External Laboratory Safety Workgroup (ELSW)
February 9 – 12, 2015
Live Meeting Summary

Attendees

- o Joseph Kanabrocki, PhD, CBSP – *Co-Chair*
- ✓ Thomas Inglesby, MD
- ✓ Michael A. Pentella, PhD, D(ABMM)
- ✓ Patty Olinger, RBP
- ✓ Fred Sparling, MD
- ✓ Jill Taylor, PhD
- ✓ Heather J. Sheeley, BA (Hons), MS.,CBiol MSB, CMIOSH, FISTR
- ✓ Domenica (Dee) Zimmerman
- o Kenneth I. Berns, MD, PhD – *Co-Chair*
- ✓ Sarah Wiley, ELSW DFO
- ✓ Richard G. Baumann, PhD*
- ✓ Herbert. B Jacobi, MS*
- ✓ Alfred C. Johnson, PhD*
- ✓ Jeffrey M. Potts, MPH, CBSP*
- ✓ James M. Schmitt, MD*
- ✓ John M. Veitch, CIH*
- ✓ Deborah E. Wilson, Dr. PH, CBSP*

o ***In attendance***
* ***NIH employee***

Summary of Meeting

Call to Order, Welcome, and Opening Remarks, February 9, 2015

Dr. Kenneth Berns, ELSW Co-Chair, Dr. Deborah Wilson, and ELSW Members

Dr. Berns and Dr. Wilson called the meeting to order. Both raised friendly sentiments of working collaboratively over the course of the following days. Dr. Wilson kicked off the meeting by describing the role of the Division of Occupational Health and Safety (DOHS). The DOHS is responsible for implementing safety and health across 27 institutes, both intramural and extramural. DOHS is not responsible for the extramural grantees, only the extramural staff. The DOHS takes care of the Bethesda campus and all other NIH campuses, excluding the National Institute of Environmental Health Sciences (NIEHS) and the National Cancer Institute (NCI) in Frederick, which have their own safety programs. DOHS works collaboratively with safety programs to ensure consistency in approaches.

ELSW NIH observations will be made accordingly:

- o Determine overall management of the laboratory safety programs at NIH, from institutional committee oversight to occupational medicine to personnel reliability.
- o Dr. Kanabrocki stated that it was his hope the Workgroup would be able to come together and provide comment that would be helpful to the NIH.

General Discussions

ELSW Members and NIH Representatives

- o **Smallpox Incidence**
  - ELSW members did not anticipate that smallpox would be found at the NIH. The incident at NIH has in some ways been the trigger for everything that is going on and is what has gotten things mobilized.
  - Ms. Olinger commended Dr. Wilson and her staff on the handling of the smallpox incident. What happened at NIH could happen at a lot of other institutions and she noted that some people would have destroyed the sample. The fact that NIH identified the sample and made it public knowing that NIH would be scrutinized was commendable.
  - Dr. Zimmerman asked how long it was from the time that Dr. Wilson received notification until Dr. Johnson was made aware of the situation. Dr. Wilson replied it was a matter of minutes. Dr. Zimmerman then asked how long from the time Dr. Johnson was made aware until the Director of NIH was informed. Dr. Johnson replied that within minutes he notified the Deputy Director of Management because the Director of NIH was out of the

country. He then immediately notified the acting Deputy Director of NIH. The Deputy Director of Intramural Research was also notified.

- **DOHS**
  - The NIH has survived many changes in directorship. Dr. Wilson stated that was true only for changes in the NIH directorships, not changes in the directorships of the Division. She explained that since 1979, there have been three Division Directors: Dr. Barkley, Dr. Robert McKinney, and herself. Since that time, the Division has pretty much remained the same, except it has gotten smaller. The Police and Fire Departments were once part of the Division. As NIH grew, these Departments grew, along with the whole ORS. The Departments were broken off into separate Divisions of a more manageable size. Also, the Division of Engineering Services, once part of the ORS, was broken off and is now the Office of Facilities Management.
- **Funding for DOHS and ORS**
  - The ORS is part of central services, which includes such things as research services; research facilities; building and facilities, which is a congressional line item; management assessment; and human resources.
  - Within the budgets of the Institutes and Centers (IC) there is the category Research Management and Support (RMS), which includes the scientific and administrative management expenses associated with the day-to-day operations. The ORS does not get a specific budget until those budgets are set for the ICs. The ICs have a Management and Budget Working Group that includes the IC Directors, Scientific Directors, and the Executive Officers. They determine what portion of the IC budgets goes to the different entities. Each year the ORS submits a request to the Working Group for all of the services it provides.
- **DOHS Oversight on Training**
  - DOHS has oversight responsibility for training at the Rocky Mountain Laboratories (RML) as well as the Frederick Campuses.
- **Leadership**
  - Strong leadership, starting with the Director of NIH who sets safety as a very high priority, has set a tone for the success of NIH's centralized safety program. The Director of NIH is committed to providing whatever resources are needed. Dr. Johnson stated that ORS has never had a problem when it comes to getting resources, even out of the budget cycle. If an issue arises, the ORS presents the issue and recommends what needs to be done to resolve it and what it will cost. The NIH looks at the request and often even before it is decided where the money will come from, sets wheels in motion to make the resources available.

