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Health laboratory licensing

This online first version has been peer-reviewed, accepted and edited,
but not formatted and finalized with corrections from authors and proofreaders

Health laboratory licensing: a policy and best-practice analysis

Markus Huber,^a Madina Andreyeva,^b Lance D Presser^c & Joanna Salvi Le Garrec Zwetyenga^b

^a Bio-risk Management and Biosafety, WHO Health Emergencies Programme, World Health Organization, Avenue Appia 20, 1211 Geneva, Switzerland.

^b Better Labs for Better Health initiative, World Health Organization Regional Office for Europe, Copenhagen, Denmark.

^c Centre for Infectious Diseases Research, Diagnostics and Laboratory Surveillance, National Institute for Public Health and Environment, Bilthoven, the Kingdom of the Netherlands.

Correspondence to Markus Huber (email: mhuber@who.int).

(Submitted: 11 October 2024 – Revised version received: 26 March 2025 – Accepted: 4 April 2025 – Published online: 3 May 2025)

Abstract

Objective To gain insight into how governments regulate their health laboratory sector, by reviewing health laboratory licensing legislation across different health care systems in a diverse range of 18 countries worldwide.

Method We selected countries for a diverse range of health-care systems, geography, income level, licensing legislation and standards adhered to. We selected aspects of health laboratory licensing that were consistently present in different countries and suitable for meaningful comparison, focusing on legislative approaches, certification and accreditation models, regulation, quality assurance, and biosafety and biosecurity requirements.

Findings Our analysis revealed that the licensing legislation for health laboratories typically encompasses two principal components: administrative procedural law and substantive law. We observed that the different ways in which countries regulate their health laboratories could be categorized within three distinct legislative approaches, namely: standalone licensing act, general licensing act and one based on a health insurance contract. Most countries used a two-step application process, comprising registration and licensing steps. License validity periods ranged over 1–5 years, with some countries opting for permanent licenses. Countries adopted diverse standards and requirements, with some mandating accreditation.

Conclusion Our findings highlight the diverse legislative approaches to health laboratory licensing, reflecting varying national capacities and regulatory priorities. Integrating robust quality standards, especially those aligned with International Organization for Standardization standard no. 15189, is essential for strengthening laboratory oversight and public health response. Effective licensing frameworks not only enhance domestic laboratory systems but also contribute to global health security through alignment with international obligations.

Introduction

Health laboratories, including public health laboratories, private and public clinical laboratories, and national reference laboratories, are integral to public health systems, performing activities such as the detection, assessment, notification and monitoring of acute health events, as described in annex 1 of the International Health Regulations (IHR) 2005.¹ The monitoring and evaluation of laboratory capacity to perform such activities is critical to ensure compliance with these regulations.²

A health laboratory license is the formal authorization granted by a regulatory body permitting a laboratory to conduct specific activities in accordance with established legal and quality standards and requirements. The issuance of a license, in either physical or digital form, establishes the foundation for the operation and management of a laboratory. The license serves as a key regulatory mechanism to ensure laboratories operate safely, maintain high-quality testing practices, and comply with public health and safety requirements. However, the World Health Organization (WHO) Better Labs for Better Health initiative has identified significant deficiencies (e.g. inconsistent licensing requirements, insufficient oversight mechanisms and a lack of enforcement) in the national regulatory frameworks of health laboratories in some Member States of the WHO European region.^{3,4} Inadequate regulation poses risks, such as compromised laboratory standards, inaccurate test results and potential harm to patients and the public. These deficiencies highlight the critical role of robust licensing legislation in ensuring the quality and safety of medical testing and diagnostic services.

To gain insight into how governments regulate their health laboratory sector, we reviewed health laboratory licensing legislation in a diverse range of 18 countries across the globe (Armenia, Australia, Austria, Canada, France, Germany, Ghana, Kyrgyzstan, Luxembourg, Malaysia, Malta, the Philippines, the Russian Federation, Switzerland, Ukraine, the United Arab Emirates, the United Kingdom of Great Britain and Northern Ireland, and the United States of America). Our study aims to support national health authorities and laboratory managers in strengthening their laboratory systems by establishing adequate licensing legislation, ultimately improving the quality of diagnostic services.

