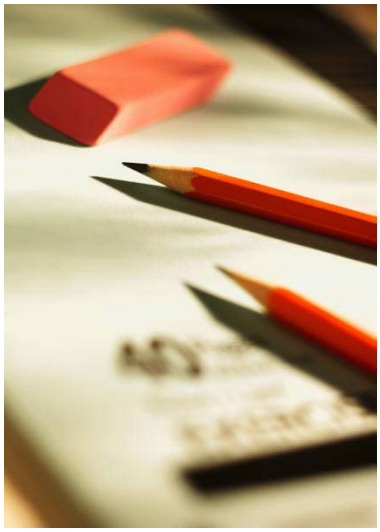
CLSI Style Guide
for Authors and Editors



This document provides guidance related to CLSI document structure and style, as well as general resources related to document development.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

July 2019

Contents

Part I. CLSI Document Structure

Introduction

Clinical and Laboratory Standards Institute (CLSI) documents describe laboratory techniques, bench and reference methods, protocols for method evaluation, and best practice recommendations that are used throughout the medical laboratory and health care arenas. To communicate these topics in a direct, concise, and easily accessible manner, CLSI documents conform to a particular format and style.

Format

The basic format of a CLSI document is an outline. Each chapter is introduced by a number and a descriptive heading and may contain subchapters.

The sections listed below represent those usually included within CLSI documents. However, the list is not all inclusive. When the document does not need a particular section, it does not need to be included. Conversely, if the document needs a section that is not listed below, the additional section should be added.

All sections marked with an asterisk (*) are mandatory for a CLSI document. Sections may be combined when appropriate. Some mandatory sections may not be required in a supplement (eg, Foreword, Key Words).

* Cover Page
    * Title and code
    * Tagline

* Front Matter
    * Abstract
    * Committee Membership
    * Contents
    * Foreword
        * Overview of Changes (for revisions)
        * Key Words

* Main Text (including tables and figures, if necessary)
    * Introduction
        * Scope
        Background
        * Standard Precautions (if applicable to document content)
        * Terminology
    Path of Workflow
    Quality System Essentials
    * Conclusion

* Supplemental Information
    * References
    Additional Resources
    Appendix(es)
    * The Quality Management System Approach
    * Related CLSI Reference Materials

1 Cover Page

1.1 Title and Code

The document's title describes, in as few words as is practical, the document's main topic(s). The code conveys the document category as well as the document number in relation to other CLSI documents. When the document is published, the edition number is displayed on the cover, in the document citation, and throughout the running headers. For example, CLSI document QMS03—*Training and Competence Assessment,* 4th ed., is the fourth edition of the third CLSI project in Quality Management Systems, and the cover page includes "4th Edition" in the upper right corner.

The terminology used in the title should be chosen carefully to ensure it accurately describes the document's contents.

1.2 Tagline

The tagline comprises one or two sentences describing the document's important features. Because the tagline is often used in CLSI marketing materials, it should be designed to stimulate user interest.

2 Front Matter

2.1 Abstract

The Abstract concisely summarizes (in approximately 150 words) the document's purpose, application, and major topic area(s).

The Abstract page also lists the document's authors. The chairholder is responsible for identifying those who should be included in the author list. Usually, the list includes the document development committee or working group members. Sometimes, other individuals (eg, document development committee contributors) are also included. The chairholder, vice-chairholder, and committee secretary are listed first, followed by the remaining authors.

2.2 Committee Membership

The Committee Membership section includes:

- Consensus Council (in consensus documents only)
- Applicable document development committee, subcommittee, and/or working group members
- Applicable CLSI staff, ie, the project manager, editorial manager, and editors
- Acknowledgment for the applicable expert panel
- Acknowledgment (general, as needed)

The Committee Membership section reflects each committee's membership at the time of its official vote. For committees that do not vote, this section reflects the membership at the time of its review period. For example, Consensus Council reviews the document at Proposed Draft vote and votes on the document at Final Draft vote. Therefore, the Consensus Council list reflects the membership at Final Draft vote. However, because the expert panel does not vote in either vote, but reviews the document at Proposed Draft vote, the expert panel list reflects the membership at Proposed Draft vote.

The committee names in the document match those used in CLSI's association management software. Though document titles might change throughout document development, committee names do not change.

Each entry is accompanied by the individual's postgraduate degree(s), professional affiliation(s), and country in which the volunteer is located.

Names of deceased committee members may be included in the author list and/or appropriate committee lists. An acknowledgment after the committee membership list may also be included, as in the following examples:

> **Acknowledgment**
>
> CLSI gratefully acknowledges the contributions of the late Dr. John Smith, ABC Laboratories, who served as an active participant on the Document Development Committee on [X] during the revision of this guideline.

> **Acknowledgment in Memoriam of our Document Development Committee Contributor and Colleague**
>
> CLSI and the Document Development Committee on [X] acknowledge the contributions of Dr. John Smith, who helped initiate this guideline and provided important contributions to its development. His work on [X] helped advance this field and stimulated many activities and efforts that will improve laboratory medicine and patient care.

2.3 Contents

The Contents section is an outline of the document's major components (ie, Abstract, Committee Membership, Foreword, main chapters, second-level subchapters, and supplemental information). It is compiled and automated by CLSI staff.

CLSI does not allow hanging subchapters. For example, when there is a Subchapter 2.1, there must be a Subchapter 2.2. This policy also applies to subsequent subchapters (eg, if there is a Subchapter 2.1.1, there must be a Subchapter 2.1.2).

2.4 Foreword

The Foreword expands the summary provided in the Abstract and discusses the need for the document. The Foreword provides appropriate background information, invites readers to comment on the material, and along with the Scope, identifies the intended audience. The Foreword is written by the committee member who is best able to discuss these topics (usually the chairholder). The Foreword also includes the following **NOTE:**

NOTE: The content of this [standard/guideline/report/document] is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

2.4.1 Overview of Changes

In all revisions (ie, second editions or higher), the Foreword includes an Overview of Changes section, which briefly discusses the revisions made since the previous edition.

2.4.2 Key Words

The Foreword concludes with (approximately) five to eight words that best represent the document's key concepts.

3 Main Text

CLSI documents are written in the **third person, present tense** (eg, "The **laboratorian examines** blood smears to determine the differential white blood cell count."). The future tense should be avoided, when possible. Active voice is also preferred.The main types of CLSI documents to which this style guide applies are:

- **standards** – CLSI documents developed through the Consensus Document Development Process that clearly identify specific, essential requirements for materials, methods, or practices for voluntary use in an unmodified form; **NOTE:** A CLSI standard may also contain discretionary elements, which are clearly identified.

- **guidelines** – CLSI documents developed through the Consensus Document Development Process that describe criteria and recommendations for a general operating practice, method, or material for voluntary use; **NOTE 1:** A guideline can be used as written or modified by the user to fit specific needs; **NOTE 2:** Mandates (ie, "must") are occasionally allowed in guidelines, when the document development group feels strongly that a particular action is either required or prohibited or when a guideline discusses provisions based on requirements; **NOTE 3:** Mandates may indicate a necessary step to ensure patient safety or proper fulfillment of a procedure.

- **reports** – CLSI documents developed through the Derivative Product Development Process that are published for informational purposes only; **NOTE 1:** Reports do not contain technical or procedural recommendations; **NOTE 2:** Reports may become guidelines through the Consensus Document Development Process.

- **supplements** – CLSI documents developed by a subcommittee and a working group(s) as an addition to a published standard or guideline.

In each document type, it is important to differentiate between imperative elements and elements that can be left to the user's discretion. The table below clarifies the intended interpretations of common terms or phrases.

Term or Phrase	Intended Interpretation
"Needs to" or "must"	Explains an action directly related to fulfilling a regulatory and/or accreditation requirement or is indicative of a necessary step to ensure patient safety or proper fulfillment of a procedure
"Require"	Represents a statement that directly reflects a regulatory, accreditation, performance, product, or organizational requirement or a requirement or specification identified in an approved documentary standard
"Should"	Describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement

The *Essential Instructions for Writing CLSI Documents* (see Standards Development Resources on CLSI website) provide additional explanations and examples of the preferred writing style.

3.1 Tables and Figures

Tables and figures should supplement rather than duplicate material found in the text. For example, illustrations can be more effective than text for highlighting patterns or differences. Tables and figures should be placed near the section of the text they supplement. They are numbered sequentially, cited by order of appearance, and have brief, descriptive titles.

A figure is any type of illustration that is not a table, including a flow chart, a line drawing, a photograph, or a bar graph. To obtain the highest possible quality in reproduction, line drawings and graphs should be computer generated. The preferred file types for figures are:

- Raster images: .jpg, .png, .tif (300 dpi or higher)
- Vector images: .ai, .eps, .indd

When raster images are used, it is important to pay attention to file size. Most photos are raster images, which are created using colored pixels. If a high-resolution image is too small to include in a document (eg, one inch), the quality will likely be distorted when the image is enlarged and the pixels are stretched. Vector images are created using mathematical formulas, rather than pixels, and they allow for more flexibility when resizing is needed.

When possible, authors are encouraged to create their own figures, tables, etc., rather than using those in published works, because the permission request process (see Part I, Section 5.1 and Part III, Section 2) can lengthen editorial turnaround times.

3.2 Introduction

This chapter includes the document scope and applicable exclusions, background information pertinent to the document's content, standard precautions information (if applicable), a "Note on Terminology" (if applicable) that highlights particular use and/or variation in use of terms and/or definitions, terms and definitions used in the document, and abbreviations and acronyms used in the document.

3.2.1 Scope

The Scope is a concise statement that identifies the purpose and application of the document. It establishes the elements to be included in and excluded from the document and identifies the intended audience, uses, and exclusions and/or limitations of the document. The Scope refers the reader to other CLSI documents, if appropriate.

3.2.2 Background

The Background subchapter is optional when introductory text leading into the document is already in the Foreword or Scope. Material from the Abstract, Foreword, or Scope should not be repeated.

3.2.3 Standard Precautions

This subchapter includes but is not limited to the Standard Precautions statement, which must be included in all documents that discuss body substances. The text of the Standard Precautions statement is found in the CLSI document template. At the discretion of the document development group chairholder, additional descriptive notes may be added to more pointedly cover the topic of a particular document.

3.2.4 Terminology

The Terminology subchapter is required and includes the following subchapters:

- **A Note on Terminology (optional)**

  The first paragraph of the Note on Terminology is found in the CLSI document template. At the discretion of the document development group chairholder, additional descriptive notes may be added to more pointedly cover the topic of a particular document. In NBS documents, the following paragraph is added:

  CLSI uses the globally applicable terms *preexamination, examination,* and *postexamination* in its documents. However, in the NBS laboratory, DBS specimens are "examined" to ensure they are satisfactory before they are "analyzed." Hence, for the purposes of CLSI NBS documents, the terms *preanalytical, analytical,* and *postanalytical* are used in place of *preexamination, examination,* and *postexamination.* Additionally, the term *analysis* is used in place of *examination.* Although contradictions among these terms might exist between new CLSI NBS documents and already published NBS documents, these contradictions will be reconciled as documents go through the routine revision process.

- **Definitions (required for standards, guidelines, and reports)**

  Each definition should be only one sentence or phrase. Any information following the initial sentence or phrase should be made into a **NOTE.** To search for accepted terms and definitions, consult CLSI's Harmonized Terminology Database at http://htd.clsi.org.

  CLSI documents should not be cited in the Definitions section.

- **Abbreviations and Acronyms (required)**

3.3 Path of Workflow

In this chapter, the requirements and/or guidance needed for each process should be described. Not every document covers each path of workflow process, and some documents do not cover the path of workflow processes at all.

3.3.1 Process Flow Chart

This subchapter should include a process flow chart. The *Essential Instructions for Writing CLSI Documents* (see Standards Development Resources on CLSI website) provide detailed information on creating flow charts. Often, text within flow chart symbols corresponds to specific chapters or subchapters. These chapter/subchapter references should be placed outside of their corresponding symbols.

3.3.2 Preexamination Activities

This subchapter includes descriptions of and recommendations related to the preexamination activities in the path of workflow as outlined below.

- Examination ordering
  - Information that needs to be included on examination requests (eg, patient identification, requester identification, clinical information)
  - Particular instructions for examination ordered (eg, patient consent, special preparation like fasting, special instructions for transfusion services)

- Specimen collection
  - Patient preparation and precollection assessment
  - Collection instructions (eg, collection containers, type and amount of specimen to be collected, special timing, special instructions such as temperature conditions and light exposure, preservatives, anticoagulants)
  - Labeling instructions

- Specimen transport
  - Special preservation or handling of specimens before their arrival
  - Proper and safe packaging, shipping, or transportation of specimens
  - Use of a pneumatic tube system

- Specimen receipt, accessioning, and processing
  - Information on where and how different types of specimens are stored
  - Tracing aliquots to original source
  - Rejection criteria
  - Specimen quality

3.3.3 Examination Activities

This subchapter includes descriptions of and recommendations related to the examination activities in the path of workflow as outlined below.

- Examination method selection
  - Customer expectations considerations
  - Laboratory-developed examination methods validation

- Examination performance
  - Quality control (QC) program (ie, schedule, QC materials to use, documented processes and procedures for QC of examination method performance, defined tolerance limits, corrective actions)

- Results review and follow-up
  - Correlating the results of concurrent examinations and any previous examinations
  - Instructions that are needed for follow-up of examination results below or above verified limits of the examination method

- Laboratory results interpretation
  - Objective criteria for the evaluation of the results of qualitative examination procedures
  - Comparisons for interpreting data (eg, reference intervals, age-specific information, alert values)
  - Interpretations of morphology

3.3.4 Postexamination Activities

This subchapter includes descriptions of and recommendations related to the postexamination activities in the path of workflow as outlined below.

- Communication of alert values and issuance of preliminary reports
  - When and how to notify appropriate parties of examination results that are predetermined "alert" or "critical" ranges
  - Confirmation of patient identity before verbal reports are given to designated persons and to ensure that results were heard correctly (ie, read-back process)

- Release of final reports
  - Elements included in the final report
  - Final report format
  - Report turnaround time
  - Corrected reports

- Specimen management
  - Specimen storage
  - Specimen indexing

3.4 Quality System Essentials

This chapter should include information related to the quality system essentials (QSEs) that is particular to the document. Generally accepted recommendations for each QSE are included in CLSI document QMS01 and should not be reiterated. Rather, CLSI document QMS01 should be referenced.

The QSEs and their corresponding topics are listed below. **NOTE:** There is no requirement to include information under each of these headings. Only relevant recommendations should be incorporated.

- Organization and Leadership
  - Commitment to quality, ethics, and good professional practice
  - Design of organizational structure to ensure quality
  - Implementation of a quality management system (QMS)
  - Allocation of resources
  - Planning for quality
  - Management review
  - Communication

- Customer Focus
  - Identification of customer expectations
  - Assessment of the laboratory's capability to meet customer expectations
  - Preparation of agreements to provide laboratory services to customers
  - Arrangements for communicating with customers
  - Monitoring customer satisfaction
  - Recording and management of complaints

- Facilities and Safety Management
  - Facility design and modification
  - Access
  - Facilities use and maintenance
  - Communications system
  - Biosafety
  - Chemical hygiene
  - Occupational health, laboratory incidents, accidents, and illnesses
  - Hazardous waste management
  - Fire prevention
  - Emergency management: preparedness, response, mitigation, and recovery
  - Radiation safety, as applicable

- Personnel Management
  - Job qualifications
  - Job introduction of personnel new to the organization
  - Management of personnel training
  - Assessment of competence
  - Performance management
  - Continuing education and professional development
  - End of employment
  - Personnel records

- Supplier and Inventory Management
  - Qualification and selection of suppliers
  - Procurement of equipment, materials, other products, or services
  - Assessment of suppliers, referral laboratories, contractors, and consultants
  - Inventory management
  - Identification and tracking of critical materials and services

- Equipment Managment
  - Selection qualification and procurement
  - Equipment qualifications
  - Calibration program
  - Maintenance program
  - Decommission of equipment no longer in use
  - Equipment records

- Process Management
  - Analysis, design, and documentation of the laboratory's path of workflow and QSE activities
  - Validation and/or verification
  - Process control
  - Change management
  - Risk management

- Documents and Records Management
  - Document management system
  - Record management system

- Information Management
  - Planning for overall information needs
  - Confidentiality of information
  - Security for data access
  - Integrity of data transfers or transmissions
  - Provision for information availability during downtime

- Nonconforming Event Management
  - Reporting and investigation of each nonconforming event
  - Classification, analysis, and trending of the collected data and information

- Assessments
  - External assessments
  - Internal assessments

- Continual Improvement
  - Use of a defined strategy for continual improvement
  - Participation in continual improvement activities at the organizational level

3.5 Conclusion

This subchapter includes a wrap-up discussion of the document's important points.

4 Supplemental Information

This chapter includes references, additional resources (if necessary), appendixes (if necessary), The Quality Management System Approach section, and the Related CLSI Reference Materials section.

4.1 References

The references follow the style outlined in the 10th edition of the *AMA Manual of Style.* See Part II, CLSI Document Style Points, for formatting requirements and examples.

4.2 Additional Resources

Occasionally, a selected reading list may be given after the References section. This list follows the same style as the References section. However, entries are listed alphabetically rather than numerically.

4.3 Appendixes

Appendixes represent material that supplements the understanding of the document but is not essential. If information is essential, it should be integrated into the main text. Appendixes should be called out in the main text (eg, "See Appendix A for more information") and should be arranged in the order in which they are first mentioned in the text.

4.4 The Quality Management System Approach

CLSI subscribes to a quality management system (QMS) approach in the development of standards and guidelines that facilitates project management, defines a document structure using a template, and provides

a process to identify needed documents. The QMS 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 approach is based on the model presented in CLSI document QMS01. Elements of the QSEs and path of workflow included in the document are in this section, along with the QSE and path of workflow information for any CLSI documents cited in the text.

4.5 Related CLSI Reference Materials

The Related CLSI Reference Materials section includes a list of CLSI publications and products that are cited within the document, along with their descriptions.

5 Additional Considerations

5.1 Copyright and Permissions

Permission must be obtained from the copyright owner to use tables, figures, or quotations from non-CLSI sources. Documentation to this effect must be on file at CLSI before any copyrighted material is used in a Proposed Draft document. Committee members are responsible for identifying material requiring permission.

When the need for permission is confirmed, the CLSI editors will process the permission request. The following source information must be provided to the project manager:

- Publisher
- Title
- Publication date
- Author(s)
- Title of journal article or chapter of book in which the original material appears
- Page numbers from the original source

Most information available on the Internet **is not** in the public domain and permission to reproduce it must be obtained just as with any printed matter.

When possible, figures should be submitted in one of the preferred file types (see Part I, Section 3.1).

5.2 Trade Names

CLSI documents do not endorse, either directly or indirectly, any specific commercial products. Therefore, trade names are not used in documents and are avoided by using generic terminology. For example, the term "Ziploc bag" could be replaced with "plastic, see-through, resealable, sandwich-type bag."

The use of drug names assigned by manufacturers is also prohibited by this policy. See Part II, Section 9, for style points related to International Nonproprietary Names and US Adopted Names.

Similarly, CLSI documents do not endorse specific companies, organizations, or contributing persons. Acknowledging an organization as the source for examples, forms, or other user aids is not permitted because inclusion could be construed as implying endorsement of that organization as an example of best

practice. Any recommendations, examples, forms, or other user aids must be presented in a generic form based on consensus scientific principles or best practices.

Part II. CLSI Document Style Points

CLSI style is based on the 10th edition of the *AMA Manual of Style.* If a style question arises for which a specific CLSI style point does not exist, the appropriate AMA style point is adopted.

Part II of this style guide contains style points that authors and editors should adhere to when preparing draft documents. Examples from published CLSI documents are included to illustrate many style points. CLSI staff members should consult these guidelines when preparing documents for voting.

When draft documents are edited, all changes must be entered using track changes. Sometimes, it is appropriate to mark up hard copies of draft documents by hand (eg, when the editors and staff assistant are formatting a document for publication). Standard proofreading marks are helpful in this situation. These are available from *The Chicago Manual of Style Online,* at https://www.chicagomanualofstyle.org/help-tools/proofreading-marks.html.

1 Abbreviations and Acronyms

Abbreviations and acronyms are shortened forms of words or phrases. The difference between the two is that abbreviations are pronounced by reading each letter, whereas acronyms are pronounced as words. For example, "CSF" ("cerebrospinal fluid") is an abbreviation, while "AIDS" ("acquired immunodeficiency syndrome") is an acronym. For simplicity, this style guide refers to "abbreviations." All guidance indicated for abbreviations also applies to acronyms.

Only well-recognized clinical, technical, and general abbreviations and symbols should be used. Author-invented abbreviations should be avoided. CLSI defines "abbreviation" and "symbol" as:

- **abbreviation** – a shortened form of a word or phrase, used to represent the whole; **EXAMPLES:** IVD = *in vitro* diagnostic; QMS = quality management system.

- **symbol** – representation, generally within an equation, of a mathematical parameter or quantity; **EXAMPLES:** *d* (difference), *n* (sample size), *x* (value), *r* (replicate); **NOTE:** See Section 12.3.2 for guidance on italicizing symbols.

Chemical formulas, enzymes, and common units of measure (se, "g," "mm," "°C") do not need to be included in abbreviations lists. See Part II, Section 30 for more information on units of measure.

Symbols lists are generally reserved for method evaluation (EP) documents. These lists appear in the form of a subchapter immediately following the Abbreviations and Acronyms subchapter. Some symbols are also used within text as abbreviations, eg, "SD" for standard deviation. In instances of overlap (ie, symbol appears in equations and also appears in the main text), the symbol appears solely in the Abbreviations and Acronyms list, rather than in both the Abbreviations and Acronyms list and the Symbols list.

1.1 General Rules

The general rules for abbreviations are:

- The full term is spelled out on first mention, and the abbreviation is included in parentheses after the term. Thereafter, the abbreviation is used. For example:
  - "Quality system essential (QSE) Assessments is one of the 12 QSEs described in CLSI document QMS01[1] and CLSI product *The Key to Quality*™,[2] which provide…"

- An abbreviation must be used at least twice, ie, its inclusion in parentheses following the full term and one more use on its own. If it is not used at least twice, only the full term is used, and the abbreviation is not included. See example and rationale below.

Example	Rationale
This guideline is applicable to documents used by medical laboratories of any size, complexity, or specialty, including point-of-care testing.	"POCT" is a common abbreviation for "point-of-care testing." However, it is not included in this guideline because the term is not used again in the main document.

Source document: *Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition* (QMS02-A6)

- Abbreviations are not used in:
  - The main document title
  - Chapter, subchapter, or appendix titles

- Abbreviations are newly introduced (ie, spelled out on first mention, followed by the abbreviation in parentheses) in each appendix (see Part II, Section 1.6 for more information).

1.2 Exceptions to the General Rules

1.2.1 Non-English Abbreviations

The following non-English terms are occasionally used:

- **CEN:** Comité Européen de Normalisation (European Committee for Standardization)

- **VIM:** *Vocabulaire International de Métrologie* (*International Vocabulary of Metrology – Basic and General Concepts and Associated Terms*)

To clarify the full terms and the abbreviations by which they are more commonly known, these abbreviations may be included in the Abbreviations and Acronyms subchapter, even when they only appear once in the document. In addition, both the term and the abbreviation (in parentheses) may be used in the text.

1.2.2 Abbreviations Not Spelled Out on First Mention

The abbreviations in the table below do not need to be spelled out on first mention. Stipulations apply for chapter and subchapter headings, appendix titles, and individual definitions:

The **bold** abbreviations may be used alone (ie, without their full terms) in:

- Chapter and subchapter headings and appendix titles
- Definitions

In addition, the **bold** abbreviations may be used even when there is only a single mention in the text. For example, if "DNA" only appears once in a document, it is permissible to use "DNA" rather than "deoxyribonucleic acid." The abbreviation is also included in the appropriate abbreviation list (ie, depending on whether it appears in the text or in a table or figure).

The remainder of the abbreviations in this table follow the general rules for chapter and subchapter headings, appendix titles, and definitions. That is, they are:

- Spelled out in chapter and subchapter headings and appendix titles
- Spelled out on first mention in each definition, followed by the abbreviation in parentheses
  - If the abbreviation is not used at least twice within a definition, only the full term is used, and the abbreviation is not included. For example, when "coefficient of variation" appears once within a definition, it should be spelled out and the abbreviation "CV" should not be used. However, when "coefficient of variation" appears twice within a definition, it should be spelled out on first mention, followed by "(CV)," and the second appearance should be replaced with "CV."

