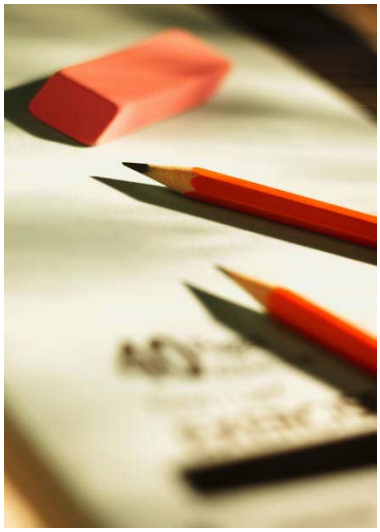
CLSI Style Guide
for Authors and Editors



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®

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Contents

Part I. CLSI Document Structure

Introduction

Clinical and Laboratory Standards Institute (CLSI) consensus 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 manner that is direct, concise, and easily accessible to the medical testing community, 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 is followed by successively numbered chapters and/or subchapters.

The sections listed below represent those usually included within most CLSI documents. However, the list is not all inclusive. When the document does not need a particular section, it need not 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. Depending on their nature, some mandatory sections may not be required in a supplement (eg, Key Words, References).

* Cover Page
    * Title and Code
    * Tagline

* Front Matter
    * Abstract
    * Committee Membership
    * Contents
    * Foreword
    * Key Words

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

* References
  Additional Resources
  Appendixes

* The Quality Management System Approach
* Related CLSI Reference Materials

1 Cover Page

1.1 Title and Code

The title of the document describes, in as few words as is practical, the main idea(s) within the text of the document. The code conveys the document category. It also denotes the document number in relation to other CLSI documents. Upon publication, the edition number of the document is displayed on the cover, as well as in the document citation and throughout the running headers.

For example, CLSI document QMS18—*Process Management,* is the first edition of the 18th CLSI project in Quality Management Systems, and the cover page includes "1st Edition" in the upper right corner.

The terminology used in the title should be chosen carefully to ensure it accurately describes the contents of the document (ie, when a document contains a reference method, the title should convey this point).

1.2 Tagline

The tagline comprises one or two sentences describing the important features of the document. As 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 is a concise summary of the content of the document (approximately 150 words) that explains the purpose and application of the document and explains the techniques used.

In addition to the abstract, this page of the document lists the primary authors of the document. This list is usually made up of the document development committee or working group members. In cases where additional individuals made significant contributions during the preparation of the document, those names are also listed.

2.2 Committee Membership

The Committee Membership page identifies the Consensus Council members, expert panel members, document development committee members, subcommittee and working group members (if applicable), and the following CLSI staff members: project manager, editorial manager, and editors.

Committee names are listed per the convention used in CLSI's internal software system, ie, "Document Development Committee on X." The same convention applies to subcommittees and working groups. Though titles of documents have the potential to 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 document.

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 the development of this document. His work on [X] helped in advancing this field, and stimulated many activities and efforts that will improve laboratory medicine and patient care.

2.3 Contents

The Contents page is an outline of primary chapters and secondary subchapters contained in the document. It is compiled and automated by CLSI staff.

When drafting the document's outline, it important to keep in mind that CLSI does not allow hanging subchapters. For example, when there is a Subchapter 2.1, there needs to be a corresponding Subchapter 2.2. If there isn't, the content of Subchapter 2.1 needs to be subsumed into the main Chapter 2 content. This policy carries through the subsequent subchapters (eg, the inclusion of Subchapter 2.1.1 necessitates the inclusion of Subchapter 2.1.2).

2.4 Foreword

The Foreword is an expanded summary of the content of the document, which also discusses the need for the standard or guideline.

The Foreword gives 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 member of the committee who is best able to discuss the key issues covered in the development of the document; this person is usually the Chairholder.

In all revisions (ie, second editions or higher), the Foreword briefly discusses the revisions made since the previous edition of the document.

2.5 Key Words

Five to eight words are selected that best represent the key concepts discussed in the document.

2.6 Consensus Process Note

All documents including the following NOTE, above the Key Words:

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.

3 Main Text

CLSI documents are generally 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, and procedures are more effectively stated as a list of imperatives. The three types of CLSI documents are:

- **Standards** – CLSI documents developed through the consensus process, clearly identifying specific, essential requirements for materials, methods, or practices for voluntary use in an unmodified form. A CLSI standard may, in addition, contain discretionary elements. These discretionary elements are clearly identified.

- **Guidelines** – CLSI documents developed through the consensus process describing criteria for a general operating practice, method, or material for voluntary use. A guideline can be used as written or modified by the user to fit specific needs. Mandates (ie, "must") are occasionally allowed in guidelines, in cases in which the mandate is based on a requirement or indicative of a necessary step to ensure patient safety or proper fulfillment of a procedure.

- **Reports** – CLSI technical documents that are published as a service for informational purposes only, and do not contain technical procedural recommendations. Reports are reviewed in accordance with requirements described in the "Documents Developed by CLSI" section of the Standards Developments Policies and Processes. These documents have the potential to become guidelines upon revision through the consensus body. Conversely, guidelines may be revised as reports.

- **Supplements** – CLSI documents that support the scope, purpose, methodology, and performance of an associated approved consensus document by providing information that updates or refines use of the consensus document.

In writing documents, it is especially important to differentiate between those elements that are imperative that the user follow and those that can be left to the user's discretion. Generally, the terms "will," "must," and "shall" indicate imperatives, and the terms "should," "could," "may," and "might" allow for user discretion.

Consistent with CLSI's definitions of a standard and a guideline, therefore, mandatory terms, such as "shall" and "must," are most appropriately used in standards, rather than in guidelines. In fact, the prevalence of such terms in a guideline indicates that it would be classified more accurately as a standard. However, as mentioned above, the definition of a guideline allows for the occasional use of such mandatory terms, eg, in cases in which the mandate is based on a requirement or related to patient safety or proper fulfilment of a procedure.

CLSI staff works with the document development groups to ensure that use of verbal forms (ie, shall, shall not; should, should not; may, need not; can, cannot) conforms to these recommendations when describing mandatory and discretionary elements in CLSI standards and guidelines. As stated previously, under the current policy, a standard may contain discretionary elements. A guideline, however, should not contain mandatory provisions unless they are presented as being based on regulatory, accreditation, or other externally imposed requirements.

3.1 Tables and Figures

Tables and figures should supplement rather than duplicate material found in the text of the document. Illustrations can be more effective to highlight patterns or differences. Tables and figures should be placed near the section of the text they illustrate. They are numbered sequentially and cited by order of appearance within the text. Each table and figure should have a brief, descriptive title. Tables and figures are styled to achieve the best visual presentation of data.

A figure is any type of illustration that is not a table, including 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. Photographs should be high-contrast, glossy, black and white, or color prints.

3.2 Introduction

This chapter includes the document scope and applicable exclusions, background information pertinent to the document content, standard precautions information (if applicable), a "Note on Terminology" (if applicable), 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 standard or guideline. It is important that the Scope establishes the elements to be included in and excluded from the document, and that it identifies the intended audience, uses, and exclusions/limitations of the document. The Scope can refer the reader to other CLSI documents, if appropriate. The Scope statement may be taken from the project proposal form.

3.2.2 Background

The Background subchapter is optional when introductory text leading into the standard or guideline is already in the Foreword or Scope. Material from the Abstract, Foreword, and 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 identical within each document, and is contained in the CLSI document template. However, at the discretion of the document development group Chairholder, additional descriptive notes may be added to more pointedly cover the topic of a particular standard or guideline.

3.2.4 Terminology

A Terminology subchapter is required, and includes the following subchapters:

- A Note on Terminology (optional)
- Definitions (required)
- Abbreviations and Acronyms (required)

The Terminology subchapter follows the Scope, Background, and Standard Precautions (when the latter two subchapters are included). Each definition should only be 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.

3.3 Path of Workflow

In this chapter, the requirements and/or guidance needed for each process should be described.

3.3.1 Process Flow Chart

This subchapter should include a process flow chart.

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, clinical information)
  - Particular instructions for examination ordered (eg, patient consent, special preparation like fasting)

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

- Sample Transport
  - Special preservation or handling of samples before their arrival
  - Proper and safe packaging, shipping, or transportation of samples
  - Use of a pneumatic tube system

- Sample Receipt and Processing
  - Information on where and how different types of samples are stored during hours
  - Tracing of aliquots to original source
  - Rejection criteria
  - Sample 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
  - Performing the examination

- 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

- 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.

- Results Reporting and Archiving
  - Elements included in the final report
  - Report turnaround time
  - Corrected reports

- Sample Management
  - Sample storage
  - Sample retention

3.4 Quality System Essentials

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

NOTE: There is no requirement to include information under each of these headings. Only relevant recommendations should be incorporated.

- Organization
  - Commitment to quality and good professional practice
  - Design of organizational structure to ensure quality
  - Allocation of resources
  - Planning for quality
  - Management review
  - Communication

- Customer Focus
  - Identifying customer and user expectations
  - Organization's capability to meet expectations
  - Measuring customer and user satisfaction
  - Recording and managing complaints (as nonconforming events)

- Facilities and Safety
  - Facility design and modification
  - Facility access
  - Facility use and maintenance
  - Facility communications system
  - Safety programs
  - Biosafety (eg, standard precautions)
  - Chemical hygiene
  - Occupational health, accidents, and illnesses
  - Hazardous waste management
  - Fire prevention
  - Emergency management preparedness, response, mitigation, and recovery
  - Radiation safety, as applicable

- Personnel
  - Job qualifications
  - Orientation to the organization
  - Management of training
  - Assessment of competence
  - Continuing education and professional development
  - Performance evaluation
  - End of employment
  - Personnel files

- Purchasing and Inventory
  - Selection qualification (SQ) based on ability to meet laboratory expectations
  - Purchase of materials or services
  - Supplier, contractor, consultant evaluation
  - Inspection and verification of received materials
  - Storage and handling of materials
  - Inventory management
  - Identification and tracking of critical materials and services

- Equipment
  - Selection qualification (SQ) and acquisition
  - Equipment qualifications: Installation (IQ), Operational (OQ), Performance (PQ)
  - Calibration program
  - Maintenance program
  - Decommission of equipment no longer in use
  - Equipment files and records

- Process Management
  - Analysis, design, and documentation of the activity
  - Process validation and/or verification
  - Process controls, to include quality control plans
  - Change management

- Documents and Records
  - Document management system: identification, creation, review, approval, revisions, periodic review, archival, storage, and retention
  - Records (data) management system: creation, identification, collection, review, revision, storage, access, retention, and disposal

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

- Nonconforming Event (NCE) Management
  - NCE reporting
  - NCE investigation
  - NCEs related to manufacturers' products
  - Classification, analysis, and trending of data and information
  - Identification of need for root cause analysis and process improvement
  - Management review of NCEs

- Assessments
  - External assessments (as applicable for organization)
  - Inspection and accreditation assessments
  - Internal assessments
  - Quality indicators
  - Internal audits

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

3.5 Conclusion

This subchapter includes a wrap-up discussion of key points of the document.

4 Supplemental Information

This chapter includes references, additional resources, 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 in numerical order.

4.3 Appendixes

Appendixes to the text may be included after the References section (or after the Additional Resources section, if applicable). If the material is essential to the understanding of the document, it should be handled as a figure or a table, or integrated into the 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, which 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—*Quality Management System: A Model for Laboratory Services.* The QMS template faces the Related CLSI Reference Materials section of the document. Elements of the QSEs and path of workflow included in the document are on this page, and the reader is referred to other CLSI documents that illustrate the remaining elements of the QMS.

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 body of the document and offers the user supplementary information to the material presented in the document. This section appears at the end of the document.

5 Additional Considerations

5.1 Copyright/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 identification of material requiring permission.

The CLSI editor is available to assist in this process and requires the following source information for the original material (ie, artwork, figures, tables, text):

- Publisher
- Title
- Date of publication
- 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.

Publishers are hesitant to release permission to reprint copyrighted material on the Internet (ie, the CLSI Shop) or in CD-ROM formats (ie, Infobase™). As such, it is important to get the process started as early as possible so there is ample time to make alternative arrangements in the event that permission is denied, or granted for a cost-prohibitive fee. Where possible, authors are encouraged to create their own figures, tables, etc., because the permission request process can lengthen editorial turnaround times.

5.2 Trade Names

Using a product's trade name may subject it to unfair criticism. It may also give it an unfair marketing advantage over other products in the marketplace. Trade names are avoided by using generic terminology. For example, replace the term "Ziploc bag" with "plastic, see-through, resealable, sandwich-type bag," or something to that effect.

The table below provides a list of generic substitutes for commonly used trademarks.

Generic Substitutes for Trademarks

Trademark	Possible Substitute(s)
Aloxite	aluminum oxide
Bakeline	polyoxybenzylmethylenglycolanhydride
Betadine	iodine/povidone
Carborundum	silicon carbide
Celite	diatomaceous earth
Kel-F	polychlorotrifluoroethylene
Lucite	polymethyl methacrylate (PMMA)
Mylar	polyester film
Nichrome	nickel-chromium resistance wire
Nujol	light mineral oil
Plexiglas	polymethyl methacrylate (PMMA)
Pyrex	borosilicate
Scotch tape	pressure-sensitive tape; transparent adhesive tape
Teflon	TFE-fluorocarbon or polytetrafluoroethylene (PTFE)
Tygon	vinyl
Vaseline	petroleum jelly
Viton	fluoroelastomer
Vycor	high silica

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 that practice is an implied endorsement of that organization as an example of best practice. Recommendations, examples, forms, or other user aids are to be generic based on consensus scientific principles or best practices.

Part II. CLSI Document Style Points

CLSI style is based upon the rules outlined in the 10th edition of the *AMA Manual of Style.* If a question of style arises for which a CLSI style point does not yet exist, the appropriate AMA style point is adopted.

The remainder of this style guide contains style points that authors and editors of documents 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. Adherence to and completion of the Document Review Checklist is also required of all Standards Development team members. See Part III, Section 4 for helpful tips related to the Document Review Checklist.

When marking up hard copies of draft documents during preparation for vote, it is helpful to use standard proofreading marks. These are available from *The Chicago Manual of Style Online,* at http://www.chicagomanualofstyle.org/tools_proof.html.

1 Abbreviations and Acronyms

Only internationally approved and accepted units of measure and some well-recognized clinical, technical, and general terms and symbols should be used in documents. 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).

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 will appear solely in the Abbreviations and Acronyms list, rather than in both the Abbreviations and Acronyms list and the Symbols list.

1.2 General Rule

- When a word or phrase is to be abbreviated, spell it out at first mention and put the abbreviation or acronym in parentheses after the word or phrase. Thereafter, use the abbreviation or acronym.

- An abbreviation or acronym should not be used only once. In such cases, use only the full term, and delete the abbreviation.

- Abbreviations and acronyms are not used in chapter or appendix titles.

- Abbreviations and acronyms are introduced anew (ie, spelled out on first mention, followed by the abbreviation/acronym in parentheses) in each appendix.

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 document 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)

1.3 Exceptions to the General Rule

1.3.1 Non-English Abbreviations

To avoid any potential confusion caused by non-English names, the following abbreviations are always included in the Abbreviations and Acronyms chapter, even when they only appear once in the document.

