# Guideline Requirements of Designation

# Conformity Assessment Bodies and Private Laboratories

**Saudi Food & Drug Authority**

**Operations Sector**

**Version number: 1.0**

**Release Date: 01/ 12/ 2019**

## Contents

## Introduction

### Purpose

The purpose of this guideline is to clarify the requirements for conformity Assessment bodies and private laboratories to obtain designation certificate from the authority for performing the missions in relation to the Authority.

### Scope of Application

This guideline applies to conformity Assessment bodies and private laboratories inside or outside the Kingdom submitting a request to the Authority for designation certificate to perform missions assigned by the Authority.

### Basic information

The Authority prepared this guideline based on “the designation Regulation of conformity Assessment bodies and private laboratories” issued under the Board of Directors’ Decision No. (1440-20-5) dated 7/ 9/ 1440.

## Requirements

| | | |
|---|---|---|
| **General** | 1 | The conformity Assessment bodies and private laboratories whether independent or dependent to Conformity Assessment Bodies, shall get a certificate from the Authority to designate them to perform the missions referred to in the designation fields determined in **Annex (3)** and/ or **Annex (4).** |
| **General designation requirements** | 2 | To obtain the designation certificate, the following shall be considered:<br>– The conformity Assessment bodies and private laboratories shall have the capacity, competence and experience to perform the missions assigned to it.<br>– The conformity Assessment bodies and private laboratories shall have legal entity in the Kingdom.<br>– The Owner shall be Saudi or foreign investor licensed from the General Authority of Investment.<br>– The conformity Assessment bodies and private laboratories shall have an electronic system for issuing technical and financial certificates, reports and all relevant procedures. The system shall include, at least, the number and details of applications submitted by customers as per country of origin or source and the number and details of the approved and rejected applications and applications requested for which a corrective procedure and which were corrected by the customer. The System shall also include the number and details of any objections submitted by customers to the results and any reports and other statistics required by the Authority in addition to documentation and archiving for a period shall not be less than (5) years. In addition, the Authority shall granted full access to this electronic system. |
| **Additional requirements for all conformity** | | The Conformity Assessment Bodies shall, if applicable, meet the following conditions:<br>– The Conformity Assessment Body shall have an acceptance certificate issued by the competent entity covered the requested designation field. |

| | | |
|---|---|---|
| **Assessment bodies** | | – The Conformity Assessment Body shall be certified in accordance with the International Standards requirements (ISO/ IEC 17065).<br>– The Conformity Assessment Body shall have a plan in the Kingdom for Saudization the jobs within (3) years for technical positions gradually at least (50%).<br>– Conformity Assessment Certificate shall not be granted:<br>○ Except after verifying the requirements of the Authority and the relevant International Standards.<br>○ If revealed difference or lack in the products quality, which did not, subjected to the corrective procedures required by the manufacturer or in the submitted documents. Moreover, shall notify the Authority directly of the same.<br>○ Except in the form approved by the Authority in accordance with the approved forms and the Conformity Certificate shall be in paper form and secured. |

| | | |
|---|---|---|
| | | – The Audit shall be acted in accordance with the following:<br>○ To inform the Establishment of the corrective procedures and non-conformity cases, if any.<br>○ To provide the Authority with the audit report in accordance with the forms approved by the Authority and within two weeks at least from the audit end.<br>○ The audit shall be perform periodically in accordance with risks Assessment.<br>– The Authority shall be regularly (quarterly) provided with the reports and statistics including the following:<br>a- The total number of the conformity certificates issued in that month detailed by the country of origin or source.<br>b- Details about counterfeit and fake material revealed in that month, including names of importers and exporters, types, names of products, quantities and counterfeiting and adulteration method, if any.<br>c- The number of objections submitted by manufacturer, importer or distributor on verification results. |

