

Decree-Law No 39-2008

of October 29

**ORGANIC STATUTE OF THE
NATIONAL HEALTH LABORATORY**

The Organic Statute of the Ministry of Health, approved by Executive Order no. 1/2008 of January 16, in its article 17, refers to the *Laboratório Nacional de Saúde* [National Health Laboratory] as a integrated service of the indirect administration of the State and constituted as a corporate and legal body governed by public law, with administrative, financial and patrimonial autonomy, therefore requiring an organic statute, as foreseen in no. 3 of the same article 17;

The Government therefore orders hereby, under the provisions of no. 3 of article 115, item (d) of article 116 of the Constitution and no. 3 of article 17, Executive Order no. 1/2008, of January 16, to be valid as law, the following:

**CHAPTER I
GENERAL PROVISIONS**

**Article 1
Scope of Application**

This statute approves the legal regimen applicable to the National Health Laboratory (*Laboratório Nacional de Saúde*), designated as LNS in abbreviated form.

**Article 2
Nature and Regimen**

1. The LNS is a corporate body governed by public law operating as a public institute with administrative and financial autonomy and its own assets, subject to the tutelage and superintendence of the Minister of Health.

2. The LNS is governed by this statute and by the legal provisions eventually and directly applicable to it, as well as by the standards of the National Health Service and, subsidiary, by the standards applicable to the organisms of the indirect State administration.

Article 3

Attributions and Competencies

1. The LNS is responsible, at the national level, for ensuring the provision of high quality laboratory services to the population, for the technical supervision of the work performed by the laboratories integrated to the national health system, and for operating as a model center for laboratory tests.

2. The following are specific duties of the LNS:

- a) Establish technical standards for the provision of laboratory services and provide guidance for their implementation;
- b) Supervise the provision of laboratory services within the National Health Service;
- c) Ensure mechanisms for quality control of all laboratories within the national health system;
- d) Ensure excellence in its operations as a model center for the national health system.

Article 4 Tutelage

1. The LNS is under the superintendence and tutelage of the Minister of Health, who will have the following duties:

- a) Establish all the standards and general criteria for laboratory work in the health arena;
- b) Establish the guidelines to govern all plans and action programs monitor their execution and evaluate its results;
- c) Approve the internal regulation of the National Health Laboratory;
- d) Control the operations of the Laboratory and assess all results obtained and quality of the care provided;
- e) Authorize the creation, extinction or modification of services and their allotment, when alterations are significant and permanent, on its own initiative or responding to a proposal by the Administrative Council;
- f) Require all the information deemed necessary for monitoring all laboratorial activities;
- g) Order auditing and inspections to assess operations;

- h) Authorize acquisition or alienation of movable property subject to registration.
2. The following are duties of the Health Minister and the Finance Minister:
- a) Approve all activity plans and annual and pluriannual budgets, without detriment of the competencies established in the Constitution and in the legislation authorizing the Plan and General Budget of the State;
 - b) Approve all activity reports and accounts;
 - c) Approve the schedules of price to be charged in the cases foreseen in the law.
3. The Health, Finance and Justice Ministers are responsible for authorizing the alienation of all movable property.

Article 5 Management Principles

The LNS must act in accordance with the following management principles and good practices:

- a) Protection of the rights of users;
- b) Promptness and quality in customer assistance, according to the means of action available;
- c) Efficient and legitimate utilization of all human and material resources available so as to obtain the highest possible level of efficacy;
- d) Allocation of services according to existing availabilities using the indispensable organization, staff and means;
- e) Authorization of expenditures in accordance with the best possible quality-cost ratio and all applicable legal and financial standards;
- f) Recruitment of management professionals based on qualification, merit and productivity;
- g) Compliance with all the technical standards for installation and operations foreseen in the laws or regulations for equivalent institutions and services of the private sector;
- h) Compliance with, and protection of, all deontological standards followed by health professionals.

Article 6

Areas of Reference

1. The area of reference of the LNS is the one established in its internal regulation and it must operate in coordination with other relevant services of the National Health Service.
2. Besides its own area of reference, the National Health Laboratory is the model laboratory and the primary entity for quality control of laboratory care for the entire country within the scope of sanitary surveillance.

