

## UNIT 9 LABORATORY PROCEDURES

### CHAPTER 38

## REGULATORY GUIDELINES IN THE MEDICAL LABORATORY

### Overview

Medical assisting students are introduced to the federal guidelines and regulations instituted to protect patients and health care professionals in the medical setting and the public in general. Emphasized are compliance with CLIA '88 standards for laboratory testing and the OSHA Bloodborne Pathogen Standard and the impact of these guidelines and regulations on the medical assistant's performance of duties in the ambulatory care setting. Students discover the importance of the strict use of and compliance with these standards, as well as with Standard Precautions. Infectious diseases and accidents in the ambulatory care setting occur through lack of education and carelessness. Medical assisting students must recognize the necessity of exhibiting professional behavior that will protect themselves and their patients from the spread of infectious diseases and maintain high safety standards in the ambulatory care setting.

### Lesson Plan

I. LEARNING OUTCOMES	ABHES	CAAHEP
A. Define, spell, and pronounce and the key terms as presented in the glossary.		
B. Identify and discuss the contents of the law of CLIA '88 and its importance to the medical assistant.	4.f	III.C.10
C. Describe how CLIA '88 regulates the use of quality control in automated hematology instruments.		
D. Recall the categories of testing and list several from the waived category.	10.b.1,2,3,4,5,6	
E. Describe CMS Form 116 and explain its purpose.		
F. Identify personal safety precautions as established by the Occupational Safety and Health Administration (OSHA).	9.i	III.C.4
G. Describe the importance of Material Safety Data Sheets (MSDS) in the health care setting.		XI.C.3
H. Identify and comply with safety signs, symbols, and labels.		XI.C.4 XI.P.1
I. Evaluate the work environment to identify safe vs. unsafe working conditions and safety techniques that can be used to prevent accidents and maintain a safe work environment.	9.i	XI.P.2
J. Analyze the professionalism questions and apply them to this chapter's content.		

### II. PROFESSIONALISM QUESTIONS

- A. Competency
  1. Did you pay attention to detail?
  2. Were you knowledgeable and accountable?
  3. Did you recognize the importance of local, state, and federal legislation and regulations in the practice setting?
- B. Initiative
  1. Did you seek out opportunities to expand your knowledge base?
  2. Did you develop a strategic plan to achieve your goals? Was your plan realistic?
- C. Integrity
  1. Did you acknowledge the scope of practice of other health care professionals?
  2. Did you immediately report any error you had made?

## III. REFERENCES

- A. Lindh, Wilburta Q., Pooler, Marilyn S., Tamparo, Carol D., Dahl, Barbara M. & Morris, Julie, A. *Delmar's Comprehensive Medical Assisting: Administrative and Clinical Competencies 5e*
- B. Text Chapter 38, References/Bibliography
- C. Any other teacher-preferred reference material, such as your program MSDS manual, website of OSHA, CLIA, and so forth

## IV. VISUAL AIDS

- A. Computer access to identified Internet resources
- B. Any other teacher-preferred visual aids (PowerPoint, etc.)
- C. Copies of available OSHA regulations, Material Safety Data Sheets (MSDSs), Standard Precautions, and CLIA '88

## V. EQUIPMENT AND MATERIALS

- A. Computer, TV monitor, and Internet access
- B. A fire extinguisher, eye-wash station, fume hoods, and other such equipment if feasible
- C. See IV: Visual Aids such as PowerPoint, etc.

## VI. SAFETY

- A. Basic classroom procedures
- B. The guidelines presented in this chapter exist to protect health care providers, their families, and patients from exposure. Discuss the students' responsibility for learning the most they can about these guidelines for their protection and the protection of their families.

## VII. PREPARATION

- A. Arrange for visual aids supplies and equipment.
- B. Collect materials.
- C. Review Chapter 38 in the text, the Study Guide, and the Instructor's Manual.

