ABSA
American Biological Safety Association
1200 Allanson Road • Mundelein, IL 60060-3808 • 866-425-1385 • 847-949-1517
Fax: 847-566-4580 • E-mail: info@absa.org • Web Site: www.absa.org

August 22, 2013

Marcy L. Hackenbrack, MCM, M(ASCP)
Standards Project Manager
Clinical and Laboratory Standards Institute
950 W. Valley Road, Suite 2500
Wayne, PA 19087

Re: Request for Comments on Draft 2 of the revised CLSI Guideline M29-A4 (Draft 2), Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline – Fourth Edition.

Ladies and Gentlemen;

The American Biological Safety Association (ABSA) is an international group of biological safety professionals and is known as one of the world's foremost resources on biological safety practices. ABSA reviewed the CLSI Guideline M29-A4 (Draft 2) Protection of Laboratory Workers from Occupationally Acquired Infections; Draft Guideline – Fourth Edition and is providing the attached comments and information.

ABSA appreciates the opportunity to provide comments and information.

Sincerely,

Barbara Fox Nellis

Barbara Fox Nellis, SM(NRCM), RBP, CBSP
President
American Biological Safety Association

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

#	Commenter Name and Affiliation	Comment Type (ie, general [ge], editorial [ed], technical [te])	Section Number (e.g., 3.1)	Paragraph/ Figure/Table/ Note (e.g., Table 1)	Comment (justification for change) by the Commenter	Proposed change by the Commenter	Resolution (to be completed by committee/chairholder)
1	American Biological Safety Association (ABSA)	ED	Foreword	(primarily hepatitis B virus [HBV], hepatitis C virus, and HIV)	Only partial abbreviation – should include all.	(primarily hepatitis B virus [HBV], hepatitis C virus [HCV], and Human Immunodeficiency Virus [HIV]).	
2	American Biological Safety Association (ABSA)	ED	Foreword	the consistent use of standard precautions recommended for HBV and HIV	Use all 3 BBP names	standard precautions recommended for HBV, HCV and HIV	
3	American Biological Safety Association (ABSA)	ED	2 Introduction	Prevention of exposure to blood-borne pathogens such as hepatitis B virus (HBV), hepatitis C virus (HCV), and HIV	Use abbreviations	Prevention of exposure to blood-borne pathogens such as HBV, HCV), and HIV	
4	American Biological Safety Association (ABSA)	ED	2	Table 2:	Missing period	Need period after www.cdc.gov/hepatitis/. (not on line below. Also need HBV column (total infected to read: 550 000-940 000.	
5	American Biological Safety Association (ABSA)	ED	4.2	Definition of biohazard	Add word material because it can be a mixture of biologicals e.g. biological materials	**biohazard (biological hazard)** – a biological agent, material or condition that constitutes a hazard to human beings or their environment; **NOTE:** Potential source of harm caused by biological agents or toxins (CWA 15793).	
6	American Biological Safety Association (ABSA)	ED	4.2	Separate biological safety cabinet def from biological safety level	Need a space for document consistency	Separate definition of BSC and biosafety level (add a line).	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

7	American Biological Safety Association (ABSA)	ED	4.2	Change organization to association in all IATA references	Wrong word	Should read: International Air Transport Association (IATA) not organization. (definitions of dangerous goods and Dangerous Goods Regulations.	
8	American Biological Safety Association (ABSA)	ED	4.2	heating, ventilation, and air conditioning systems	Use common definition	Add heating, ventilation, and air conditioning [HVAC] systems under engineering controls.	
9	American Biological Safety Association (ABSA)	ED	4.2		See comment 7 above	**packing instructions –** International Air Transport Organization (IATA); Should read: International Air Transport Association (IATA) not organization.	
10	American Biological Safety Association (ABSA)	ED	4.2		See comment 7	**proper shipping name –** any of over 3000 internationally recognized names of dangerous goods specifically listed by the United Nations and International Air Transport Organization.[21] Should read: International Air Transport Association (IATA) not organization.	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

