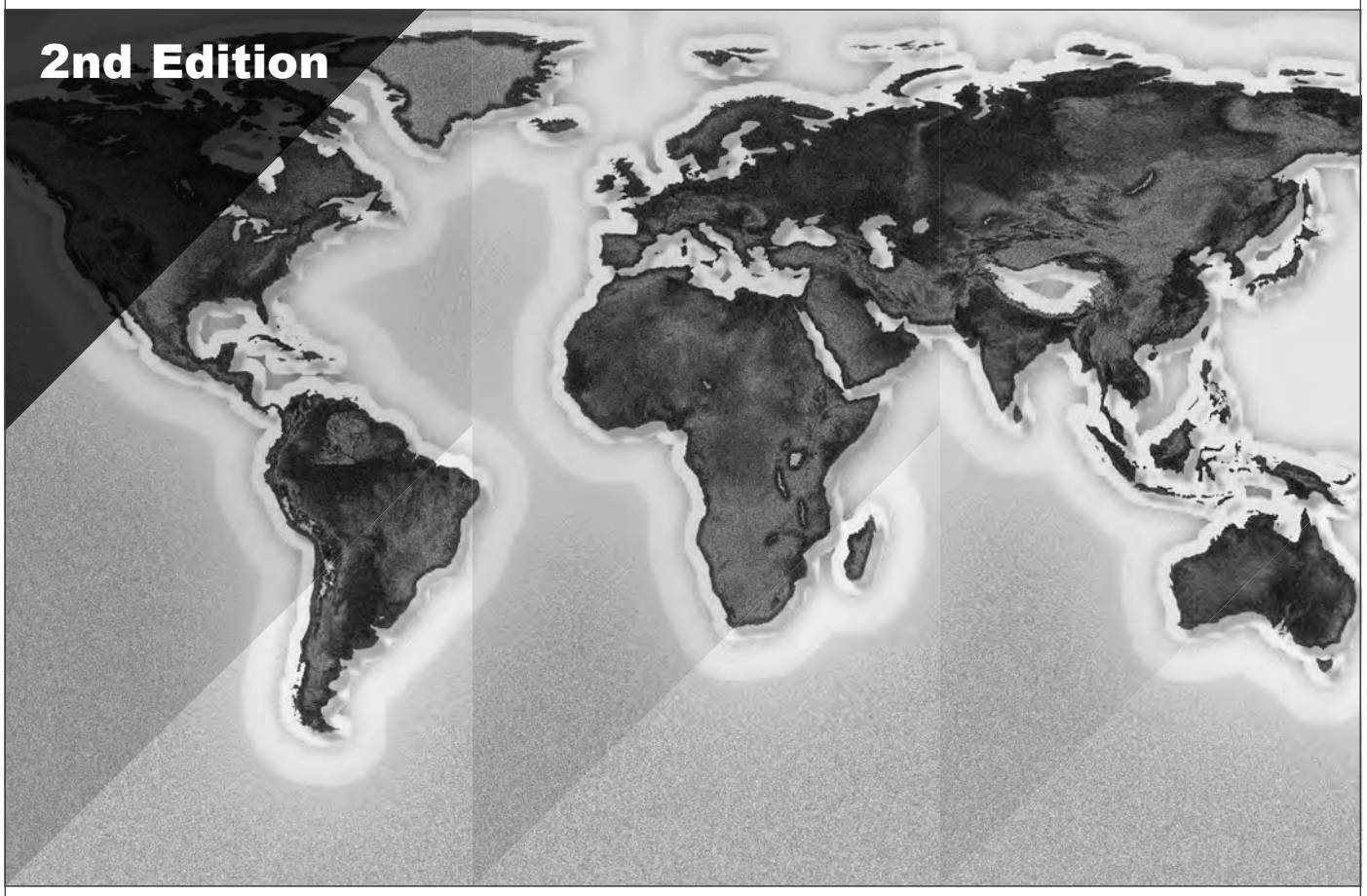
Joint Commission International Accreditation Standards for **Clinical Laboratories**

