

Recommendations of the Advisory Committee to the Director
Concerning Laboratory Safety at CDC
13 January 2015

1. Observation: Leadership commitment toward safety has been inconsistent and insufficient at multiple levels. Safety, including lab safety, is viewed by many as something separate from and outside the primary missions of public health and research. Safety is not integrated into strategic planning and is not currently part of the CDC culture, enterprise-wide. Interviews and surveys demonstrated that many employees neither understand the agency's response to accidents nor how that information is communicated to the larger agency community outside immediately affected labs. Disturbingly, the negative responses peak among those individuals who work at BSL3 and 4, especially among those holding a master's degree. Individual divisions, teams and lab groups have taken it upon themselves to implement safety programs, but this is not done in a consistent manner, nor is it done across the CDC. A clearly articulated CDC safety mission, vision or direction is lacking.
 - Recommendation: Establish a CDC brand and communicate, from the top down, a "CDC Way" that is the performance of responsible science practiced in a consistently safe manner. This should be an expectation, and all persons are accountable. This should be a performance issue but personal negative consequences should *only* be associated with failure to communicate incidents. As part of this effort, better mechanisms should be established for sharing information about safety incidents across CDC to promote transparency at all levels.
 - Recommendation: Funding for laboratory safety programs and laboratory safety training should be established from a central funding source and should be considered a fundamental mission for the CDC. This responsibility should not be outsourced to contract organizations who, ultimately, cannot be held accountable.
 - Recommendation: Create a position for a biomedical scientist in the Director's office to lead this effort, which will also support the lab scientists.

2. Observation: Governance structures do not support maintaining a culture of shared responsibility and accountability across Centers, nor the consistency of appropriate safety practices. This is, in part, a result of the organizational complexity of the CDC. For example, ESHCO and IBC/IACUC are outside the chain of command of Centers/Divisions.
 - Recommendation: Establish governance structures that provide accountability and oversight authority to a central entity for laboratory safety and compliance committees (IBC/IACUC).
 - Recommendation: The central authority ultimately accountable for performance of responsible laboratory science, laboratory safety and the ESCHO, IBC and IACUC should sit organizationally at the level of the Office of the Director.

3. Observation: Risk assessments of proposed research activities are either not being done in a standardized manner or are not being done at all. Currently, the IBC only reviews rDNA research.

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- Recommendation: Broaden the scope of the IBC to include work with pathogenic microorganisms and biological toxins or establish a centralized, standardized mechanism for consistent and thorough review and risk assessment of proposed research activities.
 - Recommendation: Risk assessments should be performed for experimental work being done at CDC. The benefits and risks of proposed experimental work should be documented before the work is undertaken.
4. Observation: Laboratory safety training is inadequate. The organizational complexity of the CDC has contributed to a fragmented, inconsistent approach to laboratory safety training. The majority of training is now conducted on-line. Training is no longer under the domain of ESHCO. The CDC does not have its own hands-on directly observed centralized safety training program. Lab-specific training and competency observations are conducted at program level and therefore, the quality is not consistent. Observational competence occurs at the local lab level; however, except for clinical labs, competency skills mapping and refresher training is not consistent.
- Recommendation: Establish a standardized lab safety training curriculum across CDC.
 - Recommendation: Establish standardized methods for competency skills mapping and refresher training.
 - Recommendation: Establish a fellowship/internship program to train scientists to serve as laboratory safety professionals who serve as liaisons between the labs and ESHCO or other central lab safety entity.
 - Recommendation: Responsibilities and facilities for lab safety training should be in-house.
5. Observation: The results of the *Culture of Laboratory Safety* survey indicate that a significant percentage of CDC staff have concerns about experiencing negative repercussions, either personally or more generally to the Agency, as a result of reporting incidents involving exposures to pathogenic organisms or other hazardous materials. Some staff members working in Select Agent laboratories fear regulatory or other negative repercussions as a result of incident reporting. One example of this was the case report of the CDC accident involving highly pathogenic H5N1 that became public in June. Interviewed scientists all along the chain in that incident were concerned that there were violations of the Select Agent rule. But there were no mentions of people being similarly concerned with biosafety. Other interviews with CDC staff also seemed to show a higher level of concern regarding SA violations than biosafety violations. This finding suggests that at least in some laboratories, biosecurity requirements are being given priority over biosafety.
- Recommendation: Efforts to establish a culture of *responsible science* and *accountability* are of critical importance. This culture of responsible science will require prompt and accurate reporting of incidents or breaches in standard protocol without fear of reprimand or punishment. (Not reporting should be considered a breach of responsibility.) Reporting is important for facilitating

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the analysis of incidents and the establishment of corrective actions to mitigate repeat occurrences. Lessons learned from these activities should be shared with the community.

- Recommendation: In this culture of safety response, ensure that scientists operating safe laboratories are recognized for their work. Some CDC scientists feel that they have been doing their work safely and appropriately all along, but they were swept up in corrective or punitive actions that should not have applied to them.
6. Observation: ESHCO is undervalued and is seen by many staff scientists as an office with focus on *compliance*. Additionally, it is perceived as an office with inadequate expertise in lab safety. For this reason, scientists in some divisions have little or no interaction with ESCHO. A related issue is that the resources dedicated to the Occupational Medicine Program appear to be inadequate. It is critical that the Occupational Medicine Program serve to support on-site research programs as well as those abroad and that it become more integral to the health monitoring/reporting/response network associated with laboratory safety.
- Recommendation: Raise the stature of ESCHO in the CDC organization by staffing it with scientists with professional qualifications in research and/or laboratory safety as well as an understanding of requirements for compliance.
 - Recommendation: Establish a fellowship/internship program to train scientists to serve as laboratory safety professionals. This training program should involve interns or fellows in the development and management of lab safety programs at the CDC as a central part of their training and professional development.
 - Recommendation: Develop a division liaison program, where each division identifies individuals who can represent their needs to a centralized EHSCO committee.
 - Recommendation: Expand the scope and capabilities of the Occupational Medicine Program to facilitate a more robust and active effort in monitoring employee health and in responding to laboratory incidents.
7. Observation: CDC is an incredibly capable organization and its value in promoting the health of our society cannot be lost. We are very concerned that the CDC is on the way to losing credibility. The CDC must not see itself as "special". The internal controls and rules that the rest of the world works under also apply to CDC. There is need for a CDC systematic approach characterized by high-level leadership support and intervention. Accountability, personal accountability not only our own actions, but the actions of others is essential. While human error is the fundamental cause of events like those challenging the CDC in recent months, it is also the reason why multiple layers of checks and balances and redundancy of controls must be built into the process of oversight and management system.
- Recommendation: The ELSW strongly encourages the CDC to track and to report on its progress in establishing programmatic elements and processes

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recommended in this ELSW report in some formal way (perhaps at the 3 month, 6 month and 12 month mark) or to provide an explanation of why it was decided to not to pursue specific recommendations. This progress doesn't necessarily need to be reported back to the ELSW - it could be back to the new Laboratory Safety Director once hired or to the Internal Laboratory Safety Working Group or some other entity - though there would be logic in briefing in back to the ELSW.

- Recommendation: The ELSW recommends that CDC laboratories go through an external review and accreditation process for all labs. The College of American Pathologists (CAP) could do this for the clinical labs. The CDC should pursue a similar accreditation for research labs, perhaps by commissioning this accreditation through the American Biological Safety Association (ABSA- <http://www.absa.org/aiahclap.html>).