- **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*)

1.3.2 Abbreviations and Acronyms Not Spelled Out on First Mention

The abbreviations and acronyms listed below do **not** need to be spelled out on first mention. This list was compiled from the *AMA Manual of Style* and supplemented with input from CLSI staff.

NOTE 1: These abbreviations are still included in the Abbreviations and Acronyms subchapter.

NOTE 2: These exceptions do not apply to the document tagline. Someone viewing the document's cover may not have access to the main text of the document, which means that the reader does not have access to the Abbreviations and Acronyms subchapter. For this reason, all abbreviations should be spelled out upon first mention in the tagline.

NOTE 3: With the exception of those in bold, these abbreviations and acronyms are still spelled out in chapter and subchapter headings and appendix titles.

NOTE 4: With the exception of those in bold, the general rule for use of abbreviations applies to the use of these abbreviations in definitions. 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 upon first mention, followed by "(CV)," and the second appearance should be replaced with "CV." Part II, Section 1.4 contains additional instructions regarding the use of abbreviations within definitions.

AIDS	**acquired immunodeficiency syndrome**
ATCC[*]	American Type Culture Collection
CD	compact disc
CD	clusters of differentiation (use with a number, eg, CD4 cell)
CD-ROM	compact disc read-only memory
CSF	cerebrospinal fluid

[*] When ATCC is used, include this footnote upon first mention: "ATCC® is a registered trademark of the American Type Culture Collection." Use the registered trademark symbol (ie, ATCC®) with all subsequent uses of ATCC organism numbers.

CST	central standard time
CV	coefficient of variation
DDT	dichlorodiphenyltrichloroethane (chlorophenothane)
DNA	**deoxyribonucleic acid**
DOS	disk operating system
dpi	dots per inch
EDTA	**ethylenediaminetetraacetic acid**
eg	for example (from the Latin *exempli gratia*)
EHR	electronic health record
EIA	**enzyme immunoassay**
ELISA	**enzyme-linked immunosorbent assay**
EST	eastern standard time
etc.	et cetera (and so forth)
F	French (add *catheter;* use only with a number, eg, 12F catheter)
FISH	**fluorescence *in situ* hybridization**
GB	gigabyte
GMT	Greenwich mean time
HIV	**human immunodeficiency virus**
HTML	hypertext markup language
http	hypertext transfer protocol
ICU	intensive care unit
ID	identification
ie	that is (from the Latin *id est*)
IQ	intelligence quotient
ISBN	International Standard Book Number
ISSN	International Standard Serial Number
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
MST	mountain standard time
nb	*nota bene* (note well)
Nd:YAG	neodymium:yttrium-aluminum-garnet [laser]
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
PST	Pacific standard time
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
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*)
vs	versus (use *v* for legal references)
WBC	white blood cell
XML	extensible markup language
zip	Zone Improvement Plan (zip code)

1.4 Abbreviations and Acronyms in the Tagline, Abstract, Foreword, and Definitions

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

- Tagline
- Abstract
- Foreword

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

Example	Rationale
Abstract: The guideline addresses the clinical significance of lead measurements; specimen collection; and lead determination by graphite furnace atomic absorption spectrometry, anodic stripping voltammetry, and inductively coupled plasma mass spectrometry.	The abbreviations "GFAAS" ("graphite furnace atomic absorption spectrometry"), "ASV" ("anodic stripping voltammetry"), and "ICP-MS" ("inductively coupled plasma mass spectrometry") are used throughout this document. However, the terms are spelled out in the document's abstract, and the abbreviations are not present, because they are not used again within the abstract.

Source document: *Measurement Procedures for the Determination of Lead Concentrations in Blood and Urine; Approved Guideline—Second Edition* (C40-A2)

The Scope represents the beginning of the main text. However, within the text, treat each definition in the Definitions chapter as an independent entity (in other words, as "mini documents"). This convention allows each definition to be quickly and easily interpreted, without requiring the reader to refer to the Abbreviations and Acronyms chapter to understand the content of a definition. Also, when these terms are entered into the Harmonized Terminology Database, users of the database will be able to understand each definition without needing to interpret the meaning of potentially unfamiliar abbreviations.

Example	Rationale
process – set of interrelated or interacting activities that transforms inputs into outputs (ISO 9000)[15]; **NOTE:** A process may be documented as a flow chart or table that describes operations in the laboratory's path of workflow or activities within a quality system essential.	The abbreviation "QSE" ("quality system essential") is used throughout this document. 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: *Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition* (QMS02-A6)

NOTE: When the full term for an abbreviation listed in the Abbreviations and Acronyms subchapter also appears in the Definitions subchapter, the abbreviation or acronym should follow the definition in bold and within parentheses (but before the en dash), even when the abbreviation or acronym is not used again within that definition. This convention signals to the reader that the abbreviation is used throughout the document.

Example	Rationale
newborn screening program (NSP) – public health or other administrative entity responsible for development, implementation, and oversight of newborn screening laws, policies, and procedures for a given newborn screening system, including education, follow-up, diagnosis, management, and evaluation.	The abbreviation "NSP" 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 document.

Source document: *Newborn Screening Follow-up; Approved Guideline—Second Edition* (NBS02-A2)

1.5 Abbreviations and Acronyms in Chapter or Appendix Titles

Abbreviations and acronyms are generally prohibited in chapter and appendix titles. Part II, Section 1.3.2 identifies exceptions (in **bold**) to this rule. In addition, with permission from the editor, certain terms may be abbreviated in chapter or appendix titles when the term is:

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

Ideally, the abbreviation in question should meet all three criteria.

Example	Rationale
8.1 The *CFTR* Gene, Mutations, and Their Classification	• "*CFTR*" is central to the topic of this document. • "*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)

1.6 Abbreviations and Acronyms in Tables and Figures

Per AMA style, a note is included below each table/figure listing the abbreviations and acronyms used within that table/figure, in order to:

- Allow the reader to interpret the table/figure without referring to the Abbreviations and Acronyms chapter.

- Eliminate the need to spell out abbreviations and acronyms within tables/figures (which often creates a cluttered, unbalanced look) when the table/figure represents the first mention of the abbreviation or acronym.
  - **NOTE:** When a table(s) and/or figure(s) represents the **only** mention in the document, the term remains abbreviated and is added to the note below the table/figure, but is not added to the main Abbreviations and Acronyms chapter. However, for Microbiology supplements that consist mostly of tables (eg, M100), the main Abbreviations and Acronyms list includes all abbreviations used throughout the document.

The abbreviations list is arranged alphabetically, and appears in 9-pt. font. The placement of the list is as follows:

- **In tables:** The list is placed below the table, including below any footnotes.
- **In figures:** The list is placed below the figure, but above the figure title.

See the example, from *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*	237*
2.0	1.3†	93†
1.5	0.8†	52†

* Observed.
† Calculated.
Abbreviations: DBS, dried blood spot; DNA, deoxyribonucleic acid.

See Part II, Section 27 for additional formatting considerations.

1.7 Abbreviations and Acronyms in Appendixes

As mentioned in Part II, Section 1.2, abbreviations and acronyms are introduced anew (ie, spelled out on first mention, followed by the abbreviation/acronym in parentheses) in each appendix.

In addition, an abbreviations list is included at the beginning of each appendix. This list includes all abbreviations in the appendix, even those that are already listed in the main document's Abbreviations and Acronyms subchapter. Abbreviations that only appear in appendixes do not need to go in the main Abbreviations and Acronyms subchapter.

An exception to the abbreviations list at the beginning of each appendix is made 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 below the table (or form, etc.) as they would in any table or figure.

2 Addresses

Cities, states, and countries (with the exception of "USA") are spelled out in full.

Always add "USA" after all US addresses.

3 Age and Sex Referents

The table below illustrates the terminology associated with various age groups.

Term	Age
Newborn	Birth to 30 days
Infant	1 month to 1 year
Child*	1 year to 12 years
Adolescent	13 through 17 years
Adult	≥18 years

* Sometimes, "children" may be used broadly to encompass persons from birth to 12 years of age.

The most common area in which these rules are called upon is the Newborn Screening (NBS) category of CLSI documents. The following paragraph, which allows a deviation from AMA style with the use of "baby," 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 30 days old, and *infant* indicates a person from 1 month 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, use the decimal form (eg, 6.5).

When a group of adults is differentiated by sex, *men* and *women* is preferred over *male* and *female.* However, when a group being described comprises children and adults of both sexes, then 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 ("an hour's wait"), not the straight apostrophe ("an hour's wait"). The same style applies to quotation marks.

5 Capitalization

The rules for capitalization in documents are conventional (eg, proper nouns; geographic 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 (unless these words appear parenthetically)
- All verbs
- All words that carry significant weight, even without meeting the criteria cited in the first two bullets (eg, "New," "Old")

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

- A noun
- An adjective
- As important as the first word

For example: Make-up; Through the Looking-Glass

6 Citation of CLSI Documents

The suggested citation for CLSI documents appears on the Copyright page of every CLSI consensus document. The format of a CLSI document citation in the References section must match the suggested citation provided on that document's Copyright page.

The citation for documents published before January 1, 2015 uses the following format:

CLSI. *Document Title.* CLSI document [Code]. Wayne, PA: Clinical and Laboratory Standards Institute; [Year].

Documents published after January 1, 2015 (excluding M02-A12 and M07-A10) use the following format:

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

When other CLSI document codes appear within the text of a document, the following convention is followed:

- In CLSI document EP17, detection limits are…

NOTE 1: The word "document" appears between "CLSI" and "EP17," rather than "standard" or "guideline."

NOTE 2: Only the root code is used. For document codes that include an approval level (ie, those published before January 1, 2015) it is not necessary to include the full approval level (eg, EP17-A2).

When a document's **own** code is mentioned within the text of the document, the following convention is followed:

- In NBS02, long-term follow-up…

NOTE 1: "CLSI document" does not precede the document code.

NOTE 2: Only the root code is used; it is not necessary to include the full approval level (ie, NBS02-A2).

NOTE 3: When documents self-refer without using the code, the specific document type should be used. For example, for NBS02, use "This guideline" instead of "This document." This style point applies to standards and reports. Supplements may 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 the *AMA Manual of 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 defined as half of 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.

8 Decimal

Place a zero before the decimal point: 0.123 (**not** .123).

9 Emphasis

In general, use **bold** 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/acronym.
- *Italicization* is reserved for publication titles.

Furthermore, **bold** is the most eye-catching, which expedites the process of choosing callouts during the layout and design portion of the production stage. See Part III, Section 6 for more information related to document callouts.

NOTE 1: The Note on Terminology uses italicization for emphasis, 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 plain).

10 Equations

Equations are numbered sequentially throughout the document. Equation numbers are:

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

When an equation is mentioned within the text, "equation" is lowercased and the equation number appears in parentheses, eg, "see equation (1)."

11 Footnotes

Footnotes in the text are indicated by superscripted, lowercase letters of the alphabet. These footnotes are automated (similar to the way references are) and are inserted by CLSI staff.

[a]
[b]
[c] . . .

Footnotes in tables and figures are indicated by the following superscripted symbols (though, for ease of reading, they are not superscripted here), and are used in the order shown:

*	Asterisk
†	Dagger
‡	Double dagger
§	Section sign
¶	Paragraph mark
#	Number sign

These symbols are inserted manually (ie, not automated), and are doubled when more are needed.

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.

12 Gene Symbols and Sequences

Contrary to AMA recommendations, gene symbols and sequences are not spelled out. At the request of the document Chairholder and/or when a document is meant for beginners, a list explaining the symbols and sequences can be included.

13 Greek Letters

The use of Greek letters over words is preferred, unless usage dictates otherwise.

For example, in chemical terms, the letter is usually preferred (β-carotene). For electroencephalographic (EEG) terms, the word is used (eg, alpha wave).

In some cases, when the Greek letter is part of the word, as in *betamethasone,* the Greek letter is spelled out and the set is closed up.

In addition, in some names, the approved nonproprietary name takes the word, not the letter, with an intervening space (eg, beta carotene). In any case, either the word or the letter must be used consistently throughout the document.

14 Headers, Footers, and Margins

The following specifications apply:

- Inside (ie, binding edge) margin: 1 inch
- Outside margin: 1 inch
- Top margin: 0.375 (ie, 3/8) inch
- Bottom margin: 0.375 (ie, 3/8) inch

Committees are encouraged to use landscaped pages sparingly, as these pages must be manually manipulated by CLSI staff to accommodate headers, footers, and margins. When documents are being prepared for the printer, these types of pages are often found to have insufficient margins. The manual reworking of these pages by CLSI staff causes delays in document publication.

15 Hyphen

A hyphen is used to join two (or more) words when they are used together as an adjective that **precedes** the noun it modified. 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.

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.

The exceptions to hyphenation rules are:

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

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

- Hyphenate all words that would otherwise create an entirely different word without inclusion of the hyphen. For example, when “re-creation” is intended, do not use “recreation.”

- Hyphenate all prefixes preceding a(n):
  - Proper noun
  - Capitalized word
  - Number (eg, post-2006 conference)
  - Abbreviation (eg, non-CLSI document)

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

- Do not hyphenate Latin phrases, eg:
  - *In vitro* diagnostic device

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

16 Latin Terms in Microbiology

The table below illustrates the formatting associated with these terms.

Usage	Style	Example
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

17 Lists (Bulleted)

Bullets are used for nonprocedural lists. For example:

List storage requirements, including:

- Container
- Temperature
- Stability (shelf life)
- Labeling

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.

In addition, bulleted lists should:

- Flow directly from the stem text, if possible.
  - Anticipatory phrases such as "as follows" and "the following" are generally not needed before the colon that introduces a bulleted list. However, when the context calls for such phrasing, ensure that a noun is inserted after "the following."

- Begin with a capital letter.

17.1 Spacing

- When each bullet only takes up one line of space, and no sub-bullets exist, no extra return appears between each bullet.
  - **NOTE:** Inserting extra spaces between second-, third-, and fourth-level sub-bullets is determined on a case-by-case basis, according to the number of sub-bullets and the overall length of the list.

- When at least one bullet takes up more than one line of space, an extra return appears between each bullet.

17.2 Punctuation

- The only punctuation that is used at the end of each bullet is a period, as applicable (ie, commas and semicolons are not used).
  - When all bullets are complete sentences, insert a period on the end of each bullet.

  - When no bullets are complete sentences (ie, they are sentence fragments), do not insert a period on the end of each bullet.

17.3 Structure

- Strive to create parallel structure in lists, ie, all items are sentences or all items are fragments.
  - If necessary, some text can be moved to sub-bullets, when this action keeps the main bullets parallel.
    - For example, lists often contain bullets that are mostly fragments, though a few fragments have extra, explanatory sentences tacked onto the end. These explanatory sentences can be moved to the next line and indented as sub-bullets. Then, each main bullet **does not** contain a period, while each sub-bullet **does** contain a period.

