Guideline for Licensing Private Laboratories

Saudi Food & Drug Authority

Operation Sector

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Disclaimer: The English version is a translation of the original in Arabic for information purposes only. In case of a discrepancy, the Arabic original will prevail.

Contents

First Chapter: General Provisions

Article (1): Terms and Definitions

The following words and expressions shall have the meanings hereby assigned to them, except where the context otherwise requires: Besides terms and definitions mentioned in the regulations issued by the SFDA.

The Kingdom*:* Kingdom of Saudi Arabia.

The Authority: Saudi Food & Drug Authority.

Private Laboratory: An authority conducting tests and measures located in the SFDA scope under standardized conditions, whether the laboratory is an independent or dependent on a confinity evaluation body.

Licensing: A process where the SFDA grant an activity license, test and analyze products commercially in Saudi Arabia.

Article (2): Objective

The guideline herein aims to:

a. Define requirements, technical requirements and procedures of licensing private laboratories.
b. Define rights and obligations of the authority and private laboratories and their legal liabilities.

Article (3): Scope

The guideline herein applies to laboratories in the Kingdom.

Second Chapter: Licensing

Article (4): Requirements and Procedures for Licensing Private Laboratories

1. Submit the following application format in (Appendix No.1).
2. Submit a copy of the laboratory commercial register form Ministry of Commerce and Investment and a copy of investment licensing from the General Authority of Investment for companies of foreign or multinational capital.
3. Submit a copy of location licensing approval issued by the competent authority.
4. The applicant shall be a Saudi national (copy of the National ID).
5. Submit the organization structure of the laboratory.
6. Submit a quality manual of the laboratory.
7. Submit an accreditation certificate from Saudi Accreditation Centre (SAC) or accreditation bodies with full membership of any of the licensing related organizations of ILAC.
8. Technical director of the laboratory must be a fulltime, specialized and Saudi.
9. A list of the technical and administrative staff, approved copy of their qualifications, training courses and job descriptions of their positions shall be submitted.
10. Submit a detailed statement of the accredited tests, products and the scope of the test to be examined and approved on prices by the authority. The document shall be submitted in an Excel spreadsheet based on the table below:

No.	Test Type	Device Used	Methods of Work	Product(s)	Price (Saudi Riyal)

11. An inclusive electronic system shall be found for the laboratory.
12. Pay the financial compensation according to (Appendix No.2).
13. An auditing visit shall be conducted by the Authority to ensure the laboratory competence; the licensing shall be issued if no notes were found.
14. Validity duration of the license is 5 years.

Third Chapter: Licensing Renewal

Article (5): Requirements and Procedures for Renewing a Private Laboratory License

Licensing application requirements applies to licensing renewing application, in addition to the following:

1. Submit a renewal application 3 months prior to date of expiry of the licensing.
2. Submit a valid commercial register.
3. Report any changes in procedures or activities in the licensed laboratory.
4. Submit a detailed statement of the accredited tests, products and the scope of the test to be examined and approved on prices by the authority. The document shall be submitted in an Excel spreadsheet based on the table below:

No.	Test Type	New/ Previously approved	Test Number in the Previous Licensing List	Methods of Work	Device Used	Product(s)	Price

Fourth Chapter: Final Provisions

Article (6): Guideline Final Provisions

First: The authority is entitled to take the suitable procedures if a violation of any of the provisions in the guideline herein existed, this include but are not limited to:

1. If there is a clear violation or abuse of the Authority's regulations and/or technical and /or administrative requirements associated with this guide, the authority has the right to take the appropriate criminal procedure, which includes the following penalties:
   A. Suspend or Shortening the licensing: The Authority is entitled to partly or fully suspend the licensing according to the defined procedures, in the cases following:
      1. Upon the private laboratory, voluntarily, request, owing to its inability to continue fulfilling the licensing area requirements for a part or full licensing.
      2. Inability to close cases of nonconformity with the licensing requirements during the period allocated by the Authority.
      3. Inability to handle any of the licensing suspension reasons during the allocated period which affect a defined part of the licensing area.
      4. Submit any false data or information.
      5. Failure to maintain accreditation in the licensing area.
      6. Inability to achieve the accreditation requirements for a part of the licensing area.
      7. Not paying the financial costs of the licensing.

   B. Licensing Revocation: The Authority is entitled to revoke the licensing permanently according to the defined procedures in the following cases:
      1. Upon the private laboratory, voluntarily, request, owing to its inability to continue fulfilling the licensing area requirements or another reason.
      2. Inability to handle any of the licensing suspension reasons.
      3. If there is an evidence on a fraudulent conduct or that the private laboratory submitted false information.
      4. Conducting any illegal activities effecting the neutrality, integrity, objectivity, and non-discrimination principles or a dishonest competition by the private laboratory or its staff (examiners, experts, employees, or contracting laboratories….etc)
      5. The laboratory failure to comply with defined obligations.

