

Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition



This guideline describes the clinical laboratory's path of workflow and provides information for laboratory operations that will assist the laboratory in improving its processes and meeting government and accreditation requirements.

A guideline for global application developed through the NCCLS consensus process.



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Abstract

NCCLS document GP26-A3—*Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition* expands on the laboratory-specific guidance presented in NCCLS document GP26-A2—*Application of a Quality System Model for Laboratory Services*. This guideline describes the clinical laboratory's path of workflow and provides information for laboratory operations that will assist the laboratory in improving its processes and meeting governmental and accreditation requirements. In addition, information from a recently published international standard for medical laboratories has been included in this version. This document, when used with NCCLS document HS1—*A Quality Management System Model for Health Care*, can provide the means for a laboratory to implement a complete quality management system.

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Foreword

This document, GP26-A3, introduces the clinical laboratory's path of workflow—that is, the processes that transform a request for a clinical laboratory service (i.e., a laboratory that performs screening, diagnostic, or monitoring examinations for patient care) through obtaining and transporting the sample, performing the examination, interpreting the results, and providing the patient's laboratory examination report.

NCCLS document GP26-A3 is intended for use in conjunction with NCCLS document [HS1](#)—*A Quality Management System Model for Health Care*, when developing a quality management system for the clinical laboratory. Additional guidelines in the NCCLS Quality Series will also be a valuable resource for additional QSE- and clinical service-specific information.

Overview of Changes

The revisions in this version of the GP26 guideline are intended principally to include the concepts published in ISO 15189, *Medical laboratories—Particular requirements for quality and competence*.¹

The document has been streamlined and a new “crosswalk” table has been introduced that correlates laboratory QSE information with its generic counterparts in [HS1](#). Laboratory-specific forms and examples are also included.

A Note on Terminology

NCCLS, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. NCCLS recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in NCCLS, ISO, and CEN documents; and that legally required use of terms, regional usage, and different consensus timelines are all obstacles to harmonization. In light of this, NCCLS recognizes that harmonization of terms facilitates the global application of standards and is an area of immediate attention. Implementation of this policy must be an evolutionary and educational process that begins with new projects and revisions of existing documents.

In order to align the usage of terminology in this document with that of ISO, the term *sample* has replaced the term *specimen* and the term *test* has replaced the term *examination*. The users of GP26-A3 should understand that the fundamental meanings of the terms are identical in many cases, and are defined in the guideline's Definitions section (see [Section 3](#)). The terms in this document are consistent with those defined in the ISO 15189 and ISO 9000 series of standards.

Key Words

Examination, path of workflow, postexamination, preexamination, processes

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1 Scope

This publication describes important activities in the path of workflow for laboratory services, including *in vitro* testing in clinical and anatomic pathology. Discipline-specific details are referenced in the Related NCCLS Publications section of this document.

This guideline is intended for use by laboratory directors, managers, supervisors, and the quality manager as a means to ensure that their laboratories have in place the policies, processes, procedures, activities, and records that support the activities described herein.

2 Introduction

This document describes the clinical laboratory's path of workflow—defined as the sequential processes in clinical laboratory activities that transform a physician's order into laboratory information. Each facility—whether large and complex, or of narrower scope such as physician's offices and point-of-care programs—needs to understand how work flows through its particular laboratory so that processes can be designed and procedures documented that will build the required level of quality into laboratory work and reduce the potential for medical error that wastes resources and harms patients.

To establish a complete quality management system, policies, processes, and procedures for activities in the clinical laboratory's path of workflow need to be combined with policies, processes, and procedures for the Quality System Essentials (QSEs). Readers of this document are strongly encouraged to combine the activities described in both GP26-A3 and the most current version of NCCLS document [HS1—A Quality Management System Model for Health Care](#), to ensure a complete infrastructure for quality management in the clinical laboratory.

This guideline presents information about the clinical laboratory's path of workflow and provides specific laboratory examples. Additional laboratory-specific information for the QSEs is also provided with relevant examples.

3 Definitions

Accreditation – Procedure by which an authoritative body gives formal recognition that an organization or person is competent to carry out specific tasks [modified from ISO/IEC 17000].²

Certification – Procedure by which a third party gives written assurance that a service conforms to specified requirements [modified from ISO/IEC 17000].²

Examination – Set of operations having the object of determining the value or characteristics of a property; **NOTES:** a) In some disciplines (e.g., microbiology), an examination is the total activity of a number of tests, observations, or measurements [ISO 15189 (3.3)]¹; b) In this document, the term “examination” replaces the term “test”; however, for the purposes of this guideline, readers can consider the terms equivalent.

Examination procedure – Set of operations, described specifically, used in the performance of examinations according to a given method [ISO 15198].³

External quality assessment – Evaluation of the laboratory’s performance on examination of samples of external origin for the purposes of determining adequacy of the laboratory’s preexamination, examination, and postexamination activities [ISO Guide 43-1].⁴

Path of workflow (clinical laboratory) – Sequential processes in preexamination, examination, and postexamination clinical laboratory activities that transform a physician’s order into laboratory information.

Postexamination procedures – Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples of the laboratory examinations [ISO 15189 (3.9)].¹

Preexamination procedures – Steps starting, in chronological order, from the clinician’s request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins. ISO 15189 [3.10].¹

Primary sample – Set of one or more parts initially taken from a system [ISO 15189 (3.11)]¹; **NOTE:** In some countries, the term “specimen” is used instead of primary sample (or a subsample of it), which is the sample prepared for sending to, or as received by, the laboratory and which is intended for examination.

Procedure – Specified way to carry out an activity of a process [ISO 9000 (3.4.5)].⁵

Process – Set of interrelated or interacting activities which transform inputs into outputs [ISO 9000:2000 (3.4.1)].⁵

Quality control – Part of quality management focused on fulfilling quality requirements [ISO 9000:2000 (3.2.10)].⁵

Quality management – Coordinated activities to direct and control an organization with regard to quality [ISO 9000:2000 (3.2.8)].⁵

Quality system essentials – Set of coordinated activities that function as building blocks for quality management.

Sample – One or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or its production; **NOTES:** a) Example: A volume of serum taken from a larger volume of serum [ISO 15189 (3.14)]¹; b) In this document, the term “sample” replaces the term “specimen”; however, for the purposes of this guideline, readers can consider the terms equivalent.

Validation – Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled [ISO 9000 (3.8.5)].⁵ **NOTES:** a) Example: Validation of the performance of a new diagnostic tool such as an internally developed, analyte-specific method or reagents, or a laboratory-developed information system; b) Manufacturers are required to validate instruments and methods before market release, e.g., FDA approval or European CE mark.

Verification – Confirmation through the provision of objective evidence that specified requirements have been fulfilled. [ISO 9000 (3.8.4)]⁵; **NOTES:** a) Example: Verification of commercial information systems, instruments, and methods; and calibration verification of results obtained on automated analyzers; b) Commercial systems need to have their manner of use verified in the user laboratory.

4 The Path of Workflow Concept

The clinical 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, or administration of the blood component. The path of workflow also includes patient follow-up as it contributes to patient outcomes. The path of workflow is essentially identical for anatomic pathology and the clinical disciplines that include the various specialties of chemistry, hematology, microbiology, immunology, and transfusion medicine. The overall path of workflow for the laboratory is shown in Figure 1.

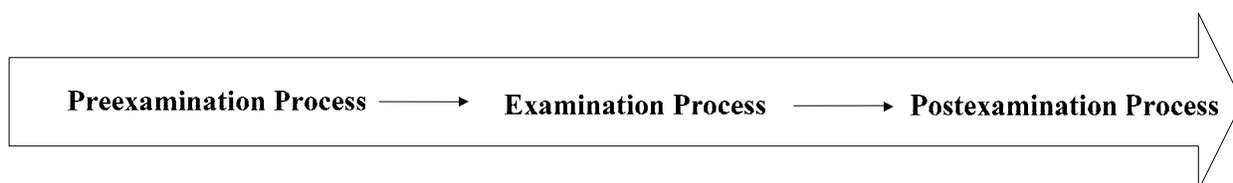


Figure 1. The Clinical Laboratory's Path of Workflow

The processes in the laboratory's path of workflow begin outside the laboratory's boundaries with the request for a laboratory examination and end outside the laboratory's boundaries with decisions made by healthcare professionals based on laboratory examination results, and clinical signs. The path of workflow includes actions performed by physicians, nurses, other clinical and allied health professionals (such as respiratory therapists), clerks, nonlaboratory sample collection personnel, transporters, and couriers. The completeness and correctness of these actions influence both sample quality and total turnaround time, and thus the accuracy and value of the laboratory examination result. Likewise, lack of completeness and correctness of these actions contributes to medical errors that could harm patients, as well as causing waste and rework. Therefore, it is incumbent upon the laboratory to ensure that processes and procedures performed by nonlaboratory personnel within the entire laboratory path of workflow are taught to such personnel, are understood and followed and meet applicable requirements.

5 The Clinical Laboratory's Path of Workflow—A Detailed Discussion

“Medical error” has been ascribed to a “failure of process.”⁶ Therefore, the clinical laboratory's best contribution to preventing any medical error for which it could be responsible is to understand the processes in its path of workflow, and improve processes where problems exist.

Each clinical laboratory should understand and document how the various processes in its path of workflow actually occur in that facility. Documenting the processes and procedures provides the basis for staff training in “how it happens here” and for assessing competence in job tasks for both laboratory and nonlaboratory personnel.

The guidance presented in the sections that follow was derived from an analysis of governmental and accreditation requirements for the clinical laboratory⁷⁻⁹ and a sorting of these requirements across the path of workflow. Additional guidance has been added from an international standard on requirements for quality in medical laboratories.¹ The requirements specify policies, processes, and procedures that the laboratory must have in place and for which it must provide objective evidence to investigators, assessors, surveyors, and inspectors that the requirements have been met.

Understanding, documenting, and training for the clinical laboratory's processes provide a high level of assurance that governmental and accreditation requirements will be met and that inspections and accreditation assessments will demonstrate compliance with the requirements. It is only through understanding and controlling the laboratory's many processes that it can become more effective in

meeting requirements, more efficient in the use of human and other costly resources, and reduce its potential for medical error. Laboratories that build the requirements into their routine daily practice will thus always be ready for external inspections and assessments.

Ideally, management and staff should prepare flowcharts for laboratory preexamination, examination, and postexamination processes. Process flowcharts identify the sequence of activities that turns inputs into outputs and identify those areas where documented instructions are needed. Once a process has been outlined on a flowchart, activities that cause problems or inefficiencies can be identified. In addition, means to make the process error-proof and failsafe can also be identified. Revised processes and procedures can then be implemented to improve performance.

[Figure 2](#) and [Table 1](#) describe a small process in the clinical laboratory service's path of workflow. This process is presented in both flowchart and table formats and describes the sequence, responsibilities, and instructions needed for collecting a blood sample for examination. The process documents provide information about "who does what and when," and shows the documented instructions needed for specific tasks that must be properly performed for success of the process.

NOTE: The flowchart and table are included as an example of a collection process and are not meant to describe the only sequence in which these activities occur.