Laboratory considerations regarding automated procedures include:

- May be required for laboratory workload and program requirements
- Definitely required for methods using 384-well MTP
- May compensate for limited hours of operation
- Requires critical scrutiny of programming, reliability, and maintenance/verification to ensure components are properly dispensed and well mixed in the reaction matrix
  - LHDs must be serviced often and validated with the help of a service representative.
- May present problems with DBS specimens
  - Blood spots may stick to automated pipetting devices, and the presence of a DBS in the plate makes programming the device more challenging.
- May require monitoring of instruments during operation

Source document: *Newborn Blood Spot Screening for Severe Combined Immunodeficiency by Measurement of T-cell Receptor Excision Circles; Approved Guideline* (NBS06-A)

In the example above, all of the main bullets are fragments. The complete sentences that appear in the fourth and fifth bullets appear as sub-bullets, in order 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, insert a period on the end of each bullet.

18 Lists (Numbered)

Numbers are used to indicate steps in a procedure.

1. Place the package in a plastic bag.
2. Place the bag in a shielded storage area.
3. Survey the area where the package has been.
   - Clearly mark all contaminated spots.
   - Restrict traffic through these areas.
4. Follow standard decontamination procedures for spills.

As illustrated in Step 3, bullets are used in the event that a numbered list contains sublevels (see Part II, Section 17).

18.1 Spacing

See Part II, Section 17.1 for rules regarding spacing between items in a numbered list.

18.2 Style

For numbered lists broken out from a paragraph, use the following style:

1.
2.
3.

For numbered lists within a paragraph, use the following style:

The first three steps of the preexamination process for blood sample collection are 1) receive request, 2) greet patient, and 3) wash hands.

NOTE: Procedural lists within paragraphs are appropriate for very short lists with little text. When appropriate, break out lists in a vertical format. This format helps to highlight the list, rather than burying it within the paragraph.

19 Mathematical Composition

19.1 Preferred Symbols

Use the **stacked plus-minus sign** to indicate addition or subtraction (eg, ±2.5%).

Use a **minus sign** (−) rather than an en dash (–) or hyphen (-) to indicate subtraction or negation.

Use a **multiplication dot** for most equations (eg, 3 kg • 9 kg).

Use the **multiplication sign** to express scientific notation (eg, 3×10^9), area (eg, 2 × 2 table), and magnification (eg, 40× magnification).

In running text and elsewhere as appropriate (eg, for clarity) use a **slash** (/) 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: $\frac{a}{b}$, $a\ b^{-1}$, $a \cdot b^{-1}$.

Use the **"approximately equal to" symbol** (≈) to indicate approximation. The **"similar to" symbol** (~) is reserved for use in geometry and calculus.

19.2 Spacing

Thin spaces should be used before and after the following mathematical symbols:

+
−
±
×
•
÷
/
=
≠

| ∩ ∫ ∏ Σ

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

< > ≤ ≥ ≈ ~

These symbols are found in the Symbols section of Microsoft® Word. A thin space should also be placed between a digit and the unit of measure. A "thin space" is defined as half the size of the current font, rounded up to the nearest whole number. For example, CLSI documents are typed in 11-pt. font. Therefore, a "thin space" is a 6-pt. space.

19.3 Subscripts

For legibility, all subscripts are lowered by 3 points, rather than using the Microsoft® Word subscripting feature. For example: x_i, not x_i.

19.4 Punctuation

Punctuation after a set-off equation (ie, one broken out from a sentence) is helpful to clarify its place within the sentence. Where 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)

20 Numbers

The following chart illustrates the general CLSI editorial policy on the use of numbers.

	Word	Numeral
Ages (of people)		X
One through nine	X	
10 and up		X
Ordinals: **first** through **ninth**	X	
Ordinals: **10th** and above		X
Percentages		X
Rounded large numbers (eg, 8 million)		X
Measures of temperature (eg, 17°C)		X
Numbers with units of measure attached (eg, 4 µg/mL)		X
Numbers in tables (eg, interpretive criteria in CLSI document M100)		X

20.1 Exceptions

Always spell out numbers at the beginning of sentences, titles, subtitles, or headings.

- *Correct:* Thirty-five employees attended the staff meeting.
- *Incorrect:* 35 employees attended the staff meeting.

- *Correct:* Seventy-two percent of volunteers responded to the survey.
- *Incorrect:* 72% of volunteers responded to the survey.

Numbers less than one should be expressed using the decimal system whenever possible.

20.2 Spelling Out Numbers

Hyphenate “twenty-one” through “ninety-nine.”

Do not use commas or “and” when numbers greater than 100 are spelled out, eg, “one hundred thirty-two.”

21 Per

To indicate “per” in units of measure, use the unit abbreviation and slash (eg, “µg/mL” for “micrograms per milliliter”).

22 Percentages

22.1 Numerals vs Words

As noted in Part II, Section 20, the percent symbol (%) is used when preceded by a number (eg, 50%).

When the percentage begins a sentence, title, subtitle, or heading, spell out the percentage. 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), as in:

- “…and 12% to 14% were between 18 and 24 years old.”

23 Periods and Quotation Marks

Periods are not used when listing a person’s credentials (eg, John Smith, MD).

A correctly placed period appears inside quotation marks.

- *Correct:* All patient and laboratory specimens are treated as infectious and handled according to “standard precautions.”

- *Incorrect:* All patient and laboratory specimens are treated as infectious and handled according to “standard precautions”.

CLSI style uses smart quotation marks (“standard precautions”), not straight quotation marks ("standard precautions"). The same style applies to apostrophes.

24 Preferred Spellings and Usages

24.1 Spelling of Commonly Used Terms and Phrases

airborne
aliquotted; aliquotting
appendixes
back pressure
backflow
bar code (noun and verb); bar-code (adjective)
bloodborne
bloodstream
brainstem
carryover (noun)
CO-oximeter and CO-oximetry
coverslip
cross section (noun); cross-section (adjective and transitive verb)
cut off (verb); cutoff (adjective and noun)
database
dataset
disk
eg (no periods)
e-mail
emm
end point (noun); end-point (adjective)

end user (noun); end-user (adjective)
fingerstick
flow chart
follow up (verb); follow-up (adjective and noun)
foodborne
gram-positive and gram-negative (*not* Gram-positive)
Gram stain (*not* gram stain)
Haemophilus Test Medium
health care (always two words)
ie (no periods)
Internet (*not* internet)
laboratory (*not* lab)
Levey-Jennings (*not* Levy)
low birth weight (noun and adjective; no hyphens per Dorland's)
matrixes
mecA
mm Hg
mould (*not* mold) in microbiology fungal documents
mucus (noun); mucous (adjective)
number (*not* No.)
offline
online
pairwise
pCO_2
pipette; pipetting; pipettor
pO_2
President-Elect
RCF (*not* rcf)
recordkeeping
RPM (*not* rpm)
set up (verb); set-up (adjective and noun)
sex (*not* gender)
start up (verb); start-up (adjective and noun)
stepwise
Taq polymerase
troubleshooting
turnaround
unit-use (adjective)
United States (noun); US (adjective); USA (in addresses)
up-to-date (always hyphenated, regardless of part of speech)
Vice-Chairholder
vs (*not* "vs." or "versus")
Web (when referring to "World Wide Web")
website (*not* "Website" or "web site")
workflow
workload
workstation
wristband

NOTE: For disputes or uncertainties regarding the spelling of medical terms outside of this list, CLSI defaults to the 32nd edition of *Dorland's Illustrated Medical Dictionary.*

24.2 Substitutions

For harmonization purposes, replace “local, state, and federal requirements,” with “regulatory and accreditation requirements.”

Do not use “body” or “bodies” when referring to organizations. Use “organizations.”

Use “medical” rather than “clinical” when referring to the medical laboratory setting. “Clinical” is reserved for the patient-centric clinical care setting.

Use “needs” (or an appropriate synonym) instead of “requires,” unless the statement directly reflects a regulatory, accreditation, organizational, or performance requirement.

Do not use “address(es)” as a verb. Appropriate substitutes include “investigate,” “cover,” “discuss,” “manage,” “handle,” “include,” “explain,” “demonstrate,” and “recognize,” among others.

Use “newborn” rather than “neonate,” except in accepted abbreviations, eg “neonatal intensive care unit (NICU).”

Where possible, avoid the use of “impact”; use “affect” (verb form) or “effect” (noun form) instead.

Change “execute” to “implement” (or another applicable synonym).

Change “since” to “because.”

Change “prior to” to “before.”

Change “employ” to “use.”

Change “utilization” and “utilize” to “use.”

Change “where” to “in which” or “for which” when applicable.

Change “while” to “although” when applicable.

Change “via” to an appropriate substitute (eg, “through” or “using”).

Where possible, change “further” to “additional” (eg, “For additional information…”).

24.3 Commonly Confused Words

“If” vs “When”

Use “if” to express possibility: “If the document is submitted for editing today, the editors will review the comments this afternoon.”

Use “when” to express a definitive outcome: “When the printer proof is approved, the document is published.”

“That” vs “Which”

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. For example:

- 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.

Use “which” in nonrestrictive clauses. Nonrestrictive clauses are set off by commas, and can be removed from the sentence without changing its meaning. For example:

- 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.

“Continuous” vs “Continual”

Use “continuous” to describe activity that never ceases. For example:

- Blood flows continuously throughout the cardiovascular system.

In this sentence, “continuously” is appropriate because blood flow is constant and unceasing.

Use “continual” to describe activity that is frequent and steady, but contains pauses. For example:

- CLSI continually publishes standards and guidelines.

In this sentence, “continually” is appropriate because CLSI steadily publishes new documents throughout each year, but does not publish new documents all day, every day.

“Staff” vs “Personnel”

“Staff” is the collective group of employees who work for an organization. The term “personnel” represents the collective group of employees and contractors performing work in a particular organization.

25 Ranges

25.1 Main Text

Use “to” to indicate ranges in the main text, eg, “five to 10 minutes.”

25.2 Tables

Use an en dash (–) to indicate ranges in tables, eg, “2–8 µg/mL.”

25.3 Exceptions

The following ranges always use the word "to," even in tables:

- Percentages
- Temperatures

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

26 References

All listed references should be cited in the text in numerical order using superscripted, Arabic numerals. All references must be available in English. Exceptions must be appropriately justified and approved by the Editorial Manager and/or Senior Director of Standards and Quality.

The main body of the document uses an automated system within Microsoft® Word that is maintained by CLSI staff. Citations in an "Additional Resources" section are listed alphabetically and are not numbered, and citations in appendixes are inserted manually.

NOTE: Within the text, superscripted reference numbers appear **after** commas and periods, but **before** semicolons and colons; for example:

- See CLSI document GP42,[1] which is an essential reference to use with this standard.
- An essential reference to use with this standard is CLSI document GP42.[1]
- See CLSI document GP42[1]; it is an essential reference to use with this standard.
- The following processes comprise the laboratory path of workflow, as described in CLSI document QMS01[1]:
  - Preexamination
  - Examination
  - Postexamination

References are listed as single entries in numerical order at the end of the document (but before any appendixes). CLSI encourages committees to use fewer references rather than many. It is not necessary to include all of the references that may be suitable to support a fact; rather, a single suitable reference for the fact is sufficient.

References should be from reputable, peer-reviewed publications, including journals, textbooks, public laws or regulations, and published standards and guidelines. References to mass circulation magazines or newspapers, materials not yet accepted for publication, and information available solely in abstracts or by personal communications are not acceptable as listed references. See the CLSI Guidelines for References for additional information.

26.1 Journals

The minimum data that must be contained in journal references are the author(s), article title, journal, year, volume number, and inclusive page numbers.

Journal references adhere to the following format:

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

Example:

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.

NOTE 1: The best source for journal article information is PubMed. CLSI defaults to the plain text style used by PubMed, with the exception of organisms (ie, Latin genus and species terms). This text should be italicized in the References section, just as it is in the main text of CLSI documents.

NOTE 2: See the *Index Medicus* for a comprehensive list of journal abbreviations.

NOTE 3: For a journal reference with more than six authors, list the first three authors, followed by the Latin phrase "et al."

NOTE 4: The semicolon after the third author indicates that the authors are writing together as part of the named committee. Where applicable, PubMed provides this information in the format listed above.

NOTE 5: Journal article titles are represented in lowercase letters, except in cases where a proper noun is mentioned, such as "College of American Pathologists Microbiology Survey Program."

NOTE 6: Though PubMed inserts a period after "media" (above) and capitalizes "Update," CLSI style combines the two sentences by replacing the period with a colon, and lowercasing the word that follows it.

26.2 Books

The minimum data that must be contained in book references are the author(s), title, place of publication, publisher, and year. The most common variations of book references are listed below.

NOTE: For a book reference with more than six authors/editors, list the first three authors/editors, followed by the Latin phrase "et al."

26.2.1 Book With an Author(s)

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

Example:

Sherlock S, Dooley J. *Diseases of the Liver and Biliary System.* 9th ed. Oxford, England: Blackwell Scientific Publications; 1993:523-528.

26.2.2 Book With an Editor(s)

Title of Book. Edition. Place of publication: Name of publisher; Year.

Example:

Thompson LF, Willson CG, Bowden MJ, eds. *Introduction to Microlithography.* 2nd ed. Washington, DC: American Chemical Society; 1994.

26.2.3 Book With a Chapter Reference

Author(s) of chapter. Title of chapter. In: Editor(s)/Author(s). *Title of Book.* Edition. Place of publication: Name of publisher; Year:Inclusive page numbers.

Example:

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.

NOTE: In cases in which the authors of a chapter are also authors or editors of the book, their names are listed in both places.

26.3 Documents Published by Organizations

Publications or documents published by organizations or groups where there are no named authors adhere to a similar format as that used for books.

Examples:

ASTM. *Standard Specification for Microscope Objective Thread.* E210-63. West Conshohocken, PA: ASTM International; 2010.

ISO. *Medical laboratories – Requirements for quality and competence.* ISO 15189. Geneva, Switzerland: International Organization for Standardization; 2012.

26.4 Federal Register and Code of Federal Regulations

Visit the US Government Publishing Office website and choose "Retrieve by Citation" to locate the Federal Register or the Code of Federal Regulations (CFR). Sometimes, the Federal Register numbers are difficult to locate. In these cases the CFR reference alone is sufficient. Suggested formats are listed below.

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). US Government Publishing Office; 2006.

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). US Government Publishing Office; 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). US Government Publishing Office; published annually.

26.5 Websites

Website references adhere to the following format:

Author/organization. Title of webpage. Website link. Access date.

Example:

US Food and Drug Administration. Critical path initiative. http://www.fda.gov/oc/initiatives/criticalpath. Accessed July 2, 2013.

27 Tables and Figures

27.1 Titles

- Titles go above the table, but below the figure.
- Titles do not require a period at the end, unless a legend immediately follows.
- Titles may contain abbreviations and acronyms. (See Part II, Section 1.6 for additional rules regarding the use of abbreviations in tables and figures.)

27.2 Alignment and Formatting

- Table headings are centered and base aligned.
- Table headings should be shaded with a grey background (the second "grey" shade in the "Shading" menu of the "Paragraph" section of the toolbar ribbon).
- When table columns contain numerals, these columns should be centered. Otherwise, table text is left justified.
- Both tables and figures are aligned with the left margin of the document.

28 Telephone Numbers

Use periods rather than hyphens: 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 representations of temperature, no space appears between the number, degree symbol, and/or Celsius sign: 8°C.

29.1 Temperature Ranges

As mentioned in Part II, Section 25.3, use "to" in temperature ranges. Only insert the degree sign and Celsius symbol after the second number: 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: 2°C ± 8°C.

