

Effective 1 January 2017

A central graphic of a glowing green and yellow globe with several white orbital lines circling it, set against a dark background with starburst effects.

# Joint Commission International Accreditation Standards for Laboratories

English

3rd Edition



# Section I: Accreditation Participation Requirements







# Accreditation Participation Requirements (APR)

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## Requirement: APR.1

The laboratory meets all requirements for timely submissions of data and information to Joint Commission International (JCI).

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## Requirement: APR.2

The laboratory provides JCI with accurate and complete information through all phases of the accreditation process.

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## Requirement: APR.3

The laboratory reports within 15 days any changes in the laboratory's profile (electronic database) or information provided to JCI via the E-App before and between surveys.

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## Requirement: APR.4

The laboratory permits on-site evaluations of standards and policy compliance or verification of quality and safety concerns, reports, or regulatory authority sanctions at the discretion of JCI.

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## Requirement: APR.5

The laboratory allows JCI to request (from the laboratory or outside agency) and review an original or authenticated copy of the results and reports of external evaluations from publicly recognized bodies.

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## Requirement: APR.6

Currently not in effect.

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## Requirement: APR.7

Currently not in effect.

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## Requirement: APR.8

The laboratory accurately represents its accreditation status and the programs and services to which JCI accreditation applies.

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### Requirement: APR.9

Any individual laboratory staff member (clinical or administrative) can report concerns about safety and quality of care to JCI without retaliatory action from the laboratory.

To support this culture of safety, the laboratory must communicate to staff that such reporting is permitted. In addition, the laboratory must make it clear to staff that no formal disciplinary actions (**for example**, demotions, reassignments, or change in working conditions or hours) or informal punitive actions (**for example**, harassment, isolation, or abuse) will be threatened or carried out in retaliation for reporting concerns to JCI.

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### Requirement: APR.10

Translation and interpretation services arranged by the laboratory for an accreditation survey and any related activities are provided by licensed and/or qualified translation and interpretation professionals who have no relationship to the laboratory.

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### Requirement: APR.11

The laboratory notifies the public it serves about how to contact its laboratory management and JCI to report concerns about safety and quality of care.

Methods of notice may include, but are not limited to, distribution of information about JCI, including contact information in published materials such as brochures and/or posting this information on the laboratory's website.

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### Requirement: APR.12

The laboratory provides services in an environment that poses no risk of an immediate threat to patient safety, public health, or staff safety.

# Section II: Patient-Centered Standards









# International Patient Safety Goals (IPSG)

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## Goal 1: Identify Patients Correctly

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### Standard IPSG.1

The laboratory develops and implements a process to improve the accuracy of patient identifications.Ⓢ

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## Goal 2: Improve Effective Communication

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### Standard IPSG.2

The laboratory develops and implements a process to improve the effectiveness of verbal and/or telephone communication for reporting critical results of diagnostic tests.Ⓢ

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## Goal 3: Improve the Safety of High-Alert Medications

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This requirement does not apply to JCI laboratory accreditation.

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## Goal 4: Ensure Correct-Site, Correct-Procedure, Correct-Patient Surgery

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This requirement does not apply to JCI laboratory accreditation.

**Note:** Some standards require the laboratory to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓢ icon after the standard text.

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## Goal 5: Reduce the Risk of Health Care–Associated Infections

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### Standard IP5G.5

The laboratory adopts and implements evidence-based hand-hygiene guidelines to reduce the risk of health care–associated infections.Ⓢ

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## Goal 6: Reduce the Risk of Patient Harm Resulting from Falls

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This requirement does not apply to JCI laboratory accreditation.

# Section III: Health Care Organization Management Standards







# Governance, Leadership, and Direction (GLD)

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## Standard GLD.1

Laboratory leadership is identified and is collectively responsible for defining the laboratory's mission and vision and creating the programs and policies needed to fulfill the mission. ④

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### Standard GLD.1.1

A qualified individual(s) is responsible for managing the laboratory service or pathology service. ④

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### Standard GLD.1.2

A qualified individual is responsible for requiring practices that respect the needs of patients and other customers. ④

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## Service and Resource Planning

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## Standard GLD.2

Leadership communicates with key stakeholders in the community to plan the type and scope of services to be provided. ④

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### Standard GLD.2.1

Laboratory leadership is responsible for providing adequate resources for the provision of planned laboratory services.

