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Executive Summary

FOR: Oversight and Investigations Subcommittee Chairman Murphy, and Energy and Commerce Committee Members

SUBJECT: The American Biological Safety Association Position Paper regarding the 16 July 2014 *Centers for Disease Control and Prevention (CDC) Anthrax Lab Incident* Hearing and the General Accounting Office (GAO) Report, High *Containment Laboratories: Recent Incidents of Biosafety Lapses*.

Recent hearings on the *CDC Anthrax Lab Incident* highlighted both weaknesses and strengths of America's biological research institutions. The solution to resolving program weakness is not closing facilities, withdrawing funding or placing additional regulatory burden on an organization without clear benefit to our nation. These measures actually impede critical biological research and production required to maintain public health, national security and emergency response capabilities, by imposing costly and restrictive requirements that lack a public or economic benefit. Congress is in a position to leverage lessons learned from recent biosafety events to strengthen America's biorisk program. Congress can do this in a cost effective manner while protecting and building on the existing mechanisms that support effective national response to current and future disease and national security threats.

Work that uses pathogenic biological agents and toxins with potentially high community or economic impact must be managed and controlled to prevent unintentional and intentional release. Specifically, the use of these materials associated with serious or lethal human disease for which preventive or therapeutic interventions may or may not be available should involve Federal government guidance that empowers and holds institutions accountable to develop sustainable biorisk management systems. These systems must be tailored to the biological agent/material utilized and the type of work and facilities/equipment employed. Biorisk management systems must include program elements such as senior management, the Institutional Biosafety Committee (IBC) and personnel accountability, experienced, competent[1, 2] biosafety professionals, biological agent inventories and risk assessments, training programs, self-assessment processes and defined metrics to promote continuous improvement (e.g., non-punitive tracking of laboratory associated infections). An effective biorisk management system must drive innovation and scientific discovery rather than hinder. The American Biological Safety Association (ABSA) supports performance-based expectations that apply to public and private institutions that handle human, animal and plant pathogens, including small and large-scale operations, clinical laboratories and academic institutions.

RECOMMENDATION 1: Establish and sustain a national registry of biosafety level 3 facilities. Refer to Attachment 1 for supporting information.

RECOMMENDATION 2: Direct Federal Agencies to endorse the establishment of a biorisk management program for facilities handling pathogenic agents. Refer to Attachment 2 for supporting information.

ABSA's members are a repository of biological safety expertise, and they are an available and essential partner to your Energy and Commerce Committee in exploring the current and future state of biological research in this country. We, the members of ABSA, formally offer our biological safety (biosafety) expertise and our partnership to address the complex underlying issues these facilities face. We would be honored and pleased to meet with you to discuss these important issues further.

[1] http://www.absa.org/bioreg.html
[2] http://www.absa.org/biocert.html

Attachment 1 – Supporting Information for Recommendation 1

RATIONALE FOR RECOMMENDATION 1: Establish and sustain a national registry of biosafety level 3 (BSL-3) facilities.

High containment facilities exist to help reduce the burden of disease both in this country and around the world through innovative research therapies, vaccines, and cures. Many of these facilities are working on the cutting edge of science and the boundaries of human knowledge. The researchers in these facilities compete, collaborate and continue to push the boundaries in new directions. Their work takes time, sometimes decades, and we never know which research projects will have the most impact. We must remember the critical purpose of these facilities and continue to support them while we evaluate the best path forward to maintain and sustain a safe work environment, healthy communities and ecosystem, a robust economy and a secure nation.

While BSL-3 facilities that are registered with the CDC/United State Department of Agriculture (USDA) Select Agent and Toxin Program are highly regulated and their identities known, there are many BSL-3 facilities in existence that do not utilize these agents, consequently their identities are unknown at the state and/or national level. Establishing and sustaining a national registry of non-select agent and toxin BSL-3 facilities, in a manner that does not compromise biosecurity, would complement the registries already maintained by the Federal Select Agent Program and benefit national security and emergency response efforts. Each public or private sector entity that owns or operates a BSL-3 facility(s) would be accountable to register their BSL-3 facility(s). Agreement on how registration information will be used and who would maintain this national registry will need to be defined.

