

ISO 15189-accredited laboratories fulfill the JCI Hospital Accreditation Standard requirements for the use of referral laboratories: report of a consensus meeting

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Abstract Accreditation of healthcare services is recommended to ensure operation according to the highest quality standards. Various initiatives, such as legislation or accreditation by ISO or JCI, may be active to support and improve quality. The growing trend toward JCI hospital accreditation raised the concern of redundancy between JCI requirements for the use of referral laboratories and the ISO 15189 accreditation for medical laboratories. This would result in needless administrative efforts for hospital laboratories to collect and maintain required documentation, as the JCI quality requirements would be guaranteed given that the referral laboratory is ISO 15189 accredited for those examinations. A consensus meeting was organized by the Working Group for Hospital Accreditation of the Belgian Zorgnet-Icuro network, the University Hospitals of Leuven and the Red Cross to discuss the avoidance of any redundancy between both standards and to issue best practice guidelines for referral laboratories. It was concluded that JCI measurable elements for referral

laboratories are covered by the ISO 15189 accreditation scope. The article substantiates the consensus that JCI and ISO quality requirements are harmonized and that accurate knowledge and interpretation of prevailing quality standards are essential to avoid redundancy in quality measures.

Keywords Quality of health care · Accreditation · Standards · ISO 15189 · JCI · Hospital · Medical laboratory

Introduction

There is an international growing attention for continuous improvement of the quality of healthcare services [1]. An established quality management system (QMS) and the acquirement of accreditation are essential. Efforts are undertaken by laboratories, hospitals, and governments to improve quality. More and more hospitals have voluntarily started moving toward accreditation. Many governments impose strict quality requirements for medical laboratories. This article is largely applicable to hospitals and laboratories throughout Europe but aims to highlight some specific issues to reflect on the situation in Belgium.

In Belgium, accreditation requirements differ depending on the type of laboratory. The quality requirements for each type are safeguarded under royal decrees of the Belgian Legislation. Centers for human genetics are to be ISO 15189 accredited for 80 % of their activities [2]. For laboratories in anatomopathology, accreditation is not mandatory, but is a requirement for the reimbursement of particular molecular oncology tests since 2009 [3]. For clinical pathology laboratories, accreditation is not mandatory for the main activities with some exceptions: national reference laboratories such as AIDS reference

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laboratories, reference laboratories for tropical and infectious diseases, and reference laboratories for microbiology [4–7]. The molecular tests for microbiology, hematology, and oncology performed in a clinical pathology laboratory also fall under a royal decree which requires ISO 15189 accreditation [2].

ISO 15189 is the gold standard for accreditation of medical laboratories [8]. The ISO 15189 is an international comprehensive standard for medical laboratories which covers both Management requirements (Chapter 4) and Technical requirements (Chapter 5). The laboratory must fulfill each element and must operate in complete concordance. Each country has its own national accreditation body (NAB) which is responsible for granting accreditations and which operates according to ISO 17011, the international standard for accreditation bodies [9].

For hospitals on the other hand, there are no specific national requirements for accreditation, although over the last years, hospitals have been increasingly encouraged by the government to start the journey toward accreditation. Following international trends, several hospitals have started international accreditation programs that are certified by The International Society for Quality in Health Care (ISQua). ISQua's International Accreditation Programme (IAP) is a global body that provides a peer review accreditation framework. The most frequently used hospital accreditation programs are the NIAZ-QMentum [10] and the Joint Commission International (JCI) Accreditation Standards for Hospitals 5th Edition [11].

Even though most hospital laboratories offer a wide range of tests for patient samples, they may refer a subset of tests to external laboratories. This may be the case for rarely performed tests, for specialized analyses or due to organizational reasons (lack of capacity, infrastructure, etc.). Of course, the quality of the services provided by these referral laboratories should be closely monitored by the referring laboratory or should be guaranteed by the contract laboratory (e.g., by means of accreditation). Both JCI and ISO 15189 state specific requirements for the use of referral laboratories.

JCI uses the term 'reference laboratory' and defines this as "a laboratory owned and operated by an organization other than the hospital, with which the hospital contacts for testing." The requirements for reference laboratories are listed in the JCI Standards for Hospitals, namely under Standard AOP.5.10 and AOP.5.10.1 [12]. These intents are specified in measurable elements (MEs) to indicate the requirements for full compliance with the standard. MEs are reviewed and scored during an on-site visit. ISO 15189 uses the term 'referral laboratory', which is defined as "an external laboratory to which a sample is submitted for examination. This is a laboratory to which laboratory management chooses to submit a sample or subsample for

examination or when routine examinations cannot be carried out. This differs from a laboratory that may include public health, forensics, tumor registry, or a central (parent) facility to which submission of samples is required by structure or regulation."

