

# Project Proposal Form



## Project Submission

Date: \_\_\_\_\_  
Submitter contact information: \_\_\_\_\_  
Name: \_\_\_\_\_  
Organization: \_\_\_\_\_  
Phone number: \_\_\_\_\_  
E-mail: \_\_\_\_\_

Proposed Title: \_\_\_\_\_

Proposed product will be (check one):  
(See Part 3 for a detailed description of products)

Consensus standard	Report
Consensus guideline	Other (please describe)

Level of intended user:

Novice	Intermediate	Advanced
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## Part 1A: Proposed Project

Is this proposal for a new document/product or a revision?

New  
Revision to: \_\_\_\_\_ (Document/product code and edition number)  
Year last published: \_\_\_\_\_  
Other (please describe) \_\_\_\_\_

Please provide answers to the questions below.

1. Provide a rationale for the project and describe its potential effect on laboratory medicine and/or health care. Describe any gaps this project may fill, why it is needed now, etc. Share ideas on how the document's effect could be assessed or measured if implemented.  
\_\_\_\_\_
2. How does this proposed project meet CLSI's mission, ie, "Develop clinical and laboratory practices and promote their use worldwide"?  
\_\_\_\_\_
3. Describe why this project would or would not be of interest to each of CLSI's three constituencies .  
**Health care professions:** \_\_\_\_\_  
**Government:** \_\_\_\_\_  
**Industry:** \_\_\_\_\_
4. Describe whether there are any related standards or guidelines already in existence or under development by another organization.  
**NOTE:** Consider regulatory and accreditation organizations, international organizations, professional societies, etc., and search relevant literature.  
\_\_\_\_\_  
\_\_\_\_\_
5. Could this document/product be developed in collaboration with a partner? If so, with whom and how?  
\_\_\_\_\_  
\_\_\_\_\_
6. Provide other important factors that should be considered when evaluating this proposal.  
\_\_\_\_\_  
\_\_\_\_\_

### Part 1B: Proposed Users

Check the boxes to indicate potential users to which this document/product would apply.

Medical laboratory  
Blood gas laboratory  
Point-of-care testing  
Public health laboratory  
Environmental laboratory  
Forensic laboratory

Veterinary laboratory  
Research laboratory  
Manufacturer  
Laboratory medicine training program  
Regulatory or accreditation organization  
Other (please describe) \_\_\_\_\_

### Part 1C: Scope

1. Briefly describe the content of the document/product.

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2. Briefly describe the content the document/product will exclude.

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3. How could this document/product be used by the international laboratory community?

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4. If this proposal is for the revision of a document/product, list any Scope information not included in the published edition that needs consideration in the revised edition.

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### Part 1D: Process(es) Covered in This Document/Product

Check boxes to indicate topic(s)/process(es) this document will include.

*Preexamination (preanalytical) processes:* Test order through sample receipt and accessioning

*Examination (analytical) processes:* Test method, validation, quality control, automated analyzer platform, laboratory results, interpretation

*Postexamination (postanalytical) processes:* Reporting results, archiving results, archiving samples

*Quality System Essential (QSE)* (List which QSE or part of a QSE, ie, Organization and Leadership; Customer Focus; Facilities and Safety Management; Personnel Management; Supplier and Inventory Management; Equipment Management; Process Management [path of workflow; method development, validation, and use]; Documents and Records Management; Information Management; Nonconforming Event Management; Assessments; Continual Improvement)

*Information technology:* Laboratory information system, interfacing, laboratory records, etc.

*Manufacturing*

*Other* (please describe)

### Part 1E: Existing Products

List applicable CLSI and other related publications that should be considered during the development of this document/product.

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### Part 1F: Draft Outline

Provide a draft outline of the chapter headings and topics (from applicable outlines included as Attachments 1 and 2 at the end of this form) for the process(es) that will be described in this document/product.

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## Part 2: Timeline

The expected timeframe from the first meeting until the document/product is submitted for editing by CLSI staff is no longer than 12 months. If this timeframe cannot be met, please explain.

## Part 3: Proposed Derivative Products

Check the derivative products listed below that could be developed with or for a document.

**NOTE:** Derivative products may or may not be developed by the document writing group.

Quick guide, wall chart, templates that provide quick access to information

White paper that presents factual information on timely or emerging topics

Handbooks, checklists, and other tools that significantly complement information in consensus documents

Video/DVD (instructional video presentation)

Software (eg, database)

Educational audioconference

Webinar

Online learning program

## Part 3B: Other Means to Promote Document/Product Information

Article in a professional journal(s) (List name of journal(s))

Presentation/workshop at professional meeting (List appropriate professional organizations and associated meetings)

Other (please describe)

## Part 4: Document Attributes

Answer the following questions. This information is essential for developing promotional and marketing materials for the document/product.