2nd Edition



Joint Commission International

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Joint Commission International

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Introduction

This second edition of the *Joint Commission International Accreditation Standards for Clinical Laboratories* contains all the standards, intent statements, and measurable elements of standards; accreditation policies and procedures; a glossary of key terms; and an index. This Introduction is designed to provide you with information on the following topics:

- The benefits of accreditation
- Joint Commission International (JCI) and its relationship to The Joint Commission (USA)
- The international accreditation initiatives of JCI
- The origin of the standards and how they are organized
- How to use this standards manual
- Special features of this manual

If, after reading this publication, you have questions about the standards or the accreditation process, please contact JCI. Contact information is located in the Foreword (page v).

Common Questions and Answers Regarding JCI Accreditation, Clinical Laboratories, and These Standards

What is accreditation?

Accreditation is a process in which an entity, separate and distinct from the health care organization, usually nongovernmental, assesses the health care organization to determine if it meets a set of requirements (standards) designed to improve the safety and quality of care. Accreditation is usually voluntary. Accreditation standards are usually regarded as optimal and achievable. Accreditation provides a visible commitment by an organization to improve the safety and quality of patient care, ensure a safe care environment, and continually work to reduce risks to patients and staff. Accreditation has gained worldwide attention as an effective quality evaluation and management tool.

What are the benefits of accreditation?

The accreditation process is designed to create a culture of safety and quality within an organization that strives to continually improve patient care processes and results. In doing so, organizations

- improve public trust that patient safety and the quality of care are priorities for the organization;
- provide a safe and efficient work environment that contributes to worker satisfaction;
- negotiate with sources of payment for care with data on the quality of care;
- listen to patients and their families, respect their rights, and involve them in the care process as partners;
- create a culture that is open to learning from the timely reporting of adverse events and safety concerns; and

- establish collaborative leadership that sets priorities for and provides continuous leadership for quality and patient safety at all levels.

What is JCI's relationship to The Joint Commission?

JCI is the international arm of The Joint Commission (US); JCI's mission is to improve the quality and safety of health care in the international community.

For more than 75 years, The Joint Commission and its predecessor organization have been dedicated to improving the quality and safety of health care services. Today, The Joint Commission is the largest accreditor of health care organizations in the United States—it surveys nearly 16,000 health care programs through a voluntary accreditation process. The Joint Commission and JCI are both nongovernmental, not-for-profit USA corporations.

What are the purpose and the goal of JCI accreditation initiatives?

JCI accreditation is a variety of initiatives designed to respond to a growing demand around the world for standards-based evaluation in health care. The purpose is to offer the international community standards-based, objective processes for evaluating health care organizations. The goal of the program is to stimulate demonstration of continuous, sustained improvement in health care organizations by applying international consensus standards, International Patient Safety Goals, and indicator measurement support. In addition to the standards for clinical laboatories contained in this second edition, JCI has developed standards and accreditation programs for the following:

- Hospitals
- Ambulatory care
- Primary care centers
- The care continuum (home care, assisted living, long term care, hospice care)
- Medical transport organizations

JCI also offers certification of programs that provide Disease-Condition-Service care such as programs for stroke care or cardiac care. JCI accreditation programs are based on an international framework of standards adaptable to local needs. The programs are characterized by the following:

- International consensus standards, developed and maintained by an international task force and approved by an international board, are the basis of the accreditation program.
- The underlying philosophy of the standards is based on principles of quality management and continuous quality improvement.
- The accreditation process is designed to accommodate the legal, religious, and/or cultural factors within a country. Although the standards set uniform, high expectations for the safety and quality of patient care, country-specific considerations related to compliance with those expectations are part of the accreditation process.
- The on-site survey team and agenda will vary depending on the organization's size and type of services provided. For example, a large multispecialty clinical laboratories may require a four-day survey by a physician, a nurse, and an administrator, whereas a smaller dental center or diagnostic center may only require a two-day survey by a smaller team.
- JCI accreditation is designed to be valid, reliable, and objective. Based on the analysis of the survey findings, final accreditation decisions are made by an international accreditation committee.

