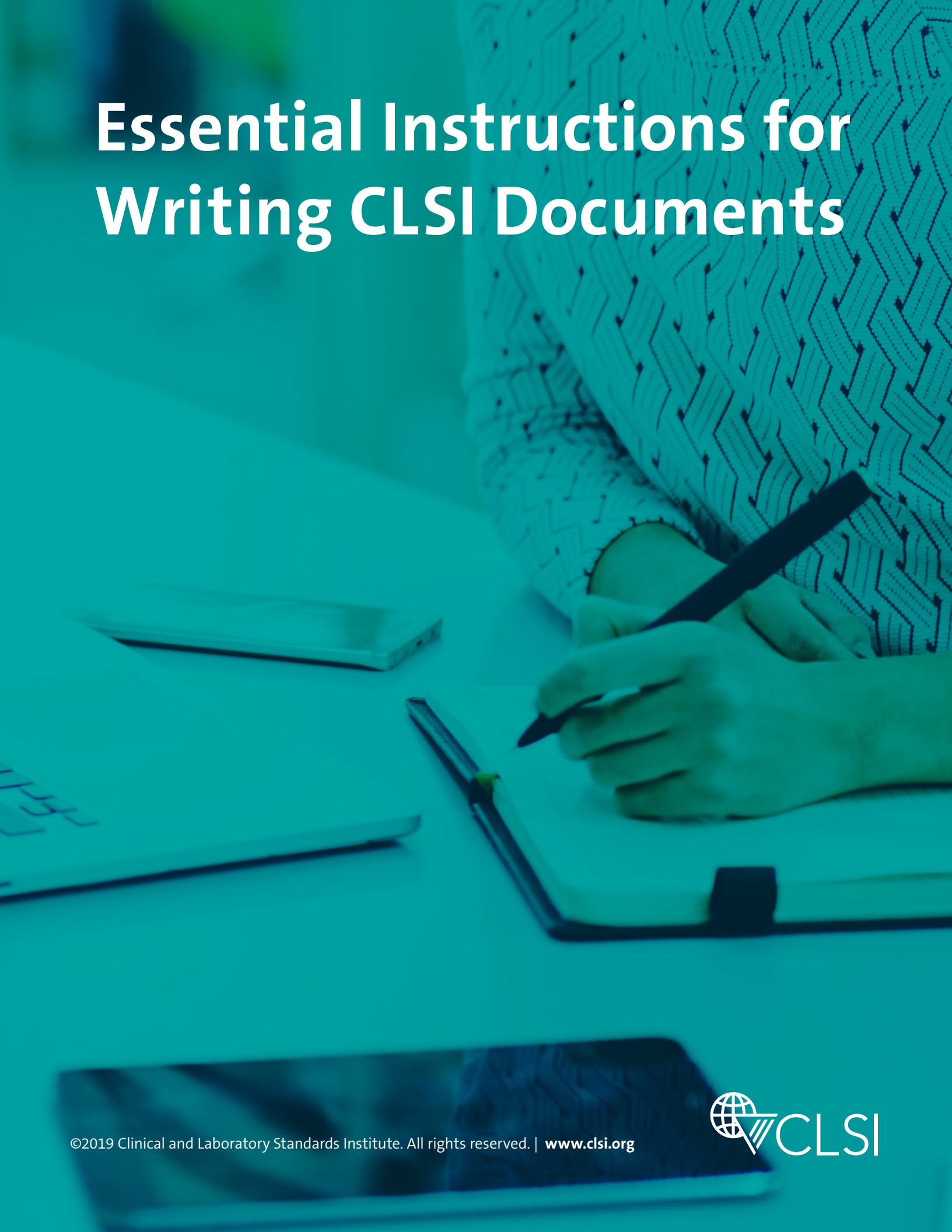
Essential Instructions for Writing CLSI Documents



CLSI

Dear Author,

These *Essential Instructions* summarize key information from the *CLSI Style Guide for Authors and Editors* so you can properly complete your volunteer writing assignment for your committee or working group's document.

By following these instructions, benefits accrue for both you and CLSI:

- Faster development of your part of the draft, so you can meet the writing deadline
- Less CLSI editing, which shortens the time to voting and document publication

Please follow these instructions when writing text for working drafts of CLSI documents. You may also refer to the *CLSI Style Guide for Authors and Editors* for more detailed information; access information is provided. You can also contact your document's project manager if you have any questions.

Sincerely,

CLSI Project Management and Editorial Staff

Foreword

CLSI document development committees, subcommittees, and working groups are responsible for producing a document that is:

- Complete, with respect to the content outline or flow chart approved in the project proposal
- Correct, with accurate technical contents and referenced facts
- Current, with respect to the available level of information
- Compliant, with the writing requirements set forth in these *Essential Instructions*

The writing group's finalized draft should be as close as possible to the final published document. Thus, writers are asked to submit their best writing efforts, achieved by adhering to the following instructions and examples.

CLSI POLICIES REGARDING CONTENT AND WRITER'S INSTRUCTIONS FOR AUTHORS—WRITING DRAFT DOCUMENT

Document Format

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

NOTE 1
The chapters listed in Appendix A represent those usually included in general CLSI documents that do not describe measurement procedures.

NOTE 2
The chapters listed in Appendix B represent those that should be included in CLSI standards or guidelines that describe measurement procedures.

NOTE 3
The chapters listed in Appendix C represent those that should be included in CLSI standards or guidelines that describe the laboratory test lifecycle.

Initial Writing of Working Draft Text

CLSI documents are used in countries where English is a second language. These documents are often translated into native languages. Therefore, it is important that the writing is easy to read and understand and can be translated without loss or change of meaning or content.

IMPORTANT NOTE
Please follow the guidance below to achieve these objectives.

Sentence Structure: General

Write declarative sentences in the third person, present tense, using active voice. CLSI wants to achieve a professional tone that is not too stiff or too familiar.

Write simple sentences: subject, verb, object.

Generally avoid long dependent leading or closing clauses.

Avoid passive writing, because it is wordy and boring.

Use active writing to relay what you want the laboratory to do.

NOTES

- Complicated sentences are difficult to translate.
- Familiar writing is too informal.

See style examples in the table below.

GENERAL EXAMPLES

Don't Say	Do Say
"It is recommended that the laboratory…" (passive)	"The laboratory should …" (active and descriptive)
"All information on the request must be checked by the phlebotomist for completeness." (passive)	"The phlebotomist must check all information on the request for completeness." (active)

Below are three styles of sentences, with examples and suggestions for when to use them.

Sentence Type	When to Use	Example of Sentence	Explanation
Declarative	Use this style for text.	"Risk evaluation, a determination of whether the risk of harm is acceptable, is central to the risk assessment process."	This sentence is easy to read, understand, and translate.
Imperative	Use this style for procedures.	**Steps** 1. Ask the patient to state and spell his or her full name. 2. Ask the patient for his or her date of birth or other patient-specific identifier. 3. Confirm the information provided verbally by comparing it with the identification band, which must be attached to the patient, and the specimen labels and/or requisition.	When a procedure is written in this style, the reader can see that he or she is the one who performs the steps.
Passive	Do not use this style at all.	"It is the responsibility of the laboratory director and the laboratory manager to ensure that the laboratory has taken all necessary measures for being ready for an external accreditation assessment." This sentence is wordy and includes unnecessary prepositional phrases.	This sentence reads better as, "The laboratory director and manager are responsible for ensuring readiness for an external accreditation assessment."

