

**Report of the Advisory Committee to the Director, CDC
Follow-up on CDC Progress**

2014 Recommendations Concerning Laboratory Safety at CDC
29 October 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.

Follow-Up Observations from October 2015

- *The CDC Director and Executive Staff are clearly engaged and committed to promoting laboratory and research safety at the CDC. It was evident to the ELSW that its recommendations are being taken seriously by CDC leadership. Since the initial ELSW visit to the CDC in 2014 much CDC effort towards achieving ACD recommendations has been invested along with the requisite allocation of resources (see below). None-the-less, the ELSW and the CDC both recognize that considerable work toward achieving a culture of safety remains undone.*
- *An additional \$7.25 M was approved in FY 2015 to support several laboratory priorities, including lab safety, and the CDC has requested an increased budget (\$20 M) to support the office and functions of the Associate Director for Laboratory Science and Safety in FY 2016. The funds were spent on staff, travel, tablets, ISO accreditation and training materials. A stable funding source for all laboratory safety functions would promote flexibility and efficiency.*
- *After an extensive search CDC has recently appointed Dr. Steve Monroe as the Associate Director for Laboratory Science and Safety with Dr. Leslie Dauphin as Deputy Director of the new Office of the Associate Director for Laboratory Science and Safety. Dr. Monroe has 29 years' experience at CDC, both as an investigator in the laboratory and a leader in management. He is very well respected. It is clear he knows CDC very well and has defined specific goals for the office including enhancing communication, developing a consistent approach to safety and training and ensuring that there is a very close relationship with*

Report of the Advisory Committee to the Director, CDC
Follow-up on CDC Progress
2014 Recommendations Concerning Laboratory Safety at CDC
29 October 2015

laboratory staff through formal and informal meetings. A large part of Dr. Monroe's job will be establishing new relationships and strengthening pre-existing ones. He is working closely with Dr. Jaffe, Associate Director for Science, to make sure their two offices synergize rather than duplicate effort. Significantly, he believes it is important to perform fundamental, applied research around safety issues and to this end is strengthening the CDC relationship with Georgia Tech and with the other HHS agencies, FDA and the NIH. One major question that remains unresolved is how ESHCO will relate to and coordinate with the ADLSS Office. Importantly, biosafety expertise within the ADLSS Office will be an element critical to its credibility and success.

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.

Follow-up Observations from October 2015

- *A lack of clarity remains around the organizational structure of the various groups providing safety services/oversight and how these groups report to or interact with the ADLSS office. Dr. Monroe has only been serving as the ADLSS for a few weeks and needs more time before judgements are made about the best course forward. Three crucial internal groups include the Institutional Biosafety Committee, which continues to review only recombinant DNA studies, the Laboratory Safety Review Board, which has focused on review of existing and new protocols for inactivation and transfer of materials from BSL3/4 labs to lower containment laboratories, and the Institutional Biosafety Board which focuses on oversight of potential dual use research of concern. Considerable cross-talk between the three groups has been created in that several members serve on multiple committees. However, these groups have no "home" and limited dedicated resources to support their work. The groups expressed concern about the consistency of their review and a lack of committed subject matter expertise due to members being pulled in multiple directions.*
- *The Occupational Medicine Group still appears to be understaffed and unsure of its role or its ability to respond to incidents, especially large-scale incidents. The responsibilities are increasing but the staffing has not been increased commensurate with the additional responsibilities. This critical laboratory/research safety function should be further reviewed and supported.*
- *CDC should install a Laboratory Information Management System (LIMS) with an up-to-date registration process for all 153 laboratories at CDC. This LIMS should be deployed as a CDC-wide protocol library providing a description of which pathogens are being actively studied, where and by whom. This database would be supportive of and augment the entire safety infrastructure by enhancing the capabilities to perform agency level risk*

Report of the Advisory Committee to the Director, CDC
Follow-up on CDC Progress
2014 Recommendations Concerning Laboratory Safety at CDC
29 October 2015

assessments, by providing insights into staff training needs and, indeed, by providing essential capabilities to deploy a rapid response to an adverse event in the laboratory.

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.
- 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.

Follow-Up Observations from October 2015

- *Work is in progress to establish an institutional entity and associated processes to perform consistent and thorough risk-assessments beyond completion of a checklist document. Important risk-assessment training has been developed for individual investigators and these training sessions have been well attended. At the moment, comprehensive risk assessments are only being performed on new processes or procedures. Further work is needed in this area and it should include work performed in the BSL-2 laboratory, as well as BSL3 and BSL4. Institutional level review and risk assessment should not be limited to recombinant DNA work but should include all pathogenic microorganisms being studied at CDC.*

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.