11	American Biological Safety Association (ABSA)	ED			See comment 7	**shipper –** anyone who ships goods by a commercial carrier, usually an employee of a company or health care facility (ie, laboratory staff member, contracted courier, and physician), offers goods for transport to a member of International Air Transport Organization, Should read: International Air Transport Association (IATA) not organization. Same for definition below **Shipper's Declaration for Dangerous Goods** – an International Air Transport Organization (IATA)-	
12	American Biological Safety Association (ABSA)	ED	4.2	Under universal precautions	3 major BBP's	add HCV	
13	American Biological Safety Association (ABSA)	ED	4.3		See comment 7	IATA International Air Transport Organization. Should read: International Air Transport Association (IATA) not organization.	
14	American Biological Safety Association (ABSA)	TE	5.1	BBP std requires a written ECP	CFR 1910.1030	Add written before Bloodborne: The OSHA Bloodborne Pathogens Standard[4] requires a Bloodborne	
15	American Biological Safety Association (ABSA)	ED	5.2	Lab standard requires a written CHP		Add written before Chemical.	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

16	American Biological Safety Association (ABSA)	ED			Disregard this comment	Have all bulleted items with same row spacing.	
17	American Biological Safety Association (ABSA)	ED	6.1.2.1			I would recommend putting nitrile gloves first as latex can cause allergies. Gloves made of latex (low-protein, powder-free), nitrile, chloroprene, or other suitable material should be available. Vinyl gloves are not recommended.[iii]	
18	American Biological Safety Association (ABSA)	ED	6.15			Under the first bullet add, Wherever possible, use safer medical devices (e.g. shielded needles, etc.).	
19	American Biological Safety Association (ABSA)	ED	6.2	A special circumstance exists in the blood bank when autologous blood is drawn from patients with HBV, HIV, or other infection	Should include all 3 BBP's of interest to OSHA	Add HCV: HBV, HIV	
20	American Biological Safety Association (ABSA)	ED	6.4.1		More specific information is needed for many lab workers regarding what immuno suppression is and its causes.	In the paragraph below, I would state that the laboratory director is responsible for training lab personnel on understanding what can cause immuno suppression (e.g. colds/flu, chronic conditions such as heart disease and diabetes, medications such as steroids, etc.) or this can be added in 4th bullet under 6.4.1.	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

21	American Biological Safety Association (ABSA)	ED	6.4.1	4th paragraph	Try to be consistent with OSHA	OSHA requires that signs include the biohazards symbol and the word Biohazard – the symbol is not enough. Place signs displaying the universal biohazard symbol and the word Biohazard should be posted on all entrances to the laboratory.	
22	American Biological Safety Association (ABSA)	TE	6.4.1	A certified BSC, preferably Class II, or o	95% of biosafety cabinets are IIA – prefer them because of negative plenums	A certified BSC, preferably Class II, should read a Certified BSC, minimally a Class IIA,	
23	American Biological Safety Association (ABSA)	ED	6.4.1	If engineering and work practice controls do not eliminate exposure, then PPE is required. PPE such as full face shields and fluid resistant laboratory clothing should be utilized for job tasks at risk for such exposure.		If engineering and work practice controls do not eliminate exposure, then PPE is required. PPE such as full face shields and fluid resistant laboratory clothing should be utilized for job tasks at risk for such exposure. A risk assessment should be conducted for each task to determine the appropriate controls and/or PPE.	
24	American Biological Safety Association (ABSA)	ED			Disregard this comment	Evaluated for effectiveness on a regular basis; replace regular with annual	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