ABSA does not support registration of biosafety level 2 (BSL-2) facilities; these facilities should be a managed at the local level.

Biological agent and toxin inventories should be documented and maintained at the local level. Currently, there is no Federal requirement to register non-recombinant, non-Select Agent or Toxin biological materials used at a facility. ABSA supports maintaining biological agent inventories at the local level but does not support registration of Risk Group 2 (RG2) or Risk Group 3 (RG3) non-select agent and toxin biological material with a government agency.

Attachment 2 – Supporting Information for Recommendation 2

RATIONALE FOR RECOMMENDATION 2: Direct Federal Agencies to endorse the establishment of a biorisk management program for facilities handling pathogenic agents.

The solution to resolving potential inadequacies in existing BSL-3 facilities must not include closing facilities, withdrawing their funding or placing additional regulatory burdens on the work without clear benefit to our nation. These measures may impede critical biological research and production required to maintain public health, national security and emergency response capabilities by imposing costly and restrictive requirements not commensurate with public or economic benefit. The better approach is to ensure the high containment facilities we have and need employ an adequate biorisk management program.

Critical elements to a successful biorisk management program include:

- **Senior Management Accountability—**top management (e.g., Deans, Directors, Presidents, etc.) must demonstrate more involvement in safety and take ultimate responsibility for the organization's biorisk management system. Institutions must develop a biorisk management framework to better support their research and place less responsibility and accountability on only one person (i.e., the Biosafety Professional). Expectations must be clearly defined and biorisk assessment training provided to researchers, competent biosafety professionals and leadership in accordance with their roles. Scientific journals should require inclusion of a brief statement on safety precautions in every research report submitted for publication to peer-reviewed journals.

- **Institutional Biosafety Committee's (IBC) Accountability—**the IBC should be accountable to approve biorisk assessments for rDNA and other work with high risk pathogenic biological agents (e.g. RG3 and RG4). Guidance should be published on how to develop and review *Workplace Hazard Analyses* or *Job Hazard Analyses*, *Standard Operating Procedures* (SOPs), *Biological Safety Manuals*, *Incident Response Plans*, and *Security Plans*. Consistent and universal templates such as freezer logs and SOPs should be developed and provided - this is both beneficial and safe science. For each grant application that involves research with high risk pathogenic agents and toxins, require a credentialed Biosafety Professional to review the grant application before submission. This approach will provide the IBC with advance notice to assist in initiating the research.

- **Experienced, Competent[3, 4] Biosafety Professionals—**experienced and competent Biosafety Professionals must be appointed to provide advice and guidance on biorisk management issues including biorisk assessments and risk mitigation strategies. Institutions must continue to motivate and support individuals with biosafety responsibilities to seek professional credentials, such as the ABSA Registered Biosafety Professional (RBP) designation or certification by the American Society for Microbiology National Registry of Certified Microbiologists (see http://www.asm.org/index.php/nrcm-cert) and ABSA (see http://www.absa.org/biocert.html). Certification is a tangible credential that documents the abilities of an individual and reassures employers a biosafety professional has been tested, proven, and is competent. Institutions must be provided funding opportunities to hire, train and sustain competent biosafety professionals. The goal of credentialing is to 1) minimize risk to the public, environment and our economy by

[3] http://www.absa.org/bioreg.html
[4] http://www.absa.org/biocert.html

identifying qualified biosafety professionals to mitigate biorisk, 2) encourage mastery of biorisk management knowledge, experience, and skills, and 3) foster professional pride and a sense of accomplishment among qualified professionals.

- **Personnel Training—**institutions must ensure that all individuals who work in, oversee, support, or manage facilities that handle pathogenic agents are appropriately trained and competent in biosafety and biosecurity principles and requirements.

- **Personnel Accountability—**personnel must be given the proper equipment and held accountable for their own safety. The minimum criteria for laboratory personal protective clothing and equipment (e.g., laboratory coats or aprons, gloves, safety eyewear) must be defined. This is beneficial to protect human health and minimize spread of contamination. An employee's competence level should be judged on appropriate education, training and experience and must be integrated into an employee's performance appraisal. All illnesses and injuries including laboratory associated infections (LAIs) should be reported and investigated, and subsequently reported to a National Registry. All employees must understand and be confident that their action will be non-punitive. Reporting and investigating LAIs is a mechanism to identify and share lessons-learned; it also allows for the modification and improvement of laboratory practices and procedures.

