



**External Laboratory Safety Workgroup (ELSW)
September 15 – 17, 2014
Live Meeting Summary**

Attendees

- | | |
|---|---|
| ✓ Joseph Kanabrocki, PhD, CBSP – <i>Co-Chair</i> | ✓ Kenneth I. Berns, MD, PhD – <i>Co-Chair</i> |
| ✓ Debra L. Hunt, DrPH, CBSP | ✓ Thomas V. Inglesby, MD |
| ✓ Patty Olinger, RBP | ✓ Michael A. Pentella, PhD, D(ABMM) |
| ✓ Fred Sparling, MD | ✓ Jill Taylor, PhD |
| ✓ Domenica (Dee) Zimmerman | ✓ Elaine Baker, ELSW DFO* |
| ✓ Heather J. Sheeley, BA (Hons), MS., CBiol
MSB, CMIOSH, FISTR | ✓ Michael Bell, Interim Director of Laboratory
Safety* |

✓ *In attendance*

* *CDC employee*

Call to Order, Welcome, and Introductions

Elaine Baker, DFO, ELSW

Update on Laboratory Safety Improvement Workgroup

Dr. Michael Bell, Interim Director of Laboratory Safety

- NIH and FDA Colleagues in attendance via teleconference.
- LSIW has implemented moratorium procedures and has evaluated 21 laboratory packages to date.
 - Laboratory activities that were necessary for patient care and public health response were prioritized in the process.
- The agency is also conducting a “Clean Sweep Process”.
 - Deadline is September 30th, 2014.
 - Most CDC laboratories have completed the process or are well underway.
 - No alarming findings to date.
- CDC will assess how to move forward from the initial and temporary convening of the LSIW.
 - To date, LSIW has met with members of various workgroups and committees, such as the Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), Safety Office and clinic, as well as staff through listening and engagement sessions.

ELSW Discussion

Dr. Joseph Kanabrocki and Dr. Kenneth Berns, Co-Chairs, ELSW and ELSW members

- ELSW’s view of its mission
 - ELSW views its mission as paving a path to develop efficiency, quality, and safe science, offering options that will set a standard for all three agencies and the general public.
- ELSW plan through 2015
 - It will be extremely helpful if the ELSW yields three to four options to include in a training proposal, two or three ways to improve and bolster QMS, and identify additional elements that need to be emphasized.
- LSIW Staff Engagement Sessions and the ELSW Laboratory Safety Survey
 - The purpose of these sessions has been to reconnect with CDC laboratory staff in open-ended discussions to identify barriers and suggestions on how to make improvements.
 - The purpose of the survey has been to conduct a “temperature check” on how safe people feel CDC is.
 - Main fear from staff is that they will be required to adhere to a policy that does not make sense and that there will be a lack of funding to fulfill the requirement.



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- Culture of Safety vs. Culture of Responsible Science
 - ELSW seeks to perhaps provide recommendations to identify a central funding source.
 - CDC is comprised of multiple cultures – research scientists, clinical laboratory staff that come from hospitals etc. A cultural paradigm is also evident in terms of the multitude of operating procedures, or lack thereof.
 - Documentation
 - The agency has many competent and well-qualified subject matter experts (SMEs) who are doing a good job of running their laboratories, but that information is passed down verbally.
- Staffing
 - Managers use various mechanisms to fill staffing needs (e.g., contractors, fellows, or an agreement with another agency). Because there are different types of staff members within laboratories, there are also various types of rules regarding communication lines, training, clinic services, etc.
 - It has been difficult to overlap outgoing and incoming staff so that delivery of knowledge is transmitted effectively.
- Education vs. Training
 - The idea of training every new employee appears to have a lot of support; however, there is a lack of resources. There is also discussion about training for non-laboratory supervisors of laboratory staff.
- Systems
 - Database systems to standardize, house, and share information are under-resourced.
 - There is no laboratory director slot within the CDC organization.
 - Various definitions of the word “laboratory” are used within the organization.
- Policies
 - Policies are in place on certain laboratory safety requirements, but not for all requirements.
 - The agency lacks a governing body that assesses every protocol.
- Committees and Governance
 - The lack of horizontal communication channels present vulnerability.
 - Cross-membership is an informal means of communication, but there is a need for formal communication channels.
 - The Associate Directors for Laboratory Science (ADLS) in the national centers are members of most of these boards and committees.
 - ADLSs are to provide communication and oversight for laboratory activities.
 - The ELSW seeks to determine how much authority the ADLSs have compared to their responsibilities.
 - Lack of governance is due to the historical structure of CDC.
 - Previous reorganizations split laboratories and led to a loss of a laboratory hierarchical system.
 - IBC focuses only on recombinant DNA work, while another group focuses only on dual-use research.
 - There is an internal and external need to tie these groups together so that they have a broader mission.
 - The Select Agent Program (SAP) impacts CDC and many other organizations; the Federal Experts Security Advisory (FESAP) has been reconstituted to evaluate SAP and so, ELSW will not be reviewing SAP.
- Biosecurity vs. Biosafety