Both definitions differ slightly, as the ISO 15189 definition distinguishes referral laboratories from national reference laboratories to which samples are sent by structure or regulation.

Throughout this article, the authors adhere to the ISO interpretation of a reference laboratory/referral laboratory, i.e., a laboratory to which samples are sent, other than the governmentally acknowledged national reference laboratories.

In the USA, the CAP Laboratory Accreditation Standard is the golden standard, and therefore, JCI auditors may be unfamiliar with the full extent of ISO 15189 accreditation which is much more common in Europe. Hence, the Working Group is concerned that JCI auditors may not be aware that ISO 15189 accreditation provides sufficient evidence for compliance with JCI requirements for the use of referral laboratories. This would result in requesting redundant proof of JCI compliance evidence. This redundancy may put unnecessary administrative strain on hospitals by demanding to collect detailed documentation from the referral laboratories (e.g., a copy of the license, a copy of the accreditation certificate, documentation of EQA participation).

The aim of this article is to clarify which JCI requirements are covered if both the referring and referral laboratories are ISO 15189 accredited. The need for hospitals to establish documentation records of referral laboratories can be moderated, by supporting that JCI measurable elements are covered by the ISO 15189 accreditation scope. Its aim is also to issue a best practice guideline for referral laboratories, to encourage them to make all necessary information easily accessible for users of referral laboratory services.

Methods

The initiative was taken by the Working Group for Hospital Accreditation of the Belgian Zorgnet-Icuro network, the University Hospitals of Leuven and the Red Cross. Zorgnet-Icuro is a network that groups and represents healthcare organizations in Flanders. Its goal is to provide a platform for knowledge exchange and to organize high-quality health care.

A consensus meeting was organized in March 2015 at which a total of 21 involved stakeholders were represented: quality managers of university and regional hospitals, staff from medical laboratories, scientific organizations, the Red

Cross, the national accreditation body (BELAC), and the Scientific Institute for Public Health (WIV-ISP), which organizes national EQA programs and is responsible for the licensing of Belgian medical laboratories in clinical pathology and in pathology [3, 4, 13].

A comparison of JCI measurable elements of the JCI Accreditation Standard for Hospitals: 5th Edition (AOP.5.10) and the ISO 15189:2012 Standard for Medical Laboratories was discussed, and best practice recommendations were issued.

Results and discussion

A comparison of measurable elements of the JCI Accreditation Standard for Hospitals: 5th Edition (AOP.5.10) and the ISO 15189:2012 scope supports that JCI's MEs for referral laboratories are covered if the hospital laboratory is ISO 15189 accredited. Table 1 gives an overview of JCI requirements and how these are guaranteed when the laboratory is accredited.

ISO 15189 has specific requirements for the use of referral laboratories. This implies that if the hospital laboratory is accredited, the quality of referral laboratories is closely monitored as specified in the ISO Standard. The laboratory director is responsible for the selection of referral laboratories and for monitoring the quality of their service (ISO 15189:2012—4.1.1.4). Reference has to be made to any work referred by the laboratory to a referral laboratory or consultant (ISO 15189:2012—4.4.1). Furthermore, the laboratory must have a documented procedure for selecting and evaluating its referral laboratories (ISO 15189:2012—4.5). The laboratory is responsible for monitoring the quality of performance and for ensuring that referral laboratories are competent to perform the requested examinations. Arrangements with referral laboratories are periodically reviewed, and a register of all referral laboratories is maintained. Results of all samples referred are kept for a pre-defined period.

JCI requires that the hospital maintains a copy of the license (JCI—AOP.5.10 M1) and a copy of the accreditation (JCI—AOP.5.10 M2) for all referral laboratories. During the consensus meeting, it was suggested that laboratories should ideally make a copy of the license and a copy of the accreditation certificate (including accreditation scope) available on their website for the users of laboratory services, or provide a direct link to the official websites to guarantee easy accessibility.

In Belgium, a frequently updated list of licensed laboratories is available on the website of the national health insurance organization, RIZIV-INAMI [14]. The list also categorizes the different types of laboratories: centers for

human genetics (code 996), anatomopathology laboratories (code 997), and clinical pathology laboratories (code 998).