Safety and Health Overview

Dr. Wilson and ELSW Members

Dr. Wilson provided the ELSW an overview of the NIH population, locations, policies and local regulations, the NIH safety organizational structure, NIH safety committees and their mandates, and NIH functional groups.

- The Division of Personnel Security and Access Control (DPSAC) is located within the Office of Security and Emergency Response, which also includes the Divisions of Emergency Preparedness and Coordination, the Fire Marshal, Fire and Rescue Services, Physical Security Management, and the Police.

Dr. Wilson next presented the DOHS organization chart, which listed the three branches within the Division.

- Safety Operations and Support Branch
- Technical Assistance Branch
- Community Health Branch

The DOHS supports the special pathogens unit in the hospital but is not responsible for that program.

- In addition to the three Branches, there is the Occupational Medicine Service (OMS) and the Safety Engineering Activity (SEA) that report to the DOHS.
  - OMS is located in the Ambulatory Care Research Facility and is perhaps the largest clinic at the NIH with between 30,000 and 35,000 patient contacts a year.
  - The SEA is a group of industrial and mechanical engineers and other support people who review drawings and participate in projects.
- **Staffing**
  - On the Bethesda campus, the DOHS has 54 fulltime federal equivalents (FTE) and roughly 160 contractors.
  - Dr. Taylor asked why the decision was made to contract out so many positions. Dr. Wilson replied that the NIH could not hire the number of FTEs needed by the safety program to do what needs to be done.
- **NIH Safety Committees**
  - There are a number of Safety Committees at the NIH, three of which report to the Director of NIH through the Intramural Director: Institutional Biosafety Committee (IBC), the Occupational Safety and Health Committee, and the Radiation Safety Committee.
    - The IBC meets monthly and reviews between 75 to 80 protocols each month
    - The IBC reviews all BSL-3 and BLS-4 work, including protocols carried out in Hamilton, Montana.
    - Health and Safety Specialists review all BSL-2 research and can elevate a protocol to the IBC for review if there is an issue of concern.
    - The IBC serves several purposes: oversees recombinant research, oversees all infectious disease work, including work with high consequence pathogens, and is a policy recommending body.
  - There are 17 Animal Care and Use Committees (ACUC), which review all of the protocols involving animals.
  - There are 25 active IC Health and Safety Committees
  - The NIH uses an electronic tool called PI Dashboard that gives a lot of access and has streamlined things administratively.
  - Decisions made by the IBC is communicated through an electronic system that automatically sends the decisions of the IBC to the Safety and Health Specialist, the PI, and if animals are involved, to the attending Veterinarian or Program Director.
- **Registered Laboratories**
  - Registered laboratories are those labs that do non-exempt recombinant DNA work or any infectious disease work with agents handled at BSL-2 or above. There are roughly 2,500 registered laboratories.
- **DOHS Safety and Health Specialists**
  - Safety and Health Specialists serve all 3,000 to 5,000 laboratories. Specialists do everything from biosafety to electrical safety to chemical safety to physical safety. They spend roughly 80 percent of their time in the field and in the laboratories, and each Specialist is in one or multiple laboratories. Their responsibilities include conducting

physical audits of the laboratories, making recommendations, following up on actions, and documenting the audits in an electronic audit system.