Abbreviation	Term
% CV	coefficient of variation expressed as a percentage
AIDS	**acquired immunodeficiency syndrome**
ATCC[a]	American Type Culture Collection
CD	compact disc
CD	cluster of differentiation (use with a number, eg, CD4 cell)
CSF	cerebrospinal fluid
CV	coefficient of variation
DDT	dichlorodiphenyltrichloroethane (chlorophenothane)
DNA	**deoxyribonucleic acid**
DOS	disk operating system
dpi	dots per inch
EDTA	**ethylenediaminetetraacetic acid**
EHR	electronic health record
EIA	**enzyme immunoassay**
ELISA	**enzyme-linked immunosorbent assay**
F	French (add *catheter;* use only with a number, eg, 12F catheter)
FISH	**fluorescence *in situ* hybridization**
GB	gigabyte
HIV	**human immunodeficiency virus**
HTML/html	hypertext markup language
http	hypertext transfer protocol
ICU	intensive care unit
ID	identification
IQ	intelligence quotient
ISBN	International Standard Book Number
ISSN	International Standard Serial Number
IU	international unit(s)
JPEG	Joint Photographic Experts Group (computer file format for digital images)
kB	kilobyte
LIS	laboratory information system
m-	meta- (use only in chemical formulas or names)
MB	megabyte
MD	doctor of medicine
nb	*nota bene* (note well)
Nd:YAG	neodymium:yttrium-aluminum-garnet [laser]

Abbreviation	Term
o-	ortho- (use only in chemical formulas)
OD	oculus dexter (right eye) (use only with a number, as in a refraction)
OS	oculus sinister (left eye) (use only with a number, as in a refraction)
OU	oculus unitas (both eyes) or oculus uterque (each eye) (use only with a number)
p-	para- (use only in chemical formulas or names)
$PaCO_2$	partial pressure of carbon dioxide, arterial
PaO_2	partial pressure of oxygen, arterial
PCO_2	partial pressure of carbon dioxide
PCR	polymerase chain reaction
PDA	personal digital assistant
PDF	portable document format
pH	**negative logarithm of hydrogen ion concentration**
PhD	doctor of philosophy
PO_2	partial pressure of oxygen
QA	quality assurance
QC	quality control
QMS	quality management system
RAM	random access memory
RBC	red blood cell
Rh	rhesus (of, related to, or being an Rh antibody, blood group, or factor)
RNA	**ribonucleic acid**
ROM	read-only memory
SAS	Statistical Analysis System
SD	standard deviation
SGML	standardized general markup language
SPSS	Statistical Product and Service Solutions (formerly Statistical Package for the Social Sciences)
TIFF	Tag(ged) Image File Format
TNM	tumor, node, metastasis
TSH	thyroid-stimulating hormone
URI	uniform resource identifier
URL	uniform resource locator
URN	uniform resource name
UV	ultraviolet
UV-A	ultraviolet A
UV-B	ultraviolet B
UV-C	ultraviolet C
VDRL	Venereal Disease Research Laboratory (add “test”)
WBC	white blood cell
XML	extensible markup language
zip	Zone Improvement Plan (zip code)

[a] When ATCC is used, this footnote is included: “ATCC® is a registered trademark of the American Type Culture Collection.” The footnote should be included on first mention in the main text (ie, Chapter 1 and beyond); often, the first mention in the main text is the Abbreviations and Acronyms subchapter. For supplements that have tables, rather than chapters, the footnote is inserted in the Abbreviations and Acronyms subchapter. Then, the registered trademark symbol (ie, ATCC®) is used with all subsequent uses of ATCC organism numbers.

The following conditions apply to the abbreviations in this table:

- These abbreviations are still included in the Abbreviations and Acronyms subchapter.

- These exceptions do not apply to the document title or tagline. Because someone viewing the document's cover might not have access to the Abbreviations and Acronyms subchapter, all abbreviations are spelled out on first mention in the title and the tagline, for clarity.

- When bolded abbreviations are used within another term in the Abbreviations and Acronyms subchapter, the bolded abbreviation is spelled out in the other full term. For example, the full term for "mRNA" is "messenger ribonucleic acid," not "messenger RNA."

1.2.3 Pronouns and Pluralization

Pronouns used before abbreviations are based on the pronunciation of the abbreviation when spoken aloud. The pronoun "an" is used before abbreviations that begin with a vowel sound (eg, "an MIC"). The pronoun "a" is used before abbreviations that begin with a consonant sound (eg, "a WBC").

To pluralize abbreviations, an "s" is added (eg, "LDTs"). If the abbreviation ends in "s" (eg, "LIS" for "laboratory information system"), "(s)" is included after the full term in the Abbreviations and Acronyms subchapter, eg, "laboratory information system(s)." This convention signifies that the abbreviation applies to both the singular and plural form of the term.

1.3 Abbreviations in the Tagline, Abstract, Foreword, and Definitions

Before the Scope, the following sections are considered independent entities (in other words, "mini documents"):

- Tagline
- Abstract
- Foreword

That is, abbreviations should be spelled out on first mention in each section or not used at all when the term only appears once in the section.

Example	Rationale
Abstract: Recommendations for managing the unique challenges associated with the increasing incidence of *Mycobacterium tuberculosis* and nontuberculous mycobacteria infections are included.	The abbreviation "NTM" ("nontuberculous mycobacteria") is used throughout this guideline. However, the term is spelled out in the Abstract, and the abbreviation is not present, because it is not used again within the Abstract.

Source document: *Laboratory Detection and Identification of Mycobacteria* (M48, 2nd ed.)

The Scope represents the beginning of the main text. However, within the text, each definition in the Definitions chapter is considered an independent entity (in other words, "mini documents"). This convention allows each definition to be quickly and easily interpreted, without the reader needing to refer to the Abbreviations and Acronyms subchapter.

Example	Rationale
quality system essential – an essential building block of a quality management system that covers, at a minimum, regulatory and accreditation requirements within a specific topic needed to fulfill those requirements and stated quality objectives.	The abbreviation "QMS" ("quality management system") is used throughout this guideline. However, it is spelled out in this definition, and the abbreviation is not present, because it is not used again within the definition.

Source document: *Management of Paper-based and Electronic Laboratory Information* (QMS22, 1st ed.)

NOTE: When an abbreviation's full term is included in the Definitions subchapter, the abbreviation should follow the definition in bold and within parentheses (but before the en dash), even when the abbreviation is not used again within that definition. This convention signals to the reader that the abbreviation is used throughout the document.

Example	Rationale
lower limit of quantitation (LLoQ) – the smallest amount of a substance that can be measured accurately.	The abbreviation "LLoQ" is not used again in this definition. However, it is included after the full term because it appears in the Abbreviations and Acronyms subchapter and is used throughout the guideline.

Source document: *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking* (EP34, 1st ed.)

1.4 Abbreviations in Chapter, Subchapter, and Appendix Titles

Abbreviations are generally prohibited in chapter, subchapter, and appendix titles. Part II, Section 1.2.2 identifies exceptions (in **bold**) to this rule. In addition, with permission from the editor, certain terms may be abbreviated in chapter, subchapter, or appendix titles when the term is:

- Common knowledge for the document's audience
- Used in many chapter/subchapter or appendix titles throughout the document
- Cumbersome to spell out on each occasion

Ideally, the abbreviation should meet all three criteria.

Example	Rationale
8.1 The *CFTR* Gene, Mutations, and Their Classification	• "*CFTR*" is central to the topic of this guideline. • "*CFTR*" appears in 11 chapter titles and one appendix title. • "*CFTR,*" as "cystic fibrosis transmembrane conductance regulator," is cumbersome to spell out.

Source document: *Newborn Screening for Cystic Fibrosis; Approved Guideline* (NBS05-A)

1.5 Abbreviations in Tables and Figures

An abbreviations list is included below each table and figure listing the abbreviations used within that table or figure. This list allows the reader to interpret the table or figure without referring to the Abbreviations and Acronyms subchapter. The table below includes style points related to the abbreviations lists.

Abbreviations List	Table	Figure
Includes abbreviations from the table **and** its title	X	
Includes abbreviations from the figure **but not** the title[a]		X
Arranged alphabetically, in 9-pt. font	X	X
Placed below the table[b]	X	
Placed above the title[c]		X

[a] Abbreviations may be used in figure titles, but they do not need to be included in the abbreviations list unless they also appear in the figure itself. An exception would be if the abbreviation in the figure title represented the first mention in the document.
[b] When a table includes footnotes, the abbreviations list appears between the table and the footnotes (ie, the order is title, table, abbreviations list, footnotes).
[c] When a figure includes footnotes, the abbreviations list appears above the footnotes (ie, the order is figure, abbreviations list, footnotes, title).

1.5.1 Abbreviations Used at First Mention in a Table or Figure

In addition to allowing the reader to interpret the table or figure, the abbreviations lists eliminate the need to spell out abbreviations within tables and figures when the table or figure represents the first mention of the abbreviation. In this scenario, the full term does not need to be reintroduced at its next mention in the main text. The abbreviations list beneath the table or figure counts as the first mention, and the abbreviation alone is used at its next mention in the text.

1.5.2 Figure Legends

Abbreviations may be used in figure legends (which includes the figure title), but standard abbreviations rules apply (ie, if it is the abbreviation's first mention, the full term is used and the abbreviation is included in parentheses). Abbreviations in figure legends do not need to be included in the abbreviations list unless they also appear in the figure itself.

1.5.3 Footnotes

Table and figure footnotes may use abbreviations that were already introduced in the document, including in the table or figure with which they are associated. If a footnote represents the first mention of an abbreviation, standard abbreviations rules apply.

1.5.4 Abbreviations Used Only in Tables and/or Figures

When an abbreviation is only used in a table and/or a figure (or in multiple tables and/or figures), the term remains abbreviated and is added to the abbreviations list below each applicable table and figure, but it is not added to the main Abbreviations and Acronyms subchapter.

NOTE: Supplements that consist mostly of tables (eg, CLSI document M100) are an exception to this rule. In these supplements, the main Abbreviations and Acronyms list includes all abbreviations used from the front matter to the end of the main text, even when they only appear within tables.

1.5.5 Examples

Examples of several scenarios are included below.

Example 1: Table that includes abbreviations and footnotes (Modified from source document: *Newborn Blood Spot Screening for Severe Combined Immunodeficiency by Measurement of T-cell Receptor Excision Circles; Approved Guideline* [NBS06-A])

Table 3. Blood Volume and Amount of DNA in DBS Punches

Punch Diameter, mm	Average Blood Volume, µL	Average DNA, ng
3.2	3.4[a]	237[a]
2.0	1.3[b]	93[b]
1.5	0.8[b]	52[b]

Abbreviations: DBS, dried blood spot; DNA, deoxyribonucleic acid.
[a] Observed.
[b] Calculated.

When possible, it is preferable to use footnotes in tables rather than "**NOTE**s" within the table itself, as shown in the example above. See Part II, Section 27 for additional formatting considerations.

Example 2: Table that includes an abbreviation not used elsewhere in the document (Source document: *Customer Focus in a Quality Management System* [QMS19, 1st ed.])

Table 11. Measurements of Laboratory Performance

Path of Workflow	Examples of Quality Indicators
Preexamination	• Test order integrity measures (eg, missed test orders, wrong test orders, duplicate test orders) • Specimen integrity measures (eg, mislabeled specimens, lost or misplaced specimens, compromised specimens, QNS specimens, wrong specimen type for the test ordered, wrong specimen container or preservative) • Customer service measures (eg, call hold time, dropped calls, problem resolution satisfaction, interpretation or consultation responsiveness)
Examination	• Test procedural measures (eg, erroneous results, delayed critical value results, QC failures)
Postexamination	• Test reporting measures (eg, critical value notification failures, turnaround time failures, erroneous and/or corrected reports, amended reports, computer or reporting downtime, uninterpretable reports)

Abbreviations: QC, quality control; QNS, quantity not sufficient.

In QMS19, "QNS" is only used in Table 11. It is included in the Table 11 abbreviations list, but it is not included in the main Abbreviations and Acronyms subchapter.

Example 3: Figure that includes an abbreviation in the title but not in the figure (Source document: *Customer Focus in a Quality Management System* [QMS19, 1st ed.])

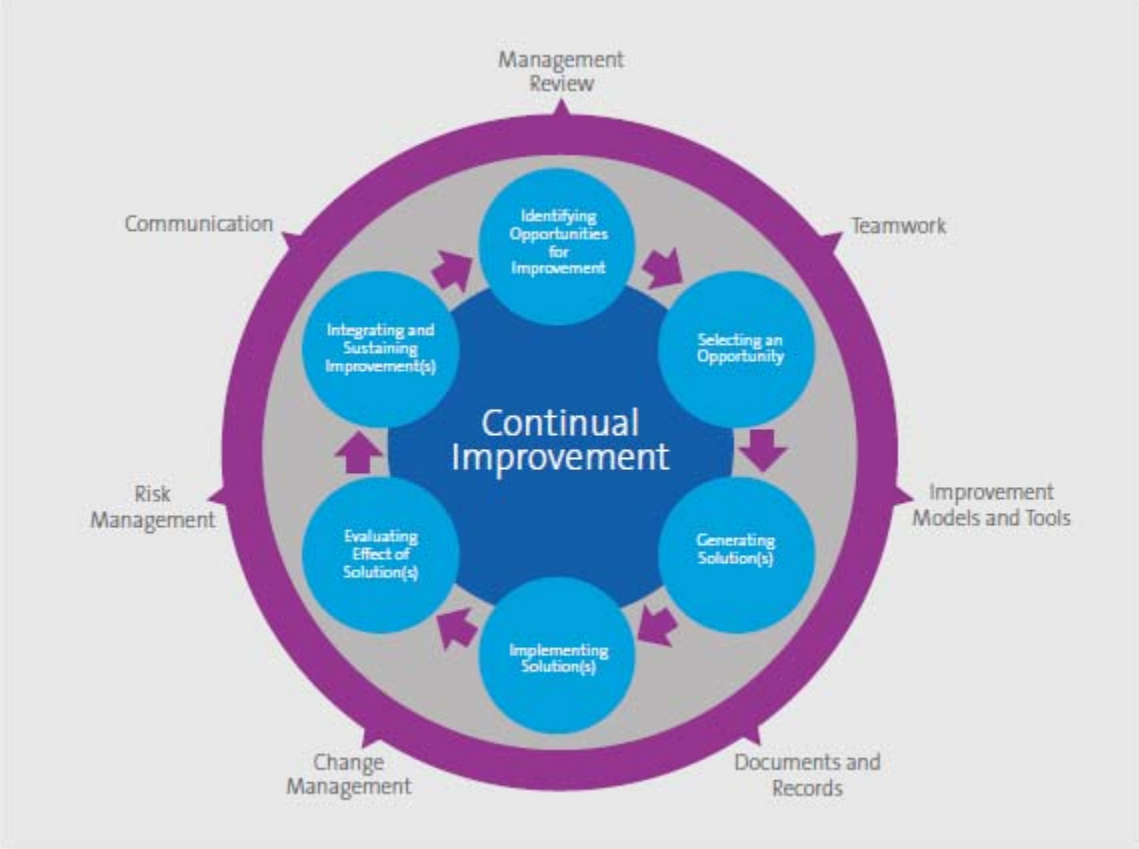


Figure 5. CI Cycle

Sometimes, for aesthetic purposes, abbreviations are not used within figures. For example, "continual improvement" is spelled out within Figure 5. Because "CI" does not appear in the figure itself, and because it has already been spelled out previously in the guideline, it can be abbreviated in the figure title without being included in a Figure 5 abbreviations list.

1.6 Abbreviations in Appendixes

As noted in Part II, Section 1.1, abbreviations are newly introduced (ie, spelled out on first mention, followed by the abbreviation in parentheses) in each appendix. To facilitate this practice, each appendix begins with its own abbreviations list. The abbreviations list is arranged alphabetically and vertically, and the heading is formatted in bold, 12-pt. font. For example:

Abbreviations for Appendix A

AMI	analytical measuring interval
EMI	extended measuring interval
LLoD	lower limit of detection
LLoQ	lower limit of quantitation
RI	reportable interval

Source document: *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking* (EP34, 1st ed.)

This list includes all abbreviations in the appendix's main text, even those that already appear in the main document's Abbreviations and Acronyms subchapter. Abbreviations that appear solely in appendixes do not appear in the main Abbreviations and Acronyms subchapter.

If abbreviations are used within tables or figures in the appendix but not in the appendix's main text, the standard rule for abbreviations in tables and figures applies. That is, when an abbreviation is used only in a table and/or a figure (or in multiple tables and/or figures), the term remains abbreviated and is added to the abbreviations list below each applicable table and figure, but it is not added to the main abbreviations list at the beginning of the appendix.

An abbreviations list is not needed when the appendix consists solely of a table(s), figure(s), or other template-like material (eg, a form). In these cases, the abbreviations can be listed solely below the table (or form, etc.).

1.7 Preferred Formatting of Select Abbreviations

Commonly used abbreviations and terms are sometimes inconsistently formatted. To ensure consistency across the CLSI library, the formats provided in the table below should be used.

Abbreviation	Term
BSC	biological safety cabinet
BSL	biosafety level
BSL-2	biosafety level 2
BSL-3	biosafety level 3
FFPE	formalin-fixed, paraffin-embedded
FMEA	failure modes and effects analysis
GC-MS	gas chromatography–mass spectrometry
GC-MS/MS	gas chromatography–tandem mass spectrometry
LC-MS	liquid chromatography–mass spectrometry
LC-MS/MS	liquid chromatography–tandem mass spectrometry
MALDI-TOF MS	matrix-assisted laser desorption/ionization time-of-flight mass spectrometry
NGS	next-generation sequencing
NWT	non-wild-type (always hyphenated, regardless of part of speech)
PBP2a	penicillin-binding protein 2a
PK-PD	pharmacokinetic-pharmacodynamic
SWOT	strengths, weaknesses, opportunities, and threats
WT	wild-type (always hyphenated, regardless of part of speech)

2 Addresses

Cities, states, and countries (with the exception of "USA") are spelled out in full. "USA" should always be included in US addresses.

3 Age and Sex Referents

The table below includes the preferred terminology for specific age groups.

Term	Age
Newborn	Birth to 28 days
Infant	29 days to 1 year
Child[a]	1 year to 12 years
Adolescent	13 to 17 years
Adult	≥18 years

[a] Sometimes, "children" may be used broadly to designate persons from birth to 12 years of age.

Age groups are most commonly used in CLSI newborn screening (NBS) documents. The following paragraph, which allows deviations from AMA style with the use of "baby" and the revised ages for "newborn" and "infant" (reflected in the table above), appears in the Note on Terminology of all NBS documents:

> In CLSI NBS documents, the terms *newborn* and *infant* have distinct meanings. *Newborn* indicates a person from birth to 28 days old, and *infant* indicates a person from 29 days to 1 year old. In situations that could apply to both (or either) age groups, the term *baby* is used.

Ages of persons are always represented with numerals (see Part II, Section 20). A mixed fraction is permitted to convey the age of an individual person (eg, 6½). When age is conveyed as a mean of multiple persons, the decimal form is used (eg, 6.5). For more information on the use of decimals vs fractions, see Section 20.1.2.

When a group of adults is differentiated by sex, *men* and *women* is preferred over *male* and *female.* However, when a group comprises children and adults of both sexes, the use of *male* and *female* is appropriate. Otherwise, *male* and *female* should only be used as adjectives.

4 Apostrophe

An apostrophe is used to show the possessive case of a noun (eg, an hour's wait). It is not used to form the plural of an abbreviation or of dates (eg, EEGs, IQs, the 1980s).

CLSI style uses the smart apostrophe (eg, an hour's wait), not the straight apostrophe (eg, an hour's wait). The same style applies to quotation marks (see Part II, Section 23).

The prime symbol (′), rather than an apostrophe or a single quotation mark, is used to indicate "prime" (eg, 5′ end).

5 Capitalization

The rules for capitalization in documents are conventional (eg, proper nouns, geographical names, sociocultural designations, proprietary names, the names of a genus when used in the singular [but not the species], specific designators [eg, Figure 1], major words in a title).

CLSI style defines "major words in a title" as:

- All words of four or more letters, including prepositions and adverbs
- All verbs
- All words that carry significant weight, even without meeting the criteria cited in the first two bullets (eg, "New," "Old")

NOTE: Major words are not capitalized when they appear parenthetically in table column headings.

When hyphenated words appear in titles, the second word is capitalized only when it is:

- A noun
- An adjective that could stand on its own (eg, not "-based"; see below)
- As important as the first word

Common examples in CLSI chapter or subchapter titles are:

- **-Specific** (eg, Allergen-Specific): do capitalize "Specific"
- **-based** (eg, DNA-based): do not capitalize "based"

6 CLSI Document Citations

The suggested citation for CLSI documents appears on each document's Copyright page. CLSI document citations in the References section must match the suggested citation provided on the most current edition of that document. The two citation formats are shown in the table below.

Published Before January 1, 2015	Published After January 1, 2015
CLSI. *Document Title.* CLSI document [Code]. Wayne, PA: Clinical and Laboratory Standards Institute; [Year].	CLSI. *Document Title.* [1st, 2nd, etc.] ed. CLSI standard/guideline/report/supplement [Code]. Wayne, PA: Clinical and Laboratory Standards Institute; [Year].

The table below shows how to refer to CLSI documents within the text.

Referring to a Different CLSI Document	Referring to the CLSI Document Being Written (eg, referring to QMS01 within QMS01)
Precede the main document code[a] with "CLSI document,[b]" eg: • In CLSI document EP17,[12] detection limits are…	When using the document code, use the main document code,[a,c] eg: • In NBS02, long-term follow-up… The document may also be referred to by its specific document type,[d] eg: • This guideline provides recommendations for laboratories on the total testing process for…

[a] Only the main document code is used. The approval level or edition number is not included.
[b] The phrase "CLSI document" is used, rather than "CLSI standard," "CLSI guideline," etc.
[c] When the document is self-referring, the code is not preceded by "CLSI document."
[d] Standards, guidelines, and reports use "this standard," "this guideline," and "this report," respectively. Supplements use "this document."

7 Comma

CLSI uses the serial comma, ie, a comma is used after each word or phrase in a series, including the final one (eg, "red, white, and blue").

Per AMA style, commas are not used to indicate thousands. In numbers of four digits, no space is used. In numbers in tens of thousands and higher, a thin space is placed after every three numerals to the left of a decimal point:

1000
10 000
100 000
1 000 000

NOTE 1: A thin space is half the font size (rounded up to the nearest whole number) of the current font size. In CLSI documents, which use an 11-pt. font, a thin space is a 6-pt. space.

NOTE 2: Monetary amounts are exempt from this rule, and commas are used instead of a thin space.

A correctly placed comma appears inside quotation marks. The table below provides an example of correct and incorrect formatting.

Correct	Incorrect
As opposed to the phrase “the laboratory needs to,” which explains an action directly related to fulfilling requirements of international, national, and accreditation organizations, the phrase “the laboratory should” describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement.	As opposed to the phrase “the laboratory needs to”, which explains an action directly related to fulfilling requirements of international, national, and accreditation organizations, the phrase “the laboratory should” describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement.

8 Date and Time Formats

Calendar dates adhere to the “DD [Month] YYYY” format, eg, 11 December 2018.

Measures of time adhere to conventional format (ie, AM and PM) rather than military time. However, military time may be used in figures that depict a 24-hour experiment or to convey times of drug dosing. The table below includes appropriate time formats.

Time or Time Frame	Formatting Example
Morning	10:30 AM
Afternoon or evening	12:00 PM
Range spanning morning to afternoon	10:30 AM–12:00 PM Eastern[a] (US) Time
Range not spanning morning to afternoon	10:30–11:00 AM Eastern[a] (US) Time

[a] Substitute “Central,” “Mountain,” or “Pacific,” as applicable.

9 Drug Names

A drug should be referred to by its International Nonproprietary Name (INN). In most cases, this name is the same as its US Adopted Name (USAN). The table below includes drugs for which the USAN differs from the INN:

INN	USAN
chlorphenamine	chlorpheniramine
glibenclamide	glyburide
isoprenaline	isoproterenol
moracizine	moricizine
orciprenaline	metaproterenol
paracetamol	acetaminophen
pethidine	meperidine
retigabine	ezogabine
rifampicin	rifampin
salbutamol	albuterol
torasemide	torsemide

AMA style recommends using the name that would be more familiar to the audience. For example, CLSI microbiology documents typically use the USAN “rifampin,” not the INN “rifampicin.”

However, in cases in which international recognition is essential, both names should be provided. For example, it is prudent to use “acetaminophen (paracetamol),” because this drug can be highly toxic. The more commonly recognized name should appear first, followed by the other name in parentheses. The

chairholder should determine which order is appropriate, and this order should be applied throughout the document.

10 Elements and Compounds

In general, the names of chemical elements and compounds should be expanded in the text at first mention, with the abbreviation following in parentheses. For particularly complicated expansions, the opposite format may be adopted (ie, abbreviation first, followed by expansion in parentheses).

Common elements and compounds, such as oxygen and water, respectively, are usually easier to express and understand than their chemical formulas. These should remain expanded throughout the document, unless the context necessitates including the chemical formulas.

In general, the document development group should consider the project's subject matter, technical level, and audience when deciding which elements and compounds to expand and abbreviate. Uncommon abbreviations for elements and compounds may be included in abbreviations lists if the audience might not easily recognize them.

11 Emphasis

In general, **bold** is used for emphasis within the text, for the following reasons:

- Underlining could be confused with a hyperlink.
- CAPITALIZING is often difficult to read and could be mistaken for an abbreviation.
- *Italicization* is reserved for publication titles.

NOTE 1: The Note on Terminology uses italicization (eg, when emphasizing different important terms), based on precedent.

NOTE 2: Punctuation following bold, underlined, or italicized text should also be bold, underlined, or italicized, respectively (except for parentheses, if the text immediately following the end parenthesis is not bold, underlined, or italicized).

12 Equations and Symbols

12.1 Equation Formatting

Equations are numbered sequentially throughout the document. When an equation is mentioned in the text, "equation" is lowercased and the equation appears in parentheses, eg, "see equation (1)." Equation numbers are:

- Placed flush right and aligned with each equation
- Contained within parentheses

General guidelines for equations include:

- Do not use a multiplication dot before a parenthesis or bracket, because parentheses and brackets already signify multiplication.

- When an equation uses both parentheses and brackets, place brackets outside parentheses.

- If possible, avoid placing a reference at the end of an equation, because it could be mistaken for an exponent.

In general, equations should be formatted in Equation Editor or MathType, using Cambria 14-pt. font. The guidelines for use of these programs are:

- Use Equation Editor or MathType for numbered equations that use symbols (eg, *β,* Σ).
- Use regular text for numbered equations that do not use symbols.

