

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

COMMENTS and RESPONSES to PROPOSED SAFETY STANDARDS

The Proposed Safety Standards were circulated for comment on November 12, 2009. The announcement and copies of the proposed standards with a crosswalk were sent to all NYS-permitted facilities (approximately 1000 facilities) as well as laboratories in application for a permit. This distribution was by e-mail to the facility, laboratory contact person and the director's personal e-mail as identified on their certificate of qualification. The documents were also posted to the CLEP website in the standards section.

The comment period ended December 21, 2009. Eighty-eight comments pertaining to 16 of the 18 standards were received from 27 facilities, organizations and individuals. Some of the comments indicated that significant changes were needed. Modifications have been made based on the comments received, including and increased stringency in two of the standards. The requirement for affixing biohazard warning labels has been made more stringent. Previously, only refrigerators and freezers were required to have warning labels with the universal biohazard symbol or with the legend "Biohazard". The requirement for areas in the laboratory to be labeled with these warnings and defined the equipment that needs to be labeled has been expanded (Revised Safety Standard 5). Contamination of rugs by microorganisms cannot be discerned visually and are now prohibited in the laboratory (Revised Safety Standard 3). Therefore, we offer the revised standards for comment until May 31, 2010.

Please note that the section for the infectious agent control program has been rearranged to begin with a risk assessment and is followed by laboratory design and practice requirements. There will be no change for the requirement of an infectious agent risk assessment with the resulting development and implementation of a biosafety program, as required in Safety Standard 1. Laboratories are expected to begin this process with an expected adoption date of the revised standards on August 1, 2010.

General Comments

There were 10 comments concerning the standards in general. Five commented that the standards as written were already in effect in their laboratory and that no changes would be needed.

General Acceptance Comments

- On behalf of the medical directors, we agree with the proposed standards and have no recommendations for revision at this time. Thank you for the opportunity to be part of this process.
- We have reviewed the attached Safety Standards document and concur with the content.
- I asked one of our Employee Health and Safety persons to review these changes in standards. It appears that our laboratory is compliant with these standards and we see no problem with other laboratories adopting them.
- The proposed standards have been reviewed and found acceptable. I have no recommendations.
- We have reviewed this document but do not have any recommendations for changes. We run limited laboratory services and feel that these guidelines are in line with current protocols.

Other General Comments

Comment:

In general, I suggest changing the word *should* used throughout the protocol to *must* or *shall*. The word *should* gives people the impression that they have a choice when they really don't. It also makes it sound like you are not really sure of your recommendation.

Response: The standard itself uses the terms "shall" and "must". The term "should" is used in the Guidance section and is intended to be less definitive and thus allows flexibility in complying with the standard. Laboratories may find other approaches to meet the intent of the standard..

Comment:

Do these apply only to NYS labs or to out-of-state labs as well?

Response: The safety standards apply to all laboratories holding a NYS permit. Laboratories located in New York State need to follow Part 70, which concerns regulated medical waste, in addition to the Safety Standards.

GENERAL ISSUES

Comments to the Crosswalk

- Please define PPE. I know it appears in the next row, but it should be defined BEFORE it is used.
- Please define or at least reference where "Universal Precautions" are actually stated so the reader can actually see the now "Standard Precautions." I don't see it in S1 in the "November 2009 Proposed Revision" document?

***Response:** The purpose of the crosswalk was to assist in understanding the proposed standards and was intended to be read as supporting information to the new standards. Therefore terms such as PPE and the outmoded Universal Precautions were not defined in the crosswalk.*

- Some note should be inserted here to indicate what, if any, changes have been made, or that no changes have been made so that the reader knows this and doesn't think that her/his copy of this documentation is incomplete. I note below that S6 covers biosafety cabinets; perhaps a note to this effect should be inserted in this area?
- Where is the revision? Sorry to be so redundant, I must be missing something critical to reviewing this document?