Blood Sample Collection Process

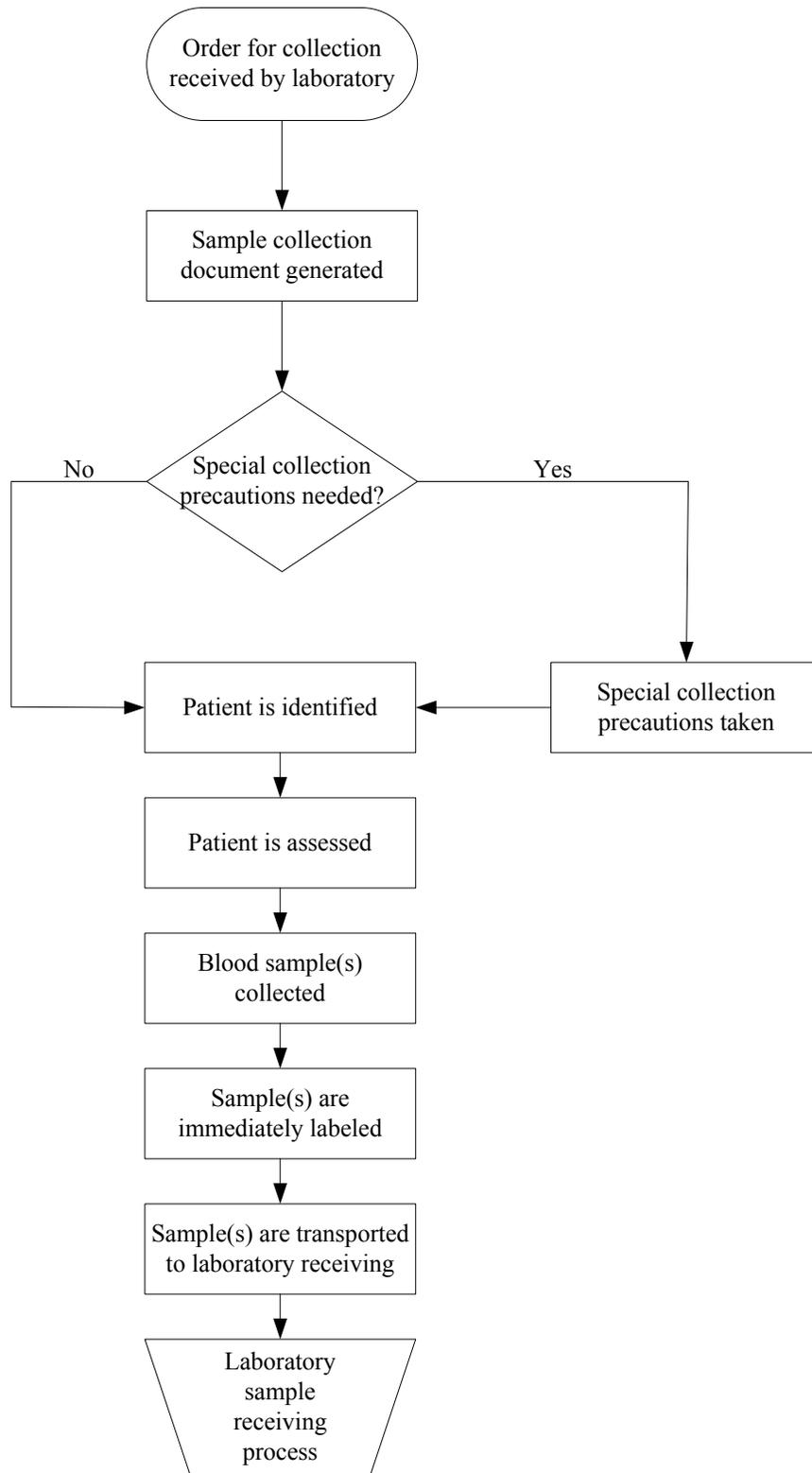


Figure 2. An Example of a Blood Sample Collection Process as a Flowchart

Table 1. An Example of a Blood Sample Collection Process as a Table

What Happens	Who is Responsible	Instructions for:
Sample collection document generated	Laboratory clerks	<ul style="list-style-type: none"> • Generating a blood sample collection list from the laboratory information system (LIS)
Special blood sample collection precautions needed	Person collecting blood sample <ul style="list-style-type: none"> – laboratory phlebotomist – patient care technician – nurse – other 	<ul style="list-style-type: none"> • Special precautions for blood collections
Patient is identified	Person collecting blood sample	<ul style="list-style-type: none"> • How to properly identify a patient
Patient is assessed	Person collecting blood sample	<ul style="list-style-type: none"> • Assessing patients prior to sample collection
Blood sample(s) collected	Person collecting blood sample	<ul style="list-style-type: none"> • Collecting blood samples by venipuncture • Collecting blood samples by capillary puncture • Collecting blood samples by arterial puncture • Collecting blood samples by line draw
Blood sample(s) labeled	Person collecting blood sample	<ul style="list-style-type: none"> • How to properly label blood samples <ul style="list-style-type: none"> - for the main laboratory - for the blood bank
Sample(s) transported to the laboratory	<ul style="list-style-type: none"> • Laboratory phlebotomist • Patient care technician • Nurse • Nursing unit clerk • Other 	<ul style="list-style-type: none"> • Transporting blood samples to the laboratory via the pneumatic tube system

5.1 Preexamination Activities

Key processes in the preexamination portion of the path of workflow for clinical laboratory specialties include all activities from the time the laboratory examinations are ordered (either by a written requisition or by a computer system order) through the time that the samples are processed and delivered to the laboratory examination location or transported to referral laboratories. For anatomic pathologists and cytotechnologists, preexamination activities extend from the time the tissue is removed or collected to the point where the slides are prepared and ready for diagnostic assessment and interpretation. The preexamination portion of the laboratory's path of workflow is shown in [Figure 3](#).

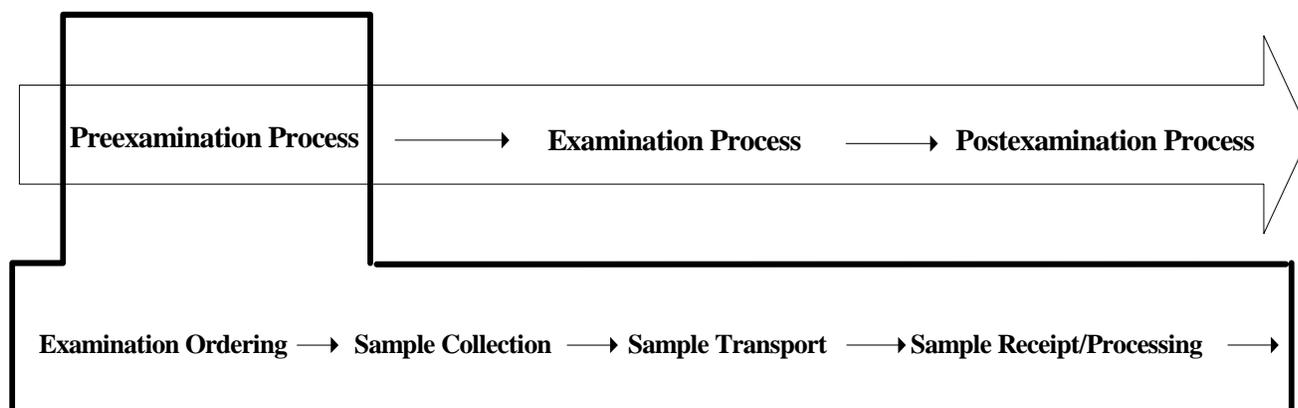


Figure 3. Clinical Laboratory Preexamination Key Processes

5.1.1 Examination Ordering

The laboratory's path of workflow begins with the practitioner's choice of the examinations to order in light of the patient's condition. Ideally, the laboratory's medical director is actively involved with the education and consultation activities needed to ensure the selection of the most appropriate examinations by authorized healthcare practitioners.

Laboratory examination requests—whether in electronic or paper format—need to contain information that identifies the patient and the requester, as well as providing pertinent clinical information, such as:

- patient identification—primary and secondary means, including provisions for providing anonymity where needed (e.g., HIV examinations);
- patient clinical information, including gender and birth date;
- authorized requester and destination of the results report (e.g., patient location or physician's office address);
- examination(s) requested; and
- type of sample and anatomic site of origin, where appropriate.

The laboratory needs to provide the following guidance and instructions for those who order laboratory examinations:

- which laboratory examinations are available;
- which laboratory examinations can be ordered STAT (i.e., performed as urgent or high-priority);
- which laboratory examinations require documentation of patient consent (e.g., blood transfusion);
- how to properly complete laboratory examination requisitions with all required information; and
- how to enter laboratory examination orders into computer systems.

Instructions for additional information may include, where applicable:

- clinical information;
- timed examinations;
- diagnosis;
- sample source; and
- surgical sample markings.

Instructions are also to be provided for blood bank requests including:

- name of blood component or product requested;
- name of therapeutic procedure (e.g., therapeutic phlebotomy or therapeutic apheresis); and
- collection or transfusion of autologous blood.

5.1.2 Sample Collection

5.1.2.1 Patient Preparation and Precollection Assessment

The laboratory is to provide guidance regarding patient preparation when such is necessary for ensuring the quality of the examination result. Information and instructions may need to be provided to patients for their own preparation before sample collection (e.g., outpatient fasting examinations and 24-hour urine collections). Before sample collection, the patient should be assessed to verify that all preparation requirements have been met. Patient assessment should also include an evaluation of any age-specific conditions that might influence the collection approach. It also should include an assessment of the appropriate collection site, contraindications, hazards, or potential complications. For example, the patient needs to fast before collecting a fasting blood glucose sample; or, venous inaccessibility in an infant or child necessitates a modification of the collection technique for acquiring a blood sample. The assessment may also include a verification of the clinical indication for the examination, for example, arterial sample collection.

5.1.2.2 Collection Instructions

Specific collection instructions are to be provided to all sample collection areas within and outside the organization for activities involved in sample collection. The sample collection instructions need to include:

- verifying patient identification at the time of sample collection, ideally using the patient's first and last names and another identifier such as birth date or medical record number;
- using any special patient identification systems (e.g., blood bank armbands);
- collecting blood by venous and capillary techniques;
- collecting the different nonblood samples (e.g., urine, stool, sputum, body fluids);

- proper labeling of samples *in the presence of the patient* with the date of collection and time, where applicable, on the label and/or request;
- recording the identity of the person who collected the sample;
- proper disposal of materials used in the collection; and
- information about the following for both in-laboratory and referral laboratory examination:
 - collection containers;
 - type and amount of sample to be collected;
 - special timing; and
 - preservatives or anticoagulants.

Sample volume requirements need periodic review so that neither insufficient nor excessive amounts of samples are collected.

The verification of patient identification and the labeling of samples at the time of collection in the presence of the patient create a vital, positive link between that patient and that sample. Violation of this link can lead to medical errors such as switched or mislabeled samples.

5.1.3 Sample Transport

Instructions need to be provided for any special preservation or handling of samples before their arrival in the laboratory. Instructions are also to be available for proper and safe packaging, shipping, or transportation of samples from the point of collection to the laboratory. Specific guidance should be available to those who would use a pneumatic tube system to transport biologic samples within the physical facility.