- **Avoid** referring to one person in the plural form.

GENERAL EXAMPLE

Don't Say	Do Say
"…when a person does something they did not intend…"	• "…when a person does something he or she did not intend…" • "…when a person does something unintended…"

- Refer to people as "who" instead of as "that" (only objects are referred to as "that").

GENERAL EXAMPLE

Don't Say	Do Say
• An employee that chooses…	• An employee who chooses…

- **Avoid** unnecessary prepositional phrases and infinitives.

GENERAL EXAMPLES

Don't Say	Do Say
"When all of the candidate's information is validated, an offer of employment is made to the candidate to begin employment at the organization on a specified date." (5 prepositional phrases, 1 infinitive)	"When all the candidate's information is validated, an employment offer is made to join the organization." (1 infinitive)
"The criteria below are used to compare the services of eligible PT providers to identify the provider that best meets the needs of the laboratory." (2 prepositional phrases, 2 infinitives)	"The criteria below can be used for comparing eligible PT providers' services and identifying the provider that best meets the laboratory's needs." (1 prepositional phrase)

- **Avoid** writing imperative statements in nonprocedure text, which implies the reader is intended to perform the action.

EXAMPLES FOR TEXT

Don't Say	Do Say
"Review the report and identify opportunities for improvement." (imperative; sounds like an instruction)	"Laboratory management reviews the report and identifies opportunities for improvement." (active; tells what happens)
"Contact the supplier to request additional information." (imperative; sounds like an instruction)	"The laboratory contacts the supplier to obtain additional information." (declarative; tells what happens)

Sentence Structure for Procedures

- Use imperative statements only when you are writing instructions in a procedure.
- **Avoid** passively worded procedures and instructions, which lead the reader to believe someone else is performing the action.

EXAMPLE OF HOW NOT TO WRITE A PROCEDURE

Step	Action
1	A test tube is labeled with the accession number of each sample to be tested.
2	3 mL of reagent is pipetted into the test tube.
3	0.5 mL of test serum is added to the tube labeled with its corresponding accession number.
4	The tubes are capped and mixed by gentle inversion.
X	*Additional instructions as needed*

The steps are all worded passively, leading the reader to believe someone else is performing the action.

EXAMPLE OF THE PREFERRED WAY TO WRITE A PROCEDURE

Step	Action
1	Label a test tube with the accession number of each sample to be tested.
2	Pipette 3 mL of reagent into each test tube.
3	Add 0.5 mL of the test serum to the corresponding labeled tube.
4	Cap each tube and mix by gentle inversion.
X	*Additional instructions as needed*

Procedures should be written as though the reader is performing each step.

The left column lists the step number in sequence. The right column states the instruction/action to take. Every step begins with an action verb that tells the reader specifically what to do.

Examples of CLSI Content That Is Easy to Read, Understand, and Translate Accurately

The following examples are taken from published CLSI documents. Each contains simple, declarative sentences. The first example clearly describes a structure and the relationship of its parts. The second example provides recommendations and good practices. The sentences in the third example, a standard, set requirements that must be followed. To simplify text, writers are also encouraged to refer to published CLSI documents whenever possible rather than repeating detailed information.

Example from a management guideline

QMS02, Quality Management System: Development and Management of Laboratory Documents

"Usually, four tiers of documents are used in a typical medical laboratory: policies, processes, procedures/job aids, and forms. *Policies* describe the organization's goals and intentions—the 'what is done and why.' *Process* maps show the sequence of events that produce a product or service—the 'how it happens.' *Procedures* (and corresponding job aids) provide step-by-step instructions—the 'how to do it.' *Forms* capture information and results generated as the process proceeds. The documents behave in a downward cascade so that a policy on the first tier sets the intent and direction for the process or processes to fulfill it, the processes describe the activities needed to turn the intent into action, and the procedures provide instructions for the activities in the processes."

Example from a technical guideline

GP40, Preparation and Testing of Reagent Water in the Clinical Laboratory

"Measurements made at intervals have the risk that an out-of-specification condition could have existed and adversely affected clinical testing during the interval between measurements. Risk will increase as the time between measurements, and between revalidations, increases with respect to the stability of the purification system. Making more frequent measurements and setting an alert threshold for a measured parameter at a more stringent level than the validated water purity can reduce the risk from gradual drift; however, this strategy does not protect against abrupt changes. A risk assessment should be carried out to establish an appropriate monitoring program."

Example from a technical standard

GP39, Tubes and Additives for Venous and Capillary Blood Specimen Collection

"The tube must be made from material that allows a clear view of the contents, unless exposure to ultraviolet or visible light would be deleterious to either the tube contents or the blood specimen after collection. No part of the container shall have a sharp edge, projection, or surface roughness capable of cutting, puncturing, or breaking the user's skin. The tube interior shall be free of visible foreign matter."

EXAMPLE of How Not to Write Draft Content for a CLSI Document

When you are looking for quality products or supplies for your medical practice or lab, it is imperative to have a list of reliable medical equipment suppliers to choose from, because selecting the right supplier for your lab equipment needs from the list is just as important as finding the perfect lab equipment. Remember that the first step in selecting suppliers is often research, particularly if the product or service has not been purchased before. There are a number of tools available for this initial phase that you should consider using that include:

- Check with group purchasing organizations to which your organization belongs, to see if a contract exists for the product that you would like to buy.
- Check the Internet for procurement related websites that deal in lab equipment and supplies.
- Engage with colleagues in other institutions who might have purchased a similar product or service to see what their issues are or may have been.
- Consult trade publications, directories, supplier catalogs, and professional journals for information about the products you're interested in.

This informal wording does not support the professional image CLSI wants in its documents and is not in alignment with CLSI style guidelines.

Stem text is wordy and does not read directly into the bullets.

Three prepositional phrases and two infinitive phrases compose 80% of the first bullet. This problem is common in working drafts.

EXAMPLE of How This Text Should Have Been Written:

When a laboratory is looking for quality products or supplies, it is essential to have a list of reliable medical equipment suppliers. Choosing the right supplier for laboratory equipment needs from this list is as important as finding the appropriate laboratory equipment. The first step in selecting suppliers is often research, particularly when the product or service has not been purchased before. Actions for this initial phase include:

- Checking with group purchasing organizations to which the organization belongs, to see whether a contract exists for the product in question
- Checking the Internet for procurement-related websites
- Talking to colleagues in other organizations who have purchased a similar product or service
- Consulting trade publications, directories, supplier catalogs, and professional journals

CLSI POLICIES REGARDING CONTENT AND WRITER'S INSTRUCTIONS FOR AUTHORS—WRITING DRAFT DOCUMENT

Process Flow Chart

Develop a flow chart to graphically represent the sequence of activities of the process being described in the document.

IMPORTANT NOTE
See **Appendix D** for detailed information on creating flow charts.

Using Information From Published CLSI Documents

Include brief—not extensive—information about what has already been published in CLSI documents and refer readers to the source document.

IMPORTANT NOTE
When contradicting content from any CLSI published document, you will need to explain the change or contradiction, because the published content was previously approved through the consensus process. For example, in the interim, there may be new information or technology has changed.