***Response:** We have noticed that when printing the document from some computers, sections of the table do not print. Apparently, there is an incompatibility between WORD version 2000 and 2003. Please verify that the document reviewed is complete by using the PDF version.*

Chemical Disinfectant

Safety Sustaining Standard of Practice 7 (Safety S7): Personal Protective Equipment (PPE) Availability, Use and Maintenance (Revised Safety S9)

Safety Sustaining Standard of Practice 8 (Safety S8): Disposable Gloves (Revised Safety S10)

Safety Sustaining Standard of Practice 14 (Safety S14): Facilities (Revised Safety S3)

Comment 1

Guidance states that chemical disinfectants are not considered an acceptable alternative to soap-and water handwashing. The CDC handwashing standards accept the use of chemical disinfectants by phlebotomists when changing gloves between patients. Why is this not acceptable in the technical sections when alternating between technical and non-technical tasks as long as hands are washed with soap and water before leaving the work area?

Comment 2

Antiseptics, in lieu of hand washing, is an acceptable alternative in the current Safety Standards of Practice 8 and has been implemented in certain setting/conditions when a hand washing facility is not readily accessible to an employee. To ensure that we are protecting both the public and our employees, antiseptic hand sanitizers are used by phlebotomists both the public and our employees, antiseptic hand sanitizers are used by phlebotomists performing home draws or a phlebotomist in a draw room of a collection station when a sink is not in close proximity. This means of disinfecting has proved to be protective of all individuals.

In addition, we also note the use of alcohol-based waterless antiseptic is also approved by OSHA and the College of American Pathologists as a means of preventing transmission of potentially infectious agents.

While we are in agreement that in the "laboratory" setting, hand washing is always available and can be used during the course of laboratory activities; we recommend that the use of chemical disinfectants be reconsidered for certain conditions.

COMMENT 3

Concur regarding the importance of appropriate hand washing practices but statements that chemical disinfectants are unacceptable alternatives seem contrary to other authoritative guidelines.

Response: *Chemical disinfectants were referred to in the three standards noted above. The use of chemical hand disinfectants is acceptable for use by phlebotomists and other patient contact settings. Clinical laboratories are required to operate at a BSL-2 or higher level (See Safety 1) and these work areas require sinks with running water. Reference: Biosafety in Microbiological and Biomedical Laboratories (BMBL5). A copy is available www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm. We have modified the guidance in the standards as appropriate.*

Director Designee

Safety Sustaining Standard of Practice 1 (Safety S1): Biohazard Risk Assessment and Biosafety Program

Safety Sustaining Standard of Practice 8 (Safety S8): Disposable Gloves (Revised Safety S10)

Safety Sustaining Standard of Practice 11 (Safety S11): Safety Breaches (Revised Safety S13)

Safety Sustaining Standard of Practice 10 (Safety S10): Regulated Medical Waste (RMW) (Revised Safety S17: Compliance with Local, State and Federal Statutes and Regulations)

Safety Sustaining Standard of Practice 16 (Safety S16): Specimen Packaging and Shipping (Revised Safety S17: Compliance with Local, State and Federal Statutes and Regulations)

COMMENT 1

We would suggest that the wording be changed to "The Lab Director, or designee, shall conduct an infectious agent risk assessment...." or "The Lab Director shall assure that an infectious agent risk assessment is conducted.....". For large laboratories such as ours safety is delegated by the Lab Director to the appropriate person(s) to manage, as are other duties. Your wording appears to be restrictive.

COMMENT 2

After letter (b) under the standard, I think there should be another bullet that says something to the affect that the risk assessment should involve the facility Safety Officer /Director if there is one, including the annual review. The reason being that the Safety Officer needs to know what the lab is working with in case there are any incidents and the safety officer has knowledge of current local requirements as well.

COMMENT 3

The laboratory director [insert **or designee**] shall.....

COMMENT 4

We recommend that this statement be reworded to: "The laboratory director or designee....."

COMMENT 5

The laboratory's risk assessmentshould guide the laboratory director [insert **or designee**] in tailoring a "glove use policy".....by the laboratory.

COMMENT 6

We recommend changing the wording to "laboratory director or designee".
As in S1, a biosafety professional is reviewing the risk assessment process and biosafety program;

COMMENT 7

b) immediately reported to the [add **area supervisor(s), safety officer, laboratory director**] and documented;

COMMENT 8

Standard: (b) immediately reported to the laboratory director and documented;

We recommend changing the wording of (b) to be consistent with the wording in Safety S12 (a):
"immediate notification of the laboratory director or designee."

