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) ☐ Other (please describe)
Please provide answers to the questions below. 1. Provide a rationale for the project and describe its potential impact on laboratory medicine and/or health care and how it can be assessed/measured. (**NOTE:** Please describe any gaps this project may fill, why it is needed now, etc.) 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 be of interest to each of CLSI's three constituencies (ie, government, industry, professions). If not of interest to a particular constituency, explain why. **Government:** **Industry:** **Professions:**

Part 1A: Proposed Project (Continued)

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 (WHO, ISO), etc.

5. Could this document/product be developed in collaboration with a partner (eg, ISO, WHO, professional society)? If so, 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 what the document/product will include.

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

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

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

5. Who is the target audience for this document/product?

Part 1D: Process(es) Covered in This Document/Product
Check boxes to indicate the type of process this document will cover. ☐ *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 and 2 at the end of this form) for the process(es) that will be described in this document/product.
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 10 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 Disseminate Document/Product Information

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

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

☐ Other (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, describe

Please expand on any selected items.

What are the benefits of using this document?

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

Please expand on any selected items.

Part 5: Possible Participants for Document Development Committee

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

- Suggest possible participants 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. 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 where 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 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)

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

Attachment 2. (Continued)	
Chapter 5	Conclusion
Chapter 6	Supplemental Information • References • Additional Resources • Appendixes • The Quality Management System Approach • Related CLSI Reference Materials