- **Reporting of Safety Concerns and Incidents**
  - NIH has in it policy that every individual has a right to report their safety and health concerns without the fear of reprisal.
  - NIH has an anonymous reporting system and an e-mail address available for individuals to send in concerns. Individuals can also report directly to their Safety and Health Specialist or to their Institute's Safety and Health Committee. They can report directly to the OMS or to the leadership of ORS, or call the Occupational Safety and Health Administration (OSHA). All reports are received by the DOHS.
  - Volume-wise, the number of concerns received are in the thousands when injury and illness reports, accident investigations, and other issues such as report of odors are all taken into account.
  - In FY2014, actual biological incidents were less than four percent of the 769 total injuries and illnesses reported.
  - Animal-related Incidents
    - NIH sees on the average of 50 incidents a year, including bites, scratches, equipment injuries, and splashes. It is the heaviest reported incident because a lot of emphasis has been placed on reporting animal related injuries.
  - NIH has actively been tracking all types of injuries and reports for over a decade.
- **Safety-Related Outreach Programs**
  - The DOHS has a broad outreach program that includes, for example, a photo contest where employees take photos of things they consider safety-related.
  - The DOHS has a Mission First Safety Always award that goes to people nominated by their Institute.
  - There is a monthly newsletter and a Safety and Health Wellness Day.
  - There is also an outreach program for the off campus buildings. An initiative recently begun involves having a Safety and Health Specialist visit an off-campus site one day a week and setting up in an office to answer questions or discuss safety-related matters.
- **Transfer of materials**
  - NIH does not conduct a high number of interagency transfer of materials like the CDC, however there are transfers conducted within the agency.
  - It is difficult to monitor daily all transfers between IC's. However, the DOHS is apprised of transfers that occur among BSL-3 laboratories with high consequence situations. The NIH does not have a centralized shipping of materials unless it is a select agent and there is a protocol in place for that. Select agents are received centrally in the DOHS
- **DOHS Laboratory Safety Training Program**
  - DOHS has a hands on training course required for young people between the ages of 18 and 20 who are first time summer students in the laboratories.
    - STARS training (Safe Techniques Advance Research Science)
    - Each year, the NIH has between 800 and 1,000 summer students.
  - The DOHS has general laboratory safety training and refresher training, bloodborne pathogens training and refresher training, and BSL-3 training. Training is delivered in a classroom and online to address different learning styles and preferences of the trainees.
  - The DOHS also has a three-week BSL-4 training course conducted onsite that is similar to the training offered at the University of Texas Medical Branch in Galveston. It is in-suit

training and is required before any laboratory worker at the IRF Frederick can move into his or her mentor training at the IRF.

- Each laboratory has a mentor program. It is the responsibility of the senior scientists or PIs to verify the proficiency of the workers and make the final decisions of when each is allowed to begin work with the pathogens in use in their laboratories.
- A hands on course in development will cover the basic mechanism of getting into a BSL-3 laboratory, proper use of personal protective equipment (PPE), exiting the laboratory, and handling materials.
- When new NIH employees come on board, they attend an orientation for a day or two where the DOHS provides instructional courses on health and safety program and the OMS. It is a goal of the DOHS to reach out and communicate with all new employees within 45 days of their coming on board.
- Tracking of training
  - NIH has a policy that the responsibility for tracking training lies with the PIs. DOHS agreed with the policy but found the need to address that PIs did not have the tools to track training. So they developed an electronic database that tracks all training, using color indicators.
  - The laboratory supervisor, the Occupational Safety and Health Committee, and the Safety and Health Specialists all have access to the database. Specialists use the tool when they do their laboratory audits to easily check the status of the workers' training. Since the introduction of the tool, training numbers have shot up.

- **Biosecurity Program**
  - DOHS works with the Division of Personnel Security and Access Control to control whose card can access what laboratory. All of the elements of the biosecurity program must be documented before anyone gains access to BSL-3 or 4 laboratories. This includes the required training and paperwork, and a background investigation.
  - The NIH has extended its Biosecurity Program to all personnel who work at BSL-3 and 4 because federal regulations preclude the NIH from putting any rules in place that exceed those of the Select Agent Regulation.
- **Notification and Communication Systems**
  - In emergencies, the DOHS can reach employees through the NIH e-mail list, which includes all NIH employees, the PI list, the Office of Research Safety global list, and the DOHS listserv.
  - The DOHS has many different tools to communicate and utilizes those tools that are best for each situation.

Biorisk Management Plan Elements

Dr. Richard Baumann, Mr. Jeffrey Potts, and ELSW Members

Mr. Potts provided an overview of the Biorisk Management Program for the ELSW. There are four components of the Biorisk Management Program: Biosafety, Biosurety, Biocontainment, and Biosecurity. Not every activity listed under the four components is done solely within the Biorisk Group and may be conducted in a coordinated effort with another Division on the campus or another group or Branch within the DOHS.

- **PI Dashboard System**
  - This system allows PIs to see all of their registrations, submit new registrations, submit amendments, inactivate registration documents, and add and remove personnel in real time. As a Biosafety Officer, Dr. Baumann sees all of the documents that are submitted. He

performs the initial risk assessment and establishes the initial review process with the investigators until it is ready to become an IBC packet, which moves the document forward for the final review by the IBC.