| | | |
|---|---|---|
| | | d- Any reports or statistics may be required by the Authority.<br>– Informing the Authority of any changes to the data of the Conformity Assessment Body or the certified establishments by it regarding contact addresses, name, location or any other changes to its data saved with the Authority.<br>– Full cooperating with the Authority Assessment Team within the visit and provide it with all facilities and means to help the Team to perform its missions.<br>– Stopping the certificates granting in the event of suspending its activities by the Authority or certification body.<br>– Saving all documents related to the Certificate after the expiry date of the designation Certificate for (5) years.<br>– In case of changing one of the complied product components, if applicable, it shall be consider as a new product. |
| **Additional requirements for Food conformity Assessment bodies** | | – The Conformity Assessment Body granting acceptance certificates for food establishments (including the entire food chain from farm to final product) desiring export to the Kingdom:<br>– The audit shall be performed by technical specialists concerned with the product nature in accordance with the Authority standards of inspectors and shall be certified by one of audit certificates (Global Food Safety Initiative).<br>– The Inspection Body shall be certified in accordance with the International Standard ISO 17020 and the Authority shall be informed with the audit results and recommendations in accordance with the forms approved by the Authority. |

| | | |
|---|---|---|
| | | – The Conformity Assessment Body granting Quality Management Systems certificates (ISO 22000) and/ or |

| | | |
|---|---|---|
| | | Hazard Analysis and Critical Control Points Certificates (HACCP):<br>– The Body shall be qualified and competent for assessment conformity in accordance with the Quality Management Systems (ISO 22000) and/ or Hazard Analysis and Critical Control Points Certificates (HACCP).<br>– The Conformity Assessment Body granting conformity certificates for food products shipments exported to the Kingdom:<br>– The Conformity Assessment Body shall be qualified and competent for calibrating conformity of the food products shipments exported to the Kingdom with the of the Food law Requirements and the Executive Regulations ,Technical Regulations and Standard Specifications adopted in the Kingdom and verifying their safety and validity for human consumption, including but not limited to:<br>o Inspecting transportation methods and containers and verifying their safety and conformity with the Authority requirements and sampling each container/ operation / batch to be similar to the shipment and then stacking and stamping the same with the conformity verification special seal on the container lock/ vehicle/ operation/ transportation batch.<br>o Verifying the food source and its conformity with the Authority requirements in the entire food chain from the farm to the final product, at the Authority request.<br>– Complying with physical and laboratory inspection methods in accordance with the Laws, Executive Regulations, Standard Specification and Requirements adopted by the Authority in global certified laboratories in accordance with the International Standard Specification (IS / IEC17025). In case of non-availability |

| | | |
|---|---|---|
| | | of the same, the Authority shall be the reference to determine the inspections methods, considering the updates of the Technical Regulations and Specifications and any new specifications and standards. |
| **Additional requirements for conformity Assessment bodies of Health, herbal and veterinary Products** | | The Conformity Assessment Bodies granting the conformity certificates of Health, herbal and veterinary Products manufacturers with the Authority requirements regarding good manufacturing practice:<br>– The Body shall be qualified and competent of conformity in accordance with the requirements, standards and of good manufacturing practice adopted by the Authority in the Good Manufacturing Code issued by the Authority (SFDA GMP Guideline), and World Health Organization (WHO). In addition, granting certificates in accordance with, and after inspecting the production line/ lines of health, herbal and veterinary products submitted for registration in the Authority.<br>– The Body shall not issue a conformity certificate not requested by the Authority or to manufacturer out of the agreed scope. |
| **Additional requirements for conformity Assessment bodies of Medical devices** | | a- The Conformity Assessment Bodies granting the Quality Management Certificates to the manufacturer of medical devices and products<br>The Conformity Assessment Body shall be quafiled for assessment the conformity of manufacturer of medical devices in accordance with the Medical Devices Interim Regulation and its Implementing Rules, Quality Management System compliant with the latest version of the Specification "Medical Devices - Quality Management Systems - Regulatory Requirements - ISO (13485)" and the relevant requirements and granting certification accordingly.<br>b- The Conformity Assessment Bodies granting the certificates of Technical Documentation Review submitted for the purpose of obtaining marketing authorization for medical devices<br>– The Conformity Assessment Body shall be quafiled for assessment the conformity and reviewing the technical |

| | | |
|---|---|---|
| | | files of the medical devices in accordance with the Medical Devices Interim Regulation and its Implementing Rules, the relevant requirements and granting certification accordingly. |

