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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 should that meet the researcher's needs. 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 their 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(s) will be directly involved in the maintenance of the laboratory, decontamination of specific laboratories, monitoring and replacement of filters, fans and control units, understanding the Building Automation System (BAS), 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 May 22, 2009 and this submission comprises our second annual report for this initiative. The Laboratory Biosafety Training Center at The University of Texas Medical Branch 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 more than 3,000 participants through the various courses offered. Below is a summary of the significant progress made over the preceding year (2011-2012) 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 the individuals supported by the TATRC award over the past reporting year 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 biosafety 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.

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

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

resources). Mr. Thompson aided in this effort until his retirement at the end of the second quarter during the past reporting year. Mr. Grimaldo is responsible for the content development of each module of the containment engineering and operations fellowship and also provides the dedicated instruction associated with each module. He also serves as the primary mentor 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. 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. Dr. Endsley will continue in the fellowship for much of the current year as she gains critical experience and masters skills needed to work in this environment.

Dr. Aysen Gargili. Dr. Gargili is a visiting scientist in the Department of Microbiology & Immunology. Dr. Gargili an internationally recognized veterinarian and tick expert from Turkey. She is a participant in the NBTC's high and maximum containment fellowship program for scientists. She began her yearlong fellowship in January 2012.

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.

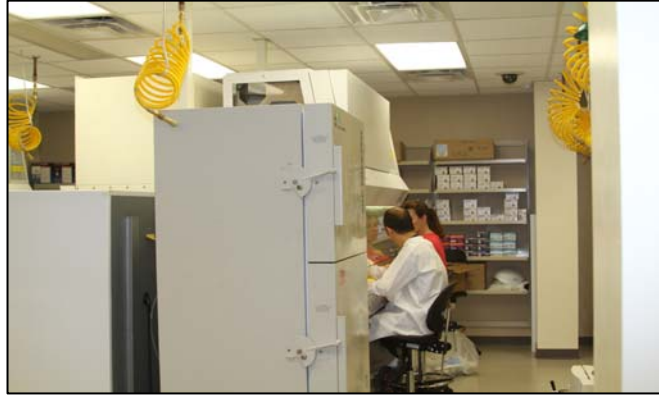
Dr. Dennis Bente. Dr. Bente is a BSL-4 researcher with the GNL at UTMB. He is an assistant professor in the Department of Microbiology & Immunology. He serves as a BSL-4 scientific mentor for the NBTC. Dr. Bente's own research concentrates on understanding how viruses cause disease with special focus on the pathogenesis of Crimean-Congo hemorrhagic fever virus.

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 who have extensive and proven experience working in the laboratory. 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.

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 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 four class II biological safety cabinets, three 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. One BSC class II cabinet also has see-through panels and **BSL-4** air connections ports. Two of the BSC cabinets are equipped with cameras inside that allow for remote demonstrations. The laboratory itself also has two cameras installed for remote demonstrations. The laboratory has two class III biosafety cabinets, 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 mitigation training allows the trainee to visualize and respond to spills and contamination with the use of fluorescent 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 state-of-the-art 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. We trained more than 50 individuals this reporting year 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 in early 2010, and the GNL BSL-4 facilities were approved for full operations in May 2010 with operations beginning in September 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.

Over the course of the past reporting year, aerobiology trainees have completed training on the BSL-4 aerobiology equipment and have successfully performed BSL-4 aerosol runs using Nipah virus and Ebola virus in the GNL. Training has also taken place on the EMKA plethysmography equipment. Aerobiology personnel continue to receive instruction and specialized training about how aerosols are generated, the safety precautions in place in aerobiology laboratories and how to quantitate virus in aerosol samples.



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 GNL.

High Through-Put Screening. We are working to develop a systematic training program focused on the safety concerns associated with high through-put screening. 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.