25	American Biological Safety Association (ABSA)	ED				This is confusing as most biosafety cabinets have sashes and splashes to the face are almost impossible. Use barrier protection or work in a BSC when subculturing blood or other liquid cultures to prevent splash exposure to the face;	
26	American Biological Safety Association (ABSA)	ED	6.5.1.3			I recommend double gloving when working with infectious agents or cultures as if spills occur, you can remove one layer, don another pair of gloves and continue your work. The second paragraph under 6.5.1 discusses double gloving but does not recommend it in preceding sentences. I recommend including it – it is stated in 6.5.1.3 but I would generally recommend it when working with infectious agents/cultures.	
27	American Biological Safety Association (ABSA)	TE	6.5			there is no mention of prescription safety glasses – these stay at the lab and allow better vision than fit over safety glasses as there is only 1 lens that minimizes distortion.	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

28	American Biological Safety Association (ABSA)	ED	7.1		The hazards associated with an infectious agent or material that is known to be, or potentially infectious could be, in the laboratory. Remove highlighted words	The hazards associated with an infectious agent or material that is known to be, or potentially infectious in the laboratory.	
29	American Biological Safety Association (ABSA)	TE	7.1.1		Include additional points regarding identification of hazards and appropriateness of mitigation measures	• Identifying the hazards associated with specific procedures • Ensuring that the proposed mitigation measures are appropriate for the level of acceptable risk	
30	American Biological Safety Association (ABSA)	TE	7.2.1.2		Include another bullet. Primary laboratory hazards may differ from mode of transmission in the environment	• Primary laboratory hazards within the laboratory (which may differ from mode of transmission in the environment i.e. aerosols, inoculation, mucous membrane contact etc). (Refer to PHAC Pathogen Specific Data Sheets)	
31	American Biological Safety Association (ABSA)	ED	7.2.1.3		Move the note from end of this section to end of paragraph " laboratory Environmental factors"		

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

32	American Biological Safety Association (ABSA)	ED	7.2.2 Last paragraph		Missing word	Management should determine which risks to protect against and which risks are acceptable, taking into account controls and procedures already in place. Additional controls are then implemented to protect against high-risk scenarios, and incident response plans are developed for low-risk scenarios. **Include highlighted word**	
33	American Biological Safety Association (ABSA)	TE	7.2.3 Second paragraph		Include Standard Operating Procedures as part of administrative controls. "*Engineering controls include safety equipment such as a BSC, sharps containers, and centrifuge safety cups (see Section 8). Administrative controls include documenting proper training and competency*"	Engineering controls include safety equipment such as a BSC, sharps containers, and centrifuge safety cups (see Section 8). Administrative controls include documenting of Standard Operating Procedures, proper training and competency Include highlighted text	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

34	American Biological Safety Association (ABSA)	ED	7.2.3 End of second paragraph		Reword this sentence: *"Working with aerosol-transmissible agents requiring high containment require more stringent engineering and design features and containment measures is discussed"*	Working with aerosol-transmissible agents requires more stringent engineering and design features and containment measures and is discussed in Section 6.3. Include highlighted text	
35	American Biological Safety Association (ABSA)	ED	7.2.4		Reword the following: *"A thorough review of all accidents, exposures, and incidents, and near misses and implementation of preventive measures is critical to success"*	*Reword as follows:* *"A thorough review of all accidents, exposures, incidents, and near misses as well as reviewing the effectiveness of control measures (which have been already implemented) is critical to success"*	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

36	American Biological Safety Association (ABSA)	GE	All of section 9		*General Comment: I think this section need to be significantly revised to include more information relevant to the use of disinfectants and a bit more on the hazards of the various disinfectants. I have attached a document with suggestions for revision of this section.*	*See attachment*	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

37	American Biological Safety Association (ABSA)	TE	9.1		*"Liquid household or reagent grade bleach is often used as an intermediate-level disinfectant. Sodium hypochlorite is corrosive to aluminum and stainless steel, and if used, should be thoroughly rinsed with distilled water or 70% ethanol. Alternatively, other intermediate-level disinfectants that have a tuberculocidal claim should be used"* • Include efficacy against microorganisms • Reword the paragraph.	*"Liquid household or reagent grade bleach is often used as an intermediate-level disinfectant effective against most viruses, fungi, vegetative bacteria and , mycobacteria. Alternatively other disinfectants that have a tuberculocidal claim may also be used as an intermediate level disinfectant however these (Intermediate level disinfectants) may not be effective against bacterial or fungal spores.*	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

