

**NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM**

Revised Safety Standards, Open for Comment until May 31, 2010

<i>Laboratory Safety Standards</i>	<i>Guidance</i>
<p>Safety Sustaining Standard of Practice 1 (Safety S1): Biohazard Risk Assessment and Biosafety Program</p> <p>The laboratory shall conduct an infectious agent risk assessment for each permit category and based on this review shall develop and implement an appropriate biosafety program that identifies the laboratory's biosafety level(s) and incorporates the use of biosafety equipment, practices and procedures that shall:</p> <ul style="list-style-type: none"> (a) be described in the laboratory's safety manual; (b) be revised as necessary and reviewed by the director at least annually; (c) minimally meet biosafety level 2 (BSL-2) criteria and incorporate, as appropriate, the use of a certified class II (or higher) biological safety cabinet (BSC) and/or other containment equipment/devices and practices intended to prevent release of infectious aerosols into the work environment; and, (d) incorporate the use of appropriate personal protective equipment (PPE) such as lab coats or gowns, face shields and disposable gloves intended to protect the worker from splashes, spills or other direct contact with infectious specimens/materials; and, (e) when applicable, include a written plan to be implemented in the event that an agent suspected of exceeding the laboratory's biosafety level/practices is encountered. The plan shall include provisions for: <ul style="list-style-type: none"> i. immediate notification of the laboratory supervisor and/or director; ii. cessation of work with the material until appropriate safety practices and PPE can be put into place or the specimen referred to an appropriate laboratory; and, iii. implementation of the employee exposure plan, if applicable. 	<p>A five-step approach to infectious agent risk assessment:</p> <ul style="list-style-type: none"> a. Identify the biorisk characteristics (e.g. pathogenicity, route of infection) and doses (concentration/volume) of agents handled by the laboratory. b. Identify laboratory practices that increase exposure risks such as aerosol-generating procedures (centrifuging, vortexing, etc.) and the use of sharps. c. Determine the appropriate biosafety level (BSL) and develop a biosafety program that includes the appropriate precautions, practices, PPE, safety equipment and facility design and access. d. Review the risk assessment process and biosafety program with biosafety professionals. e. Ensure staff knowledge and proficiency regarding the laboratory's biosafety program, including the use of PPE and safety equipment. <p>A biosafety professional is a competent person who has a relevant qualification in the field of life sciences and additional recent working experience or training in the microbiological laboratory or in laboratory infection control procedures consistent with the type of work performed by the laboratory.</p> <p>Diagnostic and health care laboratories must minimally meet BSL-2 criteria. www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm</p> <p>Aerosol-generating specimen/culture procedures (e.g. vortexing, centrifuging, pipetting, mixing) should incorporate the use of practices and equipment (e.g. BSC) or devices (e.g. closed centrifuge cups/carriers) intended to prevent release of aerosols.</p> <p>Specialty-specific requirements can also be found in the Mycobacteriology, Mycology, and Virology sections.</p> <p>References and resources: <i>Biosafety in Microbiological and Biomedical Laboratories</i>; 5th edition, CDC: www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm <i>Clinical Laboratory Safety</i>, CLSI Approved Guideline, second edition/GP17-A2 OSHA Bloodborne Pathogens: www.osha.gov/SLTC/bloodbornepathogens A copy of the instructional video <i>Essentials of Biosafety: Overview of Biosafety Principles and Use of the Biological Safety Cabinet</i> can be obtained by contacting the Wadsworth Center LRN at LRNexec@health.state.ny.us. This resource includes risk assessment information.</p>