The laboratory needs to verify that samples are transported to the laboratory:

- within the time frame appropriate to the nature of the requested examination;
- within the temperature range specified in the collection instructions; and
- in a manner that complies with all applicable safety requirements.

5.1.4 Sample Receipt and Processing

Because primary samples are the raw materials upon which laboratory personnel perform examinations that generate the results used for diagnosis and treatment of the patient, it is paramount that samples be promptly received, evaluated for acceptability, accurately accessioned, and appropriately processed.

The laboratory needs to provide clear instructions for handling and storage of samples and tissues before examination is performed. The instructions should designate where and how the different types of samples are to be stored during hours in which the laboratory's routine receiving area(s) is/are not open.

Instructions need to be provided for:

- receiving samples into the laboratory (e.g., emptying pneumatic tubes, retrieving samples from pass-through drawers and windows, emptying courier and mailing containers);
- evaluating sample labeling and paperwork for completeness and correctness;

- evaluating the condition of the sample against criteria for acceptance or rejection;
- communicating to the source location when the sample is unacceptable;
- accessioning samples into the information system (whether paper or electronic);
- processing samples (e.g., centrifuging, aliquoting, inoculating media); and
- expediting the receipt, processing, and handling of samples marked as urgent (e.g., STAT).

A tracking mechanism is needed to ensure that all samples submitted to the laboratory are actually received, accounted for, and assayed in a timely manner.

All sample aliquots need to be traceable to the original (i.e., source) sample, and the original sample needs to be traceable to the source individual. The laboratory needs to have a process for actions to be taken when samples lack proper identification. The laboratory also needs to have a process for actions to be taken when there is uncertainty in the identification of an irreplaceable or critical sample, such as cerebrospinal fluid or biopsy tissue.

The laboratory should have a process for providing feedback on issues related to sample quality to those who collect samples, including laboratory and nonlaboratory phlebotomists, physicians’ offices, outreach clients, and any remote collection sites not under the laboratory’s control. The laboratory’s expectations for sample quality and actions to be taken when the expectations are not met should be communicated to the laboratory’s clients. Agreement should be reached with regard to patient safety.

5.2 Examination Activities

Examination key processes for the clinical laboratory specialties include the activities of performing the examination, verifying the reliability of the examination results, and interpreting the findings. In the anatomic and cytopathology specialties, examination key processes include the diagnostic assessment of the slides, peer review when considered necessary, and recording of the findings.

Traditionally, laboratories have been functionally and often physically divided into the specific clinical disciplines of chemistry, hematology, microbiology, and transfusion service for specialized examination methods and instruments. More recently, many laboratories have segregated manual and automated examination methods. Each laboratory or clinical discipline, however it is organized, should identify its automated and manual examination processes. Examination key processes for the clinical laboratory’s path of workflow are shown in Figure 4.

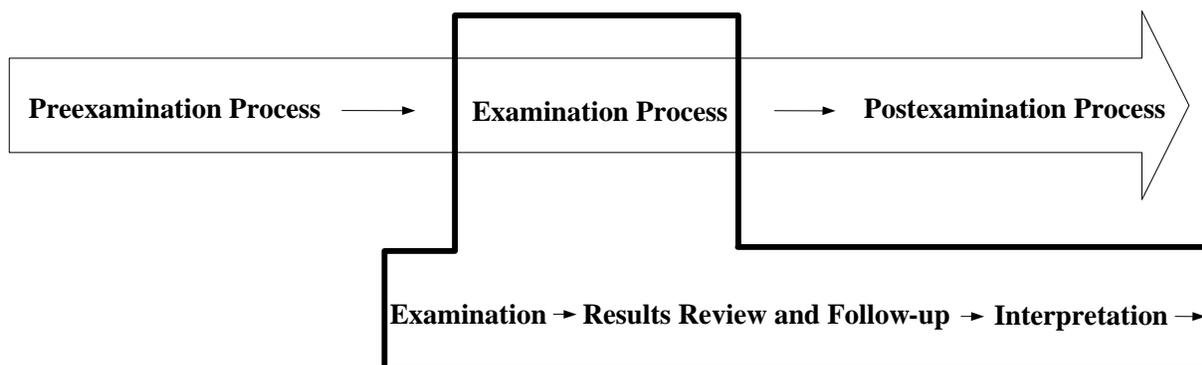


Figure 4. Clinical Laboratory Examination Key Processes

5.2.1 Examination Method Selection

The laboratory is to consider the needs of users of laboratory services when selecting which examinations and methods it will use. The laboratory needs to validate its examination processes, equipment, and computer systems—whether obtained from a vendor or developed in-house—to reduce unwanted variations that can affect patient care. The validation events need to be documented. In NCCLS document [HS1—A Quality Management System Model for Health Care](#), the general policies, processes, and procedures for controlling a clinical service’s path of workflow are discussed under QSE: Process Control, and a sample outline for the contents of a validation protocol is provided. To ensure validity of results, the laboratory will need to follow all applicable governmental, accreditation, and manufacturer requirements for quality control, measurement uncertainty, calibration of measuring systems, and traceability. Laboratory-specific guidance is also provided in this document in [Section 6.6](#).

5.2.2 Examination Performance

There needs to be documented procedures for the examinations performed in the clinical laboratory that are:

- based on the instructions for use written by the manufacturer (e.g., package inserts, operator’s manuals) or developer of a method;
- understood and followed by the laboratory staff who perform the examination; and
- available at relevant workstations.

Guidance for the preparation of laboratory examination procedures can be found in the most current edition of NCCLS document [GP2—Clinical Laboratory Technical Procedure Manuals](#). Examples in the appendixes present guidance for content and format that is appropriate for different types of examination procedures, such as automated, manual, quantitative, and qualitative examinations.

The clinical laboratory needs a system whereby the identity of the person performing or completing an activity, the date of performance, and any important environmental conditions, patient characteristics, or accessioning details can always be established. This system should include the performance of activities along the entire path of workflow, not just for laboratory examinations.

The laboratory needs to have a quality control program that includes a schedule and documented processes and procedures for quality control of examination method performance; tolerance limits; and corrective actions.

5.2.3 Review of Examination Results

The laboratory should have a process for correlating the results of concurrent examinations and any previous examinations.

Review of examination results is to be performed only by authorized personnel. Instructions for review are needed for both automated and manual examination results before data entry or transfer into computer information systems. “Autoverification” features of automated analyzers may expedite examination result entry but are to be validated before use. Control result verification procedures are needed before any patient examination results are released and need to include instructions for actions to take when control results exceed acceptable limits. Additional instructions are needed for follow-up of examination results below or above verified limits of the examination method.

5.2.4 Interpretation

The laboratory needs to document and make available:

- objective criteria for the evaluation of the results of qualitative examination procedures;
- comparisons for interpreting data (e.g., reference ranges, age-specific information, alert values);
- interpretations of morphology; and
- any other correlative or interpretive information necessary to interpret the examination results.

The anatomic pathology service needs a process to verify that the findings of the gross and microscopic examinations support the pathologic diagnoses, and that pathology findings and diagnoses correlate with the patient’s clinical information.

The laboratory needs to have designated processes for reconciling significant disparities between frozen section and final diagnoses and disparities between histological and cytological findings.

5.3 Postexamination Activities

Postexamination key processes in the path of workflow include activities related to reporting results and archiving results and sample material. Postexamination processes are shown in Figure 5.

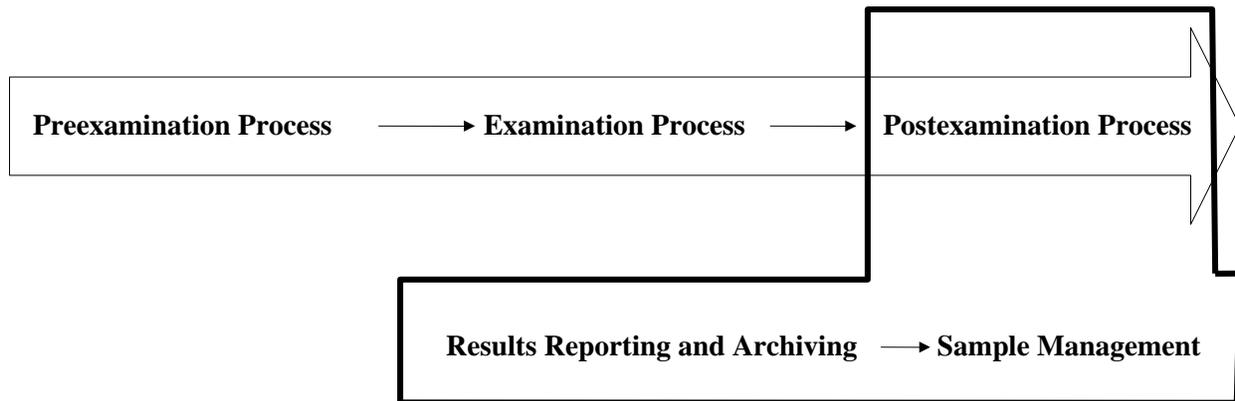


Figure 5. Clinical Laboratory Postexamination Key Processes

5.3.1 Preliminary Reports

Clear instructions are needed for staff on when and how to notify appropriate parties of examination results that are in the laboratory’s predetermined “alert” or “critical” ranges and how to document the notification. The laboratory needs to have a process in place to confirm patient identification before verbal reports are given to designated persons and to ensure that results were heard correctly. The process of producing the final report is to include any preliminary reports that were issued.

5.3.2 Final Reports

The final report is the clinical laboratory’s “product” and is the culmination of the combined processes across the entire path of workflow. The final report represents the laboratory to all its customers; its format (i.e., its content and appearance on paper and electronically) should be determined in discussion

with users of laboratory services. Reports should use standardized descriptive terminology. The laboratory needs to have processes in place so that the final report is legible, interpretable, and without mistakes in transcription. The report needs to include:

- all required elements
 - patient name, unique identifier, location
 - date (and time where appropriate) of sample collection
 - unique identifier of the person ordering the examination(s)
 - identification of the examination(s) ordered
 - date and time of receipt in the laboratory
 - results of the examination(s), with reference range(s), where appropriate
 - interpretation of results, where appropriate, and
 - other comments (e.g., sample adequacy);
- names and addresses of laboratories that performed procedures, including referral laboratories;
- all required signatures, which may be in electronic form; and
- inclusion of any consultations obtained.

In addition, processes for verification of accurate transcription and transmittal of examination results and reports, and for inclusion of reports in the patient's medical record, are necessary.

5.3.2.1 Report Turnaround Time

The laboratory needs to define expected turnaround times for each examination performed. Ideally, this is the interval from the time the examination was ordered by the physician or responsible caregiver to the time the results reach the patient record. However, it is often only possible to track the interval between sample collection or sample receipt by laboratory personnel and reporting of results. The laboratory needs to have instructions for notifying the requester when examinations that could compromise patient care are delayed.

In addition, the laboratory needs a process to monitor its turnaround times to determine whether or not the reports are meeting requirements and agreed-upon parameters.

5.3.2.2 Corrected Reports

The laboratory needs to establish a mechanism for correcting an erroneous result on a laboratory report in a manner that identifies the erroneous result as revised and maintains both the original and corrected reports on the patient's record. Procedures for correcting reports are to include instructions for both electronic and paper reports. Clear instructions are needed for how to reconcile any disparities between cytological and histological results, and between preliminary and final reports.