## VIII. INTRODUCTORY REMARKS/ACTIONS

- A. Read Learning Outcomes in the text with students to introduce the chapter.

## IX. PRESENTATION

- A. Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)
  - 1. Federal regulations are designed to set safety policies and procedures that protect patients.
  - 2. In 1967 misread Pap smears cause Congress to become more involved with regulating laboratories (culminating in CLIA '88).
  - 3. States can seek exemptions from CLIA standards and have state standards apply instead.
  - 4. Accrediting bodies are granted "deemed status."
  - 5. CLIA '88 encompasses several areas.
    - a. Designed to protect the public by regulating all laboratory tests performed on humans
    - b. Based on complexity of tests performed
    - c. Affects all aspects of the laboratory
    - d. Specifies type of test performed, training and education of personnel involved in testing, and quality control
  - 6. Categories of Testing.
    - a. Waived tests are simple and unvarying and require a minimum of judgment and interpretation
    - b. Provider-performed microscopy procedures (PPMPs) represent a subcategory of the moderate-complexity category
    - c. Moderate-complexity tests have three criteria (including PPMP)
    - d. High-complexity tests
  - 7. Contents of the Law.
    - a. Discuss the 17 components of CLIA described in this chapter
    - b. Review the text regarding CMS Form 116
    - c. List of analytes on the CLIA '88 waived list (refer to online resource listed)
    - d. Types of CLIA certificates

8. CLIA '88 Regulations for Auality Control in Automated Hematology.
    - a. Required procedures
      - (1) Calibration
      - (2) Control samples
      - (3) Proficiency testing
    - b. Check manufacturer's recommendations for particular piece of equipment
  9. Aftermath of CLIA '88.
    - a. Concerns about overload of paperwork it produces
    - b. Developments regarding postponements and funding problems
    - c. Recent findings of errors, gaps in quality in provider's office laboratories (POLs)
  10. Impact of CLIA on Medical Assistants.
    - a. Covers all laboratories even if they perform a few basic tests
    - b. Importance of documentation by medical assistants
    - c. The responsibility of medical assistants to teach and assist others who may not be trained in laboratory procedures and thereby protect the quality of testing within the POL
    - d. Penalties imposed on laboratories not complying with law
    - e. Law may become sidetracked by special interest groups
    - f. Large-scale changes may be ahead for the law
  11. Where to Find More Information Regarding CLIA '88.
    - a. Guidelines available from the Federal Register and online
  - B. Occupational Safety and Health Administration (OSHA) Regulations
    1. Intended to ensure safe and healthful work environment for employees
    2. Requirements that employer must follow to ensure employee safety and health
    3. Regulations comprise two standards
      - a. The Bloodborne Pathogen Standard
      - b. Standards for Occupational Exposure to Hazardous Chemicals in the Laboratory
        - (1) Purpose is to heighten employee awareness of risks linked with chemical dangers
        - (2) Involves employee training and identification of hazardous chemicals
        - (3) Chemical Hygiene Plan (CHP)
          - (a) Core of the OSHA safety standard
          - (b) Written plan specifying training and information requirements of standard
          - (c) Describes requirements of standard
          - (d) Written CHP and program must be operational if chemicals are stored in facility and handled by employees
          - (e) Describes three primary goals an employer must accomplish to be in compliance with OSHA standards for chemical exposure
          - (f) Requirements of CHP
          - (g) Importance of chemical standards to medical assistants
            - i. All employees must comply or face penalties
            - ii. All employees have the right to know about hazards at work site and how to handle, store, and dispose of hazardous substances
  - C. OSHA Regulations and Students
    1. Students do not fall under the OSHA guidelines but should take the same precautions
  - D. Ergonomics and cumulative trauma disorders
    1. A focus of attention by OSHA
    2. Prevention of cumulative trauma disorders and limiting repetitive actions
    3. Ergonomic work sites, training and job rotations.
    4. Reference to text chapter 11
- X. APPLICATION
- A. Use the Learning Outcomes at the beginning of Chapter 38 in the text as the basis for questions to assess comprehension.
  - B. See the Classroom Activities section below for numerous application activities.
  - C. Assign students to complete Chapter 38 in the Study Guide.

