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January 2011

GP05-A3

Clinical Laboratory Waste Management; Approved Guideline—Third Edition

Based on US regulations, this document provides guidance on the safe handling and disposal of chemical, infectious, radioactive, and multihazardous wastes generated in the clinical laboratory. Although this document is a valuable resource for a wider audience, it is intended for use primarily in the United States.

A guideline for US application developed through the Clinical and Laboratory Standards Institute consensus process.

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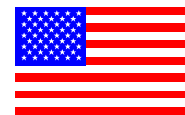
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Abstract

Clinical and Laboratory Standards Institute document GP05-A3—*Clinical Laboratory Waste Management; Approved Guideline—Third Edition* was written for use by laboratory managers and is intended to provide approaches to controlling laboratory-generated hazardous and nonhazardous waste. A brief summary of the relevant US federal regulations and laws is included. The types of waste addressed include chemical, infectious, radioactive, sharps, multihazardous, and nonhazardous. In this edition, emphasis is placed on methods for avoiding waste generation (source reduction), and reducing the volume and toxicity of unavoidable wastes (waste minimization). Options for handling, packaging, labeling, storing, recycling, transporting, treating, and disposing of each type of waste are also described. Although this document will serve as a useful resource for a wider audience, it is based on US regulations and is intended for use primarily in the United States.

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Foreword

The clinical laboratory is responsible for the proper handling and disposal of its waste from the time it is generated until its ultimate disposal. This guideline is intended to provide clinical laboratorians with general approaches to controlling laboratory-generated waste. Specific handling techniques and disposal methods are offered for the most important types of clinical waste.

Some legislative and regulatory background is included in Section 5. This section is intended to assist users in the United States in understanding the specific disposal requirements and recommendations that are detailed later in the guideline. It will also help users in other countries understand the regulatory environment that determines laboratory operations in the United States.

A series of important definitions is available in Section 4.1, and a programmatic approach to waste management—from planning to training—is presented in Sections 6 through 8. Essential strategies for pollution prevention, waste minimization, and recycling are found in Section 7. Sections 9 through 11 cover the major classes of laboratory waste: chemical, infectious, and radioactive. Section 12 summarizes multihazardous waste, and Section 13 describes special procedures for managing uncontaminated glass and plastic. Within each of these sections, the characteristics of that class of waste are addressed, as well as appropriate handling, storage, accumulation, treatment, and disposal options. Contingency planning is also addressed.

The authors have made every effort to be accurate and thorough in explaining the rules that laboratorians should be aware of, but the legal requirements and the scientific basis for proper waste disposal are voluminous, complex, and ever changing. The waste manager needs to understand the current regulations—federal, state, and local—and keep up to date with changes.

CLSI consensus documents are developed through an open process that ensures wide review and broad application. This unique approach leads to standards and guidelines for medical testing and health care services that address identified needs of both its global and national constituents. Most CLSI consensus documents are intended for global application. Under certain circumstances, however, a CLSI standard or guideline may be intended for primary use in a specific country or region.

CLSI document GP05-A3—*Clinical Laboratory Waste Management; Approved Guideline—Third Edition* is one such consensus document. Although GP05-A3 is a useful resource for a wider audience, it is intended primarily to help the US user navigate through stringent US regulations. Because disposal of laboratory waste is heavily regulated and relevant practices are widely “country specific,” the Area Committee on Quality Systems and Laboratory Practices determined that it would not be feasible to develop a comparable guideline intended for global application at this time. We hope that development of such a guideline may be possible in the future, as part of a long-term effort to harmonize regulations and practices.

The imprint of the flag and the unique tagline on the cover call attention to its national focus, and differentiate GP05-A3 from our global consensus documents.

Key Words

Hazard abatement, hazardous waste, infectious waste, laboratory management, laboratory safety, laboratory waste, medical waste, mixed waste, multihazardous waste, pollution prevention, radioactive waste, waste management, waste minimization

Clinical Laboratory Waste Management; Approved Guideline—Third Edition

1 Scope

This guideline is intended to provide information to clinical laboratories about the safe handling and disposal of hazardous wastes. It provides a brief summary of the relevant US federal regulations and laws related to laboratory waste management including chemical, infectious, radioactive, sharps, multihazardous, and nonhazardous waste. It further emphasizes methods for avoiding waste generation (source reduction) and reducing the volume and toxicity of unavoidable wastes (waste minimization); and provides options for handling, packaging, labeling, storing, recycling, transporting, treating, and disposing of each type of waste. The use of this guideline is not a substitute for awareness of current local, state, and federal regulations. The guideline itself should not be construed as a regulation. Despite the many similarities of clinical laboratories to one another, differences do exist; no single laboratory waste management program is appropriate for all facilities. This guideline should, however, provide a basis for the comprehensive waste management program in the user's laboratory. Although GP05-A3 may serve as a useful resource for a wider audience, it is based on US regulations and is intended for use primarily in the United States.