Referring to the United States and to National Requirements

- **Avoid using** colloquialisms unique to the United States or other countries, because they often do not have the same meaning as intended when translated into other languages.

- **Avoid** writing with only a US laboratory focus, **unless** the document is specifically intended for use only in US laboratories.
  - Most CLSI documents are written for an international readership.
  - US-specific documents will be so designated, and writers will be informed.

- **Avoid specifically** mentioning in the text CLIA, FDA, and other US, international, or national agencies or organizations (eg, ISO, IFCC, CAP). Instead, describe the requirement and reference the source. Follow the instructions on page 15 for how to reference ISO and US government documents.

- Prepare as an appendix specific data or other information excerpted from official documents of US, international, or national agencies and organizations and reference the source.

EXAMPLES OF COLLOQUIALISMS

Don't Use	Do Use
impact	effect or affect
execute	implement
employ or utilize	use
prior to	before
as	because

Note on Terminology

The words "must" and "shall" are used in regulatory and accreditation requirements documents. CLSI *standards* may also use these words to indicate a requirement.

- **Avoid** using "must" or "shall" in CLSI *guidelines and reports,* to avoid the statement being mistakenly interpreted as a regulatory or accreditation requirement.

- **Reserve** the use of "required" only for statements that directly reflect a regulatory, accreditation, performance, product, or organizational requirement or a requirement or specification identified in an approved documentary standard. A CLSI standard also contains requirements.

  When restating a published requirement, use the phrase "needs to." This deliberate convention is used to make it clear to readers that the activity described is not optional.

EXAMPLES

Don't Say	Do Say
"…the patient required a longer hospital stay."	"…the patient needed a longer hospital stay."
"…the information required for completing this report" (unless the information in question fulfills a regulatory, accreditation, or organizational requirement).	"…the tests required following a pandemic disease outbreak may be different than those needed following a fire" (the former reflects a requirement, while the latter does not).

Note on Terminology (Continued)

- The phrase "the laboratory needs to" explains an action directly related to fulfilling requirements of international, national, and accreditation organizations.
- Do not use "should" when the statement reflects a regulatory or accreditation requirement.
- Use words such as "should," "could," or "recommended" to reflect guidance and options for how a laboratory can meet a published requirement.

EXAMPLES

Don't Say	Do Say
"The laboratory must implement a QC program for each method." (uses requirement language)	"The laboratory needs to implement a QC program for each method." (reflects the requirement)
"The laboratory should participate in proficiency testing for each measurement method." (uses recommendation language)	"The laboratory needs to participate in proficiency testing for each measurement method." (reflects the requirement)
"The laboratory shall develop a cost-effective inventory control system." (not a requirement)	"The laboratory's inventory control system should be cost effective." (a recommendation)

Harmonized Terminology Database

Use the Harmonized Terminology Database for the definitions of internationally harmonized terms (eg, metrology).

ACCESS
http://htd.clsi.org

CLSI Quality Glossary

Where applicable, use the CLSI Quality Glossary for the definitions of internationally harmonized quality terms.

ACCESS
All terms and definitions included in the CLSI Quality Glossary can be accessed through the Harmonized Terminology Database (see link above).

Abbreviations and Acronyms

- **Use** only accepted units of measure and well-recognized clinical, technical, and general terms and symbols.
- Avoid author-invented abbreviations.
- Refer to the *CLSI Style Guide for Authors and Editors* for information on abbreviations and acronyms not spelled out on first mention and their use in chapter or appendix titles and figures and tables.

Equations

- Number equations sequentially throughout the document.
- Align equation numbers flush right in each equation.
- Put parentheses around equation numbers.

EXAMPLE

$$\delta_{bi} = Nb - (N - 1)b_i \quad (1)$$

IMPORTANT NOTE

Refer to *CLSI Style Guide for Authors and Editors*.

https://clsi.org/standards-development/resources/

References

- Include full citations for **all** applicable references in the *working draft text:*
  - Immediately follow the period at the end of the sentence to be referenced with the full document citation **in brackets**.
  - CLSI editors will extract the reference into a properly formatted references section during the editing process.

- To support the content in a document, generally cite reference material published only within the past 10 years. However, exceptions may be allowed for key landmark publications.

EXAMPLE IN WORKING DRAFT TEXT
"…in the laboratory's quality management system. [Siebels D. The Quality Management Glossary, 3rd ed. Milwaukee, WI: ASQ Quality Press, 2010.]"

IMPORTANT NOTE
Do not use footnoting, superscripting, or a reference macro in working draft text.

NOTE
Use the *CLSI Style Guide for Authors and Editors* for additional information on properly citing references.

https://clsi.org/standards-development/resources/

Citing References: General

Journal article
Author(s). Title of article (capitalize only the first word). *Journal abbreviation*. Year;Volume(Issue): Inclusive page numbers.

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

Chapter
Author(s) of chapter. Title of chapter (capitalize only the first word). In: Editor(s)/Author(s). *Title of Book (capitalize each major word)*. Edition. Place of publication: Name of publisher; Year:Inclusive page numbers.

Corresponding Reference Examples

Journal article
Miller WG, Erek A, Cunningham TD, Oladipo O, Scott MG, Johnson RE. Commutability limitations influence quality control results with different reagents lots. *Clin Chem*. 2011;57(1):76-83.

Book
Ernst D. *Applied Phlebotomy*. Philadelphia, PA: Lippincott Williams & Wilkins; 2005.

Chapter
Berte LM. The cost of quality. In: Harmening DM. *Laboratory Management: Principles and Processes*. 3rd ed. St. Petersburg, FL: DH Publishing and Consulting; 2013:339-358.

Citing References: General (Continued)

Standards, guidelines, or reports Name of organization. *Document name*. Xth (write out number) ed (if applicable). Organization document number. City, State/Province/Country: Organization: Year.	*Standards, guidelines, or reports* ISO. *Medical laboratories – Requirements for quality and competence*. ISO 15189. Geneva, Switzerland: International Organization for Standardization; 2012. CLSI. *Collection of Diagnostic Venous Blood Specimens*. 7th ed. CLSI standard GP41. Wayne, PA: Clinical and Laboratory Standards Institute; 2017. **NOTE** For CLSI documents, use the "Suggested Citation" format listed in the document. Documents published before 2015 follow this format: CLSI. *Information Technology Security of* In Vitro *Diagnostic Instruments and Software Systems; Approved Standard—Second Edition*. CLSI document AUTO11-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.
Website Author/organization. Title of Web page. Website link. Date accessed.	*Website* CDC. Healthcare-associated infections. https://www.cdc.gov/hai/. Accessed 16 January 2019.
US Government Document Agency, Department. *CFR Part Number and Title* (Codified at # CFR §#). Office of the Federal Register; published annually.	*US Government Document* Centers for Medicare & Medicaid Services, US Department of Health and Human Services. *Part 493—Laboratory Requirements: Clinical Laboratory Improvement Amendments of 1988* (Codified at 42 CFR §493). Office of the Federal Register; published annually.

Tables and Figures

- Use tables and figures to supplement (rather than duplicate) material found in the text.
- Place tables and figures near the section of the text they supplement.
- Number tables and figures sequentially and cite them by order of appearance within the text.
- Include a brief, descriptive title for each table and figure. Figure titles may be followed by a legend.
- Line drawings and graphs should be computer generated. Preferred file types for photos are .jpg, .png., and .tif.

