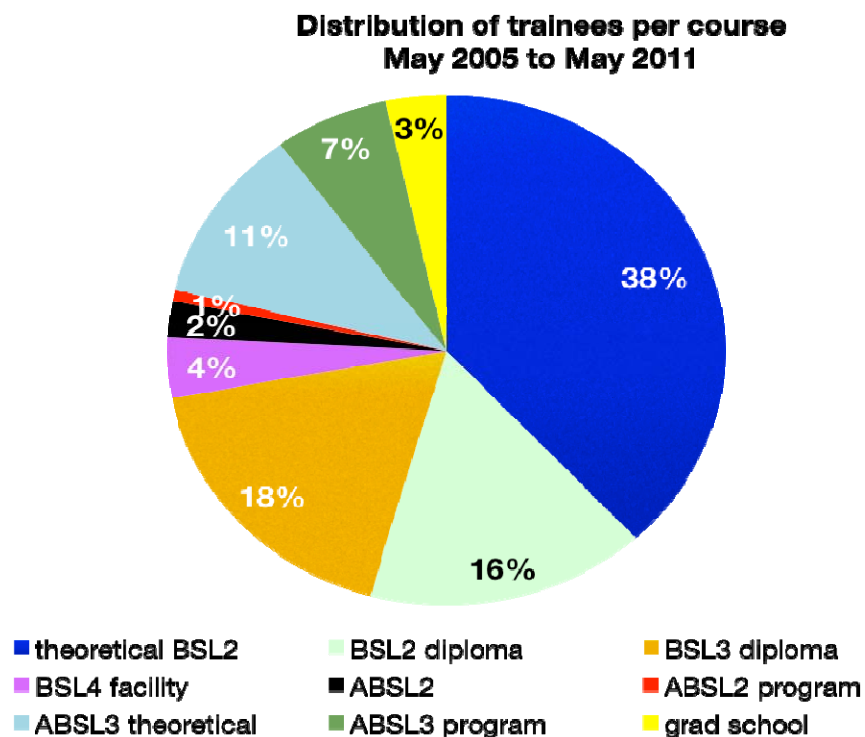


Figure 3: Distribution of trainees based on their main job occupation. Others include information services personnel, animal care staff, public relations personnel, and lawyers. In this graph we can see that as expected the scientific community is the major beneficiary of the training program, as this was designed specifically for them.

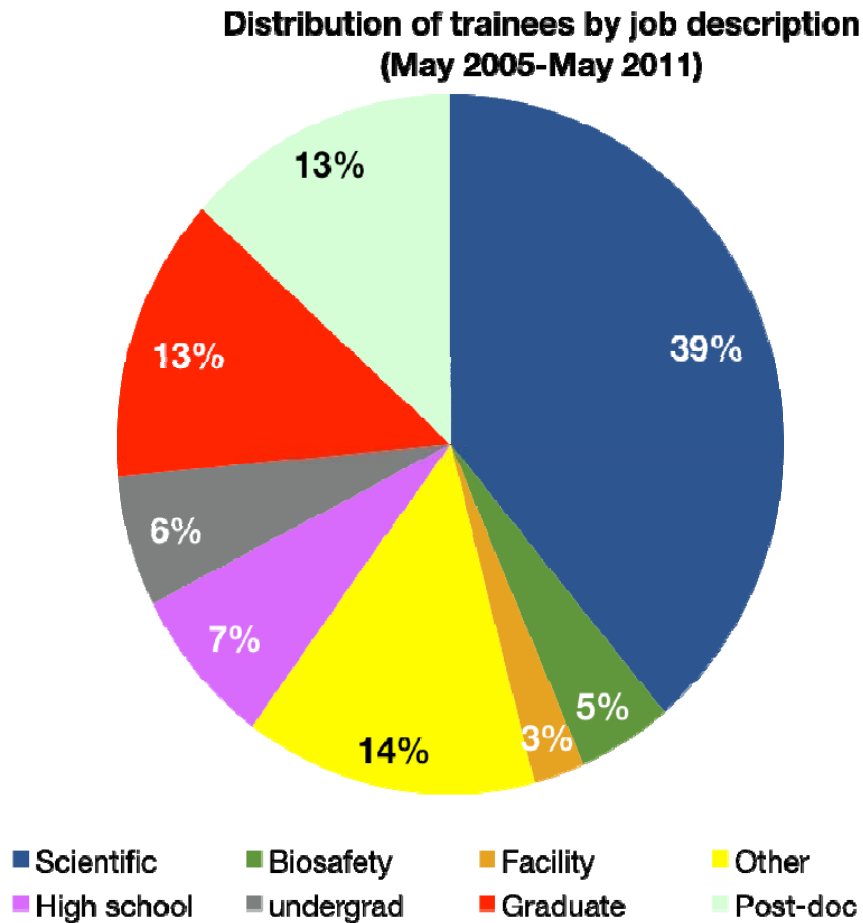


Figure 4: Distribution of the trainees based on their geographic location. UT-System includes all university members of the University of Texas group, of which UTMB is a member.

