

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

<p align="center"><b>Safety Standards S1- S22 Current (January 2008)</b></p>	<p align="center"><b>Guidance Current (January 2008)</b></p>	<p align="center"><b>Comparison with November 2009 proposed revision</b></p>
<p><b>Safety Sustaining Standard of Practice 1 (Safety S1): Standard Precautions</b></p> <p>Standard precautions shall be used in handling all specimens and reagents labeled as potentially infectious.</p>	<p><b>References:</b> Clinical Laboratory Safety; CLSI Approved Guideline-Second Edition GP17-A2</p> <p>Standard precautions means that all human blood and certain body fluids are treated as if they contain human immunodeficiency virus (HIV), hepatitis B virus (HBV) and other blood borne pathogens.</p>	<p>This standard has been updated and revised and is designated Safety Sustaining Standard of Practice 1 (Safety S1): Biohazard Risk Assessment and Biosafety Program</p> <p>Summary: The standard requires: a biosafety program that is based on an infectious agent risk assessment; all permitted clinical laboratories to meet BSL-2 criteria; appropriate use of PPE; an employee exposure plan. See also: Safety Standard of Practice 12 (Safety S12): Employee Occupational Exposure Plan.</p>
<p><b>Safety Sustaining Standard of Practice 2 (Safety S2): Training</b></p> <p>All personnel involved with handling biological or infectious material and medical waste shall receive training on the potential hazards associated with their work activities and the necessary precautions to prevent exposure to and dissemination of hazardous/infectious material. This training shall be documented.</p>	<p>At a minimum, this training should be done as part of initial employee training, and annually thereafter.</p> <p>Training should include the use of personal protective equipment (PPE). Personnel should be instructed that, following manipulation of specimens and infectious material, gloves should be removed and hands washed before using keyboards, telephones, etc. in designated clean areas of the laboratory.</p>	<p>The standard has some additional guidance and is designated as Safety Sustaining Standard of Practice 2 (Safety S2): Biosafety Program Training</p>

<p><b>Safety Sustaining Standard of Practice 3 (Safety S3): SOPM</b></p> <p>The SOPM shall contain protocols for:</p> <ul style="list-style-type: none"> <li>a) employing standard precautions;</li>   <li>a) managing exposure to blood, body fluids, semen, unfixed tissues, and specimens containing visible blood;</li> <li>b) handling infectious material, including specimens collected for the detection of emergent agents; and</li> <li>c) handling medical waste.</li> </ul>	<ul style="list-style-type: none"> <li>a) Universal precautions have been renamed standard precautions.</li> </ul>	<p>Material in this standard has been incorporated into other standards, including Safety S1.</p>
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<p><b>Safety Sustaining Standard of Practice 4 (Safety S4): Biosafety Practices - Sharps</b></p> <p>Laboratories shall comply with the following biosafety requirements:</p> <ul style="list-style-type: none"> <li>a) institute policies for the safe handling of sharps;</li> <li>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);</li> <li>c) before disposal, 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; and</li> <li>d) reusable blood tube holders shall be discarded after use with each patient.</li> </ul>	<ul style="list-style-type: none"> <li>a) The manual should include written policies for the acceptance of needles from the public. Syringes that re-sheath the needle, needleless systems, and other safety devices should be used.</li> <li>b) 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. Needles should not be removed from the holder before being discarded.</li> </ul>	<p>This standard has been renumbered as Safety Sustaining Standard of Practice 9 (Safety S9): Sharps</p>
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<p><b>Safety Sustaining Standard of Practice 5 (Safety S5): Chemical Hygiene Plan</b></p> <p>Laboratories shall develop and implement a written chemical hygiene plan that shall be available to employees upon request whenever laboratory work involves the use of hazardous chemicals. The plan shall:</p> <ul style="list-style-type: none"> <li>a) describe the use of fume hoods or other protective equipment whenever handling hazardous materials;</li> <li>b) establish procedures for exposure monitoring when permissible exposure levels of hazardous materials are exceeded;</li> <li>c) describe precautions for handling reagents containing toxic, hazardous or radioactive substances, including methods for their proper labeling and disposal;</li> <li>d) ensure proper storage of hazardous materials, including the use of a flame proof cabinets, where appropriate;</li> <li>e) establish a designated area for hazardous chemical storage and disposal;</li> <li>f) include an action plan for dealing with laboratory accidents;</li> <li>g) contain a protocol for managing documented exposure to chemical or radiological materials;</li> <li>h) contain a management protocol for maintenance of chemical and radiological exposure records on each employee;</li> <li>i) ensure that employees are provided with training regarding toxic substances in the workplace and use of protective equipment;</li> </ul>	<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>This standard has been renumbered as <b>Practice 17 (Safety S17): Chemical Hygiene Plan</b></p>
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<p>and</p> <p>j) provide that Material Safety Data Sheets (MSDS) for all chemicals in use are on file in the laboratory and are readily available to all employees at all times.</p>		
<p><b>Safety Sustaining Standard of Practice 6 (Safety S6): Radioactive Materials</b></p> <p>Laboratories must follow federal, state and local laws related to the handling of radioactive materials. Clinical laboratories located in New York State that use radioactive materials shall:</p> <p>a) have a New York State license to store radioactive materials; and,</p> <p>b) maintain documentation of inspection by the New York State Department of Health Bureau of Environmental Radiation Protection pursuant to 10 NYCRR Part 16 and ensure ongoing compliance with such regulations.</p>	<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) 458-6485 or FAX (518) 458-6434.</p>	<p>This standard has been updated so that guidance shows current contact information. It has been renumbered as <b>Safety Sustaining Standard of Practice 18 (Safety S18)</b>.</p>
<p><b>Safety Sustaining Standard of Practice 7 (Safety S7): Access</b></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.</p>	<p><b>This standard has been renumbered as Safety Sustaining Standard of Practice 13 (Safety S13): Access.</b></p>

