LABORATORY LICENSING

An essential part of the national laboratory regulatory framework
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The laboratory sector is one of the core capacities that countries must develop for the implementation of the International Health Regulations [IHR (2005)] (1), because laboratory services play a major role in all the key processes of detection, assessment, response, notification, and monitoring of acute public health events.

In 2012, the World Health Organization (WHO) Regional Office for Europe launched the Better Labs for Better Health initiative to assist Member States of Eastern Europe and Central Asia in improvement of the quality and safety of their laboratory services (2, 3).

AREAS OF ACTIVITIES

To help countries achieve much needed reforms of their public health laboratory services, Better Labs for Better Health’s collaborative activities with Member States and partners focus on four areas:

AREA 1:
Development of national laboratory policies and strategic plans.

AREA 2:
Improvement of national training programmes and implementation of laboratory quality management systems.

AREA 3:
Establishment of networks for emergency preparedness and response.

AREA 4:
Advocacy, partnership and leadership.
Five Member States – Kyrgyzstan, the Republic of Moldova, Tajikistan, Turkmenistan and Uzbekistan – had formally committed to the Better Labs for Better Health initiative by 2015.

The first step was to support them in the development of their national laboratory policies and strategic plans by establishing formally recognized national laboratory working groups (4).

One of the key gaps identified through this process was the need to revise the governance and regulatory policies pertaining to health laboratories.

If properly implemented, licensing based on national and/or international laboratory standards ensures safe, quality laboratory operations and protects the public from substandard and unethical laboratory practices ¹.

Review of the relevant legislation should therefore be included in strategic or national public health programs to ensure development and implementation of laboratory regulations, as well as the allocation of the necessary funding from the national budget.

Laboratory licensing mechanisms and how licensing is applied vary from country to country. Laboratory staff, especially managers, should be familiar with the principal provisions and concepts of the most important laws and regulations that affect laboratories across their country.

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SCOPE AND PURPOSE OF “ESTABLISHING HEALTH LABORATORY LICENSING”

“Establishing health laboratory licensing” (further – “Establishing licensing”) describes the components needed and best practices to establish health laboratory licensing in order to help governments consider potential questions and address the challenges they might face when reviewing their legislation covering laboratories.

This document aims to provide support and offer guidance to national health authorities and national health laboratory focal points in their efforts to strengthen laboratory systems. It defines the regulatory requirements for registration, licensing, certification and/or accreditation of health laboratories, and applies to all health laboratories (public, private not-for-profit and private-for-profit). It explains the difference between certification and accreditation, and details how these can be used throughout the licensing process to implement quality requirements.

“Establishing licensing” also aims to help countries fulfil the IHR monitoring and evaluation framework (5) concerning laboratory licensing and the control of laboratory quality, including strengthening national compliance, specifically with regard to core capacity requirements to detect, assess, notify and report events in accordance with the IHR (as specified in Articles 5, 6, 7, 10 and 13) (1).

Article 3, Section 4 of the IHR specifies that Member States have the sovereign right to legislate and to implement legislation in pursuance of their health policies but should uphold the purpose of the IHR when doing so.

“Establishing licensing” can also be used to identify what can be included in national legislation concerning licensing.
TARGET AUDIENCE

The target audience includes personnel responsible for developing the licensing legislation in the Ministry of Health or other responsible authorities.

It also includes regulatory authorities in charge of laboratory certification under the Ministry of Health, national accreditation bodies and conformity assessment bodies.

This document will be also useful to officials planning and managing healthcare systems and to laboratory staff.
METHODOLOGY

This guidance document is based on a review and analysis of licensing legislation pertaining to health laboratories from 17 countries.

The approach taken allows comparison of legal requirements in these countries and observes different models of certification and accreditation, as well as comparing the countries’ approaches to regulating license requirements for tests, facilities, equipment, quality control, biosafety, etc.

It refers to the WHO “Laboratory biosafety manual” (6), which will be soon replaced by its fourth edition, WHO “European guidance on standards for infectious diseases laboratories” (7), and the WHO “Laboratory quality management system” handbook (8). More specific references applicable to each key element of “Establishing licensing” are provided in relevant sections of the document.

“Establishing licensing” is organized in three main areas:

- structure of the licensing legislation,
- substantive law considerations and
- procedural law considerations.

This subdivision was chosen because it represents the common legal structure of any legislation and can therefore help foster the implementation and enforcement of the health laboratory licensing legislation.
WHY IS LICENSING NECESSARY AND WHAT CAN LICENSURE OF HEALTH LABORATORIES PROVIDE?

The Better Labs for Better Health initiative carried out an assessment of public health laboratories in a number of Eastern European and Central Asian countries (3) that highlighted significant gaps in the following areas:

- national policy,
- strategic planning for laboratory services,
- sufficient and sustainable funding,
- training of laboratory staff,
- laboratory infrastructure (old and inadequately serviced equipment, a lack of essential reagents and consumables),
- biosafety and biosecurity management,
- quality management systems,
- quality assurance and quality control protocols.

Many of these key issues can be adequately addressed with the implementation and enforcement of an elaborated and comprehensive licensing legislation.

Licensure provides the legal basis on which many aspects of laboratory operation can be sufficiently regulated. It is therefore a valuable legal initiative for health authorities in streamlining and uniting different laws into one licensing act. Such licensing legislation also provides the head of a laboratory with a comprehensive and useful overview of legal requirements to operate a laboratory and provide laboratory services.
Legislation on licensing creates a tool for the health authorities to:

- make quality management a requirement for obtaining a license:
- a license can only be obtained if the laboratory meets quality management system (QMS) requirements, as stipulated in the licensing legislation;
- or if certification or accreditation and external quality assessment (EQA) programmes are compulsory in order to obtain/keep the license;
- ensure safe and secure laboratory environments by making biosafety and biosecurity a requirement for obtaining a license (biosafety should be related to premises, personnel, transportation of biological material/samples, etc., and follow WHO’s biosafety guidelines, to ensure continued compliance through a limited validity period of the license);
- gather complete and structured information and clarify management responsibilities of the laboratory;
- exercise control over the activities of licensees to ensure fulfilment of international obligations;
- promote effective laboratory referral networking (in-country and among countries) and enhance coordination;
- protect the public from substandard and unethical laboratory practices;
- regulate the number of laboratories in defined areas, as done by some countries with the use of the licensing legislation. By registering the laboratories and corresponding addresses, the licensing authority can control the number of laboratories being set up in different locations to reflect local population density. This can contribute to a better distribution of laboratories throughout the country, help improve general access to health services (9), and also help in promoting rational and evidence-based use of laboratory services by reducing duplications within the national laboratory system and thereby generating a cost-efficient system.
1. STRUCTURE OF THE LICENSING LEGISLATION

The health laboratory licensing legislation should cover procedural law and substantive law. This objective can be reached by either listing and defining all elements/requirements of the substantive law in the licensing legislation or referring to the applicable laws (e.g. to labour laws or safety laws). The procedural law part is in every respect necessary for establishing health laboratory licensing.

