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SCIENCE, SAFETY, SECURITY Newsletter

News for the Federal Biorisk Management Policy Community

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Feedback and Submissions Welcome

We want to hear from you! Please contact Janelle Hurwitz (Janelle.hurwitz@hhs.gov) with any comments, suggestions or news ideas for future editions of S3 Newsletter. Feel free to submit general information for inclusion or drafted articles. If you have an idea, we are happy to work with you in drafting a piece. Articles should be in MS Word format, fewer than 1000 words, with author/contact name and email address. Pictures and diagrams in jpg format are encouraged and welcome. Thank you!

ANSI/ASSE Z9.14 "Testing and Performance Verification Methodologies for Ventilation Systems for Biological Safety Level 3 (BSL-3) and Animal Biological Safety Level 3 (ABSL-3) Laboratories" Leads Standard Development for High-Containment Laboratory Testing and Performance

By Farhad Memarzadeh, Chair ANSI Z9.14; Director, Farhad Memarzadeh, Chair ANSI Z9.14; Director, Division of Technical Resources, National Institutes of Health, Bethesda

On January 24, 2014, the American National Standards Institute approved the new standard, "Testing and Performance - Verification Methodologies for Ventilation Systems for BSL-3/ ABSL-3 Facilities" (ANSI/ASSE Z9.14-2014).

ANSI/ASSE Z9.14 focuses on performance verification of engineering controls related specifically to ventilation system features of BSL-3/ABSL-3 facilities. Z9.14 is the only guidance that provides a methodology to verify ventilation systems in such facilities. The standard provides one component of a more extensive graduated and risk-based approach to reaching containment goals appropriate to the risk of the agent and the laboratory activity.

The new Z9.14 standard was published in March 2014. Visit www.asse.org/standards or call ASSE Customer Service at (847) 699-2929 for more information.

A new standard, Testing and Performance-Verification Methodologies for Ventilation Systems for Biological Safety Level 3 (BSL-3) and Animal Biological Safety Level 3 (ABSL-3) Laboratories (ANSI/ASSE Z9.14-2014), was released in January 2014. The standard provides a voluntary, systematic approach to evaluate safety design features, operations, and engineering processes and controls in BSL-3/ABSL-3 laboratories and animal facilities. The recommended test methodologies in ANSI/ASSE-Z9.14 provide standardized, uniform, and consistent guidance to ensure that all reasonable facility engineering controls and prudent practices are in place to minimize, to the greatest extent possible, the risks associated with laboratory operations and the use of biohazardous materials.

The Government Accounting Office (GAO) established the need to "develop, in consultation with the scientific community, national standards for the design, construction, commissioning, and operation of high-containment laboratories, specifically including provisions for long-term maintenance." A consequence of the establishment of more U.S.-based BSL-3/ABSL-3 laboratories is the unknown level of risk when laboratory accidents occur (GAO, 2009, 2013) and the extensive amount of time and expense needed to satisfy the "subjective" demands imposed during testing and verification. ANSI/ASSE Z9.14 is the first standard to address the concerns expressed in the GAO reports.

In response to the identified need, the American Society of Safety Engineers (ASSE) and the American National Standards Institute (ANSI) conducted an extensive "gap and needs analysis" (Memarzadeh & DeBerardinis, 2012); they found that there is no single resource for a comprehensive testing methodology that can be used uniformly from one facility to another to verify that the ventilation systems in such facilities are performing appropriately. ANSI/ASSE Z9.14 provides one component of a more extensive, graduated, risk-based approach to reaching containment goals appropriate to the risk of the agent

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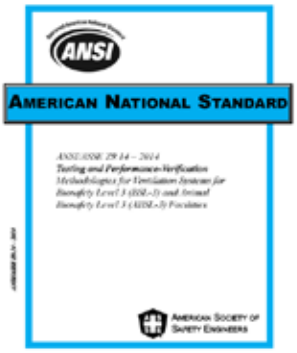
Performing a risk assessment is the critical first step in the planning, design, construction, maintenance, and safe operation of any BSL-3/ ABSL-3 facility.



and the laboratory activity for the 1,300+ BSL-3/ABSL-3 laboratories that exist in the United States (American Biological Safety Association, 2008).