30 Time

General format: 10:30 AM

Time range spanning morning to afternoon: 10:30 AM–12:00 PM Eastern* (US) Time

Time range not spanning morning to afternoon: 10:30–11:00 AM Eastern* (US) Time

* Substitute "Central," "Mountain," and "Pacific," as applicable.

31 Units of Measure

Document development committees or working groups that draft CLSI documents are required to 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 following notes provide some guidance on the conversion of certain traditional units to IUPAC/IFCC-recommended units.

- Analytes traditionally expresses per mL or dL should be expressed per liter (L).
- Analytes traditionally expressed in mass concentration (eg, g/L) should be expressed as substance concentration (eg, mol/L) (except in the case of human hemoglobin), when the molecular structure is sufficiently known.
- Analytes traditionally reported as fractions and expressed as a percent should be reported using the decimal system.
- 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 (see the conversion table on the following page). Inclusion of these units facilitates global harmonization and increases the international acceptance and use of CLSI documents.

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*	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

* American spelling; Europe uses "metre," "litre."

† The symbol for liter (l) and the number one (1) should be given distinctly different symbols. Because most typescripts give insufficient distinction, it is recommended in the United States that the capital "L" be the accepted symbol.

Part III. CLSI Document Development Resources

1 Author and Committee Member Verification

The Consensus Council roster, which appears in every CLSI document, should match the roster in the Proposed Draft document template.

All other committees should be checked against NetSuite. The document development committee (DDC) roster can be used to check the DDC list, the Author list, and the Acknowledgments section. Although they may not be DDC members, the individuals listed in the Author list and the Acknowledgments section usually have some role in the DDC (eg, contributor). If an individual listed in the Author list and/or Acknowledgments section is not found in the DDC roster, his or her information can be located using the general "Search" function in NetSuite.

While preparing a document for Proposed Draft vote, project managers should use the procedure below to check DDC, expert panel, and, when applicable, subcommittee and working group rosters. Because the Committee Membership page must represent membership at the time of Proposed Draft vote, project managers should save the exported rosters for each committee to SharePoint, using the following naming conventions:

- Document Development Committee: "[DocumentCode]_DDC_Proposed_Draft_Voting_Roster"
- Expert Panel: "[DocumentCode]_Expert_Panel_Proposed_Draft_Voting_Roster"
- Subcommittee: "[DocumentCode]_Subcommittee_Proposed_Draft_Voting_Roster"
- Working Group: "[DocumentCode]_Working_Group_Proposed_Draft_Voting_Roster"

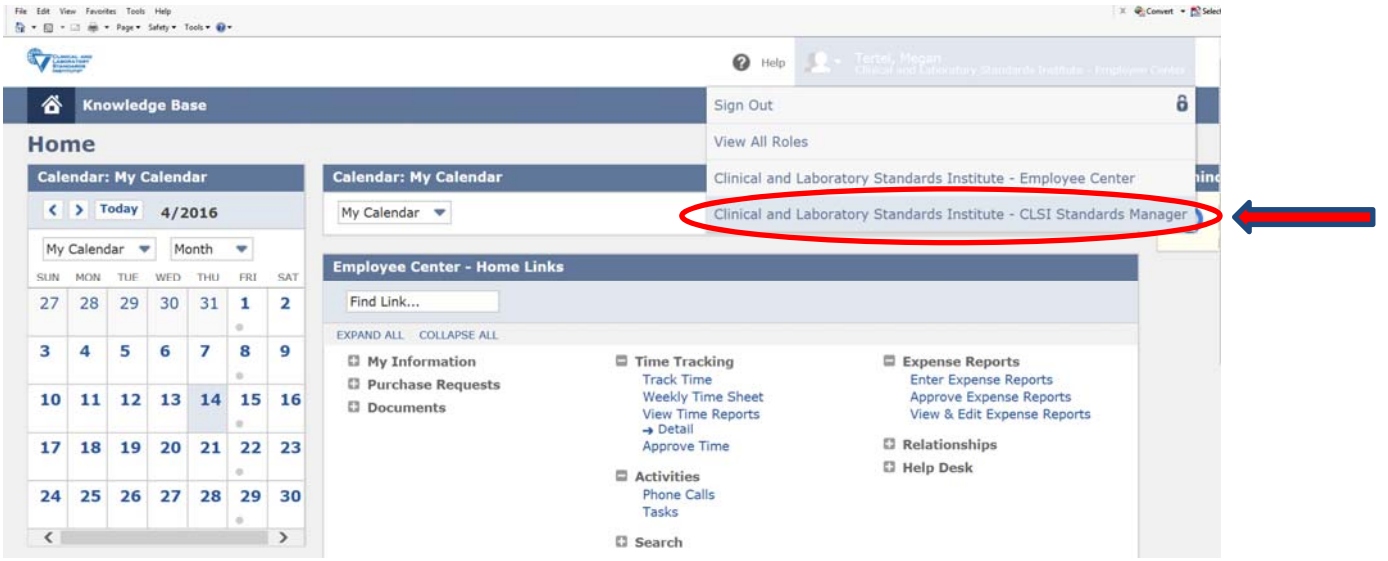
Even though each group does not vote at Proposed Draft, the roster name should still include "Voting" in the title, because it is the roster in effect at the time of voting.

Rosters should be uploaded to the appropriate project in SharePoint, using Classification "Committee_Info" and Category "Roster." Before Final Draft vote, the editors will use these saved rosters to check the author and committee lists in the document.

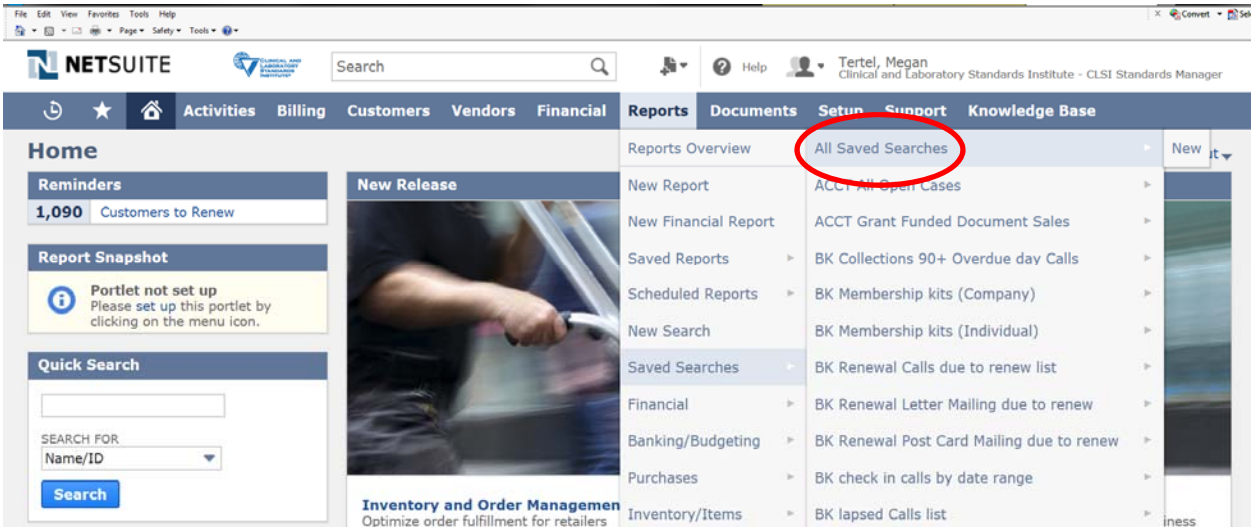
Creating a Roster

1. Log in to NetSuite at http://www.netsuite.com. (**NOTE:** Use Internet Explorer. There have been problems with certain steps when using Chrome.)

2. From the drop-down menu that displays employee name and current role, select "CLSI Standards Manager."



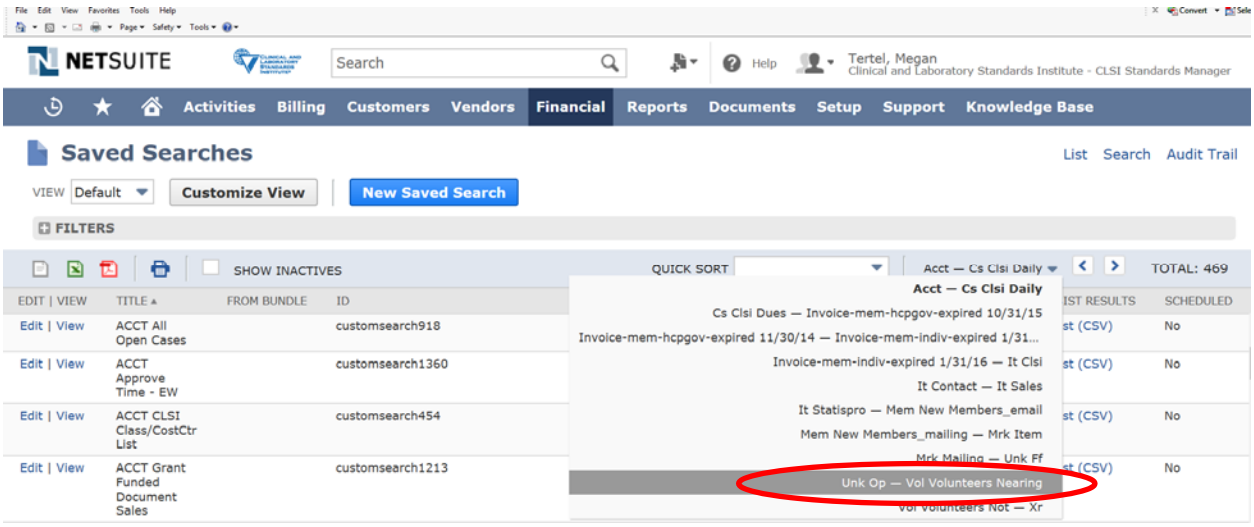
3. Hover over "Reports," "Saved Searches," and "All Saved Searches."



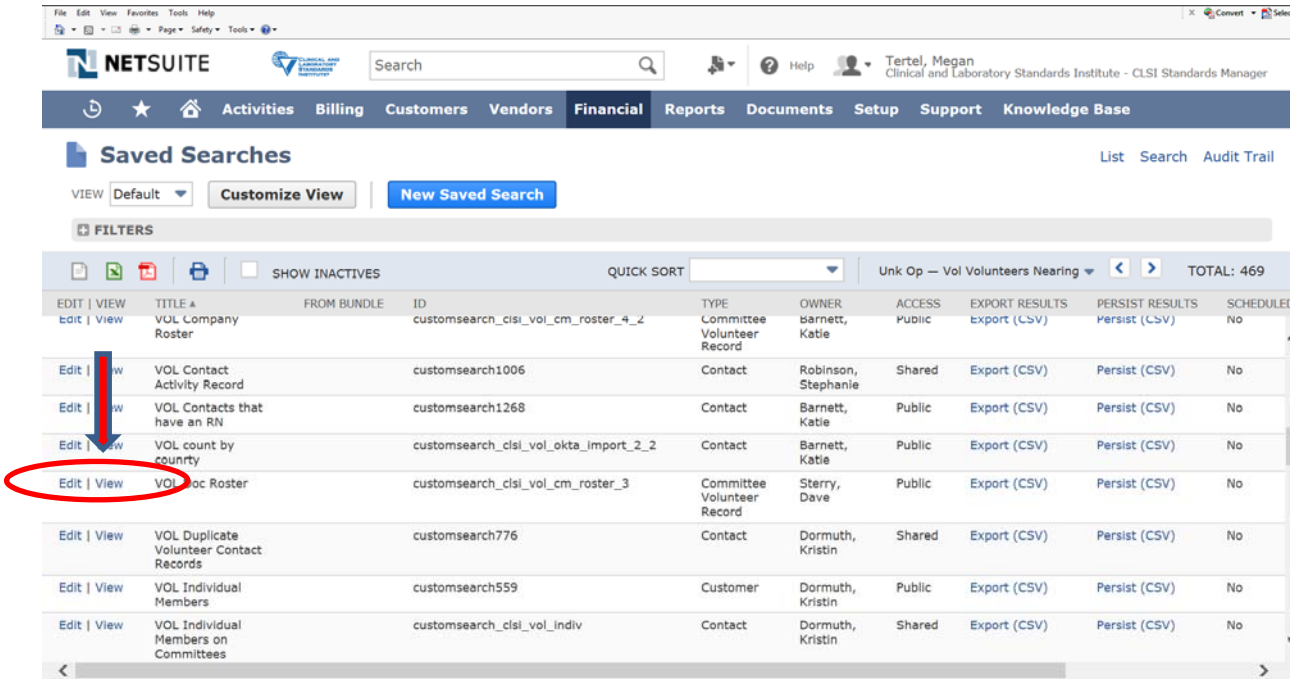
4. Click "All Saved Searches."

5. In the "From-To" section in the upper right of the screen (to the right of the "Quick Sort" drop-down menu), select the alphabetical range in which "Vol Doc Roster" would appear.

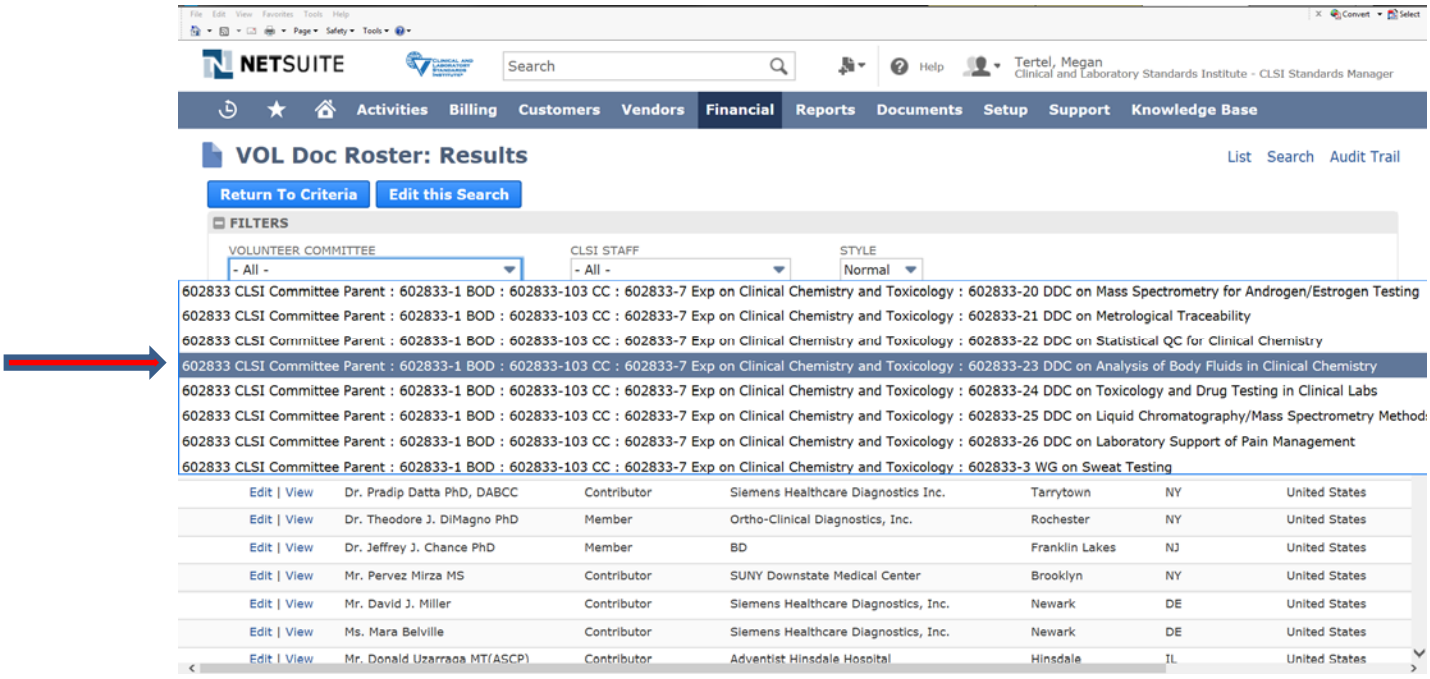
   NOTE: In the screen shot below, this range is "Unk Op – Vol Volunteers Nearing." Because "Vol Doc Roster" falls alphabetically between "Unk Op" and "Vol Volunteers Nearing," this is currently the section of the list in which the saved search is found. However, as more items are added to the "Saved Searches" category, the "bookends" of each portion of the list will change.