An example of a properly formatted equation is:

$$N \geq 2[\frac{(z_{1-\alpha/2} + z_{1-\beta})\sigma}{\delta}]^2 \quad (1)$$

12.2 Significant Digits

According to AMA style, numbers should be rounded to reflect instrument or measurement precision. For example, for a scale accurate to 0.1 kg, the weight should be expressed as 75.2 kg, not 75.23 kg.

Numbers resulting from calculations (eg, means, standard deviations) should be expressed to no more than one significant digit beyond the instrument's accuracy. For example, when one is calculating the mean of individuals weighed on a scale accurate to 0.1 kg, the weight should be expressed as 62.45 kg.

12.3 Italicization

12.3.1 Variables

Per Dorland's, a variable is "a symbol that represents an arbitrary number or an arbitrary element of a set." Variables are:

- Italicized when used in numbered equations

- Not italicized when used within text
  - This includes variables used within text that refer specifically to a numbered equation (eg, an excerpt from a numbered equation is repeated with the text).

It is sometimes difficult to discern whether a word in an equation is functioning as a variable. The following guidance is provided:

- When a word provides a full description of the variable, it does not need to be italicized, eg:

$$\text{Weight (mg)} = \frac{\text{Volume (mL)} \cdot \text{Concentration (µg/mL)}}{\text{Assay Potency (µg/mg)}}$$

- When a word is attached to an italicized variable, it should be italicized, eg, "residual" in the example below:

$$\%\ CV_{residual} = \frac{CV_{rep}}{\sqrt{n_{rep}}} = \frac{5\%}{\sqrt{5}} = 2.2\%$$

12.3.2 Symbols

Symbols are italicized when they appear in:

- Numbered equations
  - An exception is a capitalized sigma (Σ), which is not italicized.
  - When "% CV" is used in an equation, the % symbol should be regular text, and "CV" should be italicized.

- The Symbols subchapter

- Symbols lists beneath tables or figures

Symbols are not italicized when they are used in text, including symbols used within tables or figures. However, per the list above, it is appropriate to italicize the symbols in the Symbols lists beneath tables or figures.

As noted in Section 1, some symbols are also used within the text as abbreviations, eg, "SD" for standard deviation. In instances of overlap (ie, symbol appears in equations and also appears in the text as an abbreviation), the symbol appears solely in the Abbreviations and Acronyms subchapter (not the Symbols subchapter), where it is not italicized.

12.3.3 Numerals

Numerals in equations should not be italicized, even when surrounding symbols or words are italicized, eg, $X_2,TRUE-X_1,TRUE$.

12.3.4 Measurement

In the construction "*i*th," the first letter is italicized and a hyphen is not used after it, eg, *i*th, *j*th, *k*th. This is the only instance in which a variable is italicized within text.

12.3.5 "N" and "n"

"N" and "n" are italicized in equations. They are not italicized within text.

12.3.6 *P* value

"*P*" is italicized and a hyphen is not used after it. "Value" is included after "*P,*" except when "*P*" is followed by an equal sign or a greater-than or less-than symbol, eg:

- "Historically, the use of regression slope *P* value in the first step…"
- "A regression slope $P > 0.05$ can result…"

12.4 Subscripts

The default style for subscripted words, symbols, or numerals is to use the Microsoft Word® subscripting feature, eg, x_i. Sometimes, for legibility, subscripts are lowered by 3 points instead of using subscripting, eg, x_i. This decision is at the discretion of the project manager and/or chairholder.

12.5 Punctuation

Punctuation after a set-off equation (ie, a numbered equation broken out from a sentence) is helpful to clarify its place within the sentence. When appropriate, equations should be preceded and followed by punctuation, as in the example below. When an equation represents the end of a sentence, it is not necessary to include a period at the end.

The combined uncertainty would be:

$$u_c(156.0_{\text{Total}}) = \sqrt{\left(\frac{156.1 - 155.9}{2 \times \sqrt{3}}\right)^2 + 0.013^2} = \sqrt{0.0557^2 + 0.013^2} = 0.059\ \text{g}, \quad (1)$$

and the linearity and repeatability characteristics of the balance begin to have a small influence.

Source document: *Expression of Measurement Uncertainty in Laboratory Medicine; Approved Guideline* (EP29-A)

12.6 Preferred Symbols and Greek Letters

The table below includes preferred symbols, their character codes in Word (when applicable), and their name and purpose in CLSI documents. Except for those available on the keyboard ("slash," "greater than," "less than"), these symbols should be inserted using Word's Symbols list rather than by other means (eg, using the Symbols font).

Symbol (Character Code)	Name and Purpose
± (00B1)	**stacked plus-minus sign** – use this symbol to indicate addition or subtraction (eg, ±2.5%).
− (2212)	**minus sign** – use this symbol rather than an en dash (–) or hyphen (-) to indicate subtraction or negation.
• (2022)	**multiplication dot**[a] – use this symbol to signify multiplication for most equations (eg, 3 kg • 9 kg).
× (00D7)	**multiplication sign** – use this symbol to express scientific notation (eg, 3×10^9), area (eg, 2 × 2 table), and magnification (eg, 40× magnification).
/	**slash** – in running text and elsewhere as appropriate (eg, for clarity), use this symbol rather than a division sign (÷) to indicate division (eg, a / b vs a ÷ b). CLSI method evaluation (EP) documents also allow for the following formats: $\frac{a}{b}$, $a\,b^{-1}$, $a \cdot b^{-1}$.
≈ (2248)	**approximately equal to**[b] – use this symbol to indicate approximation.
<	**less than**[c] – use this symbol to indicate that the value to the left of the symbol is less than the value to the right of the symbol.
>	**greater than**[c] – use this symbol to indicate that the value to the left of the symbol is greater than the value to the right of the symbol.
≤ (2264)	**less than or equal to**[c] – use this symbol to indicate that the value to the left of the symbol is less than or equal to the value to the right of the symbol.
≥ (2265)	**greater than or equal to**[c] – use this symbol to indicate that the value to the left of the symbol is greater than or equal to the value to the right of the symbol.
µ (00B5)	**micro sign** – use this symbol in units of measure, eg, "µg/mL."

[a] The multiplication dot is called "bullet" in Word.
[b] The "similar to" symbol (~) is reserved for use in geometry and calculus.
[c] The symbols "<," ">," "≤," and "≥" are used with numerals, eg, "> 20 mL." The phrases "less than (or equal to)" and "greater than (or equal to)" are used with words, eg, "less than five minutes."

NOTE: The micro sign (µ) is frequently confused with the Greek small letter mu (µ). The preferred symbols for Greek letters are provided below.

The use of Greek letters over words is preferred (eg, "α" vs "alpha" in α1-antitrypsin, "β" vs "beta" in β2-microglobulin), unless the specific context dictates otherwise. For example, when the Greek letter is part of the word, as in "betamethasone," the word is used.

The table below includes commonly used Greek letters, their character codes in Word, and their names. These symbols should be inserted using Word's Symbols list rather than by other means (eg, using the Symbols font).

Symbol (Character Code)	Name
α (03B1)	Greek small letter alpha
β (03B2)	Greek small letter beta
γ (03B3)	Greek small letter gamma
δ (03B4)	Greek small letter delta
λ (03BB)	Greek small letter lamdba
µ (03BC)	Greek small letter mu
σ (03C3)	Greek small letter sigma
Σ (03A3)	Greek capital letter sigma

12.7 Spacing

A thin space is half the font size (rounded up to the nearest whole number) of the current font size. In CLSI documents, which use an 11-pt. font, a thin space is a 6-pt. space. Thin spaces should be used before and after the following mathematical symbols:

+ (except when "+" is used to indicate "positive")
− (except when "−" is used to indicate "negative")
±
×
•
÷
/
=
≠
|
∩
∫
∏
∑

Thin spaces should be used to the right of the following mathematical symbols:

<
>
≤
≥
≈
~

Thin spaces are not used between a digit and a unit of measure.

13 Footnotes

Footnotes in the text, tables, and figures use superscripted, lowercase letters:

[a]
[b]
[c]…

Footnotes in the text are automated and inserted by CLSI staff. Footnotes in tables and figures are inserted manually (ie, not automated). Footnote letters appear after commas and periods but before semicolons and colons. When a reference and a footnote appear next to each other, they are separated by a comma, eg, "available in the literature.[10,a]"

Footnote lettering begins with "a" in each appendix. For example, if the main text includes footnotes "a," "b," and "c," the first footnote in Appendix A will be "a," not "d."

The size of the footnote within the text, table, or figure matches the font size of the preceding text. For example, a footnote "a" after 11-pt. text is also 11-pt.

Footnotes below text, tables, or figures are in 9-pt. font, and one space is inserted between the symbol and the footnote text, eg:

[a] MIC testing only; disk diffusion test unreliable.
[b] Routine testing is not necessary.

14 Gene Symbols and Sequences

Gene symbols and sequences are:

- Italicized
- Not spelled out
- Not included in abbreviations lists

At the chairholder's request and/or when a document is meant for beginners, a list explaining the symbols and sequences can be included.

CFTR is an exception to the second and third points above. It should be spelled out ("cystic fibrosis transmembrane conductance regulator") and included in abbreviation lists. When a document includes both the *CFTR* gene and CFTR protein, both are included in abbreviations lists, as shown:

CFTR cystic fibrosis transmembrane conductance regulator (gene)
CFTR cystic fibrosis transmembrane conductance regulator (protein)

15 Headers, Footers, and Margins

One-inch margins are required on all four sides (inside [binding edge], outside, top, bottom). Insufficient margins are most frequently found on landscaped pages. Committees are encouraged to keep these requirements in mind when drafting their documents, to avoid editing delays.

16 Hyperlinks

Per CLSI's trade name policy (see Part I, Section 5.2), Web links to commercial websites are not permitted. However, links to appropriate organizations or resources are permitted. Links should adhere to the following formatting rules:

- Links should include "http" or "https."

- Links should not be split across two lines of text.

- A link that is part of a sentence should be preceded by "at," eg, "Information is available at https://www.clsi.org."

- A link that is part of a bullet should include the organization or resource name, followed by a colon and the link, eg, "CDC, Office of Infectious Diseases: https://www.cdc.gov/oid/."

- The links need to display the full Web address so that both print and Web users can locate the website. Eg, “Information is available here,” with “here” hyperlinked, is not acceptable.

17 Hyphen

A hyphen is used to join two (or more) words when they are used together as an adjective that **precedes** the noun it modifies. When the term is used **after** the noun, however, a hyphen is not used. For example:

- This guideline discusses point-of-care testing.
- This guideline discusses testing performed at the point of care.

The table below includes other common examples of hyphenation use.

Hyphenation Scenario	Example
Units of measure when used as adjectives	100-µL pipette
Area and volume dimensions used as adjectives	16- × 125-mm tube
Two-part compound adjective	low- to moderate-risk cases

Prefixes such as “anti,” “ante,” “bi,” “co,” “contra,” “counter,” “intra,” “non,” “pre,” “post,” “re,” and “semi” are normally not joined to root words using hyphens. They are joined directly to the root word, eg, “preexamination.” The exceptions that apply to prefixes are:

- To avoid awkward combinations of letters, a hyphen is used when there are double consonants (eg, post-transplant) or in some cases of double vowel constructions (eg, intra-abdominal).

- A hyphen is inserted after a prefix when it is separated from its root word by a conjunction (eg, pre- and postexamination).

- All words that would otherwise create an entirely different word without inclusion of the hyphen are hyphenated. For example, when “re-creation” is intended, “recreation” is not used.

- A hyphen is inserted after all prefixes preceding a(n):
  - Proper noun
  - Capitalized word
  - Number (eg, post-2006 conference)
  - Abbreviation (eg, non-CLSI document)

Exceptions other than those involving prefixes are:

- Combinations of words that are read together as a unit are not hyphenated, eg:
  - Amino acid levels
  - Bone marrow biopsy
  - Open heart surgery
  - Birth control methods
  - Sodium chloride solution

- Latin phrases are not hyphenated, eg:
  - *In vitro* diagnostic device
  - *In vivo* conditions

- For adjectives that are made up of more than one word, an en dash is used instead of a hyphen, eg:
  - Health care–acquired infection
    - The use of the en dash conveys that "acquired" applies to "health care" as a unit. If a hyphen were used instead, the formatting would only be conveying a "care-acquired infection."

NOTE: Adverbs ending in "ly" are not combined with the adjectives they modify (eg, "a highly susceptible microorganism").

18 Latin Terms in Microbiology

The table below shows the appropriate formatting for Latin terms (used primarily in microbiology documents), along with examples.

Usage	Style	Example
Families	Italicized	*Enterobacteriaceae*
Genus and species together, first mention	Italicized, and spelled out in full	*Streptococcus pyogenes*
Genus and species together, after first mention	Italicized, using first initial of genus, followed by a period	*S. pyogenes*
Genus alone	Capitalized, italicized	*Streptococcus*
Adjectival form of genus	Lowercased, not italicized	streptococcal
Plural form of genus	Lowercased, not italicized	streptococci

19 Lists

Lists may be bulleted or numbered. Bullets are used for nonprocedural items, and numbers are used for procedural items. Both lists should be preceded by lead-in text that leads directly into the first sentence or phrase of the listed item. Anticipatory phrases such as "as follows" and "the following" are generally not needed in the lead-in text. However, when the context calls for such phrasing, a noun should be inserted after "the following."

19.1 Bulleted Lists

The use of lead-in text sometimes results in a bulleted item being phrased as an imperative sentence, which is appropriate. Listed items are the only context in which imperatives are permitted. By using this formatting, the lead-in text + the listed text = a declarative sentence. An example is provided below.

Users will learn how to:

- Describe the difference between TAE and total error, which includes pre- and postexamination (pre- and postanalytical) components, and why EP21 focuses only on the former.
- Explain the various available sources for establishing allowable total error (ATE) goals, also called total error allowable.
- Discuss considerations for setting ATE limits, including selection of appropriate subintervals.
- Design an experiment to measure TAE and determine whether performance goals were met.

Source document: *Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures* (EP21, 2nd ed.)

Bulleted lists may also lead into complete sentences that are declarative on their own (ie, independent of the lead-in text). An example is provided below.

Features and practices of testing in the pain management setting include:

- Because of the potential for patient misuse, diversion, and addiction, the decision to test may be made as part of a clinic's protocol, a patient contract, and/or state board regulations.
- Ideally, results expected for a compliant patient point to the use of prescribed medications and the absence of any other drugs.
- Interpretation is complicated because of the limitations of urine as a specimen, variations in individual metabolic profiles, and differences in analytical techniques.

Source document: *Laboratory Support for Pain Management Programs* (C63, 1st ed.)

Bulleted lists may also lead into single words or incomplete sentences (eg, phrases, gerunds). An example is provided below.

Laboratory management needs to ensure that processes and procedures for managing personnel are effectively implemented to support the:

- Laboratory QMS
- Overall quality and service goals of the laboratory
- Laboratory path of workflow

Source document: *Laboratory Personnel Management* (QMS16, 1st ed.)

When lead-in text leads into a main topic phrase or sentence that is followed by explanatory text, there are two main formats. An example is provided below.

Available immunoassay techniques for urine drug testing include:

- **Competitive homogenous immunoassays:** These techniques are based on the principle of competitive binding in which the drug/and or metabolite(s)…

or

- **Competitive homogenous immunoassays**
  - These techniques are based on the principle of competitive binding in which the drug/and or metabolite(s)…

Source document: *Laboratory Support for Pain Management Programs* (C63, 1st ed.)

In this format, the main topic sentence may be an imperative sentence. However, the explanatory text must be a declarative sentence(s).

19.1.1 Punctuation

As shown in the examples above, bullets that are complete sentences have periods on the end, while bullets that are single words or phrases do not have periods. A period is the only punctuation that is used (eg, commas and semicolons are not used).

19.1.2 Structure

All bullets begin with a capital letter. The hierarchy of symbols in a bulleted list is:

- Main bullet
  - Second-level bullet
    - Third-level bullet
      - Fourth-level bullet
        - Fifth-level bullet

NOTE: Each symbol aligns directly with the text of the previous level. However, when tables and figures are included in bulleted lists, they are aligned with the left margin, even when the bullet level with which they are associated is indented.

When each main bullet takes up only one line of space and no sub-bullets exist, no extra return appears between each bullet. However, when at least one main bullet takes up more than one line of space, an extra return appears between each bullet. **NOTE:** Inserting extra returns when second-, third-, and fourth-level sub-bullets are used is determined on a case-by-case basis, according to the number of sub-bullets and the overall length of the list.

Bulleted lists should adhere to parallel structure, ie, all same-level bullets are complete sentences or all same-level bullets are fragments. For example, all main bullets are fragments while all second-level bullets are complete sentences. (The formats provided in the second C63 example in Part II, Section 19.1 are useful for upholding this style.) An example is provided below.

Second, in addition to one of the criteria above, a CF diagnosis involves the presence of one of the following:

- An increased sweat chloride concentration by pilocarpine iontophoresis
  - This must occur on two or more occasions in the absence of a positive newborn screening test or prenatal testing that identifies two CF-causing mutations.
- Identification of two CF-causing mutations
- Demonstration of abnormal nasal epithelial or intestinal mucosal ion transport

Source document: *Sweat Testing: Specimen Collection and Quantitative Chloride Analysis* (C34, 4th ed.)

In the example above, all the main bullets are fragments. The complete sentence that appears in the first bullet appears as a sub-bullet, to maintain parallel structure across bullets of the same level.

When no reasonable means exist to create parallel structure across bullets of the same level (ie, without distorting the meaning), and at least one of the bullets is a complete sentence, a period should be inserted on the end of each bullet.

19.2 Numbered Lists

Numbered lists are used for procedures, and each item is phrased as an imperative sentence. An example is provided below.

If the reason for an out-of-range result can be identified and easily corrected:

1. Correct the problem.
2. Document the reason.
3. Retest the QC strain on the day the error is observed.

Source document: *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically* (M07, 11th ed.)

When a numbered list contains subitems, the bullet symbols are used (see Part II, Section 19.1.2), rather than letters or Roman numerals. The numbers and bullets should use Word's automated list formatting. For example:

1. Step 1
   - Subitem 1
   - Subitem 2
2. Step 2
3. Step 3

When a subitem needs to be referred to later in the text (eg, "see step 3a"), it is permissible to use letters instead of the bullet symbol. (In this case, the numbering can be manual rather than automated.) This option should be used sparingly and only as necessary, to avoid discrepant formatting.

Procedures may also be displayed as step-action tables. An example is provided below.

The steps for preparing the inoculum are listed below.

Step	Action	Comment
1	Select colonies from growth on a supplemented Brucella blood agar plate that is 24–48 hours old.	The plate should not remain in an aerobic atmosphere for more than 30 minutes before making the suspension.
2	Lightly touch portions of 5 or more well-isolated colonies of similar morphology.	
3	Suspend the growth directly into Brucella broth or other reduced clear broth to achieve a turbidity equivalent to a 0.5 McFarland standard.	See Appendix B.

Source document: *Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria* (M11, 9th ed.)

Although step-action tables do not need titles, they follow standard table alignment and formatting style (see Part II, Section 27.1), and they contain abbreviations lists, when necessary (see Part II, Section 1.5).

19.2.1 Punctuation

Because each numbered item is phrased as an imperative sentence, a period is used at the end of each item.

19.2.2 Structure

The guidance in Part II, Section 19.1.2 regarding returns between list items, alignment of tables and figures with the left margin, and the use of parallel structure applies to numbered lists as well.

20 Numbers

The table below provides the appropriate context for the use of words vs numerals.

Context	Word	Numeral
Ages (of people)		X
One through nine[a]	X	
10 and up[b]		X
Ordinals: first through ninth	X	
Ordinals: 10th and above		X
Percentages		X
Rounded large numbers (eg, 8 million)		X
Temperature (eg, 17°C)		X
Numbers with units of measure (eg, 4 µg/mL)		X
Numbers in tables and figures[c] (eg, breakpoints in CLSI document M100)		X

[a] Including “twofold,” “threefold,” etc.
[b] Including “10-fold,” “11-fold,” etc.
[c] Not including table or figure footnotes, ie, “1” through “9” are only used in the table or figure itself.

20.1 Special Circumstances

20.1.1 Numbers Beginning a Sentence

Numbers are always spelled out at the beginning of sentences, titles, subtitles, or headings. The table below provides correct and incorrect examples.

Correct	Incorrect
Thirty-five employees attended the staff meeting.	35 employees attended the staff meeting.
Seventy-two percent of volunteers responded to the survey.	72% of volunteers responded to the survey.

20.1.2 Decimals and Fractions

Common fractions are expressed as hyphenated words, eg, three-fourths, two-thirds. Mixed fractions that include common fractions may be expressed as numerals, eg, 5¼. Mixed fractions typically involve time (eg, 3½ hours) and are used for less precise measurements that do not necessitate use of a decimal.

Decimals are used when a fraction is given with a unit of measure to reflect the measurement precision (eg, 0.5 mL). A zero is placed before the decimal point.

20.2 Spelling Out Numbers

Hyphens are used for "twenty-one" through "ninety-nine."

Commas or "and" are not used when numbers greater than 100 are spelled out, eg, "one hundred thirty-two."

21 Per

A slash is used to indicate "per" in units of measure, eg, "µg/mL" for "micrograms per milliliter."

22 Percentages

22.1 Numerals vs Words

When a percentage is represented with a numeral, the percent symbol (%) is used (eg, 50%).

However, as noted in Part II, Section 20.1.1, when the percentage begins a sentence, title, subtitle, or heading, the word forms are used in place of the numeral and percent symbol. For example, "Fifty percent of the sample population were women."

22.2 Ranges

In percentage ranges, the symbol is used after the first and second value, and the word "to" is used to separate the range (rather than an en dash), eg, "…and 12% to 14% were between 18 and 24 years old." This format applies to text, tables, and figures.

23 Periods and Quotation Marks

Periods are not used in a person's credentials in the author or committee lists (eg, John Smith, MD). For more information on the author and committee lists, see Part I, Sections 2.1 and 2.2.

A correctly placed period appears inside quotation marks. CLSI style uses smart quotation marks, not straight quotation marks. The same style applies to apostrophes (see Part II, Section 4). The table below provides examples of correct and incorrect formatting.

Correct	Incorrect
All patient and laboratory specimens are treated as infectious and handled according to "standard precautions."	All patient and laboratory specimens are treated as infectious and handled according to "standard precautions".
In flow charts, a diamond includes a question with alternative "Yes" and "No" responses.	In flow charts, a diamond includes a question with alternative "Yes" and "No" responses.

24 Preferred Spellings and Usages

24.1 Spelling of Commonly Used Terms and Phrases

The table below provides the preferred spelling of commonly used terms and phrases. Clarifications regarding parts of speech and related topics are included as necessary.

Term or Phrase	Part of Speech	Comments
0.5 McFarland turbidity standard		Also applies to "1 McFarland turbidity standard," etc.
acknowledgment		
airborne		
airflow		
aliquotted		
aliquotting		
analytical[a]		
anatomical[a]		The use of "anatomical" is preferred, except when it precedes "pathology," ie, "anatomic pathology."
appendixes		
back pressure		
backflow		
bar code	Noun, verb	
bar-code	Adjective	
benchmark		
bloodborne		
bloodstream		
brainstem		
carryover[b]	Noun	
cleanup[b]	Adjective, noun	
CO-oximeter		
CO-oximetry		

Term or Phrase	Part of Speech	Comments
coverslip		
cross section	Noun	
cross-section	Adjective, verb	
cut off	Verb	
cutoff	Adjective, noun	
database		
dataset		
disk		
eg		Per AMA style, “eg” does not use periods.
e-mail		
end point	Noun	
end-point	Adjective	
end product		
end user	Noun	
end-user	Adjective	
eyepiece		
expiry date		For the purposes of QMS documents, the phrase “expiry date” (not “expiration date”) should be used. For non-QMS documents, one version (“expiry date” or “expiration date”) should be used consistently throughout the document.
extralabel	Adjective	Not “extra-label.”
fingerstick		
flow chart		
follow up	Verb	
follow-up[b]	Adjective, noun	
foodborne		
gram-positive		Not “Gram-positive.”
gram-negative		Not “Gram-negative.”
Gram stain		Not “gram stain.”
Haemophilus test medium		
health care	Adjective, noun	
ie		Per AMA style, “ie” does not use periods.
indices		Not “indexes.”
infectious diseases	Adjective, noun	The plural “diseases” is used for both the noun and adjective form, eg, “infectious diseases specialist.”
Internet		Not “internet.”
judgment		
laboratory		Not “lab.”
leakproof		
Levey-Jennings		Not “Levy.”
lifecycle		
low birth weight	Adjective, noun	Per Dorland’s, hyphens are not used for the adjective form.
matrixes		

Term or Phrase	Part of Speech	Comments
mecA		
mm Hg		
mold		Not “mould.”
mucus	Noun	
mucous	Adjective	
needlestick		
next-generation sequencing		
non-wild-type	Adjective, noun	“Non-wild-type” is always hyphenated, regardless of part of speech.
number		Not “No.”
numerical[a]		
offline		
off-site		
online		
on-site		
pairwise		
payer		Not “payor,” eg “insurance companies and government payers.”
pCO_2		
Petri plate		Not “Petri dish.”
pipette		
pipetting		
pipettor		
pO_2		
President-Elect		
RCF		Not “rcf.”
recordkeeping		
RPM		Not “rpm.”
scatterplot		
set up	Verb	
setup[b]	Adjective, noun	
sex		Not “gender.”
start up	Verb	
start-up[b]	Adjective, noun	
stepwise		
susceptible-dose dependent	Adjective, noun	
Taq polymerase		
time frame		
time point		
troubleshooting		
turnaround		
unit-use	Adjective	
United States	Noun	
US	Adjective	
USA		“USA” is only used in addresses.
Vice-Chairholder		

Term or Phrase	Part of Speech	Comments
vs		Not “vs.” or “versus”; use “*v*” for legal references.
Web		When referring to “World Wide Web.”
Web page		
website		Not “Website” or “web site.”
wild-type	Adjective, noun	“Wild-type” is always hyphenated, regardless of part of speech.
workflow		
workload		
workstation		
wristband		
x-axis		Not “X-axis.”
x-ray		Not “X-ray.”
y-axis		Not “Y-axis.”

