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

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.

2. How does this proposed project meet CLSI's mission, ie, "Develop clinical and laboratory practices and promote their use worldwide"?

3. Describe how this project will meet the needs to each of CLSI's three constituencies. If this project is not intended for a specific constituency, please explain why.

Health care professions: _____

Government: _____

Industry: _____

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

5. 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.

6. Are there other organizations that could or should participate in the development of this document/product?

7. 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

(See Attachment 1 regarding inclusion of information on consultative services and/or clinical interpretation strategies.)

1. Briefly describe what the document/product will include.

_____

_____

_____

2. Briefly describe the content the document/product will not include.

_____

_____

_____

3. 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.

_____

_____

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.

_____

_____

_____

Part 1F: Draft Outline

Provide a draft outline of the chapter headings and topics (from applicable outlines included as Attachments 1, 2, 3, and 4 at the end of this form) for the process(es) that will be described in this document/product.

_____

_____

_____

Part 2: Timeline

The target timeframe for producing a draft document (ie, document is ready for CLSI staff to prepare for vote) is 14 months. Are there issues and/or contingencies (eg, project scope/complexity, finalization of other documents, regulatory and/or accreditation concerns) that could delay this project?

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.

- 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.)

Potential Chairholder/Vice-Chairholder	
Name:	Contacted? ☐ Yes ☐ No
Name:	Contacted? ☐ Yes ☐ No
Name:	Contacted? ☐ Yes ☐ No
Name:	Contacted? ☐ Yes ☐ No

Attachment 1. Inclusion of Information on Consultative Services and/or Clinical Interpretation Strategies

The practice of laboratory medicine and responsibilities of laboratory directors and associated laboratory professionals has evolved. In addition to professional, scientific, consultative, administrative, and educational matters related to laboratory services, clinical advice regarding test methodologies, appropriate clinical use of testing, and assistance with results interpretation is sought. With better understanding of and in response to current needs, CLSI is embracing the expansion of its document scope.

As such, where applicable, when a proposal for new or revised document is submitted, the scope may be expanded to include information on consultative services and/or clinical interpretation strategies to:

- Formulate effective strategies for laboratory directors and personnel to engage with physicians
- Establish diagnostic stewardship as an essential element of collaborative consultation
- Improve communications among health care providers and implementation of laboratory test findings to support effective delivery of patient care
- Support improved diagnosis and treatment through test utilization management and risk assessment

Attachment 2. 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 3. 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 4. 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

Attachment 4. (Continued)

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