| | | |
|---|---|---|
| | | – |
| **Additional requirements for conformity Assessment bodies of cosmetics** | | The Conformity Assessment Bodies granting the conformity certificates of the Quality Management system to the cosmetics manufacturers and shipments certificates<br>– To ensure that cosmetics products are compatible with the applicable cosmetics law, rules and instructions of the Authority and safety requirements Interim Regulation of cosmetics and Personal Care (GSO 1943).<br>– To ensure that the manufacturer, importer or distributor complies with the requirements, standards and the specifications approved by the Authority regarding test of cosmetic products and conformity assessment requirements in accordance with the International Standard Specification. (ISO/IEC 17050 pt 1 and 2).<br>– To analyze the products periodically in accordance with clear standards set by the Body, including analyze the first batch, whether imported or manufactured locally, after listing the product into the cosmetics products listing electronic system.<br>– To grant the conformity certificate for each imported shipment and each batch manufactured locally separately.<br>– The Body shall not issue any conformity certificate for the products, which are not listed previously in the cosmetics listing electronic system of the Authority. |
| **Additional requirements for private laboratories** | | The private laboratories shall:<br>– Participate in Proficiency Test required by the Authority in accordance with the of the International Standard requirements of (ISO/ IEC 17025).<br>– Submit the testing methods for each item (Testing method) in accordance with the products type in the Special Requirements.<br>– Obtain (private laboratory license) issued from the Authority. |
| **Application** | | – The documents referred to in section (A) in the "Required Documents" Section for conformity |

| | | |
|---|---|---|
| | | assessment bodies applications or the documents referred to in section (B) for private laboratory applications shall be submitted and sent to (CAB.Lab@sfda.gov.sa). |

| | | |
|---|---|---|
| | | – Pay the applicable fee in accordance with Annex (3) of the Conformity Assessment Bodies or Annex (4) of private laboratories applications.<br>– The Authority may conduct an audit and inspection visit (if required) and if the requirements are met, the authority will issue designation certificate in the required field within (10) working days.<br>Note:<br>– The certificate renewal application shall be submitted, when desired, (60) days prior to the valid certificate expiry.<br>– The Conformity Assessment Body or Private Laboratory can expand the designation field, when desired, by submitting a request for the same to the Authority. |

Required Documents

| No. | Required Documents | Remarks |
|---|---|---|
| A. Required Exhibits for CB Organizations | | |
| 1 | Designation Application Form | - Refer to Annex (1). Click here for a printable and editable version |
| 2 | The certificate of acceptance and the attachment issued by the competent entity | - A detailed breakdown of the obtained accreditations by the authority stating the date of and the country<br><br>- Such as a certificate of accreditation from the Saudi Accreditation Body (SAC) or accreditation bodies with full membership in any organization |

| | | |
|---|---|---|
| | | (IAF / ILAC) covering the field of designation |
| 3 | Commercial Register | - The Register must be valid. In the event of revoking the designation for any establishment, the Ministry of Commerce and Investment shall be notified to cancel the Commercial Register. |
| 4 | General Investment Authority License | - shall be requested in case the owner is a foreign investor. In the event that the Authority's designation is canceled for any establishment, the General Investment Authority shall be addressed to cancel the register |
| 5 | Civil Defense License | - The license must be valid |
| 6 | Municipal License | - The license must be valid |
| 7 | Organizational structure, list of technical and administrative staff and its qualifications, training courses and job descriptions | - Notarized by a letter from the owner of the establishment attesting the correctness of the data and informing the Authority in case of changing the technical staff. In addition, the powers granted to authorized persons. |
| 8 | Saudization plan for the conformity assessment bodies in the Kingdom | - (50%) as a minimum during (3) years for technical positions |
| 9 | National ID, CV, certificates of qualification and work experience | - Requested to the owner, establishment manager and related staff. |
| 10 | Proof of payment | - |
| 11 | Proposed form of conformity assessment certificate | - The proposed form should include at a minimum the following data: product name, product listing number in the Authority, number of batch or production date, quantities, |