**XI. EVALUATION**

- A. Evaluate any assigned application activities.
- B. Evaluate student participation during your presentation. Grade responses to Chapter 38 in the Study Guide.
- C. Evaluate each student's participation in group projects to ensure that each is contributing to the group's process in a productive and positive manner.

**Classroom Activities**

1. Invite a guest speaker from a local laboratory to talk about what types of regulations the laboratory has to meet and how this affects the administration of lab procedures.
2. Divide the class into six small groups. Assign each group to prepare a presentation explaining one of the six examples of ways in which health care providers should practice Standard Precautions. Students should demonstrate if appropriate.
3. Assign students to review an MSDS manual from a laboratory or hospital and write a short essay about impressions of the manual. Share essays with the class.

**Answers to Critical Thinking Boxes**

Compare whom CLIA protects with whom OSHA protects. Do they have similar missions?

CLIA protects the public by regulating labs. OSHA protects the worker. Their missions are similar in that they are both committed to safety.

If you were to develop a chemical hazard training program for your clinic, what criteria would you determine to be vital for the safety of your coworkers?

Universal Precautions; how to clean up spills; personal protective equipment; hazardous communication standard; how to read chemical labels, warning signs, and so forth (Refer to Figure 38-6A—Safety Training Criteria).

**Answers to Case Studies****Case Study 38-1**

Refer to the scenario at the beginning of the chapter. Wanda performs the microscopic examination of the urine slide even though the procedure is not a waived test. She compares her findings to Dr. Rice's assessment.

1. Besides learning more about urine components and continuing her education, what benefit does Wanda obtain by putting forth this extra effort?

Wanda not only learns more about urine components and continues her education, but she also shows that she is willing to learn more about her work and is interested in professional growth.

2. Do you think Dr. Rice will appreciate her extra effort?

Dr. Rice will undoubtedly appreciate Wanda's extra effort and continue to teach Wanda more about her specialty. The doctor may also be more willing to invest funding into Wanda's professional growth and continuing education.

**Case Study 38-2**

Marie Tyndall is a student in the Jackson Heights Community College Medical Assisting Program. She and two other classmates have been assigned the project of creating a plan for cleaning up spills that might occur in the classroom laboratory and ensuring that all students using the laboratory have been trained in the proper procedure.

1. What materials would her group need?

The students might need a computer and printer, a notebook, and the OSHA regulations for cleaning up spills. The first steps would be to design the procedure and the steps involved and then create a checklist of students who receive proper training. These activities can be as elaborate as the students want to make it, from PowerPoint presentations and spreadsheets to posters and lesson plans. Each group would need a prepackaged spill clean-up kit or supplies to create their own kit, a three-ring binder, some tabs for the binder, OSHA regulations or access to them on a computer, a computer for word processing and creating a presentation, a printer, a projector or method of presenting their finished product, and other supplies such as colored pens and paper as required for their presentation.

2. How would her group go about learning the proper steps in the clean-up process?

Study the information in the textbook, research online, and interview medical personnel in a local medical laboratory.

3. How would her group ensure that all other students in the laboratory also have the proper training?

The students could design a check-off document to assure that all the proper steps are followed and ask their students to demonstrate how they would clean up a spill.

### Answers to Certification Review Questions

1. a. medical asepsis
2. b. CDC
3. c. laboratory tests performed on specimens taken from the human body
4. b. the chemical hygiene plan
5. d. OSHA
6. c. orientation, periodic drills, and consistent enforcement of policy
7. d. the methods used in testing
8. c. CMS
9. d. 4
10. d. A medical assistant
11. a. Waived
12. c. Ergonomic Hazards
13. a. flammability of the chemical
14. d. all of the above

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