RESPONSES: *Based on the comments, we reviewed the responsibilities that are assigned through NYS law and regulation. We have made changes as noted below:*

Safety S1

We agree that the risk assessment and implementation of the biosafety program is the responsibility of both the director and the owner or management staff of the laboratory. We also have expanded the Guidance section to define a biosafety professional. The department expects the laboratory to use appropriate experts and resources to design an adequate biosafety plan. The standard has been modified.

Safety S8 – Guidance (Revised Safety S10)

The director is responsible for implementing the glove use policy. The director may delegate direct oversight but remains responsible for verifying oversight has been appropriately performed. The guidance was not modified.

Safety S11 (Revised Safety S13)

We agree that a designee is acceptable for immediate notification of any safety breach and the standard has been modified.

Safety S10 and S16 (Revised Safety S17: Compliance with Local, State and Federal Statutes and Regulations)

These standards have been combined and the director is responsible for the laboratory's compliance with applicable federal, state and local laws and regulations. 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.

Pipetting and Risk Assessment

Comment: Aerosols are not created when pipetting...we believe face shields are not needed for this manipulation when working with serum and spinal fluids as the primary source specimens.

As to Safety Standard 6 and 5 requiring BSC's and work surfaces be decontaminated at the end of each shift. It does not make sense to decontaminate them a second time, at the beginning of the next shift.

Please remember that in serology labs we are not working with cultures of bacteria or viruses. In most instances, if the immune response has started, the pathogens are most often absent from the blood. That is why serology is being used, not nucleic amplification tests.

Thank you for considering our objections to these proposed changes. It would be a major inconvenience to use face shields for all pipetting and little if anything would be gained for the laboratory worker. Probably more errors would occur since shields sometimes make vision worse and could interfere with accuracy and ease of pipetting.

Response: *Human specimens should be treated as potentially infectious in all laboratory settings. It is generally accepted that pipetting is capable of creating aerosols and splashes. There are other devices besides face shields that can protect a worker's face from splashes, such as Plexiglas barriers. Although it appears that decontaminating work surfaces at the beginning and end of each use is redundant, we do not see this activity as burdensome and the extra precaution may not only prevent contamination of specimens but also protect the health of the staff. We do not agree with the commenter that the standards as written should be relaxed for a serology laboratory.*

COMMENTS TO SPECIFIC STANDARDS

Safety Sustaining Standard of Practice 1 (Safety S1): Biohazard Risk Assessment and Biosafety Program

COMMENT

As a point of clarification is the Safety S1 standard a new expectation that labs do something different than has been done already to address safety concerns? Is there an expectation that a formal new investigation be conducted and a report written, to be available upon request?

RESPONSE: *The requirement for a risk assessment is new and necessitates a written document. There must be evidence of review and approval by the Director at least annually to verify that plan as designed is effective and is still relevant to the services the laboratory provides.*

COMMENT

Does it say somewhere that the safety audit must be performed, and documented once yearly? Actually, the real outcome is not just doing the assessment, but making sure that that the lab meets certain criteria. Seems to me you could have lab managers prepare worksheets with a list a criteria in one column and the documentation--complete with procedure numbers if necessary--showing how that criteria has been met in the next. Would make the inspectors' jobs a whole lot easier. In our lab, we're working on constructing crosswalks with hyperlinks to procedures and checklists on the computer.

RESPONSE: *The standard states that the risk assessment should be revised as necessary and reviewed by the director at least annually.*

COMMENT 1

Review the risk assessment process and biosafety program with a biosafety professional – Please define biosafety professional.

COMMENT 2

Please provide clarification on “biosafety professional” regarding credentials, certification, or other requirements.

COMMENT 3

Can you define a "biosafety professional"? Do we need to hire a consultant to review our risk assessment or is it sufficient to have the facility Infection Control Coordinator perform a review

RESPONSE: *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. This definition has been inserted in the guidance section.*

COMMENT

Is the State expecting to see an assessment for each permit category, or will an assessment for each discipline or department suffice? (for example: chemistry, hematology, etc?)

RESPONSE: *The risk assessment should be done in each permit category. Permit categories may be combined under disciplines or departments depending on the organization of the laboratory.*

COMMENT

Modify guidance: A five-step approach to [insert **infectious agent**] risk assessment; and Review the risk assessment.....with a biosafety professional[add/**professional(s).**]

RESPONSE: *Modification has been made.*

COMMENT

Please provide guidance on the knowledge and proficiency of staff: is there a frequency or competency?