CHAPTER II COMPOSITION, COMPETENCY AND OPERATIONS OF AGENCIES

SECTION I AGENCIES

Article 7 Agencies

The following are LNS agencies:

- a) The Administrative Council;
- b) The single inspector;
- c) The technical support agencies.

SECTION II ADMINISTRATIVE COUNCIL

Article 8 Composition and Nomination

1. The Administrative Council is composed of one president and four directors.
2. The Administrative Council will have the following Directors: a Director for Administrative and Support Services, a Director for Clinical Pathology and Microbiology Services, a Director for Quality Control Services and Support to the Laboratories of the National Health, and a Director for Toxicology, Water Analysis and Environmental Services.
3. The Health Minister may decide, depending on the size of the laboratory and the profile of the president, that the president will also accept the duties of another member; in this case, there will be no reason for nominating a director for that position.

4. The selection of members for the Administrative Council must conform to proven technical and professional criteria and the publication of the nominations must be accompanied with a written document with all the academic and professional curriculum vitae of the nominees.
5. The Health Minister is responsible for nominating the president and, following a proposal by the latter, the other members of the Administrative Council.
6. The members of the Administrative Council will be effective upon taking office.

Article 9 Competency

1. The Administrative Council is the collegial agency responsible for establishing all fundamental principles that must guide the organization and operations of the National Health Laboratory, as well as for monitoring its execution and performing the respective periodical evaluations.
2. The Administrative Council must perform all managerial competencies not attributed by law or regulation to any other agency, particularly the following:
 - a) Approve all action plans, budgets and accounts pertaining to management and submit them to tutelage;
 - b) Establish the necessary guidelines for better efficiency of the services provided;
 - c) Propose the creation, extinction or modification of new services;
 - d) Draft the internal regulations;
 - e) Systematically monitor and assess all activities developed by the LNS, enforcing the utilization of all the means made available to the various services and making said services accountable for the results obtained;
 - f) Establish customer assistance standards and ensure the smooth operation of all services and the quality and promptness of all laboratory tests;
 - g) Evaluate compliance with the technical guidance regarding laboratory tests, as well as all laboratory protocols appropriate to the most frequent tests and authorize the introduction of new techniques with significant incidence from the welfare and economic points of view;
 - h) Acknowledge and establish appropriate responses to user complaints and grievances;

- i) Execute all human resource policies, particularly hiring, firing, performance review, working regimen and schedules, absences and training programs, according to legal provisions;
- j) Recruit and hire staff, in accordance with applicable legal provisions;
- k) Apply disciplinary actions under the provisions of the applicable law;
- l) Establish agreements with institutions that teach and train health technicians for the provision of practical classes and internships to students and graduates;
- m) Periodically monitor compliance with the budget, and correct any deviations;
- n) Ensure regularity in the collection of revenues and expenses incurred;
- o) Authorize expenses up to the amount stipulated in the law for the highest level agencies of the organisms which are part of the indirect administration of the State with administrative, financial and patrimonial autonomy;
- p) Enforce all applicable legal and regulatory provisions.

Article 10 Operations

1. The Administrative Council will hold regular meetings every 15 days and special meetings whenever called by the president or by request of three of its members.
2. The Administrative Council can only deliberate with the presence of a majority of its members. Deliberations will be conducted by majority of votes and the president will have the casting vote.
3. Every meeting of the Administrative Council will have minutes drafted, approved and signed by all members present.

Article 11 Delegation of Competency

The Administrative Council may delegate their duties to its members.

Article 12

Binding Effect

The LNS is bound by the following:

- a) Joint signature of the president of the Administrative Council and one other Director.
- b) Joint signature of two Directors of the Administrative Council authorized by applicable delegation, as recorded in minutes;
- c) Signature of the individual with the appropriate mandate, under the terms of the law.

Article 13 Bylaws of Administrative Council Members

1. All Administrative Council members are subject to the same bylaws of the highest level Directors of the agencies of the indirect State administration in any matter not foreseen in this statute.
2. The members of the Administrative Council will perform their duties on a full time basis and may not work on any other professional activity outside of the LNS, except teaching positions on a part-time basis.
3. The remuneration of the members of the Board of Directors is established by a joint order issued by the Ministers of Finance, Health and Public Administration.