| | | |
|---|---|---|
| | | invoice number, name of manufacturer, importer or distributor, name of manufacturer company, specification number or technical regulation on which the product conformity was checked, and the certificate of conformity number |
| 12 | Details of liability insurance for the conformity assessment body | - |
| 13 | Details of the legal status of the conformity assessment body under the regulations in the Kingdom | - |
| 14 | A detailed breakdown of the certificates granted during the designation period and the list of establishments and products obtained it | - Requests upon renewal |
| 15 | Any documents requested by the Authority | - |
| B- Required documents for private laboratories | | |
| 16 | Designation form for private laboratory | - Refer to Annex (2). Click here for a printable and editable version |
| 17 | Laboratory license issued by the Authority | - The license must be valid |
| 18 | Proof of payment | - |
| 19 | Organizational structure, list of technical and administrative staff and its qualifications, training courses and job descriptions | - Notarized by a letter from the owner of the establishment undertaking the correctness of the data and informing the Authority in case of changing the technical staff. In addition, the powers granted to authorized persons. |

| | | |
|---|---|---|
| 20 | A detailed breakdown of the approved tests and the products covered by the scope of the test | - According to the publication on the Authority's website<br><br>- Provided for the approval of the prices of tests by the authority<br><br>- Must be submitted as a spreadsheet file (Excel) including test type, product and price (SAR) |
| 21 | Proposed Form of product analysis | - |
| 22 | Details of liability insurance for your laboratory | - |
| 23 | Details of the legal status of the laboratory under the regulations in the Kingdom | - |
| 24 | Details of the Laboratory's policy and arrangements for maintaining the security and confidentiality of information obtained or generated in the course of performing its duties, And details of its arrangements to ensure that its administration and its staff perform their duties independently, objectively, ethically and impartially, and to avoid any conflict of interest. | - |
| 25 | A description of the Quality management procedures of the private laboratory | - |
| 26 | A detailed breakdown of the certificates granted during the designation period and the list of establishments and products obtained it | - Requested upon renewal |
| 27 | Any documents requested by the Authority | - |

# Annexes

## Annex (1): Designation of Conformity Assessment Body Application Form

| Information of Conformity Assessment Body | معلومات جهة تقويم المطابقة |
|---|---|
| Company Name: | اسم الجهة: |
| Activity: | نوع النشاط: |
| CR | رقم السجل التجاري: |
| Scope: | مجال التعيين: |
| City: | المدينة: |
| Phone: | الهاتف: |
| Extension: | تحويلة: |
| Email: | البريد الإلكتروني: |
| Mailing Address: | العنوان البريدي: |
| Information of Director of Conformity Assessment Body in Kingdom of Saudi Arabia | معلومات مدير مكتب جهة تقويم المطابقة في المملكة |
| Name: | الاسم: |
| Nationality: | الجنسية: |
| ID No: | رقم الهوية: |
| Telephone: | الهاتف: |
| Mobile: | الجوال: |
| Email: | البريد الإلكتروني: |
| Information of Technical Representative of Conformity Assessment Body | معلومات الممثل الفني لجهة تقويم المطابقة |
| Name: | الاسم: |
| Nationality: | الجنسية: |
| ID No: | رقم الهوية: |
| Telephone: | الهاتف: |
| Mobile: | الجوال: |
| Email: | البريد الإلكتروني: |
| Official Address of Conformity Assessment Body | عنوان المقر الرئيسي لجهة تقويم المطابقة |
| Country: | الدولة: |
| City: | المدينة: |
| Telephone: | رقم الهاتف: |
| Email: | البريد الإلكتروني: |
| Mailing Address: | العنوان البريدي: |
| Conformity Assessment Body Attestation | تعهدات جهة تقويم المطابقة |

| | |
|---|---|
| We are committed that all provided information is correct and we met all requirements specified in the regulation of designation of conformity assessment bodies and private laboratories. | تعهد بأن جميع المعلومات المقدمة صحيحة والالتزام التام بجميع ما ورد في لائحة تعيين جهات تقويم المطابقة والمختبرات الخاصة. |
| Name: | الاسم: |
| Date: | التاريخ: |
| Signature: | التوقيع: |
| Owner Signature : | توقيع المالك أو من ينوب عنه: |
| Stamp:<br><br>Note: Signature shall be confirmed by Commercial Chamber | الختم:<br><br>ملاحظة: يجب تصديق التوقيع من الغرفة التجارية |