RESPONSE: *Human Resources Sustaining Standard of Practice 8 (HR S8): Competency Assessment – Non-Supervisory Staff requires annual competency for compliance with safety protocols.*

COMMENT

Guidance states that a splash barrier must be used when uncapping tubes. It states that individual face shields and bench top splash shields are acceptable. It does not comment on splash barrier phlebotomy tube caps. Since these are designed to prevent splashes, shouldn't they be acceptable as a splash prevention barrier?

RESPONSE: *We have only provided a few examples of protective barriers but other equipment and new technologies should be implemented at the discretion of the laboratory director.*

COMMENT

Guidance states that PPE must be worn whenever handling specimens that have not been treated. Does this include phlebotomy tubes containing patient samples that have not yet been opened?

RESPONSE: *Yes, once they have reached the laboratory for accessioning and/or testing.*

COMMENT

Regarding "dose" in the guidance section, how can dose be quantified? We recommend removing "dose" in the guidance as it should not be considered when handling infectious agents – there is an exposure risk or there is not an exposure risk.

RESPONSE: *The term "dose" has been removed from guidance.*

COMMENT

Laboratory access should be part of the risk assessment.

RESPONSE: *The guidance has been modified to include laboratory access.*

Safety Sustaining Standard of Practice 2 (Safety S2): Biosafety Program Training (Revised Safety S14)

COMMENT

Is there some list of minimal elements that you require training programs to have? If not, I suggest one. Maybe a worksheet on which each employee can sign off that he/she has been trained in that element.

RESPONSE: *Worksheets are typically tailored to meet the needs of the individual laboratory and their use is encouraged for the annual competency assessment.*

COMMENT

Please provide clarification on:

“Training and discussion should be supplemented with ongoing supervisory observation to ensure staff compliance with safety policies and proper use of PPE” regarding the intent and measurement of the “supervisory observation”. Does this need to be a competency and what would be expected to show as compliance with this? Does “supervisory” require that it actually be a supervisor who monitors this or can it be other staff, such as quality, education, technical leads, and safety who can also observe and ensure compliance?

RESPONSE: *As long as there is a reporting mechanism demonstrating supervisory oversight, the supervisor may delegate tasks to another non-supervisory person.*

Safety Sustaining Standard of Practice 3 (Safety S3) : Personal Practices (Revised Safety S8)

Upon reviewing the standards the writers realized that this standard is applicable to more than infectious concerns, therefore radiologic and chemical hazards have been added.

COMMENT1

Personal practices - under guidance I believe there should be a reference to " this also applies to desks in the lab areas". There may be labs that are dealing with space problems and I believe that this information should be stated more clearly.

COMMENT 2

Guidance: Personal electronic devices.....and should not be handled [replace/insert in clinical areas.] Emphasis guidance applicable to clinical staff, repair/service engineers, visitors/guests, etc.

RESPONSE: *Guidance has been expanded to incorporate these recommendations.*

Safety Sustaining Standard of Practice 4 (Safety S4): Biohazard Labels (Revised Safety S5)

COMMENT

Our laboratory does not put biohazard signs on the refrigerators since these signs are on the door as you enter the laboratory indicating that everything inside is biohazard. This has the same intent.

RESPONSE: *The reviewers referenced BMBL and OSHA and modified the standard to be in compliance with both sets of guidelines and also decided that all personnel entering the laboratory should be aware of the required PPE for each area. Therefore, we have expanded the standard to require that entryways be appropriately labeled. We feel that such redundancy is prudent in this environment of heightened safety concerns. We then clarified that equipment used or storing infectious materials outside of these areas must be labeled. Since these requirements are more stringent and quite different than what was presented in the proposed standard, we are accepting comments about the revision.*

Safety Sustaining Standard of Practice 5 (Safety S5): Food Storage (Revised Safety S7)

COMMENT

Food Storage - should there be guidance that food/drink heating units should not be in the lab either

RESPONSE:

Standards 3 and 4 clearly address that food and drink should never go beyond the laboratory door.