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## Contract and Reference Laboratory Services

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### Standard GLD.2.2

Laboratory leadership defines the process for selecting and approving contract and reference laboratory services, including services that provide blood and blood products. ④

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**Note:** Some standards require the laboratory to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a ④ icon after the standard text.

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### Standard GLD.2.2.1

Contract and reference laboratories used are licensed and accredited or certified by a recognized authority.

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### Standard GLD.2.2.2

Laboratory leadership is responsible for ensuring the consistent performance of contract and reference laboratory services.Ⓢ

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## Blood Bank and/or Transfusion Services

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### Standard GLD.2.3

A qualified individual is responsible for blood bank and/or transfusion services and ensures that services adhere to laws and regulations and recognized standards of practice.Ⓢ

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## Point-of-Care Services

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### Standard GLD.2.4

A qualified individual is responsible for the oversight and supervision of the point-of-care testing program.Ⓢ

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## Communication and Coordination

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### Standard GLD.3

Laboratory leaders ensure effective communication and coordination throughout the laboratory and with outside customers.

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### Standard GLD.3.1

Laboratory leaders develop and implement priorities for meeting the needs of clinicians, patients, and other users of laboratory services.Ⓢ

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### Standard GLD.3.2

Laboratory leaders develop and implement processes for communicating with clinicians who order tests.Ⓢ

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## Planning and Coordination of the Quality Management and Improvement Program

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### Standard GLD.4

Laboratory leaders, develop, implement, and monitor a quality management and improvement program and provide adequate resources for the program.Ⓢ

#### Standard GLD.4.1

The laboratory's quality management and improvement program identifies the goals, components, methodology, and systems required for process design and quality measurement, analysis, and improvement.Ⓢ

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#### Standard GLD.4.2

A qualified individual guides the implementation of the laboratory's program for quality improvement and manages the activities needed to carry out an effective program of continuous quality improvement within the laboratory.

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#### Standard GLD.4.3

The leaders define performance and quality control activities used to monitor the laboratory's processes and the systems used to ensure proper operation and control of these processes.Ⓢ

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## Design of New Processes

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### Standard GLD.4.4

The laboratory designs new and redesigns existing systems and processes according to quality improvement principles.

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## Data Collection for Quality Measurement

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### Standard GLD.4.5

Laboratory leaders prioritize which laboratory processes will be measured, which improvement activities will be implemented, and how success of these laboratory efforts will be measured.

#### Standard GLD.4.5.1

The laboratory's leaders identify key measures for each of the laboratory's clinical structures, processes, and outcomes.

## Standard GLD.4.5.2

The laboratory's leaders identify key measures for each of the laboratory's managerial structures, processes, and outcomes.

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## Analysis of Measurement Data

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### Standard GLD.5

Individuals with appropriate experience, knowledge, and skills systematically aggregate and analyze data in the laboratory.

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### Standard GLD.6

The laboratory uses an internal process to validate data.Ⓢ

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### Standard GLD.7

Data are analyzed when undesirable trends and variation are evident from the data.

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## Gaining and Sustaining Improvement

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### Standard GLD.8

Improvement in quality and safety is achieved and sustained.

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### Standard GLD.9

An ongoing program of identifying and reducing unanticipated adverse events and safety risks to patients and staff is defined and implemented.Ⓢ

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## Quality Management and Improvement Program Review

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### Standard GLD.10

Leaders manage the quality management and improvement program and periodically review the effectiveness, adequacy, and relevance of the monitoring and improvement activities.Ⓢ

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## Laboratory Leadership for Resource Decisions

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### Standard GLD.11

Laboratory leadership makes decisions related to the purchase or use of resources—human and technical—with an understanding of the quality and safety implications of those decisions.



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## Culture of Safety

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### Standard GLD.12

Leaders create and support a culture of safety program throughout the laboratory. ©

### Standard GLD.12.1

Leaders implement, monitor, and takes action to improve the program for a culture of safety throughout the laboratory.