38	American Biological Safety Association (ABSA)	TE	9.1		• Include additional introductory statements at the end of this paragraph regarding disinfectants. • Indicate the different classes of disinfectants noting efficacy against various microorganisms. Also mention factors which may impact efficacy.	*"There are several classes of disinfectants such as chlorine, iodine, alcohol, phenolics, quaternary ammonium compounds etc. each having its own advantages and disadvantages as well as efficacy against various microorganisms. Efficacy of these classes of disinfectants against microorganisms may be impacted by several factors including the type of surface, temperature, organic load, concentration and contact time."*	
39	American Biological Safety Association (ABSA)	ED, TE	9.1.1		Change title to include "chlorine" consistent with disinfection class	Title: 9.1.1. *Sodium Hypochlorite (Chlorine)*	
40	American Biological Safety Association (ABSA)	TE	9.1.1 Paragraph after NOTE: First sentence		• *The concentration of disinfectant used depends on the nature of the spill and of the contaminated surface* • Expand on this statement	*"The concentration of disinfectant used depends on the nature of the spill, the application e.g. general surface decontamination or spill decontamination, the type of surface, the organic load, the contact time and the microorganism involved."*	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

41	American Biological Safety Association (ABSA)		9.1.1 3rd paragraph after NOTE:		*"The time of exposure to the diluted bleach solution may be brief: a 500 mg/L solution (1:100 dilution) inactivates HBV within 10 minutes and HIV in two minutes. If the spill has been adequately cleansed before decontamination, the diluted bleach may be blotted up with disposable absorbent towels shortly after the spill area has been soaked with bleach."* • Reword this sentence	*"The time of exposure (contact time) to the diluted bleach solution may vary based on the concentration of the disinfectant (e.g. a 500 mg/L solution (1:100 dilution) inactivates HBV within 10 minutes and HIV in two minutes), the extent of surface cleaning and the organic load present on the surface. If the spill has been adequately cleaned before decontamination, the contact time of diluted bleach solution may be shortened"*	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

42	American Biological Safety Association (ABSA)	TE	11.1.1	1	Primary container is noted to be placed in a leakproof container and placed into a secondary container in the event the primary container leaks or breaks. The requirement for the secondary container to thus also be leakproof is missing. The secondary container would not be usedful in the event of a leak or break without this charachteristic	The primary container should be placed into a sealed leakproof secondary container, which will contain the specimen if the primary container breaks or leaks in transit to the laboratory	
43	American Biological Safety Association (ABSA)	TE	11.1.1	1	Recommend following the practice that the secondary container be of durable material (not a plastic bag) if the primary container is glass or made of a brittle plastic that could puncture a plastic bag if used as a secondary container.	"The primary container should be placed into a sealed secondary container, which will contain the specimen if the primary container breaks or leaks in transit to the laboratory. ***If the primary container(s) if made of glass or plastic that could puncture a plastic bag if broken, the secondary container should be made of a durable puncture-resistant material.***"	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

44	American Biological Safety Association (ABSA)	TE	11.1.1	2	Primary containers are placed into a leakproof container . Recommend adding 'leak-proof' as a feature of the secondary container also.	Specimens of tissues and biopsies should be placed into leak-proof primary containers with or without solutions or fixatives appropriate for the planned examination method (eg, staining or freezing and sectioning). This specimen container should be placed into a sturdy, sealed ***leak-proof*** secondary container for transport from the collection point to the laboratory (eg, surgery or radiology).	
45	American Biological Safety Association (ABSA)	TE	11.1.2	1	The text doesn't include how the determination is made that the outside of the secondary container is uncontaminated. While good lab practices can avoid contaminating the container, the condition is uncontrolled here and lends itself to presuming that the container exterior is not contaminated. Recommend adding a routine step to decontaminate the outside of the secondary container.	After primary containers are placed into ~~externally uncontaminated~~ secondary containers~~,~~ ***and while wearing gloves that have not handled specimens or potentially infectiout materials, decontaminate the exterior of the secondary container. Once decontaminated,*** the secondary containers may be handled without gloves.	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