5.3.3 Sample Management

5.3.3.1 Sample Storage

The laboratory needs to store samples postexamination under conditions that ensure stability so that examinations can be repeated after results are reported (where need be) and additional examinations can be performed.

The laboratory needs to specify the time period in which examinations can be repeated or added to a retained sample.

5.3.3.2 Sample Retention

The laboratory needs to have defined processes and procedures for retention of the following samples after examination is performed:

- blood, body fluids, and tissues submitted for laboratory examination
 - surgical pathology gross samples
 - tissue blocks and slides;
- autopsy
 - gross samples
 - tissue blocks and slides;
- bone marrow smears;
- blood films;
- negative, unsatisfactory, and positive cytopathology slides;
- media on abnormal cytogenetics cases; and
- blood donor and transfusion recipient blood samples.

The procedures for sample, tissue, and slide retention should include a schedule for the duration of retention that is based on governmental, accreditation, and organizational requirements.

Appendix A provides an example of a sample retention schedule prepared from U.S. governmental and accreditation requirements. International users of this NCCLS document may follow this example to prepare a similar table that reflects their national, regional, or local requirements.

It is advisable to retain a bank of stable samples that demonstrate special features (e.g., abnormally high, low, or borderline results; a rare disease; a rare composition) that may be used to validate or verify a new method, introduce a new lot or batch of a diagnostic kit, or verify a change of a standard solution. For these samples, the laboratory should determine the conditions to ensure stability (e.g., temperature, exposure to light) and the retention time.

5.3.3.3 Sample Indexing

The storage processes for retained samples, tissues, blocks, and slides need to facilitate accessibility. The laboratory needs defined procedures for retrieving samples, tissues, blocks, and slides from both short-term and long-term storage and onsite and offsite storage.

The laboratory needs a defined process and documented procedures for receipt, loan, and send-out of original samples, tissue, blocks, slides and smears.

5.4 Application of Examination Results to Patient Care

The laboratory's path of workflow is not complete until the examination results have been appropriately applied to patient care. The laboratory needs to provide healthcare practitioners with the opportunity to consult with the medical director to:

- ask any questions about the examination results or their interpretation;
- discuss the meaning of the examination results in light of the patient's particular condition; and
- obtain information about any appropriate additional or follow-up examination.

[Appendix B](#) is a listing of NCCLS documents that provide specific guidance in the preexamination, examination, and postexamination phases of the clinical laboratory's path of workflow.

6 Application of QSEs for Clinical Laboratory Services

NCCLS document [HS1](#)—*A Quality Management System Model for Health Care*, discusses 12 QSEs and provides general guidance for developing the quality management system. The remainder of Section 6 provides laboratory-specific information about each of the 12 QSEs. [Table 2](#) correlates the laboratory-specific QSE information in [Section 6](#) with its counterpart, general QSE information provided in NCCLS document [HS1](#)—*A Quality Management System Model for Health Care*.

Clinical laboratories are encouraged to review the general requirements and examples presented in the HS1 guideline, combine them with the laboratory-specific information in Section 6 and develop their own policies, processes, and procedures to implement a quality management system in their own laboratories. A laboratory will need to design its quality management system to comply with any applicable governmental, accreditation, or safety requirements. The policies, processes, procedures, and document control practices recommended in the most current editions of NCCLS documents [HS1](#) and [GP26](#) will help laboratories comply with those requirements; however, additional technical requirements may also apply for specific activities in the path of workflow.

Table 2. Correlation of Laboratory-Specific QSE Information in NCCLS GP26 with Corresponding Guidance in HS1

GP26		HS1	
Section #	Heading	Section #	Heading
6.1.1.1	The Quality Manual	4.2.2 Appendix A Appendix B Appendix C	The Quality Manual Example of a Quality Manual Table of Contents QSE Policy: Documents and Records QSE Processes
6.1.1.2	Operations Procedures Manuals	5.1.1 Appendix D Appendix E	System for Controlling Documents Document Change Request Form Sample Master Document Index
6.1.2	Records	5.1.2	System for Controlling Records
6.3.1	Personnel Processes	5.3.1 5.3.2 5.3.3 5.3.4 5.3.5 5.3.6 Appendix F Appendix G	Job Qualifications and Job Descriptions Orientation Training Competency Assessment Training and Competency Assessment Programs Continuing Education and Professional Development Orientation Program Training Program
6.3.2	The Quality Manager	5.2.3	Quality Manager
6.4	QSE: Equipment	5.4.1 5.4.2 5.4.3 5.4.4 5.4.5	Equipment Acquisition, Installation, and Identification Equipment Validation Equipment Maintenance, Calibration, and Use Troubleshooting, Service, and Repair Equipment Records
6.5.3	Purchasing	5.5.1	Purchasing
6.5.4	Inventory Management	5.5.2	Inventory
6.6	QSE: Process Control	5.6.1 5.6.2 5.6.3 5.6.4 Appendix H	Developing Flowcharts for Organization Processes Process Validation or Verification Identifying and Writing Procedures Process Control Sample Outline for a Validation Protocol
6.7	QSE: Information Management	5.7.1 5.7.2 5.7.3 5.7.4 5.7.5 5.7.6	Focus of Information Management Incoming and Outgoing Information Computer Access and Security Data Integrity Information System “Downtime” Requests for Information
6.8	QSE: Occurrence Management	5.8.1 5.8.2 5.8.3 5.8.4 5.8.5 Appendix I Appendix J	Capturing Information Occurrence Report Form Immediate Action and Investigation Occurrence Analysis Corrective Action Sample Occurrence Management Form Sample Occurrence Log
6.9.1	Accreditation Assessment	5.9.1.1	Accreditation Assessment
6.9.3	Internal Assessment - Quality Indicators	5.9.2.1 Appendix K	Quality Indicators Indicator Form
6.9.4	Internal Assessment - Internal Audit	5.9.2.2	Internal Audit Program
6.9.5	Quality Report	5.9.3 Appendix L	Periodic Reporting Quality Report Form
6.10	QSE: Process Improvement	5.10.1 5.10.3 5.10.4 5.10.5 5.10.6 Appendix M	Identifying Opportunities for Improvement Problem Resolution Process The Team Approach Quality Improvement Tools Periodic Reporting Plan-Do-Check-Act
6.11	QSE: Customer Service	5.11	QSE: Customer Service
6.12.1	Facilities	5.12	QSE: Facilities and Safety
6.12.2	Safety	5.12	QSE: Facilities and Safety

Appendix C is a comparison of the NCCLS QSEs to an international standard for a quality management system¹⁰ and an international standard specific for medical laboratories.¹

A listing of the 12 QSEs and NCCLS documents that provide guidance for specific QSEs can be found in NCCLS' current catalog. In the following sections, additional information specific to the laboratory application of the QSEs is provided.

Figure 6 shows how the major clauses of an international requirement for quality management in the medical laboratory¹ can be sorted within the quality system model presented in NCCLS document [HS1—A Quality Management System Model for Health Care](#). This figure may be useful in organizing the laboratory's quality manual and operations procedures manuals.

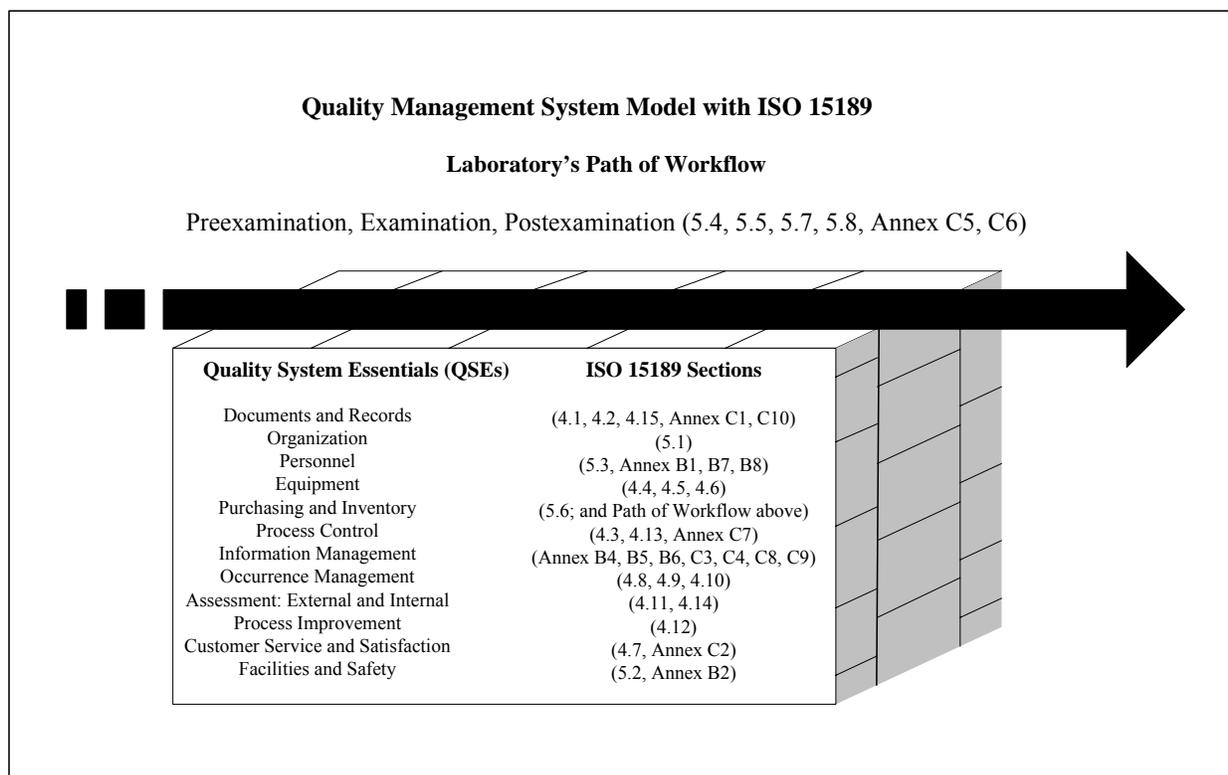


Figure 6. ISO 15189 Clauses Sorted to the NCCLS Quality Management System Model

6.1 QSE: Documents and Records

6.1.1 Documents

6.1.1.1 The Quality Manual

A clinical laboratory that operates within a quality management system will have a single quality manual that documents the policies, and includes or refers to the processes, procedures, and forms used by the laboratory's management staff to implement the QSEs throughout all the clinical disciplines in the laboratory. The quality manual is an ideal way to organize the information contained in various laboratory administrative policies, procedures, directives, and memoranda. The quality manual can also serve as a training manual for new and existing management staff, because it describes all the nontechnical processes that managers need to execute to ensure correct and sufficient resources for laboratory technical operations.

The laboratory needs to have a means to communicate the contents of the quality manual to all nonmanagerial staff as well. This may be accomplished by having each employee read the quality manual or by having a training program in which staff learn the specific QSE responsibilities that apply to their jobs.