[a] In general, the use of “-ical” rather than “-ic” as a suffix is preferred, eg, “analytical” and “numerical.” However, for some words, only “-ic” is correct, eg, “pathogenic.” Per AMA style, “the important guideline is that the terms must be consistent throughout an article or chapter, and preferably throughout the entire publication.”

[b] The decision to use a hyphen in nouns and adjectives that contain a preposition is based on *Merriam-Webster’s Collegiate Dictionary.*

For disputes or uncertainties regarding terms not included in this table, refer to the 32nd edition of *Dorland’s Illustrated Medical Dictionary.* For terms not found in *Dorland’s,* AMA style recommends *Merriam-Webster’s Collegiate Dictionary.*

24.2 Substitutions

The following table includes substitutions for commonly used terms and phrases. Clarifications are included as necessary.

Don’t Use	Do Use	Comments
Abbreviation “aka” (“also known as”)	Abbreviation “ie” (“that is”)	
Address (as a verb)	Appropriate substitute, eg: • Investigate • Cover • Discuss • Manage • Handle • Include • Explain • Demonstrate • Recognize	
“Allow” or “permit” (when “make possible” is meant)	Enable	
As (when “because” is meant)	Because	

Don't Use	Do Use	Comments
"Body" or "bodies" (when referring to organizations)	Organization(s)	
Clinical laboratory	Medical laboratory	"Medical" refers to the medical laboratory setting. "Clinical" is reserved for the patient-centric clinical care setting.
Due to (when "because of" is meant)	Because of	"Due to" is synonymous with "caused by."
Employ	Use	"Employ" is appropriate in the context of workplace employment (eg, employer, employee).
Execute	Implement	
Further	Additional	This change should be made when possible, eg, "for additional information," in place of "for further information."
Gold standard	A more precise term, eg, "reference standard."	
Impact	Affect (verb); effect (noun)	This rule does not preclude the use of "effect" in its verb form, ie, "to bring about."
Local, state, and federal requirements	Regulatory and accreditation requirements	
Mutant	Variant	This substitution applies in the context of gene alterations.
Neonate	Newborn	"Neonate" is appropriate in accepted abbreviations, eg, "neonatal intensive care unit."
Optical density	Absorbance	Per the Harmonized Terminology Database, "optical density" is a deprecated term, ie, it is no longer acceptable to use in the international standards community.
Prior to	Before	
"Require," unless the statement directly reflects a regulatory, accreditation, performance, product, or organizational requirement or a requirement or specification identified in an approved documentary standard	Need(s), necessitate(s), or an appropriate synonym	See Part I, Section 3 for more information on "needs to," "must," "require," and "should."
Since	Because	"Since" is appropriate when referring to a time point, eg, "Since the guideline's original publication…"

Don't Use	Do Use	Comments
Utilization, utilize	Use	"Utilize" and "utilization" are appropriate in the context of "blood utilization," "laboratory utilization," and "test utilization."
Various terms for one who works in a laboratory, eg: • Laboratory technician • Laboratory technologist • Medical laboratory scientist • Medical technician • Medical technologist	Laboratorian	
Via	Appropriate substitute, eg: • Through • Using	
Where	In which, for which	"Where" is still appropriate to use in the proper context (ie, referring to location).
While (when "although" is meant)	Although	

24.3 Commonly Confused Terms and Phrases

The following table includes commonly confused terms and phrases and the appropriate usage for each. Examples are included.

Term or Phrase	Usage	Example
Compared to[a]	Use "compared to" when highlighting the similarities between (ie, comparing) two things.	"The human heart can be compared to a pump."
Compared with[a]	Use "compared with" when highlighting the differences between (ie, contrasting) two things.	"Studies on *Bacteroides* spp. bacteremia clearly demonstrate increased mortality and microbiological persistence for patients receiving ineffective therapy compared with those receiving effective therapy."

Term or Phrase	Usage	Example
Continual	Use “continual” to describe activity that is frequent and steady but contains pauses.	“CLSI continually publishes standards and guidelines.” In this sentence, “continually” is appropriate because CLSI steadily publishes new documents throughout each year, but it does not publish new documents all day, every day.
Continuous	Use “continuous” to describe activity that never ceases.	“Blood flows continuously throughout the cardiovascular system.” In this sentence, “continuously” is appropriate because blood flow is constant and unceasing.
Dose	Use “dose” to refer to a quantity to be administered at one time or the total quantity administered during a specified period.	“A 400-mg dose of acetaminophen (paracetamol).”
Dosage	Use “dosage” to refer to the regulated administration of individual doses; it is often followed by “regimen.”	“A dosage regimen of 400 mg of acetaminophen (paracetamol) every four hours.”
eg	Use “eg” to mean “for example” or “such as”; it is used to introduce a noncomprehensive list.	“Examination results and related information need to be secured (eg, by encryption) and accessible only by authorized personnel.”
ie	Use “ie” to mean “that is” or “also known as”; it is used to introduce a comprehensive list.	“An N-95 respirator (ie, one with a minimum 95% efficiency rating) needs to be worn.”
If	Use “if” to express possibility.	“If the document is submitted for editing today, the editors will review the comments this afternoon.”
When	Use “when” to express a definitive outcome.	“When final sign-off is complete, the document is approved for publication.”

Term or Phrase	Usage	Example
Staff	Use “staff” to refer to the collective group of employees who work for an organization.	“All staff members are required to sign the employee handbook.”
Personnel	Use “personnel” to refer to the collective group of employees and contractors performing work in a particular organization.	“Many regulatory agencies and accreditation organizations have established requirements for all levels of personnel, from the laboratory director, to laboratory consultants, to laboratory supervisors, and to testing personnel.”
That	Use “that” to introduce a restrictive clause. A restrictive clause is a part of the sentence that cannot be removed without changing the meaning of the sentence or altering one’s ability to fully understand it.	“The guideline that published on Friday has sold 500 copies.” In this sentence, “that published on Friday” describes the specific document that has sold 500 copies.
Which	Use “which” in nonrestrictive clauses. Nonrestrictive clauses are set off by commas and can be removed from the sentence without changing its meaning.	“CLSI staff meetings, which are held on Wednesdays, provide a forum for organizational and departmental updates.” In this sentence, “which are held on Wednesdays” gives extra information about CLSI staff meetings, but it is not essential to understanding the sentence’s main intent.

[a] “As” should not precede “compared to” or “compared with.”

24.4 Preferred Phrases in Quality Management Systems Documents

Using “provide” as an example, the following bold phrases are preferred in QMS documents:

- **Policy for** providing
- **Process to** provide
- **Procedure for** providing
- **Program to** provide
- **Means to** provide
- **Plan for** providing
- **Practice for** providing

25 Ranges

25.1 Text

To indicate ranges in the text, “to” is used, eg, “five to 10 minutes.” When ranges involve units of measure, the unit is only needed after the second value, eg, “5 to 10 mg,” not “5 mg to 10 mg.”

25.2 Tables and Figures

To indicate numerical ranges in tables and figures, an en dash (–) is used, eg, “2–8 µg/mL.” To indicate ranges within tables and figures that involve words, “to” is used, eg, “BSL-1, -2, -3 (low- to moderate-risk material).”

25.3 Special Circumstances

Percentage and temperature ranges always use the word “to,” even in tables and figures.

Page ranges in references (eg, inclusive page numbers of a journal article) use a hyphen.

26 References

References support statements of fact and should be from reputable, peer-reviewed publications, including:

- Journals
- Textbooks
- Public laws or regulations
- Published standards and guidelines

References from the following publication types are **not acceptable:**

- Abstracts
- Drafts or unpublished material, eg:
  - Items presented at a meeting but not yet published
  - Material submitted for publication but not yet accepted
  - Material accepted for publication but not yet published
- Mass circulation magazines or newspapers
- Personal communications
- Posters
- Presentations
- Sources not available in English

Publication types that are not acceptable as references may be permitted in the Additional Resources section. Additional resources are publications or related material that do not meet the criteria for references but contain helpful, related information. The CLSI Guidelines for References (https://clsi.org/media/1645/clsi-guidelines-for-references_20130916.pdf) contain more information about the purpose of references. The table below shows how references and resources are represented in the document.

Document Portions	Citation Type	Appearance
Abstract section to Conclusion chapter	References	• Called out in the text in numerical order as superscripted, Arabic numerals, using an automated system that is maintained by CLSI staff • Listed in the main References section at the beginning of the Supplemental Information chapter
	Resources	• Not required to be called out in the text, although it is permissible to direct the reader to the Additional Resources section (eg, parenthetically) • Not numbered • Listed alphabetically in the Additional Resources section, after the main References section
Appendixes **NOTE:** Each appendix has its own References and Additional Resources list, as needed.	References	• Called out in the appendix text in numerical order as superscripted, Arabic numerals (manually, not automated) • Listed in the References section at the end of each appendix (eg, "**References for Appendix A**") but before any Additional Resources section
	Resources	• Not required to be called out in the appendix text, although it is permissible to direct the reader to the Additional Resources section (eg, parenthetically) • Not numbered • Listed alphabetically in the Additional Resources section at the end of each appendix (eg, "**Additional Resources for Appendix A**")

Superscripted reference numbers appear **after** commas and periods but **before** semicolons and colons. Examples are provided in the table below.

Context	Placement	Example
Next to a comma	After the comma	See CLSI document GP41,[1] which is an essential reference to use with this standard.
Next to a period	After the period	An essential reference to use with this standard is CLSI document GP41.[1]
Next to a semicolon	Before the semicolon	See CLSI document GP41[1]; it is an essential reference to use with this standard.
Next to a colon	Before the colon	The following processes comprise the laboratory path of workflow, as described in CLSI document QMS01[1]: • Preexamination • Examination • Postexamination

26.1 Journals

A journal reference includes:

- Author(s)
- Article title
- Journal
- Publication year
- Volume number
- Issue number
- Part or supplement number, as applicable
- Inclusive page numbers

The best source for journal article information is PubMed: https://www.ncbi.nlm.nih.gov/pubmed/. Journal abbreviations are also available in the *Index Medicus:* http://www2.bg.am.poznan.pl/czasopisma/medicus.php?lang=eng.

Journal citations adhere to the following basic format:

Author(s). Title of article. *Journal abbreviation.* Year;Volume(Issue):Inclusive page numbers.

Examples of common variations are included in the table below.

Type	Example	Notes
Journal article	Schapiro JM, Gupta R, Stefansson E, Fang FC, Limaye AP. Isolation of metronidazole-resistant *Bacteroides fragilis* carrying the *nimA* nitroreductase gene from a patient in Washington State. *J Clin Microbiol.* 2004;42(9)4127-4129.	• CLSI defaults to the plain text style used by PubMed, with the exception of organisms (ie, Latin genus and species terms) and gene names. As shown in the example, this text is italicized in the References section, just as it is in the main text of CLSI documents.

Type	Example	Notes
Journal article with more than 6 authors	Perret-Liaudet A, Pelpel M, Tholance Y, et al. Risk of Alzheimer's disease biological misdiagnosis linked to cerebrospinal collection tubes. *J Alzheimers Dis.* 2012;31(1):13-20.	• When a journal article has more than 6 authors, the first 3 authors are listed, followed by the Latin phrase "et al."
Journal article whose authors are writing as part of a committee	Jones RN, Krisher K, Bird D; College of American Pathologists Microbiology Resource Committee. Results of the survey of the quality assurance for commercially prepared microbiological media: update from the College of American Pathologists Microbiology Survey Program (2001). *Arch Pathol Lab Med.* 2003;127(6):661-665.	• In the example, the semicolon after the third author indicates the authors are writing together as part of a committee. • Journal article titles are represented in lowercase letters, except when a proper noun is included, such as "College of American Pathologists Microbiology Survey Program" in the example. • In the PubMed entry for this example, a period appears after "media," and "update" is capitalized. However, CLSI style combines the two sentences by replacing the period with a colon and lowercasing the word that follows it.
Journal article from a supplement	American College of Medical Genetics, Newborn Screening Expert Group. Newborn screening: toward a uniform screening panel and system. *Genet Med.* 2006;8(suppl 1):1S-252S.	• Sometimes, PubMed uses different formats for supplement issue numbers (eg, capitalizing "Suppl" or not enclosing the information in parentheses). Regardless of what format the PubMed entry uses, CLSI style uses the format shown in the example.

26.2 Books

A book reference includes:

- Author(s) or editor(s)
  - See examples below for placement of author and editor information, which varies depending on whether a specific chapter is cited.
- Chapter title, as applicable
- Book title
- Volume number and title, as applicable
- Edition number
  - Only the second edition and above are included, ie, the first edition is not indicated.
- Place of publication

- Publisher
- Publication year
- Page numbers, as applicable
  - When a specific chapter is cited, page numbers are necessary.

Book citations adhere to the following basic format:

Author(s). *Title of Book.* Edition. Place of publication: Name of publisher; Year.

Examples of common variations are included in the table below.

Type	Example	Notes
Book with an author(s)	Sherlock S, Dooley J. *Diseases of the Liver and Biliary System.* 9th ed. Oxford, England: Blackwell Scientific Publications; 1993:523-528.	
Book with an editor(s)	Thompson LF, Willson CG, Bowden MJ, eds. *Introduction to Microlithography.* 2nd ed. Washington, DC: American Chemical Society; 1994.	
Book with more than 6 authors or editors	Jorgensen JH, Pfaller MA, Carroll KC, et al., eds. *Manual of Clinical Microbiology.* 11th ed. Washington, DC: ASM Press; 2015.	• When a book has more than 6 authors or editors, the first 3 authors or editors are listed, followed by the Latin phrase "et al."
Book with a chapter reference	Cole BR. Cystinosis and cystinuria. In: Jacobson HR, Striker GE, Klahr S, eds. *The Principles and Practice of Nephrology.* Philadelphia, PA: BC Decker Inc.; 1991:396-403.	• When the authors of a chapter are also authors or editors of the book, their names are included in both the "chapter author" and "book author/editor" locations.
Book with a volume number but no volume title	Kapoor KL. *A Textbook of Physical Chemistry: States of Matter and Ions in Solution (SI Units).* Vol. 1. 5th ed. New Delhi, India: McGraw Hill Education (India) Private Limited; 2015.	• This example also includes an edition number after the volume number.

Type	Example	Notes
Book with a volume number and title	Starr C, Taggart R, Evers C, Starr L. *Cell Biology and Genetics.* Boston, MA: Cengage Learning; 2016. *Biology: The Unity and Diversity of Life;* vol. 1. 14th ed.	• In the example, *Biology: The Unity and Diversity of Life* is the name of the series; *Cell Biology and Genetics* is the first volume. • This example also includes an edition number after the volume number. • When a book includes a volume number or other identifying number as part of its title, the volume number does not need to be repeated elsewhere in the citation.
Online book	WHO. *Technical Report on Critical Concentrations for TB Drug Susceptibility Testing of Medicines Used in the Treatment of Drug-Resistant TB.* Geneva, Switzerland: World Health Organization; 2018. http://www.who.int/tb/publications/2018WHO_technical_report_concentrations_TB_drug_susceptibility/en/. Accessed 30 October 2018.	

26.3 Documents Published by Organizations

Publications by organizations or groups for which there are no named authors adhere to a similar format as the basic book format. The organization name appears in place of the author. Well-known abbreviations may be used in place of the full organization name (eg, CDC, NIST).

Examples of common citations are included in the table below.

Organization	Example	Notes
ASTM International	*Standard Specification for Microscope Objective Thread.* E210-63. West Conshohocken, PA: ASTM International; 1963.	• The "63" in the document code is the publication year that should be included in the citation. The most current reapproval year does not appear in the citation.

Organization	Example	Notes
Bureau International des Poids et Mesures (BIPM)	Bureau International des Poids et Mesures (BIPM). *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms* (VIM, 3rd edition, JCGM 200:2012). http://www.bipm.org/en/publications/guides/vim.html. Accessed 20 August 2018.	• This citation is for the *Vocabulaire international de métrologie,* ie, the *International vocabulary of metrology.* It is commonly referred to as "the VIM" and is the main source for metrological terms cited in CLSI documents.
College of American Pathologists	CAP. *CAP Accreditation Checklists.* Northfield, IL: College of American Pathologists; published annually.	• This generic citation is used for all references to CAP checklists, ie, no specific checklist is cited.
International Organization for Standardization	ISO. *Medical laboratories – Requirements for quality and competence.* ISO 15189. Geneva, Switzerland: International Organization for Standardization; 2012.	• In general, the titles of documents published by organizations are capitalized. However, ISO document titles are lowercased. • ISO document citation information is found at https://www.iso.org.
The Joint Commission	The Joint Commission. *Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing.* Oakbrook, IL: Joint Commission Resources; published annually.	

26.4 Federal Register and Code of Federal Regulations

Examples of Federal Register and Code of Federal Regulations (CFR) citations are included in the table below.

Type	Examples	Notes
Federal Register (final rule)	71 Federal Register 32244-32263. US Department of Transportation, Pipeline and Hazardous Materials Safety Administration. *Hazardous Materials: Infectious Substances; Harmonization With the United Nations Recommendations; Final Rule* (Codified at 49 CFR §171, 172, 173, and 175). Office of the Federal Register; 2006.	• Federal Register citation information is found at https://www.federalregister.gov. • In Federal Register citations, the number before "Federal Register" is the volume, and the numbers after "Federal Register" are the page numbers. • When the Federal Register is cited, the full organization name (ie, not its abbreviation) should be used. • Only final rules are codified in the CFR, which is published annually. Proposed rules and notices do not include the "Codified at…" portion of the citation.
Federal register (notice)	82 Federal Register 7920-7970. US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. *Mandatory Guidelines for Federal Workplace Drug Testing Programs.* Office of the Federal Register; 2017.	• Only final rules are codified in the CFR, which is published annually. Proposed rules and notices do not include the "Codified at…" portion of the citation.
CFR	Centers for Medicare & Medicaid Services, US Department of Health and Human Services. *Part 493—Laboratory Requirements: Clinical Laboratory Improvement Amendments of 1988* (Codified at 42 CFR §493). Office of the Federal Register; published annually. Centers for Medicare & Medicaid Services, US Department of Health and Human Services. *Part 493—Laboratory Requirements; Quality System for Nonwaived Testing; Standard: Evaluation of proficiency testing performance* (Codified at 42 CFR §493.1236). Office of the Federal Register; published annually.	• CFR citation information is found at https://www.ecfr.gov. • When a CFR is cited, the full organization name (ie, not its abbreviation) should be used. • When a specific subsection is cited (as in the second example), the title uses the "Part" name followed by a semicolon and the name of the specific section (denoted by "§" and its accompanying numbers). Any chapter and subchapter titles before the "Part" and any subparts between the "Part" and the "section" are not needed in the title.

26.5 Websites

A website reference includes:

- Author or organization
  - If no author is named (eg, if the reference is not for a specific article on a website), the organization that owns the website is used.
- Web page title
- Website link
- Access date

Website citations adhere to the following basic format:

Author/organization. Title of Web page. Website link. Access date.

Examples are included in the table below.

Type	Example	Notes
Web page with an author	Nall R. An overview of diabetes types and treatments. https://www.medicalnewstoday.com/articles/323627.php. Accessed 6 December 2018.	
Web page with no author	FDA. Critical path initiative. http://www.fda.gov/oc/initiatives/criticalpath. Accessed 6 December 2018.	Well-known abbreviations may be used in place of the full organization name (eg, CDC, NIST).
Website as a whole (ie, not a specific page)	National Center for Biotechnology Information. https://www.ncbi.nlm.nih.gov/. Accessed 11 December 2018.	

27 Tables and Figures

27.1 Tables

Tables are numbered sequentially throughout the main document. In the appendixes, the table number includes the letter of the appendix, eg, tables in Appendix B are labeled “Table B1,” “Table B2,” etc. When a document contains only one appendix, tables within the appendix are labeled “Table A1,” “Table A2,” etc., with the “A” signifying “appendix.”

Some documents use step-action tables to display procedures. Step-action tables are not titled or numbered; however, other table formatting rules apply. See Part II, Section 19.2 for more information about step-action tables. The table below includes the following basic table formatting rules:

Component	Format	Notes
Title	• Bold • Placed above the table • Major words capitalized • No period at the end • May contain abbreviations	• Titles may contain abbreviations, even when the title represents the first appearance of the abbreviation. See Part II, Section 1.5 for additional rules regarding the use of abbreviations in tables. • When a table has been previously published, the permission slug appears parenthetically, in 9-pt. font, after the title.
Column headings	• Bold • Major words capitalized • Centered and base aligned • Shaded with a grey background	• Units of measure are not capitalized in column headings, even when they meet the major words criteria (ie, at least four letters). • Units of measure are preceded with commas, rather than surrounded by parentheses, eg, "MIC, µg/mL," not "MIC (µg/mL)." • Parenthetical text is not capitalized in column headings, even when any portion meets the major words criteria (ie, at least four letters). • The grey background is applied using the second "grey" shade in the "Shading" menu of the "Paragraph" section of the toolbar ribbon (White, Background 1, Darker 15%).
Content	• Upper left justified for regular text • Upper centered for numerals	• Numerals (not words) are used for numbers in tables (see Part II, Section 20).
Alignment	• Tables are aligned with the left margin. • When possible, tables should extend to the right margin.	

Examples are included below. See Part II, Section 1.5.5 for more table examples.

Example 1: Table that includes units of measure in the column headings and a mix of text and numerals in the content (Source document: *Analysis of Body Fluids in Clinical Chemistry* [C49, 2nd ed.])

Table 4. Example Interference Testing Results

Sample	Specimen	Control Nontreated Result, units	Test Pretreated Result, units	Difference	% Difference
1	Pleural fluid 1	370	370	0	0
2	Pleural fluid 2	265	264	−1	−0.4
3	Pleural fluid 3	390	395	5	1.3
4	Peritoneal fluid 1	98	97	−1	−1.0
5	Peritoneal fluid 2	54	55	1	1.9
6	Peritoneal fluid 3	135	134	−1	−0.7

Example 2: Table title that includes permission slug after title (Source document: *Colistin Breakpoints for* Pseudomonas aeruginosa *and* Acinetobacter *spp.* [MR01, 1st ed.])

Table 4. Unbound Fraction of Colistin in Plasma of Critically Ill Patients and Healthy Humans[8]
(Reprinted from *Int J Antimicrob Agents,* Vol 35 / No 2, Falagas ME, Rafailidis PI, Ioannidou E, et al., Colistin therapy for microbiologically documented multi-drug resistant gram-negative bacterial infections: a retrospective cohort study of 258 patients, pp. 194-199, © 2010, with permission from Elsevier.)

27.2 Figures

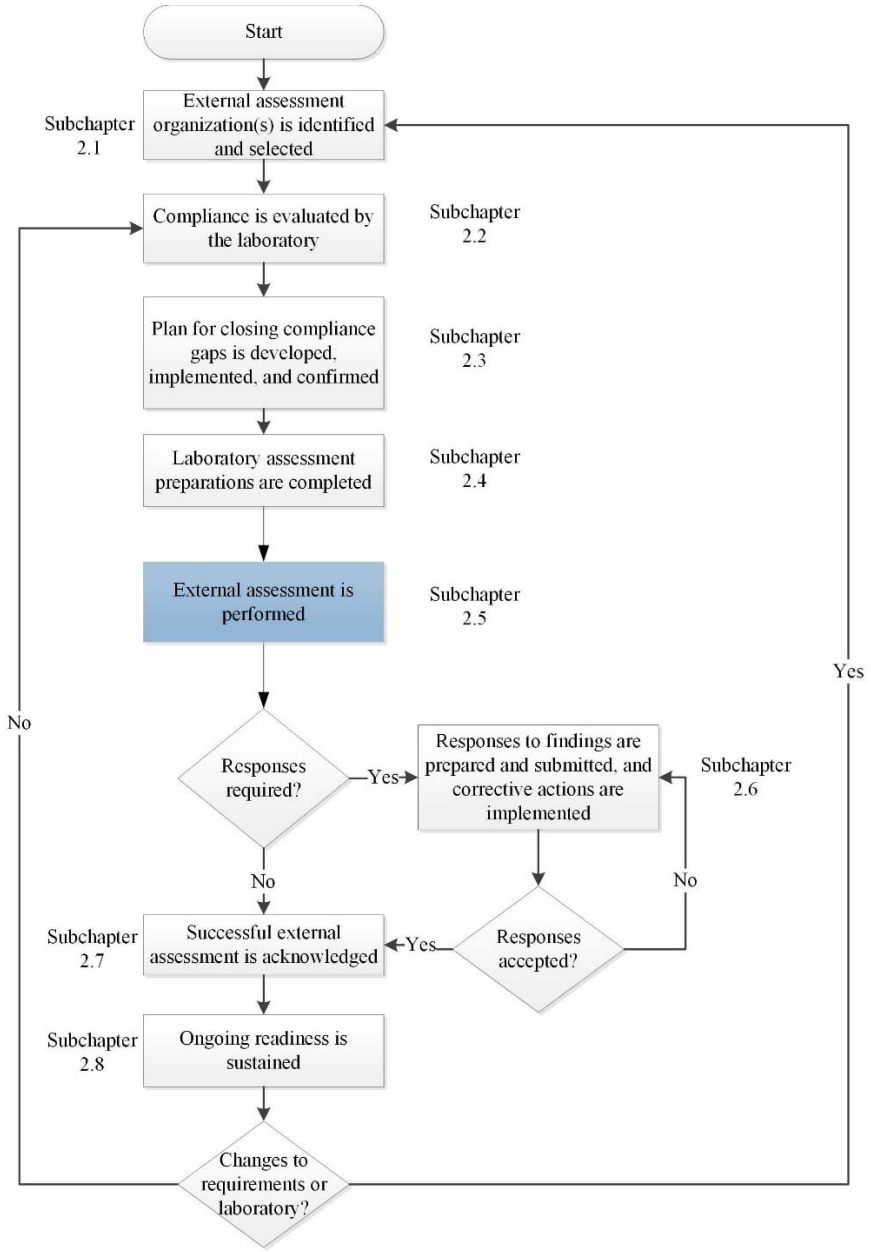
Figures are numbered sequentially throughout the main document. In the appendixes, the figure number includes the letter of the appendix, eg, figures in Appendix B are labeled "Figure B1," "Figure B2," etc. When a document contains only one appendix, figures within the appendix are labeled "Figure A1," "Figure A2," etc., with the "A" signifying "appendix." The table below includes the following basic figure formatting rules:

Component	Format	Notes
Title	• Bold • Placed below the figure, including below any abbreviations and footnotes • Major words capitalized • No period on the end, unless it is immediately followed by legend text • May contain abbreviations	• Titles may contain abbreviations, even when the title represents the first appearance of the abbreviation. See Part II, Section 1.5 for additional rules regarding the use of abbreviations in figures. • When a figure has been previously published, the permission slug appears parenthetically, in 9-pt. font, after the title.