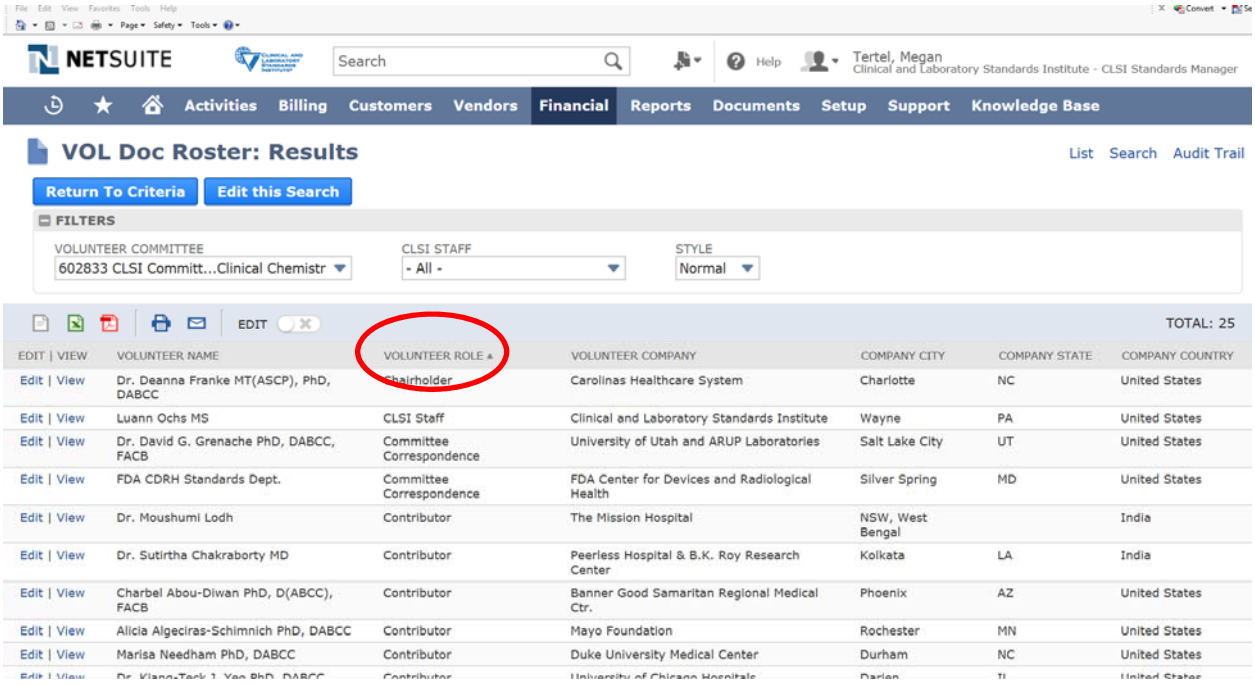
6. Scroll to "Vol Doc Roster" and click "View."



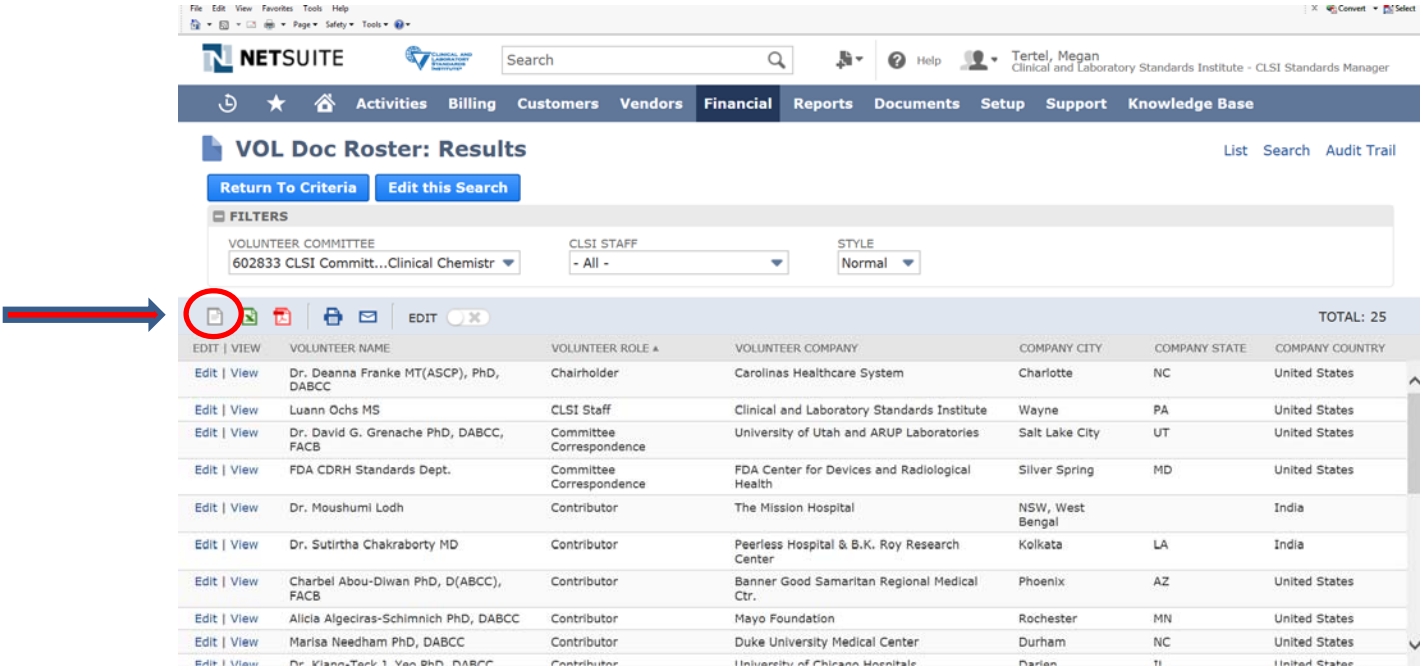
7. Click on "FILTERS," near the top left of the screen. In the "Volunteer Committee" drop-down menu, navigate to the appropriate committee. For example, when checking the DDC for C49, click on "DDC on Analysis of Body Fluids in Clinical Chemistry." (The DDC name closely resembles, and often matches, the document name.)



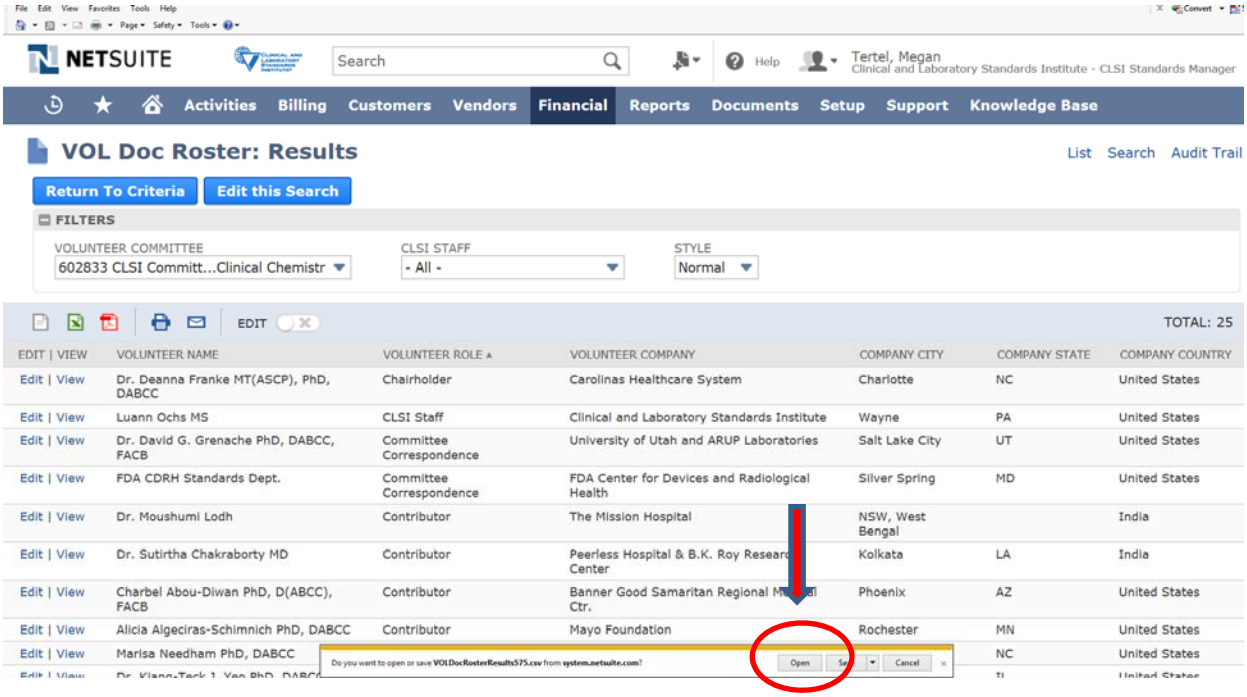
8. After selecting the committee, click "Volunteer Role," which groups the list alphabetically according to committee roles (eg, contributor, member).



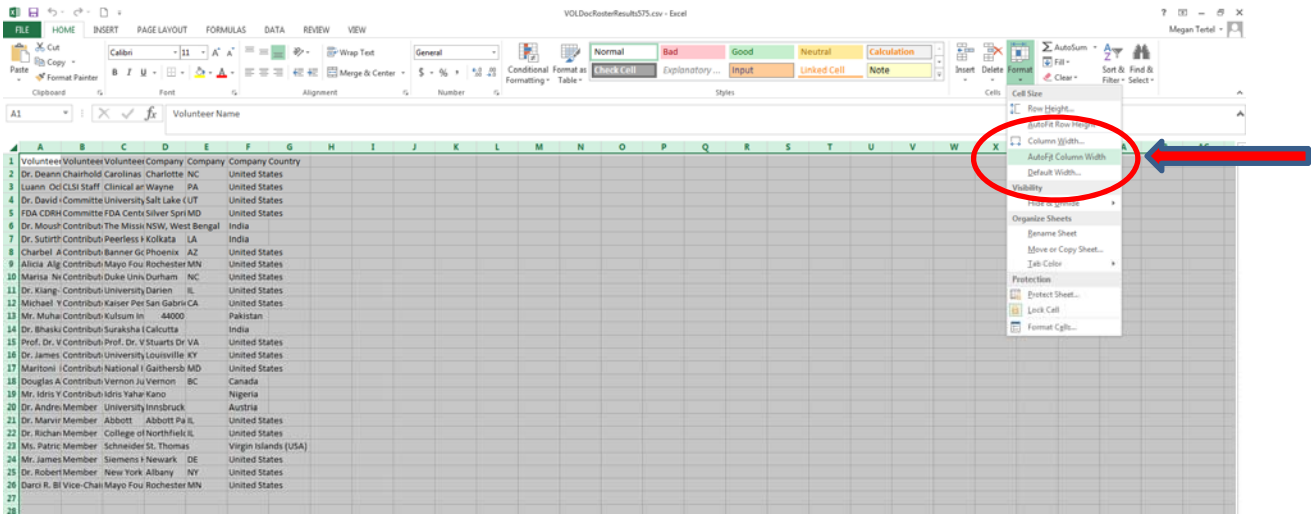
9. Near the upper left portion of the screen, click the "Export - CSV" icon.



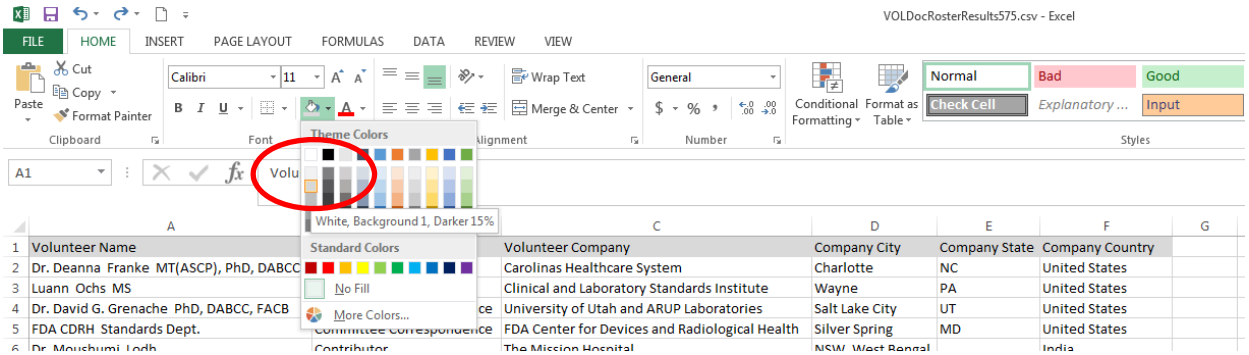
10. When asked "Do you want to open or save **[file name]** from **system.netsuite.com**?" click "Open."



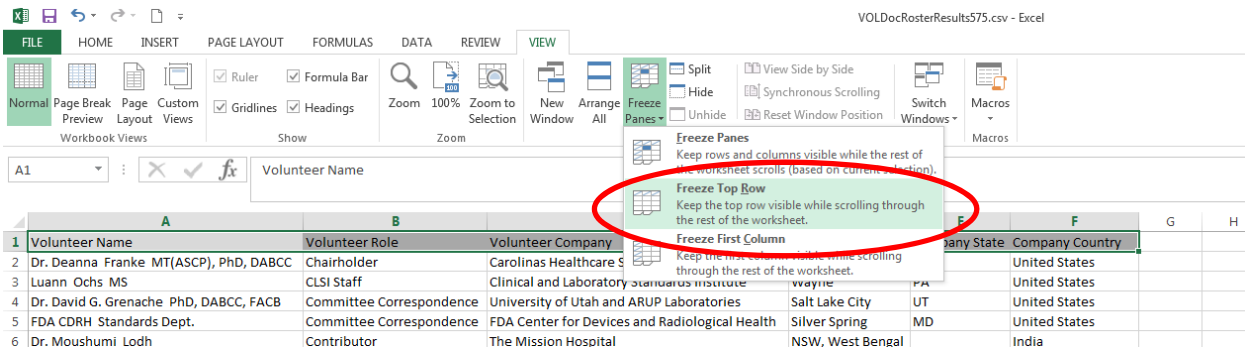
11. When the spreadsheet opens, hold down the "Ctrl" key and hit the "A" key. In the "Format" menu, select "AutoFit Column Width."