The ventilation system of a BSL-3/ABSL-3 laboratory is central to its performance and operation. It is specifically designed to prevent unintended release of infectious biological agents that may cause unintended human and animal exposures internally to the working environment or externally to the outside environment. It is critical that the ventilation system conform to current biocontainment guidelines and regulations (*Biosafety in Microbiological and Biomedical Laboratories*; *BMBL*; U.S. Department of Health and Human Services [HHS], Centers for Disease Control [CDC], National Institutes of Health [NIH], 2009; Association for Assessment and Accreditation of Laboratory Animal Care [AAALAC], 2010).

Typically, the design of U.S. BSL-3/ABSL-3 laboratories is guided by the criteria defined in the *BMBL*, the *NIH Design Requirements Manual* (if the facility is NIH funded), the U.S. Department of Agriculture (USDA) Agricultural Research Service (ARS) select agent regulations and local codes where applicable.

Scope and Use of ANSI/ASSE Z9.14

ANSI/ASSE Z9.14 covers:

a. Directional airflow—a primary testable target
b. Airlocks and anterooms—double-door interlocking
c. Primary containment systems—focus on biosafety cabinets
d. Building ventilation system (alarm/interface with decontamination systems and other systems that would influence the automation)
e. HVAC testing—air-handling units, exhaust fans, redundancy in systems, dampers, related to plumbing
f. Filtration
g. ABSL-3 and integration of Individually Ventilated Cages (IVC) static caging systems, other elements, downdraft tables (ventilation implication)
h. Document validation (systems based)
i. Pressure reversal—provides methodologies that allow a facility to comply with *BMBL*
j. Failure testing—addresses need, types, and frequency
k. Leakage issues related to HVAC
l. Qualifications of testers

The standard uses a risk assessment and performance-based approach and as such is adaptable to any size or type of BSL-3/ABSL-3 facility. The standard is designed to be fully compatible with biorisk management systems and national and international health and safety management systems without duplicating or contradicting their requirements. ANSI/ASSE Z9.14 may be useful for (a) facilities that have similar functions and risks, but do not follow the same testing methods for ventilation; (b) facilities that cannot meet the ventilation recommendations of the most current *BMBL* when renovating or retesting; and (c) users who require help in test performance. It may be used as an adjunct standard operating procedure or along with other methodologies that may be available to ensure that the ventilation system in a BSL-3/ABSL-3 facility provides a safe environment for building occupants and the external environment.

ANSI/ASSE Z9.14 applies specifically to new or existing laboratories; and research, pharmaceutical, and insectary facilities designed to perform at the BSL-3/ABSL-3 level if there has been a change of agents, procedures, key personnel, renovation, change of use, or decommissioning. ANSI/ASSE Z9.14 also covers the inspection of the ventilation system components of any laboratory designed to handle agents and infected animals that require BSL-3/ABSL-3 containment as defined by the latest edition of the *BMBL*. The standard provides users with guidance on what ventilation system components should be inspected visually; verification procedures to ensure that system components provide for the safe operation of the facility's ventilation system (i.e., directional inward airflow, response to failures, minimizing leakage, etc.); and methodologies to help comply with current local, state, federal requirements, and industry standards and best practices.

Performing a risk assessment is the critical first step in the planning, design, construction, main-

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tenance, and safe operation of any BSL-3/ABSL-3 facility. When deficiencies are identified through a risk assessment or in the course of testing and verification, an iterative corrective action plan (CAP) ensures that testing and verification procedures can be performed in a safe and secure manner for all personnel involved. ANSI/ASSE Z9.14 provides a sample CAP and several hazard risk matrices. In addition, the standard gives guidance for collecting, preparing, and retaining documentation; performing visual inspection; and testing and verification methodologies for the performance of ventilation system components.

The ANSI/ASSE Z9.14 Committee, chaired by Farhad Memarzadeh (NIH) and Vice Chair Louis DiBerardinis (MIT), is made up of experts from safety organizations and associations including:

- American Biological Safety Association (ABSA)
- American Society for Microbiology (ASM)
- Association of Public Health Laboratories (APHL)
- International Federation of Biosafety Association (IFBA)
- Controlled Environment Testing Association (CETA)
- National Energy Management Institute (NEMI)
- U.S. government agencies (Department of Health and Human Services [including the National Institutes of Health and Centers for Disease Control and Prevention,] Department of Agriculture—Agricultural Research Service, Department of Homeland Security)
- U.S. and Canadian academic institutions (e.g., University of Texas, Cornell University, Carleton University, Harvard University, Texas A&M University, University of Pittsburgh, University of Louisville, University of California—Irvine, Massachusetts Institute of Technology)

The Committee also includes commissioning engineers, biomedical facility ventilation systems engineers, biorisk management experts, as well as qualified users and facility managers.

