Congressional Testimony - 27 April 2023 - Bob Hawley

MAJOR POINTS:

- The origin of biological safety - Origin at Fort Detrick, Maryland with the efforts of Dr. Arnold Wedum and his promotion of applied biosafety to enhance protection of the workers and environment.
- Personal Experiences as Director of Safety and Radiation Protection at the U.S. Army Medical Research Institute of Infectious Diseases and serving as Command Biological Safety Officer for the U.S. Army Medical Research and Development Command.
- Accidents, incidents, and mishaps do not just happen - they are caused, usually because of the unsafe behavior of people. They can be avoided or mitigated. There is a need for a centralized database of accidents, illnesses, and mishaps. Analysis of these reports of laboratory incidents could help improve laboratory safety and oversight and determine why the incidents occurred and how they can be prevented in the future.
- What is a biosafety professional? A biosafety professional is a competent person capable of identifying existing and predictable hazards in the workplace, or working conditions which are hazardous, or dangerous to employees.
- Enthusiasm. A biosafety professional must be enthusiastic about their work and recruit cheerleaders for their profession and promote their profession every day.

TESTIMONY:

- Greeting: Congressman Griffith, members of the committee, colleagues, and friends:

- The origin of biological safety, or biosafety, was at the United States Army Biological Research Laboratories at Camp Detrick, now known as Fort Detrick, in Fredrick, Maryland, by Dr. Arnold G. Wedum, Director of Industrial Health and Safety (1946-1969). Dr. Wedum, who is revered as the person most responsible for creating our profession, is considered the Father of Modern Biosafety. Through the efforts of Dr. Wedum, we saw the development of safer work practices, the biological safety cabinet, advances in aerobiological safety, and environmental monitoring. The development of biosafety concepts has roots in the work promoted by Dr. Wedum. The type of laboratory work, the principles and practices used, and the type of facilities needed were established on the determination of risk. This was a risk-based approach - what I want to emphasize is that no one procedure or technique can be used for all laboratory research and development procedures - putting it bluntly, one size does not fit all. A risk assessment is conducted, followed by a risk management procedure whereby the risk is mitigated or eliminated. Also implemented was a Special Procedures Section that performed medical examinations on personnel assigned to work in the biowarfare sections, and the Special Immunizations Program that began as an immunization program to provide an additional measure of protection of laboratory workers against occupational infections. Dr. Wedum directed many applied biosafety research projects that allowed us to better understand the interactions of laboratory procedures and workers, and subsequently be able to mitigate the negative impact of these interactions. It is unfortunate that today we do not continue to pursue applied biosafety research because of funding constraints. The recommendation of the Trans Federal Task Force

report of 2009 to “Develop and maintain a robust program of applied biosafety and biocontainment research to create additional and update existing evidence-based practices and technologies” has not gained momentum.

- My experience with the U.S. Army Safety Program was with the Medical Research and Development Command at Fort Detrick during the period 1988 through 2003. The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) is the Department of Defense's (DoD) lead laboratory for medical biological defense research. USAMRIID was my extended family - everyone treated each other as family members. As an analogy, we were like spokes in a wheel moving smoothly to accomplish our mission of Research for the Soldier - protecting the warfighter from biological threats, and also investigating disease outbreaks and threats to public health. We operated within an ideal climate of safety where everyone embraced and practiced a culture of safety. During this time serving as Biosafety Officer at USAMRIID, I was also designated Command Biosafety Officer. In this role, I was tasked to inspect national and international contract and university laboratories to assess their capability and safety program prior to the release of funding. This was an excellent example of command and control and also allowed me the opportunity to champion biosafety and learn alternative approaches to challenging situations and policies.

- Accidents, incidents, or mishaps in the laboratory or in any workplace environment do not just happen - they are caused, usually because of the unsafe behavior of people. Included in these causes are violation of rules or procedures, inadequate training, failure to understand the process or procedure, fatigue, and mental status. Most mishaps can be mitigated or eliminated

through adequate coaching, mentoring, or training using the best practices for facilities, equipment, and procedures. I am a firm proponent that we have an opportunity to gain experience from our incidents, mishaps, accidents, or near-mishaps by sharing our experiences - without negative consequences. The Trans Federal Task Force report of 2009 proposed a Centralized Incident-Reporting, Analysis, and Information-Sharing System. The report further stated that an analysis of reports of laboratory incidents could help improve laboratory safety and oversight, determine why the incidents occurred and how they can be prevented in the future. Implementing this recommendation would provide a resource for generating and sharing lessons learned, and promoting the need for new or revised guidelines, practices, or training. Such a national centralized database of laboratory incidents must be characterized by openness and engagement by all involved individuals. The database must be managed and maintained by an organization that provides an independent assessment, and has no vested interest in the organization reporting an incident. Information about incidents within the database must be candid, and truthful. Some examples of such centralized databases include (1) the National Transportation Safety Board Aviation Accident Database and Synopses, (2) the National Automotive Sampling System that is a representative sample of police reported motor vehicle crashes of all types, from minor to fatal, and (3) the National Electronic Injury Surveillance System that collects data on consumer product-related injuries. Many states have a central repository for the collection, analysis, and distribution of motor vehicle accident reports and crime statistics. It is important to realize that such databases are not new - their purpose is to document the exact details of the occurrence. Information on accidents, incidents, and mishaps can be used as an aid to risk assessment helping to develop solutions to potential risks.

- A biosafety professional is defined as a competent person who is capable of identifying existing and predictable hazards in the workplace, or working conditions which are unsanitary, hazardous, or dangerous to employees. This individual is authorized to take prompt corrective measures to eliminate these hazards. A biosafety professional is an individual with post-baccalaureate education, continuing education courses, and credentials such as a Registered Biosafety Professional and a Certified Biological Safety Specialist. These credentials are managed and administered by the American Biological Safety Association International. It is most desirable for a biosafety professional to have laboratory experience. This experience is of great value for communicating with laboratory workers, and is a valuable asset to help an individual earn respect and credibility with the workforce. The requirement for training laboratory workers and biosafety professionals must be continually emphasized. Just as we wish to provide the perfect meal using a proven recipe, in the laboratory we strive for accuracy and perfection of our research or diagnostic outcome by using a proven recipe - this recipe we call a standard operating procedure. This assures that our products are not only consistently similar, but also that other workers can reproduce or validate what was done by others. Although experience can be obtained by formal training, coaching, mentoring, and observation, I emphasize the importance of developing an apprenticeship program - similar to an internship and residency program prior to practicing medicine or dentistry, or a post-doctoral assignment following graduate studies. An apprenticeship provides real-time experience with accomplished and seasoned people offering individuals new to the field additional foundation building blocks such as learning and applying new biosafety principles and practices and furthering their interpersonal and communication skills. An apprenticeship program is very much needed at the present time because of not only the proliferation of high and maximum containment laboratories, but also the

few numbers of individuals entering the biosafety field. It is also prudent to comment that there is a need for additional engineering personnel competent in the operation of these sophisticated laboratories. Although there are opportunities to enroll in short-term courses for continuing education, a concern is the lack of higher education institutes offering coursework leading to an advanced degree in safety or biological safety.

- Biosafety practitioners have to be enthusiastic about their work and recruit cheerleaders for their profession. I hope that my comments will reveal the passion I have for biosafety and the continuing desire to learn from my colleagues.