## Annex (2): Designation private laboratory Application Form

| Information of Laboratory | معلومات مختبر خاص |
|---|---|
| Company Name: | اسم الجهة: |
| Activity: | النشاط: |
| CR | رقم السجل التجاري: |
| Scope: | المجال: |
| City: | المدينة: |
| Phone: | الهاتف: |
| Extension: | تحويلة: |
| Email: | البريد الإلكتروني: |
| Mailing Address: | العنوان البريدي: |
| Official Address of Laboratory | عنوان المقر الرئيسي للمختبر الخاص |
| Country: | الدولة: |
| City: | المدينة: |
| Telephone: | رقم الهاتف: |
| Email: | البريد الإلكتروني: |
| Mailing Address: | العنوان البريدي: |
| Information of Director of Laboratory in Kingdom of Saudi Arabia | معلومات مدير المختبر الخاص بالمملكة |
| Name: | الاسم: |

| | |
|---|---|
| Nationality: | الجنسية: |
| ID No: | رقم الهوية: |
| Telephone: | الهاتف: |
| Mobile: | الجوال: |
| Email: | البريد الإلكتروني: |
| Technical Representative of Laboratory in Kingdom of Saudi Arabia | معلومات الممثل الفني للمختبر الخاص بالمملكة |
| Name: | الاسم: |
| Nationality: | الجنسية: |
| ID No: | رقم الهوية: |
| Telephone: | الهاتف: |
| Mobile: | الجوال: |
| Email: | البريد الإلكتروني: |
| Official Address of Laboratory | عنوان المقر الرئيسي للمختبر الخاص |
| Country: | الدولة: |
| City: | المدينة: |
| Telephone: | رقم الهاتف: |
| Fax No.: | رقم الفاكس: |
| Email: | البريد الإلكتروني: |
| Mailing Address: | العنوان البريدي: |
| Laboratory Attestations | تعهدات المختبر الخاص |
| We are committed that all provided information is correct and we met all requirements specified in the regulation of designation of conformity assessment bodies and private laboratories. | تعهد بأن جميع المعلومات المقدمة صحيحة والالتزام التام بجميع ما ورد في لائحة تعيين جهات تقويم المطابقة والمختبرات الخاصة. |
| Name: | الاسم: |
| Date: | التاريخ: |
| Signature: | التوقيع: |
| Owner Signature : | توقيع المالك أو من ينوب عنه: |
| Stamp:<br><br>Note: Signature shall be confirmed by Commercial Chamber | الختم:<br><br>ملاحظة: يجب تصديق التوقيع من الغرفة التجارية |

## Annex (3): Scope of Designating Conformity Assessment Bodies

| Activity | Designation Scope | Verification Procedure | Mandatory Application | Financial Equivalent | |
|---|---|---|---|---|---|
| | | | | Designate & renew | Add Countries |
| Food | Approval of exporting establishments | verify the conformity of exporting facilities to authority's conditions | Countries selected by the authority | (20.000) | (1000) |
| | Establishments issuing QMSs certificates (ISO 22000) & HACCP certificates | Verify the conformity of QMSs certificates (ISO 22000) & HACCP certificates | As per the strategic plan of the authority | (40.000) | - |
| | Certificates of Conformity for shipments | Verify that shipments are in Conform to the Saudi and / or Gulf standard specifications | As published on the authority website | (20.000) | (1000) |
| Drug | Certificates of Conformity for manufacturers of Health, herbal and veterinary products subject to registration | Verify the Conformity to the authority requirements | As per the risk assessment and for the defined manufacturers by the authority | (40.000) | - |
| Medical Devices | Inspection establishments and manufacturers of Medical devices to check of Quality Control system | Verify the Conformity of the establishments and manufacturers of Medical devices to the authority requirements and Quality Control management system (ISO 13485) | As per risk assessment | (40.000) | - |
| | Assessment of the Technical File to verify the conformity of the systems and | Verify the Conformity of the Medical Products and Devices to the authority conditions | As per risk assessment | (40.000) | - |

| | | | | | |
|---|---|---|---|---|---|
| | requirements of the authority to get the marketing authorization for Medical Devices | | | | |
| Cosmetics | Manufacturers Inspection | Verify the conformity to the authority requirements | As per risk assessment | (40.000) | - |
| | Certificates of Conformity for shipments | Verify the Conformity to the authority requirements | As per risk assessment | (20.000) | (1000) |

**NOTE**:

1- The Authority will collect a fee for each conformity certificate for food and cosmetics (1000 riyals/ certificate).