Safety Sustaining Standard of Practice 6 (Safety S6): Biological Safety Cabinets (BSC)

COMMENT

I am the Safety Officer for the American Red Cross Detroit NTL. I have a question about the **Biological Safety Cabinet** referred to in the New York State Department of Health Clinical Laboratory Evaluation Program. Please provide specifics on what this is and/or what the Health Department's expectation is. For example, does a Flammable Liquid Safety apply?

RESPONSE: BSCs are for protection against infectious agents, not chemicals. We address the handling of chemicals in Safety Standard 17(now 16) and refer to the need for a chemical fume hood. The lab should use the MSDS provided with all chemicals and write a chemical hygiene plan accordingly.

COMMENT

In the Guidance, "The BSC should be located away from doors and windows....." should be removed because the sentence before states that fluctuation must be verified. If a lab can prove that the doors and windows did not affect air flow, how can we state that should not be located there?

RESPONSE: There is always a concern when BSCs are located near doors, windows or in high-traffic areas.

Safety Sustaining Standard of Practice 7 (Safety S7): Personal Protective Equipment (PPE) Availability, Use and Maintenance (Revised Safety S9)

COMMENT

Why allow laboratory coats to be worn in public areas?

RESPONSE: Lab coats may be worn as part of uniform to distinguish staff from visitors in a facility. For example, phlebotomists when traveling through the hospital may wear lab coats. These would be considered "clean" and must not be stored for reuse in areas where PPE are stored.

COMMENT 1

In (b) add that PPE are properly stored as described in the Guidance section

COMMENT 2

Please add more guidance to the description of storing those lab coats worn in public areas and the need for separation from lab coats used in work areas or stations. I find that staff will commonly hang lab coats that have been used in a workstation next to lab coats that are used by phlebotomists when going to patient rooms.

RESPONSE: The guidance has been modified accordingly.

COMMENT

Splash barriers cannot ensure that the face will be completely protected from potentially infectious liquids or sprays. Users complain that face shields "fog" when they exhale, interfering with clinical functions [Enforcing usage becomes a problem]. Face shields increase lab supply costs and according to some inspectors, do not provide adequate protection since their foam headbands are not impervious to liquids.

RESPONSE: An option to the use of a face shield when working at the open bench is to use a Plexiglas splash shield.

COMMENT

Regarding PPE, specifically eye and face protection, the guidance states that glasses or goggles do not provide adequate protection. This could be misleading to laboratory staff that eye protection is not required. The OSHA Bloodborne Pathogen Standard, 1910.1030 (d)(3)(x) states: Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

RESPONSE: *We disagree that this statement is misleading.*

Safety Sustaining Standard of Practice 8 (Safety S8): Disposable Gloves (Revised Safety S10)

COMMENT

Are any circumstances that warrant the use of double-glove wearing? What is the quality assurance, and how test, to assure the glove integrity has not been compromised?

RESPONSE: *The use of double gloves would be at the discretion of the laboratory director or designee. Gloves should be properly stored, not washed or reused and observed for tears and punctures.*

COMMENT 1

"(f) must be removed and discarded immediately upon task completion at each work station (e.g. BSC, bench space)"

COMMENT 2

Please provide clarification on the meaning of "task", each step in a procedure can be considered a different task. Technologists routinely rotate between workstations in the course of performing a single Standard Operating Procedure. This statement in the standard is not feasible when taken in conjunction with the statement in Safety S7: "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." This would result in technologists going from their workstations to clean sinks between each task.

We suggest that the (f) be reworded to state: gloves should be removed between tasks to reduce the transfer of contamination between workstations as applicable.

COMMENT 3

Standard should clearly state that personnel at collection stations should remove gloves before touching or handing materials, like a pen or paperwork, that will be used by the general public after handling urine samples. I visited a collection site where I was handed a pen to be used to sign paperwork to after the lab person, wearing gloves, had handled my unclean urine sample.

RESPONSE: *One expectation of this standard is to avoid contamination of communal-use items such as phones, pens and keyboards that may be used by individuals who are not wearing gloves because these items are perceived as "clean". Items used by individuals performing technical tasks should be clearly marked e.g. with colored tape to indicate that they are considered part of the "dirty" work environment.*

COMMENT 1

Gloves *should* be changed between patients? Isn't this mandatory, not optional?

COMMENT 2

In (a), Please add more guidance on those situations where gloves are "optional". Changing gloves between patients when performing phlebotomy should not be optional.