How were the standards initially developed and refined for this second edition?

A 12-member International Standards Subcommittee, composed of experienced physicians, nurses, administrators, and public policy experts, guides the development and revision process of the JCI international

accreditation standards. The subcommittee consists of members from six major world regions: Latin America and the Caribbean, Asia and the Pacific Rim, the Middle East, Central and Eastern Europe, Western Europe, and Africa. The work of the subcommittee is refined based on an international field review of the standards and the input from experts and others with unique content knowledge.

All international standards are reviewed and approved by the JCI Accreditation Committee, also an international group.

How are the standards organized?

The standards are organized around the important functions common to all health care organizations. The functional organization of standards is now the most widely used around the world and has been validated by scientific study, testing, and application.

The standards are grouped by those functions related to providing patient care and those related to providing a safe, effective, and well-managed organization. These functions apply to the entire organization as well as to each department, unit, or service within the organization. The survey process gathers standards compliance information throughout the entire organization, and the accreditation decision is based on the overall level of compliance found throughout the entire organization.

Are the standards available for the international community to use?

Yes. These standards are available in the international public domain for use by individual health care organizations and by public agencies in improving the quality of patient care. The standards alone can be downloaded at no cost from the JCI Web site for adapting them to the needs of individual countries. The translation and use of the standards as published by JCI require permission.

When there are national or local laws related to a standard, which applies?

When standard compliance is related to a law or regulation, whichever sets the higher or stricter requirement applies.

How do I use this standards manual?

This international standards manual can be used to

- guide the efficient and effective management of a health care organization;
- guide the organization and delivery of patient care services, and efforts to improve the quality and efficiency of those services;
- review the important functions of a health care organization;
- become aware of those standards that all organizations must meet to be accredited by JCI;
- review the compliance expectations of standards and the additional requirements found in associated intent statements;
- become aware of the accreditation policies and procedures and the accreditation process; and
- become familiar with the terminology used in the manual.

What are the "measurable elements" of a standard?

The measurable elements of a standard are those requirements of the standard and its intent statement that will be reviewed and assigned a score during the accreditation survey process. The measurable elements simply list what is required to be in full compliance with the standard. Each element is already reflected in the standard or intent statement. Listing the measurable elements is intended to provide greater clarity to the standards and to help organizations educate staff about the standards and prepare for the accreditation survey.

What is the Strategic Improvement Plan (SIP)?

A Strategic Improvement Plan (SIP) is a required written Plan of Action that the organization develops in response to "not met" findings identified in the Official Accreditation Findings Report. The written SIP is expected to

- establish the strategies/approach that the organization will implement to address each "not met" finding;
- describe specific actions the organization will use to achieve compliance with the "not met" standards/measurable elements cited;
- describe methodology to prevent reoccurrence and sustain improvement over time; and
- identify the indicators that will be used to evaluate the effectiveness of the improvement plan (submission of data to occur over the subsequent three years).

The SIP must demonstrate that the organization's actions lead to full compliance with the standards and measurable elements. The SIP must be approved by the JCI Central Office staff before the Accreditation Certification Letter and Gold Seal will be awarded.

How frequently will the standards be updated?

Information and experience related to the standards will be gathered on an ongoing basis. If a standard no longer reflects contemporary health care practice, commonly available technology, quality management practices, and so forth, it will be revised or deleted. It is currently anticipated that the standards will be revised and published at least every three years.

What does the "effective" date on the cover of this second edition of the standards manual mean?

The "effective" date found on the cover means one of two things:

1. For clinical laboratories already accredited under the first edition of the standards, this is the date by which they now must be in full compliance with all the standards in the second edition. Standards are published at least six months in advance of the "effective" date to provide time for organizations to come into full compliance with the revised standards.
2. For clinical laboratories seeking accreditation for the first time, the "effective" date indicates the date after which all surveys and accreditation decisions will be based on the standards of the second edition. Any survey and accreditation decisions before the "effective" date of the second edition will be based on the first edition standards.