Mentored training typically extends beyond a given reporting quarter. The BSL4 mentorship program provides a hands-on training experience under the tutelage of a senior staff scientist (mentor) with guidance from other experienced laboratorians in the real-world environment of a functioning BSL4 laboratory. The experience includes an orientation to the laboratory environment by a senior BSL4 scientist and then working experience with tasks germane to the proposed tasking of the person being mentored.

As the GNL laboratory has been brought online additional modules and the Shope laboratory continues to operate, our cadre of experienced scientists and scientific staff continues to expand (see figure on pg. 11). This is actually decreasing the individual burden of training as it is spread across a larger number of scientists and staff. The numbers of staff that have passed into and out of the mentorship program is presented in **Table 1**. Though the figure on pg. 11 captures data only through January 2012, it is interesting to note that between May 2011 and May 2012, 23 individuals began their initial BSL-4 training and proceeded on to mentored training in the BSL4 laboratory. Of those 23 individuals, 13 have successfully completed their mentorships and progressed to independent access. The remaining 10 individuals are in various stages of completing their mentored training requirements.

In the BSL-3 mentorship category, we signed off on more than 15 individuals for independent BSL-3 access over the past reporting year. Furthermore, we currently have at least 3 trainees in the pipeline who lack less than one hour of additional required mentor training to achieve full access.

A more extensive listing of the number of individuals trained during the year can be found in **Table 1**.

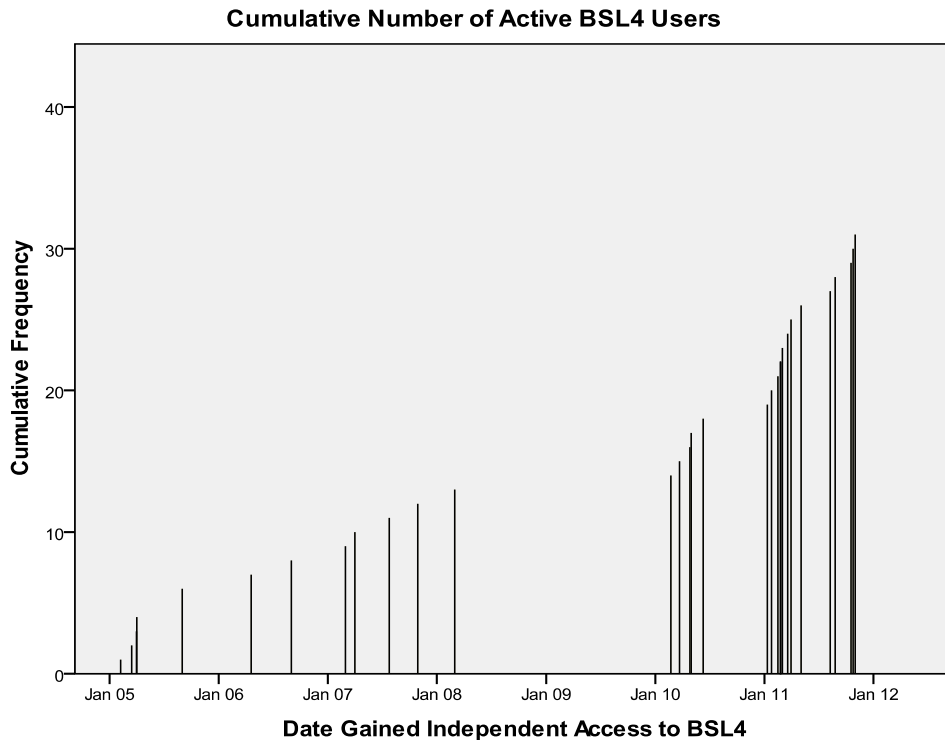


Figure: Cumulative number of active BSL4 Users approved for independent access.

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. We have two fellows now in training, and one fellow who has transitioned from the program to a permanent UTMB faculty position involving BSL-4 pathogen research.