A list of all accredited laboratories, including the accreditation scope, can be found on the website of the national accreditation body BELAC [15]. Since 2006, BELAC is the only Belgian accreditation organization by royal decree [16]. BELAC is internationally recognized by the European co-operation for Accreditation (EA), the International Laboratory Accreditation Cooperation (ILAC), and the International Accreditation Forum (IAF). An overview of the number of accredited laboratories according to laboratory type is illustrated in Fig. 1. In total, there are 241 licensed medical laboratories in Belgium. The greater part of laboratories is situated in Flanders. The majority of medical laboratories in Belgium are clinical pathology laboratories. There are only eight centers for human genetics, which are all ISO 15189 accredited. Approximately 30 % of the clinical pathology and pathology laboratories are accredited.

Zorgnet-Icuro, as an umbrella organization for hospitals in Flanders, collects accreditation data and publishes a list of hospitals that have started the accreditation pathway on its website, including the chosen accreditation program and the survey dates. Table 2 gives an overview of the accreditation status of hospitals in Flanders. Sixty out of 65 hospitals have chosen for accreditation. One acute hospital and four revalidation hospitals will not start the accreditation pathway. In December 2015, a total of seven hospitals had already obtained accreditation, of which five are accredited by JCI and two by NIAZ. Another 53 hospitals have started the accreditation process.

With regard to transparency of the quality of laboratories, an exemplary initiative is the Orphanet database for rare diseases. Orphanet offers a worldwide database of medical laboratories which can be solicited by disease or gene name, by country, city, laboratory, or by professional. Interestingly, search results can be filtered by accreditation status and/or by participation in external quality assurance (EQA) schemes [17]. This database is recommended to retrieve information about accreditation and EQA participation of laboratories performing tests in the field of rare diseases.

According to JCI, the hospital must document that the referral laboratory participates in proficiency testing programs (JCI—AOP.5.10 M3). However, this requirement is automatically fulfilled if the referral laboratory is ISO 15189 accredited for those examinations. Indeed, accreditation implies that the laboratory participates in external quality assessment programs (5.6.3). Moreover, in Belgium, participation in EQA programs is mandatory for licensing by royal decree, apart from accreditation [2–4, 18]. This means that even non-accredited laboratories have to participate in the EQA programs offered by the

Table 1 Comparison of JCI and ISO 15189:2012 elements with an explanation of compliance

JCI measurable element	JCI ME content	ISO 15189 element or other compliance measure	Explanation of compliance
AOP.5.10 M1	The hospital maintains a copy of the license, from a recognized licensing authority, for all reference laboratories used by the hospital	Outcome of consensus meeting: Copy should be made available from the laboratory's website, or a direct link to a published governmental list should be foreseen	Laboratory should provide a link to a copy of the license on its website, or a list should be available on the website of the national licensing organization
AOP.5.10 M2	The hospital maintains a copy of the certificate or letter of accreditation or certification, from a recognized laboratory accreditation or certification program, for all reference laboratories used by the hospital	Outcome of consensus meeting: copy (including the scope) should be made available from the laboratory's website or a direct link to a published list by the NAB should be foreseen	Laboratory should provide a link to a copy of the accreditation or to the NAB's website, where all accredited laboratories are listed, including the accreditation scope
AOP.5.10 M3	The hospital maintains documentation that any reference laboratory used by the hospital participates in an outside proficiency testing program	ISO 15189:2012—5.6.3: Interlaboratory comparisons	If a laboratory is accredited and the test is included in the accreditation scope, the laboratory must participate in proficiency testing programs
AOP.5.10.1 M1	The frequency and type of performance expectation data from reference laboratories are determined by the hospital	ISO 15189:2012—4.2.2.2: Quality Manual ISO 15189:2012—5.4.2.d, 5.4.2.h, 5.4.2.j: Information for patients and users ISO 15189:2012—4.14.7: Quality indicators	The quality policy, QMS, and organizations structure are included in the Quality Manual Information on the examinations offered are made available for users of the laboratory services: This includes required samples, sample volumes, special precautions, turnaround time, biological reference intervals, and clinical decision values. Instructions for sample transportation and the laboratory's criteria for accepting and rejecting samples are communicated Quality indicators to monitor performance throughout critical aspects of pre-examination, examination and post-examination processes are established. The process of monitoring quality indicators is planned and periodically reviewed. Turn-around times for all examinations are established and periodically reviewed
AOP.5.10.1 M2	The qualified individual responsible for the laboratory or a qualified designee reviews the performance expectation data from reference laboratories	ISO 15189:2012—4.15: Management review ISO 15189:2012—4.5.1a through 4.5.1.d: Selecting and evaluating referral laboratories and consultants	The management review assesses the QMS at planned intervals and includes a large scope of evaluation types. The laboratory is responsible for selecting referral laboratories and consultants, and for monitoring their competence and quality. Arrangements are periodically evaluated, and records of reviews and referral laboratories and consultants are maintained
AOP.5.10.1 M3	The responsible individual or qualified designee takes action based on the results	ISO 15189:2012—4.15: Management review ISO 15189:2012—4.1.1.4.i: Laboratory director	Causes of nonconformities and process problems are analyzed Opportunities for improvement and the need for changes to the QMS are assessed Actions arising from management review are completed within a defined timeframe The laboratory director has the necessary competence and is responsible for selecting referral laboratories and monitoring the quality of their services