Methods

Our selection of the 18 countries included in this study was guided by key criteria to ensure a comprehensive and representative analysis of health laboratory licensing legislation. These criteria included diversity in health-care systems (public, private and mixed),

geographic and economic representation (low-, middle- and high-income countries) and regulatory models (in terms of the different approaches to licensing legislation). We also selected countries for a range of certification and accreditation standards requirements (e.g. International Organization for Standardization standard, ISO 15189⁵ or national alternatives), legislative transparency (publicly accessible or translatable laws) and policy relevance, including both established frameworks and recent reforms.

Three authors collected legislative data independently, each assigned a subset of countries based on their language proficiency. WHO translators translated legislation into English where necessary. Following the initial data collection in January 2024, two authors conducted the analysis, identifying and categorizing the legislative approaches and licensing aspects. The review process compiled overlapping contributions from several authors, with consensus used to address and resolve any inconsistencies.

Because the key aspects of the licensing legislation were not predefined but emerged inductively during our review of national legislation, we did not use a standardized data extraction template. We selected aspects of health laboratory regulation that appeared consistently in different countries and could be meaningfully compared, enabling an analysis of legal requirements, major legislative approaches, certification and accreditation models, regulation, quality assurance, and biosafety and biosecurity requirements. To organize our qualitative data, we used the consolidated criteria for reporting qualitative research framework.⁶

Results

Legislative approaches

Our analysis revealed that the licensing legislation for health laboratories typically encompasses two principal components: administrative procedural law and substantive law. Administrative procedural law is pivotal in delineating the process by which licenses are issued or denied, (i) detailing the precise steps, requirements and criteria to which applicants must adhere; and (ii) providing directives for the licensing authority on how to review and evaluate applications, ensuring a transparent and standardized evaluation process. Substantive law either (i) specifies and delineates all standards and requirements of the licensing framework; or (ii) refers to quality, labour or safety regulations, or to established guidelines. We observed that the different ways in which these separate components are enacted could be categorized within three distinct legislative approaches, namely: a standalone licensing act, a

general licensing act or a model based on a health insurance contract. Table 1 presents the identified properties of each approach.

Standalone licensing act

This approach concentrates most regulatory aspects that govern health laboratories into a single legislative act, combining administrative procedural law and substantive law. The act covers the application process and the required documentation to be submitted to the licensing authority, and is often accompanied by a list of minimum criteria to ensure the quality and safety of the operations of the health laboratory. Through the act, the government regulates the reasons for granting, refusing or renewing licenses; license validity period; the implementation of licensing control; and the suspension, renewal, termination and revocation of licenses. We noted that health laboratory licensing follows this approach in Canada (specifically, Saskatchewan), France, Malaysia, Malta and the Philippines (Table 2).

General licensing act

This approach establishes a hierarchy of different laws. The administrative procedural law and the substantive law are separated and enforced through different acts. The highest level represents legislation on the general aspects of licensing, which is complemented by legislation specifically addressing licensing of medical and/or public health activities and legislation regarding the substantive law of the laboratory operation. The general licensing act determines the rules for issuance, renewal and withdrawal of any license. A related act describes the requirements for licenses for medical and/or public health activities, mostly accompanied by a document determining the required standards. In contrast to the standalone licensing act, we noted that this approach utilizes general guidelines for any medical and/or public health activity or health facility. We observed that health laboratories in Armenia, Ghana, Kyrgyzstan, the Russian Federation, Ukraine, the United Arab Emirates and the USA followed this legislative approach (Table 2).

Based on health insurance contract

In the third approach, the related acts regulate the contract between the health laboratory service provider and the insurance companies (which are often publicly owned), and establish mandatory requirements to operate the laboratory. Because of significant issues with reimbursement of services provided by health laboratories in the last century (e.g. in the USA), insurance companies established rules and guidelines to ensure quality enforcement and conduct, and participation in external audits.⁷ Referring to these rules and guidelines is often an obligation of health insurance legislation. The health insurance companies use

standard contract forms describing the requirements of the laboratory, which can be stricter than those stipulated in the respective legislation. To receive reimbursement, the laboratory service provider must comply with the terms of the contract. In some countries (e.g. Australia, Germany, Luxembourg and the United Kingdom), mandatory participation in a certification or an accreditation programme might be required by such a contract. Our analysis revealed that health laboratories in Australia, Austria, Germany, Luxemburg, Switzerland and the United Kingdom followed a licensing approach based on health insurance contract (Table 2).