It remains the countries’ decision, what elements each country want to include in the procedural law part, and how each country want to structure their licensing legislation.

As described in the next section, there are various possibilities, how countries approached to structure their licensing legislation.

1.1 LEGISLATIVE APPROACHES TO REGULATING AND LICENSING LABORATORIES

There are three major legislative approaches to licensing of health laboratories. All approaches aim to set criteria or standards to control the operation of the laboratory, but they differ in the amount of laws and the level of complexity for the operators. The number and nature of the legal instruments that governments use to regulate the operation of health laboratories also varies notably.

The three licensing approaches are:

1. stand-alone licensing act,
2. general licensing act,
3. health insurance contract-based licensing.
1.1.1 Stand-alone licensing act

This approach concentrates the clear majority of regulatory aspects that govern health laboratories into one legislative act. The act is often accompanied by or includes a minimal list covering the criteria to ensure the quality and safety of the operations of the health laboratory or refers to the applicable norms for this purpose. The act covers the application process and the documents that must be submitted to the licensing authority. Through the act, the government regulates the reasons for granting or renewing licenses, limitations to the license validity period, the implementation of licensing control, and the suspension, renewal, termination and revocation of licenses. Certain requirements for staff and premises are defined, as are the responsibilities of the head of the health laboratory, and reporting responsibilities. This approach is used in, among other countries, Canada (province of Saskatchewan), France, Malaysia, Malta and the Philippines.

1.1.2 General licensing act

This approach sets up a hierarchy of different legal acts. The highest level represents legislation on the general aspects of licensing, which is supplemented by legislation on the licensing of medical activities. In most cases there is no legislation specific to the licensing of health laboratories.

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 activities, mostly accompanied by a document determining the required standards. In contrast to the stand-alone licensing act, this approach utilizes general guidelines for any medical activity or health facility. This means that it is often challenging for health laboratories to ascertain which laws apply and which standards to implement. To solve this problem, governments or laboratory associations establish guidelines or lists of minimum criteria. Although these documents are in some cases not legally binding, they provide a good basis for self-assessment.

This approach is used in, among other countries, Armenia, United Arab Emirates (Abu Dhabi), Kyrgyzstan, the Russian Federation, Ukraine and the United States of America.
1.1.3 Health insurance contract-based licensing

In countries with a long history of insuring people against ill-health, insurance companies have a significant influence on the development of medical practices and are keen on implementing cost-efficient procedures in health facilities. Because there were major problems with reimbursement of services provided by health laboratories in the last century [e.g. the United States (10)], insurance companies established rules and guidelines to ensure quality enforcement and conduct, and participation in external audits. The referral to the established rules and guidelines from the insurance companies are often validated as an obligation under health insurance legislation. Insurance contract-based licenses are based on a contractual relationship between the health laboratory and the insurance company.

The health insurance company uses standard contract forms that describe the requirements and standards for operation of the laboratory. These requirements can be stricter than requirements stipulated in legislation. In order to receive reimbursement, the service provider must comply with the terms of the contract. These could include mandatory participation in an accreditation program.

This approach is used in, among other countries, Austria, Germany, Luxembourg, Switzerland, and the United Kingdom.
The legal requirements concerning the structure, functions, personnel requirements and other related aspects for laboratories should be stated in a minimal number of legislative acts to facilitate their implementation. Preferably, there is a publicly available compilation of all applicable laws and regulations for laboratories.

Some countries regulate all these elements in their licensing legislation. Other countries regulate the elements of the substantive part in other parts of the legislation. The choice of which elements the licensing legislation of each country should include remains the country’s decision.
2.1 HEALTH LABORATORY OPERATIONAL REQUIREMENTS FOR OBTAINING A LICENSE

2.1.1 Laboratory equipment

Minimum requirements for installation, calibration, certification, use and maintenance of equipment (equipment management) based on safety, QMS and any other country-specific standards must be specified. The laboratory equipment requirements should stipulate that:

- equipment appropriate for performed or intended tests must be available,
- an updated list of all equipment and consumables must be maintained,
- equipment must be in good working order at all times. Regular inspection, service and cleaning of the used equipment is necessary. These duties should be recorded in a log-book and implemented as standard operating procedures (SOPs). These documentations shall be available at any given time, so that an unannounced inspection can assess the corresponding SOPs and records. Prior to operating a specific machine, an employee must be trained and instructed how to use the machine properly.

Legislation on laboratory equipment procurement should cover:

- procurement practices that facilitate bulk procurements and reduce costs, including:
  - consolidation and centralization of warehousing operations;
  - ensuring sustainable procurement (for example, buying LIMS software is expensive for one laboratory, but more affordable if several laboratories make a joint order and share the software);
  - creating inventory and distribution systems that are independent from authorities other than the laboratory related authorities;
  - availability of equipment for maintenance of the cold chain.

Some examples of best practice in procurement can be found in the WHO “Manual for procurement of diagnostics and related laboratory items and equipment” (11).
2.1.2 Human resources

Head of the laboratory

The head of a health laboratory shall be duly qualified, with appropriate training and experience. For certain laboratory services (e.g. genetics, forensics) the requirements can be stricter (e.g. must be enlisted as a medical doctor, with prespecified training time and experience level). In addition, the candidate’s criminal record should be reviewed.

Personnel

Legislation should reflect requirements for laboratory personnel and specify their qualifications. An important step in this regard is aligning the standard staff positions and qualifications with international standards.