In summary, the challenge for a standard of this scope is to be flexible enough for old and new facilities, to recognize that not all risks are equal, and to address normal and failure modes—particularly directional airflow and contaminants. ANSI/ASSE Z9.14 is a voluntary technical standard and methodology that provides detailed information on the testing and performance-verification of ventilation and related systems required within a BSL-3/ABSL-3 facility; it is the first standard of its kind. It will help to educate biosafety professionals and biocontainment engineers who must specify or perform tests regarding the performance of ventilation systems in BSL-3/ABSL-3 facilities.

The use of ANSI/ASSE Z9.14 as an approved testing methodology will provide consistency in the industry and serve as a first step in meeting the GAO recommendations on high-containment laboratories and other code and regulations. The criteria in the standard may be supplemented, expanded, or consolidated as required by the specific testing and verification effort, the organization, and the regulatory and policy requirements specific to each facility.

ANSI/ASSE Z9.14 (2014) may be purchased online at ABSA, ANSI, or ASSE websites.

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The U.S. National Bioeconomy Blueprint

by Dana Perkins, Ph.D., dana.perkins@hhs.gov

The emerging bioeconomy is fueled by innovation and provides opportunities for job growth while requiring changes in the regulatory and policy climate necessary to achieve its benefits.

The global synthetic biology market was valued at about USD 1.8 billion in 2012 and is expected to reach a market worth of about USD 13.4 billion in 2019. The rapid growth of the global synthetic biology market is credited to the increased demand for renewable fuels and bio-based chemicals and inexpensive drugs and vaccines manufactured using synthetic biology technologies and products. In 2012, Europe contributed the largest share of the global synthetic biology market with North America coming in second. The emerging bioeconomy is fueled by innovation and provides opportunities for job growth while requiring changes in the regulatory and policy climate necessary to achieve its benefits.

"Bioeconomy" is defined in the U.S. National Bioeconomy Blueprint (April 2012) as the "economic activity that is fueled by research and innovation in biological sciences." The Bioeconomy Blueprint highlights the current growth of today's U.S. bioeconomy based primarily on the development of three foundational technologies: genetic engineering, DNA sequencing and automated high-throughput manipulation of biomolecules.

The U.S. National Bioeconomy Blueprint describes five strategic objectives:

- Support R&D investments that will provide the foundation for the future bioeconomy;
- Facilitate the transition of bioinventions from research lab to market, including an increased focus on translational and regulatory sciences;
- Develop and reform regulations to reduce barriers, increase the speed and predictability of regulatory processes, and reduce costs while protecting human and environmental health;
- Update training programs and align academic institution incentives with student training for national workforce; and
- Identify and support opportunities for the development of public-private partnerships and precompetitive collaborations where competitors pool resources, knowledge, and expertise to learn from successes and failures.

A similar bioeconomy strategy, Innovating for Sustainable Growth: A Bioeconomy for Europe, was developed by the European Union (EU), in order to focus Europe's common efforts in this diverse and fast-changing part of the economy. The EU strategy outlines a comprehensive bioeconomy-based approach to address today's ecological, environmental, energy, food supply and natural resource challenges. The EU strategy also notes that a significant information gap persists between science and society and that "citizens need to be engaged in an open and informed dialogue throughout the research and innovation process. They need to be provided with reliable insight into the benefits and risks of innovative technologies and existing practices, and more ample opportunities to debate new findings and their implications."

The U.S. National Bioeconomy Blueprint also emphasizes that a clear understanding of the benefits and risks of bioproducts is critical to the future bioeconomy. The Bioeconomy Blueprint notes that the modification of biological organisms and construction and use of organisms not found in nature carry potential safety and security risks if misapplied, raising issues of responsible conduct including ethics, responsible use, and environmental awareness, among others. The Bioeconomy Blueprint provides synthetic biology as a historical example of balancing concern for these risks while maximizing benefits. In support of maximizing such a balance, President Obama asked the Presidential Commission for the Study of Bioethical Issues in 2010 to develop

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recommendations for the U.S. government to ensure that America reaps the benefits of synthetic biology while identifying appropriate ethical boundaries and minimizing risks.