Table 1 continued

JCI measurable element	JCI ME content	ISO 15189 element or other compliance measure	Explanation of compliance
AOP.5.10.1 M4	An annual report of the data from reference laboratories is provided to hospital leadership to facilitate management of contracts and contract renewals	ISO 15189:2012—4.15: Management review ISO 15189:2012—4.5.1.c: Selecting and evaluating referral laboratories and consultants	The interval between management reviews is not greater than 12 months, and findings from management reviews are recorded and reported to laboratory staff. Arrangements with referral laboratories and consultants are evaluated periodically, and records of periodic reviews are maintained

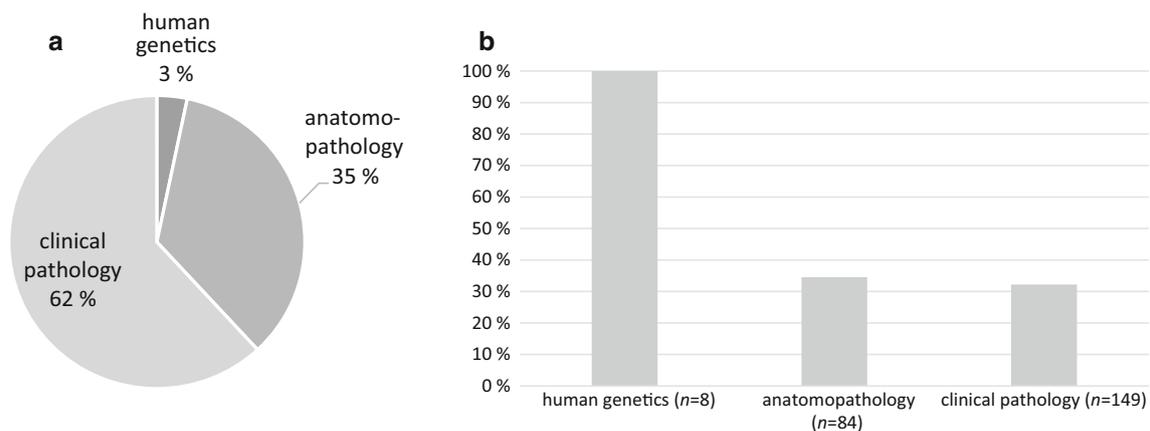


Fig. 1 **a** Distribution of the types of medical laboratories in Belgium ($n = 241$). **b** Overview of the number of accredited laboratories in Belgium according to laboratory type

Table 2 Overview of the accreditation status of hospitals in Flanders

Accreditation status	Number of hospitals ($n = 65$)
JCI accredited	5 (8 %)
NIAZ accredited	2 (3 %)
JCI accreditation pathway started	18 (27 %)
NIAZ accreditation started	30 (46 %)
Accreditation started but no details which standard	5 (8 %)
Total accredited or accreditation pathway started	60 (92 %)

Scientific Institute for Public Health (WIV-ISP) to maintain their license and to obtain reimbursement for medical tests.

Due to the ISO 15189 requirements for the Quality Manual, for the availability of information for users of laboratory services, and for the establishment of quality indicators (ISO 15189:2012—4.2.2.2 and 5.4.2.d, 5.4.2.h, 5.4.2.j, and 4.14.7), the frequency and type of performance

expectation data of the referral laboratory can be monitored (JCI—AOP.5.10.1 M1).