Article 14 Duration and Cessation of Duties

1. The members of the Administrative Council will be nominated for three-year terms, which can be renewed for an equal period of time.
2. The members of the Administrative Council will cease their duties in the following cases:
 - a) Lapse of their respective terms;
 - b) When a deputy takes office, under the terms of the law;
 - c) Due to permanent disability or supervening incompatibility;
 - d) Due to resignation;

- e) Due to dismissal decided by the entity which nominated the Director, following consultation with the proposing entity, in the event of proven and serious violation while in service.
 - f) In the sequence of conviction, in the event of a felonious offense.
3. In the case of individual cessation of the term, the new member is always nominated for a four-year term.

Article 15 Dissolution

The Administrative Council can be dissolved by determination of the Health Minister in the event of serious irregularities in its operations, considerable excess of expenses incurred in relation to expenses budgeted, or deterioration of the results of the activities, including the quality of services provided, without appropriate justification.

Article 16 Duties of the President

1. The following are special duties of the President of the LNS Administrative Council:
 - a) Submit to the Health Minister any matter subject to the superintendence and tutelage of the latter;
 - b) Preside at the Administrative Council;
 - c) Enforce all legal and regulatory provisions and control the operations of all services;
 - d) Represent the LNS in and out of court, when no other agents have been assigned by it self.
2. Whenever mandated by urgent circumstances and whenever it is unfeasible to summon the Administrative Council, the President can practice any acts under the competency of the Administrative Council, subject to ratification at the first subsequent meeting.
3. The President is replaced in his absences and impediments by the member who is the Director of Administrative and Support Services.

SECTION III

INSPECTION AGENCY

Article 17 Sole Inspector

1. The sole inspector is an official account reviser or accountant assigned by an order issued jointly by the Minister of Finance and the Minister of Health for a three-year term, renewable for equal periods of time.
2. The sole inspector is not entitled to any remuneration and will fulfill his term as part of his regular duties as a government employee, with a minimum of monthly periodicity.

Article 18 Duties

1. The sole inspector will be in charge of internal inspections of the financial management of the National Health Laboratory, specially the following:
 - a) Examine the legality of all acts of a financial nature conducted by the Administrative Council, as well as their conformity with this statute and other applicable LNS standards, namely standards regarding the integrated organisms of the indirect administration of the State with administrative, financial and patrimonial autonomy;
 - b) Monitor the execution of all activity plans and compliance with the budget;
 - c) Periodically review the accounting of the LNS;
 - d) Issue opinions about the criteria for evaluation and amortization of assets;
 - e) Issue opinions about activity reports and accounts documents;
 - f) Issue opinions about the financial performance and management of LNS;
 - g) Issue opinions about acquisition, alienation and burden affecting real estate or movable assets subject to registration;
 - h) Communicate to tutelage any management irregularities found.
2. In order to fulfill his duties, the sole inspector may:
 - a) Request information and clarification to the Administrative Council about LNS activities;
 - b) Propose outside audits.

SECTION IV

TECHNICAL SUPPORT AGENCIES

Article 19 Technical Support Agencies

1. The technical support agencies are designed to provide advice to the Administrative Council and the Directors about matters under their competency, either upon request from the latter or on its own initiative.
2. The technical support agencies are the Technical Council and the Ethics Commission, as well as others eventually created and included in the internal regulation of the National Health Laboratory.

Article 20 Technical Council

1. The Technical Council includes the following:
 - a) the Administrative Council;
 - b) the department heads.
2. The Technical Council holds quarterly meetings presided by the President and is responsible for issuing opinions about the projects included in the action plans and activity reports of the LNS, as well as about its operations and efficiency, and for proposing measures deemed appropriate for the resolution of the problems detected.

Article 21 Ethics Commission

1. The Ethics Commission will have four to six members assigned by the President among analysis's, laboratory technicians and specialists in the field of laboratory tests, and will be presided by the member elected by his peers.
2. The following are duties of the Ethics Commission:
 - a) Care for the protection of human dignity in all laboratory activities;
 - b) Issue opinions about ethical issues in the domain of laboratory activities;
 - c) Present and monitor all laboratory essay cases;
 - d) Promote the disclosure of general principles of bioethics.