Dr. Gavin Bowick is the first NBTC fellow who has transitioned from the NBTC fellowship to a permanent UTMB faculty position. Dr. Janice Endsley is the second fellow sponsored by the program. As indicated previously, 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.

Dr. Aysen Gargili is the program's third fellow. Dr. Gargili an internationally recognized veterinarian and tick expert from Turkey who is also participating in the maximum containment fellowship program for scientists and will be spending a year onsite at UTMB (she began her fellowship in January 2012). She is working with Dr. Dennis Bente and a team of researchers to establish colonies of vector ticks from Turkey and elsewhere and will be studying how the virus is maintained and transmitted in nature. This is the first step in what we hope will grow into sustained field and laboratory collaborations with Turkish students and scientists. Dr. Gargili will also study the various methods and mechanics of biocontainment as a part of her fellowship.

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 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.

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 since 2010. Sessions in the series continue to be of

great interest to students, faculty and community members and are consistently attended by large crowds drawing positive attention and feedback.

Summary of Biosurety and Biosecurity training activities this past year:

Topics in Biosecurity Symposia Series.

- **September 29, 2011.** The NBTC hosted the third session of this symposia series which featured a discussion with special guest **Mr. Edward H. You, a Supervisory Special Agent in the Federal Bureau of Investigation's Weapons of Mass Destruction Directorate, Biological Countermeasures Unit.** Mr. You is responsible for creating programs and activities to coordinate and improve FBI and interagency efforts to identify, assess, and respond to potential intentional biological threats or incidents. These efforts include expanding FBI outreach to the biological sciences community to address biosecurity. Before being promoted to the Weapons of Mass Destruction Directorate, Mr. You was a member of the FBI Los Angeles Field Office Joint Terrorism Task Force and served on the FBI Hazardous Materials Response Team. Mr. You has also been directly involved in policy-making efforts with a focus on biosecurity. He holds *ex officio* positions on the NIH National Science Advisory Board for Biosecurity and the Synthetic Biology and Engineering Research Center Scientific Advisory Board. He is also an active Working Group member of the National Security Council Interagency Policy Committee on Countering Biological Threats; is the FBI representative on the Executive Order 13546 Select Agent Program Federal Experts Security Advisory Panel; and presented, on behalf of the FBI, to the Presidential Commission for the Study of Bioethical Issues regarding biosecurity and synthetic biology. A capacity crowd attended Mr. You's presentation.



Pictured left: The Honorable Susan Ehrlich, UTMB Adjunct Faculty Member; GNL Director Dr. Jim Le Duc, and Mr. You. Pictured right: A capacity crowd attended the session, including students, faculty and special guests from UTMB Police, the local FBI office and members of the community.

- **November 7, 2011.** The fourth session of the series featured a lively conversation on the origins of the biodefense enterprise as well as on combating weapons of mass destruction. Special guests for this session were **Dale Klein, PhD** and **Stewart Simonson, JD.** Dr. Klein is **Associate Vice Chancellor for Research in the Office of Academic Affairs for The University of Texas System.** Before joining UT System, he had a distinguished career overseeing nuclear, chemical and biological matters for the federal government including service as **Chairman of the U.S. Nuclear Regulatory Commission** and as **U.S. Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense** programs. Mr. Simonson has more

than 20 years of experience serving in leadership roles in the public and private sectors, including nearly five years with the **U.S. Department of Health and Human Services (HHS)** where he served in several senior positions including deputy general counsel and the first appointee to the role of **Assistant Secretary for Preparedness and Response**. He is currently general counsel for the Washington, DC based **Futures Group**. Dr. Klein is an expert in nuclear energy and during his presentation we were fortunate to learn details of his recent trip to Japan to assist in the US response following the Fukushima disaster and his observations on the current status of the recovery efforts and looming challenges.

