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CDC Progress on Laboratory Safety

Media Advisory

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The Centers for Disease Control and Prevention today released a series of updates and actions taken showing its progress in laboratory safety. CDC reported on its response to the Animal and Plant Health Inspection Service's (APHIS) Agricultural Select Agent Program's (ASAP), part of the U.S. Department of Agriculture, summary of findings on the anthrax incident. CDC also reported findings of an internal CDC investigation on the H5N1 flu lab incident, and actions taken in response to findings of both the APHIS and CDC investigations into the H5N1 incident.

"CDC is working intensively to make our labs to be models not only of scientific rigor but also of safety," said CDC Director Tom Frieden, M.D., M.P.H. "We will implement changes identified in these reviews – and more – so that we can continue the critical laboratory science needed to protect health in the US and around the world."

Internal report on H5N1 flu lab incident

CDC today released the findings of its internal investigation into the May 23, 2014 inadvertent cross-contamination of a low pathogenic avian influenza (LPAI) A (H9N2) virus sample with a highly pathogenic avian influenza (HPAI) A (H5N1) virus and the subsequent shipment of the contaminated culture to an external high-containment laboratory.

The report summarized the circumstances related to the event, outlines how this event may have happened, and provides recommendations for preventing similar incidents in the future.

The report found that:

- The incident did not appear to have posed a safety risk since the virus was handled solely under laboratory conditions appropriate for containment of HPAI H5N1 virus (biosafety level 3 with enhancements or BSL-3E), and were shipped with proper permits and packaging.
- The contamination most likely happened due to the failure of a laboratory scientist to adhere to established best practices and the absence of an approved laboratory team-specific protocol for the work being done.
- There was a lack of awareness and understanding about reporting requirements for Select Agents, such as H5N1, which contributed to the delay in reporting this incident.

APHIS H5N1 flu lab incident report and CDC response

On July 29, 2014, CDC received the report on the APHIS H5N1 flu lab investigation, which shared many of the same findings as the CDC report on the incident. CDC is reviewing both reports in detail to address the factors that led to this incident, including gaps in laboratory protocols, failure to adhere to best practice lab procedures, incomplete record-keeping, and lack of awareness about Select Agent reporting requirements.

On August 11, as required, CDC responded to APHIS on their incident report, outlining corrective actions being taken to address their findings.



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- Implementing standardized testing for cross-contamination of samples before they are transferred to other locations or to other laboratories within CDC.
- Re-assessing current use of BSL-3 enhanced space to ensure that work done on Select Agents and non-Select Agents is separated by an appropriate amount of time to reduce the chances that cross-contamination can occur.
- Identifying and closing gaps in existing skills and knowledge of laboratory staff and providing additional extensive training. This includes training to further clarify incidents that qualify as reportable under Select Agent regulations.
- Additional actions will be taken as needed.

Actions taken in response to APHIS summary of findings on anthrax incident

On July 25, 2014, CDC finalized its response to the APHIS summary of findings, dated July 10, 2014, related to the June incident in CDC labs involving *Bacillus anthracis* (anthrax).

Several immediate steps have already been implemented and reported by CDC, including the institution of a moratorium on the movement (i.e., transfer inside or outside the agency) of biological materials from BSL-3 or BSL-4 facilities. The moratorium will remain in place pending lab-by-lab review of policies and procedures for laboratory safety and security.

Additional actions implemented include the following:

- Creation and appointment of a CDC Director of Laboratory Safety to serve as the single point of accountability to improve all laboratory safety protocols, practices, and procedures;
- Establishment of an internal Biosafety Working Group under the direction of the CDC Director of Laboratory Safety ; and
- Establishment of an external group on biosafety comprising leading scientists and biosafety experts, which will advise the Biosafety Working Group to the CDC Director.

In addition, CDC has provided to APHIS example protocols for inactivation of anthrax and also a plan outlining required refresher training of laboratory personnel with access to anthrax on the appropriate use of the inactivation protocol. The plan includes new procedures to document correct use of the protocol as well as new oversight of individuals using the protocol.

“The work of safety is never complete,” said Dr. Michael Bell, interim director of laboratory safety. “We will continue to take all necessary steps to maintain safety and advance CDC’s critical laboratory science work, so that CDC labs are the most scientifically rigorous and the safest in the world.”

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