Follow-Up Observations from October 2015

- *It is clear that the CDC has accepted the responsibility for further developing and delivering its own lab safety training program. Efforts are underway to broaden the available on-line training and to develop subsequent lab-specific, directly observed training to assess technical competency. Funds for a lab safety training facility at CDC have also been requested.*

Report of the Advisory Committee to the Director, CDC
Follow-up on CDC Progress
2014 Recommendations Concerning Laboratory Safety at CDC
29 October 2015

- *The Laboratory Leadership Service (LLS) and training program was established very rapidly and the first class of seven fellows has begun. Fellows enter the program with a doctoral degree plus two years' experience in a lab with an interest in a career in laboratory management. CDC Divisions are currently hosting and training Fellows who will also be placed in State Labs in years to come. Safety best practices and how to perform risk assessments is part of the training they receive but was not immediately evident to the ELSW how much of the training is about Lab Management versus Lab Safety. In the future, the CDC envisions that the LLS Fellows will play a critical role in performing fundamental applied research around lab safety, provided the supporting funds are made available.*
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 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.

Follow-Up Observations from October 2015

- *Not all CDC staff are yet engaged in developing a "CDC Way". The response rate to the second staff survey was disappointingly low, perhaps indicating "survey fatigue". There is still some apprehension about the possibility of retribution if staff, especially contractors, report accidents or safety concerns. Consequently, there is a need to work on building trust in the reporting processes and resultant management response. There is also the sense from some staff that a significant portion of the CDC reaction to the accidents has been in the form of increased paperwork and that signing a form does not necessarily lead to a fundamental improvement in safety culture. Some staff also expressed ambivalence around the reliance on cameras as a secondary verification method and at least some staff prefer the "two man process" rather than cameras.*

Report of the Advisory Committee to the Director, CDC
Follow-up on CDC Progress
2014 Recommendations Concerning Laboratory Safety at CDC
29 October 2015

- *There is a sense from some staff that the Chamblee Campus has a strong and effective safety culture, and that the persistent challenges are at the Roybal Campus.*
 - *There is some apprehension that the establishment of global CDC requirements and protocols that are appropriate for the biological sciences would be applied across the board and would not be applicable to the chemical sciences.*
 - *Communication is viewed as very important by CDC leadership and the Agency is committed to openness and transparency. Morale has suffered in the last year because of these events and the public response to them. CDC needs to actively engage with external media. CDC should better articulate to the public the rationale for the laboratory work that CDC does to protect the public health, and it should be demonstrated more clearly the progress that has been made. This could help in the public understanding of biosafety at CDC and would help restore pride in some of the scientists working at CDC who have been discouraged by the safety challenges of the last year. It is equally important for CDC leadership to clearly articulate to the internal CDC community the plan and path forward vis-à-vis laboratory safety.*
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 ESHCO. 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 ESHCO 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 ESHCO 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.

Follow-Up Observations from October 2015

- *An intense internal review of ESHCO has been/is being conducted. This review was incomplete and still in process at the time of this ELSW visit to the Atlanta CDC campus. A new staffing plan has only recently been developed and has not yet been reviewed internally. A search for a new ESHCO Director is underway. Problems with the performance of ESHCO are not new. Previous ESHCO leadership was not provided with adequate administrative support to facilitate improvements in the service delivered by ESHCO. Neither the organizational home for ESHCO, nor decisions about which functions should remain with ESHCO and which functions should be moved to the ADLSS office, have been determined. The ELSW feels strongly that while operational aspects and building-*

Report of the Advisory Committee to the Director, CDC
Follow-up on CDC Progress
2014 Recommendations Concerning Laboratory Safety at CDC
29 October 2015

related issues could reside in OSSAM, biosafety should reside in the ADLSS Office in order to avoid creating a "responsibility without authority" situation for the ADLSS Office.

- *Once reorganization and staffing plans have been approved and established, a Safety Manual, standard operating procedures as well as templates and tools to help scientific staff need to be developed and applied consistently and appropriately.*
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 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>).

Follow-Up Observations from October 2015

- *A Laboratory Information Management System (LIMS) that contains all the laboratory registration data on protocols and pathogens as well as information on laboratory incidents and near-misses would provide a way to assist in the institutional risk assessment process, provide a basis for determining task/agent- specific training needs and to track progress in the development of lab safety programs.*
- *External accreditation remains an important barometer by which the CDC can gain additional insights as it continues to implement improvements to its safety culture. A number of external accreditation options exist (e.g. ISO, ABSA), but the CDC should choose carefully which accreditation agency would best support CDC lab safety improvement efforts given the broad scope of activities performed and risks faced in CDC laboratories.*