TABLES
The table title goes **above** the table, and every major word is capitalized.
Example: **Table 1. Testing Considerations for Fastidious Organisms**

FIGURES
The figure title goes **below** the figure, and every major word is capitalized. The legend includes any explanatory text that immediately follows the title. See page 28 for an example.

NOTE
Refer to the *CLSI Style Guide for Authors and Editors* for more information on tables and figures.

https://clsi.org/standards-development/resources/

Trade Names

- **Avoid** the use of trade names by using generic terminology.
- If a trademark needs to be used, an appropriate disclaimer will be included in the document.

EXAMPLE
Replace the term "Ziploc bag" with "clear plastic, resealable, sandwich-type bag" or something to that effect.

Units of Measure

- Use **only** the International Union of Pure and Applied Chemistry/International Federation of Clinical Chemistry and Laboratory Medicine (IUPAC/IFCC)–recommended units.

NOTE
Refer to the *CLSI Style Guide for Authors and Editors* for detailed information.

https://clsi.org/standards-development/resources/

Appendixes

- CLSI document users value having examples of forms, diagrams, checklists, and other useful information in the appendixes.
- When needed, obtain permission from your organization before submitting a form, diagram, or other document.
  - Provide CLSI with documentation of the organization's permission.
- Whenever possible, **submit a Word or Excel file of a form**. When a Word or Excel file is not available, send a clearly readable blank PDF version so the form can be recreated.
- **Avoid** submitting PDF files of documents; submit only Word files to allow for editing.

NOTE
Facility-specific information, eg, facility name and location, computer codes, and department names, needs to be removed from a form or document before submission. CLSI publishes only generic versions of forms and documents in appendixes.

The Quality Management System Approach in CLSI Documents

CLSI provides products for laboratories to build and maintain a solid quality management foundation that will meet applicable requirements and support the laboratory's technical work. Other CLSI documents present information on how to achieve and maintain technical excellence in preexamination, examination, and postexamination activities in the various laboratory disciplines.

Benefits of the quality management approach include an understandable model that represents laboratory work in small or large facilities and in any discipline, consideration of applicable regulatory and accreditation requirements, and identifiable subjects for developing CLSI documents and derivative products. These and other benefits all have the focus of clearly communicating how to achieve quality laboratory services for patient care and safety.

NOTE
Every CLSI document and product directly relates to one or more places on the quality management system model (see **Appendix E**).

IMPORTANT NOTE
CLSI editors will add standardized text about **The Quality Management System Approach in CLSI Documents** to the end of every CLSI document during the publication process.

OTHER INSTRUCTIONS FOR WRITING—IN ALPHABETICAL ORDER

Addresses

- Where applicable, write out cities, states, and countries in full (with the exception of "USA").
- Always add the country for addresses, including USA.

EXAMPLE

- ISO, Geneva, Switzerland

Age and Sex

- *Men* and *women* are preferred over *male* and *female* when a group of adults is differentiated by sex.
- Use *male* and *female* when a group being described comprises children and adults of both sexes. Otherwise, *male* and *female* should only be used as adjectives.

Terminology Associated With Various Age Groups

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

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

Apostrophe

- Use an apostrophe to show the possessive case of a noun.
- Do not use an apostrophe to form the plural of an abbreviation or of dates.

EXAMPLES

Don't	Do
A laboratorys staff	A laboratory's staff
An hours wait	An hour's wait
Laboratory method's in use today…	Laboratory methods in use today…
The 1980's	The 1980s

Capitalization

Capitalize **only**:

- Proper nouns
- Geographical names
- Sociocultural designations
- Proprietary names
- The names of a genus when used in the singular (but not the species)
- Specific designators, with or without numbers
- "Major words" in a title

NOTE
Refer to the *CLSI Style Guide for Authors and Editors* for additional information.

https://clsi.org/standards-development/resources/

NOTE
"Major words" includes all words of four or more letters, including prepositions, and all verbs.

OTHER INSTRUCTIONS FOR WRITING—IN ALPHABETICAL ORDER

Comma

- CLSI uses the serial comma; therefore, **do use** a comma before the last word in a series.

EXAMPLE
red, white, and blue

Do not use commas to indicate thousands. In numbers of four digits, no space is used.

EXAMPLE
1000
10 000
100 000
1 000 000

- **Do use** commas in monetary amounts.

EXAMPLE
$ 10,000
$ 1,150.25

Decimal

- Place a zero before the decimal point.

EXAMPLE
0.123 (**not** .123).

Emphasis

- **Use bold** for emphasis within the text.
- **Do not use** underlining, capitalizing, or italics.

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

Footnotes

- Include footnoted text in the body of the document indicated by a parenthetical statement that it is a footnote.
- **Staff will extract the text and create the footnote in the proper editorial format**.

  Indicate footnotes in tables and figures with superscripted, lowercase letters in alphabetical order.

EXAMPLE

Figure 4. Fishbone Diagram for Identification of Potential Failure Modes (Footnote: "This fishbone diagram is an example; it is not all-inclusive.")

Hyphen

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

EXAMPLE

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

IMPORTANT NOTE

Prefixes such as "anti," "ante," "bi," "co," "contra," "counter," "intra," "non," "pre," "post," "re," and "semi" are normally not joined to root words using hyphens. They are joined directly to the root word, eg, "preexamination."

- When two prefixes are used in sequence, hyphenate the first, followed by the second prefix joined directly to the root word.

EXAMPLE

"…when pre- and postexamination factors are considered."

NOTE

Refer to the *CLSI Style Guide for Authors and Editors* for exceptions.

https://clsi.org/standards-development/resources/

OTHER INSTRUCTIONS FOR WRITING—IN ALPHABETICAL ORDER

Lists (Bulleted)

- Bullets are used for nonprocedural lists.
- The hierarchy of symbols in a bulleted list is:
  - Main bullet
    - Second-level bullet
      - Third-level bullet
        - Fourth-level bullet
          - Fifth-level bullet

EXAMPLE

List storage requirements, including:

- Container
  - Glass
  - Plastic
    - Bottles
    - Pipettes
- Temperature
- Stability (shelf life)
- Labeling

Lists (Numbered)

- Numbers are used to indicate steps in a procedure.

EXAMPLE

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.

Mathematical Composition

- Use the **stacked plus-minus sign** to indicate addition or subtraction.
- Use a **multiplication dot** for most equations.
- Use the **multiplication sign** to express scientific notation, area, and magnification.
- Use a **slash** (/) rather than a **division sign** (÷) to indicate division.
- Use the **"approximately equal to" symbol** (≈) to indicate approximation.

EXAMPLE (stacked plus-minus sign)
± 2.5%

EXAMPLE (multiplication dot)
3 kg • 9 kg

EXAMPLES (multiplication sign)
3×10^9, 2 × 2 table, 40× magnification

NOTE
Refer to the *CLSI Style Guide for Authors and Editors* for related spacing and punctuation rules.

https://clsi.org/standards-development/resources/

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
Rounded large numbers (eg, 8 million)		X
Measures of temperature (eg, 17°C)		X
Numbers in tables and figures (eg, breakpoints in CLSI document M100)		X

NOTE
Refer to the *CLSI Style Guide for Authors and Editors* for exceptions.

https://clsi.org/standards-development/resources/

OTHER INSTRUCTIONS FOR WRITING—IN ALPHABETICAL ORDER

Percentages

- Spell out the percentage if it begins a sentence, title, subtitle, or heading.