Component	Format	Notes
Content	• A figure is any type of illustration that is not a table, including a flow chart, a line drawing, a photograph, or a bar graph.	• Flow charts are created using Microsoft Visio®. • Line drawings and graphs should be computer generated (eg, using Microsoft Excel®). • Axis labels should be included for graphs, but a general label describing the whole graph is not necessary (ie, it is redundant with the figure title beneath the graph). • Units of measure (eg, in a graph's axis labels) are preceded with commas, rather than surrounded by parentheses, eg, "Time, days," not "Time (days)." • See Part I, Section 3.1 for more information about figure file specifications.
Alignment	• Figures are aligned with the left margin.	

Examples are included below. See Part II, Section 1.5.5 for another figure example.

Example 1: Flow chart with a footnote (Source document: *Analysis of Body Fluids in Clinical Chemistry* [C49, 2nd ed.]).



[a] Five basic symbols are used in process flow charts: oval (signifies the beginning or end of a process), arrow (connects process activities), box (designates process activities), diamond (includes a question with alternative "Yes" and "No" responses), pentagon (signifies another process).

Figure 3. External Assessment Process Flow Chart[a]

Example 2: Figure title that includes permission slug after title (Source document: *Interpretive Criteria for Identification of Bacteria and Fungi by Targeted DNA Sequencing* [MM18, 2nd ed.])

Figure 1. Diagrammatic Representation of 16S rRNA Gene and Relative Primer Positions[12] (From Petti CA. Detection and identification of microorganisms by gene amplification and sequencing. *Clin Infect Dis.* 2007;44:1108-1114. Reprinted with permission.)

28 Telephone Numbers

Periods, rather than hyphens, are used in telephone numbers, eg, 555.123.1234.

The CLSI telephone and fax numbers are preceded by "+1.":

- Telephone: +1.610.688.0100
- Fax: +1.610.688.0700

29 Temperature

In temperature measurements, no space appears between the number, the degree symbol, and the Celsius sign, eg, 8°C.

29.1 Temperature Ranges

As noted in Part II, Section 25.3, "to" is used in temperature ranges. The degree sign and Celsius symbol are only inserted after the second number, eg, 2 to 8°C.

29.2 Plus/Minus Relationships

As opposed to the format of a temperature range, the degree sign and Celsius symbol appear after the first **and** second numeral in a "plus/minus" temperature relationship, eg, 2°C ± 8°C.

30 Units of Measure

30.1 Preferred Units

CLSI documents must use the International Union of Pure and Applied Chemistry/International Federation of Clinical Chemistry and Laboratory Medicine (IUPAC/IFCC)–recommended units whenever feasible. The IUPAC/IFCC-recommended units are a limited subset of SI units (the International System of Units).

The table below provides some guidance on the conversion of certain traditional units to IUPAC/IFCC-recommended units.

Analytes Traditionally Expressed…	Should Be Expressed…
Per mL or dL	Per liter (L)
In mass concentration (eg, g/L)	As substance concentration (eg, mol/L),[a] when the molecular structure is sufficiently known
Analytes Traditionally Reported…	**Should Be Reported…**
As fractions and expressed as a percent	Using the decimal system

[a] Except in the case of human hemoglobin.

In addition:

- Units of pressure should be reported as Pascal (Pa) instead of mm Hg (except for blood pressure measurements).

- All reagent components should include the substance concentration (mol/L).

However, when other units are considered appropriate for a specific document, the SI units should be added parenthetically. Inclusion of these units facilitates global harmonization and increases the international acceptance and use of CLSI documents. The table below provides information on recommended and nonrecommended units.

IUPAC/IFCC-Recommended Units

Quantity	Unit	Unit Symbol	Recommended Subunits	Units Not Recommended
Length	meter	m	mm, µm, nm	cm, µ, u, m, Λ
Area	square meter	m^2	mm^2, μm^2	cm^2, μ^2
Volume	cubic meter liter[a]	m^3 L	dm^3, cm^3, mm^3, μm^3 mL, µL, nL, pL, fL	cc, ccm, μ^3, u^3, λ, uL, µµL, uuL
Mass	kilogram	kg	g, mg, µg, ng, pg	Kg, gr, γ, ug, mµg, mug, γγ, µµg, uug
Number	dimensionless		10^9, 10^6, 10^3, 10^{-3}	all other factors
Amount of substance	mole	mol	mmol, µmol, nmol	M, eq, val, g-mol, mM, meq, mval, µM, µeq, µval, nM, neq, nval
Mass concentration	kilogram per liter	kg/L	g/L, mg/L, µg/L, ng/L	g/mL, %, g%, %(w/v), g/100 mL, g/dL, °/oo, g°/oo, °/oo(w/v), mg%, mg%(w/v), mg/100 mL, mg/dL, ppm, ppm(w/v), µg/dL, γ%, ppb, ppb(w/v), µµg/mL, uug/mL
Mass fraction	dimensionless		10^{-3}, 10^{-6}, 10^{-9}, 10^{-12}	kg/kg, g/g, %, %(w/w), g/kg, °/oo, °/oo(w/w), mg/kg, ppm, ppm(w/w), µg/kg, ppb, ppb(w/w), ng/kg
Volume fraction	dimensionless		10^{-3}, 10^{-6}	L/L, mL/mL, %, %(v/v), vol%, mL/L, °/oo, °/oo(v/v), µ/L, ppm, ppm(v/v)
Substance concentration	mole per liter	mol/L	mmol/L, µmol/L, nmol/L	M, eq/L, val/L, N, n, mM, meq/L, mval/L, µM, uM, µeq/L, nM, neq/L
Molality	mole per kilogram	mol/kg	mmol/kg, µmol/kg	m, mmol/g, µmol/mg, mm, µm, um
Mole fraction	dimensionless		10^{-3}, 10^{-6}	mol/mol, %, mol%, mmol/mol/ °/oo, mol °/oo, µmol/mol
Number concentration	reciprocal liter	L^{-1} or 1/L	$10^{-3}L^{-1}$; 10^{-3}/L; 10^3L^{-1}; 10^6L^{-1}; 10^9L^{-1}; 10^3L; 10^6L; 10^9L	L/mL, mL^{-1}, L/µL, L/uL, μL^{-1}
Rate of conversion	katal; Unit	kat (mol/s); U/L	nkat; mU/L; µU/L	U/dL

30.2 Abbreviations

Units of measure should be spelled out (eg, minute, millivolt) unless they are part of a compound unit (eg, mg/dL) or are being used with a specific numerical value (eg, 30 g).

When used with a specific value, most units of measure do not need to be expanded at first mention. Exceptions are listed in the table below. For these units of measure, the abbreviations are expanded at first mention, with the abbreviation following in parentheses. The abbreviation is used thereafter. The rules for abbreviations lists (noted in Part II, Section 1.5) apply to these abbreviations. That is, if the first mention is in a table or figure, the abbreviation is used in the table or figure and spelled out in the Abbreviations list below the table or figure. If the abbreviation is also used in the main text (ie, not solely in tables or figures), it is also included in the main Abbreviations and Acronyms subchapter.

Unit of Measure	Abbreviation
base pair	bp
day	d[a]
hour	h[a]
international benzoate unit	IBU
millisecond	ms[a]
minute	min[a]
month	mo[a]
second	s[a]
week	w[a]
year	y[a]

[a] Use the abbreviation only in virgule constructions, tables, or figures.

Abbreviations for units of measure not included in this table may be included in abbreviations lists as needed (eg, if an abbreviation is uncommon and the audience might not easily recognize it).

For clarity, US units of measure (inches, feet, etc.) should always be spelled out in full. When possible, their use should be restricted to US-centric documents and they should be accompanied by SI units.

Part III. CLSI Document Development Resources

1 Author and Committee Member Verification

The Consensus Council roster, which appears in every CLSI standard and guideline, should match the roster in the Proposed Draft document template. All other rosters are generated from NetForum.

In NetForum, the "STD Committee List for Documents" report should be used to generate rosters. It contains:

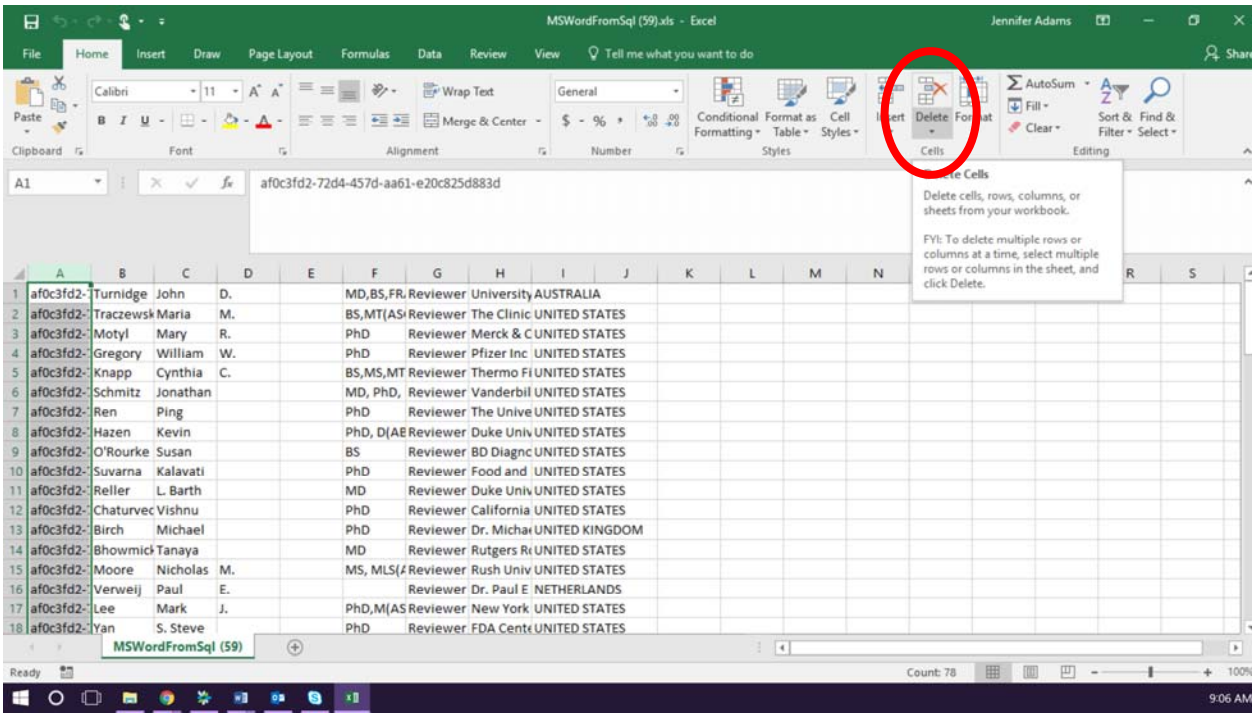
- Volunteer's last name, first name, middle initial, credentials
- Committee role
- Affiliation (ie, requested organization name)
- Country

To access and export this report:

1. Access the Committee module by selecting "Committee" from the drop-down list in the upper left.
2. In the menu below the module options, select "Management" and "Query Committee."
3. In the "Load an Existing Query" drop-down menu, select "STD Committee List for Documents."
4. Scroll to the bottom of the screen and select "Run Query."
5. In the "Committee Participant" drop-down menu, select the committee name and click "Go."
6. In the "Export" options in the upper right, select "Export Raw Data to Excel."

In the resulting spreadsheet, the data should be sorted to list members first, followed by contributors, advisors, and reviewers. The list should be in alphabetical order. Sorting is accomplished as follows:

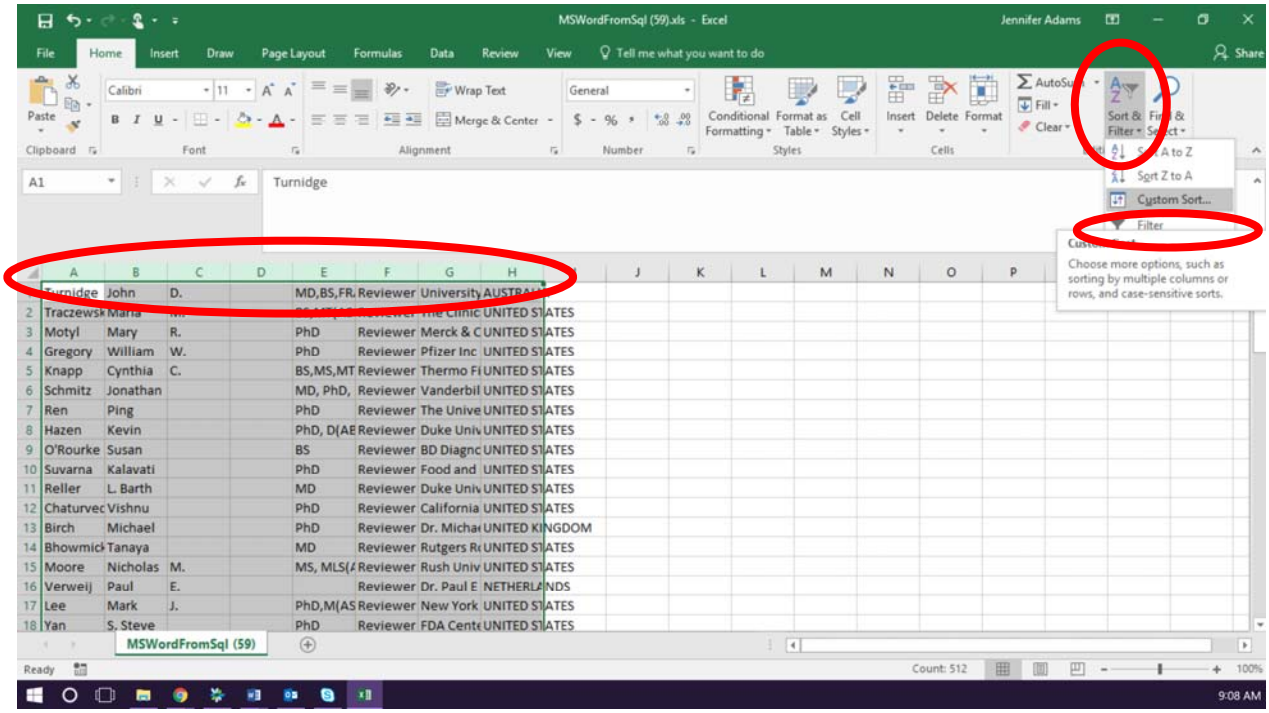
1. Delete Column A.



2. Highlight the columns to be sorted.

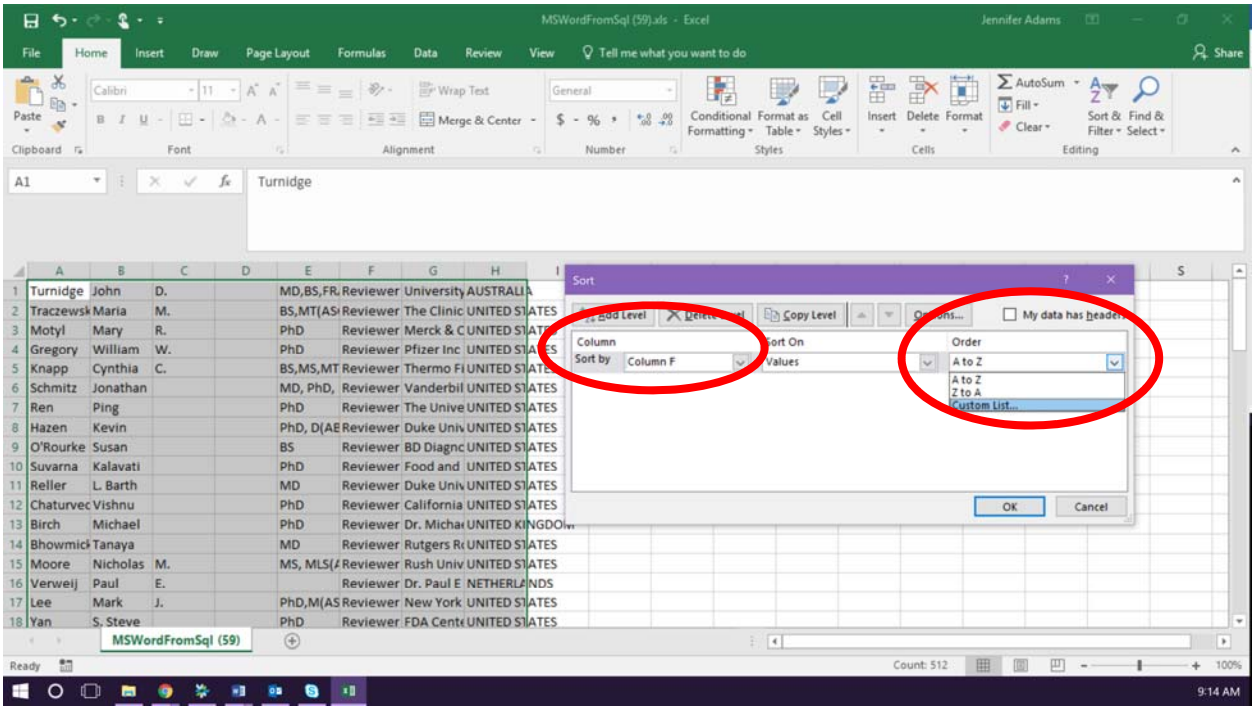
3. Click on “Sort & Filter.”

4. Click on “Custom Sort.”



5. Click on “Sort by” drop-down list and select “Column F.”

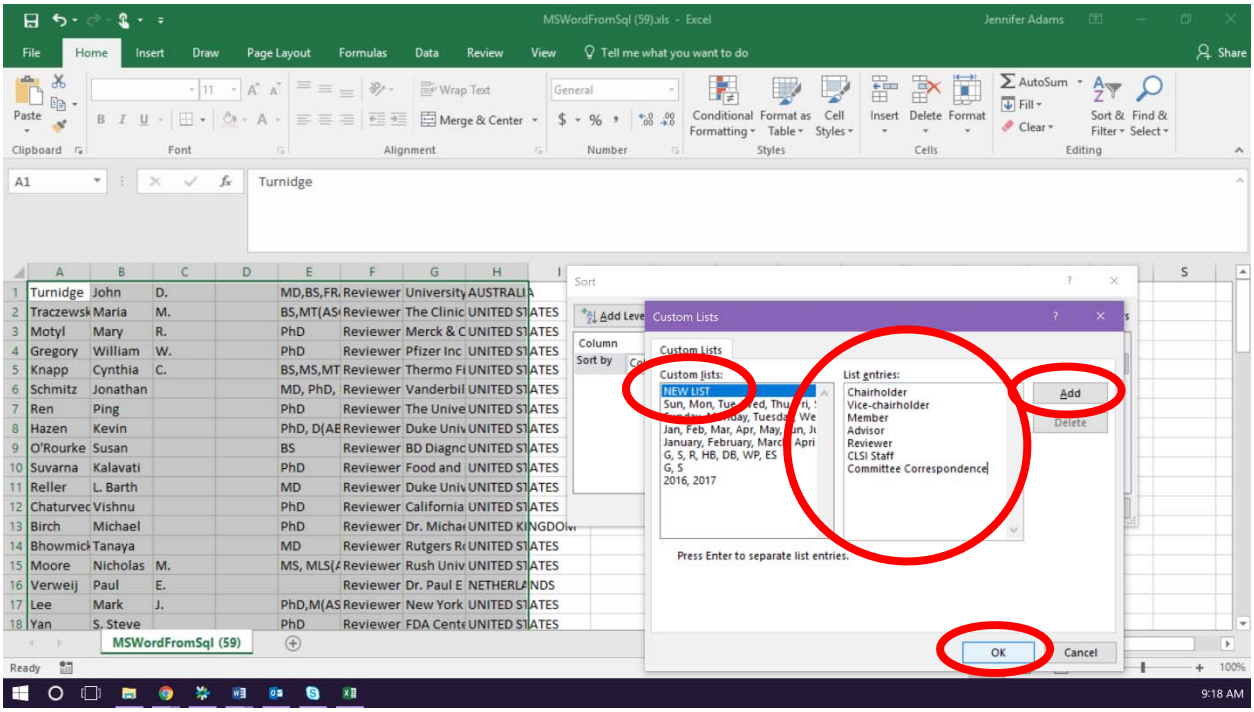
6. Click on “Order” drop-down list and select “Custom List…”



7. Create a “NEW LIST” by clicking “Add.”

8. Type applicable committee roles in the “List entries:” field (ie, Chairholder, Vice-Chairholder, Member, Advisor, Reviewer, CLSI Staff, Committee Correspondence **OR** Chairholder, Vice-Chairholder, Contributor, CLSI Staff, Committee Correspondence).

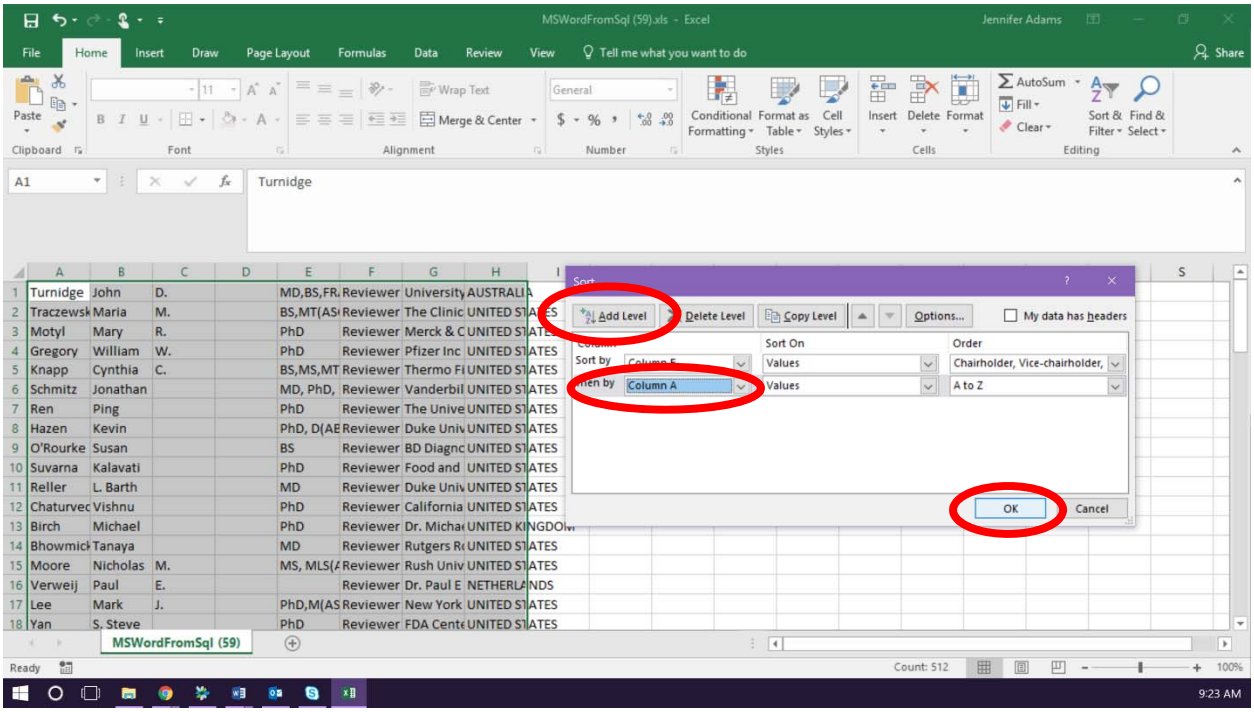
9. Click on “OK.”



10. Click on “Add Level.”

11. Select “Column A” from drop-down list. (**NOTE:** Retain default order, ie, “A to Z.”)

12. Click on “OK.”



After sorting is complete, the project manager should save the committee lists to the appropriate library in SharePoint, using Classification "Committee_Info" and File_Category "Roster." The following naming conventions should be used:

- **Document development committee lists:** [DocCode]_Proposed_Draft_Vote_DDC_Committee_List
- **Subcommittee lists:** [DocCode]_Proposed_Draft_Vote_SC_Committee_List
- **Working group lists:** [DocCode]_Proposed_Draft_Vote_WG_Committee_List
- **Expert panel lists:** [DocCode]_Proposed_Draft_Vote_ExP_Committee_List

Even though each group does not vote at Proposed Draft, the roster name should still include "Vote" in the title, because it is the roster in effect at the time of voting.