12. For ease of use, highlight and freeze the top row of the spreadsheet.
    - To highlight, highlight (with the cursor) the top row and select a highlighting color from the menu.



    - To freeze, highlight (with the cursor) the top row. In the "View" menu, select "Freeze Panes" and "Freeze Top Row." This feature keeps the top row visible while scrolling through the spreadsheet.



13. Save exported roster in SharePoint, using naming convention and tags noted above. **NOTE:** In order to maintain formatting (eg, column widths), save file as Excel file rather than CSV file.

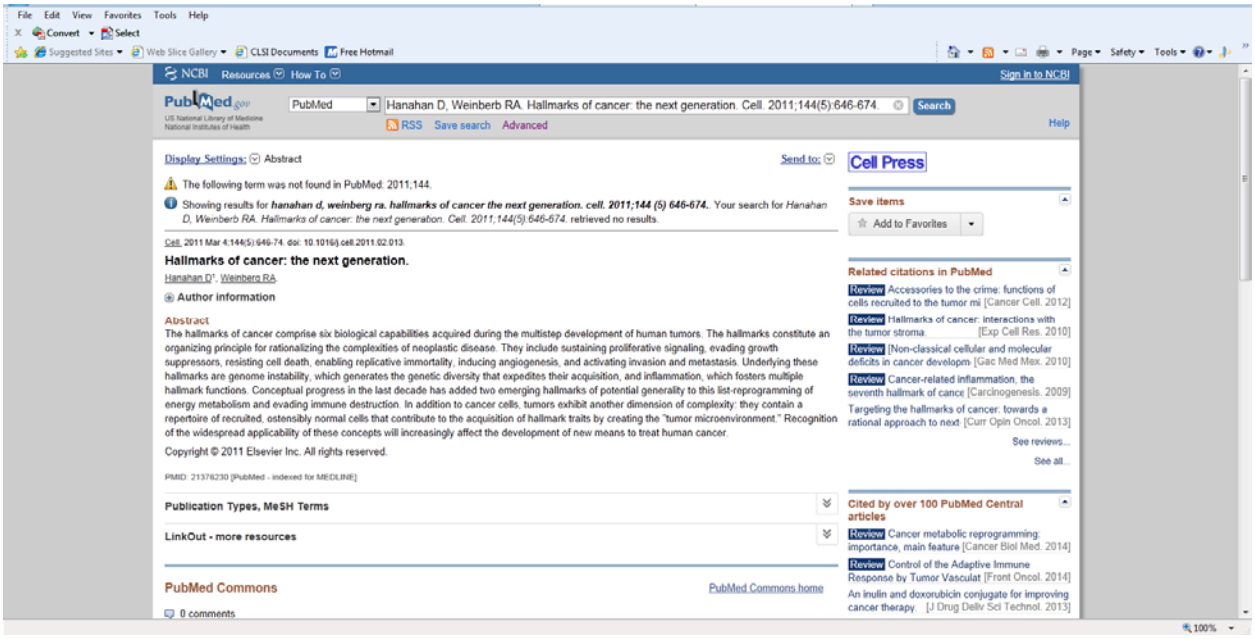
2 Permission Requests

A permissions log is included at the bottom of the transmittal form submitted with the document for Proposed Draft editing. The log contains information for all figures and tables in the document that require permission. If a figure or table does not require permission (eg, it was created by one of the document's authors, and was never published elsewhere), these items can also be added to the permissions log as a reminder that permission is not needed. This practice is helpful when documents contain numerous tables and/or figures.

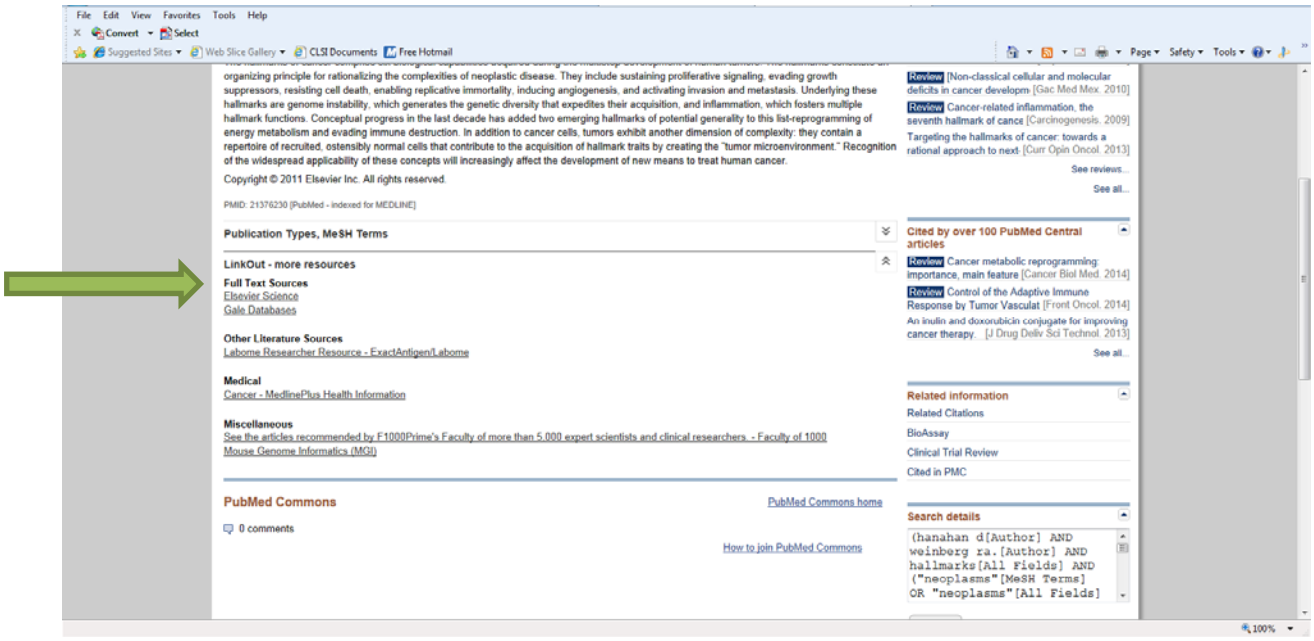
2.1 Journal Articles

If a figure or table was originally published in a journal article, permission for its use can generally be obtained through the Copyright Clearance Center.

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

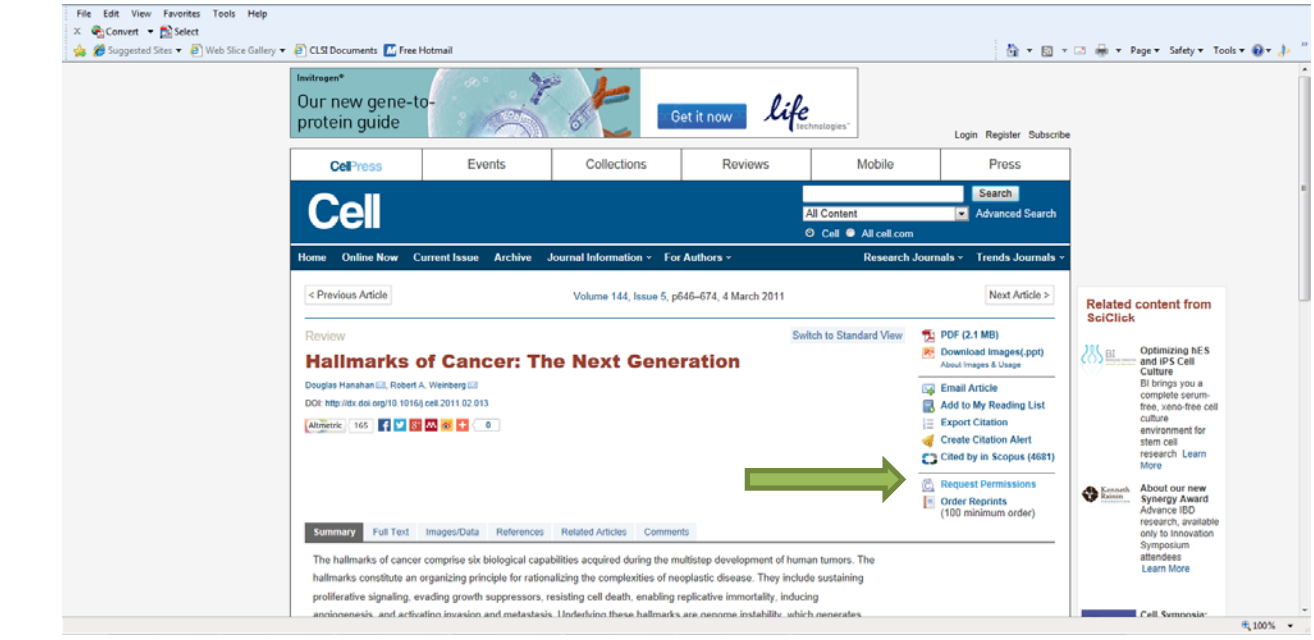


2. Scroll down and click on "LinkOut – more resources." (**NOTE:** This wording will sometimes differ, depending on what journal is being viewed.)



3. In the "Full Text Sources" section, click on "Elsevier Science." (Most of our permissions 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.

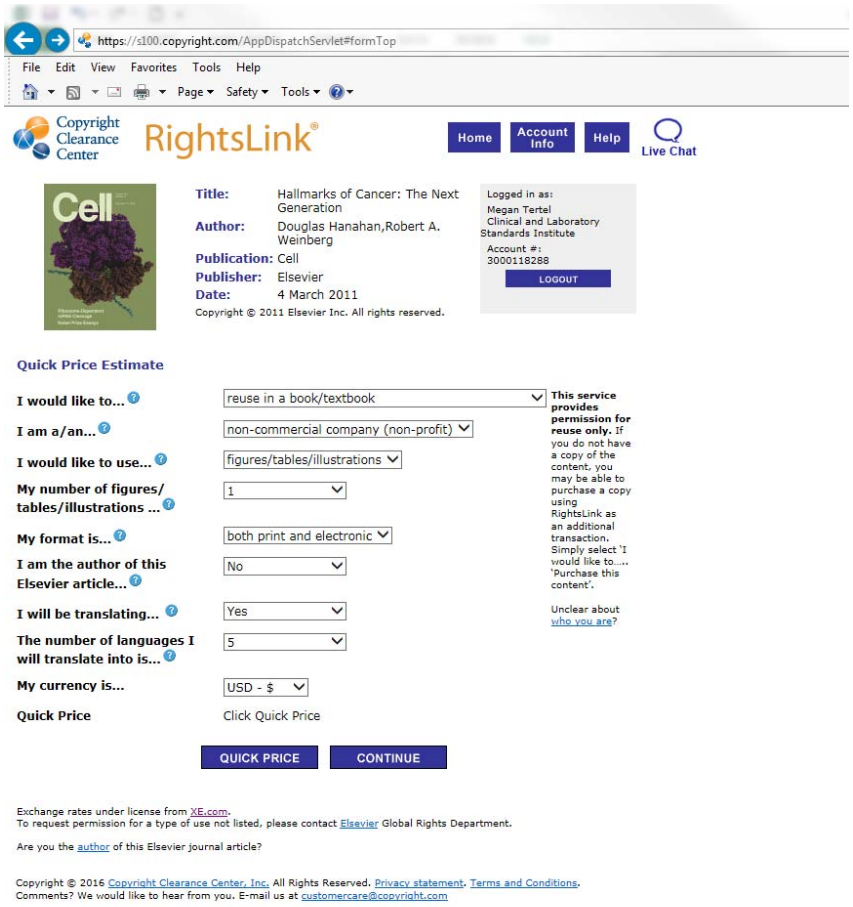
6. Using the drop-down menus, answer each question appropriately.
   - I would like to… reuse in a book/textbook.
   - I am a/an… non-commercial company (non-profit).
   - I would like to use… figures/tables/illustrations.

- My number of figures/tables/illustrations… 1.
- My format is… both print and electronic.
- I am the author of this Elsevier article… No.
  - **NOTE:** If the author of the journal article is also an author of the CLSI document, we should ask the project manager to obtain permission from the volunteer for the CLSI editors 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.



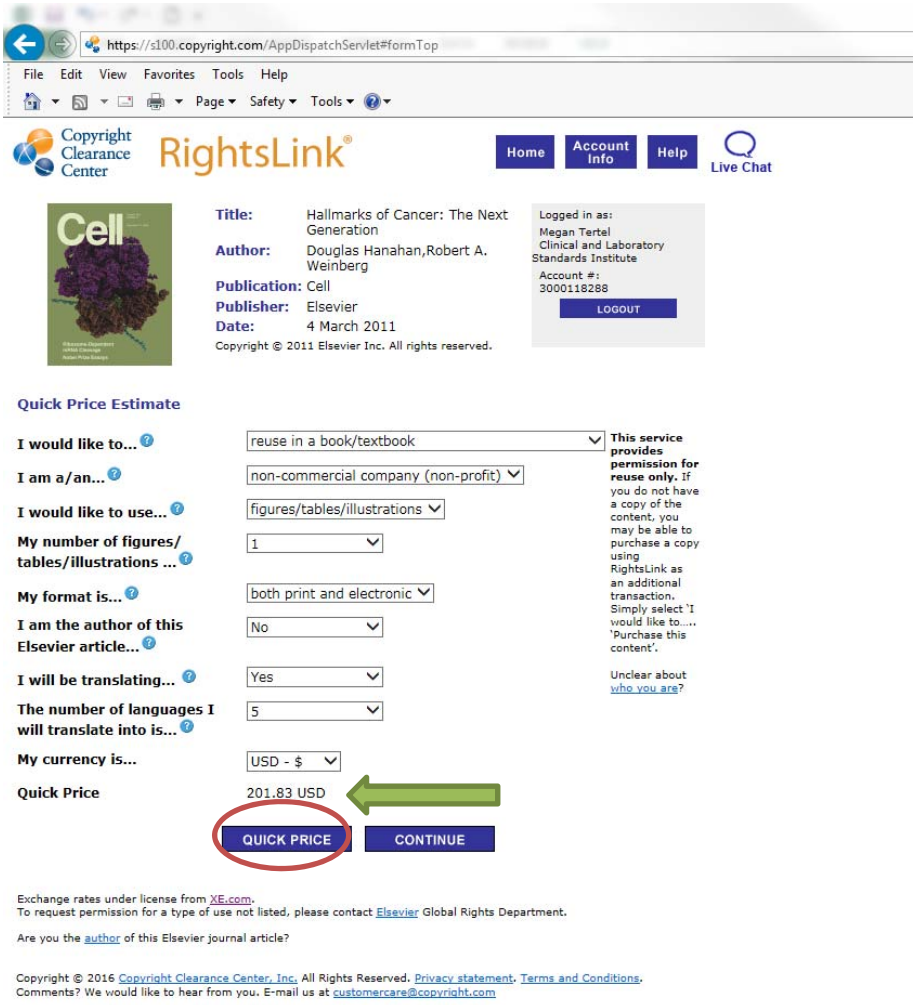
10. Repeat step #6, using the following responses, to obtain an Infobase quote.
    - I would like to… reuse in a CD-ROM/DVD.
    - My billing country is… United States.
    - I am a/an… non-commercial company (non-profit)
    - I would like to use… figures/tables/illustrations.