EXAMPLE
"Fifty percent of the sample population were women."

- Use the symbol in each number of a percentage range after the first and second value.

EXAMPLE
"…and 12% to 14% were between 18 and 24 years old."

Period

- Do not use periods when listing credentials.

EXAMPLE

- John Smith, MD
- Mary Jones, MA, MT(ASCP)
- Robert Brown, MBA

- Place the period at the end of the sentence inside quotation marks.

EXAMPLE

Incorrect	Correct
"All patient and laboratory specimens are treated as infectious and handled according to 'standard precautions'."	"All patient and laboratory specimens are treated as infectious and handled according to 'standard precautions.'"

Ranges

- Use "to" to indicate ranges in the main text.

EXAMPLE
five to 10 minutes

NOTE
Refer to the CLSI Style Guide for Authors and Editors for exceptions.

https://clsi.org/standards-development/resources/

Appendixes

Appendix A. CLSI Document Content Outline That Aligns With the CLSI Quality Management System Model (as published in CLSI document QMS01[1])

CLSI documents are to conform as closely as possible to the structure described here. This standard structure provides a common look and feel to documents that enables readers to easily locate content regardless of the document's discipline or intended use.

Tagline

Abstract

Foreword

Chapter 1 Introduction
- 1.1 Scope
- 1.2 Background
- 1.3 Standard Precautions (only as needed)
- 1.4 Terminology

Chapter 2 Chapter title
- 2.0 Overview of process flow and flow chart with chapter/subchapter numbers
- 2.1 – 2.x Main content of document in process flow order to contain:
  - All or part of a QSE **or**
  - Preexamination, examination, and postexamination activities in a given discipline (as applicable to document scope) **or**
  - An examination process or method

Chapter Y Quality System Essentials (for non-QSE documents)
- Y.0 General description of chapter content
- Y.1 – Y.12 QSE content, as applicable

Chapter Z Conclusion

Last Chapter Supplemental Information
- References
- Additional Resources
- Appendixes
- The Quality Management System Approach (prepared by CLSI)
- Related CLSI Reference Materials (prepared by CLSI)

NOTE: When drafting the document's outline, 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).

Reference for Appendix A

[1] CLSI. *A Quality Management System Model for Laboratory Services*. 5th ed. CLSI guideline QMS01. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.

Appendix B. Outline for CLSI Documents That Discuss Measurement Procedures

CLSI documents are to conform as closely as possible to the structure described here. This standard structure provides a common look and feel to documents that enables readers to easily locate content regardless of discipline or intended use of a document.

NOTE: When drafting the document's outline, 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).

Tagline

Abstract

Foreword

Chapter 1 Introduction

- 1.1 Scope
- 1.2 Background
- 1.3 Terminology
- 1.4 Standard Precautions
- 1.5 The Path of Workflow (includes diagram and descriptive text from CLSI document QMS01[1] shown at the end of this appendix)[a]

Chapter 2 Preexamination Activities

- 2.1 Precollection Patient Assessment and Preparation
- 2.2 Specimen Collection
- 2.3 Specimen Transport
- 2.4 Specimen Receipt and Processing
  - 2.4.1 Specimen Acceptance Criteria (if unique to this method)
  - 2.4.2 Centrifugation or Other Preexamination Processing
  - 2.4.3 Sample Storage Before Examination
  - 2.4.4 Sample Preparation Before Examination

Chapter 3 Examination Activities

- 3.1 Instrumentation
  - 3.1.1 Description of Instrumentation
  - 3.1.2 Calibration
    - 3.1.2.1 Calibration Materials

Appendix B. (Continued)

Appendix B. (Continued)

[a] The laboratory's path of workflow consists of preexamination, examination, and postexamination processes, beginning with an order for a laboratory examination, tissue analysis, or blood component, and proceeding to provision of the report, any necessary follow-up consultation as it contributes to patient care, or administration of blood components. The path of workflow is essentially identical for anatomic pathology and the clinical disciplines that include, for example, the various specialties of chemistry, hematology, microbiology, immunology, and transfusion medicine.

The path of workflow includes actions performed by physicians, nurses, other clinical and allied health professionals (such as respiratory therapists), clerks, nonlaboratory specimen collection personnel, transporters, and couriers. The completeness and correctness of these actions influence both sample quality and total turnaround time, and thus the trueness and value of the laboratory examination result; lack of these actions contributes to medical errors that could harm patients, as well as cause waste and rework. The overall path of workflow for the laboratory is shown in Figure B1.

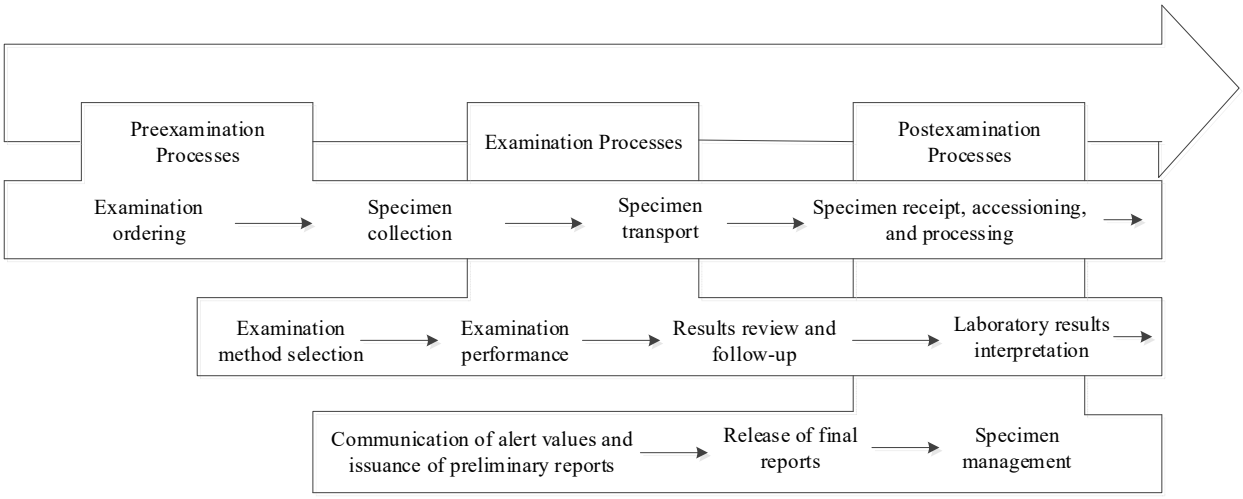


Figure B1. The Laboratory's Path of Workflow (Adapted from CLSI document QMS01[1])

Reference for Appendix B

1 CLSI. *A Quality Management System Model for Laboratory Services*. 5th ed. CLSI guideline QMS01. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.