Together with positions stipulated in sub-paragraphs 4.1.2.1 and 4.1.2.7 of ISO 15189:2012 (12) and Section 19 of the WHO “Laboratory biosafety manual” (6), the following personnel needs to be in place in laboratories:

- head of the laboratory,
- medical or scientific doctor,
- quality management specialist,
- biological risk specialist/safety specialist (in small laboratories without such a position the relevant functions are typically performed by the head of laboratory or the quality management specialist),
- laboratory specialist (bio-technologist, chemist-analyst),
- phlebotomist, unless linked to an entity with phlebotomists, such as a hospital,
- an engineer, unless linked to an ‘entity with engineers’ or maintenance contracts are up to date with competent firms/persons.

Any revision of the corresponding qualifications should be performed jointly by the national laboratory community and the health authority.
The use of health information systems (HIS), particularly laboratory information management systems (LIMS), to validate, manage, deliver, process, and store data should ease the traceability of the information throughout the laboratory testing workflow.

Before the use of LIMS, the following should be ensured:

- All rules and procedures related to data management, reporting, and aggregation are in line with Article 45 of IHR and national legislation for notifying WHO about emergencies;
- Information on test results can be exchanged vertically and horizontally within the laboratory services structure and with third-party authorities and organizations in emergencies;
- A legal basis is prepared for the transition of laboratories from paper-based information management to the use of electronic LIMS, including data reporting and sharing (I3).

Since the HIS is often regulated in many separate laws, it is more useful to make references in the licensing legislation to the applicable laws. Nevertheless, the inspection for the correct implementation and maintenance of an adequate LIMS might be led or supervised by the licensing authority. Therefore, the licensing law should give the mandate for inspecting the LIMS to the licensing authority and refer to the applicable health information legislation.
2.1.4 Quality management system

The licensing legislation should mandate quality management, and link certification/accreditation requirements and participation in EQA programmes to the licensing process. If certification or accreditation is not a requirement for the licensing, it is essential that the licensing legislation defines at least the minimal criteria for an adequate QMS. A suitable framework for these minimal criteria is the usage of the 12 quality system essentials (QSEs). These QSEs were adapted from the Clinical and Laboratory Standards Institute’s (CLSI) guideline for implementing quality management in clinical laboratories GP26-A3.2 (14); now revised and published under the name “A quality management system model for laboratory services” (15). How these QSEs should be implemented can be found in the WHO handbook “Laboratory quality management system” (8).

The 12 QSEs together cover all aspects of a QMS:

1. Organization
2. Personnel
3. Equipment
4. Purchasing and inventory
5. Process control
6. Information management
7. Documents and records
8. Occurrence Management
9. Assessment
10. Process improvement
11. Customer service
12. Facilities and safety.
Control of the laboratory quality through accreditation and certification

The certification/accreditation certificate can be a part of the package submitted to obtain a license. Unlike a license, certification and accreditation are official recognitions that a laboratory is, respectively, complying with specific requirements (certification) and is competent to provide service (accreditation). Certification and accreditation aim to ensure the safety and the quality of tests, while promoting a culture of continual quality improvement within the individual laboratory (16). Certification can be a useful tool to give a laboratory credibility by demonstrating that its services comply with recognized levels of quality. Accreditation is the most advanced level of public control in the conformity assessment system.

Accreditation is used in regulated sectors and voluntarily in other areas and increases trust in conformity assessment – also internationally. An accreditation certificate demonstrates the technical capacity of an organization and therefore the fact that it complies with the adopted standards.

Different models can be used to control the quality of laboratories through certification and/or accreditation:

- **Voluntary accreditation** against international laboratory standards (e.g. Finland, Ireland, Netherlands, most developing countries). Laboratories that wish to obtain an international recognition of quality may decide to get accredited against an international standard, but this process is not required by law.

- **Mandatory accreditation** against international laboratory standards (e.g. Australia, Canada, Dubai, France). All laboratories are obliged to obtain the specified accreditation. In this approach there may be a need for a transition period for the laboratories to prepare to meet the international standards.

- **A mixed model**: certain laboratories are subject to mandatory accreditation against international laboratory standards (e.g. reference and centralized laboratories, etc.), whereas accreditation is voluntary for other laboratories. These other laboratories typically must comply with national laboratory standards to obtain certification (e.g. Belgium, Thailand, some states in the United States of America).

WHO recommends that countries with limited resources should have national laboratory standards as a minimum requirement, while national reference laboratories are encouraged to aim at meeting international standards such as ISO 15189 (17, 18). A minimum set of requirements/standards for laboratories seeking to implement QMS can be found in the WHO “European guidance on standards for infectious diseases laboratories” (7).

The choice of the approach remains the country’s decision and whatever approach is chosen, it should be integrated into the licensing process.
The accreditation/certification process of the health laboratory

In the accreditation process, a laboratory is visited by representatives from an accreditation body which has itself been accredited by ISO 17011:2017 (19). The fact that the accreditation body is accredited ensures an impartial and objective process providing the most transparent and internationally recognized way of providing trustworthy conformity assessment results. The health laboratory accreditation can be recognized internationally, if the standard used to accredit the laboratory is equivalent to ISO 15189 (for instance) and if the accreditation body has a mutual recognition arrangement (MRA) with other accreditation bodies.

In the certification process, a laboratory is visited by representatives of a conformity assessment body or authoritative body. It is not compulsory for the inspecting organization to be accredited. The fact that the authoritative body is not accredited does not necessarily mean it is not reputable, but it does not provide independent confirmation of competence.

The International Laboratory Accreditation Cooperation

The International Laboratory Accreditation Cooperation (ILAC) is the international organisation for accreditation bodies operating in accordance with ISO/IEC 17011 (19) and involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025) (20), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189) (12), inspection bodies (using ISO/IEC 17020) (21) and proficiency testing providers (using ISO/IEC 17043) (22).

Accreditation bodies around the world, which have been evaluated by peers as competent, have signed an arrangement that enhances the acceptance of products and services across national borders. The purpose of this arrangement, the ILAC MRA, is to create an international framework to support international trade.

Each accreditation body that is a signatory to the ILAC MRA commits to (23):

- maintain conformity with the current version of ISO/IEC 17011 “Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies”;
- ensure that all laboratories and inspection bodies that are accredited comply with appropriate laboratory and inspection bodies standards (currently ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories”, ISO 15189 “Medical laboratories – Requirements for quality and competence”, and ISO/IEC 17020 “Conformity assessment – Requirements for the operation of various types of bodies performing inspection”).