The U.S. National Bioeconomy Blueprint also notes that "Regulations are essential for protecting human health and the environment and reducing safety and security risks associated with potential misapplications of technology. When they are not carefully crafted or become outdated, however, they can become barriers to innovation and market expansion and discourage investment." The fast pace of life sciences technological advances and the inherent dual use nature of biotechnology pose particular challenges to ensuring the exclusive peaceful use of science and technology while not over-regulating the field and stymieing innovation.

Starting from an alternative perspective, focused primarily on biosecurity, the participants in the December 2013 international conference in support of implementing Security Council Resolution 1540 (2004) "Risks, challenges and responses: Industry's effective practices in responding to biosecurity risks" representing international and national industry associations, global industrial enterprises, regional biosafety organizations, governments and civil society, also recognized that the complexity created by differences in regulatory safety and security approaches and a high number of overlapping regulations can present a major burden for biological R&D as well as vaccine manufacturing, not only in developed countries but also in developing countries where this complexity may be perceived as delaying economic development and interfering with the conduct of legitimate trade.

Participants noted that further work is needed in several areas, including on the development of codes of conduct to establish security awareness as an effective industrial practice, in particular in areas that are beyond governmental regulation and facilitation of cooperation between industry and civil society with law enforcement at both the national and the international levels. Participants emphasized that any control or regulatory measures concerning biological threats and biosecurity must be designed to be risk-based and proportionate so as not to impede legitimate trade and the peaceful and beneficial conduct of life sciences R&D activities. Nonetheless, they also underscored the need for further awareness raising for scientists, engineers and other stakeholders, who might not necessarily see the significance of their work in relation to biosecurity and WMD non-proliferation.

Further reading:

Letter dated 3 February 2014 from the Chargé d'affaires a.i. of the Permanent Mission of Germany to the United Nations addressed to the President of the Security Council re: 'Risks, challenges and responses: Industry's effective practices in responding to biosecurity risks - A Conference in Support of Implementing Security Council resolution 1540 (2004)', Wiesbaden, Germany, 3-4 December 2013: http://www.un.org/en/ga/search/view_doc.asp?symbol=S/2014/76.

"...Regulations are essential for protecting human health and the environment and reducing safety and security risks associated with potential misapplications of technology..."

The Global Health Security Agenda: Taking Action to Reduce Biological Threats

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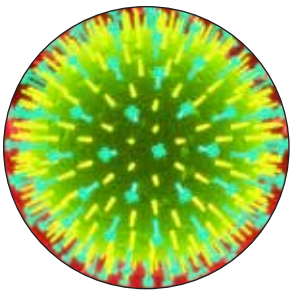
Infectious disease outbreaks—whether originating from natural sources, a deliberate attack or an accidental release—can rapidly spread internationally, claiming lives and causing economic damage.



Infectious disease outbreaks—whether originating from natural sources, a deliberate attack or an accidental release—can rapidly spread internationally, claiming lives and causing economic damage. The continued emergence and geographic spread of MERS-Coronavirus—which began in 2012 in the Arabian Peninsula and has since spread to 20 countries, including the United States—highlights the fact that biological threats originating anywhere in the world are a threat everywhere. The economic losses resulting from biological events are also significant. The 2003 SARS epidemic, the 2009 H1N1 influenza pandemic, and the 2013 H7N9 avian influenza outbreak each resulted in billions to tens of billions of dollars in economic losses. These infectious diseases know no boundaries, and combatting these biological threats is more than just a health issue; it is a security, economic, and development challenge as well.

Recognizing the importance of taking action to combat biological threats, the U.S. government and 29 international partners, launched the Global Health Security (GHS) Agenda in February 2014, to prompt international action to achieve measurable improvements in global health security. Since that time, more than 50 countries have participated in GHS Agenda events.

A key focus of the Agenda is catalyzing action to implement the World Health Organization (WHO) International Health Regulations (IHR, 2005), which require WHO Member States to develop and maintain capacities to strengthen global health security. Through the work of WHO, political support for the IHR has grown, but converting this support into action has been challenging. Almost 10 years after WHO Member States reached agreement on the IHR, 80 percent are still not fully compliant.