- December 2, 2011.** The fifth and final 2011 session of the series featured a review of current federal science policy with specific emphasis on how to foster stronger medical countermeasures programs. **George W. Korch, Jr., PhD** led this informative discussion that featured a review of the findings of the **Federal Experts Security Advisory Panel which he co-chairs**. Included was a review of the process currently underway to establish a tiered ranking of select agents and how those pathogens currently proposed as Tier 1 agents were selected. **Dr. Korch is a senior science advisor to the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services**. He also retired from a distinguished career in the U.S. Army where he served as **commander of the USAMRIID and as the director of the Department of Defense Medical Chemical and Biological Defense Research Program**.



Session 4: (l to r) Dr. Dale Klein, UT System; GNL Director Dr. Jim Le Duc, and Mr. Stewart Simonson, Futures Group.



Session 5: (l to r) Dr. George Korch, Jr., HHS; and GNL Director Dr. Jim Le Duc.

- March 15, 2012.** The sixth session of the series featured **Dr. Robert Swanepol** as the guest speaker. Dr. Swanepol, a member of the **Zoonoses Research Unit and the Faculty of Health Sciences at the University of Pretoria in South Africa** provided an international perspective on biosecurity research in his talk “Biosafety and biosecurity challenges of investigating hazardous endemic diseases in South Africa.” Dr. Swanepol is the former director of the Special Pathogens Unit at the National Institute for Communicable Diseases in South Africa, home to one the only true BSL4 facility in sub-Saharan Africa. Dr. Swanepoel recently joined the University of Pretoria where he heads the Zoonoses Research Unit and is about to commission their own BSL3 laboratory. He described the trials and tribulations of building and operating a maximum containment facility in Africa, while sharing stories of his adventures investigating outbreaks of Ebola, Marburg, Rift Valley fever and many other emerging diseases. We are excited about the possibility of exchanges of students and faculty as his new unit comes on line. During his visit to campus, Dr. Swanepol also had the

opportunity to meet with many of our infectious disease researchers and tour the research facilities.

- **March 21, 2012.** The seventh session of the series featured **Dr. Onder Ergonul** as the guest speaker. Dr. Ergonul is a **professor at Koc University School of Medicine in Istanbul, Turkey**. He also serves as general secretary of Turkish Society of Clinical Microbiology and Infectious Diseases. His symposium talk entitled, “Crimean-Congo Hemorrhagic Fever and Biosecurity” detailed much of the history of his international research on the disease. He discussed the discovery of Crimean-Congo hemorrhagic fever (CCHF) in Turkey where over the past decade he has led efforts to recognize this often fatal disease previously unknown in the country, but that today causes more than 1,000 cases annually. CCHF is a tick-borne virus and a researcher here at UTMB’s GNL, **Dr. Dennis Bente**, is spearheading a research program to study this deadly disease in partnership with the team in the GNL insectary, and an internationally recognized tick expert from Turkey, **Dr. Aysen Gargili**. As mentioned previously in this report, Dr. Gargili is participating in a yearlong fellowship here at UTMB as part of the NBTC’s maximum containment fellowship program for scientists. The team is establishing colonies of vector ticks from Turkey and elsewhere and will be studying how the virus is maintained and transmitted in nature. This is the first step in what we hope will grow into sustained field and laboratory collaborations between UTMB and Turkish students and scientists.



Session 6: (l to r) Dr. Jim LeDuc, GNL director; Dr. Tom Ksiazek, NBTC director, Dee Zimmerman, Biosafety Director and Dr. Swanepol.



Session 7: Dr. Ergonul during his presentation.

NBTC Website.

Over the past reporting year, the new NBTC website has continued to develop - www.utmb.edu/nbtc. The new course training schedule for 2012 was added to the website. We also updated our staff listing with new members of the training team. Per its intent, this 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 continue to develop a dedicated section focused on biosecurity which will offer a comprehensive review of the topic and practical guidance.

Onsite training and related updates.