National accreditation by national accreditation body can be recognized internationally if an MRA is in place. This MRA could happen only, if the standard used is an international standard or equivalent to it (24).
Integration of accreditation and certification in the licensing process

The technical regulation authorities in charge of the development of the licensing requirements and corresponding legislation should collaborate with the health authorities to ensure that laboratory quality requirements are implemented using national and/or international laboratory standards.

There are two options for integrating laboratory standards into the licensing process:

- Include references to the applicable laboratory standards (e.g. guidelines from an independent community, minimal criteria list from the health authority, mandatory accreditation against ISO 15189) in the licensing legislation;
- Set out the laboratory standards in the licensing legislation and include them as licensing requirements. In contrast to the first option, the political decision-makers and the legislator integrate the standards into national legislation.

Countries that have implemented mandatory certification/accreditation have had at least the following three elements in place:

- A policy framework that makes certification or accreditation a requirement for laboratories,
- Defined quality standards against which laboratories can be assessed,
- Conformity assessment bodies authorized to assess laboratories and their performance against the designated quality standards.
International standards

International standards have been developed to allow international recognition of quality, such as the standards from the International Organization for Standardization (ISO), the International Society for Quality in Health Care (25), the Joint Commission International (26) and the CLSI, formerly the National Committee on Clinical Laboratory Standards.

ISO published these documents relating to the accreditation process of health laboratories:

- ISO 15189:2012 “Medical laboratories -- Requirements for quality and competence” (12),
- ISO/IEC 17025:2017 “General requirements for the competence of testing and calibration laboratories” (20).

The CLSI published the following documents that are relevant to QMS in medical laboratories:

- HS1-A2 “A quality management system model for health care”, 3rd ed. (27),
- QMS01 “A quality management system model for laboratory services”, 5th ed. (15).

National standards

National standards have been developed by some countries to be closer to the needs of laboratories within the country. These standards are used as regulatory standards to introduce quality management in laboratories and are largely based on international standards.

Certification standards

The ISO 9001:2015 “Quality management systems – Requirements” (28) is used by organizations to demonstrate their ability to consistently provide products and services that meet customer and management requirements and to demonstrate continuous improvement, while the ISO 15189 and ISO 17025 focus in addition on technical requirements (being competent in providing reliable results).
WHO has long recognized that biosafety and biosecurity are important international issues. Working in laboratories involves a high risk of exposure to various chemicals, infectious materials, fire hazards, gas leaks, etc. The environment is also at risk of contamination from both the hazardous materials used and the wastes generated in the laboratory. Safety in laboratories, therefore, includes protection of both the staff and the environment from hazardous materials.

Biosafety and biosecurity legislation applied to laboratories should cover:

- alignment between the country’s terminology and international standards; this will help to develop a common understanding of the terms used;
- harmonization of the requirements for transportation of samples with the UN Model regulations for the transport of dangerous goods (29);
- possibility of sharing with WHO and international referral laboratories biological materials, including pathogens, for verification and public health response purposes in accordance with the Article 46 of IHR;
- requirements for premises that ensure a safe working environment and sufficient space to allow for biosafety activities during laboratory operations;
- requirements for infectious waste management;
- precautions for fire safety, for the storage of flammable liquids, for compressed and liquified gases, for electrical hazards and for chemical or radioactive substances.
The following key international documents can be used for implementation of biosafety and biosecurity requirements:

- Laboratory biosafety manual (6) (a new edition of the “Laboratory Biosafety Manual”, with a risk-based approach, will be published);
- WHO guidance on implementing regulatory requirements for biosafety and biosecurity in biomedical laboratories – a stepwise approach (in press) (this document guides the reader step by step to develop a national regulatory framework for biosafety and biosecurity in biomedical laboratories);
- Biorisk management. Laboratory biosecurity guidance, WHO (30);
- Safety in health-care laboratories, WHO (31);
- Guidance on regulations for the transport of infectious substances 2019–2020, WHO (32);
- UN Model Regulations on the transport of dangerous goods (29);
- ICAO Technical instructions for the safe transport of dangerous goods by air (46);

International standards for biosafety:

- ISO 35001:2019 “Biorisk management for laboratories and other related organisations” (33),
2.1.6 *Health laboratory building requirements*

Laboratory premises should be officially owned or leased with related documents available.

The infrastructure of laboratories should be planned according to the type of services provided, and basic infrastructure facilities should include but not be limited to:

- reception room/area;
- specimen collection room/area, with nearby toilets;
- specimen/sample/slide storage room/area including cold storage, where applicable;
- water supply suitable for analytical purposes;
- adequate power supply;
- analytical work area;
- dedicated area for cleaning laboratory glassware and sterilization/disinfection;
- designated areas for the collection of medical wastes, general storage for supplies and equipment, in addition to a storing area/cabinet for hazardous materials (these must be clearly labelled);
- adequate ventilation, climate control and lighting arrangements;
- separate room/area for meetings/administrative work;
- separate facilities/area for staff for hand washing, eating and storing food, drinks, etc.

The licensing legislation should stipulate that if premises are renovated or modernized in a way that might impact the safety of operations, the license must be renewed (see sub-section License Renewal in Section 3.3.3).
2.1.7 Management responsibilities

Management must show that it can maintain a high standard of operation. Before the license can be obtained, the management can be required to demonstrate that it is capable of the following responsibilities (35):

- developing a mission, vision and scope for the health laboratory;
- ultimate responsibility for the safety of personnel and for ensuring safe practices;
- ultimate responsibility for the quality of the health laboratory service;
- controlling that all healthcare professionals working in the laboratory hold current and appropriate qualification certificates and have the necessary training and skills to deliver the services provided;
- assigning qualified persons or a team to manage and review fire safety, quality control and biosafety/biosecurity precautions.

