

# شــعبــة الــتــرجــمــة الرســميــة Official Translation Department

# **Private Laboratories Law**

Royal Decree No. M/3 April 21, 2002

**Translation of Saudi Laws** 



## NOTE:

The translation of Saudi laws takes the following into consideration:

- Words used in the singular form include the plural and vice versa.
- Words used in the masculine form include the feminine.
- Words used in the present tense include the present as well as the future.
- The word "person" or "persons" and their related pronouns (he, his, him, they, their, them) refer to a natural and legal person.



# Private Laboratories Law

# Article 1

In this Law, the following terms shall have the meanings assigned thereto.

- A. **Competent Ministry:** Ministry of Commerce, Ministry of Health, Ministry of Agriculture and Water, Ministry of Industry and Electricity, Ministry of Municipal and Rural Affairs, or other ministries specified by the Implementing Regulations, as applicable.
- B. **SASO:** Saudi Standards, Metrology, and Quality Organization.
- C. **Goods:** Commercial goods produced locally or imported, whether in the form of materials, devices, tools, or any other form.
- D. **Test:** Any analysis, calibration, or examination which aims to determine the characteristics of performance, efficiency, effectiveness, or conformity.
- E. Laboratory: A place where goods are tested.

## Article 2

The competent minister may seek the assistance of licensed national private laboratories to test local and imported goods.

# Article 3

An initial license shall be granted to laboratories upon satisfaction of the following conditions:

- a) The applicant must be a natural or legal Saudi person.
- b) The applicant must appoint a Saudi technical director for the laboratory.
- c) The applicant must appoint qualified staff and provide necessary laboratory equipment and devices according to the volume and nature of the work, as determined by the competent ministry and SASO.

## Article 4

The categories of laboratories and the conditions which must be met by each category shall be determined by Implementing Regulations upon SASO's recommendation.

## Article 5

The procedures and period for license issuance shall be determined by the Implementing Regulations.

# Article 6

A holder of an initial license shall be given a period of not more than six months to complete the following:

- a) The laboratory's organizational structure.
- b) The appointment of the laboratory's technical staff and the provision of a certified copy of their academic degrees and training certificates.



c) SASO's accreditation in accordance with the Quality Mark and Certificate of Conformity and Service Accreditation (laboratory accreditation). If the requirements are not completed prior to the lapse of the six-month period, the initial license shall be deemed revoked.

# Article 7

- A. The competent ministry shall issue the license to a private laboratory upon satisfaction of the following:
  - 1. Completing the requirements provided for in Article 6 and specifying the types of goods and tests as well as the maximum price of each test.
  - 2. Paying the license fee: five thousand riyals for the main laboratory and two thousand five hundred riyals for each branch.
- B. The license term shall be five years and the licensee may renew such license by filing an application to the competent ministry at least three months prior to the license expiration date. Such renewal shall commence from the license expiration date.

#### Article 8

The competent ministry shall issue a list of goods which must undergo testing by a private laboratory 60 days prior to assigning such testing to the private laboratory and after announcing the same in the Official Gazette. The Ministry of Finance and National Economy (Customs Directorate) shall be notified thereof.

## Article 9

The laboratory must comply with the following:

- a) Limiting testing to goods specified in the license.
- b) Complying with professional standards, maintaining work confidentiality, and ensuring equipment is in good condition.
- c) Maintaining records of test results for a period of not less than five years.
- d) Displaying the license, organizational structure, technical departments, testing costs, and SASO's accreditation certificate in a conspicuous place near the laboratory's entrance. Any amendment thereto must be approved by the ministry.
- e) Maintaining confidentiality when transporting samples and test results.

#### Article 10

- 1. The competent ministry's technicians shall collect and process samples according to approved standard specifications.
- 2. The owner of imported goods may not dispose of said goods prior to final testing.
- 3. The owner of locally-produced goods may not dispose of said goods prior to their approval by the relevant agency.
- 4. The prepared sample shall be delivered to the private laboratory together with a document accurately describing the sample and indicating the required tests, in accordance with approved standard specifications.
- 5. The laboratory shall, within 15 days from the date of collecting the samples,

return the results along with the remainder of the samples; if the samples are completely consumed, a proof thereof shall be presented to the providing party. The competent ministry shall be notified of the testing results within a period not exceeding 25 days from the date of collecting such samples.

6. Goods shall be tested at the expense of their owner.

# Article 11

Without prejudice to any harsher penalty provided for in any other law, any person who violates any of the provisions of this Law shall be subject to one or more of the following penalties:

- 1. A warning.
- 2. A fine of not less than five thousand riyals and not more than twenty thousand riyals.
- 3. Suspension of the license for a period of not less than 30 days and not more than 60 days.
- 4. Withdrawal of the license if the offense is repeated.

# Article 12

Delay fines shall be applied as follows:

- 1. One thousand rivals for every year of delay to be paid upon license renewal. Renewal shall commence from the license expiration date.
- 2. If the laboratory fails to submit the results within the period specified in Article 10(4), a fine equal to the costs of the test subject of the violation shall be imposed.

## Article 13

The supervision and inspection of laboratories and the detection of violations of the provisions of this Law and the regulations and decisions issued for its implementation shall be carried out by qualified officers. The Implementing Regulations shall specify:

- 1. the authority or authorities responsible for their appointment;
- the powers of officers authorized to access and inspect laboratories; detect violations; seize samples, documents, and devices subject of the violation; and conduct investigations, as well as specify the cases where the assistance of security agencies may be sought; and

3. the authority which may grant access to laboratories for inspection.

Monitoring, inspection, and detection officers shall be of good conduct and shall maintain confidentiality, and shall, upon carrying out their duties, present their credentials and indicate the purpose of their visit.

## Article 14

The Implementing Regulations shall determine investigation and prosecution procedures as well as the authority responsible therefor.



# Article 15

The Board of Grievances shall decide cases relating to violations of this Law and shall impose penalties.

# Article 16

The Minister of Commerce shall, in coordination with the Ministry of Commerce, Ministry of Health, Ministry of Agriculture and Water, Ministry of Industry and Electricity, and the Ministry of Municipal and Rural Affairs, issue the Implementing Regulations of this Law.

# Article 17

This Law shall be published in the Official Gazette and shall enter into force 180 days from the date of its publication.