6.1.1.2 Operations Procedures Manuals

In addition to the quality manual, each of the clinical disciplines needs to have technical operations manuals that contain the documented processes, procedures, and forms for the operations in the discipline's path of workflow. NCCLS document [GP2—Clinical Laboratory Technical Procedure Manuals](#) provides guidance for how to prepare process, procedure, and form documents.

6.1.2 Records

6.1.2.1 Records Management

The laboratory needs to establish and implement the following processes and procedures for its quality and technical records:

- identification (on the record);
- collection;
- indexing;
- access;
- maintenance; and
- disposal.

Record-keeping systems need to store laboratory records in a manner that maintains integrity, protects accessibility, and facilitates retrieval. In addition, the confidentiality of patient-specific information *must* be protected.

6.1.2.2 Record Retention

The laboratory needs to establish a record retention schedule that meets governmental, accreditation, and organizational retention requirements for the following types of laboratory records:

- examination requisitions;
- worksheets and instrument printouts;
- quality control results and actions taken;
- external quality assessment (proficiency testing);
- equipment calibration and maintenance;
- examination method verification;

- software verification;
- blood donation and transfusion;
- patient examination reports;
- staff training and competence;
- internal and external audits and inspections; and
- occurrence, nonconformance, and complaint records and action taken.

[Appendix D](#) provides an example of a record retention schedule prepared from governmental and accreditation requirements. International users of this NCCLS guideline may follow this example to prepare a similar table that reflects their national, regional, or local requirements.

Paper and electronic record systems need to store laboratory records in a manner that maintains integrity, protects accessibility, and facilitates retrieval. In addition, the confidentiality of patient-specific information *must* be protected.

6.2 QSE: Organization

If the laboratory posts and/or distributes a published organizational chart, a process is necessary to ensure that all copies are current.

Also necessary is an overall documented plan for laboratory quality improvement that:

- covers all aspects of laboratory services;
- is implemented as designed;
- is coordinated with other facility quality improvement programs; and
- is appraised regularly for effectiveness.

6.3 QSE: Personnel

6.3.1 Personnel Processes

The clinical laboratory's human resources are its most valuable and costly. To ensure the quality of laboratory services to its customers and job satisfaction of laboratory personnel, the laboratory needs to maintain processes and procedures for the following key elements:

- establishment of job qualifications that meet governmental, accreditation, and organizational requirements;
- development of a recruitment and retention program;
- inclusion of job qualifications in job descriptions;
- maintenance of current job descriptions that are based on job duties in the path of workflow;

- training and ongoing competency assessment based on work processes and procedures in the portion of the path of workflow performed in that job;
- a plan to ensure adequate staffing for the work to be done;
- provision of opportunities to participate in and document professional growth and development; and
- working within the organization's performance appraisal and rewards programs.

NCCLS document [GP21](#)—*Training and Competence Assessment*, provides guidance for developing and documenting training of laboratory employees.

[Appendix E](#) is an example of a job description based on actions performed in the path of workflow by the person in that job position.

6.3.2 The Quality Manager

The laboratory needs to appoint a quality manager (however named) with delegated responsibility and authority to oversee compliance with the requirements of the quality management system. The quality manager is to report directly to the level of laboratory management at which decisions are made on laboratory policies, processes, procedures, and resources.

6.4 QSE: Equipment

In addition to the policies, processes, and procedures described for equipment in NCCLS document [HS1](#), the clinical laboratory needs to maintain a history file for each piece of equipment (including replacement equipment) that includes records of the following:

- selection;
- acquisition;
- installation qualification;
- identification;
- validation or verification;
- calibration program;
- maintenance program;
- service and repair; and
- equipment files and records.

Any piece of equipment that leaves the control of the laboratory, for any reason or for any amount of time, needs to be verified for suitability upon return, before placing it into service.

6.5 QSE: Purchasing and Inventory

6.5.1 Provision of Laboratory Services

The laboratory needs to have processes and procedures for initial and ongoing reviews of contracts to provide its medical laboratory services to other services or facilities. The contract review process needs to ensure that:

- requirements for the laboratory's services are defined, documented, and understood by involved parties;
- the laboratory has the capabilities and resources to meet the requirements;
- the processes and procedures to be used by the laboratory meet the contract requirements and clinical needs of the user of the laboratory's services;
- amendments and changes to contract provisions are discussed and documented; and
- any deviations from the contract are reported to the clients.

6.5.2 Use of Referral Laboratory Services

The laboratory needs to have an established process for evaluating and selecting referral laboratories. The needs of the users of the referring laboratory's services are to be considered when selecting and monitoring the quality and competence of the referral laboratory and any consultants used.

Agreements with referral laboratories are to be periodically reviewed for the following, with documentation of the reviews:

- requirements of both parties are defined, documented, and understood;
- the referral laboratory can meet the requirements;
- there are no conflicts of interest;
- examination selections are appropriate for their intended use; and
- respective responsibilities for the interpretation of the examination results are clearly defined.

The referring laboratory needs to maintain a listing of all referral laboratories it uses, a log of all samples sent to each referral laboratory, and a record of examinations for each sample.

The referring laboratory needs to have a process to provide the referral laboratory results and findings to the person making the original request. The report needs to include:

- the name and address of the referral laboratory;
- a copy of the referral laboratory's report; **or**
- when the referring laboratory makes the report, all essential elements of the referral laboratory report without alterations that could affect clinical interpretation.

The referring laboratory needs to have a means to ensure that the performance of any referral laboratory it uses meets all required regulations and standards.

NCCLS document [GP9](#)—*Selecting and Evaluating a Referral Laboratory* provides useful information on this subject.

6.5.3 Purchasing

The laboratory should work with the organization's materials management service to develop and document a clear understanding of which service performs which activities in the processes of vendor qualification, selection, and evaluation, and in the process of purchasing the materials used in laboratory procedures.

6.5.4 Inventory Management

The laboratory should develop an inventory management system that is fiscally responsible while maintaining adequate accessibility to all materials and supplies necessary for laboratory operations.

The laboratory needs to have procedures for storage of consumable materials, as well as processes to maintain adequate supplies on-hand. For identified critical materials, records of the following are to be maintained:

- date received;
- lot number;
- whether or not acceptance criteria were met and any follow-up; and
- date material is placed in service, or disposition if not used.

6.6 QSE: Process Control

To ensure the best contribution to patient care, clinical laboratory personnel should understand and document the processes in the laboratory's path of workflow. Work processes should be supported by documented procedures and related forms. Performance verification of any new or changed processes anywhere in the path of workflow needs to occur before implementation. By developing an understanding of the processes that move a request for laboratory services from examination ordering through reporting of results, laboratory personnel will be better positioned to identify key factors that influence the laboratory's ability to reduce turnaround times.

The laboratory needs to follow all required activities to fulfill governmental and accreditation requirements for examination method performance specifications. For published or commercial examination methods, the laboratory needs to verify that it can perform the method consistent with the claims for the method. If a method is modified or developed in-house, the laboratory needs to validate method performance in accordance with its established validation process, and document all such validations. NCCLS "EP" series guidelines provide useful information for examination method evaluation. NCCLS document [GP29](#)—*Assessment of Laboratory Tests When Proficiency Testing is Not Available* also provides important information.

The laboratory needs a means for establishing reportable ranges and biological reference intervals for examination procedures before implementation. The laboratory needs to have a process to demonstrate that the reportable ranges for the examinations performed on new instruments, reagent kits, or systems are comparable to those established by the manufacturer.

The laboratory needs a means to verify the comparability of patient examination results throughout the clinically appropriate ranges for examinations performed using different methodologies or instruments or at different examination sites.

The laboratory needs to have a quality control program that includes a schedule and documented processes and procedures for quality control of examination method performance; tolerance limits; and corrective actions.

6.7 QSE: Information Management

The clinical laboratory needs to have defined processes for receiving and handling patient information. The processes need to ensure the accessibility, security, confidentiality, and privacy of patient information in both paper-based and electronic information systems. Where required, that laboratory also needs to have processes and procedures for charging and billing for provision of examination services.

The laboratory needs to have an established process for implementing an information (computer) system that meets established requirements for:

- computer environment;
- documenting processes and procedures;
- system security;
- data entry and reports;
- data retrieval and storage, including backup procedures;
- hardware and software;
- system maintenance;
- interfaces; and
- networks.

6.8 QSE: Occurrence Management

The laboratory needs to have a procedure for anyone on its staff to document and report problems in laboratory operations or issues that may interfere with patient care services. Such problems can be identified through any of the following means:

- practitioner or patient complaints;
- nonconforming quality control or calibration results;
- nonconforming external quality assessment results;
- nonconforming reagents or consumables;
- staff comments;

- findings from internal or external audits; and
- management reviews.

The laboratory's occurrence management process needs to include the following activities:

- documentation of each episode of nonconformity;
- immediate remedial action;
- consideration of the medical significance of any nonconforming examinations, where appropriate;
- notification of the requesting physician;
- cessation of examination and reporting as necessary;
- recall or identification of any nonconforming examination results, where necessary;
- definition of further actions to be taken;
- designation of personnel responsible for resolving the problem; and
- definition of responsibility for resuming examination.

The occurrences and nonconformances should be classified as to where in the path of workflow they occur and where they are detected so that appropriate corrective action aimed at removing the root cause of the problem can be planned and implemented.

6.9 QSE: Assessment

6.9.1 Accreditation Assessment

Medical laboratories are subject to many different external assessments—both voluntary and mandatory—to determine if regulations, standards, and requirements are being met. Each governmental and accreditation organization has its specific program requirements such as scope, assessment schedule, assessment processes, proficiency testing requirements, estimation of the uncertainty of measurement, etc., and may assess to different standards.

The laboratory needs to ensure that its quality management system meets the requirements of the many regulations, standards, and accreditation requirements to which it is subjected. The model for a quality management system described in the most current edition of NCCLS document [HS1—A Quality Management System Model for Health Care](#), provides a framework for categorizing the various regulations, standards, and requirements so that policies, processes, and procedures that incorporate these requirements can be developed and implemented.

It is important to note that accreditation of a laboratory is different from certification of a quality management system (see [Section 3, Definitions](#)).

6.9.2 External Quality Assessment/Proficiency Testing (EQA/PT)

The laboratory needs to participate in an external quality assessment/proficiency testing program or other external assessment activity that provides an external means of verifying examination method performance. The program is to include, where possible, a means to determine the reliability of examination results on patient samples for which no EQA/PT program is offered. (Please refer to the most current edition of NCCLS document [GP27—Using Proficiency Testing \(PT\) to Improve the Clinical Laboratory](#), for additional information.) When examination procedures are performed for which neither calibration nor control materials are available, laboratories need a means to verify the reliability of examination results. Each governmental and accreditation organization has its specific EQA/PT program requirements such as scope, examination schedule, and evaluation processes. Laboratories need to determine the requirements for the EQA/PT programs to which it subscribes.

6.9.3 Internal Assessment – Quality Indicators

Laboratory management needs to identify and monitor quality indicators that measure process performance in preexamination, examination, and postexamination operations in the laboratory's path of workflow, and, therefore, measure the laboratory's contribution to patient care. Examples of suggested and published laboratory quality indicators are presented in [Appendixes F and G](#).

The laboratory's performance on these should be compared to external benchmarks; this may be a requirement for some laboratories.