Optional:
- providing documentation and a policy for waste management;
- ensuring consistency of the laboratory’s service contracts;
- ensuring that staff authorized to sign test results and allowed to interpret test results are qualified for these tasks; the level of authorization should be clear to all personnel and be under constant supervision by the head of the laboratory;
- ensuring the ongoing participation in EQA and communication of the performance to the staff;
- providing possibilities for continuing professional development of all laboratory personnel;
- supporting the development of policies and procedures to assist the laboratory to provide safe and quality service and appointing responsible staff to develop and review the organization’s documents;
- supervising and reviewing the documentation on quality control, corrective actions, policies and procedures;
- strategic planning of the health laboratory service and the direction of development of the services to be provided;
- implementing and supervising laboratory reports and data management;
- establishing a grievance mechanism for clients, which includes the possibility of expressing dissatisfaction or concerns about the health laboratory service;
- taking action to prevent recurrent problems;
- reporting any unforeseeable or unexpected health-related incidents to the health authorities.
3. PROCEDURAL LAW CONSIDERATIONS

3.1 LICENSING AUTHORITY

3.1.1 Responsible authorities for the licensure process

The licensing legislation must clearly define the following points:

- which authority oversees licensing authority (that might be a unit within a health authority or several units/authorities, e.g. a Ministry of Health unit in charge of the licenses for private and hospital laboratories, and a public health authority for the licenses for public health laboratories);
- the roles and responsibilities of the licensing authority and the division of responsibilities among authorities, if several authorities/units are involved;
- whether the authority issuing licenses should operate at national or at state/regional/local levels;
- the arbitration body and the type of court that shall be appointed to handle legal disputes between the licensing authority and the laboratory;
- the authority that is mandated to control and investigate compliance with legal requirements;
- the agencies in charge of accreditation or certification, if accreditation or certification is a licensing requirement.

Whichever authorities have been designated, the legislation should stipulate the following:

- The licensing authority should have the right to carry out scheduled and unscheduled inspections of licensed laboratories. Random inspections should be allowed on reasonable grounds, such as patients’ complaints, incidents in the laboratory, failure under EQA schemes, etc.
- It should be mandatory to implement recommendations deriving from assessment visits. If not implemented, measures such as temporary suspension of operations and license revocation should be stipulated.
However, such control mechanisms should correlate to and be in line with legislation promoting the removal of administrative barriers for business and the prevention of corruption. For instance, online application for the license could help to reduce the length of the license application process and make it more transparent.

### 3.1.2 Roles and responsibilities of the licensing authority

The licensing authority should be perceived more as a partner assisting with fulfilment of all the requirements and standards, than as a controlling authority. It should foster compliance with legislation by providing required information to the health laboratories and should give advice whenever the laboratory requests it. It should therefore be obliged by law to gather, analyse and publish information regarding legitimate operation of a health laboratory, and laboratories should be obliged to provide such an information.

The legislation should give the licensing authority the right to grant, refuse, temporarily suspend or ‘revoke a license, and to impose appropriate penalties. Decisions to grant or refuse to grant the license shall be bound to the reasons stated in the licensing legislation or in the respective regulations.

The licensing authority should be required to publish regulations on the standards and requirements for obtaining a health laboratory license.

The legislation should give the licensing authority the right to inspect and control compliance of the health laboratories with the requirements and standards stipulated in the licensing legislation. The inspection and control can be assigned to a body or an authority. In this case the licensing authority has to supervise the assigned body or authority. The duties and competences of the inspectors must be defined in the licensing legislation, as well as how an onsite inspection has to be conducted.

Likewise, the licensing authority should have the power to demand an initial registration and application request from all the existing health laboratories within a specified period (e.g. 6 weeks), following the enforcement of the licensing legislation.

The licensing authority should maintain and publish a list of all registered and licensed health laboratories.
3.2 SCOPE OF THE HEALTH LABORATORY LICENSE

The license for operating a specific laboratory can include a wide range of different laboratories. The health laboratory itself could be part of a hospital or diagnostic centre or be providing an independent service. The laboratory facility could be a freestanding building or integrated into a hospital complex. The ownership structure could be in the public or private sector, or in a combination of both. A health laboratory can also be classified by the scope of service that it provides (different class and specialty).

3.2.1 List of licensed activities/types of tests

Activities and types of tests performed by a laboratory can be licensed in the following ways:

- a general license under which tests performed by the laboratory are not specified in the licensing legislation;
- a detailed list of tests to be performed by the laboratory is specified in the licensing legislation;
- certain classes of specific tests to be performed by the laboratory are specified in the licensing legislation (e.g. simple, moderate and high complexity tests).

In the general license application process, licensing authorities can review the list of performed tests as a separate document within the license application package.

In the case where licensing legislation specifies the tests laboratories must perform in order to be licensed, it is recommended that the list of laboratory tests should not to be limited to specific activities only but should also include a category named “other activities” or “other tests” (these are called an open list). The open list allows any additional test to be listed in the application and be legitimately covered by the licensing legislation, which avoids amendments to the licensing legislation whenever new types of tests and more advanced technologies need to be implemented.
3.3 ADMINISTRATIVE PROCESS FOR OBTAINING AND MAINTAINING A LICENSE

3.3.1 General application process for obtaining a license

The usual application process might include two steps:

- registering with the Ministry of Health or any designated authority (e.g. licensing authority) – in some cases this process is accompanied by a preliminary approval of some kind;
- application for a license to operate a laboratory or provide a health laboratory service after registration has been completed.

Application in some countries is limited to one step, and registration is done when the application is being processed.

3.3.2 Step 1: Registration with the licensing authority

The first step is the registration process (sometimes called preliminary licensing, authorization or the approval process) for the laboratory. In this process the licensing authority collects information about the laboratory and controls its compliance with the relevant regulations.

The status (name, ownership, location and head of the laboratory) of all health laboratories (government-owned and private) is requested and documented in a register. In some countries the modus for applying is paper-based, in others it can be paper-based or online, and in some countries only online application is possible.

The registration document is only valid for a specified period. The management of the laboratory must apply for the license (sometimes called a permanent license or license to operate) during this period. Upon request, the period can be prolonged by the licensing authority.

The initial registration and review of the legal requirements for the health laboratory can have two different implications:

- It provides a legal basis for the laboratory to establish its service. The registration does not authorize providing service to clients.
- It provides the legal basis to establish the laboratory and provide service to clients. This option is used when accreditation or certification is mandatory for obtaining a license. Since accreditation can only be properly evaluated in daily operations, the laboratory has to provide service to clients prior to the license application. The legal requirements for registration in this scenario are stricter and often accompanied by an onsite inspection.
Successful registration does not oblige the licensing authority to license the health laboratory.

**Application for registration of the health laboratory**

The laboratory must apply for its registration to the licensing authority prior to the effective start of operations. It should be unlawful to provide service without registration. Prior to the application for registration, some consultations with authorities (construction and building authority, tax authority, trade authority) should be required and approvals to build or establish the laboratory obtained.

Licensing legislation can specify registration fees for registration and these fees can include onsite inspection.