Appendix C. Outline for CLSI Documents That Discuss the Laboratory Test Lifecycle

Tagline

Abstract

Foreword

Chapter 1 Introduction

- 1.1 Scope
- 1.2 Background
- 1.3 Terminology
- 1.4 Standard Precautions

Chapter 2 Overview of the Laboratory Test Lifecycle (includes laboratory test lifecycle process flow chart annotated with chapter/subchapter numbers and an overall text description)

Chapter 3 The Laboratory Test Lifecycle

- 3.1 Phase 1: Feasibility and Design
  - 3.1.1 Literature Review
  - 3.1.2 Clinical Usefulness/Intended Use
  - 3.1.3 Feasibility Assessment
  - 3.1.4 Assessment of Legal Right to Use
  - 3.1.5 Marketing Assessment
- 3.2 Phase 2: Test Method Development
  - 3.2.1 Instrumentation
  - 3.2.2 Reagents
  - 3.2.3 Calibrators
  - 3.2.4 Controls
  - 3.2.5 Process and Procedure
  - 3.2.6 Validation Criteria Set
- 3.3 Phase 3: Equipment Qualification
- 3.4 Phase 3: Operational Qualification
- 3.5 Phase 3: Performance Qualification
  - 3.5.1 Documented Method Validation Plan
  - 3.5.2 Critical Experiments
    - 3.5.2.1 Precision
    - 3.5.2.2 Measuring interval

Appendix C. (Continued)

Appendix C. (Continued)

- 4.5 Supplier and Inventory Management
  - 4.5.1 Reagent Package Inserts or Recipes
  - 4.5.2 Other Materials (as needed)
- 4.6 Equipment Management
  - 4.6.1 Equipment and Instrument Calibration Plans
  - 4.6.2 Equipment and Instrument Maintenance Plans
- 4.7 Process Management
  - 4.7.1 Method Verification Plan
  - 4.7.2 Performance Qualification of Method Performance Specifications
  - 4.7.3 Clinical Software Verification Plan
  - 4.7.4 Operator's (and Software User) Manuals
  - 4.7.5 Quality Control Plan
  - 4.7.6 Proficiency Testing Plan
  - 4.7.7 Change Control
- 4.8 Documents and Records Management
  - 4.8.1 Verification Records and Approvals
  - 4.8.2 Approved User Process and Procedure Documents
- 4.9 Information Management
- 4.10 Nonconforming Event Management
- 4.11 Assessments
  - 4.11.1 Reviews of Effectiveness
    - 4.11.1.1 Quality Control Plan
    - 4.11.1.2 Calibration Plan
    - 4.11.1.3 Proficiency Testing Results
- 4.12 Continual Improvement

Chapter 5 Method Retirement

- 5.1 Archiving Documents
- 5.2 Archiving Records
- 5.3 Closing Equipment Master File
- 5.4 Disposing of Equipment No Longer in Use
- 5.5 Disposing of Reagent (as needed)
- 5.6 Internal and External Customer Notifications

Appendix C. (Continued)

5.7 Regulatory, Accreditation, and Proficiency Testing Provider Organization Notifications (as applicable)

Chapter 6 Conclusion

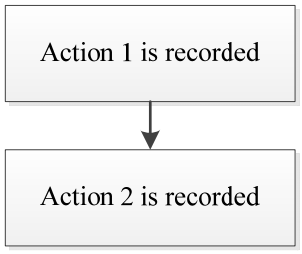
Chapter 7 Supplemental Information

- References
- Additional Resources
- Appendixes
- The Quality Management System Approach (prepared by CLSI)
- Related CLSI Reference Materials (prepared by CLSI)

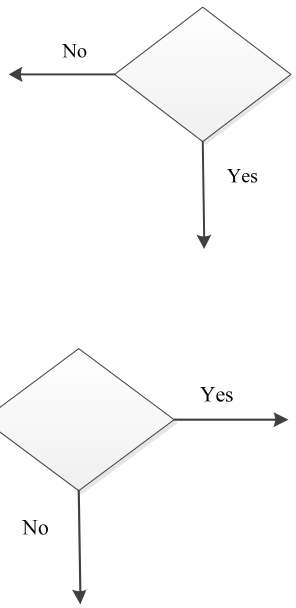
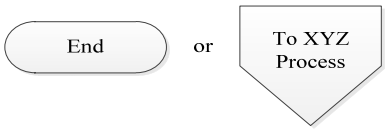
Appendix D. How to Construct a Process Flow Chart (adapted from CLSI document QMS02[1])

Process: a set of interrelated or interacting activities that transforms inputs into outputs.

When properly completed, a flow chart depicts the sequence of activities between the predefined beginning and end of the selected process, ie, "which department/function does what" is shown by the actions inside the rectangles, and the "when" is shown by the sequence of the activities.

Stage	Description	Flow Chart Symbols
Process boundaries are set.	Ovals with the word "Start" or "End" in them identify the beginning and the end of a process, respectively. The start oval can also describe a condition that starts the process. For example, "Specimens arrive" is a condition that can start a process.	
Activities are recorded in the order in which they actually happen in the workplace. They describe what happens, eg, "Venipuncture is performed," or "Sample is labeled." Do not use an action verb as the first word in process actions, because it leads the reader to believe he or she is responsible for everything in the process.	• The facilitator conducting the process flow chart session asks, "Then what happens?" The answer (activity) is recorded in a rectangle. • This question and answer sequence continues as each subsequent action and the responsible function are identified and recorded. • Symbols are connected by arrows that show the direction of flow.	

Appendix D. (Continued)

Stage	Description	Flow Chart Symbols
Alternative actions are encountered.	Ask a question that has a "No" or "Yes" answer. The correct process flow goes straight down the chart, with deviations from the correct flow going off to the left or right based on the answer to the "No" or "Yes" question.	
Process is completed.	The process either ends or connects to another process.	

Documenting a Process

All functions involved in the process need representation when the process flow chart is prepared. These functions include persons outside the laboratory, as applicable.

Facilitator

The facilitator documents the flow chart as it is being constructed. A dry-erase board is far more effective than paper flipcharts due to the large amount of erasing and redrawing that occurs as the discussion progresses.

Appendix D. (Continued)

Useful Rule

Every action box in a process flow chart must have one of the following final connections:

- The action box connects to another action box.
- The action box connects around and up to a previous action box or decision diamond.
- The action box connects to an "End" symbol or to another process.

Process Identifies Procedures

The activity in each rectangle consists of a set of steps that need to be separately documented as instructions that inform the involved department/function "how to" perform that activity. These instructive documents are commonly called "procedures" and describe all the necessary steps to follow and decisions needed to successfully complete the action inside the rectangle. A single-process flow chart therefore represents a set of procedures, each of which must be performed correctly by the responsible party or parties for the entire process to have a successful outcome. The action in the rectangle defines the beginning and the end of the procedure.