<i>Laboratory Safety Standards</i>	<i>Guidance</i>
<p>Safety Sustaining Standard of Practice 2 (Safety S2) Employee Occupational Exposure Plan</p> <p>The laboratory shall establish an employee infectious agent exposure control plan appropriate for the testing and procedures performed by the laboratory. The plan shall include:</p> <ul style="list-style-type: none"> (a) immediate notification of the laboratory director or designee of an occupational exposure or of an employee exhibiting symptoms consistent with an occupational exposure; (b) medical risk assessment; (c) diagnostic testing and treatment, as appropriate; (d) root cause investigation; and, (e) implementation of corrective action and retraining as necessary. 	<p>The employee exposure plan should be developed based on the laboratory's infectious agent risk assessment (see Safety S1) and should take into account the specimen types received and the procedures performed.</p> <p>b)The plan should provide options for the employee to consult their own physician or a physician provided by the laboratory.</p> <p>The OSHA website (www.osha.gov/SLTC/bloodbornepathogens) provides information regarding OSHA's bloodborne pathogens standard (Title 29 of the Code of Federal Regulations 1910.1030) and details what employers must do to protect workers at reasonable risk of coming into contact with blood and other potentially infectious materials that may contain HIV, HBV or HCV. These requirements do not take into account exposures risks for other agents or other routes of exposure such as those that may be encountered in laboratories performing culture procedures.</p>

<i>Laboratory Safety Standards</i>	<i>Guidance</i>
<p>Safety Sustaining Standard of Practice 3 (Safety S3): Facility Design</p> <p>Laboratory facilities shall be designed to ensure that infectious agents cannot be transmitted to health care workers or the general public and shall include:</p> <ul style="list-style-type: none"> a) a pest management plan which ensures that pests cannot act as a mechanical vector to spread infectious agents; b) sufficient space between benches, cabinets and equipment to allow adequate cleaning; c) flooring and furniture located in the testing laboratory must be impervious to liquids and capable of being easily cleaned and decontaminated. Carpets and rugs must not be used in the laboratory where specimens are handled or manipulated. d) Work surfaces that are impervious to liquids and resistant to moderate heat and the chemicals used for cleaning and decontamination; e) adequate hand washing facilities within the laboratory work area; f) eye wash facilities; g) emergency showers, if appropriate; and, h) doors, preferably self-closing, to facilitate access control. 	<ul style="list-style-type: none"> a) The pest management plan can include mechanical barriers such as screens on the windows to prevent flies from entering the laboratory or visual inspection of the structural integrity of the facility. c) Chairs and other furniture used in the laboratory work area should be covered with a non-fabric material that can be easily decontaminated. e) Minimally, laboratories should be designed so that hand washing facilities are located near each exit. Additional, hand washing facilities should be located so that there is easy access for use prior to handling communal objects (e.g. phone, keyboard, etc). Chemical disinfectants are not considered an acceptable alternative to soap-and-water hand washing in the BSL-2 or higher clinical laboratory setting. <p>Patient Service Centers are under the auspices of the laboratory and must also follow this standard including the placement of hand washing facilities. When collecting urine sample for chain of custody (forensic) purposes attempts should be made to provide hand washing facilities to the donor without compromising the integrity of sample.</p> <ul style="list-style-type: none"> g) Emergency showers are required where employees may be exposed to caustic or corrosive chemicals.
<p>Safety Sustaining Standard of Practice 4 (Safety S4): Access</p> <p>Access to the laboratory shall be limited or restricted as required to protect the public and/or employees.</p>	<p>The laboratory director is responsible for defining and approving the levels of access and identifying the laboratory's biosecurity practices, as appropriate for the setting. See <i>Biosafety in Microbiological and Biomedical Laboratories</i>; 5th edition, CDC: www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm</p>