- During this reporting year, the NBTC also provided facility engineering and maintenance consultation to the **National Aeronautics and Space Agency's Johnson Space Center** team responsible for constructing laboratory space in Houston, Texas for the future processing of planetary and space samples received from expeditions to Mars. Representatives from the lunar sample curation team visited our laboratories and consulted with both scientific and engineering staff.
- This past year the NBTC ABSL2 and ABSL3 courses were accepted by AALAS for continuing education credit. Credits will be given out based on contact time with each trainee.
- The NBTC informational booth was present at the following professional meetings during this reporting year:
 - The **American Society for Microbiology General Meeting** , May 20 – 25, 2011 in New Orleans, LA
 - The **American Society for Virology Annual Meeting**, July 15 – 21, 2011 in Minneapolis, MN
 - **63rd American Association for Laboratory Animal Science National Meeting**, October 1-7, 2011 in San Diego, CA
 - **54th Annual American Biological Safety Association Biosafety Conference/Meeting**, October 26 -November 3, 2011 in Anaheim, CA
 - **60th Annual Meeting of the American Society of Tropical Medicine and Hygiene**, December 3-9, 2011 in Philadelphia, PA
 - **The American Society for Microbiology Biodefense Meeting**, February 25 – 30, 2012 in Washington, DC
- Dr. Brocard co-taught a course “Basic Risk Assessment” (an ABSA owned course) at the 54th annual ABSA meeting October 26-Nov 3, 2011 in Anaheim, CA.
- Biosafety training program personnel traveled to **Baylor University** in Waco, TX in 2011 to provide BSL3 training to new users.
- Dr. Brocard successfully completed and passed the National Registry of Certified Microbiologists (NRCM) examination in Biological Safety Microbiology and is now a Certified Specialist Microbiologist. This is the first step towards the Certificate for Biosafety professionals (CBSP).

- The ABSL3 course became a certificate (1 credit hour) with the graduate course. Below are all of the biosafety training courses registered with the graduate school:
 - Basic BSL2, BBSC 6217
 - BSL2 programs, CTPS 6112
 - BSL3 programs, CTPS 6203
 - ABSL2 programs, CTPS 6114
 - ABSL3 programs, CTPS 6118

- Throughout the past year, resident biocontainment engineer Mr. Miguel Grimaldo, actively participated as a member of the ANSI Z9.14 Committee to development of an **American National Standards Institute (ANSI)** standard for "Testing and Performance Verification Methodologies for Ventilation Systems for Biological Safety Level 3 (BSL-3) and Animal Biological Safety Level 3 (ABSL-3) Facilities." This work has included the writing and/or revision of sections of the standards, conference calls and participation of an "All-Hands" Meeting held on the Emory University campus in Atlanta, Georgia. It is expected that the standard should be ready for public review by the end of 2012.

- Mr. Grimaldo co-taught an eight-hour course on "Waste Water Management for Unique Laboratory Operations" at the 54th Annual American Biological Safety Association (ABSA) meeting October 28-Nov 3, 2011 in Anaheim, CA.

- Mr. Grimaldo was invited to present his work on "Development of Autoclave Decontamination Cycles: Animal Carcasses and Laboratory Waste" at the at the 54th Annual American Biological Safety Association (ABSA) meeting October 28-November 3, 2011 in Anaheim, CA.