Common Flow Chart Problem

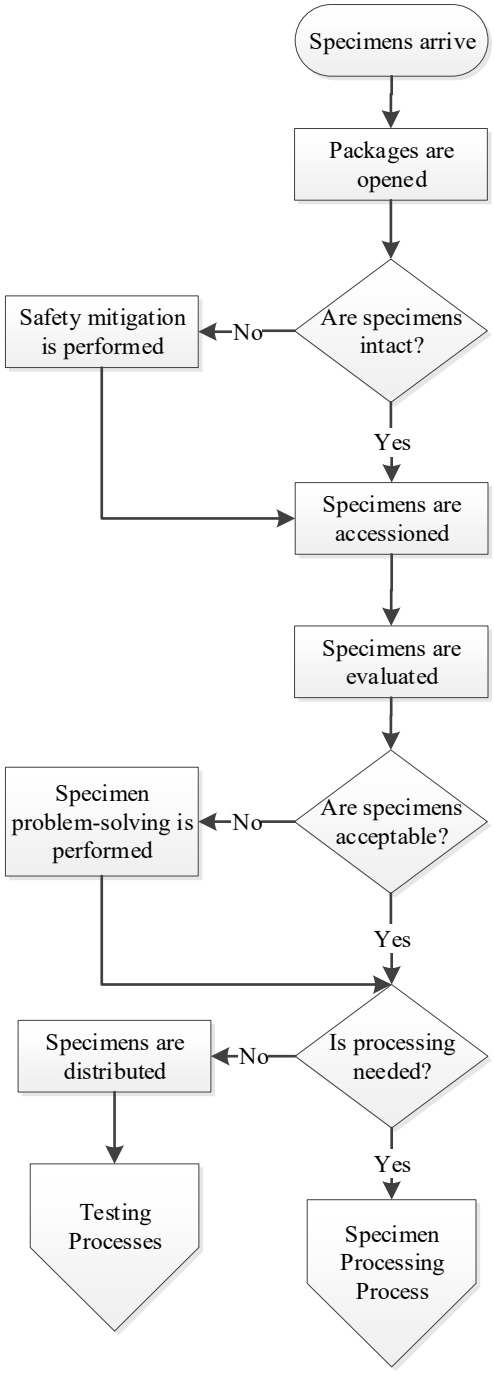
Rectangles are meant to describe a complete activity; however, flow chart developers often put only a single action into a rectangle. For example, a box might say, "Report is given to supervisor." When developing flow charts, ask this question for **each** box: "Do I need to write instructions for how to complete the activity in this box?" In the example above, the answer would surely be "No"—a procedure document is **not** needed for instructing someone to hand a report to another person or put it into an inbox. Therefore, the action in that box is probably the last step of the procedure in the box before it.

Training and Initial Competence Assessment

Work happens in processes, not discrete procedures; therefore, staff from all departments/functions involved in the process need training to understand the **processes** in which they are involved and how to perform the procedures they are responsible for in each process. Following the training, initial assessment provides some degree of assurance that each employee understands his or her responsibility within assigned processes and can demonstrate successful accomplishment of the procedures he or she will perform in each process.

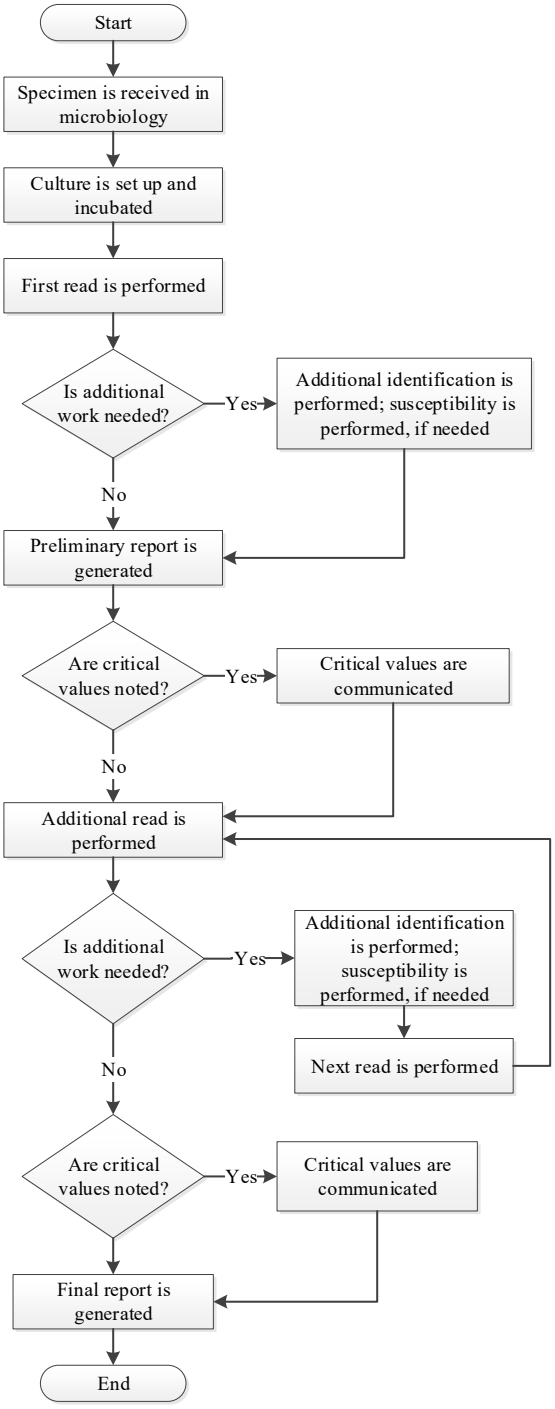
Appendix D. (Continued)

Example Process Flow Chart: Laboratory Specimen Receiving Process



Appendix D. (Continued)

Example Process Flow Chart: Bacteriology Culture Process



Reference for Appendix D

[1] CLSI. *Quality Management System: Development and Management of Laboratory Documents; Approved Guide—Sixth Edition*. CLSI document QMS02-A6. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

Appendix E. Quality Management System: A Foundation for CLSI Documents

The CLSI model for quality management in the laboratory setting, shown in Figure E1, is constructed of a foundation of 12 generic management elements that support the laboratory's technical preexamination, examination, and postexamination functions in any discipline. The model's construction derives from periodically sorting regulatory and accreditation requirements applicable to medical laboratories into generic categories and arranging the categories to reflect how laboratory work is accomplished.