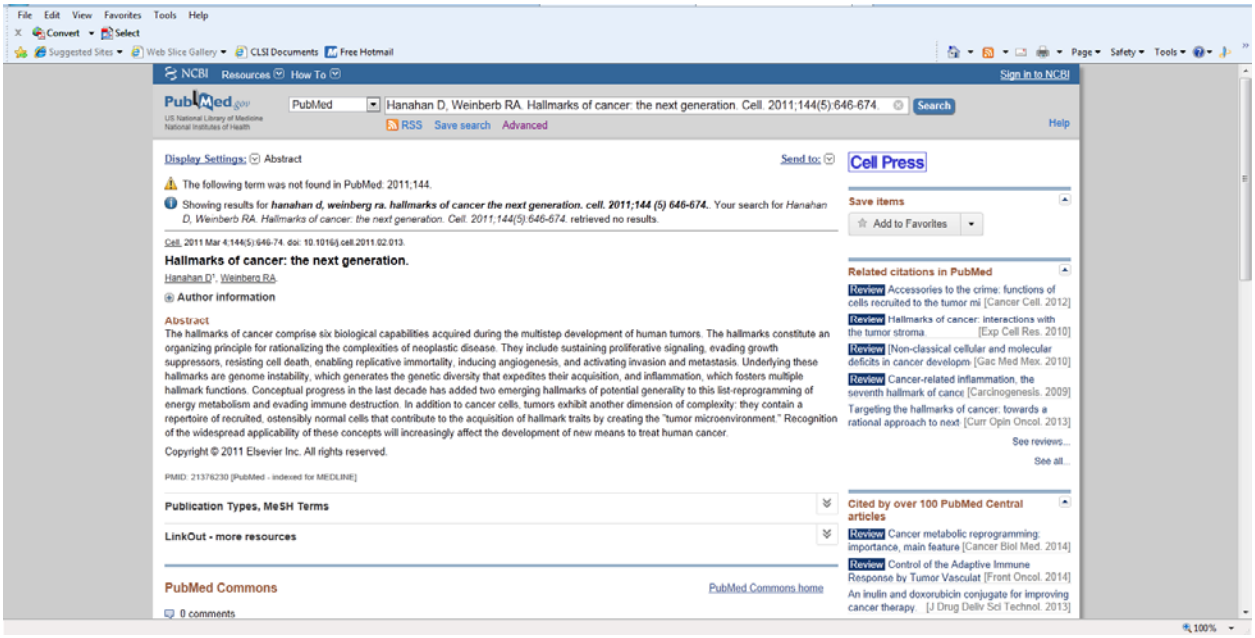
2 Permission Requests

Each document is submitted for editing with a transmittal form spreadsheet, which includes a Figure_Table_Tracking_Worksheet tab. This tab contains the information the editors need to request permission for tables and figures that were previously published.

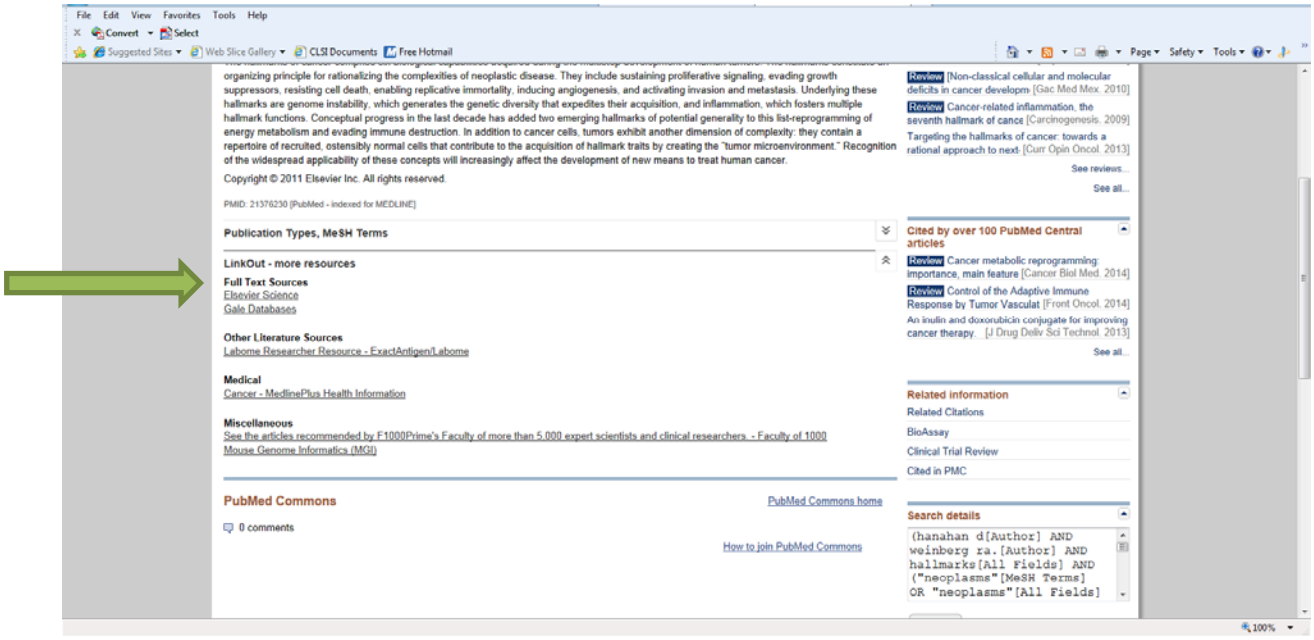
2.1 Journal Articles

When a figure or table was originally published in a journal article, permission for its use can generally be obtained through the Copyright Clearance Center. Throughout this procedure, file name conventions for figures are provided. When applicable, "table" should be used in place of "figure."

1. Enter the journal article information into PubMed, just as when checking references.

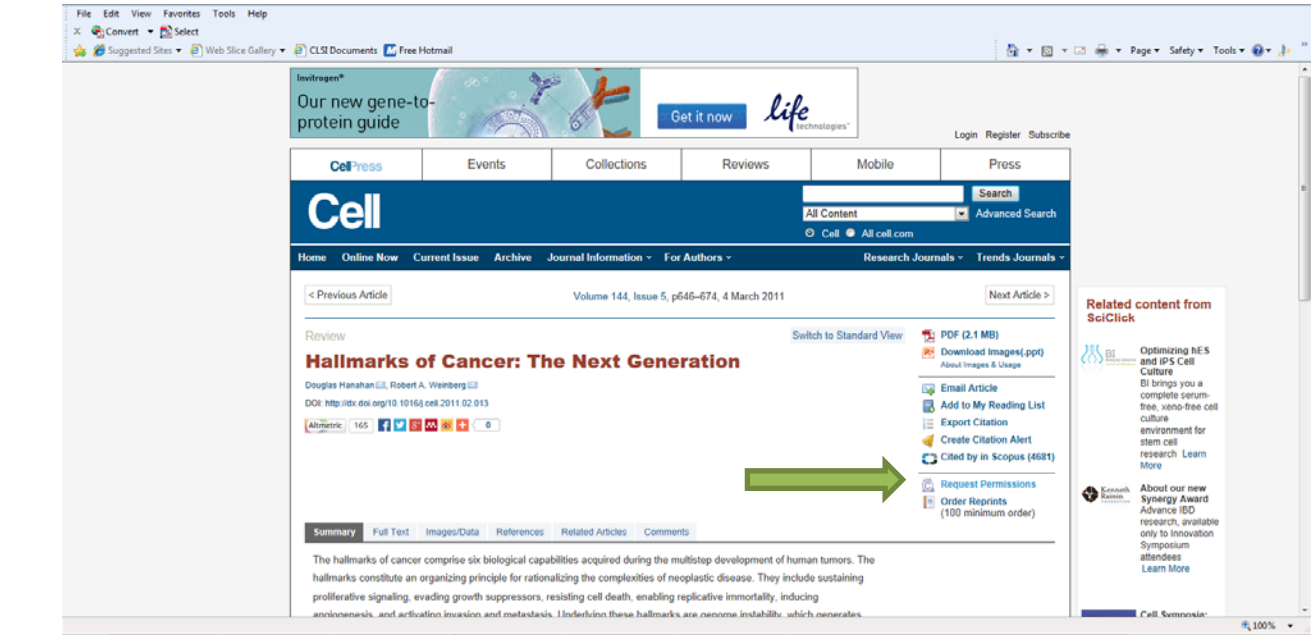


2. Scroll down and click on "LinkOut – more resources." (**NOTE:** This wording sometimes differs, depending on what journal is being viewed.)



3. In the "Full Text Sources" section, click on "Elsevier Science." (Most permissions requested through Copyright Clearance Center are granted by Elsevier.)

4. Click on "Request Permissions." (Again, the placement and language of this section may vary.)



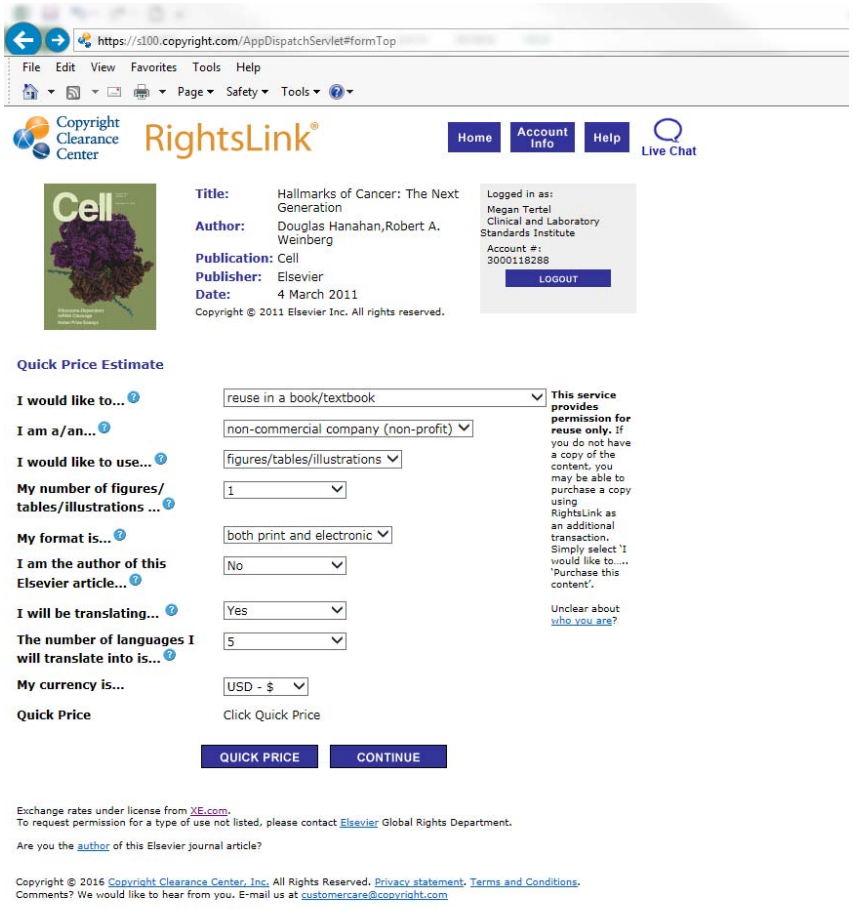
5. The site redirects to the Copyright Clearance Center website. Enter user ID and password.

6. Using the drop-down menus, answer each question appropriately.
   - I would like to… reuse in a book/textbook.
   - I am a/an… non-commercial company (non-profit).
   - I would like to use… figures/tables/illustrations.
   - My number of figures/tables/illustrations… 1.
   - My format is… both print and electronic.
   - I am the author of this Elsevier article… No.
     - **NOTE:** When the author of the journal article is also an author of the CLSI document, the editor should ask the project manager to obtain permission from the volunteer for the CLSI editor to act as the volunteer's proxy in requesting permission for use of the table or figure. If such documentation is obtained, select "Yes." This often results in a reduced or waived fee.
   - I will be translating… No.
   - My currency is… USD - $.

7. Click "Quick Price" and make a note of the quoted price.

8. Repeat step 6, answering "Yes" to the translation question and "5" for number of languages (Spanish, Russian, Korean, Portuguese, Vietnamese).

9. Click "Quick Price" and make a note of the quoted price.

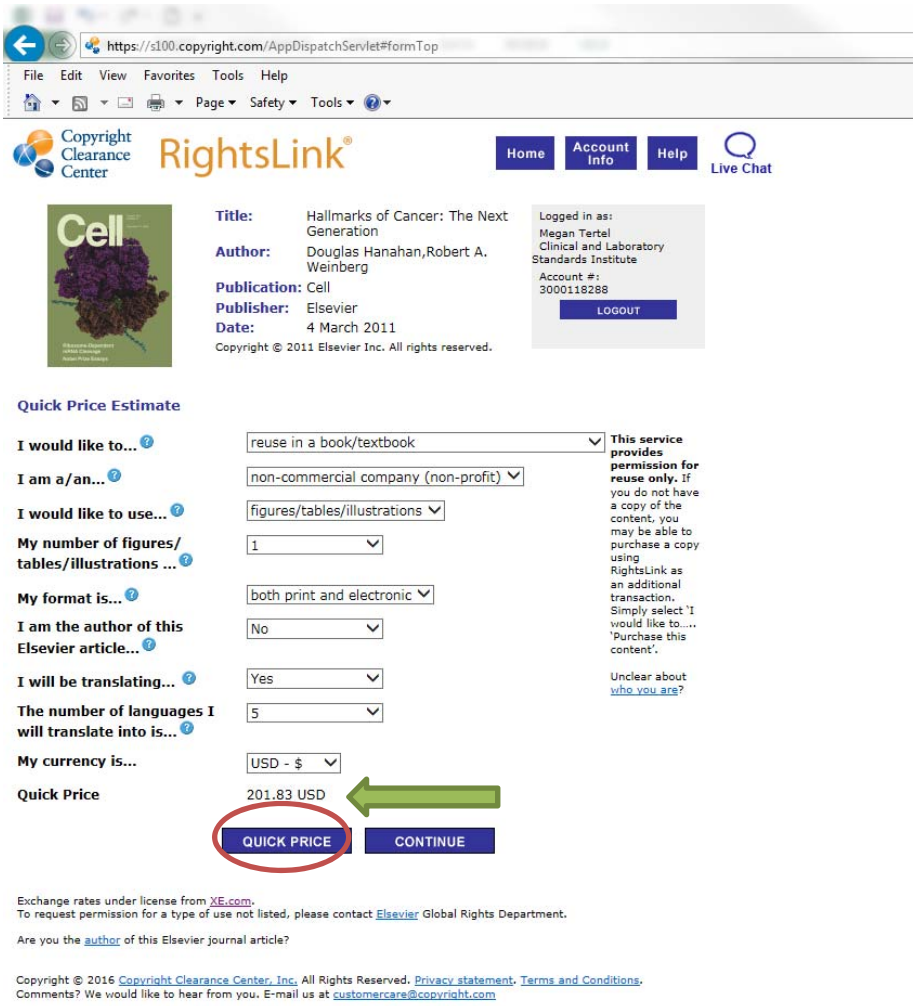


10. Repeat step 6, using the following responses, to obtain an Infobase quote.
    - I would like to… reuse in a CD-ROM/DVD.
    - My billing country is… United States.
    - I am a/an… non-commercial company (non-profit).
    - I would like to use… figures/tables/illustrations.
    - My number of figures/tables/illustrations… 1.
    - I am the author of this Elsevier article… No.
    - I will be translating… No.
    - My currency is… USD - $.

11. Click "Quick Price" and make a note of the quoted price.

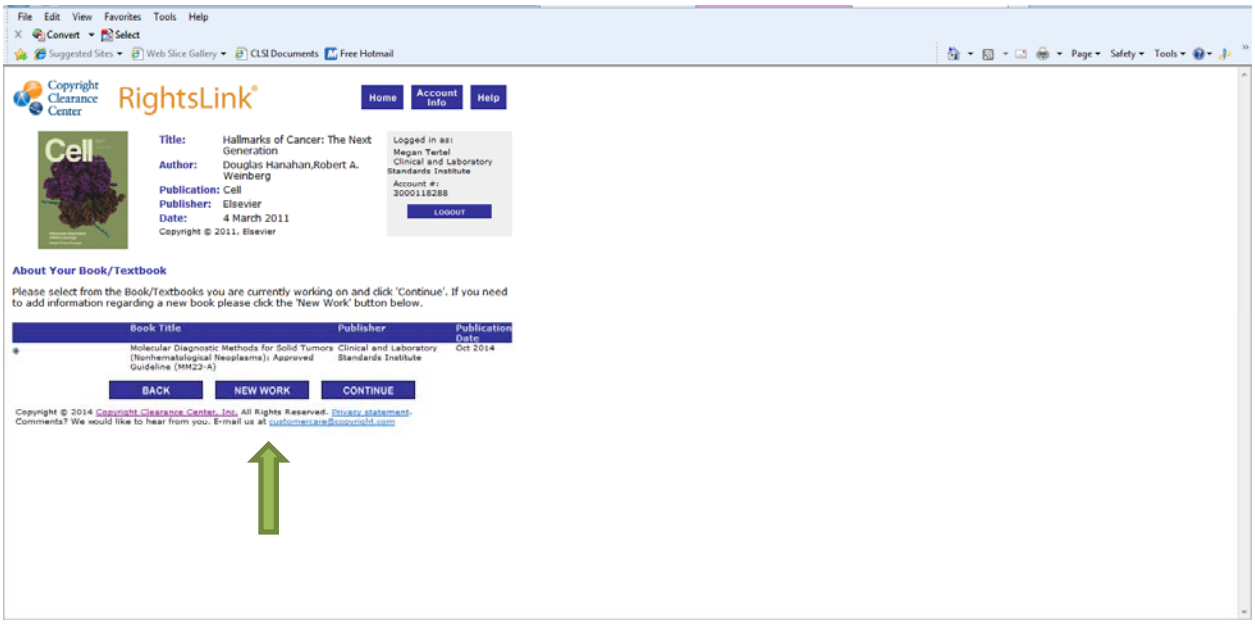
NOTE 1: For a high English-only book/textbook quote (> $250), high CD-ROM quote, or a denied permission for either request, notify the project manager. The project manager may need to contact the committee to see if an alternative table or figure can be used. If the translation quote is even higher, provide this information as well.

NOTE 2: For a high translation quote (> $250) or a denied permission, notify the project manager. The project manager will work with the committee to attempt to replace the figure, determine whether the high fee is affordable, and/or ask Marketing whether there are plans for the document to be translated. If there are no plans to translate the document, the permission request can proceed without the translation component. If the figure cannot be replaced, the fee is not affordable, and the translation plans are unknown, Marketing will be notified that the document cannot be translated. This information should be recorded in the master permission log.



12. If all prices are acceptable, re-enter the book/textbook information including the translation component, click "Quick Price," and click "Continue."

13. Recent titles for which permission was requested may appear. If the permission request pertains to a CLSI document not listed, select "New Work."

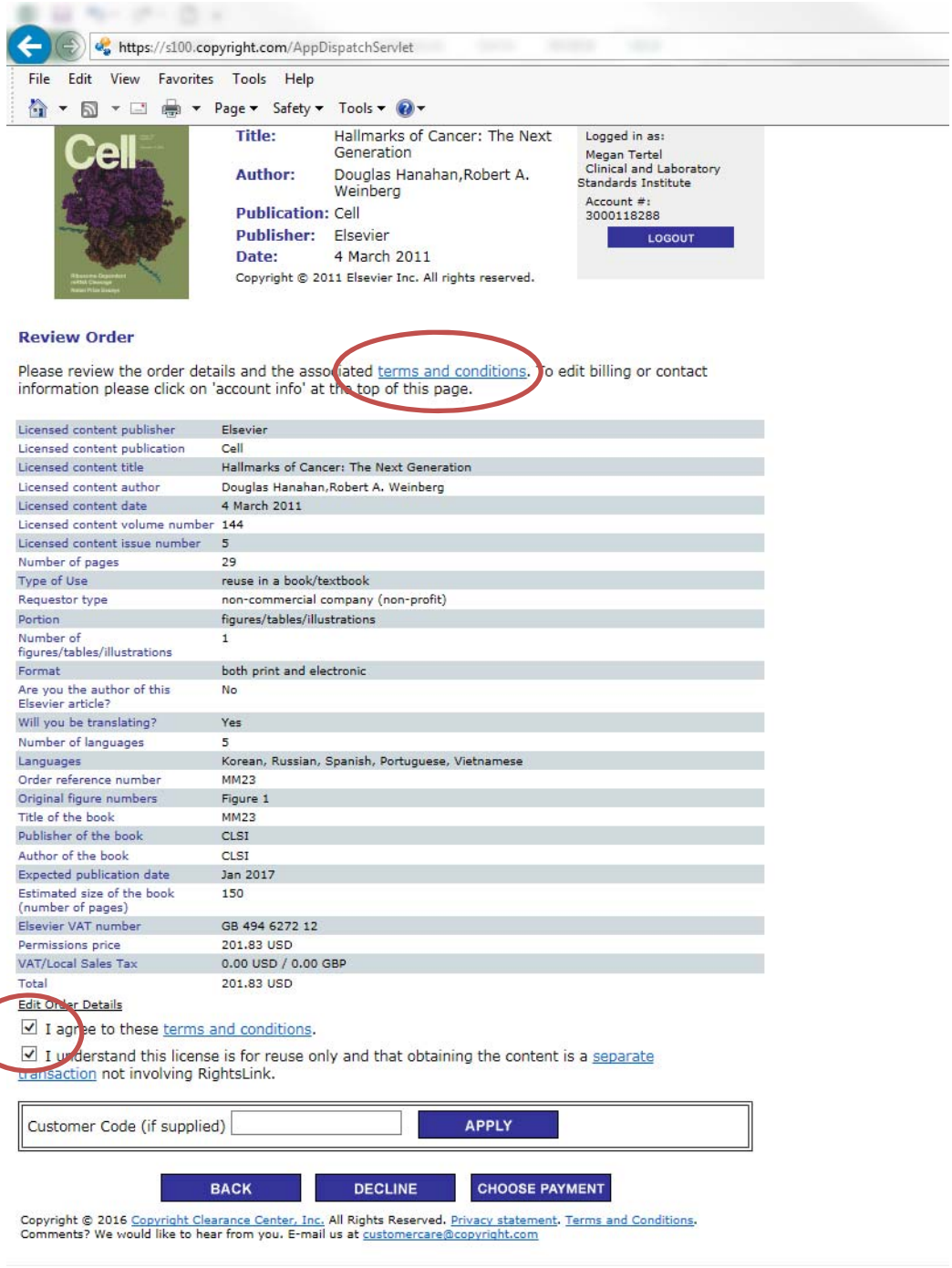


14. Enter the title, author ("Clinical and Laboratory Standards Institute"), and publisher of the book ("Clinical and Laboratory Standards Institute"). Enter the anticipated publication date and the estimated number of pages, and select "Continue."

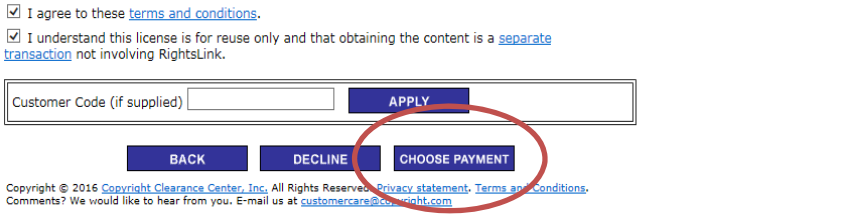
15. Enter the document code in the "Order Reference Number (optional)" field, and select "Continue."

16. The details of the order will appear, including a link to the terms and conditions. It is important to read the terms and conditions and ensure CLSI's intended use is in compliance with the terms. For example, authors sometimes make alterations to published figures, but these terms and conditions may specify that alterations are not permitted. If this is the case, the permission request process should be halted, and the editorial manager should be notified of the issue. The publisher will likely need to be contacted directly regarding CLSI's intended alterations.

    If CLSI's intended use is in compliance with the terms and conditions, check the boxes regarding agreement to terms and conditions and knowledge that the license will not provide a copy of the table or figure.