- From June 2011 to May 2012, Mr. Grimaldo responded to requests for information/guidance on biocontainment related issues from the following:
 - **Lovelace Respiratory Research Institute** regarding membrane filter testing.
 - **University of Massachusetts Medical School** regarding BSL3 lab construction.
 - **University of North Dakota Research Foundation** regarding BSL3 air balance.
 - **Montana State University** on autoclave cycle development.
 - **University of Monterey, Mexico** regarding BSL3 Facility Commissioning and Testing.
 - **NIH Integrated Research Facility** in Ft. Detrick, MD regarding autoclave cycles and APR door operations for BSL4 Laboratories.
 - **The Animal Health Research Center (CISA)** Valdeolmos in Madrid, Spain, regarding autoclave cycle development.
 - The **National Biodefense Analysis and Countermeasures Center (NBACC)** at Ft. Detrick, MD regarding membrane filter types used on the effluent decontamination systems.
 - **University of Montana** regarding autoclave cycles.
 - **Centers for Disease Control and Prevention's Office of Health and Safety** regarding the decontamination and certification of Membrane (PTFE) filters used on vent lines of BSL4 and BSL3 Enhance Laboratories.

- As part of the ongoing collaboration with other institutions who are home to biocontainment research facilities, Mr. Grimaldo actively participates on the conference calls for the Facility Operations Group of the **NIH/NIAID National Biocontainment Laboratory/Regional Biocontainment Laboratory Network**.
- This past reporting year, Mr. Grimaldo continued to provide BSL4 Facility Operations training to one of **Centers for Disease Control and Prevention's Select Agent Program** Inspectors at UTMB and via conference calls.
- Mr. Grimaldo was invited to present "Biocontainment Challenges for Handling and Life Detection of Extraterrestrial Samples" at the **Life Detection in Extraterrestrial Samples Conference** in La Jolla, California at the Samuel H. Scripps Auditorium in February, 2012.

Table 1.

Summary of training courses offered and number of participants in each course, May 2009 through May 2012.

Training Course/Module	May-Dec 2009	Jan-Dec 2010	Jan-Dec 2011	Jan-March 2012	Apr-May 2012	Total
BSL4	9	34	43	8	8	102
BSL3	45	87	95	10	20	257
BSL2 Theoretical	107	156	254	17	38	572
BSL2 hands-on	64	73	99	12	13	261
ABSL3 Theoretical	29	55	52	15	6	157
ABSL3 hands-on	29	36	50	11	4	130
ABSL2 Theoretical	N/A	N/A	81	9	11	101
ABSL2 hands-on	N/A	N/A	44	10	10	64
Graduate Program	48	35	32	0	0	115
Aerobiology	19	5	2	8	0	34
Autoclave	195	27	46	27	5	300
High Throughput Safety training	8	11	3	2	0	24
Non-human primate theoretical	16	15	99	2	7	139
Non-human primate hands-on	N/A	N/A	91	11	7	109
BSL3 mentorship	36	41	24	7	5	113
ABSL3 mentorship	N/A	N/A	38	5	11	54
Specialized training (PAPR; intro - to Micro-Animal handling certificates)	18	0	29	33	13	93
Total trained	623	575	1082	187	158	2625

Figure 1. Total number of trainees from 2005-2012. As expected the number of trainees has continuously been increasing as indicated by the percentage noted atop each year.