46	American Biological Safety Association (ABSA)	GE	11.1.2	1	Statement leads to inconsistent practices. Gloves should be worn by all staff if the risk assessment shows it is necessary or recommended. Staff wearing gloves may track contamination to surfaces others touch without gloves. The flexibility to wear gloves in the event that the lab worker's skin is broken or otherwise compromised is a good practice also (in the event gloves are not routinely worn) but should be more explicitly stated.	"…gloves are not required but may ***determined to be used by all lab workers or by an individual lab worker following appropriate risk assessment*** ~~be used voluntarily~~."	
47	American Biological Safety Association (ABSA)	TE	11.1.2	2	Recommend adding disinfection step when handling grossly decontaminated forms.	"If original requisitions or forms must be retained … they should be placed into a biohazard bag ***and the bag surface decontaminated*** before being archived."	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

48	American Biological Safety Association (ABSA)	TE	11.1.2	3	Recommend handling contaminated containers in a biosafety cabinet,	"Upon receipt in the laboratory, all specimen containers should be examined for visible contamination or breakage before being removed from the secondary container. ***Open secondary containers carrying leaking or broken primary containers in a biosafety cabinet."***	
49	American Biological Safety Association (ABSA)	ED	11.1.3	4	Recommend a stronger statement	"~~Enclosure in a secondary container is considered a best practice.~~ ***Place primary containers carrying potentially infectious materials in a secondary container during storage to follow best practices."***	
50	American Biological Safety Association (ABSA)	ED	11.1.4	5	Recommend adding consideration of other incubator components that may be contaminated.	Microbiology and tissue culture incubators …Special considerations … ***Special considerations for incubators following a spill or contamination should include potential decontamination and/or replacement of tubing, gaskets, filters, fans, and other potentially exposed incubator components.***	
51	American Biological Safety Association (ABSA)	ED	11.1.4	3	Recommend adding DOT term for Materials of Trade so reader can consult regulation for more details.	The transportation of small quantities of infectious substances … is exempt from most US Department of Transportation (DOT) regulations ***(Materials of Trade)*** if the specimens are transported by …"	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

52	American Biological Safety Association (ABSA)	ED	11.1.4	3	Recommend against stating that the DOT regulations are 'lenient' and using the word 'only'as there can be an unintentional message conveyed. There are additional specifications such as an informed driver and reportable quantities etc. Not having to complete shipping training could be added as an advantage of this DOT exception.	"Such substances … according to DOT regulations; however, these regulations ~~are~~ allow relative ***flexibility*** ~~ly~~ ~~lenient~~ and ~~state~~ ***require*** that the substances ~~need only~~ be in leakproof containers, sealed securely..."	
53	American Biological Safety Association (ABSA)	TE	11.1.4	3	Recommend adding common OSHA requirement for biohazard labeling.	"OSHA regulations still apply during this type of transportation of infectious substances~~.~~ s***uch as the requirement to label bloodborne pathogens or other potentially infectious material with the universal biohazard symbol."***	
54	American Biological Safety Association (ABSA)	TE	11.2.2	2	Recommend adding the terminology used by DOT/IATA	"primary container ***/receptacle***" "secondary container ***/packaging***" "outer container ***/packaging***"	
55	American Biological Safety Association (ABSA)	TE	11.2.2	2	Recommend adding detail of absorbent packing material	"secondary … and able to contain a damaged primary container ***with sufficient packing material to absorb liquid contents"***	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