- PI Dashboard Metrics for FY2014: 229 new pathogen requests, 155 new recombinant DNA requests, 335 amendments, and 197 inactivation requests.
- The dashboard has a firewall that does not allow DOHS to have access to the OMS records, but OMS has access to PI Dashboard so they are aware of the pathogens in use. She stated that it is very clean cut as to what if any medical information the DOHS staff is privy to.

- **Risk Assessments**
  - Risk assessments are conducted at the PI level.
  - Safety and Health Specialists conduct follow up visits to the laboratories working with Risk Group 2 pathogens. At BSL-3 level laboratories, Specialists will ask for standard operating procedures (SOP) for certain procedures and pieces of equipment and work more at that detail of the research protocols.
  - In addition to electronic signatures required by the investigator in the PI Dashboard, every single person associated with the protocol is required to submit an electronic signature attesting to the fact they he or she understands the protocol, has been trained in the hazards associated with it, and is fully informed.
  - Staff of the BRM Group visit BSL-3 laboratories twice a year to conduct safety surveys. One visit is unannounced and one is scheduled to allow time for a conversation with laboratory staff.
- **Biosecurity**
  - DOHS is responsible for visiting scientists who are listed in the NIH Enterprise Directory and have NIH badges. Visiting Scientists use the same credentials as other staff. Guest Researchers, Contractors, and summer students are all listed in the NIH Enterprise Directory.
  - The Biosecurity component does part of the personal records screening including the Collective Foreign Threats Assessment using a third-party software program called Visual Compliance.
  - The Biosecurity program also contains a behavioral health-screening component, and DOHS does annual interviews and provides services to individuals who may be experiencing certain personal problems.
  - Insider threat awareness is part of all biosecurity training and is included in the annual discussions between the behavioral specialist and researchers.
- **Biological Surety**
  - The goals of the Biological Surety Program are to: ensure a trained, responsible and reliable workforce; foster rigorous procedures to protect employee health and promote a safe work environment; enhance the safety culture by promoting worker cohesiveness, resilience, trust, respect and reliability; preserve the integrity of the research being conducted; and protect valuable research materials and products.
  - Biosurety components conduct an initial evaluation of each person in the Biosurety Program and all requirements must be met before the person is granted access to their laboratory. Annual evaluations are also conducted.
  - The Biosurety component administers a safety questionnaire of about 130 questions and a depression and anxiety screening exam.

- **Biocontainment**
  - The TAB is responsible for the Primarily Barrier Contract, however, the Biorisk Management Program reaches out to TAB for information when doing the laboratory surveys and testing. The Safety Engineering Activity (SEA) performs annual validations in all high and maximum containment laboratories.
  - High Containment Task Force, which started about five years ago. It is a Memorandum of Understand between the NIAID, the ORF and the ORS. It is a formal partnership established to maintain and operate the NIAID occupied intramural BSL-3 and BSL-4 laboratories and vivarium spaces. The intent is to decrease the vulnerability and risk to the NIH.
- **Biosurety**
  - Select Agent Program and the Biosurety Program are both under the Biorisk Management Program. There is some overlap in job responsibilities for the staff, which helps with coordination between the Programs.

Laboratory Visits, February 10-11, 2015

ELSW Members

During this meeting, ELSW members visited NIH laboratories and conducted staff engagement sessions with NIH staff.

Closing Session, February 12, 2015

ELSW Members

Dr. Kanabrocki, Workgroup Chair, opened the Exit Briefing by expressing gratitude on behalf of the Workgroup to Dr. Wilson and her staff for being gracious hosts, for their time, and for ensuring that the Workgroup was given every opportunity to make the most of their time during their four-day visit.

Preliminary Observations

- **Leadership**
  - NIH has a great laboratory safety program that begins with the program's leadership. The NIH's expectation for high levels of safety standards and safety awareness is evident in many ways and is to be applauded. It was clear to the Workgroup that NIH sets laboratory safety, and safety in general, as a very high priority.
- **Organizational Structure**
  - The Workgroup reviewed the organizational structure and the role of the Institutional Biosafety Committee (IBC) and the institute / center (IC) safety committees and found that the establishment of these groups and their interactions is supportive in maintaining a culture of responsibility and accountability across the Institutes.
  - The PI Dashboard is a great tool that supports the organizational structure.
  - In terms of the IBC, the Workgroup found some ambiguity concerning the review of non-recombinant DNA high-risk protocols and the role of the IBC in these reviews. This task now falls to the Biosafety Officer and is quite a workload for one individual. It can be daunting. The Workgroup recognized that the Biosafety Officer is doing a good job, however, suggests that NIH consider providing additional staff in this area. In addition, the Workgroup believes that review of non-recombinant protocols is an important function that should involve the IBC.
  - The IBC and safety committees without any incentive to do so. The Workgroup suggests that these individuals be offered a reward or incentive of some kind as a thank you,

perhaps in the form of money or continuing educational credits, or in other ways that would thank them for their service.