What is new in this second edition of the manual?

There have been many substantial changes to this second edition of the clinical laboratories manual. A thorough review is strongly recommended. Some of the most significant changes are the following:

- A new chapter contains the International Patient Safety Goals.
- The format and grouping of the standards were changed to remove the extensive redundancy that resulted when the format of the ISO 15189 lab standards was used for the first edition.
- All the standards related to management and leadership were combined into one chapter. In the first edition, these requirements were spread over several chapters.
- All laboratory quality control processes were placed into one chapter, and a quality control for molecular testing was added.
- Standards related to development and control of policies and procedures were added and placed in one chapter.
- Resource management and management of the laboratory environment were combined into one chapter.

- The requirements from the chapter titled "Planning, Development, and Provision of Laboratory Services" (PDP) were divided into other chapters, with related requirements.
- The Glossary has been updated and expanded.
- The Index has been expanded significantly to facilitate navigation between related standards and topics.

International Patient Safety Goals (IPSG)

Goals

The following is a list of all goals. They are presented here for your convenience without their requirements, intent statements, or measurable elements. For more information about these goals, please see the next section in this chapter, "Goals, Standards, Intents, and Measurable Elements."

IPSG.1 Identify Patients Correctly

IPSG.2 Improve Effective Communication

IPSG.3 Not applicable for laboratories

IPSG.4 Ensure Correct-Site, Correct-Procedure, Correct-Patient Surgery

IPSG.5 Reduce the Risk of Health Care–Associated Infections

IPSG.6 Not applicable for laboratories

Goals, Standards, Intents, and Measurable Elements

Goal 1: Identify Patients Correctly

Standard IPSG.1

The organization develops an approach to improve accuracy of patient identifications.

Intent of IPSG.1

Wrong-patient errors occur in virtually all aspects of diagnosis and treatment. Patients may be sedated, disoriented, or not fully alert; may change beds, rooms, or locations within the organization; may have sensory disabilities; or may be subject to other situations that may lead to errors in identification. The intent of this goal is twofold: first, to reliably identify the patient as the person for whom the service or treatment is intended; second, to match the service or treatment to that individual patient.

Policies and/or procedures are collaboratively developed to improve identification processes—in particular, the processes used to identify a patient when giving medications, blood, or blood products; taking blood or other specimens for clinical testing; or providing any other treatments or procedures. The policies and/or procedures require at least two ways to identify a patient, such as the patient's name, identification number, birth date, or other ways. The patient's room number or location cannot be used for identification. The policies and/or procedures clarify the use of two different identifiers in different locations within the organization, such as in ambulatory care or other outpatient services, the emergency department, or operating theatre. Identification of the comatose patient with no identification is also included. A collaborative process is used to develop the policies and/or procedures to ensure that they address all possible identification situations.

Measurable Elements of IPSG.1

- ❑ 1. A collaborative process is used to develop policies and/or procedures that address the accuracy of patient identification.
- ❑ 2. The policies and/or procedures require the use of two patient identifiers, not including the use of the patient's room number or location.
- ❑ 3. Patients are identified before administering medications, blood, or blood products.
- ❑ 4. Patients are identified before taking blood and other specimens for clinical testing.
- ❑ 5. Patients are identified before providing treatments and procedures.

Goal 2: Improve Effective Communication

Standard IPSG.2

The organization develops an approach to improve the effectiveness of communication among caregivers.

Intent of IPSG.2

Effective communication—which is timely, accurate, complete, unambiguous, and understood by the recipient—reduces errors and results in improved patient safety. Communication can be electronic, verbal, or written. The most error-prone communications are patient care orders given verbally and those given over the telephone, when permitted under local laws or regulations. Another error-prone communication is the reporting back of critical test results, such as the clinical laboratory telephoning the organization to report the results of a critical lab value.