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- The focus on security should not be lowered, but at a minimum the focus on biosafety should be raised to the same level.
- Root Causes
 - Lack of resources and the execution of right protocols are the two salient root causes.
 - Other root causes include governance structure, buy-in, attitudes, training, systems, time pressure etc.

Biorisk Management System Elements

Patty Olinger, Member, ELSW - Director of the Environmental Health and Safety Office at Emory University

- Biorisk encompasses biosafety and biosecurity, where the hazards are biological agents and their products.
- Biorisk management systems are needed because it is important to provide assurance that risk is being managed effectively, efficiently, and proportionately. Risks must be identified, assessed, and managed in a structured way using recognized approaches with reasonable controls that are proportionate and appropriate to the risk.
- A biorisk management plan is performance-based and sets out requirements for, and places responsibility on, organizations to demonstrate that appropriate and validated risk reduction procedures have been established and implemented.
- Prescriptive-based standards outline the detailed technical requirements for the output.
 - Performance-based standards outline the functional requirements for the output and describe what needs to be achieved.
- When management is supportive of the process, it provides the people who are trying to implement a management system visible support.

Update on ELSW Laboratory Safety Survey

Dr. Kathleen Ethier, Director of the Program Performance and Evaluation Office (PPEO)

- The Laboratory Safety Survey was conducted through SurveyMonkey® and closed on September 12, 2014.
- The survey was disseminated to approximately 1500 laboratory staff, with 621 responses.
- Demographics:
 - 50% worked in CDC laboratories for greater than 10 years, 27% for 5 years or less, and 23% for 6 to 10 years.
- Education:
 - 47% reported having a DMV, MD, or PhD; 29% with a Master's Degree; 23% with a Bachelor's Degree; and less than 1% have no college education.
- Laboratory Level and Area of Research:
 - 76% spend most of their time within BSL-2 laboratories.
 - 26% work with animals, 11% work with potentially infectious arthropods, 31% work with select agents, and 83% work with pathogenic microorganisms. More than one answer could be selected, so those are not mutually exclusive. In terms of primary focus areas, 23% work with bacterium; 30% with viruses; 10% with fungi, mycobacteria, and parasites (which were combined because so few people work in each area); 13% in animal/human clinical materials; 5% in toxins; and 19% in "other."
- Perceptions of Leadership and Safety:
 - 83% of respondents agreed that CDC laboratories are safe, 77% agreed that CDC has a strong culture of safety in laboratories, however, close to 20% did not agree.