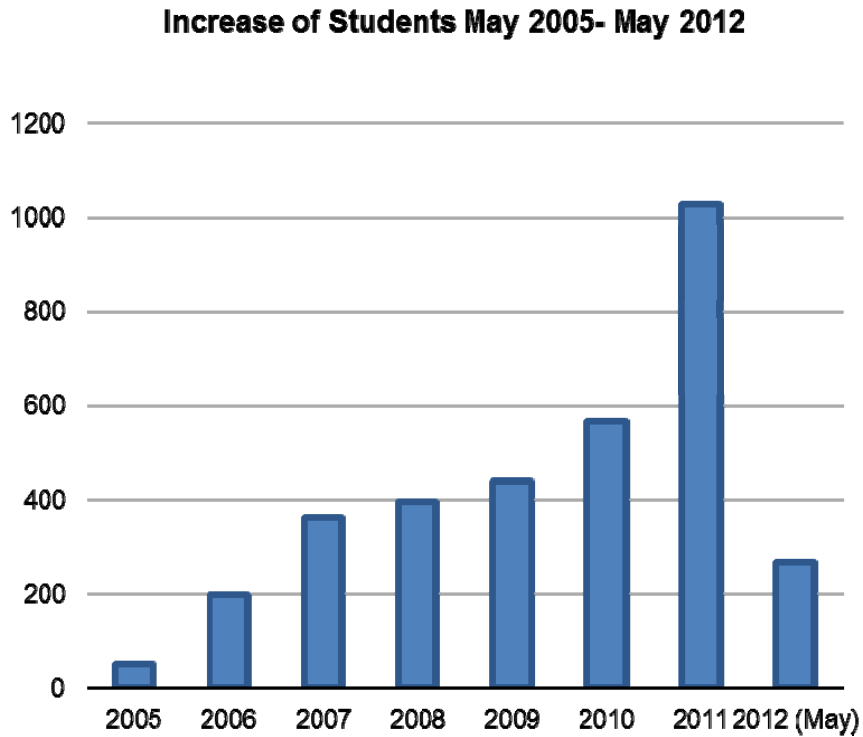


Figure 2. Distribution of trainees based on the courses taken. As expected the number of trainees follows the normal biosafety level pyramid with a large amount of BSL-2 trainees and then fewer as the biosafety level increases.

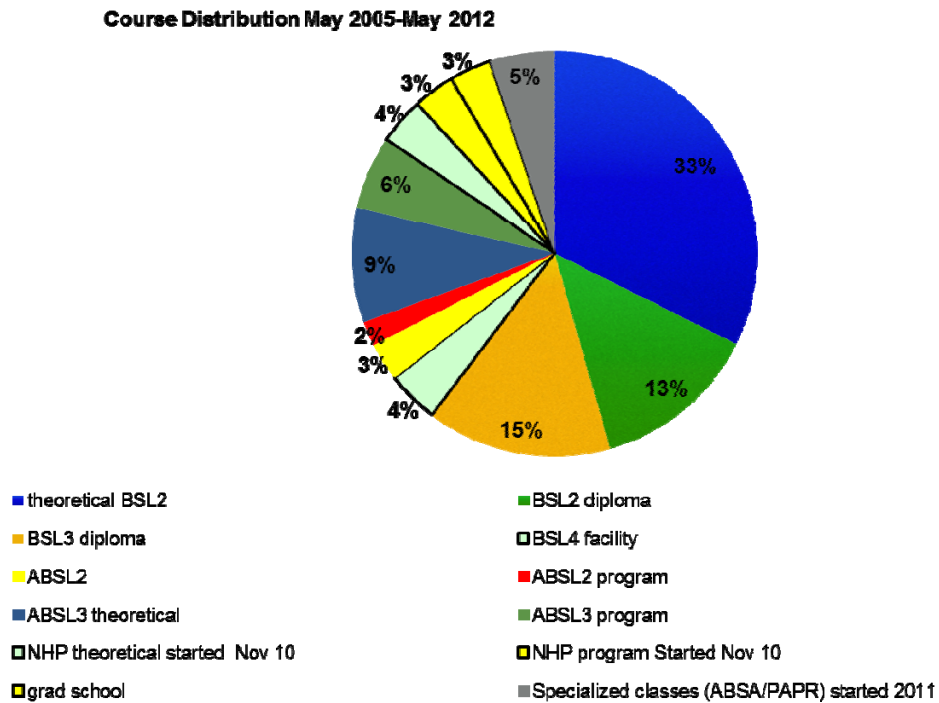
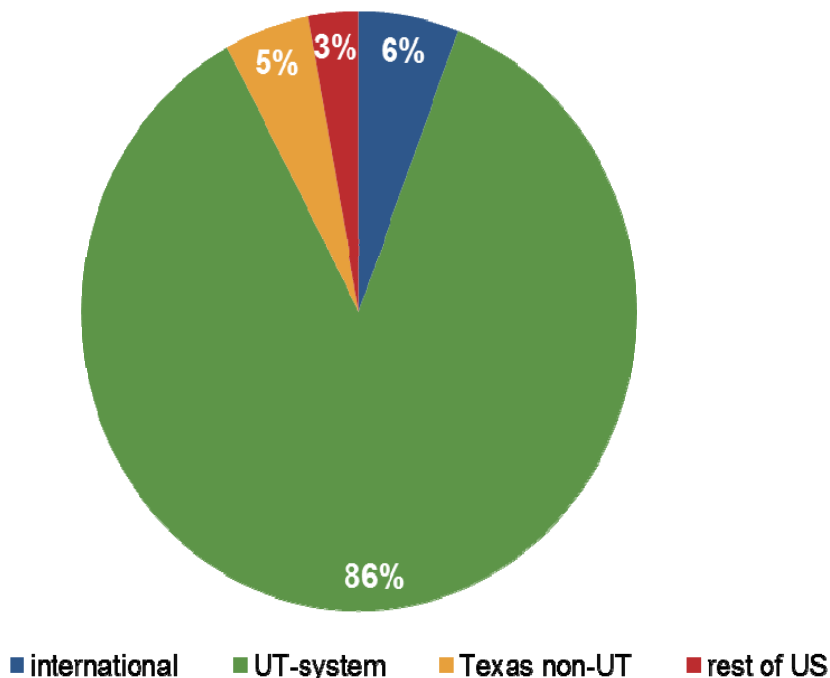