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<p>Safety Sustaining Standard of Practice 5 (Safety S5): Biohazard Labels</p> <p>Warning labels with the universal biohazard symbol or with the legend “Biohazard” shall be affixed:</p> <p>a) On or adjacent to the door or entranceway of a laboratory room or a subdivided area within a modular room where clinical specimens or other potentially infectious materials are handled, stored, processed, manipulated or tested; and,</p> <p>b) On each refrigerator, freezer, incubator or other equipment that is located in a hallway or other type of open access or passage area and is used for storing/holding clinical specimens or other potentially infectious materials.</p>	<p>Activities described in Safety Standard S8 are prohibited in areas covered in a and b.</p> <p>a) Applying labels to equipment within these labeled rooms/areas is optional.</p> <p>Clerical or data entry stations not requiring the use of PPE may be designated as such within the laboratory area at the discretion of the laboratory director. However, these areas must be clearly delineated from the technical areas and writing instruments, phones, keyboards, etc. in the clerical/data entry areas must be dedicated to those areas and must not be used by individuals wearing PPE. Activities described in Safety Standard S4 are prohibited in these areas.</p> <p>There should be a system in place that prevents maintenance and/or repairs to be performed on “dirty” equipment without adequate use of PPE and/or decontamination.</p>
<p>Safety Sustaining Standard of Practice 6 (Safety S6): Biological Safety Cabinets (BSC)</p> <p>Laboratories utilizing a BSC shall:</p> <p>a) decontaminate the BSC with an appropriate disinfectant before and after each use and immediately following a spill or splash;</p> <p>b) monitor the air flow while in use;</p> <p>c) test and certify the BSC <i>in situ</i> at the time of installation within the laboratory, at any time the BSC is moved, and at least annually thereafter; and,</p> <p>d) document that all users are trained in the proper use of the BSC and are periodically observed for compliance with defined practices.</p>	<p>The need for a class II or higher BSC should be determined based on the laboratory's biohazard risk assessment (see Safety S1).</p> <p>Airflow monitoring may be accomplished by the use of a magnehelic or similar device, or a device built into the cabinet, with or without an alarm.</p> <p>During installation it should be verified that fluctuations of the room supply and exhaust air do not cause the BSC to operate outside the parameters for containment. BSCs should be situated so as to avoid interference of airflow such as by opening of doors or personnel traffic. The BSC shall be certified according to the <i>National Sanitation Foundation (2002), Standard 49, Class II (laminar flow) Biohazard Cabinetry</i>, Ann Arbor, MI.</p> <p>Informational resources: <i>Biosafety in Microbiological and Biomedical Laboratories</i> www.cdc.gov/od/ohs/biosfty/bmbl5/bmb15toc.htm.</p> <p>Wadsworth Center's instructional video <i>Essentials of Biosafety: Overview of Biosafety Principles and Use of the Biological Safety Cabinet</i> can be obtained by contacting the LRN at LRNexec@health.state.ny.us.</p> <p><i>Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, 3rd edition</i> www.cdc.gov/od/ohs/biosfty/primary_containment_for_biohazards.pdf</p> <p>Specialty-specific requirements can also be found in the Mycobacteriology, Mycology, Virology, Cytogenetics and Histocompatibility sections.</p>