# Management of Information (MOI)

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## Management and Implementation of Documents

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### Standard MOI.1

Written documents, including policies, procedures, and programs, are managed in a consistent and uniform manner.Ⓢ

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### Standard MOI.1.1

The policies, procedures, plans, and other written documents that guide consistent and uniform clinical and nonclinical processes and practices are fully implemented.Ⓢ

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## Preanalytic Policies and Procedures

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### Standard MOI.2

Procedures for ordering preanalytic tests are defined in writing.Ⓢ

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### Standard MOI.2.1

Policies and procedures are developed to provide step-by-step specimen collection protocols for each type of specimen submitted to the laboratory.Ⓢ

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### Standard MOI.2.2

Policies and procedures are developed to guide how specimens are accessioned and processed in the laboratory.Ⓢ

**Note:** Some standards require the laboratory to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓢ icon after the standard text.

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## Analytic Policies and Procedures

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### Standard MOI.3

The laboratory has current written descriptions and instructions for performing test methods and procedures.Ⓢ

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## Postanalytic Policies and Procedures

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### Standard MOI.4

The laboratory develops policies, procedures, and controls for the post-examination processes.Ⓢ

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### Standard MOI.4.1

The laboratory has defined the process of measuring turnaround times.Ⓢ

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### Standard MOI.5

The laboratory develops and implements a written policy that defines the storage and maintenance requirements for records, retained specimens, slides, tissues, and blocks.Ⓢ



# Staff Qualifications and Education (SQE)

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## Human Resources

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### Standard SQE.1

Laboratory leaders define the desired education, skills, knowledge, and other requirements of all staff members.

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## Staff Qualifications

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### Standard SQE.1.1

Each staff member's responsibilities are defined in a current job description.Ⓟ

### Standard SQE.1.1.1

Licensed Independent Practitioners (LIP) who provide services to the medical laboratory (such as a pathologist) are required to have education, licensure/registration, and other credentials required by law or regulation verified and kept current.

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### Standard SQE.1.2

Supervisory staff and other leaders have the training and expertise to perform all responsibilities.

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## Staff Orientation and Education

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### Standard SQE.2

All new staff members are oriented to the organization and the laboratory area(s) where they are assigned, as well as to their specific job responsibilities.

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### Standard SQE.2.1

Each staff member receives ongoing in-service and other education and training to maintain and/or to improve staff skills, knowledge, and competence.

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## Competence Assessment and Performance Evaluation

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### Standard SQE.3

Following orientation and/or training, and at least annually thereafter, the competence of each staff member to perform assigned responsibilities is assessed.Ⓟ

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### Standard SQE.3.1

Documented personnel information is maintained for each staff member.Ⓟ

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## Staff Health and Safety Program

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### Standard SQE.4

The laboratory provides a staff health and safety program, directly or through contract.Ⓟ



# Facility Management and Safety (FMS)

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## Infrastructure—Basic Facilities

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### Standard FMS.1

Laboratory leaders provide for basic facilities and comply with relevant laws, regulations, and facility inspection requirements.

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## Laboratory Space and Resources

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### Standard FMS.2

The laboratory leaders plan and provide for sufficient space and resources to support all laboratory areas.

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#### Standard FMS.2.1

Laboratory storage areas have sufficient space and are maintained under proper conditions for storage.

#### Standard FMS.2.2

Records, information, and other patient data are protected from loss, destruction, tampering, unauthorized access, and unsafe storage conditions.

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## Utilities Management

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### Standard FMS.3

The laboratory establishes and implements a program to ensure that all utility systems operate effectively and efficiently.Ⓢ

#### Standard FMS.3.1

Utility systems are inspected, maintained, and improved.Ⓢ

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### Standard FMS.3.2

There is a system to test critical operating components for utility systems and provide for emergency backup for critical utilities.Ⓢ

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## Laboratory Equipment and Other Materials

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### Standard FMS.4

Laboratory leaders ensure that analytic and other equipment, as well as other material resources required for the provision of services, are adequate and available.Ⓢ

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### Standard FMS.4.1

The laboratory establishes and implements a program for inspecting, testing, and maintaining medical equipment and documenting results.Ⓢ

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### Standard FMS.4.1.1

A historical record is maintained for each analytical instrument and piece of equipment used by the laboratory.