CHAPTER III SERVICES

Article 22
Organization

1. The activities of the LNS will include the following services:
 - a) Administrative and Support Services;
 - b) Clinical Pathology and Microbiology Services;
 - c) Quality Control Services and Laboratory Support Services for the National Health Service;
 - d) Toxicology, Water and Environmental Analysis Services.
2. The LNS internal regulations must establish the framework and roles of all services, departments and functional units within its organization.
3. All Services are directed by one Director, to be nominated under the terms of the provisions of article 8 .

CHAPTER IV
MANAGEMENT OF ECONOMIC, FINANCIAL
AND HUMAN RESOURCES

Article 23
Autonomy and Management Instruments

1. Without detriment to the powers of tutelage, the LNS is responsible for managing its own economic, financial, patrimonial and human resources and must conduct all the actions necessary for that purpose within its attributions and competencies.
2. The financial and patrimonial management of the LNS is disciplined by the provisional management and accounting instruments foreseen in the general law regulating all the organisms of the indirect administration of the State with administrative, financial and patrimonial autonomy and, in any case, by the following instruments:
 - a) The annual schedule, which includes the activities plan, financial budget and exploration budget;
 - b) Medium-term plan;
 - c) Management report;
 - d) Balance sheet and income statement;

e) Social balance sheet.

3. The accounting must meet the needs of management and allow for permanent budgetary control of each department and functional unit.

Article 24 Patrimony

1. The LNS will have its own patrimony, which will include all the assets and rights it has acquired under any title.

2. The LNS can administrate and dispose of any assets that are part of its patrimony, within the limitations stated in this statute, and must keep an updated inventory of all its assets.

3. Without detriment of the provisions in article 4, the LNS can acquire all the assets it needs to conduct its activities, in accordance with the standards applicable to the organisms integrated into the indirect administration of the State with administrative, financial and patrimonial autonomy, as well as the guidance, support and control from the National Director of Administration, Logistics and Appropriation of the Ministry of Health.

4. The LNS is also responsible for managing all the State assets that have been granted to it while said assets are being used for the purpose of conducting its duties.

Article 25 Financial Autonomy

1. The LNS Administrative Council is exclusively responsible for collecting revenues and incur in expenses inherent to its activities, provided they are included in the approved budgets.

2. The following are LNS revenues:

- a) The appropriations of the General State Budget;
- b) Other appropriations, co participations and subsidies of the State or other entities;
- c) Payments for laboratory assistance by private sector users or by any other mode not foreseen for general users;
- d) Payments for care provided by third parties;

- e) Payments for laboratory assistance rendered to non beneficiaries of the National Health Service;
- f) Payments of legally stipulated contributions;
- g) The product of revenues obtained from its own assets;
- h) The product of donations;
- i) The product of payments from liabilities of users or third parties for violations of the rules, or felonious use of the services or the materials.

Article 26
Human Resources

1. LNS personnel will be governed by the same regimen used for *função pública* [government work] employees, while specialists, analysts and laboratory technicians can be hired under the regimen of individual work agreement.
2. Health professionals providing services at the LNS are registered with the Ministry of Health under the terms of Executive Order no. 144/2004, of September 1st.

CHAPTER V
FINAL AND TRANSITORY PROVISIONS

Article 27
Supplementary Regulations

Without detriment to the provisions in this statute, the LNS Administrative Council must submit to the approval of the Minister of Health the draft for the ministerial statute regulating the organic and functional framework of the LNS, as well as its Internal Regulation and all the management documents necessary for its operations, within a period of six months counting from the date when its members take office.

Article 28
Staff

The staff currently providing services at the LNS will maintain the same legal and functional status as before, while any staff currently governed by the bylaws applied to *função pública* employees will be integrated into the respective staff as a result of an individual evaluation foreseen in article 119 of Law no. 8 /2004, of June 16.

Article 29

Effective Date

This statute will be effective on the day immediately following its publication.

Approved by the Council of Ministers on June 11, 2008

The Prime-Minister,

Kay Rala Xanana Gusmão

The Minister of Health,

Nelson Martins

Promulgated on 10- 17- 2008.

Publication

The President of the Republic

José Ramos-Horta