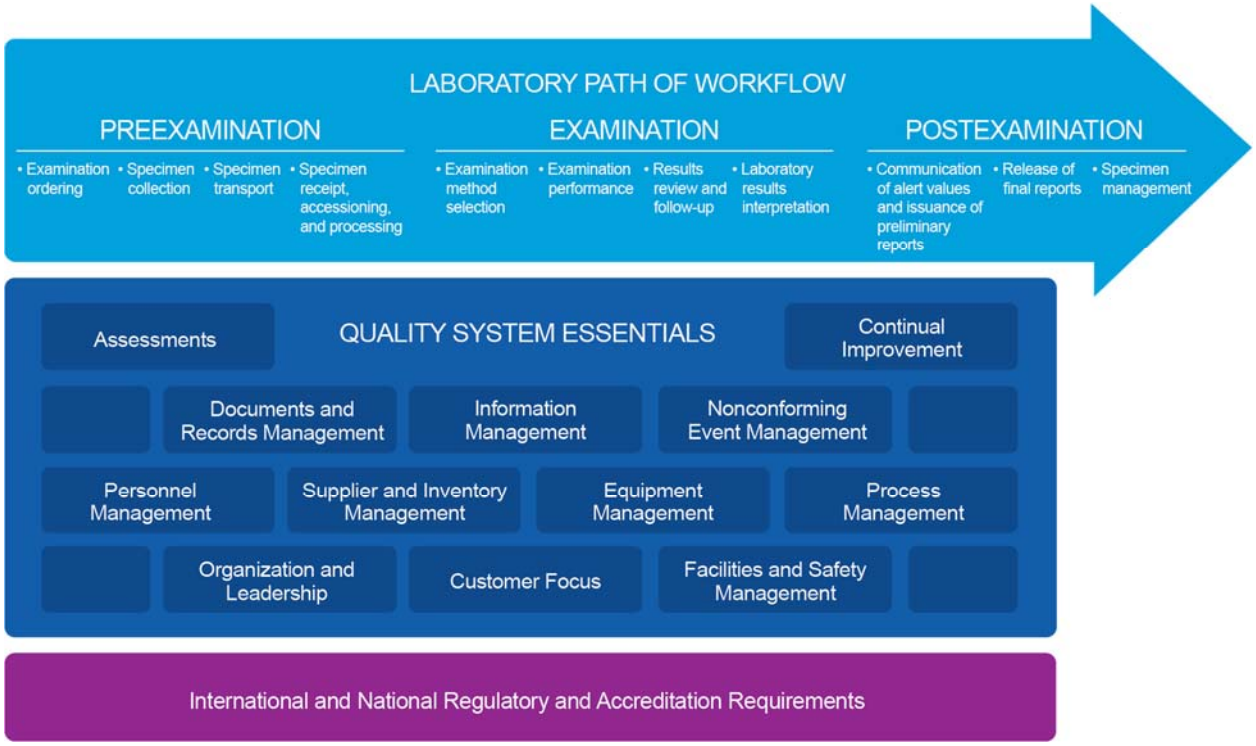


Figure E1. The CLSI Quality Management System Model (Reproduced from CLSI document QMS01[1])

The quality system essentials (QSEs) are foundational building blocks of quality in any setting. When a QSE is missing or not well implemented, it means that the regulatory and/or accreditation requirements in that QSE are not being met or not being met effectively; thus, problems will occur in preexamination, examination, or postexamination activities. For example, when the laboratory lacks defined processes for maintaining current, complete, and correct policies, processes, and procedures, there will be problems in all areas of laboratory workflow, whereas lack of attention to calibration and maintenance of laboratory analyzers will manifest as problems in examination processes.

Reference for Appendix E

1 CLSI. *A Quality Management System Model for Laboratory Services*. 5th ed. CLSI guideline QMS01. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.

Appendix F. Examples of Foreword, Scope, and Background

Foreword

The Foreword expands the summary provided in the abstract and discusses the need for the standard, guideline, etc. The Foreword provides appropriate background information, invites readers to comment on the material, and along with the Scope, identifies the intended audience. In all revisions (ie, second editions or higher), the Foreword includes an Overview of Changes section, which briefly discusses the revisions made since the previous edition.

Appendix F. (Continued)

Example from a microbiology guideline
M24, Susceptibility Testing of Mycobacteria, Nocardia *spp., and Other Aerobic Actinomycetes*

"This standard includes recommendations for testing *Mycobacterium tuberculosis* complex (MTBC), certain nontuberculous mycobacteria (NTM), *Nocardia* spp., and other aerobic actinomycetes. Currently, sufficient data exist to support recommendations for antimicrobial susceptibility testing (AST) of MTBC, *Mycobacterium avium* complex (MAC), *M. kansasii, M. marinum,* the rapidly growing mycobacteria (RGM), *Nocardia* spp., and certain other aerobic actinomycetes. Breakpoints for some NTMs, *Nocardia* spp., and other aerobic actinomycetes are based on organism population distributions, clinical data, breakpoints used for other organisms, and the experience of experts in the field. M24 was revised in response to new developments in mycobacterial susceptibility testing and comments from laboratorians who perform routine mycobacterial and/or aerobic actinomycete testing. Additional revisions are anticipated as more relevant data become available.

Overview of Changes

This standard replaces the previous edition of the approved standard, M24-A2, published in 2011. Several changes were made in this edition, including:

- Removed information related to the short-incubation, liquid-radiometric testing system, because this system is no longer available
- Expanded the description of molecular testing for both MTBC and NTM to determine antimicrobial susceptibility or resistance
  - For MTBC, Table 3 (Considerations for Molecular or Repeat Testing After Initial Testing on MTBC Using a Commercial Short-Incubation Broth System) and text are included to describe the integration of molecular and culture-based test results for the best possible prediction of the expected drug efficacy.
  - For NTM, text is included to describe integration of molecular techniques to assist in determining efficacy of macrolides and amikacin in the treatment of infections caused by MAC and various RGM.
- Added a description of recently discovered challenges to MTBC AST accuracy with use of rapid broth systems and/or the agar proportion method, particularly limited sensitivity in detection of low-level resistance to rifampin and ethambutol
- Added information in Appendix A regarding the relationship of pharmacokinetics and pharmacodynamics in determining breakpoints and interpretive criteria
- Updated all breakpoint and quality control tables and moved them to a newly created informational supplement, CLSI document M62[1]

Appendix F. (Continued)

Scope

The Scope (within the Introduction chapter) is a concise statement that identifies the purpose and application of the standard, guideline, etc. It is important that the Scope:

- Establishes the elements to be included in and excluded from the document
- Identifies the intended audience, uses, and exclusions and/or limitations of the document

For example:

This guidelines specifies recommendations for…

The intended users of this guidelines are…

This guideline:

- Is not intended for use by…
- Is not intended to provide…
- Does not cover…

Appendix F. (Continued)

Example from a point-of-care testing guideline

POCT04, Essential Tools for Implementation and Management of a Point-of-Care Testing Program

"Many potential sites are eligible for point-of-care testing (POCT). To achieve producing patient test results comparable with those from the medical laboratory, this guideline provides essential tools for implementing and managing POCT in both clinical and nonclinical settings. Depending on the location, individuals who may perform POCT and for whom this guideline is intended include:

- Nurses and physicians in acute care units in hospitals and emergency rooms
- Cardiac perfusionists in operating rooms
- Visiting home nurses
- Emergency medical technicians
- Nurses in clinics, schools, and colleges
- Pharmacists and pharmacy technicians in pharmacies
- Non–health care professionals at various employment settings, such as drug rehabilitation centers, law enforcement facilities, public screening sites, insurance companies, and physician office laboratories (POLs)

This guideline does not cover patient self-testing and the handling of results generated in this manner. Additionally, this guideline only applies to tests that involve the collection of patient specimens. Thus, examination devices such as breath analyzers, transcutaneous meters, and continuous glucose monitoring devices are outside the scope of this guideline."

Appendix F. (Continued)

Background

The Background (within the Introduction chapter) is optional when introductory text leading into the standard, guideline, etc., is already in the Foreword or Scope. Material from the Abstract, Foreword, or Scope should not be repeated.

Example from a method evaluation guideline (**NOTE:** Text shown is an excerpt from the guideline's full Background section.)
EP33, Use of Delta Checks in the Medical Laboratory

"Delta checking can be used for multiple purposes, the most common of which include:

- Identifying cases of patient specimen misidentification
- Identifying other specimen-related issues (eg, specimen contamination, inappropriate specimen handling, specimen interferences such as hemolysis, and inappropriate anticoagulants or preservatives)
- Identifying examination (analytical) issues, including reagent problems, measurement procedure shifts or drifts, and interinstrument differences (when more than one instrument is used for a measurand), although this topic is beyond the scope of this guideline
- Acting as the 'sentinel' of an important change in patient status

Delta check alerts have been used primarily as part of quality improvement in the laboratory. Any delta checking program necessarily detects differences in a measurand due to causes in all four areas, but not all four areas may be deemed important to monitor and act upon. Laboratories should identify their particular needs and customize their delta checking programs accordingly."

NOTES

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