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### Standard FMS.4.2

There are defined processes in place for validating and maintaining computer software and information when they are used by the laboratory.Ⓢ

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## Reagents and Other Supplies

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### Standard FMS.4.3

The laboratory follows written guidelines for the periodic evaluation of all reagents, including water, to provide for accuracy and precision of results.Ⓢ

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### Standard FMS.4.4

Laboratory records include documentation of required information for reagents, and reagents are completely and accurately labeled.

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## Safety and Security

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### Standard FMS.5

There is a plan to ensure that laboratory services and facilities are safe and secure.Ⓢ



**Note:** This plan may be part of an organizationwide plan for laboratories that are within other accredited organizations, such as a hospital.

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## Hazardous Materials and Waste

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### Standard FMS.6

The laboratory has a program for the inventory, handling, storage, and use of hazardous materials.Ⓢ

### Standard FMS.6.1

The laboratory has a program for the control and disposal of hazardous materials and waste.Ⓢ

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### Standard FMS.6.2

The laboratory uses a coordinated process to reduce the risks of infection.Ⓢ

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### Standard FMS.6.3

When radioactive materials are used in the laboratory, processes are developed and implemented for their safe handling, monitoring, and use.Ⓢ

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## Work Environment—Laboratory Fire Safety

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### Standard FMS.7

The laboratory establishes and implements a program for the prevention, early detection, suppression, and abatement of, and the safe exit from the facility in response to, fires and nonfire emergencies.Ⓢ

### Standard FMS.7.1

The laboratory regularly tests its fire and smoke safety program, including any devices related to early detection and suppression, and documents the results.Ⓢ





# Quality Control Processes (QCP)

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## Quality Control Common to All Areas of Testing

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### Standard QCP.1

Quality control processes are established for each test method, and data from these processes are available and used to monitor and ensure the stability of test systems.Ⓢ

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### Standard QCP.1.1

The laboratory has a program of external graded interlaboratory comparison testing, or proficiency testing, for analytes for each specialty and subspecialty for which such testing is available.Ⓢ

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### Standard QCP.1.1.1

Proficiency sample testing is performed in the same manner as patient sample testing.

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### Standard QCP.1.1.2

The laboratory uses a system for verifying the accuracy and reliability of test results obtained for those tests not included in the formal proficiency testing program.Ⓢ

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### Standard QCP.1.2

The laboratory has a process to evaluate and correlate the relationship between results for the same test performed with different methodologies or instruments or at different sites.Ⓢ

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### Standard QCP.1.3

The laboratory performs initial validation for new instruments and analytic systems to verify that the method(s) will produce accurate and reliable results.

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### Standard QCP.1.4

The laboratory validates electronic or internal monitoring systems prior to using them for routine quality control.

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### Standard QCP.1.5

The laboratory develops and implements a process for calibration, calibration verification, and function checks of instruments and analytic systems used for testing.Ⓢ

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### Standard QCP.1.6

The quality control processes of the laboratory include a process for a coordinated review of patient results, quality control results, and instrument function checks.Ⓢ

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### Standard QCP.1.7

The laboratory takes remedial action for deficiencies identified through quality control measures or authorized inspections and documents such actions.Ⓢ

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## Specialty Quality Control

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### Histopathology

**Note:** Requirements in Standards QCP.1–QCP.1.7 that are applicable to histopathology also apply.

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### Standard QCP.2

There are quality control processes in place for surgical pathology and autopsy services.Ⓢ

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### Standard QCP.2.1

The laboratory implements processes for ensuring proper identification, preservation, and documentation of receipt of surgical specimens sent for analysis.Ⓢ

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### Standard QCP.2.1.1

The laboratory implements processes for ensuring accurate results when immunohistochemistry is performed.Ⓢ

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### Standard QCP.2.2

The laboratory implements quality control and assurance processes for evaluating the ongoing qualifications of individuals who perform gross analysis of tissue.Ⓢ

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### Standard QCP.2.3

There are defined processes to document the ongoing proficiency of individuals who perform microscopic analysis of tissue.Ⓢ

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### Standard QCP.2.4

The laboratory has implemented processes to ensure access to required patient information and cross-reference the information to assist in providing a complete and proper diagnosis.