2- The Authority shall not deduct a fee for the quality certificates of the Manufacturers.

## Annex (4): Scope of Private Laboratories Designation

| Activity | Designation Scope | Verification Process | Mandatory Application | Financial Equivalent for designate and Renew (SR) |
|---|---|---|---|---|
| Food | Product inspection and analysis | Imported and manufactured products are inspected and analyzed at the expense of the importer or manufacturer | Mandatory as per risk assessment | (1000) |
| Feed | Product inspection and analysis | Imported and manufactured products are inspected and analyzed at the expense | Mandatory as per risk assessment | (1000) |

| | | | | |
|---|---|---|---|---|
| | | of the importer or manufacturer | | |
| Drug | Product inspection and analysis of products | Imported and manufactured products are inspected and analyzed at the expense of the importer or manufacturer | Mandatory as per risk assessment | (1000) |
| Tobacco | inspection and analysis of imported products | Imported products are inspected and analyzed at the expense of the importer | Mandatory to all products | (1000) |
| Cosmetics | Product inspection and analysis | Imported and manufactured products are inspected and analyzed at the expense of the importer or manufacturer | Mandatory as per risk assessment | (1000) |
| Medical Devices | Product inspection and analysis | Imported and manufactured products are inspected and analyzed at the expense of the importer or manufacturer | Mandatory as per risk assessment | (1000) |
| | Product inspection and analysis | Imported and manufactured products are inspected and analyzed at the expense of the importer or manufacturer | Mandatory as per risk assessment | (1000) |

## Annex (5): Definitions & Abbreviations

| | |
|---|---|
| Kingdom | Kingdom of Saudi Arabia |
| Authority | Food And Drug Authority |
| Conformity Assessment Body | A body that verifies the conformity of products and / or establishments and / or manufacturer with the conditions and requirements of the Authority and includes inspection bodies, certification bodies, laboratories and any other conformity assessment bodies added by the Authority for its future activity. |
| Private laboratory | A body which performs tests and measurements that fall within the scope of the work of the Authority under standard conditions, whether the private laboratory stand alone or affiliated to conformity assessment bodies. |
| Competent body | The accepted body which is authorized and designate by the Authority (SFDA) to carry out the conformity assessment procedures specified in the regulations and technical specifications of the product categories it supervises. |
| Designate | A government mandate for the conformity assessment bodies and laboratory to perform specific conformity assessment activities |
| Designation Scope | A specific scope of work provided by the conformity assessment bodies or a private laboratory on behalf of the Authority. |
| Food Facility | Any legal body that performs work related to food handling throughout the food chain process, with the exception of household kitchens |
| Conformity Assessment | Proof that specific conditions and requirements of the Authority related to a product, process, system, person or body have been met. |
| Accreditation | Approval of a third party authorized to verify conformity bodies that formally indicate the competence of the conformity assessment body to perform specific tasks. |
| Verification of Conformity | Prove that the product, service, process, system, body, or person meets the necessary requirements for each of them under applicable technical legislation and regulations. |
| Testing | A technical process consisting of determining one or more features of the conformity subject according to a particular procedure, and from conventional tests measuring dimensions and determining chemical composition, microbiological purity |

| | |
|---|---|
| | and microbiological strength, or other physical properties of materials such as defect-free. |
| Inspection | A set of conformity assessment procedures through which the concepts of collecting specific information are applied by monitoring (testing, measuring) and then making judgments on the appropriateness of use and adherence to the specific requirements of the Technical Regulations and related technical specification. |
| Grant of Certification | It is a mechanism whereby a conformity assessment body performs the processes of (inspection, testing / inspection and Preview) and certifies that (product / service / process / system / person) is committed to the application of conformity assessment procedures specified in the relevant regulation or technical specification. |
| Product | Everything produced and issued by any process or group of manufacturing or analytical processes and directed to the consumer for consumption or use. |
| Sampling | Activity associated with obtaining a representative sample of the conformity assessment component according to the procedure. |
| Conformity Certificates | Third party certification of products, processes, systems or persons. |

**Note:** This document translated from Arabic version originally.