

Laboratory Safety Improvement Recommendations
Progress as of July 1, 2015

CDC, Report on the Inadvertent Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1, August 8, 2014

Recommendation	Completed	Pending Actions
Recommendations relating to the Influenza Division laboratory – Immediate		
1 <i>Test all cultures and other preparations done by the Team 1 laboratory scientist involved in this incident to identify any other cross contamination.</i>	✓	
2 <i>Test all preparations which were transferred by Influenza Division over the last year to other laboratories (both within and outside CDC) for cross contamination with multiple subtypes of influenza.</i>	✓	
3 <i>Institute SOPs in all Influenza Division laboratories for processing of multiple subtypes of influenza. This action should include finalization of the high-containment laboratory guidelines that are not currently in an approved SOP.</i>	✓	
4 <i>Prioritize activities to allow laboratory scientists to complete mission-critical work and minimize the need to complete lower priority work at the same time. Determine which, if any, activities can be eliminated without significant impact on the Division’s mission.</i>	✓	
5 <i>Designate the Virology, Surveillance and Diagnosis Branch chief as an additional select agent Principal Investigator.</i>	✓	
6 <i>Institute mandatory daily record keeping to document the conduct of procedures such as cell culture inoculation and the materials used.</i>	✓	
7 <i>Develop and implement SOPs that ensure strict measures are in place to prevent inadvertent cross contamination of influenza subtypes by requiring temporal separation when processing low pathogenic avian influenza (LPAI) and highly pathogenic avian</i>	✓	

	Recommendation	Completed	Pending Actions
	<i>influenza (HPAI) virus subtypes</i>		
8	<i>Institute personnel actions as appropriate.</i>	✓	
9	<i>Ensure that all Influenza Division staff are appropriately trained and understand when events are reportable and to whom (both for select agents and non-select agents).</i>	✓	
10	<i>Revise the current management notification policy regarding potential exposures or illness to include other criteria for notification (e.g., unauthorized transfer of a select agent)</i>	✓	
11	<i>Ensure effective and routine training for all appropriate division personnel on select-agent regulations and requirements for compliance.</i>	✓	
12	<i>Review all SOPs in the Influenza Division branches to ensure they are up to date and reflect current best practices. Ensure that written, approved SOPs are provided to all laboratory scientists.</i>	✓	
13	<i>Ensure that the electronic select agent inventory is accurate and up to date.</i>	✓	
Recommendations relating to the Influenza Division laboratory – Longer-term			
14	<i>Reassess all procedures for working with H5N1 and other HPAI viruses, including how and where this work is done at CDC and how it relates to CDC's mission.</i>	✓	
15	<i>Establish comprehensive quality control measures to include exclusivity testing of materials (i.e. testing to exclude the presence of other organisms) before transfer to internal and external laboratories.</i>	✓	
16	<i>Broaden exclusivity testing of incoming samples to ensure the safety of laboratory scientists who work with the samples and their derivatives.</i>	✓	
17	<i>Establish Division-wide specimen database(s) to better communicate what specimens are available, what testing has been done and still needs to be done, and where all passages of virus samples are located.</i>		In addition to implementing STARLIMS 10, the Influenza Division is addressing additional enhancements to improve communication.

	Recommendation	Completed	Pending Actions
18	<i>Enhance training for select agent compliance, including scenario-based training for laboratory scientists and leadership to understand when events are reportable. Implement regular staff meetings with the RO to receive updates and advice regarding select agent issues.</i>	✓	
19	<i>Identify additional select agent Principal Investigators as necessary to ensure that all staff who work with select agents are under the supervision of a select agent Principal Investigator for the project.</i>	✓	
20	<i>Review all ID SOPs to ensure consistency and reduce redundancy.</i>	✓	

Recommendations relating to all CDC infectious disease laboratories

21	<i>Ensure that all ID staff are appropriately trained to understand when biosafety events are reportable and to whom they should be reported (both for select agents and non-select agents), and, more broadly, ensure that all CDC laboratory scientists receive such training. A site-specific SOP for event notification should be in place in each laboratory.</i>	✓	
22	<i>All laboratories should develop written SOPs describing laboratory safety requirements for accepting specimens.</i>		The Specimen Policy Board will conduct an annual review of all laboratories to ensure adherence to the standard procedure for accepting specimens.
23	<i>Ensure that laboratory scientists are appropriately trained to understand when events are reportable and to whom (both select agents and non-select agents). A site-specific notification SOP should be in place in each laboratory.</i>		Formalize training and expand beyond select agent programs.

Recommendations relating to CDC and other organizations

24	<i>Enhance staffing at CDC's internal select agent program. Additional support should be provided for an individual dedicated to training. Administrative support is needed to ensure that the RO and staff can provide site-specific training for laboratories.</i>		Recruit and select a Safety and Occupational Health Manager to enhance the staff of the internal select agent program
25	<i>Conduct Table top exercises and drills to help enable CDC laboratory scientists to recognize when events are reportable to management. These practices should not</i>	✓	

	Recommendation	Completed	Pending Actions
	<i>be limited to select agents, but should include all laboratories that work with BSL-3 or BSL-4 pathogens.</i>		
26	<i>DSAT and APHIS should provide additional guidance to the RO on reporting of incidents similar to the one described in this report, specifically reporting of unauthorized transfers as a release.</i>	✓	