



Quality requirements in clinical laboratory

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Laboratory medicine accreditation organizations standards set benchmarks in health care safety and quality for clinical laboratories. In order for these external evaluation, and standards setting organizations, to assure themselves that their standards meet international best practice requirements, and to provide confidence to the public and their clients, many seek international recognition through participation in international external evaluations of their standards and organization.

The International Society for Quality in Health Care (ISQua) is a non-profit, independent, health care quality organization with members and contacts in over 100 countries covering six continents. The ISQua 'Guidelines and Principles for the Development of Health and Social Standards' specify requirements for competence and quality that are internationally recognized, consistent with current professional knowledge, and aligned to the principles of continuous quality improvement. They are relevant to all health care services, not just laboratory medicine, and acknowledge that a country could have its own specific regulations or requirements. The standards are developed through a collaborative, consultative and consensus building process that involves international experts and organizations, academics and client organizations. They were also mapped to certain ISO standards. The ISQua standards are regularly reviewed and updated to ensure relevance, applicability, incorporation of research recommendations and reflect current best practices.

Historically quality requirements for laboratory medicine have focused on the laboratory testing processes and the use of tools such as external proficiency testing. The ISQua standards cover pre and post examination requirements for structure, process and outcome measurement, emphasizing leadership and management, human resources, patient and staff safety, quality improvement, patient and service user focus and organizational performance. These elements are not always under the direct control of the clinical laboratory, but they emphasize the importance of the laboratory management link with the larger organizational role in patient centeredness, planning, performance, safety and risk.

The Diagnostic Accreditation Program (DAP) of British Columbia, Canada accredits five diagnostic services one of which is laboratory medicine. It is a regulatory body and obtains its authority through the DAP Bylaws of the College of Physicians and Surgeons of British Columbia. The DAP establishes performance standards, evaluates the diagnostic service to achieving the performance standards, and monitors laboratories through the establishment of proficiency testing programs. The DAP operates on a continuous quality improvement model and remains highly committed to supportive, peer based approaches to accreditation that fosters a culture of continuous quality improvement. The DAP has twice successfully obtained ISQua accreditation for its laboratory medicine standards and organizational performance.

This presentation will explore the incorporation of the ISQua quality requirements into laboratory medicine standards. The principles of continuous quality improvement, peer review and transfer of knowledge will be highlighted.