- 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.

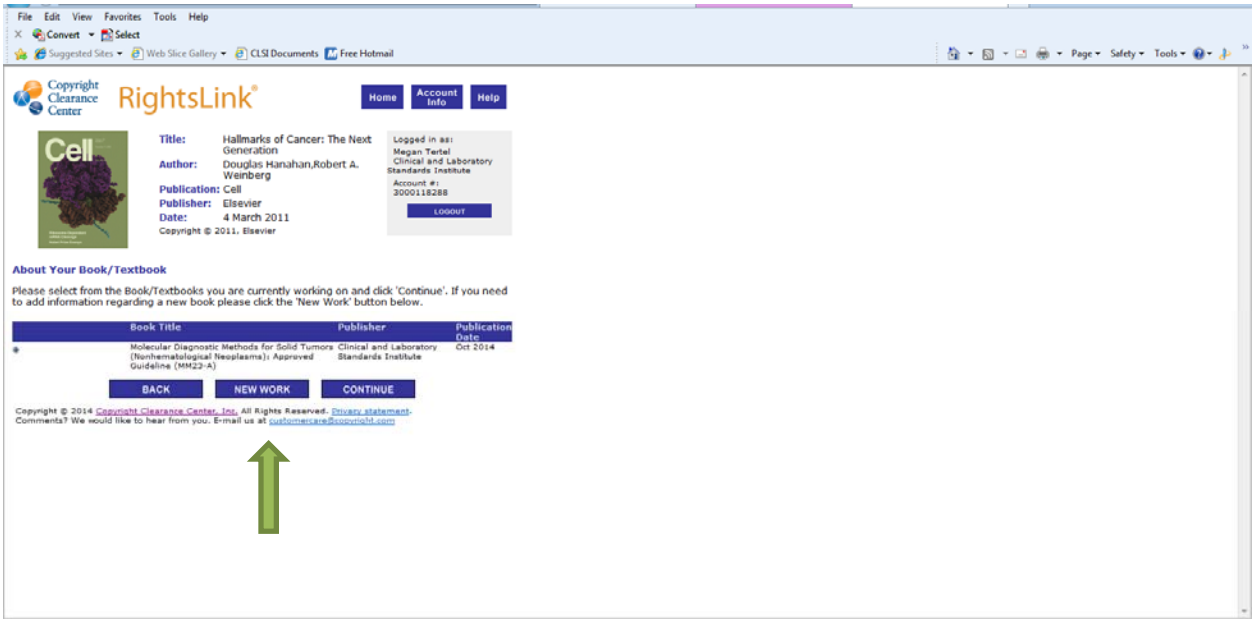
NOTE 1: For a high English-only book/textbook quote (> $250), high CD-ROM quote, or a denied permission for either request, notify the project manager. The project manager may need to contact the committee to see if an alternative table or figure can be used instead. If the translation quote is even 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. If the figure cannot be replaced, Marketing will be notified that the document cannot be translated.



12. If all prices are acceptable, re-enter the book/textbook information, 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."

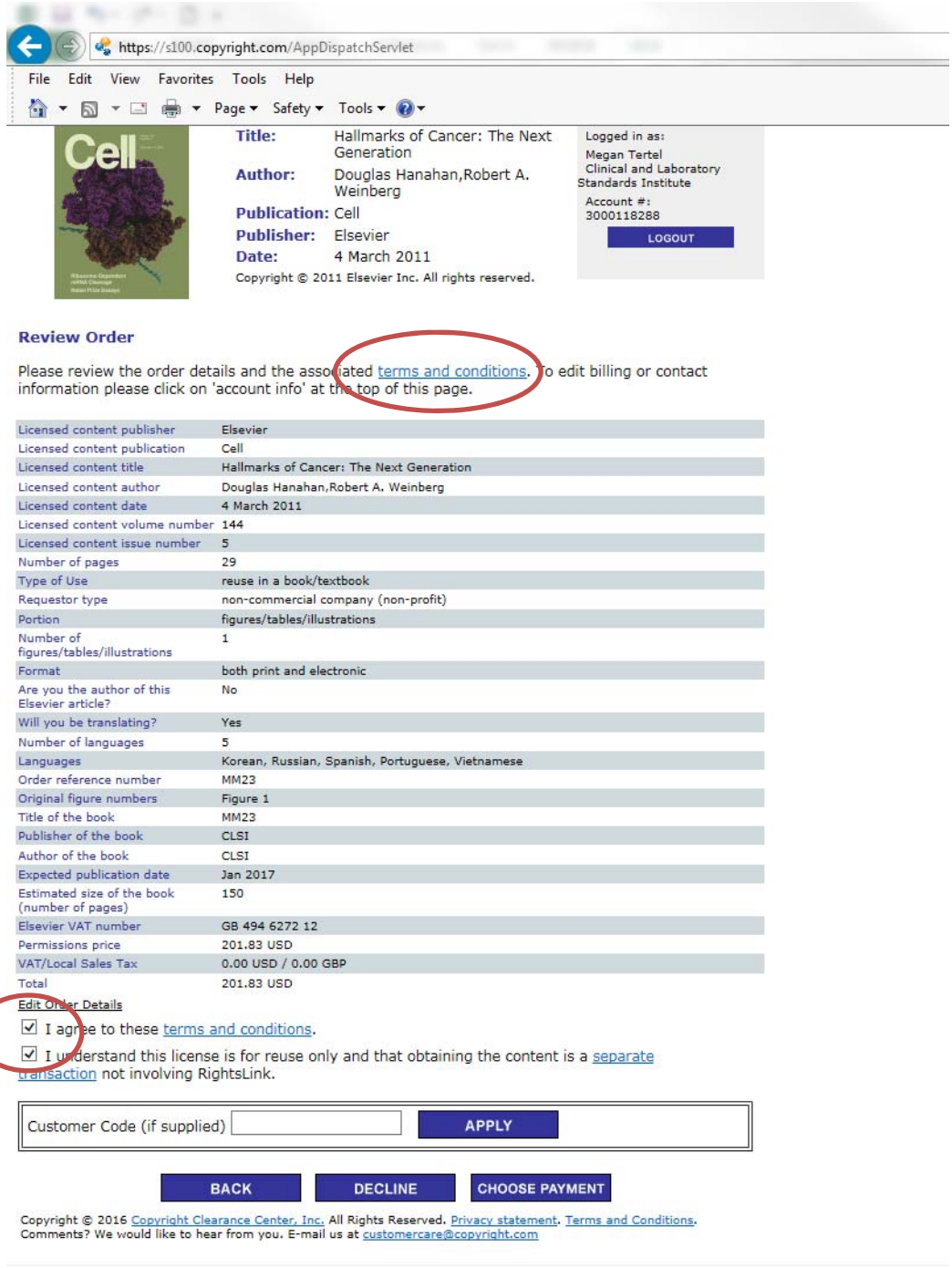


14. Enter the title, author ("Clinical and Laboratory Standards Institute"), and publisher of the book ("Clinical and Laboratory Standards Institute"). Enter the anticipated publication date, and the estimated number of pages, and select "Continue."

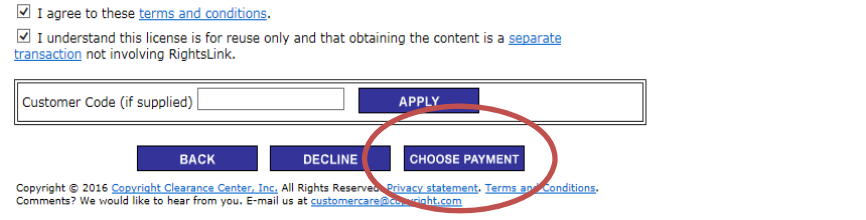
15. Enter the document code in the "Order Reference Number (optional)" field, and select "Continue."

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 project manager should be notified of the issue.

    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.

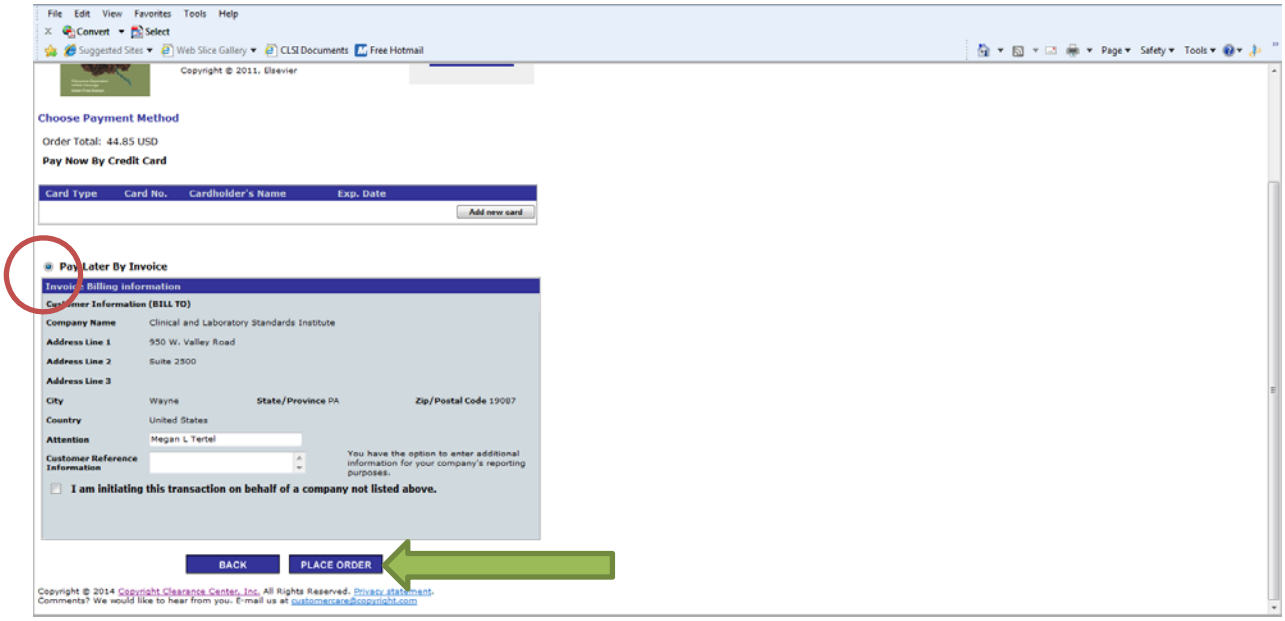


17. Select "Choose Payment."



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 webpage. Convert the webpage to a PDF by right-clicking and choosing "Convert to Adobe PDF."

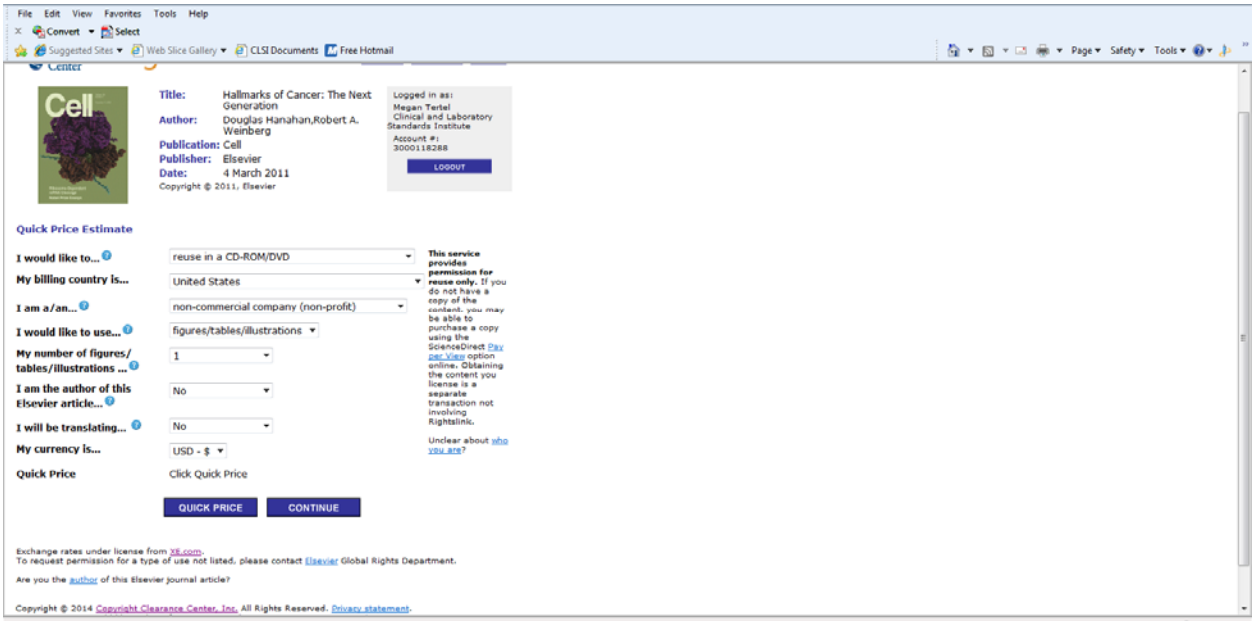
22. Save the PDF to the desktop, naming the file "DocumentCode_Figure[#]_License_Book."

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

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" for "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. Repeat items #7 to #17, above.

28. Save the PDF to the desktop, naming the file "DocumentCode_Figure[#]_License_Infobase."

29. Upload the file to the appropriate project in SharePoint (Classification: "Editorial"; Category: "Permissions"; Subcategory: "License").

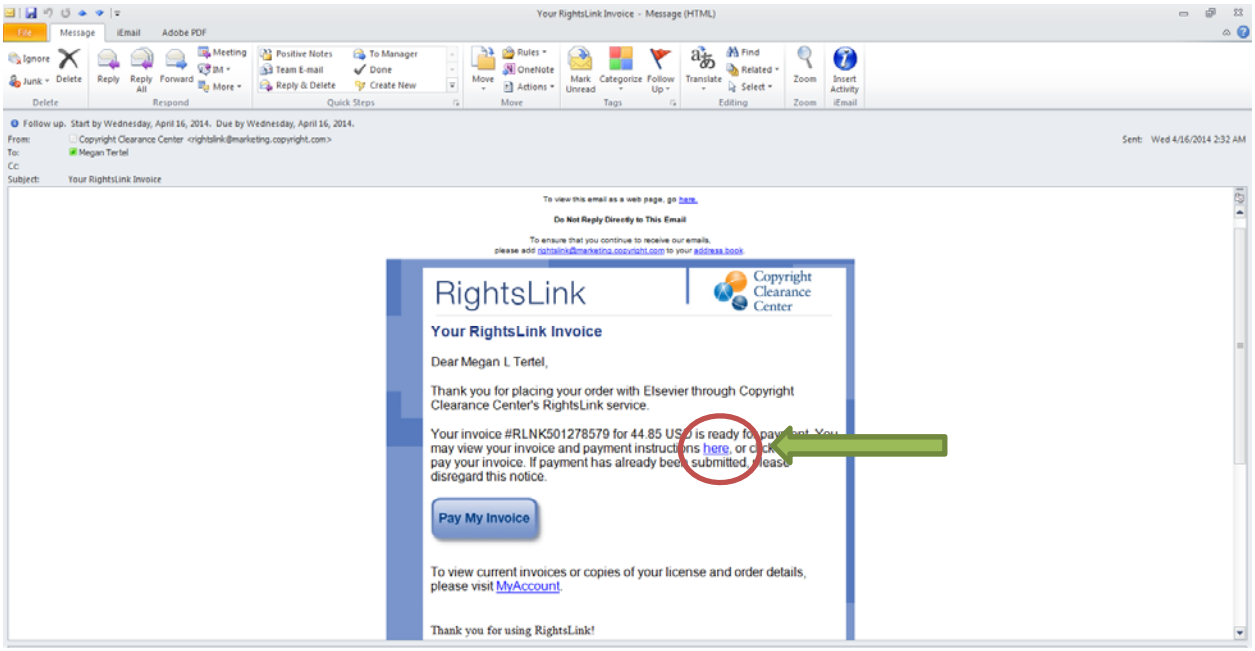
30. Delete the file from the desktop.