The application for the registration should be accompanied by the registration form and all documents required by the licensing legislation. If particular documents lack information or provide insufficient information, the licensing authority should specify a period within which the applicant must submit the necessary information; and if the necessary information is not submitted on time, the application should be considered withdrawn, and the applicant must submit a new application. The licensing authority can also ask for further information based on legal grounds.

Depending on the chosen process, the licensing authority can demand an onsite inspection in the registration process as a legal requirement. The result of this inspection should be clearly communicated to both the licensing authority and the management of the laboratory, and corrective actions should be suggested.

If an application for registration is rejected by the licensing authority, the licensing authority should provide reasons and, if applicable, offer suggestions for corrective actions.
### List of documents and information required for registration

According to international practice, a registration package for health laboratories should include the following:

- application form (template provided by the licensing authority);
- the address or addresses of the laboratory facility and its subordinates;
- the name of the owner or person(s) leasing the laboratory facility; if applicable the rental/leasing agreement;
- the names of all persons who have a material financial interest in the laboratory facility and, if the persons are shareholders, the percentage of the shares that they own;
- the name and contact information of the person responsible for the daily operation of the laboratory facility;
- information about any existing or potential conflict of interest that the applicant may be aware of;
- a floor plan showing the laboratory layout, with each room numbered and labelled, as well as documents containing fire-safety, biosafety and biosecurity precautions, accompanied by an approval document from the building and construction authority;
- a list of all laboratory tests that are proposed to be provided by the laboratory facility;
- a description of the function and capacity of major equipment to be used in the laboratory facility;
- the proposed hours of operation of the laboratory facility;
- the proposed number of employees including arrangements for employee training;
- information on involvement in accreditation or certification activities;
- information on EQA programmes in which the laboratory participates;
- information on SOPs, and mission and vision statements;
- information on handling medical wastes, accompanied by a (preliminary) contract with a refuse collection company;
- documentation of malpractice insurance for the management of the laboratory.
The request for the following information is optional:

- list of animals used or intend to be used in the daily operation of the laboratory,
- registration certificate with the tax authority,
- the proposed laboratory information management system,
- financial calculations and considerations.

**Criteria for rejecting registration of a health laboratory**

The licensing legislation must clarify the criteria for rejecting a health laboratory’s application. These criteria provide the legal basis for the licensing authority to reject an application and generate transparency for both parties.

If an application to register a health laboratory through the licensing authority is rejected, a detailed list of issues and, if applicable, a list of corrective actions should be provided. The license applicant can then resubmit the application with applicable fees.

The health authority can define and stipulate several grounds for refusal in the licensing legislation. For instance, the grounds could be (36):

- There is no demand for an expansion of the laboratory services (see Section 3.4 Assessing the need for laboratories).
- The applicant is not able to provide the intended laboratory service.
- The applicant is not of good character, i.e. has been convicted of an offence involving fraud or dishonesty, is an undischarged bankrupt (if the applicant is a sole proprietor).
- The partners are not of good character, i.e. a partner has been convicted of an offence involving fraud or dishonesty or is an undischarged bankrupt (if the applicant is a partnership).
- The applicant has not implemented adequate and efficient management, and an administration structure to support the proper conduct of the laboratory service.

**Legal identity and facility name**

The licensing legislation must clearly state, whether natural persons and/or the health laboratory as a legal entity can acquire licenses.

The initial registration process for a new health laboratory can provisionally be under the name of the laboratory owner. Decisions from the licensing authority about the health laboratory’s registration will be therefore directed to the laboratory owner as a natural person, since the laboratory cannot be established as a company. Therefore, it is useful to dedicate one paragraph in the licensing legislation to this issue, so that not only established companies, but also natural persons can apply for the initial registration. The name of the facility must be carefully chosen and should not mislead the public in any way regarding the extent and type of service the health laboratory provides. Once the facility name is chosen, it should not be permitted to change it without the licensing authority’s prior approval (35).
3.3.3 Step 2: Licensure of the health laboratory

The second step is the licensure process of the laboratory, during which the licensing authority verifies the information collected during the registration process and collects new information from the laboratory, preferably from the daily operations.

Usually, a license is a special permit for a legal entity or an individual to carry out specific activities. It is supported by a document issued by the licensing authority on paper or in digital form.

The license provides the legal basis for the management of the laboratory to operate the laboratory.

Licensing process

The laboratory should apply to the licensing authority for the license for provision of the laboratory service after the laboratory is registered with the licensing authority, except the countries, where registration is not required.

Licensing legislation usually specifies fees for the licensing process. These fees can include onsite inspection and should be paid during the application process.

The application for the license should be accompanied by the licensing application form, the registration certificate, if registration is required, and all other documents required by the licensing legislation. If documents lack information or provide insufficient information, the licensing authority should specify a period within which the applicant must submit the necessary information; and if the necessary information is not submitted on time, the application should be considered withdrawn, and the applicant must submit a new application. The licensing authority can also ask for further information based on legal grounds.

During the licensing process the licensing authority usually performs or arranges an onsite inspection. The result of this inspection should be clearly communicated to applicant and corrective actions should be suggested. If the licensing legislation requires accreditation or certification, the onsite inspection should be performed by the accreditation or certification body. The inspection body should be obliged to share any information on the result with the licensing authority but should not be permitted to give any information to third parties.

If an application for the license is rejected by the licensing authority, the licensing authority should provide reasons and offer suggestions for corrective actions.

The license should be granted if every requirement is fulfilled and the licensing authority is satisfied that the operation of the health laboratory will provide a safe, secure and quality-driven service.
List of documents and information required for licensing

According to international practice, a licensing package for health laboratories could include the following:

- application form (template provided by the licensing authority);
- initial registration (also called authorization, approval or preliminary license) letter from the licensing authority (if it is required by legislation) or if registration is not required and licensing is done in one step – documents listed under the 2nd–7th bullets in the sub-section “List of documents and information required for registration”, section 3.3.2 “Step 1: Registration with the licensing authority”;
- confirmation of payment of the prescribed licensing fee;
- list of personnel containing information about their names, qualifications and experience;
- malpractice insurance certificates for all personnel;
- list of provided tests;
- information on successful voluntarily involvement of the laboratory in accreditation or certification process; if the laboratory is obliged to be accredited/certified, the confirmation of the successful participation in the accreditation or certification process;
- information on the laboratory’s contracts and arrangements with external services and suppliers;
- a description of the function and capacity of major equipment to be used in the laboratory facility.
Further optional information includes:

- a list of the animals in use;
- documentation on the laboratory’s electronic health care system connection and service agreement with the IT service provider;
- list of the laboratory’s consumables, reagents and stock of antidotes;
- the laboratory's SOPs and documentation covering the laboratory’s policies, mission and vision;
- documentation on the laboratory’s quality management system;
- documentation on the laboratory’s biosafety and biosecurity measures;
- documentation on the laboratory’s LIMS and HIS.