6.9.4 Internal Assessment – Internal Audit

Laboratory management needs to have a defined program and schedule for conducting internal audits. Laboratories can refer to the most recent edition of NCCLS document [HS1—A Quality Management System Model for Health Care](#) for a discussion of internal auditing.

6.9.5 Quality Report

The laboratory needs to periodically report its findings from external and internal assessments and occurrences to the organization's quality function and to its own executive management for review.

6.10 QSE: Process Improvement

The laboratory should use information from any of the following sources to identify areas in any part of its path of workflow where improvement is needed:

- customer satisfaction surveys;
- external inspections and assessments;
- proficiency test results;
- quality indicators;
- occurrence reports; and
- internal quality audits.

It is the laboratory's responsibility to initiate action on, and participate in, opportunities for process improvement, regardless where they occur. The laboratory may be required to report its process improvement activities and results to the organization's quality management function.

6.11 QSE: Customer Service

The laboratory needs to assess the satisfaction of its external physician, nursing, referring customers, and patients with the quality of its services on an ongoing basis. In addition, the satisfaction of the laboratory's internal customers—its staff—with the quality of communication, documentation, training, competence assessment, and operations processes should also be determined. Actions are to be taken to improve laboratory services based on response to the satisfaction assessment results. Laboratory staff can be a good source of suggestions for areas in which operations can be streamlined to improve customer service.

6.12 QSE: Facilities and Safety

6.12.1 Facilities

6.12.1.1 Laboratory Design, Space Allocation, and Access

The laboratory should work with the organization's facility planning function to develop processes for laboratory building and renovation projects. The projects should ensure the best possible design for work process flow and ergonomics. The laboratory needs a means to ensure that governmental, accreditation, and organizational requirements for current and planned space are met.

There needs to be a process to ensure that laboratory-specific environmental requirements (e.g., energy sources, lighting, ventilation, water, refuse disposal) are met. NCCLS document [GP18—Laboratory Design](#) provides useful information on this subject.

In sample collection areas, the laboratory needs to consider accommodations for disabled patients, comfort, privacy, and safety, as well as optimization of collection conditions.

The sample collection area, as well as the examination environment, is not to invalidate results or adversely affect the requirements of any examination parameter.

When cross-contamination is possible between adjacent laboratory sections, or there are incompatibilities, effective separation is needed. Examples include nucleic acid amplification testing, a quiet workspace without interruptions for cytopathology screenings, and a temperature-controlled environment for the computer system.

Appropriate measures need to be taken to control access to—and use of—examination areas, samples, and supplies.

6.12.1.2 Laboratory Environment Monitoring

The laboratory needs to monitor, document, and control its environmental conditions as required or where they may influence the quality of results. Such conditions include (as appropriate to technical activities):

- sterility;
- dust;

- electronic interference;
- radiation;
- humidity;
- electrical supply;
- temperature;
- sound levels; and
- vibration levels.

6.12.1.3 Storage Space and Storage Conditions

The laboratory needs to provide relevant storage space and environmental conditions to ensure the continuing integrity of the following:

- samples;
- slides;
- histology blocks;
- retained microorganisms;
- reagents;
- laboratory supplies;
- equipment;
- documents;
- manuals;
- records; and
- files.

6.12.2 Safety

6.12.2.1 Safety Training

To meet governmental and accreditation requirements, the laboratory needs to have well-defined processes for training all staff in the following safety programs:

- internal and external emergency preparedness (e.g., fire, tornado, disaster);
- infection control, (e.g., tuberculosis exposure, Creutzfeld-Jacob disease);

- universal precautions;
- personal protection equipment;
- chemical hygiene;
- disposal of hazardous waste;
- bioterrorism preparedness; and
- radiation safety.

6.12.2.2 Safety Management

ISO standard 15190: *Medical laboratories—Requirements for safety*¹¹ and NCCLS document [GP17](#)—*Clinical Laboratory Safety* provide guidance in the following areas:

- management responsibilities;
- facility management (design, identification of hazards, housekeeping practices, etc.);
- radiation safety;
- chemical safety;
- emergency preparedness (fire, evacuations, electrical equipment, first aid, etc.);
- biologic safety (biologic materials handling, transport, and waste; safety cabinets; personal protective equipment; handwashing; etc.); and
- personnel (staffing; training; responsibilities; reporting of incidents, accidents, and occupational illness; etc.).

The laboratory needs to have a means (such as a safety committee or a safety audit) to ensure that: personnel have access to required safety documents (e.g., Material Safety Data Sheets, Chemical Hygiene Plan); safety requirements are continuously met; and personnel comply with the requirements.

7 Conclusion

Understanding and documenting the policies, processes, and procedures in the laboratory's path of workflow is a means to begin to improve quality in laboratory services. Ideally, each laboratory should invest the time needed to analyze its operations processes, because in so doing, needed procedures become readily identified, as do inefficiencies, redundancies, and opportunities for error. In addition, with an understanding of laboratory processes, the development of training and competence programs follows easily. Governmental and accreditation requirements can be integrated into laboratory operations most effectively when they are viewed from the perspective of the path of workflow.

For the laboratory to make a positive contribution to patient care, it must understand, document, train to, and monitor its path of workflow. The laboratory will have a complete quality management system when these actions are combined with policies, processes, and procedures for the QSEs.

Laboratories must expand their view of quality beyond the departmentalized quality assurance activities of the last decades to keep pace with the growing role of total quality management in today's competitive environment. Quality management systems are being used successfully in the world's manufacturing and service sectors. These systems can be applied to benefit laboratory services as well.

Each clinical discipline within the laboratory can use the same quality system essentials to manage its path of workflow. The laboratory's executive management can develop one universal set of policies, processes, and procedures for the QSEs that apply to all the clinical disciplines in the entire laboratory.

Uniform processes and procedures for implementing the quality management system within the laboratory reduce medical errors and reduce opportunities for costly discrepancies, conflicts, and competition for limited resources among the laboratory's clinical disciplines. Using the same quality system essentials for each clinical discipline integrates the quality management system across the entire laboratory service.

By combining the policies, processes, and procedures for the quality system essentials described in NCCLS document [HS1](#)—*A Quality Management System Model for Health Care*, with the guidance for the laboratory's path of workflow provided in this document, the laboratory can implement a quality management system that incorporates the major requirements of international, governmental, and accreditation requirements. The laboratory could also serve as a model for quality management system implementation in other clinical services in the organization, thus truly helping to improve patient safety.

This guideline presents a working model that will enable champions for change to take the first steps in improving quality management in laboratory services.

References

- ¹ ISO. *Medical laboratories—Particular requirements for quality and competence*. EN/ISO 15189. Geneva: International Organization for Standardization; 2003.
- ² ISO. *Conformity assessment – Vocabulary and general principles*. ISO/IEC 17000. Geneva: International Organization for Standardization; 2004.
- ³ ISO. *Clinical laboratory medicine—In vitro diagnostic medical devices—Validation of user quality control procedures by the manufacturer*. ISO 15198. Geneva: International Organization for Standardization; 2004.
- ⁴ ISO. *Proficiency testing by interlaboratory comparison—Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies*. ISO Guide 43-2. Geneva: International Organization for Standardization; 1997.
- ⁵ ISO. *Quality management systems—Fundamentals and vocabulary*. ISO 9000. Geneva: International Organization for Standardization; 2000.
- ⁶ Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Washington, D.C.: National Academy Press; 2003.
- ⁷ Centers for Medicare and Medicaid Services. Department of Health and Human Services. *Part 493—Laboratory Requirements: Clinical Laboratory Improvement Amendments of 1988*. Code of Federal Regulations, Title 42, Parts 430 to end. U.S. Government Printing Office. Published annually.
- ⁸ Joint Commission on Accreditation of Healthcare Organizations. *Comprehensive Accreditation Manual for Pathology and Laboratory Services*. Oakbrook Terrace, IL: JCAHO. Published annually.
- ⁹ Commission on Laboratory Accreditation, College of American Pathologists. *Inspection checklists for laboratory accreditation*. Northfield, IL: CAP. Published annually.
- ¹⁰ ISO. *Quality management systems—Requirements*. ISO 9001. Geneva: International Organization for Standardization; 2000.
- ¹¹ ISO. *Medical laboratories—Requirements for safety*. ISO 15190. Geneva: International Organization for Standardization; 2003.

Appendix A. Example of a Sample Retention Schedule

Laboratory Name: _____

Types of Samples	Sample Retention Period				
	[Laboratory's chosen retention period]	CLIA	CAP	JCAHO	[Other organization]
Serum/CSF/body fluids		Not specified	24 hours		
Blood films, body fluid slides • Normal		Not specified	7 days		
Blood films, body fluid slides • Abnormal		Not specified			
Cytology • Negative slides/unsatisfactory		5 years from examination date	5 years	5 years from examination date	
Cytology • Positive/suspicious		10 years	5 years	5 years from examination date	
Bone marrow smears		10 years	10 years		
Bone marrow biopsy		10 years			
Fine needle aspirates		10 years	10 years		
Histology slides		10 years		10 years	
Cytogenetic slides		Not specified			
DNA samples (molecular genetics)		Not specified			
Fertility testing lab morphology slides		Not applicable			
Wet and formalin-fixed tissue		Until final report is issued	2 weeks after final report	7 days after final report	
Paraffin blocks		2 years from examination date	5 years	2 years from examination date	

This example was modified from the table contributed by the Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, Minnesota, U.S.A.

Appendix B. The Laboratory's Path of Workflow and Supporting Documents

Path of Workflow Portion	NCCLS Supporting Document*		
Sample Collection and Transport	C31 C34 C38 H11 GP15 GP20 GP23 H3 H4 H21 LA4 M15		
Sample Receiving and Processing	H18		
Examination	C24 H44 M33 C28 H45 M34 C40 H47 M35 C42 H48 M38 C43 H49 M42 H17 H51 M44 T/DM6 H52 MM1 T/DM8 M7 MM2 GP16 M11 MM3 H2 M21 MM5 H7 M24 MM6 H15 M26 H17 M27 H22 M28 H30 M31		

*For a complete description of the documents mentioned in the table, please contact the Executive Offices for a copy of the current NCCLS catalog. Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: exoffice@nccls.org; Website: www.nccls.org

Appendix C. Comparison of NCCLS QSEs to the Requirements of ISO 9001:2000 and ISO 15189:2003

NCCLS QSEs ¹	ISO 9001:2000 ²	ISO 15189:2003 ³
Organization	4.1 General requirements 5.1 Management commitment 5.3 Quality policy 5.4 Planning 5.5 Responsibility, authority, communication 5.6 Management review 6.1 Provision of resources	4.1 Organization and management 4.2 Quality management system 4.15 Management review Annex C.1 General ethics Annex C.10 Financial arrangements
Personnel	6.2 Human resources	5.1 Personnel
Equipment	7.6 Control of measuring and monitoring devices	5.3 Laboratory equipment Annex B.1 General Annex B.7 Hardware and software Annex B.8 System maintenance
Purchasing and Inventory	7.4 Purchasing	4.4 Review of requests and contracts 4.5 Examination by referral laboratories 4.6 External services and supplies
Process Control	7.1 Planning of product realization 7.2 Customer-related processes 7.3 Design and development 7.5 Production and service provision	5.4 Preexamination procedures 5.5 Examination procedures 5.6 Assuring the quality of examination procedures 5.7 Postexamination process 5.8 Reporting of results Annex C.5 Examination Annex C.6 Reporting results
Documents and Records	4.2 Documentation requirements	4.3 Document control 4.13 Quality and technical records Annex C.7 Storage/retention of medical records

continued on next page

Appendix C. (Continued)