RESPONSE: *It is strongly recommended that gloves be changed between patients but it is not mandated. It is at the discretion of the laboratory.*

Safety Sustaining Standard of Practice 12 (Safety S12) Employee Occupational Exposure Plan (Revised Safety S2)

COMMENT

Preventing droplet transmission seems to me even more important. Why recommend rather than mandate? If you are shy about dictating process, then go right to the outcome: labs must document that they prevent droplet transmission.

RESPONSE: *We are unsure of the intent of this question in the context of the laboratory. Droplet transmission is usually a term concerning the route of infection for a particular infectious disease.*

Safety Sustaining Standard of Practice 14 (Safety S14): Facilities (Revised Safety S3)

COMMENT 1

As in our comments in S8 regarding hand washing upon task completion: Please provide clarification on the meaning of "task", each step in a procedure can be considered a different task. Technologists routinely rotate between workstations in the course of performing a single Standard Operating Procedure. This statement in the standard is not feasible when taken in conjunction with the statement in Safety S7: "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."

This would result in technologists going from their workstations to clean sinks between each task.

COMMENT 2

Standard should clearly state that sinks should be available at collection stations so the general public can wash their hands after obtaining a urine samples, even when the sample is for chain-of-custody.

RESPONSE: *We have renamed the standard Facility Design and modified the guidance to describe the appropriate placing of hand washing facilities in the laboratory, including patient service centers.*

COMMENT

It is not unusual for laboratories to have carpets. Some major have carpeting in their laboratory. We have thoroughly investigated the feasibility and have effective corrective action plan for any spill. The rugs are well maintained and there are no contamination issues even after two years. Suggest changing the guidance to state that it is recommended not to use carpets. Then add if carpets are used the feasibility and a detailed written SOPM addressing cleaning and decontamination of carpeted areas is needed. The carpeting must allow for easy removal of contaminated areas and this removal must be performed immediately after the carpet is contaminated. Detailed records of such removal must be available for review.

The rationale for installing carpet was that due to design problems, the ceiling had to be lowered in the laboratory and there was considerable concern for excessive noise problems. A carpet was installed so that sections can be replaced very easily. Vacuuming is done on a daily basis. The hospital safety department did approve this design.

Response:

Contamination of rugs and carpets by microorganisms cannot be discerned visually. We modified the standard to prohibit the use of carpets and rugs in the laboratory where specimen are handled or manipulated. Due to the increased stringency, we present this requirement for comment.

Safety Sustaining Standard of Practice 15 (Safety S15): Work Surface Decontamination (Revised Safety S12)

COMMENT

You recommend a bleach solution—why not just mandate it so that it does not become a negotiation during inspection? Or, put it in terms of using either a 1:5 solution or document that whatever it is you are using is at least as effective?

RESPONSE: *There are acceptable alternatives to bleach for work surface decontamination..*

Safety Sustaining Standard of Practice 17 (Safety S17): Chemical Hygiene Plan

Due to the references to radiological materials this standard has been renamed and renumbered as Safety Sustaining Standard of Practice 15 (Safety S15) Chemical Hygiene and Radiological Safety Plan

COMMENT

What special precautions does facility make for pregnant histotechs to minimize or avoid exposure to hazardous organic solvents (xylene, toluene), DAB, formaldehyde, formamide, etc. and handling of fresh specimens (grossing, frozen cuts)? Since safety levels for adults are not necessarily safety levels for the developing fetus, there has to be safety standards aimed at protecting the fetus also.

RESPONSE: *Laboratories need to develop a chemical hygiene plan based on the information in the MSDS.*

COMMENT

- In the statement "plan should be available *upon request*", remove the statement " *upon request*" as is unclear what the intent is.
- In (d), guidance needs to be added on what is appropriate.
- In (j), the term "are on file in the laboratory" is outdated as most labs use online systems for their MSDSs.

RESPONSE: *This standard has been modified accordingly.*

Safety Sustaining Standard of Practice 18 (Safety S18): Radioactive Materials (Revised Safety S16)

COMMENT

Modify (c) to include the guidance - Document that employees are *initially trained and annually* in the handling and disposal of radioactive materials.

RESPONSE: *This standard has been modified accordingly and the training requirements are now explicitly stated in the standard.*