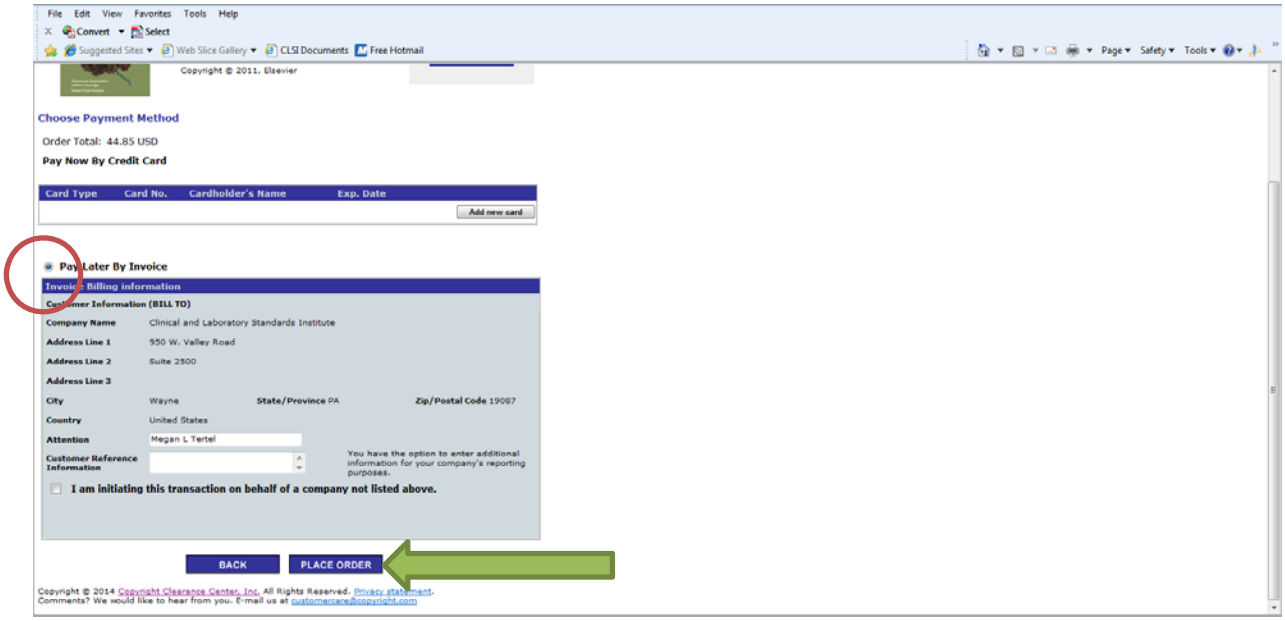


17. Select “Choose Payment.”



18. Select "Pay Later by Invoice." When permission requests have been submitted through Copyright Clearance Center in the past, CLSI's contact information will already appear in the "Invoice Billing Information" box. If this is the first permission request under a particular user ID, enter the CLSI address.

19. Select "Place Order."



20. When the order summary is returned, select "Get the Printable License."

21. The license (which matches the terms and conditions viewed previously) opens in a Web page. Convert the Web page to a PDF by right-clicking and choosing "Convert to Adobe PDF."

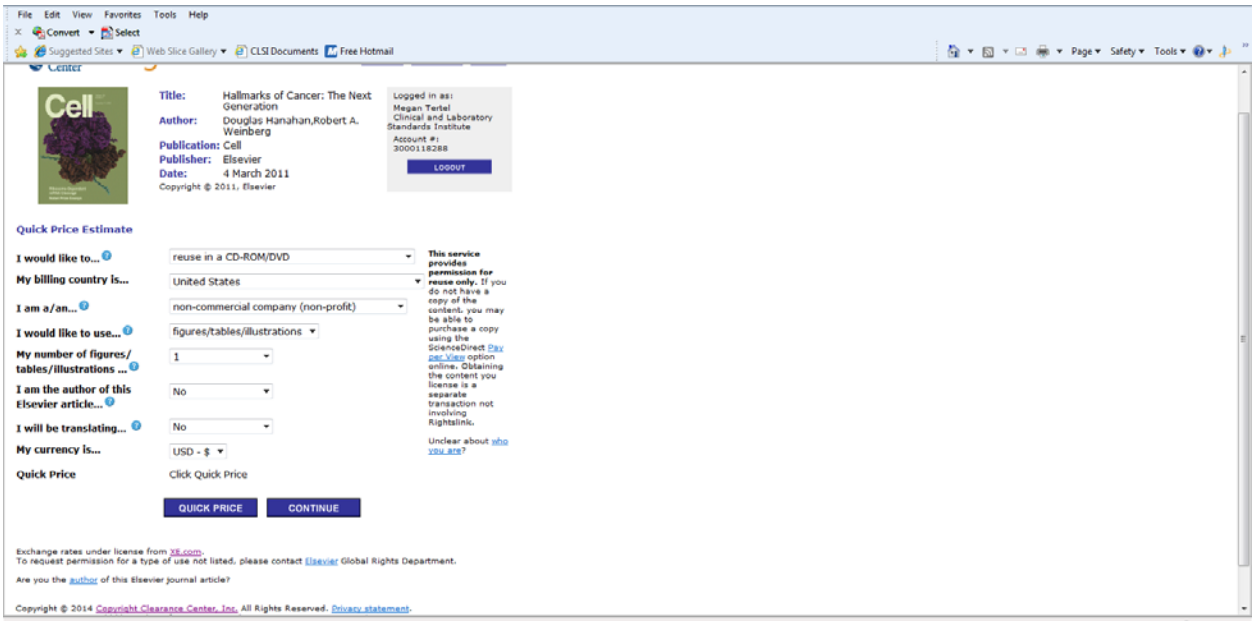
22. Save the PDF to the desktop, naming the file "[DocCode]_Figure_[#]_License_Book."

23. Upload the file to the appropriate project in SharePoint (Classification: "Editorial"; File_Category: "Permissions").

24. Delete the file from the desktop.

25. On the Copyright Clearance Center website, select "Order More."

26. Using the drop-down menus, answer each question appropriately, substituting "reuse in a book/textbook" with "reuse in a CD-ROM/DVD."
    - I would like to… reuse in a CD-ROM/DVD.
    - My billing country is… United States.
    - I am a/an… non-commercial company (non-profit).
    - I would like to use… figures/tables/illustrations.
    - My number of figures/tables/illustrations… 1.
    - I am the author of this Elsevier article… No.
    - I will be translating… No.
    - My currency is… USD - $.



27. Click “Quick Price” and “Continue.”

28. Repeat steps 13 to 21, above.

29. Save the PDF to the desktop, naming the file “[DocCode]_Figure_[#]_License_Infobase.”

30. Upload the file to the appropriate project in SharePoint (Classification: “Editorial”; File_Category: “Permissions”).

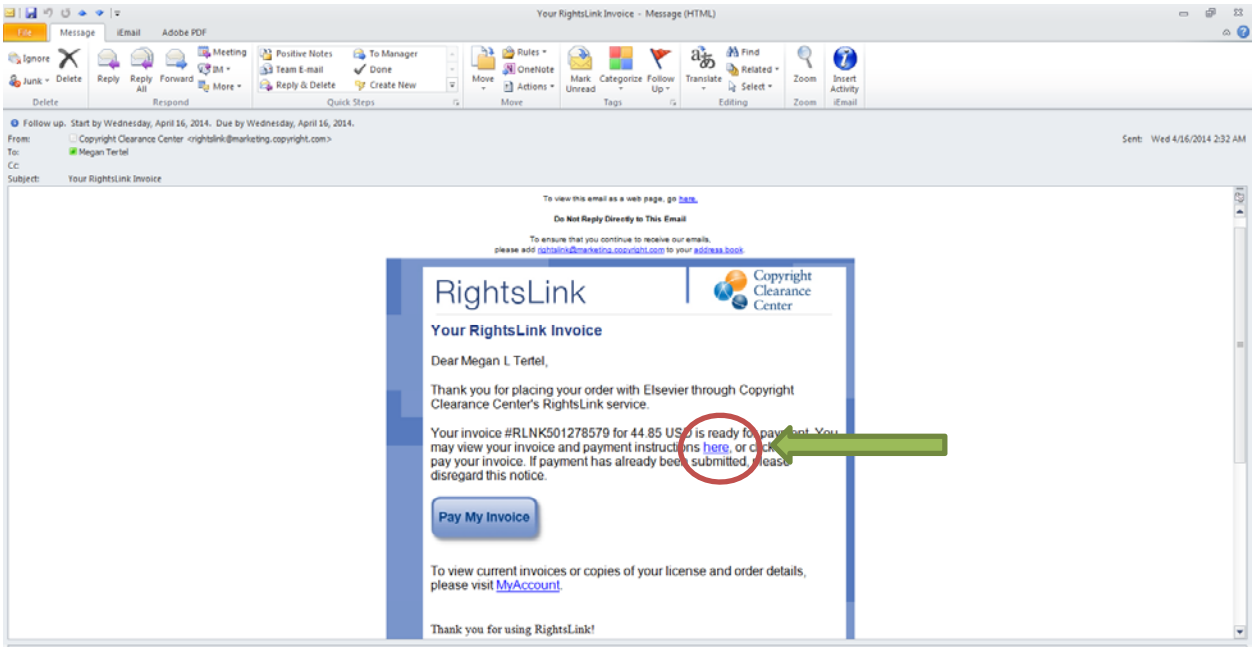
31. Delete the file from the desktop.

32. Update the Comments column in the transmittal form tracking worksheet tab to indicate that permission was requested and received through the Copyright Clearance Center, including the date of the request.

33. Update each column of the master permissions log with the permission information. The permission slug format is sometimes included in the terms and conditions. When it is not, the following format is used:
    - (Reprinted with permission from *Archives of Pathology & Laboratory Medicine,* from Wagar EA, Friedberg RC, Souers R, Stankovic AK. Critical values comparison: a College of American Pathologists Q-Probes survey of 163 clinical laboratories. *Arch Pathol Lab Med.* 2007;131(12):1769-1775.)
        – **NOTE:** If the table or figure has been modified, “Reprinted” is replaced with “Adapted” in the example format above.

34. By the next business day, the invoices will arrive via e-mail. (Confirmation of the order arrives via e-mail immediately. This confirms that the transaction was successfully submitted but does not serve as an invoice. A hard copy invoice will also arrive several days later; this invoice can be discarded.)

35. Open the e-mail containing the "Book" invoice and click the link for viewing the invoice.



36. Save the invoice as a PDF to the desktop, naming the file "[DocCode]_Figure_[#]_book_invoice_from_CCC_[date]."

37. Upload the file to the appropriate project in SharePoint (Classification: "Editorial"; File_Category: "Permissions").

38. Delete the file from the desktop.

39. Open the e-mail containing the "CD-ROM/DVD" invoice and click the link for viewing the invoice.

40. Save the invoice as a PDF to the desktop, naming the file "[DocCode_Figure_[#]_Infobase_invoice_from_CCC_[date]."

41. Upload the file to the appropriate project in SharePoint (Classification: "Editorial"; File_Category: "Permissions").

42. Delete the file from the desktop.

43. Submit the invoices to the Accounting department according to the "Entering_a_Purchase_Order_Procedure" in the QMS library in SharePoint.

2.2 Permissions Other Than Journal Articles

Permissions other than journal articles (eg, material from a website or book) are usually obtained via e-mail. Throughout this procedure, file name conventions for figures are provided. When applicable, "table" should be used in place of "figure."

1. After the source is identified, search the organization's or publisher's website for an appropriate contact.

2. Draft an e-mail to the appropriate contact. When necessary, the highlighted text is included.

> Dear Permissions Associate,
>
> The Clinical and Laboratory Standards Institute (CLSI) requests permission to reprint one figure (see attached) from an AACC publication (Glick MR, Ryder KW, Glick SJ, Woods JR. Unreliable visual estimation of the incidence and amount of turbidity, hemolysis, and icterus in serum from hospitalized patients. *Clin Chem.* 1989;35[5]:837-9).
>
> If permission is granted, the copyrighted material will be reprinted in the forthcoming CLSI document *Hemolysis, Icterus, and Lipemia/Turbidity Indices as Indicators of Interference in Clinical Laboratory Analysis* (C56), which will be available in print, electronic, CD-ROM, and quick reference guide formats. CLSI requests nonexclusive world reprint rights in all languages in all editions of the work. CLSI also requests an original high-resolution file of the requested figure. If this file type is not available, CLSI requests permission to recreate the figure.
>
> Thank you for your kind attention. Please let me know if there is a fee, or whether I need to take any additional steps, as well as how to cite the material.
>
> Sincerely,

3. To attach a table or figure to the e-mail, create a single PDF page from the Word file for the page containing the table or figure.

4. Update the Comments column in the transmittal form tracking worksheet tab to indicate that permission was requested, including the date of the request.

5. In the event that additional information is requested from the responder (eg, regarding CLSI, the print run, pricing), the following information can be provided:

> CLSI is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine by developing and implementing clinical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability. More information about CLSI can be found on our website: www.clsi.org.
>
> CLSI document [X] will be distributed to our approximately 320 member organizations in the form of a secure PDF. The document will also be available for purchase on the CLSI Shop for [select price: $140 (for Word publications); $180 (for InDesign publications)], in print and secure PDF form. The initial print run is less than 200 documents. CLSI document [X] will also be included in Infobase®, a CD-ROM published at the beginning of each year that contains all of the documents in CLSI's library. Approximately 450 CD-ROMs are produced each year. CLSI document [X] will also be included in eCLIPSE®, an online subscription to all of the documents in CLSI's library. Publications on the eCLIPSE platform are available in HTML and secure PDF formats. eCLIPSE has approximately 375 subscribing organizations.

6. Each time a follow-up communication is sent or received, update the Comments column in the transmittal form tracking worksheet with any new details.

7. If permission is received and no fee is required:
   - Save the e-mail to the desktop.
   - Rename the file "[DocCode]_Figure_[#]_Permission" (or "[DocCode]_Table_[X]_Permission," as applicable).
   - Upload the file to the appropriate project in SharePoint (Classification: "Editorial"; File_Category: Permissions").
   - Delete the file from the desktop.
   - Update the Comments column in the transmittal form tracking worksheet tab to indicate that permission was received and by whom, including the date of receipt.
   - Update each column of the master permissions log with the permission information. If the publisher does not provide a permission slug, see permission slug format in Part III, Section 2.1, step 33.

8. If permission is received and a fee is required:
   - Save the e-mail to the desktop.
   - Rename the file "[DocCode]_Figure_[#]_Permission."
   - Upload the file to the appropriate project in SharePoint (Classification: "Editorial"; File_Category: "Permissions").
   - Delete the file from the desktop.
   - Update the Comments column in the transmittal form tracking worksheet tab to indicate that permission was received and by whom, including date of receipt.
   - Update each column of the master permissions log with the permission information. If the publisher does not provide a permission slug, see permission slug format in Part III, Section 2.1, step 33.
   - Request an invoice (if one was not already provided).
   - Save the invoice as a PDF to the desktop, naming the file "[DocCode]_Figure_[#]_invoice_from_[organization_name]_[date]."
   - Upload the file to the appropriate project in SharePoint (Classification: "Editorial"; File_Category: "Permissions").
   - Delete the file from the desktop.
   - Submit the invoice to the Accounting department according to the "Entering_a_Purchase_Order_Procedure" in the QMS library in SharePoint.

3 Terminology

3.1 Breakpoint, Epidemiological Cutoff Value, and Interpretive Category Definitions for Microbiology Susceptibility Testing Documents

3.1.1 Antimicrobial Susceptibility Testing

breakpoint – minimal inhibitory concentration (MIC) or zone diameter value used to categorize an organism as susceptible, susceptible-dose dependent, intermediate, resistant, or nonsusceptible; **NOTE 1:** MIC or zone diameter values generated by a susceptibility test can be interpreted based on established breakpoints; **NOTE 2:** See **interpretive category.**

epidemiological cutoff value (ECV) – the minimal inhibitory concentration (MIC) or zone diameter value that separates microbial populations into those with and without phenotypically detectable resistance (non-wild-type [NWT] or wild-type [WT], respectively). The ECV defines the highest MIC or smallest zone diameter for the WT population of isolates.

Commented [MT1]: Editor's note: The inclusion of "or smallest zone diameter" only applies for aerobic bacteria (eg, M02, M07, M45, M100). It does not apply for anaerobes (eg, M11).

EXAMPLE:

Interpretive Category	ECVs	
	MIC, µg/mL	Zone Diameter, mm
Wild-type	≤4	≥20
Non-wild-type	≥8	≤19

- **wild-type (WT)** – an interpretive category defined by an ECV that describes isolates with no detectable mechanisms of acquired resistance or reduced susceptibility for the antimicrobial (antifungal) agent being evaluated.

- **non-wild-type (NWT)** – an interpretive category defined by an ECV that describes isolates with detectable mechanisms of acquired resistance and reduced susceptibility for the antimicrobial (antifungal) agent being evaluated.

interpretive category – category derived from microbiological characteristics, pharmacokinetic-pharmacodynamic parameters, and clinical outcome data, when available; **NOTE 1:** Minimal inhibitory concentration (MIC) or zone diameter values generated by a susceptibility test can be interpreted based on established breakpoints; **NOTE 2:** See **breakpoint.**

EXAMPLE:

Interpretive Category	Breakpoints	
	MIC, µg/mL	Zone Diameter, mm
Susceptible	≤4	≥20
Susceptible-dose dependent	8–16	15–19
Intermediate	8–16	15–19
Resistant	≥32	≤14
Nonsusceptible	>4	<20

MIC or zone diameter value breakpoints and interpretive categories are established per CLSI document M23 for categories of susceptible, intermediate, and resistant (and susceptible-dose dependent and nonsusceptible, when appropriate).

- **susceptible (S)** – a category defined by a breakpoint that implies that isolates with an MIC at or below or a zone diameter at or above the susceptible breakpoint are inhibited by the usually achievable concentrations of antimicrobial agent when the dosage recommended to treat the site of infection is used, resulting in likely clinical efficacy.

- **susceptible-dose dependent (SDD)** – a category defined by a breakpoint that implies that susceptibility of an isolate depends on the dosage regimen that is used in the patient. To achieve levels that are likely to be clinically effective against isolates for which the susceptibility testing results (either MICs or zone diameters) are in the SDD category, it is necessary to use a dosage regimen (ie, higher doses, more frequent doses, or both) that results in higher drug exposure than that achieved with the dose that was used to establish the susceptible breakpoint. Consideration should be given to the maximum, literature-supported dosage regimen, because higher exposure gives the highest probability of adequate coverage of an SDD isolate. The drug label should be consulted for recommended doses and adjustment for organ function; **NOTE:** The concept of SDD has been included within the intermediate category definition for antimicrobial agents. However, this is often overlooked or not understood by clinicians and microbiologists when an intermediate result is reported. The SDD category may be assigned when doses well above those used to calculate the susceptible breakpoint are supported by the literature, widely used clinically, and/or approved and for which sufficient data to justify the designation exist and have been reviewed. When the intermediate category is used, its definition remains unchanged.

- **intermediate (I)** – a category defined by a breakpoint that includes isolates with MICs or zone diameters within the intermediate range that approach usually attainable blood and tissue levels and for which response rates may be lower than for susceptible isolates; **NOTE:** The intermediate category implies clinical efficacy in body sites where the drugs are physiologically concentrated or when a higher-than-normal dosage of a drug can be used. This category also includes a buffer zone, which should prevent small, uncontrolled, technical factors from causing major discrepancies in interpretations, especially for drugs with narrow pharmacotoxicity margins.

- **resistant (R)** – a category defined by a breakpoint that implies that isolates with an MIC at or above or a zone diameter at or below the resistant breakpoint are not inhibited by the usually achievable concentrations of the agent with normal dosage schedules and/or that demonstrate MICs or zone diameters that fall in the range in which specific microbial resistance mechanisms are likely, and clinical efficacy of the agent against the isolate has not been reliably shown in treatment studies.

- **nonsuceptible (NS)** – a category used for isolates for which only a susceptible breakpoint is designated because of the absence or rare occurrence of resistant strains. Isolates for which the antimicrobial agent MICs are above or the zone diameters are below the value indicated for the susceptible breakpoint should be reported as nonsusceptible; **NOTE 1:** An isolate that is interpreted as nonsusceptible does not necessarily mean that the isolate has a resistance mechanism. It is possible that isolates with MICs above the susceptible breakpoint that lack resistance mechanisms may be encountered within the wild-type distribution after the time the susceptible-only breakpoint was set; **NOTE 2:** The term "nonsusceptible" should not be used when the text is describing an organism/drug category with SDD or intermediate and resistant interpretive categories. Isolates that are in the categories of "intermediate" or "resistant" could be called "not susceptible" rather than "nonsusceptible."

3.1.2 Antifungal Susceptibility Testing

breakpoint – minimal inhibitory concentration (MIC)/minimal effective concentration or zone diameter value used to categorize an organism as susceptible, susceptible-dose dependent, intermediate, resistant, or nonsusceptible; **NOTE 1:** MIC or zone diameter values generated by a susceptibility test can be interpreted based on established breakpoints; **NOTE 2:** See **interpretive category.**

epidemiological cutoff value (ECV) – the minimal inhibitory concentration (MIC)/minimal effective concentration value that separates microbial populations into those with and without phenotypically detectable resistance (non-wild-type [NWT] or wild-type [WT], respectively). The ECV defines the upper limit of susceptibility for the WT population of isolates. **NOTE:** Often referred to as the "epidemiological cutoff" or "ECOFF."

Commented [MT2]: **Editor's note:** "Minimal effective concentration" is included for moulds only. It is not included for yeasts or bacteria.

EXAMPLE:

Interpretive Category	ECVs	
	MIC, µg/mL	Zone Diameter, mm
Wild-type	≤4	≥20
Non-wild-type	≥8	≤19

- **wild-type (WT)** – an interpretive category defined by an ECV that describes isolates with no detectable mechanisms of acquired resistance or reduced susceptibility for the antimicrobial (antifungal) agent being evaluated.

- **non-wild-type (NWT)** – an interpretive category defined by an ECV that describes isolates with detectable mechanisms of acquired resistance and reduced susceptibility for the antimicrobial (antifungal) agent being evaluated.

interpretive category – category derived from microbiological characteristics, pharmacokinetic-pharmacodynamic parameters, and clinical outcome data, when available; **NOTE 1:** Minimal inhibitory concentration (MIC) or zone diameter values generated by a susceptibility test can be interpreted based on established breakpoints; **NOTE 2:** See **breakpoint.**

EXAMPLE:

Interpretive Category	Breakpoints	
	MIC, µg/mL	Zone Diameter, mm
Susceptible	≤4	≥20
Susceptible-dose dependent	8–16	15–19
Intermediate	8–16	15–19
Resistant	≥32	≤14

MIC or zone diameter value breakpoints and interpretive categories are established per CLSI document M23 for categories of susceptible, intermediate, and resistant (and susceptible-dose dependent and nonsusceptible, when appropriate).

- **susceptible (S)** – a category defined by a breakpoint that implies that isolates with an MIC at or below or a zone diameter at or above the susceptible breakpoint are inhibited by the usually achievable concentrations of antimicrobial agent when the dosage recommended to treat the site of infection is used, resulting in likely clinical efficacy.

- **susceptible-dose dependent (SDD)** – a category defined by a breakpoint that implies that susceptibility of an isolate depends on the dosage regimen that is used in the patient. To achieve levels that are likely to be clinically effective against isolates for which the susceptibility testing results (either MICs or zone diameters) are in the SDD category, it is necessary to use a dosage regimen (ie, higher doses, more frequent doses, or both) that results in higher drug exposure than that achieved with the dose that was used to establish the susceptible breakpoint. Consideration should be given to the maximum, literature-supported dosage regimen, because higher exposure gives the highest probability of adequate coverage of an SDD isolate. The drug label should be consulted for recommended doses and adjustment for organ function; **NOTE:** The concept of SDD has been included within the intermediate category definition for antimicrobial agents. However, this is often overlooked or not understood by clinicians and microbiologists when an intermediate result is reported. The SDD category may be assigned when doses well above those used to calculate the susceptible breakpoint are supported by the literature, widely used clinically, and/or approved and for which sufficient data to justify the designation exist and have been reviewed. When the intermediate category is used, its definition remains unchanged.

- **intermediate (I)** – a category defined by a breakpoint that includes isolates with MICs or zone diameters within the intermediate range that approach usually attainable blood and tissue levels and for which response rates may be lower than for susceptible isolates; **NOTE:** The intermediate category implies clinical efficacy in body sites where the drugs are physiologically concentrated or when a higher-than-normal dosage of a drug can be used. This category also includes a buffer zone, which should prevent small, uncontrolled, technical factors from causing major discrepancies in interpretations, especially for drugs with narrow pharmacotoxicity margins.

- **resistant (R)** – a category defined by a breakpoint that implies that isolates with an MIC at or above or a zone diameter at or below the resistant breakpoint are not inhibited by the usually achievable concentrations of the agent with normal dosage schedules and/or that demonstrate MICs or zone diameters that fall in the range in which specific microbial resistance mechanisms are likely, and clinical efficacy of the agent against the isolate has not been reliably shown in treatment studies.

3.1.3 Veterinary Antimicrobial Susceptibility Testing

breakpoint – minimal inhibitory concentration (MIC) or zone diameter value used to categorize an organism as susceptible, intermediate, resistant, or nonsusceptible; **NOTE 1:** MIC or zone diameter values generated by a susceptibility test can be interpreted based on established breakpoints; **NOTE 2:** See **interpretive category (for breakpoints); NOTE 3:** Also known as "clinical breakpoint."

interpretive category (for breakpoints) – category derived from microbiological characteristics, pharmacokinetic-pharmacodynamic parameters, and/or clinical outcome data; **NOTE 1:** Minimal inhibitory concentration (MIC) or zone diameter values generated by a susceptibility test can be interpreted based on established breakpoints; **NOTE 2:** Categories used for breakpoints include susceptible, intermediate, resistant, and nonsusceptible.

EXAMPLE 1:

Interpretive Category	Breakpoints	
	MIC, µg/mL	Zone Diameter, mm
Susceptible	≤4	≥20
Intermediate	8–16	15–19
Resistant	≥32	≤14
Nonsusceptible	>4	<20

EXAMPLE 2: An *Escherichia coli* was isolated from a canine urine specimen. The MIC for enrofloxacin was 0.25 µg/mL. Using the breakpoints listed below, the MIC for the isolate is categorized as susceptible because it is <0.5 µg/mL.

Interpretive Category	Enrofloxacin Breakpoints	
	MIC, µg/mL	Zone Diameter, mm
Susceptible	≤0.5	≥23
Intermediate	1–2	17–22
Resistant	≥4	≤16

MIC or zone diameter value breakpoints and interpretive categories are established per CLSI document VET02 for categories of susceptible, intermediate, and resistant (and nonsusceptible, when appropriate).

- **susceptible (S)** – a category defined by a breakpoint that implies that isolates with an MIC at or below or a zone diameter at or above the susceptible breakpoint are inhibited by the usually achievable concentrations of antimicrobial agent when the dosage recommended to treat the site of infection is used, resulting in likely clinical efficacy.