<p><b>Safety Sustaining Standard of Practice 8 (Safety S8): Washing Facilities</b></p> <p>Hand washing facilities or antiseptic and eye wash facilities and showers, if required, shall be readily accessible to laboratory employees.</p>	<p>The laboratory director should determine if eye wash stations or showers are needed. Eye wash stations and showers should be routinely tested subject to a policy established by the laboratory.</p> <p>All laboratory personnel should wash their hands following completion of laboratory activities, removal of protective clothing, before leaving the laboratory, and immediately upon contamination.</p>	<p>Material in this standard has been incorporated into several new and/or revised standards:</p> <p>Hand washing: Safety Sustaining Standard of Practice 7 (Safety S7): Personal Protective Equipment (PPE) Availability, Use and Maintenance; Safety Sustaining Standard of Practice 8 (Safety S8): Disposable Gloves; Safety Sustaining Standard of Practice 14 (Safety S14): Facilities</p> <p>Eyewash: Safety Sustaining Standard of Practice 14 (Safety S14): Facilities</p> <p>Emergency shower: Safety Sustaining Standard of Practice 14 (Safety S14): Facilities</p>
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<p><b>Safety Sustaining Standard of Practice 9 (Safety S9): Biological Safety Cabinets</b></p> <p>Laboratories shall be equipped with appropriate class of biological safety cabinets (BSC) for the type of testing performed and:</p> <ul style="list-style-type: none"> <li>a) decontaminate the BSC at the start and end of each clinical application and immediately following a spill or accident with disinfectants that are effective against the agents of concern;</li> <li>b) monitor the air flow while in use;</li> <li>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</li> <li>d) document that all users are trained in the proper use of the BSC and are periodically observed for compliance with defined practices.</li> </ul>	<p>The appropriate selection and use of biosafety cabinets are defined in the CDC publication “Biosafety in Microbiological and Biomedical Laboratories” and on the CDC website. Proper use of biosafety cabinets is described in a video prepared by the Wadsworth Center’s Laboratory Response Network and is available on the Department’s Health Provider Network.</p> <p>b) The 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>c) 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. The BSC should be located away from doors and windows that can be opened and heavily traveled areas. 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><b>Specialty Requirements</b></p> <p>Mycobacteriology: TB11  Mycology: MY1  Virology: VR14  Cytogenetics: CG4  Histocompatibility: HC20</p>	<p>This standard has been renumbered as Safety Sustaining Standard of Practice 6 (Safety S6): Biological Safety Cabinets (BSC).</p>
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<p><b>Safety Sustaining Standard of Practice 9 (Safety S9): Biological Safety Cabinets</b></p> <p>Laboratories shall be equipped with appropriate class of biological safety cabinets (BSC) for the type of testing performed and:</p> <ul style="list-style-type: none"> <li>a) decontaminate the BSC at the start and end of each clinical application and immediately following a spill or accident with disinfectants that are effective against the agents of concern;</li> <li>b) monitor the air flow while in use;</li> <li>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</li> <li>d) document that all users are trained in the proper use of the BSC and are periodically observed for compliance with defined practices.</li> </ul>	<p>The appropriate selection and use of biosafety cabinets are defined in the CDC publication “Biosafety in Microbiological and Biomedical Laboratories” and on the CDC website. Proper use of biosafety cabinets is described in a video prepared by the Wadsworth Center’s Laboratory Response Network and is available on the Department’s Health Provider Network.</p> <ul style="list-style-type: none"> <li>b) The 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.</li> <li>c) 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. The BSC should be located away from doors and windows that can be opened and heavily traveled areas. 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.</li> </ul> <p><b>Specialty Requirements</b></p> <p>Mycobacteriology: TB11  Mycology: MY1  Virology: VR14  Cytogenetics: CG4  Histocompatibility: HC20</p>	
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<p><b>Safety Sustaining Standard of Practice 10 (Safety S10): Work Surfaces</b></p> <p>Laboratory work surfaces shall be</p> <ul style="list-style-type: none"> <li>a) decontaminated with a disinfectant following spills of potentially infectious material, and at the start and completion of work activities; and</li> <li>b) impervious to water and resistant to moderate heat and the chemicals used to decontaminate the work surface and equipment.</li> </ul>	<p>Use of a 1:10 dilution of a 5.25% solution of sodium hypochlorite (household bleach), prepared daily or 1:5 dilution for solutions prepared weekly is recommended.</p>	<p>This standard has been renumbered as Safety Sustaining Standard of Practice 15 (Safety S15): Work Surface Decontamination.</p>
<p><b>Safety Sustaining Standard of Practice 11 (Safety S11): Cleanliness</b></p> <p>Laboratory facilities are constructed to ensure that infectious agents cannot be transmitted to health care workers or the general public. The laboratory has:</p> <ul style="list-style-type: none"> <li>a) a pest management plan which ensures that pests cannot act as a mechanical vector to spread infectious agents;</li> <li>b) sufficient space between benches, cabinets and equipment to ensure adequate cleaning; and</li> <li>c) flooring and furniture located in the testing laboratory can be easily cleaned.</li> </ul>	<ul style="list-style-type: none"> <li>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.</li> <li>c) Carpets and rugs should not be used in the laboratory. Chairs and other furniture used in the laboratory work area should be covered with a non-fabric material that can be easily decontaminated.</li> </ul>	<p>Material in this standard has been incorporated into Safety Sustaining Standards of Practice 14 (Safety S14), which also includes requirements for hand washing facilities, eye wash facilities, etc.</p>