- **Division of Occupational Health and Safety**
  - The DOHS is recognized NIH-wide as the central authority in support of laboratory safety. The division has a very strong leader in Dr. Wilson, and there is no question of who is in command of operations. This is a huge accomplishment.
  - The DOHS is responsive and there are frequent communications from the office.
  - The Occupational Medical Service (OMS) is extremely strong and comprehensive and provides a total, across-the-board occupational health care program. It is clear that OMS works well in collaboration with DOHS.
- **Risk Assessment**
  - Risk assessments are performed in a collaborative manner and involve the Principal Investigators (PI), the IBC, and staff of the DOHS. There is ambiguity concerning review of non-recombinant DNA protocols and the Workgroup suggests that the Biosafety Officer be provided additional support.
  - With respect to DURC, the Workgroup found that the risk assessment reviews are sophisticated and involve the NIH leadership. It is an NIH priority that staff, PIs, and students are educated concerning DURC. The Workgroup suggests that as part of the DURC reviews, it would be useful to consider whether there is potential risk for the release of an organism that could be potentially harmful. He added that this suggestion goes beyond what the National Security Agency (NSA) has recommended, but that the Workgroup believed it would be useful.
- **Laboratory Safety Training Program**
  - The program is strong and is offered centrally through the DOHS by a variety of training methods, including hands-on, online, and in-person, and includes the NIH Visiting Scientists.
  - Laboratory-specific training is conducted at the local level.
  - The Workgroup found some variability in the competency assessments at the BSL-2 level and suggests that the training program examine to what degree and how it confirms and verifies the technical competencies of staff working at the BSL-2 level.
  - Dr. Kanabrocki repeated that the Workgroup heard numerous times that reporting of laboratory safety incidents is done without concern of reprisal, adding that this is exactly the culture all safety programs should strive to achieve.
- **Risks and Challenges**
  - Contractors
    - There is a large number of contractors working at NIH and the agency will need to determine how best to manage this group and ensure that all are included in the safety program. The Workgroup could not offer any suggestions on how to address this challenge.
  - BSL-2 Laboratories
    - One issue that came up several times during the Workgroup interviews was the use and non-use of personal protective equipment (PPE), in particular lab coats and safety glasses at BSL-2. The Workgroup suggested that NIH leadership send a strong message that the use of appropriate PPE in all labs is an expectation.
    - Another challenge is the confirmation of the technical competency and documentation of training of the BSL-2 laboratory workers.

- Facilities
  - The Workgroup observed that many of the laboratories were largely crowded. The Workgroup suggested that it is important to have DOHS involved in the initial thinking of the design of future laboratory space.
- IBC
  - The Workgroup found it concerning of the open-endedness of the protocols the IBC reviews. Members suggested that NIH consider having expiration dates on protocols reviewed by the IBC. The NIH's electronic system provides an opportunity to do this in an effective way.
- Culture
  - The Workgroup recommended that DOHS do a survey, which unlike the survey done three years ago on the culture of safety, that focuses more on laboratory personnel and laboratory safety.

o **Additional Comments**

- NIH culture has been very interesting to the Workgroup and they have all been impressed. This particular culture has very complex groups with lots of administrative independence yet tied together vertically and horizontally in a way where people are empowered but not competing, and are working together.

Closing Remarks

Ms. Wiley, Dr. Wilson, and ELSW Members

Ms. Wiley, Designated Federal Official for the Workgroup, stated that the next meeting of the Advisory Committee would be on April 23, 2015. The Workgroup is targeted to have its report ready before that meeting.

Dr. Wilson thanked the Workgroup for their time and effort and stated that while DOHS is homegrown, it could be inbred. She stated that it is good to have people from outside the organization taking an independent look, and NIH appreciates that. Dr. Wyatt agreed. He stated that NIH also appreciates the spirit of the conversations and the spirit that the Workgroup brought to their recommendations. Dr. Wyatt stated it was a collaborative, collegial experience. Dr. Kanabrocki responded that it was the Workgroup's honor to be at the NIH.

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