## **Cytopathology**

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### **Standard QCP.3**

A pathologist or physician qualified in cytology maintains the quality of the cytopathology services through direct supervision.Ⓢ

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### **Standard QCP.3.1**

The cytology laboratory has a process to measure, assess, and improve quality.Ⓢ

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## **Laboratory Testing**

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### **Clinical Chemistry, Hematology, Coagulation, and Point-of-Care Test Systems**

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### **Standard QCP.4**

The laboratory leaders have defined quality control processes for all clinical chemistry, hematology, and coagulation tests, including point-of-care test systems.Ⓢ

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### **Standard QCP.4.1**

For tests that produce quantitative results the laboratory defines and follows quality control guidelines.Ⓢ

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### **Standard QCP.4.2**

The laboratory has quality control processes in place for blood film evaluation and differential counts.Ⓢ

## **Microbiology**

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### **Standard QCP.5**

The laboratory has quality control processes when performing bacteriology, mycobacteriology, and mycology.Ⓢ

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### **Standard QCP.5.1**

Antimicrobial, antimycobacterial, and antifungal susceptibility testing systems are verified with approved reference organisms.

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### **Standard QCP.5.2**

All stains are tested with appropriate controls.

## **Molecular Microbiology Testing**

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### **Standard QCP.5.3**

There are adequate quality control procedures when molecular microbiology testing is performed.

## **Parasitology**

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### **Standard QCP.6**

If the laboratory is performing parasitology, appropriate reference materials, equipment, and methods are used.

## **Virology**

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### **Standard QCP.7**

If the laboratory performs tests for identifying viruses, records are maintained and controls to identify erroneous results are used.

## **Urinalysis and Clinical Microscopy**

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### **Standard QCP.8**

The laboratory implements processes to ensure the quality of tests performed in urinalysis and clinical microscopy.Ⓢ

## **Diagnostic Immunology and Serology**

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### **Standard QCP.9**

The laboratory runs serologic tests on unknown specimens, including those for syphilis, concurrently with a positive control serum of known titer and a negative control, or controls of graded reactivity, to ensure specificity of antigen reactivity.

### **Standard QCP.10**

The laboratory uses written quality control procedures that provide diagnostic reliability and patient and staff safety when it uses in vitro radioisotopes.Ⓢ

### **Standard QCP.10.1**

Any laboratory performing in vivo testing uses an appropriate quality control system for such testing and equipment performance checks.Ⓢ

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## Blood Bank and Transfusion Services

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### Director Responsibility

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#### Standard QCP.11

A qualified individual is responsible for blood bank and/or transfusion services and ensures that services adhere to laws and regulations and recognized standards of practice.Ⓢ

### Blood Typing

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#### Standard QCP.12

The laboratory tests patient blood samples with typing sera and reactive cells of a known type to determine the correct ABO group and Rh type.

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## Donor Selection and Testing

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#### Standard QCP.13

There are defined procedures and practices for blood donor selection and blood collection by trained staff.Ⓢ

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#### Standard QCP.13.1

A detailed history of a donor is performed prior to selection for blood donation.

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#### Standard QCP.13.2

An adequate physical examination is performed prior to approving the individual as a blood donor.

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#### Standard QCP.13.3

Written guidelines are implemented when autologous blood is collected.Ⓢ

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#### Standard QCP.14

Blood and related donor records are properly identified, and the identification is maintained from collection through the time the unit is transfused.

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#### Standard QCP.15

Donor blood undergoes routine testing before being used for transfusion.Ⓢ

#### Standard QCP.15.1

Process controls are used to ensure appropriate tracking and prevent blood from being released prematurely.Ⓢ

## **Blood Component Preparation or Modification**

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### **Standard QCP.16**

When components are prepared or modified by the organization, there are defined procedures for their processing and storage, and appropriate quality control measures are taken.Ⓢ

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### **Whole Blood**

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#### **Standard QCP.16.1**

Tests and processes are used to maintain the quality of whole blood. This includes whole blood from which components and products are to be processed.Ⓢ

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### **Red Blood Cells**

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#### **Standard QCP.16.2**

Defined processes are implemented to maintain the quality of red blood cells.Ⓢ

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### **Platelets**

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#### **Standard QCP.16.3**

Defined processes are used to ensure the quality of platelets.Ⓢ

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### **Plasma**

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#### **Standard QCP.16.4**

Defined processes are used to ensure the quality of plasma.Ⓢ

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### **Cryoprecipitated AHF**

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#### **Standard QCP.16.5**

Defined processes are used to ensure the quality of cryoprecipitated AHF.Ⓢ



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## Blood and Component Storage Requirements (for Donor Facility and Blood Transfusion Services)

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### Standard QCP.17

Storage areas used for blood and components are appropriate for the volume and variety of components stored.