- **Biological Agent Inventories and Risk Assessments—**organizations should maintain an inventory of the biological agents utilized and stored in their areas. In addition, for work with pathogenic agents and toxins a system should be established, implemented and maintained for hazard identification and risk assessment, management and communication.

- **Self-Assessment Process—**organizations should establish a self-inspection and audit program commensurate with the risk associated with the work to ensure compliance with Government, local and institutional requirements. This self-inspection program may also be leveraged to identify opportunities for program improvement. In addition, organizations should support third party accreditation of high containment facilities (similar to the Association for Assessment and Accreditation of Laboratory Animal Care International - AAALAC - for animal care programs[5]). In response to the Trans-Federal Task Force findings, ABSA now offers accreditation services for U.S. BSL-3 and ABSL-3 facilities[6] that are not under the jurisdiction of the U.S. Select Agent and Toxins Regulations. Accreditation is an indicator of quality and good science. Accreditation communicates the institution's commitment to excellence and conveys they are serious about setting, achieving, maintaining and sustaining high standards.

- **Metrics to Promote Continuous Improvement—**organizations should define what leading and lagging indicators to utilize to assess the suitability and effectiveness of the biorisk management system and to evaluate where continual improvement of the system can be made. Metrics utilized may include evaluations of incidents and accidents (including laboratory associated infections), results from walk-through inspections, deviations from procedures, analysis of documentation and records, debriefs from emergency response drills, etc.

Biosafety professional associations, regulators and representatives from public and private institutions handling human, animal and plant pathogens, including small and large scale operations,

[5] http://www.aaalac.org/accreditation/

[6] http://www.absa.org/aiahclap.html

clinical labs and academic institutions, must be involved in discussions about the future of biorisk management regulations. We believe this is a call to action to all stakeholders involved in life science research, development, production and education. Biorisk management is a multi-disciplinary issue that requires a multi-disciplinary approach.

Any process that is implemented must be proven effective and be performance-based with a management system approach. To ensure we strengthen, rather than hinder, public and private sector organizations we must evaluate methods that have the potential to improve safety without compromising productivity. To this end, Congress should consider and leverage what is currently being pursued outside of the regulatory environment to effectively manage biorisk:

- Industrial research environments follow NSF International[7], International Organization for Standardization[8] (ISO), and Food and Drug Administration[9] (FDA) requirements and have third party evaluations, which effectively manage and prevent incidents similar to those that occurred at the CDC, FDA and USDA.
- There is a global effort to develop a new ISO work product for *Biorisk Management.*[10,11,12]
- Many universities across the country are developing task forces[13] to evaluate their own safety culture needs in response to highly publicized laboratory incidents[14, 15, 16]

To this end, we recommend that Congress direct Federal agencies which provide biosafety guidance to endorse the use of biorisk management systems for all organizations which handle pathogenic agents.

ABSA is comprised of more than 1,400 members, representing 37 countries as well as the U.S. Members include microbiologists, veterinarians, industrial hygienists, engineers, architects, physicians, nurses, and others with technical expertise, from academia and research institutions, government facilities and private industry. ABSA offers biological safety expertise and support and can help Congress define an effective biorisk management strategy. The repository of biological safety expertise is an available and essential partner to your Energy and Commerce Committee, the research community, and others in exploring the current and future state of biorisk management in this country. We will be honored and pleased to meet with you to discuss these issues further.

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[7] http://www.nsf.org/about-nsf/
[8] http://www.iso.org/iso/home.html
[9] http://www.fda.gov/default.htm
[10] http://www.uab.cat/doc/CWA15793_2011
[11] http://www.absa.org/aiaupdate.html
[12] http://www.ebsaweb.eu/cwa_15793
[13] http://web.stanford.edu/dept/EHS/cgi-bin/lsctf/
[14] http://sherisangji.com/about/
[15] http://www.csb.gov/texas-tech-university-chemistry-lab-explosion/
[16] http://www.cidrap.umn.edu/news-perspective/2007/07/cdc-suspends-work-texas-am-biodefense-lab