Criteria for rejecting a license application

As in the registration process, the licensing legislation must clarify the criteria for rejecting an application to license the health laboratory. These criteria provide the legal basis for the licensing authority to reject an application and generate transparency for both parties.

If a license application is rejected by the licensing authority, a detailed list of issues and, if applicable, a list of corrective actions should be provided. The license applicant can then resubmit the application with applicable fees.

There can be several grounds for refusal that the health authority can define and stipulate in the licensing legislation. The following is an overview of possible considerations:

- The applicant has not registered with the licensing authority, if such a registration is required by legislation.
- The applicant is not capable of providing the offered laboratory service.
- The applicant has not implemented adequate and efficient management and an administration structure to support the proper conduct of the laboratory service.
- The applicant does not fulfil all requirements stipulated in the licensing legislation.
License renewal

The license renewal process is used in two different scenarios:

- when the laboratory is obliged to renew its license due to the expiration of the license's validity period;
- whenever there is a change that has a lasting effect on the operation of the laboratory (e.g. planning to build additional laboratory capacity, offering different tests, etc.).

Compared to a new application, the renewal process should take less time and the application fees should be lower. If an onsite inspection is needed, additional fees can be charged. The application process should be clearly described in the licensing legislation and preferably accompanied by a short explanatory document for the laboratory owners.

If the requirements for the renewal of a license are fulfilled, the licensing authority should renew the license for the period specified in the licensing legislation (e.g. one or two years). In some instances (e.g. voluntarily participation in an accreditation process of the health laboratory) to be defined by the licensing authority, the legislation could allow for prolongation of the license validity period without going through the full license renewal process.

License validity period

The validity period of the license ensures consistency in compliance with legal obligations. Licenses are usually issued for a period of one to two years to have regular control of whether the laboratories are still fulfilling the licensing requirements. An application for a renewal of the license should be made prior (e.g. 30 days) to the expiration of the license.
ALTERATION OF THE LABORATORY OPERATION

A licensee should be required to notify the regulating authority within fourteen days of the occurrence of any change in the operation of the licensed laboratory. The regulating authority should provide a comprehensive list of conditions for which the licensee must notify the appropriate authority. For example, the replacement of head of the laboratory, or a change of entity, premises or ownership should require an application for a renewal of the license; failing this the license should be automatically revoked within a specified period of time after the change.

LICENSE EXPIRATION

The licensee’s failure to file an application for the renewal of the license within the specified time should result in the expiration of the current license upon the license’s last effective date. Continued operation after expiration of the license should result in financial penalties and in prosecution as a legal offence.

TEMPORARY SUSPENSION OR REVOCATION OF THE LICENSE

The licensing authority should be empowered to suspend or revoke any license or authorization that it has issued. If the continuing operation of the health laboratory poses an imminent risk to the safety of patients or the personnel, the licensing authority should be empowered to issue an order revoking the laboratory’s license. An inspection team should help resolve the issues and provide guidance to the health laboratory management. If the same issues appear repeatedly, the licensing authority should cancel the license and ban the laboratory from making a new application.
Voluntary cancellation of the license

In the case of voluntary cancellation of the provided service, the laboratory management should be required to make a formal cancellation request to the licensing authority. Because health laboratories have to keep both records and materials from patients for a prolonged period, a safe and secure process for the cessation of a health laboratory should be developed and published by the health authority. Ensuring security and integrity of patient data, as well as ensuring that transport of any patient’s material will not result in its deterioration, are key challenges that should be adequately addressed. The request for cancellation of a laboratory service should therefore be made prior (e.g. 50 days) to the license’s last effective date. Legislation should stipulate that the management of the health laboratory must comply with these regulations.

Replacement of the head of the laboratory

If an upcoming replacement of the head of the laboratory is planned, the licensee should be obliged to notify the licensing authority prior (e.g. 14 days) to the change. The information provided to the licensing authority should include the reasons for the change, the coming head of the laboratory’s name, previous positions, criminal record, education, prior training and experience.

Licensing and registration fees

The licensing legislation can prescribe licensing and registration fees. These fees should cover the costs of onsite inspection for the registration process and the licensing process, as well as the costs for the entire administrative process in the background. Usually, the licensing fees cover the licensing authority’s operating costs. Consequently, the operation and maintenance of the licensing authority should not lead to further costs for the government.

The licensing legislation should also regulate reinspection, including how the fees should be paid and in what periods. Licensing legislation can in some cases allow for an increase (e.g. capped in the legislation at 20 percent maximum) of the prescribed fee, if the administrative process is more complicated than normal (e.g. the license applicant forgets to send the right documents or sends documents with errors), or if the process of inspection is only possible with specific constraints (e.g. license applicant does not prepare the necessary papers for the inspection or forgets the appointment).
3.4 ASSESSING THE NEED FOR LABORATORIES

The assessment of a new laboratory within the registration or licensing process provides the health authority with a legal instrument to regulate the number of new laboratories in a certain area. The following preconditions for an effective assessment process must be fulfilled:

- The demand for laboratories must be clear and should be evaluated and adapted on a continuing basis, based on a nation-wide health plan. This plan shall be made public, so that new applicants have the possibility to see the demand in a certain area.
- In order to avoid abuse, the grounds for rejecting an application for registration of a new laboratory must be clearly set in the licensing law.
- The possibility of opposing applications for registration could lead to a legal dispute. Therefore, the licensing authority has to implement and validate an arbitration process, as well as give the mandate to the relating arbitration body/court.

Investigative body: legislation in some countries assigns the authorization to evaluate the need for another laboratory to the head of the health authority (e.g. Canada, France, Malaysia) or to an independent agency (e.g. Austria – Gesundheit Österreich GmbH).