56	American Biological Safety Association (ABSA)	ED	11.2.4.1	1	Recommend text change for clarification.	"(b) a substance that is categorized as either Category A or B ***or*** might be unknown or difficult to determine.	
57	American Biological Safety Association (ABSA)	ED, GE	12.2	Types of Medical Waste	Improved clarification – neither term is in section 4.2 definitions and I've found from past training it's not obvious to many workers what these terms mean.	• Pathological waste – add (tissues, organs, body parts, blood & body fluids removed during surgery, autopsy and biopsy) • Isolation wastes – add (waste from patient isolation rooms – see infectious waste)	
58	American Biological Safety Association (ABSA)	TE	17.1.1		Include another bullet regarding content of training to be included in the documentation system This section is well documented, very thorough	• Training documentation system should also include the content/objectives of the training that was provided	
59	American Biological Safety Association (ABSA)	GE	Appendix C	Table Characteristics: Colony Morphology	If the format would allow, an actual picture under the morphology description would add to the clarity to the guidance	Add picture of agar plate with subject bacteria	
60	American Biological Safety Association (ABSA)	ED	Appendix C	Table Characteristics: Colony Morphology	No hyphen in nonhemolytic	Take hyphens out of nonhemolytic (some are correct and some are not)	

Special Reviewers
M29 (Draft 2), *Protection of Laboratory Workers From Occupationally Acquired Infections; Draft Guideline—Fourth Edition*
8 July 2013 – 22 August 2013
Please return your comment table as an email attachment to standard@clsi.org or mhackenbrack@clsi.org.

61	American Biological Safety Association (ABSA)	ED	Appendix C	Table: Tests: B anthracis	Mistake: You SHOULD perform catalase test in a BSC ONLY	Change to read: Catalase positive (caution: perform catalase test in a BSC ONLY)	

1 Clean-up and Good Housekeeping Practices

1.1 Disinfectants and Sterilants

The FDA and the EPA share regulatory authority for the labeling and use of disinfectants and sterilants.[i] The FDA regulates chemical germicides formulated as antiseptics, preservatives, or drugs that are used on or in the human body, and sterilants and high-level disinfectants for processing reusable medical and dental devices. The EPA regulates the other disinfectants used for laboratory disinfection and housekeeping purposes. In addition, some states regulate disinfectants used for general disinfection of environmental surfaces. The manufacturer's label should always be the source of information on the safety and efficacy of any disinfectant or sterilants used in the laboratory.

Definition of Sterilization
Definition of disinfection

There are several classes of disinfectants such as chlorine, iodine, alcohol, phenolics, quaternary ammonium compounds etc. each having its own advantages and disadvantages as well as efficacy against various microorganisms. Efficacy of these classes of disinfectants against microorganisms may be impacted by several factors including the type of surface, temperature, organic load, concentration and contact time.

Chemical Sterilants

Glutaraldehyde	Variable	N/A
Hydrogen peroxide	6% – 30%	N/A
Formaldehyde	6% – 8%	N/A
Chlorine dioxide	Variable	N/A
Peracetic acid	Variable	N/A

Include

- *General use and efficacy, concentrations, contact times*
- *Advantages*
- *Disadvantages*

Chemical Disinfectants

Glutaraldehyde Ortho-phthalaldehyde	Variable 0.55%	High to intermediate High
Hydrogen peroxide	3% – 6%	High to intermediate
Formaldehyde	1% – 8%	High to low
Chlorine dioxide	Variable	High
Peracetic acid	Variable	High
Chlorine compounds	500–5000 mg/L Free/available chlorine	Intermediate
Alcohols (ethyl, isopropyl)	70%	Intermediate
Phenolic compounds	0.5% – 3%	Intermediate to low
Iodophor compounds	40 – 50 mg/L free iodine; up to 10 000 mg/L available iodine	Intermediate to low
Quaternary ammonium compounds	0.1% – 0.2%	Low

Include

- *General use and efficacy, concentrations, contact times*
- *Advantages*
- *Disadvantages*

Include the chart on the microbial resistance and the level of disinfection required t various level of resistance.