<i>Laboratory Safety Standards</i>	<i>Guidance</i>
<p>Safety Sustaining Standard of Practice 7 (Safety S7): Food Storage</p> <p>Food and drink (including glucose solutions) shall be stored outside the work areas in cabinets or refrigerators designated for this purpose and not in refrigerators or areas where clinical specimens or other infectious or potentially infectious materials may be present.</p>	
<p>Safety Sustaining Standard of Practice 8 (Safety S8): Personal Practices</p> <p>Food storage/preparation, eating, drinking, smoking, handling contact lenses, applying cosmetics or lip balm and use of personal electronic devices are prohibited in work areas that present a reasonable likelihood of occupational exposure to chemical and radiologic hazards or infectious materials.</p>	<p>Regarding exposure to infectious materials, an area where clinical specimens or other potentially infectious materials are handled, processed or tested is considered to present a reasonable likelihood of exposure to infectious materials.</p> <p>Personal electronic devices (e.g. cell phones, beepers) or other personal items should be handled in a manner that ensures they do not become contaminated and should not be handled at the work station. This practice applies to students, non-lab personnel and visitors who have been given access to the laboratory.</p>
<p>Safety Sustaining Standard of Practice 9 (Safety S9): Personal Protective Equipment (PPE) Availability, Use and Maintenance</p> <p>The employer shall:</p> <ul style="list-style-type: none"> (a) provide PPE as appropriate for the type of work performed (see Safety S1) at no expense to the employee; (b) ensure that PPE is accessible at the worksite, properly maintained and that used PPE is not stored in clean areas; (c) provide cleaning, maintenance and/or disposal at no cost to the employee; (d) ensure that employees are trained in the proper use of PPE prior to use, including donning and doffing; (e) not allow employees to wear PPE outside the work area; and, (f) not allow employees to remove PPE or laboratory coats from the premises. 	<p>PPE should be worn whenever there is a risk of contact with infectious materials or hazardous materials. The type of PPE that should be utilized in a particular setting should be determined as part of the biohazard risk assessment (Safety Standard 1) and the chemical hygiene and radiological safety plan (Safety Standard 15).</p> <p>Regarding use of PPE, personnel should use disposable gloves and a protective laboratory coat or gown whenever handling or manipulating fresh, frozen or diluted patient specimens that have not been treated to eliminate infectious risk. Additionally, a splash barrier capable of protecting the face should be used whenever performing manipulations on these materials that may produce splashes (e.g. capping/uncapping containers, pipetting/dispensing, vortexing, mixing/diluting, shaking). Face protection can be accomplished by using an individual face shield, a bench-top splash shield or a BSC with proper positioning of the worker. Glasses or goggles do not provide adequate protection.</p> <p>PPE should be removed immediately upon contamination.</p> <p>PPE should be removed upon completion of work and properly discarded or decontaminated and stored if reusable.</p> <p>Hands should be washed immediately upon removing PPE. Chemical disinfectants are not considered an acceptable alternative to soap-and-water hand washing in the clinical laboratory setting.</p> <p>Laboratory coats designated for wear in public areas should not be used as PPE and should be stored in a clearly defined clean area away from potential contact with coats or smocks used as PPE.</p> <p>PPE such as PAPRs (Powered Air Purifying Respirators) or respirators should be examined prior to each use and should be inspected annually. A visual inspection of the hosing, bonnet, and unit as well as a battery check should be performed every time the unit is used.</p> <p>Annual competency assessment should include the proper use of all PPE as described in the Human Resource standard for Competency Assessment of Non-Supervisory Staff.</p>

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<p>Safety Sustaining Standard of Practice 10 (Safety S10): Disposable Gloves</p> <p>The laboratory's biosafety program shall include a policy regarding use of disposable gloves when handling infectious or potentially infectious materials including that gloves:</p> <ul style="list-style-type: none"> (a) must be worn when handling primary specimens; (b) must be worn when handling any items for which there is a likelihood that such handling may result in direct contact with infectious or potentially infectious material; (c) must be worn when the employee has cuts, scratches or other breaks in the skin and is handling infectious or potentially infectious material, regardless of likelihood of direct exposure; (d) must be removed and discarded immediately upon contamination; (e) must be removed and discarded immediately upon task completion at each work station (e.g. BSC, bench space) followed by hand washing; and, (f) must not be washed or reused. 	<p>The laboratory's risk assessment (see Safety Standard S1) should guide the laboratory director in tailoring a "glove use policy" that is based on the type of work performed by the laboratory. Optional glove use during activities not related to handling infectious or potentially infectious material should be at the discretion of the laboratory director.</p> <ul style="list-style-type: none"> a) The term "primary specimen" refers to all fresh, frozen or diluted patient specimens that have not been processed or treated to eliminate infectious risk. e) Chemical disinfectants are not considered an acceptable alternative to soap-and-water hand washing in the BSL-2 or higher clinical laboratory setting. e) Caution should be observed in removing gloves; snapping or stretching the gloves may result in aerosol formation. <p>Removing gloves immediately upon leaving each workstation greatly reduces the likelihood for inadvertent contamination of communal and personal objects (e.g. phones, pencils, keyboards, etc).</p> <p>When used for phlebotomy procedures, gloves should be changed between patients.</p>
<p>Safety Sustaining Standard of Practice 11 (Safety S11): Sharps</p> <p>The laboratory biosafety program shall include the following practices:</p> <ul style="list-style-type: none"> a) training for the safe handling of sharps; b) needles shall not be recapped, or removed from syringes or other devices, unless it can be demonstrated that no alternative is feasible or that such action is required by a specific procedure (e.g., collection of blood gas specimens); and, c) used disposable needles shall not be bent, sheared, broken, removed from syringes or otherwise manipulated by hand, but shall be placed in a puncture-proof, leak-proof container used for sharps disposal. 	<p>The safety manual should include written policies for the acceptance of specimens that include needles. Syringes that re-sheath the needle, needle-less systems, and other safety devices should be used. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) should be used for phlebotomy or the aspiration of fluids.</p> <p>See Safety S17.</p>