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- 77% agreed that CDC leadership (defined as Director, Center Directors, and Division Directors) emphasize the importance of laboratory safety, 81% said that their laboratory supervisors do not allow laboratory workers to cut corners, 81% agreed that laboratory coworkers follow laboratory safety protocols and procedures, and 82% said that they have the tools and materials needed to follow safety protocols. Additional assessments will be made of the demographics particularly related to the approximately 20% who said they did not agree with these statements.
- Perceptions of Safety Protocols:
 - 85% agreed that existing CDC laboratory safety protocols are appropriate for the work that they do, 81% agreed that the laboratory safety protocols are effective, 86% said that they have always reported safety issues of concern, 67% agree that their coworkers always report safety issues of concern, 19% gave a neutral response, and 14% disagreed that their coworkers report safety issues of concern.
 - Communication across laboratories may be an issue:
 - 76%, felt that they were well-informed about incidents that occurred in their laboratories, but 47% did not feel they were well-informed about safety incidents in other CDC laboratories.
- Resources for Laboratory Safety:
 - The most used sources for laboratory safety information in the past 12 months were laboratory SOPs (89%). Of those who used laboratory SOPs (the denominator being the 89%), 85% agreed that they were helpful. The least used was the National Institutes of Health Laboratory Safety Monograph, which had only been used by 6% of respondents in the last 12 months.
- Personal Experience:
 - 21% said that they had been involved in an incident that had been reported to the CDC Safety Office. Of those involved in an incident, 81% agreed that their program and the Safety Office had responded promptly, but only 61% agreed that the response from the Safety Office had led to changes in their labs that would address the problem.

ELSW Laboratory Safety Survey – Discussion Points

ELSW Members

- The survey was anonymous, individuals cannot be identified.
- While 70% or 82% seem like large numbers, the fact that there are remnants of 20% and more disagreeing with some of these elements is concerning.
- Qualitative data will be characterized into themes.
 - Uncharacterized responses will also be provided to the Workgroup to ensure that the impact of an individual's response is not lost via characterization.

Laboratory Staff Engagement Sessions

ELSW Members

- During this timeframe, ELSW members interviewed a diverse range of laboratory staff members to gain further insight into a variety of laboratory activities and issues throughout the agency.

ELSW Direction and Timeline

Dr. Michael Bell, Interim Director of Laboratory Safety and ELSW Members

- The Workgroup seeks to provide input with various levels of granularity, but at a high level to ensure that the agency can move on their recommendations.



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- While reorganization may seem to be a viable recommendation, that recommendation poses a large feat for the agency.
- The ELSW will provide separate recommendations from those of the LSIW.

Laboratory Visits

ELSW Members

- During this meeting, ELSW members visited the following CDC laboratories:
 - Environmental Health Laboratories (Chamblee Campus)
 - Tuberculosis Laboratory (Roybal Campus)
 - Congo Basin Monkeypox Laboratory (Roybal Campus)

Overview: Advisory Committee to the Director, CDC (ACD)

Elaine Baker, DFO, ELSW

- The results of the ELSW's deliberations, including options, suggestions, and recommendations, must be considered by the ACD. Drs. Berns and Kanabrocki will provide updates to the ACD regarding the status of the ELSW's work. The first update will be at the ACD meeting on October 22, 2014. Drs. Berns and Kanabrocki will present options from the ELSW to the ACD when the Workgroup determines that the options are ready to be submitted for consideration. The ACD will vote on any recommendations from the ELSW.

Meeting with ADLSs/General Laboratory Safety Discussion

Dr. Michael Bell, Interim Director of Laboratory Safety and ELSW Members

- The role of ADLS
 - ADLSs themselves perceive that any division with a laboratory branch should include at least one biosafety representative, preferably at the division level rather than imbedded in the branch so that the person does not report to the Branch Chief.
- Committees and Boards
 - There is a lack of systematic linkages between the various committees and boards.
 - A new framework should be a home to all of the groups and should interconnect them, providing directional content of training, a career path, and focus for the complexity of CDC's facilities and campus locations.
- Facility and Systems Issues
 - CDC's laboratories are self-contained and a more robust means for sharing information is needed.
- The Environment, Safety, and Health Compliance Office (ESHCO)
 - The IBC and the ADLSs could focus on safety and ESHCO could focus solely on compliance.
- Full-time Safety Officer Position and Biosafety Office / Single Point of Accountability
 - The Safety Officers should elevate problems early so that they can be handled before personnel resort to workarounds. The safety office should be the backbone of these efforts.
 - A higher level Biosafety Officer Position is currently being created.
 - There is a need to determine resources and funding necessary to create this opportunity.
- IBC
 - IBC is comprised of 17 volunteers who meet and work without administrative support or a budget. They are not housed in an organizational structure at CDC.
 - Structure change is necessary; may need to be administered under the new safety office.
 - Roles of the IBC members need to be identified.