What are the key features included in this document/product? \_\_\_\_\_

- Updated information
- New methods or technologies
- Proven process
- Provision of guidance
- Other (please describe)

**Please expand on any selected items.** \_\_\_\_\_

What are the benefits of using this document/product? \_\_\_\_\_

- Meet regulatory or accreditation requirements
- Meet quality or organizational objectives
- Satisfy customers
- Other (please describe)

**Please expand on any selected items.** \_\_\_\_\_

## Part 5: Document Development Committee

- Describe specific expertise needed for development of this proposed document/product.

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- Suggest possible chairholder and vice-chairholder and whether they have been contacted regarding potential interest. (**NOTE:** Proposals lacking a potential chairholder and vice-chairholder will not be evaluated.)

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### Potential Chairholder/Vice-Chairholder

Name:	Contacted?	Yes	No
Name:	Contacted?	Yes	No
Name:	Contacted?	Yes	No
Name:	Contacted?	Yes	No

### Attachment 1. CLSI Document Content Outline That Aligns With the CLSI Quality Management System Model

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 when needed)
- 1.4 Terminology: Definitions and Abbreviations

#### Chapter 2: Chapter title

- 2.0 Overview of process flow and flow chart with section 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: Conclusion

#### Last Chapter: Supplemental Information

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

## Attachment 2. Outline for CLSI Documents That Discuss Measurement Procedures (ie, Test Methods)

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.

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

### 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
    - 3.1.2.2 Metrological Traceability
    - 3.1.2.3 Verifying the Required Measurement Accuracy at Defined Intervals
- 3.2 Reagents
  - 3.2.1 Preexamination Storage
  - 3.2.2 Acceptance Testing (as applicable)
  - 3.2.3 Reagent Preparation for Examination
  - 3.2.4 Other, relevant (as applicable)
- 3.3 Instructions for Performing the Examination
- 3.4 Quality Control
  - 3.4.1 Quality Control Materials
  - 3.4.2 Quality Control Data Assessment
- 3.5 Proficiency Testing (External Quality Assessment)
- 3.6 Statistical Analysis

### Chapter 4: Postexamination Activities

- 4.1 Biological Reference Intervals or Clinical Decision Values
- 4.2 Results Review and Interpretation
- 4.2 Results Reporting
- 4.3 Sample Storage After Examination

### Chapter 5: Conclusion

### Chapter 6: Supplemental Information

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

## Attachment 3. Document Outline for the Laboratory Test Life Cycle

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.

Tagline

Abstract

Foreword

### Chapter 1: Introduction

1.1 Scope

1.2 Background

1.3 Standard Precautions (as needed)

1.4 Terminology: Definitions and Abbreviations

### Chapter 2: Overview of the Laboratory Test Life Cycle

(Laboratory test life cycle process flow chart annotated with section numbers and an overall text description)

### Chapter 3: The Laboratory Test Life Cycle

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 ("SOP")

3.2.6 Validation criteria set

3.3 Phase 3: Equipment Qualification

3.4 Phase 3 Continued: Operational Qualification

3.5 Phase 3 Continued: 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

3.5.2.3 Detection capability

3.5.2.4 Clinical validation

3.5.2.5 Accuracy

3.5.2.6 Reference intervals

3.5.2.7 Analytical specificity

3.5.2.8 Stability

3.6 Design, Development, and Validation Records

3.6.1 Validation plan documents

3.6.2 Approvals at each phase

3.6.3 Validation results

3.6.4 Draft method process and procedure documents

3.6.5 References

3.6.6 Package insert (as needed)

3.6.7 Clinical software development and validation documents and approvals

3.6.8 Any cost, marketing, or other analysis

**Chapter 4: Quality System Essentials for Implementation in the Testing Laboratory**

- 4.1 Organization and Leadership
- 4.2 Customer Focus
  - 4.2.1 Internal and external customer notification plans
  - 4.2.2 Regulatory and accreditation organization notifications, as applicable
  - 4.2.3 Other notification, as needed
- 4.3 Facilities and Safety Management
- 4.4 Personnel Management
  - 4.4.6 Training Plan
  - 4.4.7 Initial competence assessment plan
  - 4.4.8 Ongoing competence assessment plan
- 4.5 Supplier and Supply 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 plan
  - 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
  - 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 QC Plan
    - 4.11.1.2 Calibration plan
    - 4.11.1.3 PT results
- 4.12 Continual Improvement

**Chapter 5: Method Retirement**

- 5.1 Archival of documents
- 5.2 Archival of records
- 5.3 Close of equipment master file
- 5.4 Disposition of equipment no longer in use
- 5.5 Reagent disposition, as needed
- 5.6 Internal and external customer notifications
- 5.7 Regulatory, accreditation, and PT provider organization notifications, as applicable

**Chapter 6: Conclusion****Last Chapter: Supplemental Information**

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