

Appendix 1: Level One and Level Two Chemical Laboratory

All applicants are required to address critical tasks and measures related to laboratories as described in the main body of this document. In addition to those critical tasks, Level Two and Level One chemical laboratories are required to respond to the activities described below.

Additional Activities for Level Two Chemical Laboratories:

1. Accept clinical specimens and begin analysis within 24 hours of receiving the call for assistance from CDC.
2. Demonstrate proficiency to rapidly detect and measure Level-Two chemical agents (such as cyanide-based compounds, heavy metals, and nerve agents) in CLINICAL specimens within 24 hours of the request from CDC. Currently, CDC methods for Level-Two chemical agents use the analytical techniques of inductively coupled plasma mass spectrometry and gas chromatography mass spectrometry. The list of Level-Two chemical agents will expand as methods are developed or modified. Tandem mass spectrometry methods are not required for Level-Two chemical agents.
3. Develop and maintain plans and procedures for adequate and secure :
 - clinical specimen transport and handling
 - worker safety
 - appropriate Bio-Safety Level (BSL) conditions for working with clinical specimens
 - staffing and training of personnel
 - quality control and assurance
 - triage procedures for prioritizing intake and testing of specimens or samples before analysis,
 - secure storage of critical agents and samples of forensic value
 - appropriate levels of supplies and equipment needed to respond to chemical terrorism events
 - securing facilities, reagents, and equipment
 - Special requirements
4. Maintain one Ph.D. chemist, or an individual with equivalent experience (M.S. with 5 years experience), and multiple laboratory support personnel.
5. Procure and maintain the following equipment: ICP-MS, GC-MSD

Additional Activities for Current Level One Chemical Laboratories (new Level One applicants-see below):

1. Accept clinical specimens and begin analysis within 24 hours of receiving the call for assistance from CDC.
2. Demonstrate proficiency to rapidly detect and measure Level-Two and Level-One chemical agents (such as cyanide-based compounds, heavy metals, and nerve agents, mustards and selected toxic industrial chemicals) in CLINICAL specimens within 24 hours of the request from CDC.
3. Develop and maintain plans and procedures for adequate and secure:
 - clinical specimen transport and handling
 - worker safety

- appropriate Bio-Safety Level (BSL) conditions for working with clinical specimens
 - staffing and training of personnel
 - quality control and assurance
 - triage procedures for prioritizing intake and testing of specimens or samples before analysis,
 - secure storage of critical agents and samples of forensic value
 - appropriate levels of supplies and equipment needed to respond to chemical terrorism events
 - securing facilities, reagents, and equipment
 - Special requirements
4. Maintain multiple Ph.D. chemists, or individuals with equivalent experience (M.S. with 5 years experience), and multiple support personnel. One Ph.D. (or individual with equivalent experience) in analytical chemistry with a minimum of two years experience in supervising laboratory personnel. Additionally, two laboratory personnel to operate a tandem quadrupole mass spectrometer and conduct biological sample preparation using standard techniques such as solid phase extraction.
 5. Procure and maintain the following equipment: ICP-MS, GC-MSD, tandem mass spectrometer capable of running liquid chromatography analyses (new gas chromatograph and liquid chromatograph)
 6. In collaboration with CDC and other Level-One laboratories, participate in method development and validation studies.
 7. Provide surge capacity to CDC and serve as a referral laboratory for Level-Three and Level-Two laboratories.
 8. Develop and implement a plan for 24/7 staff coverage in the event of a chemical terrorism emergency. Documentation of this plan should be provided to CDC to coordinate efforts
 9. Attend required meetings and trainings to help prepare for a chemical event.

Instructions for New Level One Chemical Laboratory Applicants

In addition to completing all current Level-Two trainings and successfully completing method validation, new applicants must also have successfully completed at least one proficiency test for each method and be in “qualified” status. New applicants should also address the following:

1. Planning Meetings: Propose to send up to 3 persons to the CDC or other locations 4 times during the first year of the cooperative agreement to meet with CDC staff and other Level One laboratory funding recipients
2. Describe existing laboratory space that will be designated for personnel and equipment necessary for measuring in humans, chemicals likely to be used in a terrorist attack. At a minimum, the space described should meet the following specifications:
 - a. overall laboratory space is a minimum of 400 square feet with a width no smaller than 10 feet (approximately 160 square feet will be used in the future for a floor model mass spectrometer, most likely to be a LC/MS/MS mass spectrometer)
 - b. a minimum of 12 feet of bench space (approximately 1.5 feet deep); 4 feet for a bench top mass spectrometer and 8 feet for work space

- c. availability of a chemical fume hood with minimum dimensions 4 x 2 feet (length x depth).
 - d. suitable air conditioning to cool the interior to between 64 and 70 F and should have at least two exhaust ports with flexible tubing
 - e. availability of a deionized water source
 - f. adequate drawers and shelves for storage of instrument expendables, glassware, and supplies.
3. Describe activities performed by your laboratory to complete Level Three and Level Two activities
4. Propose hiring or designating one PhD (or equivalent experience) in analytical chemistry with a minimum of two years in experience in supervising laboratory personnel and two additional laboratory personnel necessary to operate a tandem quadrupole mass spectrometer and conduct biological sample preparation using standard techniques such as solid phase extraction.
5. Propose to purchase or acquire by direct assistance a tandem mass spectrometer capable of running liquid chromatography (LC/MS/MS) analysis (estimated cost \$360,000-400,000).