<i>Laboratory Safety Standards</i>	<i>Guidance</i>
<p>Safety Sustaining Standard of Practice 12 (Safety S12): Work Surface Decontamination</p> <p>Laboratory work surfaces shall be decontaminated with an appropriate disinfectant following spills of infectious or potentially infectious material, and at the start and completion of work activities.</p>	<p>When using diluted household bleach (5.25% sodium hypochlorite), it is recommended that 1:10 dilutions be prepared daily.</p>
<p>Safety Sustaining Standard of Practice 13 (Safety S13): Safety Breaches</p> <p>The laboratory safety manual shall include the procedure for decontaminating spills and splashes of infectious or potentially infectious material. Such incidents, as well as other safety breaches, shall be:</p> <ul style="list-style-type: none"> a) cleaned immediately and surfaces decontaminated using an appropriate disinfectant; b) immediately reported to the laboratory director or designee and documented; c) assessed for the need to implement the employee exposure plan; d) investigated to identify cause; and, e) followed up with remedial action and retraining as necessary. 	<p>Spill decontamination protocols should be adequate for the spill size, location (e.g. floor, inside BSC) and nature of the spilled material. Minimally, prior to cleaning the site, the spill should be confined using an absorbent material and treated with an effective disinfectant for an appropriate period of time.</p> <p>Procedures should include guidance for safe clean-up and disposal of broken glass and other sharps.</p>
<p>Safety Sustaining Standard of Practice 14 (Safety S14): Biosafety Program Training</p> <p>All personnel involved with handling clinical specimens and other infectious or potentially infectious material and/or medical waste shall receive training on the laboratory's biosafety program including the potential hazards associated with their work activities and the practices and procedures intended to avoid exposure to and/or dissemination of infectious material. This training shall be conducted as part of initial employee training and annually thereafter and shall be documented.</p>	<p>Training should include familiarization with the laboratory's occupational exposure plan.</p> <p>Training and discussion should be supplemented with ongoing supervisory observation to ensure staff compliance with the laboratory's safety policies and proper use of PPE.</p>

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<p>Safety Sustaining Standard of Practice 15 (Safety S15): Chemical Hygiene and Radiological Safety Plan</p> <p>Laboratories shall develop and implement written chemical hygiene and radiological safety plans that shall be available to employees upon request whenever laboratory work involves the use of hazardous chemicals or radiologic materials. The plan shall:</p> <ul style="list-style-type: none"> a) describe the use of fume hoods or other protective equipment whenever handling hazardous materials; b) establish procedures for exposure monitoring when permissible exposure levels of hazardous materials are exceeded; c) describe precautions for handling reagents containing toxic, hazardous or radioactive substances, including methods for their proper labeling and disposal; d) ensure proper storage of hazardous materials, including the use of a flame proof cabinets, where appropriate; e) establish a designated area for hazardous chemical and radiological material storage and disposal; f) include an action plan for dealing with laboratory accidents; and maintain eye wash and emergency shower facilities for such incidents; g) contain a protocol for managing documented exposure to chemical or radiological materials; h) contain a management protocol for maintenance of chemical and radiological exposure records on each employee; i) document that employees are provided with training regarding toxic substances and radiological materials in the workplace and use of protective equipment prior to beginning work with these materials and annually thereafter.; and, j) provide ready access for all employees to Material Safety Data Sheets (MSDS) for all chemicals in use by the laboratory. 	<p>The laboratory should have proper ventilation systems to rid the area of fumes created from hazardous material. Acceptable OSHA limits for formaldehyde or xylene should not be exceeded.</p> <p>Minimally, training should be conducted as part of initial employee training and annually thereafter.</p> <p>f) Emergency showers are required where employees may be exposed to caustic or corrosive chemicals.</p>