NCCLS QSEs ¹	ISO 9001:2000 ²	ISO 15189:2003 ³
Information Management		Annex B.4 System security Annex B.5 Data entry and reports Annex B.6 Data retrieval and storage Annex C.3 Information Annex C.4 Consent Annex C.8 Access to laboratory records Annex C.9 Other purposes
Occurrence Management	8.3 Control of nonconforming product	4.8 Resolution of complaints 4.9 Identification and control of nonconformities 4.10 Corrective action
Assessments: External and Internal	8.1 General 8.2 Monitoring and measurement 8.4 Analysis of data	4.11 Preventive action 4.14 Internal audits
Process Improvement	8.5 Improvement	4.12 Continual improvement
Customer Service and Satisfaction	5.2 Customer focus	4.7 Advisory services Annex C.2 General principles
Facilities and Safety	6.3 Infrastructure 6.4 Work environment	5.2 Accommodation and environmental conditions Annex B.2 Environment

References for Appendix C

1. NCCLS. *A Quality Management System Model for Health Care*. HS1. Wayne, PA: NCCLS; 2004.
2. ISO 9001:2000. *Quality management systems—Requirements*. Geneva, Switzerland: International Organization for Standardization; 2000.
3. ISO 15189:2003. *Medical laboratories —Particular requirements for quality and competence*. Geneva, Switzerland: International Organization for Standardization; 2003.

Appendix D. Example Record Retention Schedule

	[Laboratory retention here]	Governmental/Accreditation Organization			
		CLIA	CAP	JCAHO	[Other organization]
Types of Records	Retention period				
Examination requisitions <ul style="list-style-type: none"> • Cytogenetics • Molecular genetics 		2 years	2 years	2 years	
Examination requisitions <ul style="list-style-type: none"> • Extramural (e.g., outreach) 		2 years	2 years	2 years	
Examination requisitions <ul style="list-style-type: none"> • Clinical trials 		Not applicable			
Patient examination reports (clinical and pathology) <ul style="list-style-type: none"> • Intramural • Extramural (e.g., outreach) • Clinical trials 		Pathology: 10 years Cytology: 5 years 2 years; except immunohematology as specified by FDA (21 CFR 606.160 (b)(3) (11)(b)(3) iv & (d))	2 years	5 years: immunohematology and histocompatibility 10 years: histology, cytology, and bone marrow 25 years: cytogenetic	
Procedures (SOPs) <ul style="list-style-type: none"> • Discontinued • Archived versions 		Discontinue date plus 2 years	Discontinue date plus 2 yrs	Discontinue Procedures: 5 years: immunohematology, histocompatibility, and tissue banking 2 years: all others	
Instrument printouts (i.e., worksheets, work lists, load lists, photographed images)		2 years; except immunohematology as specified by FDA (21 CFR 606.160 (b)(3) (11)(b)(3) (v))	2 years	2 years: unless retrievable by an electronic source	

This example was modified from the table contributed by the Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, Minnesota, U.S.A.

NOTE: Regional or local requirements may apply to access to patient medical records.

Appendix D. (Continued)

	[Laboratory retention here]	Governmental/Accreditation Organization			
		CLIA	CAP	JCAHO	[Other organization]
Types of Records	Retention period				
Calibration records		2 years	2 years	2 years	
Photographed images and work lists containing patient results for Molecular Genetics and Cytogenetics		2 years			
Instrument/equipment <ul style="list-style-type: none"> • Preventative maintenance (daily, monthly, quarterly, yearly) records • Service repair and record 		2 years	2 years	2 years for daily, weekly or monthly performance examination and function checks Life of instrument-major repairs, parts replacement, and annual maintenance	
Records of monitoring of temperature controlled spaces, heating and cooling devices		2 years			
Quality control (QC) records Quality assurance (QA) records		2 years	2 years 5 years for immuno-hematology	5 years: immuno-hematology, histocompatibility, and tissue banking 2 years: all others	
Methodology changes Normal range changes Reporting unit changes		Not specified	2 years		

This example was modified from the table contributed by the Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, Minnesota, U.S.A.

NOTE: Regional or local requirements may apply to access to patient medical records.

Appendix D. (Continued)

	[Laboratory retention here]	Governmental/Accreditation Organization			
		CLIA	CAP	JCAHO	[Other organization]
Types of Records	Retention period				
Proficiency testing (records of examination handling, preparation, processing, examination, results of reporting, the signed attestation statement, and feedback reports)		2 years	2 years	2 years	
Employee continuing education Employee training including safety training Employee competence		2 years			
Employee medical record (contains the record of vaccinations against Hepatitis B or the signed statement declining vaccination)		Not specified			

This example was modified from the table contributed by the Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, Minnesota, U.S.A.

NOTE: Regional or local requirements may apply to access to patient medical records.

Appendix E. Excerpt From a Position Description Showing Duties in the Path of Workflow

POSITION DESCRIPTION

Position Title: **Laboratory Assistant**

Date:

Department: Laboratory

Written by: Client Services QSE Workgroup

Facility:

Reports to: Client Services Supervisor,
PM Shift Supervisor, or
Night Shift Supervisor

Position Summary

The Laboratory Assistant performs and/or coordinates a variety of clerical, phlebotomy, and sample processing procedures to ensure quality patient care on adult, pediatric, and neonatal populations. The Laboratory Assistant processes telephone requests; enters patient data and examination requisition data into the computer; coordinates and performs sample collection processes; prepares all types of laboratory samples adhering to sample acceptance criteria; and distributes or dispatches samples to correct examination location.

Principal Accountabilities

<p>Orders for Examinations</p> <ul style="list-style-type: none"> • Establishes customer contact • Schedules functions and takes verbal and fax orders • Verifies order • Registers patient in computer • Enters orders • Creates collection lists/labels • Maintains chain of custody 	<p>Processes Samples</p> <ul style="list-style-type: none"> • Processes samples • Transports samples (i.e., prepares for delivery to core laboratories, reference laboratories, etc.)
<p>Collects and Receives Samples</p> <ul style="list-style-type: none"> • Chooses age-specific approach • Identifies patients • Collects samples • Labels and documents sample collection • Provides post-phlebotomy care and instructions • Delivers samples • Receives samples • Delivers to processing area/technical area 	<p>Uses Laboratory Information System</p> <ul style="list-style-type: none"> • Generates and reviews reports • Distributes reports • Handles inquiries • Stores documents and records • Performs proper downtime procedures • Enter charges for services

This example was contributed by Sutter Health Laboratories, Sacramento-Sierra Region, Sacramento, California, U.S.A.

Appendix F. Examples of Laboratory Quality Indicators by Path of Workflow

Determining rate of, and source of, and reasons for:

Patient Assessment

- unstated reasons for examination orders
- inappropriate reasons for examination orders

Examination Requests

- requests for missing, required, or critical information

Sample Collection

- locations/sites without current sample collection instructions
- patients without appropriate identification at time of sample collection
- samples collected at improper time

Sample Transport

- samples received without special handling or required preservation
- samples delayed in transport

Sample Receipt/Processing

- samples received without appropriate accompanying document
- nature of problems with unacceptable samples

Examination and Review

- examination results exceeding turnaround times to
 - critical areas
 - outreach clients
 - routine areas

Laboratory Interpretation

- disparities in diagnosis between
 - frozen section and final diagnosis
 - cytologic and pathologic diagnosis
- misidentification of cell types in blood and body fluids

Results Reporting

- events when alert values were not reported or documented
- completeness/correctness of reports
- delayed reports
- corrected reports due to reporting errors
- disparities between preliminary and final reports

Postexamination Sample Management

- retained materials and samples unable to be retrieved

Laboratory Information System

- security violations
- unscheduled downtimes
- inability to retrieve archived patient results and information

Clinical Interpretation and Application

- inappropriate action taken after report of alert value

Safety

- needlestick injuries of laboratory personnel

Appendix G. Published Laboratory Quality Indicators Grouped by Path of Workflow and QSE

Patient Assessment

Practice guideline implementation
Stool microbiology (patient selection)
Duplicate test ordering
Hepatitis test ordering
Thyroid function test ordering

Examination Request

Ordering accuracy
Accuracy of order transmission
Verbal order evaluation
Outpatient test order accuracy

Sample Collection/Labeling

Complications of phlebotomy
Phlebotomy efficiency
Outpatient phlebotomy success rate and reasons for recollection
Wristband evaluation
Patient identification accuracy
Blood culture contamination rate
Timing of therapeutic drug monitoring
Timeliness of early morning sample collection

Sample Transport

Transit time
STAT transit time
Timeliness of urine sample transport

Sample Receiving/Processing

Adequacy of fine needle aspiration
Cervicovaginal cytology sample adequacy
Autopsy permit adequacy
Laboratory sample acceptability
Hematology sample acceptability
Chemistry sample acceptability
Sputum sample adequacy

Examination and Review

Samples for gross examination
Proficiency testing
Quality control
Autopsy turnaround time

Examination and Review (continued)

Testing turnaround time
Routine outpatient test turnaround time
Gynecology cytology turnaround time
Nongynecology cytology turnaround time
Emergency department turnaround time
Blood product preparation turnaround time
Turnaround time outliers
STAT test turnaround time outliers
Point-of-care coagulation testing
Glycohemoglobin measurement in diabetes
Type and screen completion for scheduled surgical procedures

Laboratory Interpretation

Frozen section - final section correlation
Fine needle cytohistological correlation
Cervical biopsy - cytology correlation
Deferred diagnosis
Uncertainty expressed in prostate needle biopsy diagnoses
Pathologic staging of breast carcinoma

Results Reporting

Results reporting
Timeliness of critical value reporting
Morning rounds inpatient test availability
Report adequacy (autopsy, breast carcinoma, lung carcinoma, surgical pathology)
Correct physician sent report
Charting of results
Critical diagnosis reporting
Reporting error

Clinical Interpretation and Application

Autologous blood utilization
Blood utilization
In-date blood product wastage
Transfusion errors
Critical test results
Medical record physician note assessment
Blood culture utilization
Nosocomial infection rate
Cumulative antimicrobial susceptibility patterns
Autopsy result utilization
Follow-up of abnormal gynecology cytology
Frequency of gynecology cytology ASCUS
Surgical pathology consultation practice

Appendix G. (Continued)**QSE: Organization**

Cost of bedside vs. laboratory glucose testing

QSE: Personnel

Competence evaluation
Employee retention

QSE: Process Control

Comparative cost of in-house vs. reference
laboratory testing
Comparative cost of laboratory vs.
distributive laboratory testing

QSE: Occurrence Management

Incidents

QSE: Internal Assessment

On-site inspections/assessments
Self-inspections/assessments

QSE: Service and Satisfaction

Satisfaction with phlebotomy
Satisfaction with outpatient sample collection
Customer satisfaction
Complaints
Quality of telephone responsiveness
Operating-room blood delivery time
Reference laboratory service quality
Physician satisfaction with laboratory services

QSE: Facilities and Safety

Safety

Reference for Appendix G

Q-Probes. Northfield, IL: College of American Pathologists; 2002.