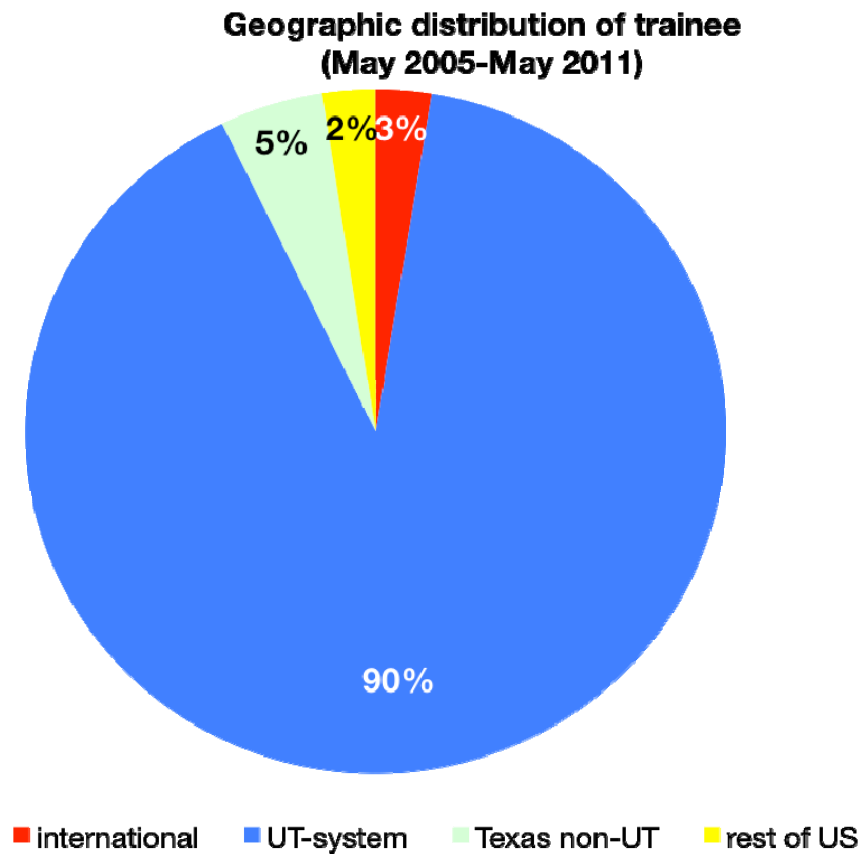
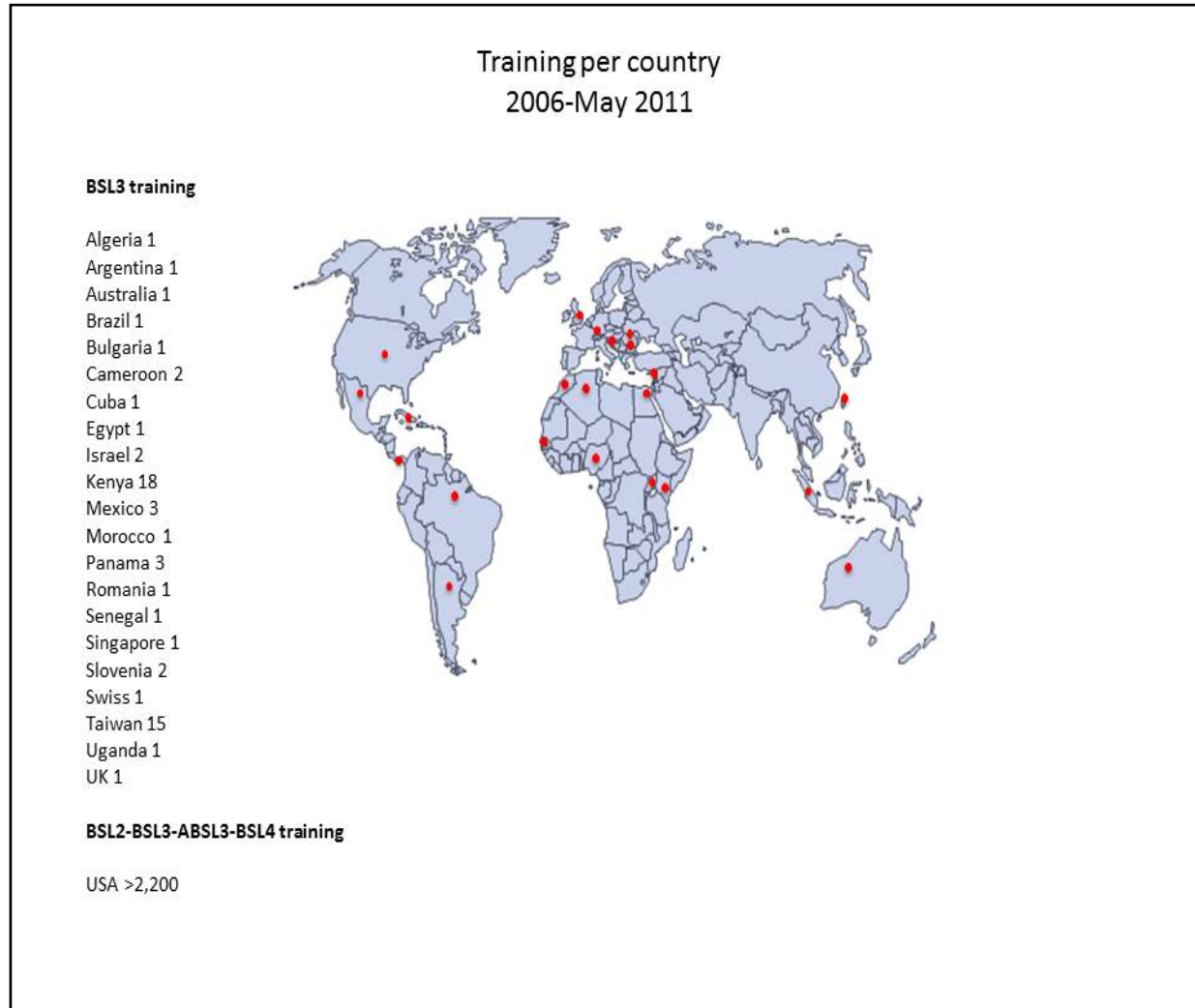