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- Need to determine if the IBC should be renamed to Recombinant DNA Advisory Committee (RAC).

Agency Organization Discussion

ELSW Members

- The ELSW overview of the organizational chart of CDC
 - Members observed the need for the ADLS to work directly with scientists.
- Challenges of having contractual work within the structure of CDC.

Development of Recommendation Themes

ELSW Members

- The following themes emerged from discussions:
 - IBC Scope
 - Risk Assessment
 - Safety Protocol Review
 - Training
 - Competence
 - Leadership and Buy-In
 - Organization
 - Resources
 - Communication and Buy-In
 - Mission Growth
 - Biosecurity over Biosafety

White House Memo: “Enhancing Biosafety and Biosecurity in the United States”

Elaine Baker, DFO, ELSW

- The ELSW reviewed the language of the memo to clarify their goals and objectives.

Debriefing with Dr. Frieden

ELSW Members

Dr. Thomas Frieden spoke with the ELSW via teleconference during the last day of the in-person meeting. He thanked the ELSW for their work, recognized and expressed appreciation for their commitment.

- ELSW observations have generated the following common themes:
 - The organization and mission of CDC have evolved over the years. Much more is being asked of the CDC now than in the past. Perhaps some of the safety mechanisms have not evolved in parallel with the growth and evolving mission of CDC.
 - The process of risk assessment and how and by whom it is done is another major theme. The ELSW has discussed whether a more formal process should be established.
 - The risk assessment theme is connected to the role of the IBC and whether that role should be expanded, or whether another entity should be created for support and oversight of risk assessment, including oversight of the types of research being conducted and the agents being manipulated.
 - Training has been another major theme in the ELSW’s deliberations. They have discussed the role of a central office in training, the roles of the individual divisions and laboratories in training, and other related issues.
 - There are questions regarding the availability of appropriate resources. Another theme, the recent focus on biosecurity, as whether that focus has had a negative impact on safety in the laboratories and on biosafety.



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Wrap up and Adjournment

Dr. Joseph Kanabrocki and Dr. Kenneth Berns, Co-Chairs, ELSW

- The ELSW identified their next steps, indicating that they will gather their observations into a coherent form.
- Additional conference calls are scheduled to inform them as they formulate robust recommendations that will have impact.
- Drs. Berns and Kanabrocki will address the ACD at their meeting in October 2014.

CDC Staff Present:

Thomas Frieden, MD, MPH

Director
Centers for Disease Control and Prevention

Rima Khabbaz, MD

Deputy Director for Infectious Diseases

Laboratory Safety Improvement Workgroup

Mary Brandt, PhD

Research Microbiologist
Mycotic Diseases Branch
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National Center for Emerging and Zoonotic
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Darin Carroll, PhD

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Leslie Dauphin, PhD

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National Center for Emerging and Zoonotic
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Lisa Delaney, MS

Environmental Health Specialist
National Institute for Occupational Safety and
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Kathleen Ethier, PhD

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Jean Patel, PhD

Health Scientist
Division of Healthcare Quality Promotion
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Jim Pirkle, MD, PhD

Director, Division of Laboratory Sciences
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National Center for Emerging and Zoonotic
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Michael Shaw, PhD

Senior Advisor for Laboratory Science
Office of Infectious Diseases

Sarah Wiley, MPH

Senior Advisor
Office of Infectious Diseases

Liz York, MS

Associate Director for Quality and Sustainability
Office of Safety, Security, and Asset
Management

FDA Staff Present (via teleconference):

Stephen Ostroff, MD

Acting Chief Scientist

NIH Staff Present (via teleconference):

Deborah E. Wilson, DrPH, CBSP

RADM US Public Health Service Director

Mary Groesch, PhD

Senior Advisor for Science Policy
Office of Biotechnology Activities

Allan Shipp, MHA

Director of Outreach
Office of Biotechnology Activities

Others Present:

Kendra Cox

Medical & Scientific Writer/Editor
Environmental Scientist
Cambridge Communications, Training, &
Assessments, Inc. (CCTA)

Susanna Kim

Deloitte Consulting, LLP, Contractor
Centers for Disease Control and Prevention
Business Integrity and Strategic Management
Unit (BISM)

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