1.1.1 Sodium Hypochlorite

Liquid household or reagent grade bleach is often used as an intermediate-level disinfectant. Sodium hypochlorite is corrosive to aluminum and stainless steel, and if used, should be thoroughly rinsed with distilled water or 70% ethanol. Alternatively, other intermediate-level disinfectants that have a tuberculocidal claim should be used. Sodium hypochlorite should not be mixed with other laboratory reagents or household chemicals (ie, toilet bowl cleaners, rust removers, vinegar, acids, or ammonia-containing products) because hazardous gases may be produced (e.g., chlorine and other chlorinated species). The commercial bleach product is usually a 5.25% solution of sodium hypochlorite (50 000 mg/L of free available chlorine) but can range from 5.0% to 6.15%. The EPA encourages the use of registered bleach products for use as surface disinfectants, because the products have been tested for safety and performance when used according to the label instructions.[ii] Table 4 lists commonly used aqueous dilutions of the commercial product.

Table 4. Dilutions of Household Bleach

Dilution Ratio	Volume (Parts) of Bleach	Volume (Parts) of Water	Sodium Hypochlorite (%)	Available Chlorine (mg/L)
Undiluted	Undiluted	0	5.25	50 000
1:10	1	9	0.5	5000
1:100	1	99	0.05	500

NOTE: All dilutions should be made daily with tap water to prevent the loss of germicidal action during storage.[iii-v,vi] If tap water is used, chlorine bleach solutions should be made fresh daily. If distilled or deionized water is used, the disinfectant solution may retain its activity longer; however, activity should be verified with the vendor or by testing for the active ingredient.

The concentration of disinfectant used depends on the nature of the spill and of the contaminated surface. For example, if the surface cannot adequately be cleaned before disinfection, a 1:10 dilution of commercial liquid household bleach (0.5% sodium hypochlorite equal to 5000 mg/L of free available chlorine) may be needed. If the surface is hard and smooth and has been adequately cleaned, a 1:100 dilution of bleach (0.05% sodium hypochlorite equal to 500 mg/L of free available chlorine) may be sufficient. Both of these dilutions are sufficiently powerful to kill mycobacteria (e.g., they are "tuberculocidal").

All visible traces of dried blood or body fluid should be removed from a surface or medical device before decontamination. The dried blood should be wetted and softened with diluted bleach or detergent disinfectant. If the material cannot be removed by wiping, repeat the application and allow to stand for a longer period of time until the material can be wiped off. After removal of the dried blood or body fluid, disinfect or sterilize as appropriate (e.g., depending on the intended use of the surface or device).

The time of exposure to the diluted bleach solution may be brief: a 500 mg/L solution (1:100 dilution) inactivates HBV within 10 minutes and HIV in two minutes. If the spill has been adequately cleansed before decontamination, the diluted bleach may be blotted up with disposable absorbent towels shortly after the spill area has been soaked with bleach.

For large spills of cultured or concentrated infectious agents, the spill should first be covered with an absorbent material, flooded or mixed with an approved hospital disinfectant that is at least tuberculocidal or a 1:10 dilution of sodium hypochlorite, and then allowed to stand 10 minutes. (20 to 30 minutes may be necessary).

1.1.2 Hospital Disinfectants

In the United States, hospital disinfectants that are tuberculocidal may be used for decontamination.

Examples of effective product classes include:

- Phenolic disinfectants
- Chlorine-containing agents; and
- Tinctures of quaternary ammonium compounds with appropriate label designation as "tuberculocidal."

In other regions of the world, accelerated hydrogen peroxide is widely used as an alternative to bleach for environmental disinfection of blood and other body fluid spills.