Figure 5: The world map below indicates the diversity of national and international trainees coming to the NBTC for containment training over the course of the program.



KEY RESEARCH ACCOMPLISHMENTS:

- A comprehensive, standards-based training program has been established and implemented to prepare individuals for work at all levels of biocontainment.
- Advanced, mentored training is available to select fellows with exceptional skill who desire to expand their research activities to include studies at the BSL-4 level.
- A unique fellowship has been created to train the next generation of containment laboratory containment facility operations professionals prepared to oversee the safe operations of these complex facilities.
- A novel training opportunity addresses the safety considerations emerging at the interface of high through-put screening of potentially infectious material.
- As part of our participation in the national dialogue on biosecurity – and as a service to the research community – we also established the *Topics in Biosecurity Symposia Series*. Both sessions offered thus far – in November 2010 and February 2011 – were attended by large crowds and drew positive attention and feedback.

REPORTABLE OUTCOMES:

- A total of 855 training experiences were provided to trainees, staff and external participants. These courses ranged from basic introduction to biocontainment to mentored hands-on research under BSL-4 containment conditions.
- Two doctoral level fellows are participating in advanced mentored training to become independent investigators able conduct their research under BSL-4 containment.
- One individual was selected for the facility operations fellowship and has begun training in the operation and maintenance of a major biocontainment facility.
- Specialized training and dedicated courses (Pre-conference course: "BSL-3 Operations and Management" and "BSL3 for biosafety professionals: what they need to know") was provided to participants at an important national scientific meeting relevant to scientists working in biocontainment, the American Biological Safety Association annual meeting (October 2010).
- Literature describing the NBTC program was made available at manned booth hosted at the following meetings: American Biological Safety Association annual meeting, the American Society of Tropical Medicine and Hygiene annual meeting (November 2010), the ARS/ABSA meeting (Feb 2010), the American Society of Microbiology Biodefense meeting (Feb 2010) and the 2nd African Biosafety Association annual meeting.
- Round table discussions led on the topic of "Training and Mentorship" in biosafety, and two formal presentations, "Creating a culture of Biosafety" and "BSL4 Graduate Student Training Process" were offered at the NBL-RBL facilities network meeting, Boston, 2-5 May 2010.
- Guidelines for Biosafety, Laboratory Competency were published in the MMWR April 15, 2011 / 60(02); 1-6, Dr. Brocard was a member of the expert panel.

- A formal report relevant to the safe operations of containment laboratories was published in the peer reviewed journal, Emerging Infectious Diseases: LeDuc, J.W., Anderson, K., Bloom, M.E., Carrion Jr., R., Feldmann, H., Fitch, J.P., Geisbert, T.W., Geisbert, J.B., Holbrook, M.R., Jahrling, P.B., Ksiazek, T.G., Patterson, J., Rollin, P.E. 2009. Potential Impact of a Two-Person Security Rule on Biological Safety Level-4. Emerging Infectious Diseases 15 (7), July 2009 online only. ISSN: 1080-6059.

CONCLUSIONS:

The National Biocontainment Training Center offers a robust and intensive training program devoted to all aspects of biological safety, biocontainment, and biosecurity. This program offers unique, hands-on training to trainees, staff and external partners at all levels of biocontainment, including focused, mentored training in the BSL-4 laboratory.

Over 850 persons benefited from one or more of these training courses, many of whom are now pursuing graduate education and using these specialized skills in the newly constructed GNL containment facilities. Intensive, mentored fellowship programs were established to offer opportunities for in-depth training in research under BSL-4 conditions and also in containment laboratory operations and maintenance. These fellowships help address the critical national shortage of well-trained containment laboratory scientists and facility operations specialists.

REFERENCES:

None.