NCCLS consensus procedures include an appeals process that is described in detail in Section 8 of the Administrative Procedures. For further information, contact the Executive Offices or visit our website at www.nccls.org.

Summary of Consensus/Delegate Comments and Working Group Responses

GP26-A3: *Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition*

General

1. This is a comprehensive document and an interesting comparison with the Australian standard ISO-IEC 17025 used in Australian Laboratories (mandatory compliance).
 - **ISO-IEC Standard 17025 was used as a basis for developing the laboratory-specific requirements contained in ISO 15189: *Medical laboratories—Particular requirements for quality and competence*. NCCLS document HS1—*A Quality Management System Model for Health Care* can be used to implement the requirements of ISO 17025 in any kind of measurement service or the requirements of ISO 15189 in a medical laboratory service.**
2. The term examination is used. This term might be appropriate for morphological examinations. For clinical chemical investigation of measurands in body fluids, the term measurement should be used.
 - **The consensus of the international workgroup that updated HS1 was to use the exact terminology used in ISO 15189, *Medical laboratories—Particular requirements for quality and competence*. In that document, the term “examination” is used to mean “test.” To avoid further confusion, the workgroup also decided not to introduce any other synonyms.**
3. This document could be shorter.
 - **The committee believes that the document is the appropriate length for the content covered.**

Section 1, Scope

4. The scope doesn't specify whether it refers to both *in vitro* and *in vivo* diagnostic examinations.
 - **The Scope has been modified for clarification. The following text has been added:**

“This publication describes important activities in the path of workflow for laboratory services, including *in vitro* testing in clinical and anatomical pathology.”

Section 3, Definitions

5. The list of definitions, on page 2, should include a definition of quality control. HS1-A2, *A Quality Management System Model for Health Care*, includes the definition of quality control, however, the Quality Management System Model for Laboratory Services does not. Quality Control is a QSE. Page 23, Section 6.6, last paragraph, indicates: “The laboratory needs to have a quality control program that includes...” Page 11, Section 5.2.2, last paragraph, also refers to quality control. Quality control is discussed in the guideline, but is not defined.
 - **The definition of quality control from HS1 has been added.**

Section 4, The Path of Workflow Concept

6. Second paragraph, page 3: Decisions are made based on laboratory examination and clinical signs. Add “and clinical signs” at the end of the sentence.
 - **This addition has been made.**

Section 5, The Clinical Laboratory's Path of Workflow—A Detailed Discussion

7. Figure 2: In current laboratory practice, many collection tubes are already labeled, before blood sample(s) are actually collected. This fact should be mentioned as a note.

- **The text has been modified as follows:**

“NOTE: The flowchart and table are included as an example of a collection process and are not meant to describe the only sequence in which these activities occur.”

8. Figure 2. Missing “no” after special collection precautions needed.

- **This editorial correction has been made.**

9. Figure 2: In various institutions around the world, sample collection is done by the medical team and not by the laboratory personnel. In these cases, more educational work and better cooperation should be reached. Add a note that when the medical team collects the sample, the process is slightly modified. The medical team should transfer the sample and the test request with relevant data to the laboratory.

- **See response to Comment 7.**

10. Figure 2: It is sometimes crucial to the validity of the test to take into account dietary, treatment, and other patient’s conditions that may affect the results. Add to third step: prerequisites? If yes, then the patient should be interviewed and medical team or files should be verified to find out about the best timing for sample blood collection. Add to box before last: relevant essential data should be reported.

- **A box has been added to the flowchart to represent assessment of the patient for the issues discussed in Section 5.1.2.1. Table 1 has also been modified to reflect this addition.**

11. Figure 2. Missing “no” after special collection precautions needed.

- **This editorial correction has been made.**

12. Table 1: The same comments as for Figure 2. The following are missing in Table 1:

- “Special precautions for blood collections,” add “and prerequisites.”
- After: Patient is identified you may add an additional row: Data about patients’ preparation/conditions and compatibility with required test.
- Accessing samples into the information system...
- Processing samples...etc.

- **A row has been added to the table to represent assessment of the patient for the issues discussed in Section 5.1.2.1.**

The activities for accessioning and processing samples are part of another flowchart titled, “Laboratory Sample Receiving Process” indicated by the wedge-shaped symbol in the flowchart that follows the transport activity.

Section 5.1.1. Examination Ordering

13. Modify the following, “Instructions are also to be provided for blood bank requests ~~for~~ including...”

- **This editorial correction has been made.**

Section 5.1.2.2. Collection Instructions

14. Last paragraph. Patient identification can be done by name, social security number, and other identification. Verification of patient identity should be preferably done using two means: name and some identification number to avoid any confusion.

- **The first bullet has been modified to read: “verifying patient identification at the time of sample collection, ideally using the patient’s first and last names and another identifier such as birth date or medical record number.**

Section 5.1.3. Sample Transport

15. The laboratory needs to verify a few other parameters like proper tube, proper preservation when applicable, proper preparation of the patient, clarity of identification, etc. In some countries, laboratory is also involved in judging the fitness of the examination to the purpose.

- **These issues are covered in Section 5.1.4, Sample Receipt and Processing.**

16. Modify the following, “Specific guidance should be available to those who would use ~~the~~ a pneumatic tube system...”

- **This editorial correction has been made.**
17. Modify the following, “Within the temperature ~~interval~~ range specified ...”

- **This editorial correction has been made.**

Section 5.1.4, Sample Receipt and Processing

18. The laboratory instructions should be communicated with the medical team and agreed upon.
- **The following sentences have been added to last paragraph in Section 5.1.4: “The laboratory’s expectations for sample quality and actions to be taken when the expectations are not met should be communicated to the laboratory’s clients. Agreement should be reached with regard to patient safety.”**

Section 5.2, Examination Activities (or Section 5.3, Postexamination Activities)

19. Postexamination activities should include evaluation of the correlation between different test results performed at the same time and the previous examination results in the medical records. This may be added to Section 5.2.3 or Section 5.3.2.
- **The following sentence has been added to the beginning of Section 5.2.3: “The laboratory should have a process for correlating the results of concurrent examinations and any previous examinations.”**

Section 5.2.1, Examination Method Selection

20. ISO 15189 refers to many issues which support and ensure validity of results. These issues include: traceability, measurement uncertainty, equipment calibration, etc. These guidelines do not mention these important aspects, which inflict to the meaning of any result reported by the medical laboratory. There are two possibilities: 1) add a statement in the scope saying that these guidelines only refer to the proper management of a medical laboratory but do not relate to its competence; or 2) elaborate Section 5.2.1 to include these issues mentioned in chapter 5 of ISO 15189.
- **Additional text has been added to Section 5.2.1 mentioning the issues raised in this comment. It reads, “To ensure validity of results, the laboratory will need to follow all applicable governmental, accreditation, and manufacturer requirements for quality control, measurement uncertainty, calibration of measuring systems, and traceability.”**

Additional text has been added to Section 6 for clarification, as well. It reads, “A laboratory will need to design its quality management system to comply with any applicable governmental, accreditation, or safety requirements. The policies, processes, procedures, and document control practices recommended in the most current editions of HS1 and GP26 will help laboratories comply with those requirements; however, additional technical requirements may also apply for specific activities in the path of workflow.”

Section 5.3.2, Final Reports

21. The laboratory is required to report the results with reference range. There is no guideline how to determine the reference range. Guidance to an acceptable practice should be added, or referred to another document.
- **NCCLS document C28—*How to Define and Determine Reference Intervals in the Clinical Laboratory* has been added to Appendix B and to the list of Related NCCLS Publications to address this recommendation.**

Section 5.3.3.1, Sample Storage

22. A bank of stable samples, especially those resulting in borderline results, may have an added value in the lab. Those may be used for introduction of a new batch of a diagnostic kit, change of standard, introduction of a new examination method, etc. Add: stable samples bearing special features (i.e., borderline results, rare composition, rare disease) should be retained for prolonged periods of time. Analysis of these may assist the lab in changes of examination procedure, introduction of new standards and kits, etc.
- **Section 5.3.3.1, Sample Storage, has been modified to reflect the commenter’s suggestion.**
23. In some cases, the laboratory may need to retain all samples for a long period of times such as to learn about the dynamic of a disease (i.e. toxoplasmosis, CMV). Change the text to include: The laboratory should consider and define a policy and procedures regarding retention of samples. The policy should define the:
- Conditions to ensure stability (temperature, container light, etc).
 - Retention time.

– Time frame in which an examination may be redone (which tests may be repeated or added at which time range).

- **Section 5.3.3.2 on Sample Retention has been modified to reflect the commenter’s suggestion.**

Section 6. Application of QSEs for Clinical Laboratory Services

24. Modify the following, “...Appendix C...”; management is spelled incorrectly.

- **This editorial correction has been made.**

Section 6.9.3. Internal Assessment – Quality Indicators

25. Modify the following, “The laboratory’s performance on these should be compared....”

- **This editorial correction has been made.**

Related NCCLS Publications*

- C24-A2** **Statistical Quality Control for Quantitative Measurements: Principles and Definition; Approved Guideline—Second Edition (1999).** This guideline provides definitions of analytical intervals; plans for quality control procedures; and guidance for quality control applications.
- C28-A2** **How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline—Second Edition (2000).** This document provides guidance for determining reference values and reference intervals for quantitative clinical laboratory tests.
- GP2-A4** **Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition (2002).** This document provides guidance on development, review, approval, management, and use of policy process, and procedure documents in the laboratory testing community.
- GP9-A** **Selecting and Evaluating a Referral Laboratory; Approved Guideline (1998).** This guideline provides an outline of reasons and criteria for choosing a referral laboratory. A checklist for evaluating potential referral laboratories is included to assist in the decision process.
- GP17-A2** **Clinical Laboratory Safety; Approved Guideline—Second Edition (2004).** This document contains general guidelines for implementing a high-quality laboratory safety program. The framework is adaptable to any laboratory.
- GP18-A** **Laboratory Design; Approved Guideline (1998).** This guideline provides a foundation of information about laboratory design elements that can be used to help define the issues being considered when designing a laboratory.
- GP21-A2** **Training and Competence Assessment; Approved Guideline—Second Edition (2004).** This document provides background and recommended processes for the development of training and competence assessment programs that meet quality regulatory objectives.
- GP22-A2** **Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition (2004).** This guideline considers continuous quality improvement (CQI) as five integrated quality system components, which include Quality Planning, Quality Teamwork, Quality Monitoring, Quality Improvement, and Quality Review.
- GP27-A** **Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline (1999).** This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool.
- GP29-A** **Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline (2002).** This guideline will suggest workable alternatives for evaluating the accuracy of an assay when standard interlaboratory comparison programs are unavailable.
- HS1-A2** **A Quality Management System Model for Health Care; Approved Guideline—Second Edition (2004).** This document provides a model for providers of healthcare services that will assist with implementation and maintenance of effective quality management systems.

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

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