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### Standard QCP.17.1

Storage areas for blood and components are monitored to ensure that appropriate temperatures are maintained.

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### Standard QCP.18

The laboratory implements a process for identification and traceability of specimens; reagents; test results; and blood, blood components, and products.Ⓢ

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## Blood Transfusion Services

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### Testing of Blood Prior to Transfusion

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### Standard QCP.19

The laboratory tests donor blood and recipient blood with potent typing sera and adequately reactive cells of a known type to determine the correct ABO blood group and Rh type.Ⓢ

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### Standard QCP.19.1

The potency and reliability of reagents used for ABO grouping, Rh typing, antibody detection, and compatibility determinations are tested for reactivity.Ⓢ

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### Standard QCP.20

Before blood is administered, compatibility testing and antibody testing are performed.

### Selecting Blood and Components for Transfusion

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### Standard QCP.21

Specific procedures are followed when selecting blood and components for transfusion.Ⓢ

## **Blood Issuance and Transfusion**

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### **Standard QCP.22**

The director of blood transfusion services provides guidance on the practices and procedures for blood and component transfusion.Ⓟ

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### **Standard QCP.22.1**

There are defined processes for checking blood out of the blood bank before transfusion.Ⓟ

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### **Standard QCP.22.2**

Processes used prior to and during blood administration are defined and implemented.Ⓟ

## **Recognizing Suspected Transfusion Reactions**

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### **Standard QCP.22.3**

The director has defined criteria for recognition of transfusion reactions, as well as steps to take when symptoms occur.Ⓟ

## **Blood Donor and Transfusion Services Record Requirements**

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### **Standard QCP.23**

When the laboratory draws donor blood, prepares blood components, stores blood and/or components, and/or issues blood for transfusion, there are specific records that must be maintained.

## **Therapeutic Apheresis**

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### **Standard QCP.24**

The laboratory (or designated department in a hospital setting) performs, monitors, and documents therapeutic apheresis procedures.

## **Histocompatibility Testing**

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### **Standard QCP.25**

When performing histocompatibility testing, the laboratory uses screening techniques for donors and recipients.Ⓟ

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### **Standard QCP.25.1**

The laboratory performs mixed lymphocyte cultures or other recognized methods to detect cellular-defined antigens according to defined methods.Ⓟ

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### Standard QCP.25.2

The laboratory performs HLA serologic typing of both donor and recipient as appropriate to the study or individual procedure performed.Ⓢ

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### Standard QCP.25.3

Before transplantation is performed, the laboratory crossmatches potential recipients and donors using the most reactive and recent sera, as appropriate to the study or individual procedure performed.

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### Standard QCP.25.4

The laboratory uses reagents and antisera that are specific and verified with controls when available.

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### Standard QCP.25.5

Storage of records and specimens is addressed.

## **Cytogenetics Testing**

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### Standard QCP.26

Laboratory procedures and practices in cytogenetics provide for accurate results.Ⓢ

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### Standard QCP.26.1

Laboratory records identify the media used, the reactions observed, and the details of each step of the identification procedure.

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### Standard QCP.26.2

The laboratory obtains and includes in the interpretative report all required clinical information.

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### Standard QCP.26.3

The laboratory maintains individual sample identification during all phases of testing and reporting.Ⓢ

## **Molecular Testing**

### Standard QCP.27

The laboratory follows written policies and procedures for molecular testing.Ⓢ

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### Standard QCP.27.1

Validation studies include representatives from each specimen type expected to be tested in the assay and specimens representing the scope of reportable results.Ⓢ

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### Standard QCP.27.2

The laboratory establishes quality control limits, reference ranges, and reportable ranges.

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### Standard QCP.27.3

The laboratory verifies each test run of patient samples in molecular pathology, using quality controls.Ⓢ

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### Standard QCP.27.4

The laboratory follows written policies and procedures for molecular testing and documents a complete and thorough report.Ⓢ

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### Standard QCP.27.5

Molecular genetic testing reports include specific testing information.

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