<p><b>Safety Sustaining Standard of Practice 12 (Safety S12): Specimen Handling</b></p> <p>All procedures involving the manipulation of blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying and creation of aerosols.</p>	<p>It is recommended that biological safety cabinets and other primary containment devices (e.g., aerosol-free centrifuge cups) be used for procedures that have high potential for creating aerosols or infectious droplets. Mouth pipetting of specimens must not be practiced: Mechanical devices, which may include pipet bulbs, shall be used for all specimen pipetting procedures.</p> <p><b>Specialty Requirements</b></p> <p>Mycobacteriology: TB12 Mycology: MY2</p>	<p>The material in this standard has been incorporated into Safety Sustaining Standard of Practice 1 (Safety S1): Biohazard Risk Assessment and Biosafety Program.</p>
<p><b>Safety Sustaining Standard of Practice 13 (Safety S13): Safety Breaches</b></p> <p>All blood and body fluid spills shall be cleaned up immediately with an appropriate disinfectant, and all spills, exposures or other breaches in safety protocol:</p> <ul style="list-style-type: none"> <li>a) shall be reported to the laboratory director;</li> <li>b) shall be documented and investigated; and,</li> <li>c) shall immediately be addressed with remedial action, when necessary, and documented.</li> </ul>		<p>This material has been revised and renumbered as Safety Sustaining Standard of Practice 11 (Safety S11): Safety Breaches.</p>