6. Upon discover of discrepancies in reports issued by the private laboratory.
7. If there are remarks or it became clear to the Authority the uselessness of the laboratory.
8. Failure to maintain accreditation in the licensing area.

2. If a failure or non-conformity is found on the private laboratory performance, the Authority shall be entitled to impose the penalty according to the regulations enforced in the Authority.

Second: Rights and Obligations of the Authority

1. The Authority is entitled to use and deploy the information provided by the private laboratory in a manner as it considered appropriate.
2. The Authority is entitled to check all testing methods prepared by the private laboratory.
3. The Authority is entitled to ensure the validity of the information provided in a manner as it considered appropriate.
4. Supervision periodically on the private laboratory shall be conducted by the Authority to ensure it commitment to the regulations and requirements of the Authority, which includes inspection visits based on the Authority's approved methods.
5. The Authority shall not be held responsible of the private laboratory mistakes.
6. Confidentiality of the information shall be guaranteed by the Authority which were checked by the Authority's employees and employees contracted with during the private laboratory licensing process.
7. The Authority is obliged to consider any complaint submitted by the private laboratory or beneficiaries of its services and to study them objectively and take what is necessary to address them in accordance with specific procedures established by the authority.
8. The Authority is obliged to deploy a list of licensed private laboratories in the Authority's website.

Third: Rights and Obligations of the Private Laboratories

1. The private laboratory shall be obliged to follow up with the Authority's laws, regulations, guidelines, requirements, circulars and instructions in licensing matters in case of issuance, and any amendments or additions in the authority website.
2. Adherence to all the requirements and updates of the technical regulations approved by the authority.
3. The Private laboratory shall be entitled to object to the authority decision of not licensing and submit justification during (30) days after the decision issuance date and objection shall be based on the statuary measures followed.
4. Adherence to cooperate and facilitate the authority officials during the inspection visits.
5. Adherence to conduct the authority recommendations after the inspection visits, create an accredited corrective plan, and define the period of time necessary to conduct such.
6. Issue the test results based on the laws, technical regulations, requirements and to legally bare the damage resulted from the issuance.
7. Maintain the intellectual property of the standard specification, beside information critical to the beneficiaries.
8. The private laboratory is committed to the independence, neutrality, integrity and confidentiality shall be bound to the information obtained or accessed by its employees or by those contracted during and after the period of its authorization and shall not disclose any information concerning the services provided by it and shall not make final disclosure without the prior written consent of the Authority and only in certain cases assessed by the Authority.
9. Retention of beneficiary files for at least 5 years from the expiration date for reference when needed.
10. Report immediately to the Authority in the event that the private laboratory cannot continue to fulfil the licensing requirements
11. The private laboratory must perform all the tasks entrusted to it. If the private lab assigned a third party to perform some of its functions, it must be subjected to all the requirements defined, and the private laboratory must take a written approval from the Authority and provide a copy of the contracts concluded between the private lab and the third part, taking full responsibility for those services provided by the third party.
12. Commitment to provide a sufficient number of technical and scientific competencies in accordance with the standards of the Authority.

13. Adherence to not to share any documents of the Authority with any other entity, whether inside or outside the Kingdom, except with the prior written consent of the Authority, and to bear full responsibility for the security of the information submitted for the performance of its mission.
14. Adherence to not to use the name of the Authority for advertising or slogans placed on products.
15. Adherence to report suspicious cases or related irregular practices to the Authority.
16. The licensed private laboratory is entitled, during the period of validity of the licence, to increase the number of tests, and to send an application containing details of the new tests and their certification issued by the Saudi Accreditation Center (SAC) or full-membership accreditation devices in any ILAC organization covering the licensing area.
17. The licensed private laboratory is entitled to licence another branch to which the requirements and procedures for licensing the private laboratory apply.
18. The private laboratory shall not waive the licence or terminate the activity until the approval of the authority has been obtained.
19. Adherence to appoint a Saudi representative of the private laboratory to serve as the point of contact with a certified letter of authorization.
20. Adherence to show the licence, organizational structure, technical sections, test prices and certification at an apparent location in the laboratory, as well as to publish it on the laboratory website.
21. Adherence to perform all licensed tests in accordance with the method of operation adopted in the Authority's licence and at its approved prices.
22. Adherence to notify the Authority of any updates or change in the private laboratory, whether technical or administrative, during the period of the licence.
23. Adherence to take the approval of the Authority when adding a new test.
24. Adherence to carry out competence tests organized by the Authority.