Application process

We observed that the license application process commonly included two steps:

(i) registration (sometimes called preliminary licensing, authorization or approval process) and (ii) licensure. Key aspects of this process are provided in Table 2 for all countries analysed.

The first step entails registering with the national health ministry or any designated authority (e.g. licensing authority). This process is sometimes accompanied by a preliminary approval (e.g. France, Malaysia and the United Arab Emirates), during which the licensing authority collects information about the laboratory and ensures compliance with the relevant regulations. The initial registration and review of the legal requirements for the health laboratory can have two different implications. First, they provide a legal basis for the laboratory to establish its service (the registration alone does not authorize the provision of services to clients). Second, it provides the legal basis to establish the laboratory and authorizes the laboratory owner to provide services to clients. This option is used when accreditation or certification is mandatory for obtaining a license (e.g. Australia, France, Ukraine, the United Kingdom and the USA). Since accreditation and certification can only be properly evaluated in daily operations, the laboratory has to provide services to clients before the license application. The legal requirements for registration in this scenario are stricter and often accompanied by an initial onsite inspection, and the laboratory must apply for its registration to the licensing authority before the effective start of operations.

The second step is the licensure process of the laboratory, during which the licensing authority verifies the information collected during the registration process and gathers new information from the laboratory, preferably from daily operations. The laboratory applies for the license after completing the registration with the licensing authority.

In some countries (e.g. Armenia, Ghana, Kyrgyzstan and the Russian Federation), the application process is limited to a single step, and registration is conducted when the application for a license is being processed by the licensing authority.

Validity period

We noted that licenses are usually issued for a period of 1–3 years, so that licensing authorities can regularly determine whether laboratories are continuing to fulfil their licensing requirements. The health laboratory licensing legislation usually outlines the process for license renewal. We noted that permanent licenses are issued in France, Germany, Kyrgyzstan, Luxemburg, Ukraine and the United Kingdom, but these permanent licenses can be temporarily suspended or revoked if the health laboratory fails to meet licensing requirements. We provide license validity periods for all countries analysed in Table 2.

Fees

We observed that all countries prescribe a registration and/or a licensing fee (Table 2). In some countries (e.g. Malta, the Philippines, Ukraine and the United Arab Emirates) these fees cover the cost of onsite inspection for the registration and licensing process, as well as the cost of the entire administrative process.

Standards and requirements

We noted that health laboratories in the analysed countries regulate the legal standards and requirements concerning the structure, functions, personnel requirements and other related aspects either in their licensing legislation or by referring to applicable laws or guidelines. For example, in the Philippines, Switzerland and United Arab Emirates, the laboratory licensing laws are accompanied by a publicly available compilation of all applicable laws and regulations for laboratories.

We also observed that the practice of implementing standards in licensing legislation varies between countries, with some overlap (Table 3). The relevant authorities publish and update a minimum criteria list in 12 of the 18 countries analysed (Armenia, Australia, Canada, Ghana, Kyrgyzstan, Luxemburg, Malta, the Philippines, the Russian Federation, Ukraine, the United Kingdom and the USA); developed an individual country-specific mandatory accreditation in six countries (Australia, Canada, France, Luxembourg, the United Kingdom and the USA); regulate only certain aspects of all possible requirements and standards observed in their licensing legislation in two countries (Austria and Malaysia); and chose mandatory ISO 15189 accreditation as a requirement for the laboratory service provider

either to operate or to obtain reimbursement from the insurance companies in one country (France). Health laboratories in seven countries (Australia, France, Germany, Luxembourg, Switzerland, the United Arab Emirates and United Kingdom) are regulated by the relevant authorities with standards and requirements that are based on ISO 15189.

The sources of law for each country are provided in the online repository²⁸ and in Table 3.