<p><b>Safety Sustaining Standard of Practice 14 (Safety S14): Specimen Packaging</b></p> <p>All diagnostic and infectious specimens must be packaged for shipping in compliance with applicable regulations.</p>	<p>Infectious substances are substances known to contain or reasonably expected to contain pathogens. Diagnostic specimens are any human or animal material, including excreta, secretions, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected humans or animals.</p> <p>Shipping regulations are promulgated from international and federal agencies. Check with the transportation carrier for any additional packaging requirements.</p>	<p>This standard has been revised and extensive guidance was developed. This material has been renumbered as Safety Sustaining Standard of Practice 16 (Safety S16): Specimen Packaging and Shipping.</p>
<p><b>Safety Sustaining Standard of Practice 15 (Safety S15): Specimen Packaging Containers</b></p> <p>Containers used during the transportation of medical waste shall be constructed to prevent leakage of blood and other potentially infectious liquids.</p>		<p>Guidance was developed for this standard and it has been renumbered as Safety Sustaining Standard of Practice S10 (Safety S10): Regulated Medical Waste.</p>
<p><b>Safety Sustaining Standard of Practice 16 (Safety S16): Biohazard Labels</b></p> <p>Warning labels with the universal biohazard symbol or with the legend "Biohazard" shall be affixed to:</p> <ul style="list-style-type: none"> <li>a) refrigerators and freezers containing blood or other potentially infectious material; and,</li> <li>b) containers used to transport clinically diagnostic specimens which are reasonably known to contain infectious agents and are to be shipped outside the facility. These specimens shall be contained within the enhanced mailing systems as prescribed by the International Guidelines.</li> </ul>	<p>Refrigerators or freezers labeled with the words regulated medical waste or infectious waste should be relabeled with biohazard or with the universal warning symbol.</p> <p>b) Refer to 49 CFR 171, 172, 173, and 178. These are federal regulations and can be found at <a href="http://hazmat.dot.gov/67fr-53118.pdf">http://hazmat.dot.gov/67fr-53118.pdf</a>.</p>	<p>Material included in item (a) has been renumbered as Safety Sustaining Standard of Practice 4 (Safety S4): Biohazard Labels. Material included in item (b) has been incorporated into Safety Sustaining Standard of Practice 16 (Safety S16): Specimen Packaging and Shipping.</p>

<p><b>Safety Sustaining Standard of Practice 17 (Safety S17): Personal Protective Equipment Availability</b></p> <p>Laboratories shall provide appropriate personal protective equipment, and ensure that such equipment is properly maintained and accessible at the work site.</p>	<p>The use of two laboratory coats, one (soiled) to be used exclusively for testing done in the laboratory and one (clean) for procedures performed outside the laboratory (e.g., phlebotomy procedures performed in the patient’s room) is recommended. Storage of “clean” and “dirty” laboratory coats should be delineated.</p> <p>Disposable gloves should not be washed or reused.</p>	<p>This material has been revised and renumbered as Safety Sustaining Standard of Practice 7 (Safety S7): Personal Protective Equipment (PPE) Availability, Use and Maintenance. This standard also includes a requirement for PPE training.</p>
<p><b>Safety Sustaining Standard of Practice 18 (Safety S18): Personal Protective Equipment Use</b></p> <p>Employees shall remove all personal protective equipment before leaving the laboratory work area; personal protective equipment, including laboratory coats, shall not be taken home or otherwise off the premises by laboratory personnel. Laboratories shall clean, launder and/or dispose of personal protective equipment at no cost to the employees.</p>		<p>This material has been incorporated into Safety Sustaining Standard of Practice 7 (Safety S7): Personal Protective Equipment (PPE) Availability, Use and Maintenance.</p>
<p><b>Safety Sustaining Standard of Practice 19 (Safety S19): Disposable Gloves</b></p> <p>Disposable gloves shall be:</p> <ul style="list-style-type: none"> <li>a) worn whenever it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, or when handling or touching contaminated items or surfaces;</li> <li>b) used when the employee has cuts, scratches or other breaks in his or her skin; and,</li> <li>c) removed and discarded if they become soiled.</li> </ul>	<p>When worn for phlebotomy procedures, gloves should be changed between patients.</p>	<p>This material has been revised and renumbered as Safety Sustaining Standard of Practice 8 (Safety S8): Disposable Gloves.</p>

<p><b>Safety Sustaining Standard of Practice 20 (Safety S20): Personal Practices</b></p> <p>Eating, drinking, smoking, handling contact lenses, and applying cosmetics or lip balm is prohibited in work areas that present a reasonable likelihood of occupational exposure to hazardous/infectious materials.</p>		<p>This standard has been renumbered as Safety Sustaining Standard of Practice 3 (Safety S3): Personal Practices.</p>
<p><b>Safety Sustaining Standard of Practice 21 (Safety S21): Food Storage</b></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 areas where blood or other potentially infectious materials are present.</p>		<p>This standard has been renumbered as Safety Sustaining Standard of Practice 5 (Safety S5): Food Storage.</p>
<p><b>Safety Sustaining Standard of Practice 22 (Safety S22): Regulated Medical Waste</b></p> <p>Laboratories must follow all local, state and federal safety laws for the handling of regulated medical waste.</p>	<p>Laboratories located in New York State should refer to Title XIII and Section 1389 of NYS Public Health Law and Part 70 of NYCRR for requirements on the storage, treatment and disposal of regulated medical waste, available at <a href="http://www.wadsworth.org/labcert/clep/clep.html">http://www.wadsworth.org/labcert/clep/clep.html</a></p>	<p>This standard has been renumbered as Safety Sustaining Standard of Practice 10 (Safety S10): Regulated Medical Waste (RMW).</p>