Appendices

Appendix (1): Application Format for Licensing and Renewal Private Laboratories

☐ License ☐ Renew	☐ ترخيص ☐ تجديد
Date:	التاريخ:
Application No.:	رقم الطلب:
Laboratory Information	معلومات المختبر
Laboratory name:	اسم المختبر:
City:	المدينة:
District:	الحي:
Building No.:	رقم المبنى:
Street:	الشارع:
Zip Code:	الرمز البريدي:
P.O Box:	صندوق البريد:
Telephone:	رقم الهاتف:
Fax No:	رقم الفاكس
e-mail	البريد الكتروني:
Website address:	الموقع على الشبكة العنكبوتية:
GPS:	إحداثيات الموقع:
Owner Information	معلومات المالك
☐ Company ☐ Establishment	☐ شركة ☐ مؤسسة
Name:	الاسم:
Trade Registry No:	رقم السجل التجاري
Trade Registry Date:	تاريخ السجل التجاري:
Owner name (Individuals):	أسم المالك (للأفراد):
National ID No:	رقم الهوية الوطنية:
Issuance Date:	تاريخ الإصدار :
Issuance Place:	مكان الإصدار
Expiry Date:	تاريخ الانتهاء:
Mobile No.:	رقم الجوال:
Telephone:	رقم الهاتف:

Fax No:	رقم الفاكس:
e-mail:	البريد الكتروني:
If the owner is not the contact person. the responsible person information shall be filled	*يجب تعبئة معلومات الشخص المسئول عن الاتصال المباشر مع الهيئة إذا كان غير مالك المنشأة
Information Contact	معلومات الاتصال
Name:	الاسم:
Position:	الوظيفة:
Mobile No.:	رقم الجوال:
Telephone:	رقم الهاتف:
Fax No:	رقم الفاكس:
E-mail:	البريد الكتروني:
Technical Staff	الكوادر الفنية

م	العدد Number	التخصص Major
1		
2		
3		
4		
5		

مجالات المختبر	

Laboratory Manager Commitment	تعهدات مدير المختبر
In case of termination of my contract with the establishment for any reason, I promise to inform SFDA within fifteen days start by last working day.	أتعهد في حال إنهاء تعاقدي مع المنشاة لأي سبب كان بإبلاغ الهيئة في فترة أقصاها خمسة عشر يوما من تاريخ آخر يوم عمل.
I only test of goods specified by license for inspection.	أتعهد بالاقتصار على إجراء الفحص والاختبار للسلع المحددة بالترخيص.
I promise to maintain the level of performance and accuracy according to professional examination in all honesty and truthfulness and impartiality should .also maintain and safety devices.	أتعهد بالمحافظة على مستوى الأداء والدقة وفقاً لأصول المهنة في الفحص بكل أمانه وصدق وتجرد والمحافظة على العمل وسلامة الأجهزة.
I promise to commitment to confidentiality when transferring the samples and test results, and no .information except to specialists	أتعهد بالالتزام بالسرية عند نقل العينات ونتائج الاختبار وعدم إعطاء أي معلومات إلا للمختصين.
I have read the regulation of laboratories Guidelines issued by Royal decision No m/3 dated 8-2-1423 HJ and I promise to follow all its content and any regulations followed Also I promise to follow any future regulation issued by SFDA.	قرأت اللائحة التنفيذية لنظام المختبرات الخاصة الصادر بالمرسوم الملكي رقم م/٣ وتاريخ ٨-٢-١٤٢٣هـ واتعهد بالالتزام بما جاء فيها وبأي تعاميم وقرارات صدرت من الهيئة. كما اتعهد بالالتزام بأي تنظيمات مستقبلية تقرها الهيئة العامة للغذاء والدواء.
I have read the Saudi Food and Drug Authority regulation issued by Royal decision No M/6 dated 25/1/1428 H and I promise to follow all its content and any regulations followed Also I promise to follow any future regulation issued by SFDA.	قرأت نظام الهيئة العامة للغذاء والدواء الصادر بالمرسوم الملكي رقم م/٦ وتاريخ ٢٥-١-١٤٢٨هـ وأتعهد بالالتزام بما جاء فيه وبأي تعاميم وقرارات صدرت من الهيئة. كما أتعهد بالالتزام بأي تنظيمات مستقبلية تقرها الهيئة العامة للغذاء والدواء.
Name:	الاسم:
Date:	التاريخ:
Signature:	التوقيع:
Commitment	التعهد
We are committed that all provided information is correct and we met all requirements specified in the regulation of licensing of private laboratories.	نتعهد بأن جميع المعلومات المقدمة صحيحة والالتزام التام بجميع ما ورد في دليل ترخيص المختبرات الخاصة.
Name:	الاسم:
Date:	التاريخ:
Signature:	التوقيع:

Owner Signature :	توقيع المالك أو من ينوب عنه:
Official Stamp Note: Signature shall be confirmed by Commercial Chamber	الختم الرسمي ملاحظة: يجب تصديق التوقيع من الغرفة التجارية

Appendix (2): Financial Compensation

Licensing Type	Financial Compensation
Final licensing or licensing renewal	5000
Branch licensing or renewal	2500