Quality management content

We compared the quality management content of the various existing legislations for laboratory licensing with the 12 quality system essentials defined by the Clinical and Laboratory Standards Institute.²⁹ Fig. 1 indicates the number of countries out of the 18 analysed in which each of the quality system essentials was included in the requirements of the health laboratory licensing legislation. The analysis does not provide any assessment of the enforcement mechanisms or qualitative robustness of each component in the licensing legislation. Our data reveal that although core operational quality system essentials are widely adopted in health laboratory licensing, more strategic and progressive quality elements, such as customer focus and continual improvement, remain underrepresented.

Discussion

Our comparative review of health laboratory licensing legislation in 18 countries has highlighted the significant diversity in regulatory approaches and the absence of a universally adopted framework, but also a common goal of safeguarding public health through effective laboratory oversight. Our findings reveal broad alignment on infrastructure and operational domains, but limited regulatory attention to continuous quality improvement, highlighting the need for more comprehensive quality assurance integration globally.

We identified three major legislative approaches, each of which presents unique mechanisms for oversight and quality control, affecting laboratory performance differently. Understanding the relative strengths and limitations of these approaches will help policy-makers to choose and adapt frameworks that can sustainably enhance laboratory quality and ultimately protect public health. The standalone licensing approach offers the most comprehensive form of oversight, as it is tailored specifically to laboratory operations. Countries that implement this model typically demonstrate strong alignment with international standards and more robust mechanisms for inspection, enforcement and continuous quality improvement. These frameworks tend to have a direct, positive impact on laboratory performance by ensuring that only facilities meeting defined standards are allowed

to operate. The general licensing approach, in which laboratory licensing is embedded within broader health-care or institutional frameworks, may provide less specialized attention to laboratory-specific requirements. Although more administratively efficient, this model may struggle to ensure consistent performance across laboratory types unless paired with strong, sector-specific guidelines. Licensing approaches based on health insurance contracts regulate laboratories through contractual obligations tied to reimbursement by insurance providers. Although this model can incentivize compliance with performance standards, especially in privatized health systems, it may lack the regulatory authority to enforce sanctions or mandate corrective actions in the public interest.

The effectiveness of any licensing model is context dependent. For example, in countries with a strong public health infrastructure and sufficient regulatory capacity, a standalone licensing act can be effectively implemented and enforced. Conversely, in settings with constrained resources or decentralized governance, general or contract-based models may be more feasible initially, even if less robust. Cultural, legal and economic contexts also shape the success of licensing models. In highly privatized health systems, models based on health insurance contracts may leverage market mechanisms to drive compliance. What the three approaches have in common is that they impact not only the legal instruments used and standards and requirements enforced, but also the responsibilities of regulatory authorities and insurers, especially in systems where insurance providers play a central role in enforcing quality standards.

Another critical dimension of licensing legislation is the enforcement of standards and quality management systems. Although 12 countries maintain a published list of minimum criteria, and others incorporate or require accreditation (often aligned with ISO 15189), the depth and breadth of quality assurance integration vary widely. Moreover, the role of international standards, particularly ISO 15189, emerges as a potential unifying benchmark. Countries leveraging these standards, whether through direct legal requirements or insurance contracts, may be better positioned to align with global health security objectives and cross-border recognition of laboratory competence. However, without mechanisms to monitor implementation, enforce compliance and evaluate performance, well-drafted legislation may fail to achieve its intended impact.

Our findings are directly relevant to the obligations of countries under IHR (2005).¹ By establishing clear standards, oversight processes and mechanisms for accountability, licensing systems support the functional capacity of national laboratories and their integration

into public health surveillance networks. Licensing mechanisms help establish minimum standards for infrastructure, staff qualifications, equipment, procedures, quality control and biosafety, which are essential for delivering accurate and timely diagnostic services. By enforcing these standards, licensing promotes consistency, accountability and alignment with international best practice.

Our study had several limitations in terms of scope. First, the laboratory sector is subject to a comprehensive framework of laws and regulations, extending beyond the remit of this review. Within a single country, various laws and regulations may govern different types of health laboratories, leading to potential variations in the licensing process, application procedures, and standards and requirements for compliance. Although we made efforts to accurately categorize countries according to specific licensing approaches, different laboratories within a single country may exhibit diverse licensing processes. Second, our study did not include consultations with national authorities or stakeholders, which would be a valuable component for future research to validate and contextualize findings. Finally, countries without formal laboratory licensing systems were not assessed, as the study focused on analysing and comparing existing legislative frameworks; our findings may therefore not be globally generalizable.