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<p>Safety Sustaining Standard of Practice 16 (Safety S16: Radioactive Materials)</p> <p>Clinical laboratories located in New York State that use radioactive materials shall:</p> <ul style="list-style-type: none"> a) have a New York State license to store radioactive materials; and b) maintain documentation of inspection by the NYSDOH Bureau of Environmental Radiation Protection pursuant to 10 NYCRR Part 16 and ensure ongoing compliance with such regulations. 	<p>For laboratories located in New York State, questions concerning the storage and disposal of radioactive materials should be directed to the New York State Department of Health Bureau of Environmental Radiation Protection at 518-402-7550 or berp@health.state.ny.us.</p>

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<p>Safety Sustaining Standard of Practice 17 (Safety S17): Compliance with Local, State and Federal Statutes and Regulations</p> <p>The director shall ensure that the laboratory complies with all applicable local, state and federal laws, regulations and requirements for:</p> <ul style="list-style-type: none"> a) packaging and shipping of infectious substances; b) storage, treatment and disposal of regulated medical waste; and c) storage, handling and disposal of chemicals and radiologic waste. 	<p>Laboratories located in New York State must comply with statutory requirements for storage, treatment and disposal of RMW as cited in Article 13, Title XIII, Section 1389 of NYS Public Health Law (http://www.wadsworth.org/labcert/regaffairs/clinical/titleXIII.htm) and in Part 70 of NYCRR (http://www.wadsworth.org/labcert/regaffairs/clinical/70.pdf). These regulations provide specific information regarding the use, labeling, handling, packaging and disposal of sharps and containers used for disposal of RMW generated by laboratories.</p> <p>Packaging and shipping requirements vary based on several factors including the type of specimen; likelihood that the specimen contains a category A or Category B pathogen; and the type of carrier/shipper being used (e.g. commercial carrier; private ground carrier; air transport). The laboratory must therefore review applicable Department of Transportation (DOT) and International Air Transport Association (IATA) requirements as well as requirements that may be in place by a commercial transporter.</p> <p>Packaging and shipping regulations are defined in the U.S. DOT Hazardous Materials Regulations (HMR; 49CFR Parts 171-180) available at http://ecfr.gpoaccess.gov. DOT regulations were harmonized with United Nation (UN) recommendations in 2006 (https://hazmatonline.phmsa.dot.gov/servers/publications_documents). IATA guidelines are available at http://www.iata.org.</p> <p>Under IATA requirements, every person responsible for packaging and shipping category A infectious substances must be trained every 24 months and be certified to package and ship by their institution.</p> <p>Patient specimens fall into one of several categories including those that:</p> <ul style="list-style-type: none"> a. are not subject to the provisions of the DOT dangerous goods regulation (e.g. dried blood spots; fecal occult blood); b. meet the definition of a category A (UN 2814 or UN2900) infectious substance (e.g. blood specimen known or reasonably suspected to contain Ebola virus; c. meet the definition of a category B (UN 3373) biological substance (e.g. blood specimen known or suspected to contain HBV); or, d. are eligible for “exempt” packaging and shipping provisions (e.g. routine cholesterol screening) (IATA only); <p><i>Note: As of Jan 2007, the use of the shipping names Diagnostic specimens and Clinical specimens is not permitted.</i></p>