To accelerate progress on IHR implementation, as well as other biological threat reduction initiatives—and more broadly to reduce the threats posed by infectious disease outbreaks—the GHS Agenda focuses on three overarching categories: Preventing Avoidable Epidemics, Detecting Threats Early, and Responding Rapidly and Effectively to save lives. These three categories are supported by nine GHS Agenda objectives, each focused on building a specific capability. For example, in support of the "Detecting Threats Early" category, one objective focuses on training and deploying the workforce necessary for detecting disease outbreaks. To ensure that progress toward these goals can be tracked and assessed, measureable targets are being developed for each of them.

The GHS Agenda does not stop with targets. To bridge the gap between political support and action, the Agenda borrows from the security sector's Nuclear Security Summit (NSS) "gift baskets" model. NSS gift baskets are commitments made by the highest levels of government—Heads of State—which make countries accountable to the rest of the international community. This mechanism served as a model for the creation of GHS Agenda "Action Packages"—high level, political commitments to accelerate improvement of global health security capabilities. Action packages shift the discussion from whether or not a

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country supports global health security, to how they are actively working to improve it.

Functionally, Action Packages are collections of discreet activities that, when taken together, drive progress toward one or more of the GHS Agenda objectives. For example, to support the objective of "Promoting national biosafety and biosecurity systems," an Action Package is being developed to consolidate collections of dangerous pathogens into a minimal number of safe and secure facilities, to reduce the risk of diversion or accidental release. This action package also aims to establish a culture of responsibility in the bioscience research community, so researchers will be cognizant of the risks associated with work on dangerous pathogens. Another

Action Package focuses on developing real-time, interconnected disease surveillance networks at national and regional levels, to enhance situational awareness and reduce the response time to emerging biological threats. In crafting these and all Action Packages, emphasis is placed on taking a multi-sectoral approach that includes contributions from the human and animal health sectors as well as the security sector.

The Action Package concept debuted internationally at the first GHS Agenda commitment meeting in Helsinki in early May and discussed at the World Health Assembly several weeks later. In preparation, the U.S. government interagency had collaboratively developed example Action Packages to serve as a starting point for discussion and to spur creative thinking. Twelve packages were initially drafted, with at least one for each of the nine objectives set out by the GHSA. Countries were invited to modify and customize Action Packages to reflect their national priorities.

International support for the GHS Agenda and Action Packages was evident during these initial interactions, and a number of countries have since stepped forward and volunteered to lead Action Packages or make commitments to support them. Several small groups of countries with similar interests are working together collaboratively on this effort.

The G7 declared its support for the GHS Agenda by "working with partner countries to strengthen compliance with the World Health Organization's (WHO) International Health Regulations and enhance health security around the world." The G7 commitment includes "building global capacity so that we are better prepared for threats such as the recent Ebola outbreak in West Africa and working together, in close cooperation with WHO, to develop a Global Action Plan on antimicrobial resistance."

The U.S. government has made its own commitment to the GHS Agenda. Over the next five years, it will work with 30 countries, totaling at least 4 billion people, to develop model systems that enhance global health security. The U.S. Centers for Disease Control and Prevention and the Department of Defense have already begun working with other U.S. agencies and 12 partner countries to mitigate biological threats and build partner capacity.

The United States will host a White House-led GHS Agenda meeting on September 26, 2014. Like the rest of the Agenda, the meeting is focused on action. The countries in attendance will announce commitments as part of Action Packages developed in advance of the meeting. Key objectives of the meeting will include leveraging the momentum of the GHS Agenda to encourage additional countries to make commitments, as well as setting the Agenda on a sustainable course for the next five years. The U.S. government interagency team supporting the GHS Agenda is optimistic that the September event will succeed in reaching these goals.

For more information about the GHS Agenda, visit: http://www.globalhealth.gov/global-health-topics/global-health-security/ghsagenda.html

The United States will host a White House-led GHS Agenda meeting on September 26, 2014.

Richard G. Lugar Center for Public Health Research in Tbilisi hosts participants to the World Congress on CBRNe Science and Consequence Management

By MAJ Dana Perkins, Ph.D. dana.s.perkins.mil@mail.mil and Selwyn Jamison, Selwyn.Jamison@ic.fbi.gov

The keynote presenter was Mr. Andrew Weber, Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, USA.