To conclude, our findings suggest that effective licensing frameworks must go beyond administrative compliance. Licensing should function as a strategic instrument to strengthen laboratory systems, enabling countries to implement robust quality management systems; ensure adherence to biosafety and biosecurity protocols; improve accountability and transparency; and facilitate data sharing and public health response coordination. Supporting efforts to harmonize standards and requirements, particularly in regions with frequent cross-border health challenges, could significantly strengthen domestic health systems but also advance global health security and collective preparedness.

Competing interests:

None declared.

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Table 1. Properties of three main legislative approaches in a multi-country comparison of health laboratory legislation

Property	Standalone licensing act	General licensing act	Based on health insurance contract
Character of the legal acts	A single specific legal act	A single general legal act on licensing and more specific legal acts relating to the operation of the laboratory	A single act regulating the contract between the laboratory and the insurance company, and more specific legal acts
Quality enforcement	Controlling authority	Controlling authority	Controlling authority and insurance companies
Governmental supervision	Significant	Significant	Moderate
Application process	Registration and/or licensing	Registration and/or licensing	Personnel registration and contract with insurer
License function	Permission to operate	Permission to operate	Basis for reimbursement

Table 2. Health laboratory license and application process comparison for 18 countries, 2024

Country	Legislative approach	Character of awarded license	License validity period	Application process	Application fees
Armenia	General	License to operate a medical laboratory	5 years	Single-step process: applying for a license with licensing agency, health ministry	License fee set by law on state fees
Australia	Health insurance	Accreditation to operate a medical laboratory	3 years	Two-step process: laboratories obtain accreditation from the National Association of Testing Authorities; laboratory scientists register with the Australian Health Practitioner Regulation Agency	Fees vary depending on the accreditation and registration processes
Austria	Health insurance	License to operate a medical laboratory	Permanent	Two-step process: registration as the laboratory manager; signing a contract with the insurance company	Federal medical board registration fee
Canada	Standalone	License to operate a medical laboratory	1 year	Two-step process: application for a license; mandatory participation in quality assurance program	Fees determined by the health ministry
France	Standalone	Administrative authorization	Permanent	Two-step process: administrative authorization; accreditation process	Costs related to the accreditation process
Germany	Health insurance	Contract with the insurance company	Permanent	Two-step process: registering the laboratory manager; signing a contract with the insurance company	Federal medical board registration fee
Ghana	General	Preliminary license, long-term license	6 months or 3 years	Single-step process: obtain a license from the medicines and medical devices department under the health ministry	License fee and annual retention fee
Kyrgyzstan	General	License to operate a medical laboratory	Permanent	Single-step process: applying with the health authority	Fees determined by the health ministry (may vary according to services offered)
Luxembourg	Health insurance	Contract with the insurance company	Permanent	Two-step process: registering the laboratory manager; contract with the insurance company	Fee set by national authorities
Malaysia	Standalone	Approval and license	1–3 years	Two-step process: application for approval; application for a license within 3 years	Fee set by national authorities
Malta	Standalone	License for private medical diagnostics laboratories	1 year	Two-step process: application submitted to the health care standards directorate; inspection by the health care standards directorate	Annual license fee
Philippines	Standalone	License for clinical laboratories	1 year	Two-step process: registering with the health department or Facilities and Services Regulatory Bureau; license application	License fee set by the health department

Russian Federation	General	License to operate a medical laboratory	5 years	Single-step process: registration with health authority and compliance with federal norms	Set by federal authorities
Switzerland	Health insurance	Contract with the insurance company	Permanent or 5 years for microbiological laboratories	Two-step process: registering the laboratory manager; contract with the insurance company	Cost of registering the laboratory manager
Ukraine	General	Preliminary license, accreditation	Permanent	Two-step process: health ministry license; accreditation via national authority	License and accreditation fees
United Arab Emirates	General	Preliminary license, accreditation	1-year preliminary license	Two-step process: online registration and application on the health department's website; onsite inspection	Fee set by the health department
United Kingdom	Health insurance	Contract with the insurance company	Permanent	Two-step process: registering the laboratory manager; contract with the insurance company	Cost of clinical pathology accreditation
United States	General	Clinical Laboratory Improvement Amendments certificate	Varies by certificate type	Two-step process: certification through Centers for Medicare and Medicaid Services; accreditation by approved bodies	Costs of clinical laboratory improvement amendments