Figure 3. Distribution of the trainees based on their geographic location. UT-System includes all university members of the University of Texas group, of which UTMB is a member.

Geographic Distribution of Trainees May 2005- May 2012



KEY RESEARCH ACCOMPLISHMENTS 2011-2012:

- 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*. Sessions offered thus far continue to be attended by large crowds and draw positive attention and feedback. Planning is underway to continue the series with 2012-2013 sessions.

REPORTABLE OUTCOMES 2011-2012:

- Since the inception of UTMB's Laboratory Biosafety Training Program, prior to the TATRC funding award in 2009, more than 3,000 individuals have been instructed in the safe research and operation in biocontainment laboratories. The vast majority of these trainees have taken part in the program since 2009 when TATRC funding allowed for significant growth of the program.
- Requests for external biosafety training are being continuously received. Some examples include:
 - Members of our team of biosafety trainers were requested by the Baylor University Institute of Medicine in Waco, Texas to provide BSL3 training for their staff in December 2011. Eleven individuals received BSL3 theoretical and practicum training.
 - Battelle Corporation also requested BSL3 and ABSL3 training for their staff in January 2012. Four individuals received BSL3 theoretical and practicum training and four individuals received ABSL3 theoretical and practicum training on rabbits and guinea pigs.
 - The year ahead looks to be equally busy. Immediately upcoming will be a training session requested by the City of Laredo, Texas. The City's health department has requested that the NBTC provide BSL-3 training to six of their personnel in June of 2012.
- Dr. James W. LeDuc, the principle investigator in the NBTC award, published two nationally recognized commentaries regarding training during the reporting year. Dr. LeDuc and colleague Dr. David R. Franz, the Vice President and Chief Biological Scientist at the Midwest Research Institute and Senior Advisor to the Office of the Assistant to the Secretary of Defense for Nuclear, Chemical and Biological Defense Programs jointly published the following:
 - *Balancing Our Approach to the Insider Threat*. Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. Volume 9, Number 3, 2011.
 - *Genetically Engineered Transmissible H5N1: A Call for Laboratory Safety and Security*. Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. Volume 10, Number 1, 2012.

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 3,000 persons have 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 have been established to offer opportunities for in-depth training in research under BSL-4 conditions and also in containment laboratory operations and maintenance. These fellowships are proving quite successful and are helping address the critical national shortage of well-trained containment laboratory scientists and facility operations specialists.

REFERENCES:

None.