- **intermediate (I)** – a category defined by a breakpoint that includes isolates with MICs or zone diameters within the intermediate range that approach usually attainable blood and tissue levels and for which response rates may be lower than for susceptible isolates; **NOTE 1:** The intermediate category implies clinical efficacy in body sites where the drugs are physiologically concentrated or when a higher-than-normal dosage of a drug can be used. This category also serves as a buffer zone, which should prevent small, uncontrolled, technical factors from causing major discrepancies in interpretations, especially for drugs with narrow pharmacotoxicity margins; **NOTE 2:** The intermediate category implies clinical efficacy in body sites where the drugs are physiologically concentrated or when a higher-than-normal dosage of a drug can be used. This category also serves

Commented [MT3]: Editor's note: Depending on the document's intended audience, "nonsusceptible" may be omitted from the definition.

Commented [MT4]: Editor's note:

NOTE 2 and **EXAMPLE 1** are appropriate for typical VET documents that are intended for laboratory use, where the rarely reported term "nonsusceptible" is understood by laboratorians.

NOTE 2, with "nonsusceptible" removed, and **EXAMPLE 2** are used for projects (eg, VET09) with a different primary intended audience(s) from that described above.

Commented [MT5]: Editor's note: The examples are labeled "EXAMPLE 1" and "EXAMPLE 2" for Style Guide purposes only. The appropriate example will be selected per the document's intended audience, and it will be labeled "EXAMPLE" in the document.

Commented [MT6]: Editor's note:

NOTE 1 is appropriate for typical VET documents that are intended for laboratory use, for which details about "small, uncontrolled, technical factors causing major discrepancies in interpretations, especially for drugs with narrow pharmacotoxicity margins" is information well understood by laboratorians **or** clinical pharmacologists.

NOTE 2 is used for projects with a different primary intended audience(s) from that described above.

as a buffer zone to prevent the inherent variability of antimicrobial susceptibility testing methods from leading to erroneous categorization.

- **resistant (R)** – a category defined by a breakpoint that implies that isolates with an MIC at or above or a zone diameter at or below the resistant breakpoint are not inhibited by the usually achievable concentrations of the agent with normal dosage schedules and/or that demonstrate MICs or zone diameters that fall in the range in which specific microbial resistance mechanisms are likely, and clinical efficacy of the agent against the isolate has not been reliably shown in isolates with similar phenotypes.

- **nonsusceptible (NS)** – a category used for isolates for which only a susceptible breakpoint is designated because of the absence or rare occurrence of resistant strains. Isolates for which the antimicrobial agent MICs are above or the zone diameters are below the value indicated for the susceptible breakpoint should be reported as nonsusceptible; **NOTE 1:** An isolate that is interpreted as nonsusceptible does not necessarily mean that the isolate has a resistance mechanism. It is possible that isolates with MICs above the susceptible breakpoint that lack resistance mechanisms may be encountered within the wild-type distribution after the time the susceptible-only breakpoint was set; **NOTE 2:** The term "nonsusceptible" should not be used when the text is describing an organism/drug category with intermediate and resistant interpretive categories. Isolates that are in the categories of "intermediate" or "resistant" could be called "not susceptible" rather than "nonsusceptible."

epidemiological cutoff value (ECV) – the minimal inhibitory concentration (MIC) or zone diameter value that separates microbial populations into those with and without acquired and/or mutational resistance based on their phenotypes (non-wild-type or wild-type, with the ECV defining the highest MIC or smallest zone diameter for the wild-type population of isolates; **NOTE 1:** ECV is also sometimes referred to as "ECOFF"; **NOTE 2:** See **interpretive category (for epidemiological cutoff values).**

interpretive category (for epidemiological cutoff values) – category derived from microbiological characteristics; **NOTE 1:** Minimal inhibitory concentration (MIC) or zone diameter values generated by a broth dilution or disk diffusion test can be interpreted based on established epidemiological cutoff values (ECVs); **NOTE 2:** Categories used for ECVs include wild-type and non-wild-type.

EXAMPLE:

Interpretive Category	ECVs	
	MIC, µg/mL	Zone Diameter, mm
Wild-type	≤4	≥20
Non-wild-type	≥8	≤19

- **wild-type (WT)** – an interpretive category defined by an ECV that describes isolates with no phenotypically detectable mechanisms of acquired resistance and without reduced susceptibility for the antimicrobial agent being evaluated.

- **non-wild-type (NWT)** – an interpretive category defined by an ECV that describes isolates with presumed or known mechanisms of acquired resistance and reduced susceptibility for the antimicrobial agent being evaluated.

Commented [MT7]: Editor's note: The order of definitions as shown here (ie, breakpoint, interpretive category [for breakpoints], epidemiological cutoff value, interpretive category [for epidemiological cutoff values]) is the order in which these definitions should appear in VET documents. The VAST volunteers would like to follow logical rather than alphabetical order for these definitions.

Commented [MT8]: Editor's note: Include reference:

European Committee on Antimicrobial Susceptibility Testing (EUCAST). EUCAST definitions of clinical breakpoints and epidemiological cut-off values. http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/EUCAST_SOPs/EUCAST_definitions_of_clinical_breakpoints_and_ECOFFs.pdf. Accessed February 6, 2019.

3.2 Specimen and Sample Definitions

The CLSI-preferred definitions for "specimen" and "sample" are derived from ISO 15189:

specimen – discrete portion of a body fluid, breath, hair, or tissue taken for examination, study, or analysis of one or more quantities or properties assumed to apply for the whole.

sample – one or more parts taken from a specimen.

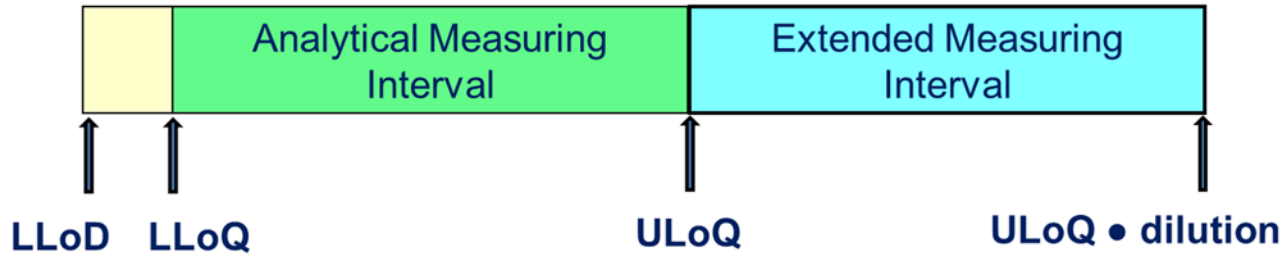
Some documents may use different definitions depending on the subject matter. For CLSI's method evaluation (ie, EP) documents, the important distinction is that a sample has been modified, usually by spiking something into it, or by dilution, whereas the specimen is the native component taken from the body. The specimen has been unaltered except that it may have been centrifuged to separate the cells from the serum or plasma. Appropriate notes should be included regarding the specific usage in the document. It is critical for users of the document to understand when they are supposed to go back to the specimen and use that for the testing vs when they use the prepared sample. The EP documents use the definitions and notes below.

sample – one or more parts taken from a system and intended to provide information about the system or to serve as a basis for a decision about the system (modified from ISO 15193); **EXAMPLE:** A volume of serum taken from a larger volume of serum (ISO 15189); **NOTE:** For the purposes of [Document Code], a sample may be physically or chemically changed from the original patient specimen (see **specimen**), as in having been spiked with a potentially interfering substance.

specimen – discrete portion of a body fluid, breath, hair, or tissue taken for examination, study, or analysis of one or more quantities or properties assumed to apply for the whole (ISO 15189); **NOTE:** For the purposes of [Document Code], a specimen is the component taken directly from the body, with or without anticoagulants and preservatives, that has not been physically or chemically changed, except that it may have been centrifuged (ie, blood cells have been separated from the serum or plasma).

3.3 Limits of Detection Definitions

CLSI document EP34—*Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking* describes how to dilute or spike samples to obtain results outside of the analytical measuring interval. For example, if a sample has a glucose value of 830 mg/dL, but the test only measures up to 600 mg/dL, EP34 explains how to correctly dilute the sample and compute the result. Using such a dilution, the laboratory can effectively extend its measuring interval to much higher values. This new region is called the "extended measuring interval." For quantitative measurement procedures, it is represented as:

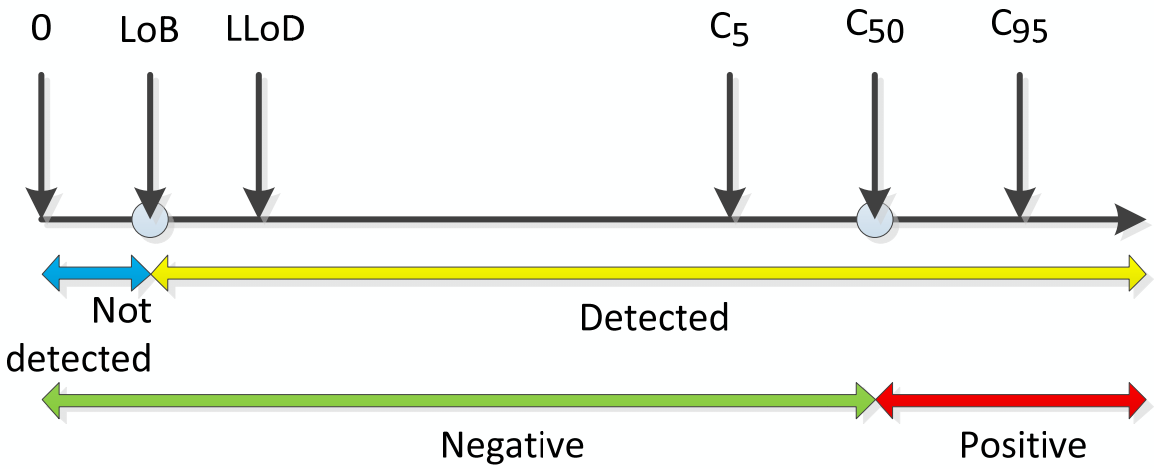


The updated terms, abbreviated in the figure above, are:

- **lower limit of detection (LLoD)** – the smallest amount of a substance for which one can reasonably be assured that the substance is actually present.
- **lower limit of quantitation (LLoQ)** – the smallest amount of a substance that can be measured accurately.
- **upper limit of quantitation (ULoQ)** – the largest amount of a substance that can be measured accurately.
- **ULoQ • dilution** – upper limit of quantitation multiplied by the dilution factor. This is the largest amount of the substance that can be measured after the sample is diluted by the dilution factor.

Not shown in the figure, but also applicable, is the limit of blank (LoB). This is the value lower than or equal to the LLoD, ie, the highest value that could be obtained for a sample with a concentration of zero measurand. Often, the LoB and LLoQ are the same value.

For qualitative measurement procedures that give only positive or negative results, some of the same abbreviations are used, and some are different:



In this case, the LoB and LLoD are the same as described above. An analyte is detected above the LoB and accurately measured above the LLoD. However, there is a cutoff value above which the result is reported as positive and below which the result is reported as negative. The cutoff might be close to the LLoD, or it might be much higher if the laboratory does not want to call the result positive until it reaches a higher threshold concentration. This is often the case in drug testing because the laboratory wants to be sure it is measuring the drug and not an interfering substance.

The cutoff is called the "C_{50}" because a sample with a concentration exactly at the cutoff will be reported as negative 50% of the time and as positive 50% of the time. At a concentration equal to C_5, the result will be called positive 5% of the time, and at C_{95}, the result will be called positive 95% of the time. This is due to imprecision, also known as "variability." For some tests, manufacturers call the region between C_5 and C_{95} the "indeterminate zone" because of the result variability. Frequently, qualitative test results must be subsequently confirmed by another, more definitive method.

4 Document Review Checklist Tips

4.1 Searching for US-Centric Terms and Commonly Confused or Misused Terms

Per the Document Review Checklist, project managers should perform a search for US regulatory and accreditation organizations and commonly confused or misused terms as part of their pre-editing preparations. These terms are:

accuracy
accurate
actual
analyte
analytical
analytical method
bias
biosafety level
CAP
CDC
CDRH
Center for Devices and Radiological Health
Centers for Disease Control and Prevention
Centers for Medicare & Medicaid Services
CFR
Class I
Class II
CLIA
clinical
clinical evaluation
Clinical Laboratory Improvement Amendments
Clinical Laboratory Management Association
CMS
Code of Federal Regulations
College of American Pathologists
diagnostic
diagnostic evaluation
diagnostic sensitivity
diagnostic specificity
error
facility
FDA
Federal Register
Food and Drug Administration
HIPAA
imprecise
imprecision
inaccuracy
inaccurate
institution
interval
JCAHO

Joint Commission
level
measurand
measurement error
measurement procedure
measuring range
medical
MSDS
national
National Institutes of Health
NIH
precise
precision
qualification
qualify
repeatability
repeatable
reportable range
reproducibility
reproducible
sample
sensitive
sensitivity
SOP
specificity
specimen
total analytical error
total error
total imprecision
total precision
true
trueness
uncertainty
United States
US
USA
valid
verification
verified
verify
within-run

4.2 Performing a Cross-Reference Check

Per the Document Review Checklist, documents must be cross-reference checked to ensure all mentions of "chapter," "subchapter," "section," "appendix," "figure," "table," "CLSI," "see," and "refer" are correct. When performing the cross-reference check for "CLSI," ensure that CLSI documents are:

- Called out in the text, accompanied by references on first mention in the text, and accompanied by cross-references on subsequent mentions in the text

- Correctly represented in The Quality Management System Approach section

- Correctly represented in the Related CLSI Reference Materials section

4.2.1 Cross-Reference Check for CLSI Documents: Main Text

4.2.1.1 Ensuring CLSI Documents Are Accompanied by a Reference or Cross-Reference

1. Perform a search for "CLSI" in the main text and record the reference number of each CLSI document cited in the text.

2. If a CLSI document is mentioned in the text but not referenced, insert a comment for the staff assistant to insert a reference or cross-reference, as appropriate.
   - In the References section, search for the CLSI document that is missing a reference in the text.
   - Double-click on the reference number of the CLSI document, which sends the cursor to the location in the main text where the reference first appears.
   - If the CLSI document with the missing reference appears before the location where the reference first appears, ask the staff assistant to move the first mention of the reference to the location of the CLSI document that is missing a reference, replacing the existing first mention with a cross-reference.
   - If the CLSI document with the missing reference appears after the location where the reference first appears, ask the staff assistant to insert a cross-reference.
   - If the CLSI document with the missing reference does not appear in the References section, ask the staff assistant to insert a new reference and include the citation in the comment balloon.

4.2.1.2 Ensuring CLSI Documents Are Called out on First Mention

1. In the References section, perform a search for "CLSI."

2. Double-click on the reference number of each CLSI document, which sends the cursor to the location in the main text where the reference first appears.

3. If no mention of the CLSI document appears in the text, insert "(see CLSI document [Code])" before the reference number. For example:
   - **Incorrect:** Additional information on QMS implementation is available.[10]

   - **Correct:** Additional information on QMS implementation is available (see CLSI document QMS01[10]).

4.2.1.3 Ensuring CLSI Documents Are Called out on Subsequent Mentions

1. Perform a search for each superscripted appearance of each reference number, using the list compiled above (see Part III, Section 4.2.1.1, step 1).
   - For example, if CLSI document QMS01 is reference 10, go to Find → Advanced Find → Enter "10" → More → Choose "Find whole words only" → Format → Font → Superscript → OK → Find Next.
     – **NOTE:** The original reference does not appear as part of this search. If the above search yields a "not found" message, no cross-references to the original reference appear in the document.

2. If no mention of the CLSI document appears in the text in front of the cross-reference:
   - Hold down the "Ctrl" key and click on the cross-reference, which sends the cursor to the location in the main text where the reference first appears.
   - If the cross-reference number and main reference number are the same, return to the location of the cross-reference and insert the CLSI document code as shown above (see Part III, Section 4.2.1.2, step 3).
   - If the cross-reference number and main reference number are different, the references and cross-references are not properly linked. For example, QMS01 is reference 10, but superscripted instances of "10" in the document are linking to reference 9.
     – Insert a comment for the staff assistant to update the references, providing a brief description of the problem (eg, "QMS01 is reference 10, but the cross-references are displaying as 11").
     – **NOTE:** The cross-reference check should be repeated after the staff assistant corrects the problem.

4.2.2 Cross-Reference Check for CLSI Documents: Appendixes

In appendixes, the references are not automated. Therefore, the first instance of each reference does not link to its appendix's References list. To check the first and subsequent mentions of CLSI documents in appendixes:

1. Perform a search for "CLSI" in the appendix and record the reference number of each CLSI document cited in the appendix.

2. Perform a search for "CLSI" in the References list for that appendix and compare it with the information recorded in step 1 (ie, ensure that all CLSI documents that appear in the appendix's main text are represented in the appendix's References list, and vice versa).

3. Return to the beginning of the appendix and perform a search for each superscripted appearance of each reference number (ie, to ensure that each CLSI document is called out in the text).
   - See above (Part III, Section 4.2.1.3, step 1) for instructions on modifying the search function for superscripted numbers.

4.2.3 The Quality Management System Approach

The Quality Management System Approach section includes a quality system essential (QSE) grid and a path of workflow (POW) grid. These grids show the QSEs and path of workflow processes that are covered in each CLSI document cited in the main text and appendixes. To check this section:

1. Using the document codes recorded during the CLSI cross-reference check, ensure all CLSI documents cited in the main text and appendixes are represented in the QSE grid.
   - **NOTE:** All CLSI documents cover at least one QSE, but not all CLSI documents cover any path of workflow processes.

2. Using the document codes recorded during the CLSI cross-reference check, ensure CLSI documents that are **not** referenced in the document do not appear in either grid.

3. Check the QSE and POW columns of the CLSI document log in SharePoint to ensure document codes are assigned to the correct columns of the QSE and POW grids.
   - **NOTE:** The QSE and POW grids should reflect the current published edition of each document. If any cited document is listed as "IP" ("in progress") in the Status column of the document log, double-check the QSE and POW grids in the published document itself. Sometimes, when a revision is in progress, the QSE and POW grids of the document log are updated to reflect the upcoming edition, rather than the current published edition.

4.2.4 Related CLSI Reference Materials

The Related CLSI Reference Materials section includes each CLSI document cited in the main text and appendixes. To populate and check this section:

1. Using the document codes recorded during the CLSI cross-reference check, ensure all CLSI documents cited in the main text and appendixes are represented in the Related CLSI Reference Materials list.

2. Using the document codes recorded during the CLSI cross-reference check, ensure CLSI documents that are **not** referenced in the document do not appear in this section.

3. Check the document codes, titles, publication years, and taglines against the published documents (ie, in the Published Products library in SharePoint).

4.3 Searching for Duplicate References

Per the Document Review Checklist, a search for duplicate references should be performed. If duplicate references are found, they should be flagged for removal by the staff assistant.

1. Navigate to the References section and copy its contents.

2. Paste the contents of the References section into a new, blank Word document.

3. Highlight the contents, and click the "Sort" button (located in the Paragraph section of the toolbar ribbon, and labeled with a vertically stacked "AZ" and a downward-facing arrow).

4. Choose Sort by Paragraph (which should already be set as the default option) and click "OK."

This procedure sorts the references in alphabetical order. Sometimes, because of formatting glitches within the References section, a few items are left out of order at the end of the list. These items must be manually reordered within the alphabetized list.

Duplicate references appear in sequential order in the alphabetized list. When duplicates are identified:

1. Locate the duplicate references in the main References section.

2. Record the reference numbers and other identifying information (eg, the first two authors) of the duplicate references.

3. Insert a comment to the staff assistant requesting that the duplicate reference be removed.
   - It is helpful to include some portion of the reference's content, rather than just the reference numbers, eg, "References 5 and 64 (Brown AB, Smith CD) are duplicates."

5 Published Document Mark-ups

The document excerpts below show how each code and title is formatted in the published document, as well as other items the editor must manually mark up for the staff assistant when preparing a document for publication. Some of this information is also covered in the Boilerplate Text for Published Documents file; the presentation below displays it in the context of a published document.

Code, publication date, and "replaces" information above document title:

M23, 5th ed.
January 2018
Replaces M23, 4th ed.

Code, title, and ISBN information in the Abstract:

Abstract

Clinical and Laboratory Standards Institute guideline M23—*Development of* In Vitro *Susceptibility Testing Criteria and Quality Control Parameters* offers guidance for developing breakpoints and QC ranges for antimicrobial susceptibility tests against aerobic and anaerobic bacteria, and selected fungi, according to CLSI antimicrobial susceptibility testing standards. It describes the data used by the Subcommittees on Antimicrobial Susceptibility Testing and Antifungal Susceptibility Tests to establish these breakpoints and QC ranges for antimicrobial agents, including microbiological data, pharmacokinetic and pharmacodynamic characteristics, and clinical data. As antimicrobial agents are used in practice, additional experience accrued may be used to reassess breakpoints or QC ranges. Users of these guidelines should understand that susceptibility test results cannot predict clinical outcomes with absolute certainty. They should be used along with the best clinical judgment and laboratory support to draw the best conclusions to serve the patient.

Clinical and Laboratory Standards Institute (CLSI). *Development of* In Vitro *Susceptibility Testing Criteria and Quality Control Parameters.* 5th ed. CLSI guideline M23 (ISBN 1-56238-824-8 [Print]; ISBN 1-56238-843-6 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2018.

Code throughout running headers:

M23, 5th ed.

Code, title, and previous editions on the Copyright page:

Suggested Citation

CLSI. *Development of* In Vitro *Susceptibility Testing Criteria and Quality Control Parameters.* 5th ed. CLSI guideline M23. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

Previous Editions:
November 1986, October 1990, August 1992, July 1994, April 1998, May 2001, October 2008, January 2016

ISBNs, ISSNs, volume, and issue number on the Copyright page:

ISBN 1-56238-824-8 (Print)
ISBN 1-56238-843-6 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic) Volume 38, Number 6

Code and surrounding text in the Quality Management System Approach section:

QSE grid:

When the Document…	The Text Above the QSE Grid Reads…
Covers a single QSE	M23 covers the QSE indicated by an "X."[a]
Covers more than one QSE	M23 covers the QSEs indicated by an "X."[a]

[a] This text is in 10-pt. font, as shown in the Proposed Draft document template.

POW grid:

When the Document…	The Text Above the POW Grid Reads…
Covers a single POW process	M23 covers the medical laboratory path of workflow process indicated by an "X."[a]
Covers more than one POW process	M23 covers the medical laboratory path of workflow processes indicated by an "X."[a]
Does not cover any POW processes	M23 does not cover any of the medical laboratory path of workflow processes.[a]

[a] This text is in 10-pt. font, as shown in the Proposed Draft document template.

Code, title, edition, publication year, and tagline format for CLSI documents cited in the Related CLSI Reference Materials section:

M02 **Performance Standards for Antimicrobial Disk Susceptibility Tests. 13th ed., 2018.** This standard covers the current recommended methods for disk susceptibility testing and criteria for quality control testing.

For second and subsequent pages in this section, "**Related CLSI Reference Materials (Continued)**" should be inserted in bold, 13-pt. font at the top of each page. The footnote from the first page does not need to be repeated.

6 Callouts in CLSI Documents

The following resource provides information related to callouts in CLSI documents published in InDesign.

Definitions and related criteria for each type of callout are included. Additional formatting notes related to bulleted lists, checklist items, numbered chapters, numbered lists, and document key words are also provided.

Callouts in CLSI Documents

Definitions of Callouts

Important Note – 1) a caution or warning; **2)** something that is a regulatory requirement; **NOTE:** The text in an Important Note can be paraphrased, as long as the intended meaning is not changed.

IMPORTANT NOTE:

Important note example. This is how this callout will be presented in the document. Make sure to adhere to the criteria for this callout.

***i*Reminder –** a resource or information reminder that highlights the need to refer to CLSI documents or other resources.

REMINDER:

*i*Reminder example. This is how this callout will be presented in the document. Make sure to adhere to the criteria for this callout.

Note – a strong recommendation that should be emphasized; **NOTE:** The text in a Note can be paraphrased, as long as the intended meaning is not changed.

NOTE:

Note example. This is how this callout will be presented in the document. Make sure to adhere to the criteria for this callout.

Callout Boxes – boxes that include text that is called out in a box instead of in a sidebar on the page.

This is an example of what a generic callout box would contain. Please make sure to adhere to the criteria that have been established for this type of callout box.

Criteria for Callouts

- Each callout should contain a maximum of 30 words.
- A maximum of three callouts should appear in the sidebar of each page.
- No text should be set in bold in the callouts unless it appears in bold in the Word document.

Types of Callout Boxes

Bulleted Lists

Bulleted lists within the body of the text and bulleted lists set within callout boxes can be used interchangeably, at the discretion of the graphic designer. **The stem sentence should be included with the bulleted list.**

This is how the stem sentence will be presented:

- Bullet item number 1
- Bullet item number 2
- Bullet item number 3 (etc.)

Check Marks

Include notations for check marks in any callout boxes only for checklist items. **The stem sentence should be included with the check-marked list.**

This is how the stem sentence will be presented:

- ☑ Checklist item number 1
- ☑ Checklist item number 2 (etc.)

Additional Formatting Rules

Numbered Chapters

All numbered chapters (eg, Abbreviations and Acronyms, Symbols) are set in their own sections within the body of the text, instead of in sidebars.

Numbered Lists

Numbered lists in Word documents connote procedural steps. Therefore, those items must remain numbered in the redesigned file.

Key Words

Key words are placed in a box at the end of the Foreword.