Table 3. Source of health laboratory licensing standards and requirements for the 18 countries analysed, 2024

Country	Main list or source of legal acts for standards and requirements	Implementation	Year of enactment
Armenia	Governmental Decree of Republic of Armenia no. 867, 29 June 2002 ^{8,a}	Minimum criteria list ^b	2002
Australia	Requirements for medical pathology services, third edition, 2018 ⁹	Mandatory accreditation based on a minimum criteria list (based on ISO 15189) ^c	2018
Austria	Guidelines to the laboratory-catalogue, Hauptverband der Sozialversicherungen, 2018 ¹⁰	Requirements have to be met	2018
Canada	The Medical Laboratory Licensing Regulations, 2009 ¹¹	Mandatory accreditation based on a minimum criteria list	1995
France	Order no. 2010–49 relative to the medical biology, 13 January 2010 ¹²	Mandatory ISO 15189 accreditation	2010
Germany	Guidelines of the Bundesärztekammer for quality assurance: medical laboratory examinations, Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (Rili-BÄK), 2019 ¹³	Guideline based on ISO 15189	2019
Ghana	National guidelines for laboratory testing and reporting on respiratory infectious diseases in health facilities in Ghana, first edition, 2020 ¹⁴	Minimum criteria list	2011
Kyrgyzstan	Decree of the Kyrgyz Republic Cabinet of Ministers no. 678, 14 December 2023 ^{15,a}	Minimum criteria list	2024
Luxembourg	Grand-Ducal regulation of 27 May 2004 determining the minimum criteria for medical analysis laboratories ¹⁶	Minimum criteria list or mandatory ISO 15189 accreditation	2004
Malaysia	Act 674 Pathology laboratory act, 2007 ¹⁷	Requirements have to be met	2007
Malta	Ministry for Health and Active Ageing, Healthcare Standards Directorate, Superintendence of Public Health 2019 ¹⁸	Minimum criteria list	2019
Philippines	Assessment tool for licensing a general clinical laboratory, 2021 ¹⁹	Minimum criteria list	2021
Russian Federation	Governmental Decree of the Russian Federation no. 852, 1 June 2021 ²⁰	Minimum criteria list	2021
Switzerland	Kriterien zum Betreiben von medizinischen Laboratorien (KBMAL) 3.0, 2017 ²¹	Guideline based on ISO 15189	2017
Ukraine	Cabinet of Ministers of Ukraine Decree no. 285, 2 March 2016 ²²	Minimum criteria list	2016
United Arab Emirates	Health Authority Abu Dhabi clinical laboratory standards, 2011 ²³	Mandatory ISO 15189 accreditation	2011
United Kingdom	Care Quality Commission Guidance for providers on meeting the regulations, 2015 ²⁴	Clinical Pathology Accreditation; ^d minimum criteria list (based on ISO 15189)	2015
United States	Title 42 – The public health and welfare act, Subpart 2 – Clinical laboratories ²⁵	Clinical Laboratory Improvement Amendments; ^e minimum criteria list or College of American Pathologists accreditation ^f	1988

ISO: International Organization for Standardization.

^a A regulation relating to the standards and requirements was at draft stage at the time of analysis.

^b A comprehensive list of standards and requirements is incorporated in the respective legislation.

^c ISO 15189: 2022 medical laboratory accreditation: requirements for quality and competence.

^d Clinical Pathology Accreditation (United Kingdom) Ltd provides a means to accredit clinical pathology services and external quality assessment schemes.²⁶

^e A series of amendments (Title 42 Code of Federal Regulations Part 493: Clinical Laboratory Improvement Amendments) for establishing laboratory standards.²⁷

^f The College of American Pathologists accredits laboratories testing specimens from humans or animals using methodologies and clinical application within the expertise of the programme. Laboratories must be appropriately licensed to perform testing when required by law. College of American Pathologists accreditation meets the required Clinical Laboratory Improvement Amendments standards.

Fig. 1. Number of countries including each quality system essential in their health laboratory licensing process requirements, 18 countries, 2024