31. Update the "Permission Requested (Date/NA)" column in the permissions log to indicate that permission was requested through the Copyright Clearance Center (eg, "4/15/16 – via CCC").

32. Include the permission slug in the permissions log. Sometimes, the publisher supplies this information in the terms and conditions. When the publisher does not provide the format, use the following format, in 9-pt. font:
    - (Adapted 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.)

33. 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.)

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



35. Print the invoice.

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

37. Print the invoice.

38. On the hard copy invoices, print the following information:
    - Category: Copyright Expense
    - Department: Standards
    - Class: [Document Code]

39. Obtain a signature on the invoices from the Senior Director of Standards and Quality.

40. Update the "Permission Received (Yes/No/NA)" column in the permissions log to indicate that permission was received through the Copyright Clearance Center (eg, "Yes – 4/15/16 – from CCC").

41. Place the signed invoices in the "Accounts Payable" inbox on the Accounts Payable Coordinator's desk.

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.

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.

> 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.
>
> Thank you for your kind attention. Please let me know if there is a fee, or whether I need to take any further 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 figure/table.

4. Update "Permission Requested (Date/NA)" column in the permissions log to indicate that permission was requested, and from whom (eg, "e-mailed 'cancergovstaff@mail.nih.gov'").

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 600 member organizations in the form of a password-protected PDF. The document will also be available for purchase on the CLSI Shop for $130, in print and password-protected PDF form. The initial print run is approximately 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 375 CD-ROMs are produced each year.

6. Each time a follow-up communication is sent or received, update the "Permission Requested (Date/NA)" column in the permissions log with any new details.

7. If permission is received and no fee is required:
   - Save the e-mail to the desktop.
   - Rename the file "DocumentCode_Figure[X]_Permission."
   - Upload the file to the appropriate project in SharePoint (Classification: "Editorial"; Category: Permissions"; Subcategory: "License").
   - Delete the file from the desktop.
   - Update the "Permissions Received (Yes/No/NA)" column in the permissions log to indicate that permission was received (eg, "Yes – 4/16/16 – from the National Cancer Institute").

8. If permission is received and a fee is required:
   - Save the e-mail to the desktop.
   - Rename the file "DocumentCode_Figure[X]_Permission."
   - Upload the file to the appropriate project in SharePoint (Classification: "Editorial"; Category: "Permissions").
   - Delete the file from the desktop.
   - Request an invoice (if one was not already provided).
   - Print the invoice.
   - On the hard copy invoice, print the following information:
     – Category: Copyright Expense
     – Department: Standards
     – Class: [Document Code]
   - Obtain a signature on the invoice from the Senior Director of Standards and Quality.
   - Update the "Permissions Received (Yes/No/NA)" column in the permissions log to indicate that permission was received (eg, "Yes – 4/16/16 – from the National Cancer Institute").
   - Place the signed invoice in the "Accounts Payable" inbox on the Accounts Payable Coordinator's desk.

3 Terminology

3.1 "Breakpoint" 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, nonsusceptible, or resistant; **NOTE 1:** MIC or zone diameter values generated by a susceptibility test can be interpreted based upon established breakpoints; **NOTE 2:** See **interpretive category.**

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 upon 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

*Formerly "interpretive criteria."

MIC or zone diameter value breakpoints or 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 zone diameters 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 is dependent on the dosing regimen that is used in the patient. In order 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 dosing regimen (ie, higher doses, more frequent doses, or both) that results in higher drug exposure than the dose that was used to establish the susceptible breakpoint. Consideration should be given to the maximum approved 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 approved and used clinically, and where 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 zone diameters 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 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 zone diameters 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 subsequent to the time the susceptible-only breakpoint was set; **NOTE 2:** The term "nonsusceptible" should not be used when 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."

epidemiological cutoff value (ECV) – the minimal inhibitory concentration (MIC) value or zone diameter value that separates microbial populations into those with and without acquired and/or mutational resistance based on their phenotypes (wild-type or non-wild-type). The ECV defines the upper limit of susceptibility for the wild-type population of isolates.

EXAMPLE:

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

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

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

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, nonsusceptible, or resistant; **NOTE 1:** MIC or zone diameter values generated by a susceptibility test can be interpreted based upon established breakpoints; **NOTE 2:** See **interpretive category.**

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 upon 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

*Formerly "interpretive criteria."

MIC or zone diameter value breakpoints or 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 zone diameters 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 is dependent on the dosing regimen that is used in the patient. In order 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 dosing regimen (ie, higher doses, more frequent doses, or both) that results in higher drug exposure than the dose that was used to establish the susceptible breakpoint. Consideration should be given to the maximum approved 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 approved and used clinically, and where 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 zone diameters 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 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 zone diameters 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 subsequent to the time the susceptible-only breakpoint was set; **NOTE 2:** The term "nonsusceptible" should not be used when 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."

epidemiological cutoff value (ECV) – the minimal inhibitory concentration (MIC)/minimal effective concentration value or zone diameter value that separates microbial populations into those with and without acquired and/or mutational resistance based on their phenotypes (wild-type or non-wild-type). The ECV defines the upper limit of susceptibility for the wild-type population of isolates.

EXAMPLE:

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

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

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

3.1.3 Veterinary Antimicrobial Susceptibility Testing

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

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 upon established breakpoints; **NOTE 2:** See **breakpoint.**

EXAMPLE:

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

*Formerly "interpretive criteria."

MIC or zone diameter value breakpoints or 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 zone diameters 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:** 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 zone diameters 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 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.

- **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 zone diameters 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 subsequent to the time the susceptible-only breakpoint was set; **NOTE 2:** The term "nonsusceptible" should not be used when 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) value or zone diameter value that separates microbial populations into those with and without acquired and/or mutational resistance based on their phenotypes (wild-type or non-wild-type). The ECV defines the upper limit of susceptibility for the wild-type population of isolates.

EXAMPLE:

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

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

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

3.2 "Specimen" and "Sample"

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.

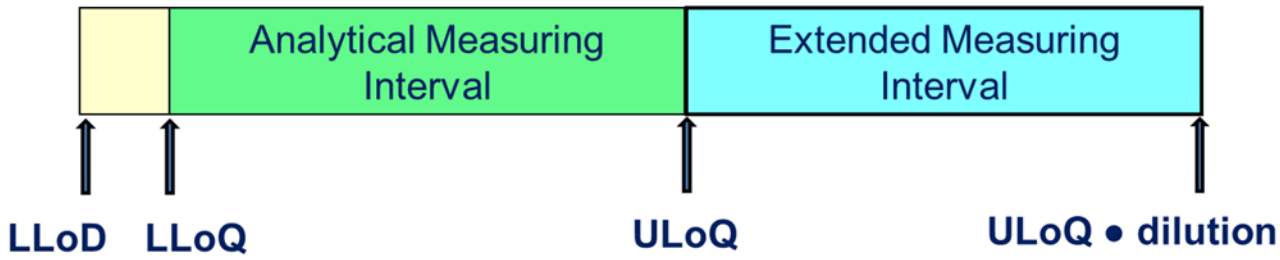
Some documents may use different definitions depending on the subject matter. For CLSI's method evaluation (ie, EP) documents, the important distinction is that a sample has been modified, usually by spiking something into it, or by dilution, whereas the specimen is the native component taken from the 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 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

The terminology for the limits of detection was recently updated. With the introduction of the upcoming guideline EP34—*Evaluation of Extended Measuring Interval Through Specimen Dilution and Spiking,* CLSI will offer a document that describes for laboratories 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.

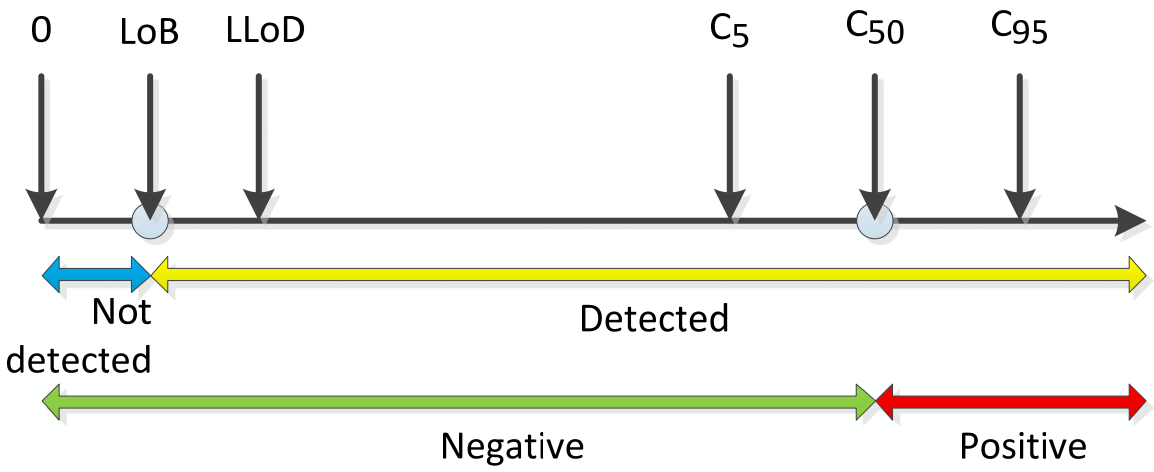
- **Lower limit of quantitation (LLoQ)** – the smallest amount of a substance that can be measured accurately.

- **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. Something 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, the project manager should perform a search for commonly confused or misused terms as part of his or her pre-editing preparations. These terms are listed below:

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," "appendix," "figure," "table," "see," "refer," and "CLSI" 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: First Mention in the Text

1. In the References section, search for "CLSI."
2. Double-click on the reference number of each CLSI document, which sends the cursor to the spot in the document 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.
   - **Incorrect:** Additional information on QMS implementation is available.[10]
   - **Correct:** Additional information on QMS implementation is available (see CLSI document QMS01[10]).

4.2.2 Cross Reference Check for CLSI Documents: Subsequent Mentions in the Text

1. Record the reference numbers for each CLSI document in the References section.
2. Perform a search for each superscripted appearance of each reference number.
   - 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 show up as part of this search. If the above search yields a "not found" message, then no cross references to the original reference appear in the document.
3. If no mention of the CLSI document appears in the text in front of the cross reference, insert the document code as shown in Step #3 in **Cross Reference Check for CLSI Documents: First Mention in the Text,** above.

4.2.3 The Quality Management System Approach

1. Include each CLSI document that is referenced in the document and its appendixes in the QSE grid and the Path of Workflow grid (if applicable, ie, not all CLSI documents follow the path of workflow).
2. Ensure CLSI documents that are **not** referenced in the document do not appear in the grids.

3. Check the CLSI Document Log in SharePoint (Standards Development → Resources → CLSIDocumentLog) to ensure that document codes are correctly assigned.

4.2.4 Related CLSI Reference Materials

1. Include each CLSI document in the Related CLSI Reference Materials section that is referenced in the document and its appendixes.

2. Ensure CLSI documents that are **not** referenced in the document do not appear in this section.

3. Check the published documents for correct document codes, titles, publication years, and taglines.

4.3 Duplicate References

Duplicate references should be flagged for removal by the staff assistant.

1. Go to the References section, and copy its contents.

2. Paste the contents of the References section into a new, blank Microsoft® 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, due to formatting glitches within the References section, a few items are left out of order and must be manually reordered within the alphabetized list.

Once all items appear in alphabetical order, scroll slowly through the list. Duplicate references appear in sequential order. Identify where these references appear in the document, and notify the staff assistant that the duplicate reference should be removed.

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, but the presentation below displays it in the context of a published document.

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

M23, 4th ed.
January 2016
Replaces M23-A3

Commented [MT1]: This information is right justified and appears above the document title and the horizontal line.

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 interpretive criteria and QC ranges for antimicrobial susceptibility tests against aerobic and anaerobic bacteria, and selected fungi performed by CLSI antimicrobial susceptibility testing standards. It describes the data used by the Subcommittees on Antimicrobial Susceptibility Testing and Antifungal Susceptibility Tests to establish these interpretive criteria 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 interpretive criteria 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.

Commented [MT2]: The edition is not included after this use of the code or title.

Clinical and Laboratory Standards Institute (CLSI). *Development of* In Vitro *Susceptibility Testing Criteria and Quality Control Parameters*. 4th ed. CLSI guideline M23 (ISBN 1-56238-925-4 [Print]; ISBN 1-56238-926-2 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2016.

Commented [MT3]: The edition is included after the title, but not after the code.

Commented [MT4]: The ISBN information should be manually inserted in this format.

Code throughout running headers:

M23, 4th ed.

Commented [MT5]: The code appears in the upper left corner of left-hand (even) pages, and the upper right corner of right-hand (odd) pages.

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

Suggested Citation

CLSI. *Development of* In Vitro *Susceptibility Testing Criteria and Quality Control Parameters*. 4th ed. CLSI guideline M23. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

Commented [MT6]: The "Suggested Citation" includes the edition after the title, but not after the code.

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

Commented [MT7]: The "Previous Editions" lists the months and years of previous editions of this CLSI document.

This information can be pulled from the Copyright page of the previous edition, eg, the information for M23, 4th ed. was pulled from the Copyright page of M23-A3.

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

ISBN 1-56238-925-4 (Print)
ISBN 1-56238-926-2 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic) Volume 36, Number 2

Commented [MT8]: The ISBN/ISSN information appears in the bottom left corner of the Copyright page, and the Volume and Number are inserted in the bottom right corner of the Copyright page.

Code in the Quality Management System Approach section:

M23 covers the QSE indicated by an "X." For a description…

M23 does not cover any of the medical laboratory path of workflow steps. For a description…

Commented [MT9]: The edition is not included after the code above the QSE and POW grids in the Quality Management System Approach section.

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. 12th ed., 2015.** This standard contains the current Clinical and Laboratory Standards Institute–recommended methods for disk susceptibility testing, criteria for quality control testing, and updated tables for interpretive zone diameters.

Commented [MT10]: The edition is not included after the code.

Commented [MT11]: The title, edition, and publication year follow this format.

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.