As specified in the ISO Standard, information available for the users of laboratory services includes the types of clinical services offered (including examinations referred to other laboratories), information concerning the examinations offered (samples required, sample volumes, precautions, turnaround time, etc.), instructions for completion of the request form, instructions for preparation of the patient, instructions for transportation of samples, requirements for patient consent, criteria for accepting and rejecting samples, a list of factors known to affect the examination or the result interpretation, etc. The laboratory establishes quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination, and post-examination processes (e.g., number of unacceptable samples, number of registration errors, etc.).

Quality indicators are evaluated by a planned process (establishing objectives, methodology, interpretation, limits, action plan, and duration of measurement) and are periodically reviewed to assure appropriateness.

Turnaround times that reflect clinical needs are established and subject to periodic evaluation.

The quality control policy, the scope of the quality management system, the management structure, the roles and responsibilities of laboratory management, and the structure of documentation are extensively elaborated in the Quality Manual.

Moreover, the JCI International Patient Safety Goals require defining critical values for each type of diagnostic test and a process for reporting critical results (IPSG.2.1).

ISO 15189 requires a review of the quality management system (ISO 15189:2012—4.15) at planned intervals (no greater than 12 months) to ensure its suitability, adequacy and effectiveness, and support of patient care. A large scope of evaluation results are included in this management review (user feedback, internal audits, quality indicators, performance of suppliers, results of external quality assessment participation, risk management, etc.). This information is analyzed for causes of nonconformities and patterns that indicate process problems. Opportunities for improvement and the need for changes to the quality management system are assessed, and actions arising from management review are completed within a defined time-frame. These actions cover the JCI requirements stated under AOP.5.10.1 M2, M3, and M4.

Moreover, the competence and quality of the selected referral laboratories and consultants are monitored, periodically evaluated, and a register of all referral services is maintained (ISO 15189:2012—4.5.1a through 4.5.1.d). The laboratory director is a person with the necessary competences and is responsible for selecting referral laboratories and for monitoring the quality of their services (ISO 15189:2012—4.1.1.4.i). These ISO 15189 requirements assure the periodic review of performance expectation data by a qualified designee (AOP.5.10.1 M2, M3 and M4).

Conclusion and recommendations for referral laboratories

ISO 15189 accreditation provides evidence for continued assurance of high-quality services for the tests included in the accreditation scope. This quality assurance by ISO 15189 accreditation, in addition to the documentation of licensing by the Belgian authorities, fully meets the JCI requirements concerning referral laboratories, at least for tests included in the referral laboratory's accreditation scope.

Recommendations toward laboratories include:

1. For licensed and accredited laboratories, it is unnecessary to arrange Service Level Agreements (SLA) between the hospital and the referral laboratory. In case

the hospital prefers to establish SLAs with their referral laboratories, this can be limited to the requirement that the referral laboratory is licensed and ISO 15189 accredited for the referred tests.

Gathering documentation such as a copy of the license, a copy of the accreditation certificate, copies of EQA results etc., is unnecessary. Licensing and accreditation evidence are available at the BELAC website and at the website of the national health insurance organization, RIZIV-INAMI, and can be made available on the referral laboratory's website. EQA results of the referral laboratory do not need to be requested as ISO 15189 accreditation guarantees surveillance of test quality, EQA participation, as well as communication of any corrective and preventive actions.

2. It is strongly advised for each laboratory to make the following information available on its website:

- An overview of the tests that are performed, including
 - Test frequency and sample flow
 - Turn-around times
 - Pre-analytical requirements (sampling requirements and transport to the laboratory)
 - Particular specifications of the analysis
 - Whether or not the test is included in the accreditation scope (if yes, this implies EQA participation for the particular disease/parameter)
- Lists of specialists and contact details of the laboratory
- Link toward the license (governmental organization) and/or link to a copy of the license with the registration number
- Link to the website of the national accreditation body, where the accreditation status and the accreditation scope can be found.

From the discussion at the consensus meeting, the ascertainment deemed that quality systems and other quality requirements, whether stated by ISO or JCI Standard or by legislation, should support each other and should serve the same purpose. This has been proven for Belgium, where the international ISO 15189, the JCI Standard for Hospital Accreditation and the Belgian legislation are harmonized and are asking for highly comparable quality requirements.

However, excessive administrative pressure should be avoided by not demanding redundancy in documentation and service agreements. This article proves that JCI and ISO quality requirements are harmonized and that accurate knowledge and interpretation of prevailing quality standards is essential to avoid redundancy in quality measures.

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Compliance with ethical standards

Conflict of interest None.

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