1.2 Procedures and Products

Sterilization and disinfection procedures generally used in health care facilities are able to sterilize or disinfect medical devices and decontaminate and sanitize surfaces. Germicidal activity is classified as high- , intermediate- , or low-level (see Table 5). Critical medical devices that penetrate tissues, (e.g., making contact with normally sterile areas of the body) or through which blood flows should be sterilized before use (e.g., bone-marrow needles). Semicritical medical devices that come into contact with mucous membranes should be sterilized or receive high-level disinfection before use. Blood-borne pathogens such as HBV, HCV, and HIV are usually inactivated by all levels of disinfectants. However, OSHA requires the use of EPA-registered disinfectants that are tuberculocidal or effective against HIV and HBV.

Several commercial, quaternary, ammonium-based, housekeeping products have recently been approved by EPA to make claims of activity against HIV and HBV. However, if the user is processing samples other than blood or serum, it is recommended to use a tuberculocidal disinfectant to handle other types of organisms, such as enteroviruses. Refer to the manufacturer's instructions for exposure times and conditions and a list of micro-organisms inactivated by the product.

Table 5. Activity Levels of Selected Liquid Germicides (Favero MS, Bond WW. Chemical disinfection of medical and surgical materials. In: Block SS, ed. *Disinfection, Sterilization, and Preservation.* 5th ed. Philadelphia: Lippincott Williams and Wilkins; 2001. Adapted with permission of the authors and Lippincott Williams and Wilkins)[iii] For details regarding the use of these compounds, refer to the original publication.

Procedure/Product	Aqueous Concentration	Activity Level
Sterilization		
Glutaraldehyde	Variable	N/A
Hydrogen peroxide	6% – 30%	N/A
Formaldehyde	6% – 8%	N/A
Chlorine dioxide	Variable	N/A
Peracetic acid	Variable	N/A
Disinfection		
Glutaraldehyde Ortho-phthalaldehyde	Variable 0.55%	High to intermediate High
Hydrogen peroxide	3% – 6%	High to intermediate
Formaldehyde	1% – 8%	High to low
Chlorine dioxide	Variable	High
Peracetic acid	Variable	High
Chlorine compounds	500–5000 mg/L Free/available chlorine	Intermediate
Alcohols (ethyl, isopropyl)	70%	Intermediate
Phenolic compounds	0.5% – 3%	Intermediate to low
Iodophor compounds	40 – 50 mg/L free iodine; up to 10 000 mg/L available iodine	Intermediate to low
Quaternary ammonium compounds	0.1% – 0.2%	Low

NOTE: A recent memorandum of understanding between FDA and EPA places the sole regulatory responsibility for chemical sterilant/high-level disinfectants with FDA. The memorandum of understanding also placed the regulatory responsibility for environmental (housekeeping) germicides solely with EPA.

[i] FDA. Memorandum of understanding between the US Food and Drug Administration, Public Health Service and the Department of Health and Human Services and the US Environmental Protection Agency. MOU 225-93-4005. http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116796.htm. Accessed July 3, 2013.

[ii] Sehulster L, Chinn RY; CDC; HICPAC. Guidelines for environmental infection control in health-care facilities: recommendations of the CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR Recomm Rep*. 2003;52(RR-10):1-42.

[iii] Favero M, Bond W. Chemical disinfection of medical surgical material. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. 5th ed. Philadelphia, PA: Lippincott, Williams and Wilkins; 2001:881-917.

[iv] Rutala WA, Weber DJ. Uses of inorganic hypochlorite (bleach) in health care facilities. *Clin Microbiol Rev*. 1997;10(4):597-610.

[v] Rutala WA, Cole EC, Thomann CA, Weber DJ. Stability and bactericidal activity of chlorine solutions. *Infect Control Hosp Epidemiol*. 1998;19(5):323-327.

[vi] US Environmental Protection Agency, Office of Pesticide Programs. Standard operating procedure for handling spills of biohazardous material. SOP Number: MB-13-03. http://www.epa.gov/pesticides/methods/atmpmethods/MB-13-03.pdf. Accessed July 3, 2013.