The World Congress on CBRNe Science and Consequence Management took place on 1-5 June 2014, in Tbilisi, Georgia. The Congress was organized by the government of Georgia (Ministry of Defense, Ministry of Labor, Health and Social Affairs, National Center for Disease Control and Prevention), Organization for the Prohibition of Chemical Weapons (OPCW), European Union, and the United Nations International Crime and Justice Research Institute (UNICRI).

US Ambassador Richard Norland and Georgian Prime Minister Garibashvili sign the agreement transferring complete ownership of CPHRL over to the Georgian government.

Its honorary director was the Georgian Prime Minister Irakli Gharibashvili. The Congress explored the scientific, technical, medical, policy, and consequence management aspects, as well as the effects of CBRNE threats on communities and the individual in addition to each layer of infrastructure and government echelon (presentations are available on the congress website at: http://www.cscm-congress.com. More than 200 participants from over 30 countries were in attendance.

The keynote presenter was Mr. Andrew Weber, Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, USA. Mr. Weber emphasized the "*unbreakable bond between the United States of America and Georgia, and between our people*." He went on saying that "*Georgia is a natural location for this Congress because since independence, Georgia has been a leader in the cause of preventing the proliferation of weapons of mass destruction and terrorism. My first visit to Georgia was in 1998, when we had a project to remove highly enriched uranium for safekeeping outside of Georgia. Since then, we have worked together in improving Georgia's interdiction capability, preventing nuclear smuggling, and strengthening the system for monitoring infectious disease outbreaks, which is part of the global efforts to counter biological threats.*

Georgia is contributing to the global health security agenda and is playing a leadership role in this..."

Other speakers from the U.S. government included representatives of the U.S. Department of Health and Human Services / Centers for Disease Control and Prevention; US Department of Defense [Defense Threat Reduction Agency; U.S. European Command; U.S. Army (7th Civil Support Command; 20th CBRNE Command)], and FBI.

The Congress also included a guided tour at the Richard G. Lugar Center for Public Health Research (CPHRL) in Tbilisi, whose mission is to promote public and animal health through infectious disease detection, epidemiological surveillance, and research for the benefit of Georgia, the Caucasus region, and the global community. Of note, the CPHRL construction was funded by the U.S. government; it began in 2006 and was completed in December 2009. CPHRL was officially opened on 18 March 2011 and is now under the jurisdiction of the National Center for Disease Control and Public Health of Georgia. CPHRL is a state-of-the-art biological research facility (BSL-3) which is

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Richard G. Lugar Center for Public Health Research in Tbilisi hosts participants to the World Congress on CBRNe Science and Consequence Management cont. from pg. 8

expected to enhance regional and international research collaborations aimed at building public health capacity and enhancing infectious disease detection and prevention.

During the closing ceremony of the World Congress on CBRNe Science and Consequence Management, US Ambassador Richard Norland and Georgian Prime Minister Garibashvili signed an international agreement transferring complete ownership of CPHRL over to the Georgian government, in the presence of half of Georgia's Cabinet and a large media presence.

The World Congress on CBRNe Science and Consequence Management also included a combined US-Georgia practical demonstration by the US Army 7th Civil Support Command's 773rd Civil Support Team and Georgian Ministry of Internal Affairs' CBRN Rapid Response Team on biological sampling and decontamination. The demonstration took place in front of CPHRL.

The current global environment is defined by multiple challenges to human and international security, from inter-state or ethnic conflicts and organized crime, to public health emergencies, potential misuse of science and technology, and the omnipresent risk of CBRN terrorism. These

773rd Civil Support Team demonstrates biological sampling and decontamination procedures.

diverse and complex challenges multi-sectoral mitigation strategies and robust laboratory, surveillance, veterinary, medical, and public health capacities in all countries in the world. The challenges we all face are also opportunities to work in collaboration, within and across borders to foster improved preparedness and response to public health emergencies regardless of cause, and to enhance our joint action and unity of mission at the national, regional, and international level.

Mr. Weber emphasized the *"unbreakable bond between the United States of America and Georgia, and between our people."*

Mr. Weber and Brigadier General Paul Benenati congratulate the 773rd Civil Support Team at the end of the field demonstration.