2 Introduction

The total volume of medical waste generated per laboratory can vary depending on the volume of the tests performed. Most waste that is generated can be disposed of as ordinary waste or can be recycled. Recycling is an important element of controlling the amount of material that is dumped in landfills and the cost of waste disposal.

Many clinical laboratories are part of a larger institution, so coordinating waste disposal practices with other parts of the institution is important. Although the laboratory itself may be a small generator of waste, its waste flow affects the institution's overall generation of waste. Coordination among different departments and the realization of senior management of the importance of waste control improves the safety of the institution, protection of the environment, and efficient operation of the institution.

Waste management regulations are long and detailed, and in some cases, vary from each other. The laws, rules, and regulations promulgated by various government agencies and private organizations are ever changing. Clinical laboratories need to constantly monitor for these changes and adjust their procedures to maintain compliance.

3 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all known infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard and universal precaution guidelines are available from the US Centers for Disease Control and Prevention (CDC).¹ For specific precautions for preventing the laboratory transmission of all known infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all known infectious diseases, refer to CLSI document M29.²

4 Terminology

4.1 Definitions

The following definitions are included to help the reader understand terms as they are used in this document. These are not legal definitions. Because laws change and definitions are complex, readers should refer to current regulations for legal definitions. See the Additional References section for a list of applicable laws, rules, regulations, and guidelines.

broker – a consultant, contractor, or waste transport firm that evaluates waste material, determines the appropriate disposal method, and makes arrangements for transport and disposal.

carcinogen – any substance capable of causing malignant tumors in humans or animals; **NOTE:** See the Agency for Toxic Substance and Disease Registry's (ATSDR's³) Annual Report on Carcinogens for current information on carcinogens.

chemical waste – this category includes chemical waste that is regulated as hazardous waste, as well as unregulated chemical waste that poses a risk to health and to the environment; **NOTE:** Most chemical waste is regulated as hazardous waste. See **hazardous waste**.

corrosive – any substance that causes visible destruction of human tissue at the site of contact; **NOTE:** The Environmental Protection Agency (EPA) defines corrosivity as a substance that is highly acidic (pH ≤ 2.0) or highly alkaline (pH ≥ 12.5).

decontamination – *for infectious waste*, a procedure that eliminates or reduces microbial contamination to a safe level with respect to the transmission of infection; **NOTE:** Sterilization and disinfection procedures are often used for decontamination of infectious waste; other procedures are available for chemical and radioactive material decontamination. See **infectious waste**.

diagnostic specimen – excreta, secretions, blood, and its components, tissue, tissue fluids, etc., that may contain an etiologic agent and is used for diagnosis.

disinfection – a procedure that kills pathogenic microorganisms but not necessarily their spores; **NOTE:** Chemical germicides formulated as disinfectants are used on inanimate surfaces (eg, medical devices); they should not be used on skin or body tissues.

disposal – act of indefinitely sequestering either treated or untreated waste, such as by burial in a landfill or waste pile; **NOTE:** Indiscriminate release to the environment is also considered disposal.

etiologic agent – a viable microorganism or its own toxin that causes, or may cause, human infection.

generator – a firm or institution that creates waste.

hazardous material (HAZMAT) – as referenced in Department of Transportation regulations, a substance or material that has been determined by the Secretary of Transportation to be capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and which has been so designated; **NOTE:** Hazardous wastes, regulated medical wastes, and most forms of low-level radioactive waste are hazardous materials.

hazardous waste – regulated hazardous waste is *chemical* waste that singly, or in combination, poses an immediate or potential threat to human health or to the environment and that, singly or in combination, requires special handling, processing, or disposal; **NOTE:** This includes chemical wastes that may be

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI document HS01—*A Quality Management System Model for Health Care*. The quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The QSEs are as follows:

- Documents and Records
- Organization
- Personnel
- Equipment
- Purchasing and Inventory
- Process Control
- Information Management
- Occurrence Management
- Assessments—External and Internal
- Process Improvement
- Customer Service
- Facilities and Safety

GP05-A3 addresses the QSEs indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Documents and Records	Organization	Personnel	Equipment	Purchasing and Inventory	Process Control	Information Management	Occurrence Management	Assessments—External and Internal	Process Improvement	Customer Service	Facilities and Safety
		GP21									X
											M29

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care*.

Related CLSI Reference Materials*

- GP21-A3** **Training and Competence Assessment; Approved Guideline—Third Edition (2009).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.
- M29-A3** **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

SAMPLE

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