The assessment criteria can be included in the licensing legislation or the legislation can mandate an authority to establish such criteria. This list should provide a comprehensive overview, but is not limited to the below mentioned criteria:

- number of existing facilities and provided tests (e.g. can be exceeded max. 25-50% higher as suggested in the national health plan),
- location of the new laboratory (including the distance between related laboratories),
- class and specialty of proposed tests,
- number of samples collected, transported and referred,
- cost of providing and developing additional testing,
- the effect on the quality of patient care and access to care, etc.

As certain aspects of the assessment are not necessarily based on hard facts, it is an advantage to authorize an independent body to perform the assessment. This independent body can assess the need from an objective point of view, while being guided by the objectives from the health authority’s national health plan.
The following issues can potentially be included in the licensing legislation:

- **Regulations**
  - specimen collection, transportation and referral policies,
  - mandatory immunization of laboratory personnel,
  - supplies and stocks of consumables,
  - handling and reporting shortages of consumables,
  - procurement practices for laboratory equipment and consumables,
  - advertising the health laboratory services,
  - developing capacities to rapidly acquire the necessary supplies in emergency situations;

- **Processes onsite inspection,**
  - modification of the laboratory service due to an additional class and specialty, or to a discontinued class or specialty,
  - temporary closure of the health laboratory,
  - reviewing/implementing effective systems for delivering supplies;

- **Authorization to seize a laboratory’s equipment;**

- **requirements for laboratory budget preparation in compliance with international standards, to support and improve effective and efficient budget planning;**

- **establishing a small national stock of reagents and consumables for immediate use in an emergency.**
## TERMS AND ABBREVIATIONS

### TERMS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Accreditation</td>
<td>Procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks (37).</td>
</tr>
<tr>
<td>Accreditation (and certification) body</td>
<td>An organization or agency with the authorized right and authority to inspect a facility (e.g. laboratory) and provide written evidence of its compliance (certification) and competence (accreditation) with a standard (8). According to the ISO definition, the accreditation body is an accredited organization or agency and the certification body is an organization or agency with an authorized right and authority that can choose whether or not to be accredited (37).</td>
</tr>
<tr>
<td>Biosafety</td>
<td>Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release (30).</td>
</tr>
<tr>
<td>Biosecurity</td>
<td>Laboratory biosecurity describes the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their loss, theft, misuse, diversion, unauthorized access, or intentional release, whether or not the bio risk(s) is acceptable (30).</td>
</tr>
<tr>
<td>Certification</td>
<td>The provision by an independent body of a written assurance (a certificate) that the product, service or system (e.g. laboratory) in question meets specific standards (37).</td>
</tr>
<tr>
<td>Conformity assessment body</td>
<td>A body that performs conformity assessment activities including calibration, testing, certification and inspection (38). <strong>Note</strong>: conformity assessment activities performed by conformity assessment bodies include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification.</td>
</tr>
<tr>
<td>Head of the laboratory</td>
<td>The legal representative of the laboratory, usually the owner or medical director of a health laboratory. Can be different from the license applicant or the licensee.</td>
</tr>
<tr>
<td>Health laboratory</td>
<td>Any specialized facility that performs laboratory testing on specimens to provide information for achieving defined health-related purposes, such as medical diagnostics, disease surveillance, food quality control and research (8). For the purpose of this document, a more general definition of “health laboratories” is used to include other laboratories performing functions related to the health sector. These include government-owned, public health laboratories and private medical laboratories.</td>
</tr>
<tr>
<td>License</td>
<td>A special permit to carry out specific activities as a legal entity or an individual that is supported by a document issued by the licensing authority on paper or in digital form.</td>
</tr>
<tr>
<td>License applicant</td>
<td>A legal entity or an individual applying to the licensing body for a license.</td>
</tr>
<tr>
<td>Licensee</td>
<td>A legal entity (private, public or governmental) or an individual holding a license.</td>
</tr>
</tbody>
</table>
**Licensing**

The activity of licensing bodies for granting and renewing (if a limited license validity period is stipulated by law) a license, the implementation of licensing control mechanisms, suspension, termination and revocation of licenses, formation and maintenance of the register of licenses.

**Licensing authority**

A public organization authorized by law and, if applicable, its territorial branches engaged in licensing.

**Licensure**

The granting of ability to practice, usually provided by a national agency. Licensure is usually based on demonstrated knowledge, training and skills. Generally, when laboratory licensure is used, it is a legal requirement for operation (8).

**Minimum set of requirements**

A list of defined criteria governing the operation of a health laboratory. This list constitutes the minimum acceptable state of the laboratory operation.

**Mutual recognition arrangement**

An agreement signed by the signatory accreditation bodies to recognise the equivalence of the accreditation programs operated within the scope of their signatory status (39).

**Procedural law**

Legal rules that govern the process for determining the rights and obligations of involved parties (40).

**Standards**

Requirements for the regulation of processes are recorded in documents called “standards”. National and international quality standards are developed and maintained by several organizations (12).

**Substantive law**

Legal rules that determine the rights and obligations of individuals and collective bodies (40).

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**ABBREVIATIONS**

- **CLIA** Clinical laboratory improvement amendments
- **CLSI** Clinical and Laboratory Standards Institute
- **EQA** External quality assessment
- **HIS** Health information system
- **IHR** International Health Regulations (2005)
- **ILAC** International Laboratory Accreditation Cooperation
- **ISO** International Organization for Standardization
- **LIMS** Laboratory information management system
- **MRA** Mutual recognition arrangement
- **QMS** Quality management system
- **QSE** Quality system essential
- **SOP** Standard operating procedure
- **WHO** World Health Organization
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REFERENCES


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- Governmental Resolution of Republic of Armenia on approval of the licensing procedures for drug production, pharmacy business and implementation of medical care and service, as well as for curricula of medical education in colleges and universities, and the licensing forms of carrying out the mentioned activities # 867, dated June 29, 2002.

Australia

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The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

Member States:

Albania
Andorra
Armenia
Austria
Azerbaijan
Belarus
Belgium
Bosnia and Herzegovina
Bulgaria
Croatia
Cyprus
Czechia
Denmark
Estonia
Finland
France
Georgia
Germany
Greece
Hungary
Iceland
Ireland
Israel
Italy
Kazakhstan
Kyrgyzstan
Latvia
Lithuania
Luxembourg
North Macedonia
Malta
Monaco
Montenegro
Netherlands
Norway
Poland
Portugal
Republic of Moldova
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