Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Regulations for Designation of Conformity Assessment Bodies

Saudi Food & Drug Authority

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Chapter One: General Provisions

Article One: Introduction

The Saudi Food & Drug Authority (SFDA), in accordance with the Law issued by Royal Decree No. (M/6) dated 25/01/1428 AH, Article Twenty-Two of which stipulates that "The Authority may seek assistance from governmental or private entities to perform some of its tasks,"

And Article Twenty-Two of its Executive Regulations issued by the Board of Directors Resolution No. (7-7-1428) dated 25/07/1429 AH, which stipulates that "The Authority shall set forth rules and requirements for licensing private laboratories and conformity assessment offices whose specialization falls within the Authority's scope of work. The SFDA is also responsible for defining the requirements and procedures for accrediting certificates issued by these entities."

These Regulations have been prepared for the designation of Conformity Assessment Bodies as official entities to collaborate with the Authority in completing any of the tasks assigned to it.

Article Two: Definitions & Expressions

The following definitions apply throughout this document unless the context clearly indicates otherwise. These definitions supplement those found in other applicable regulations issued by the Authority.

KSA: Kingdom of Saudi Arabia.

Authority (SFDA): Saudi Food and Drug Authority.

Conformity Assessment Body: means an entity responsible for verifying that products, establishments, or factories meet the Saudi Food and Drug Authority’s requirements and specifications. This includes inspection bodies, certification bodies, laboratories, and any other entities the Authority designates for conformity assessment activities.

Designated Body: means a Conformity Assessment Body formally accredited and authorized by the Saudi Food and Drug Authority to conduct specific conformity assessment procedures outlined in relevant regulations and technical specifications. This authorization covers defined product categories and establishments under the Authority's oversight.

Designation: means a governmental authorization granted to a Conformity Assessment Body to perform specified activities for the analysis and assessment of conformity of a product, test, process, system, person, or entity that has met the stipulated requirements.

Scope of Designation: means the defined area of operation within which a Conformity Assessment Body provides services on behalf of the Authority.

Conformity Assessment: means demonstration that the requirements and specifications set by the Authority, related to a product, test, process, system, person, or entity, have been fulfilled.

Accreditation: means a third-party attestation (by an Accreditation Body) provided to a Conformity Assessment Body, formally confirming its competence, impartiality, and consistency of operations in performing specified conformity assessment activities.

Testing: means any analysis, calibration, or examination conducted to determine the performance characteristics, efficiency, effectiveness, or conformity of a product.

Inspection: means an examination of products, competencies, entities, organizations, processes, services, systems, procedures, projects, data, designs, materials, or claims, to determine their compliance with specific requirements or based on professional judgment aligned with general requirements.

Certification: means a mechanism by which a Conformity Assessment Body carries out operations (testing and analysis/inspection and auditing) and confirms and declares that a (product/service/process/system/person) adheres to the conformity assessment procedures outlined in the relevant regulation or technical specification.

Product: means anything produced and derived from any manufacturing or analytical process, or a set of such processes, intended for consumption or use.

Sampling: means an activity related to obtaining a representative sample of a conformity assessment element in accordance with established procedures. The sample is taken from the environment or from entities holding a designation to carry out their tasks in analyzing products under their control.

Food Establishment: means any systematic entity performing work related to food handling within the stages of the food chain. Except home kitchens.

Guidance Manual: means a manual clarifying all procedures and requirements for designating Conformity Assessment Bodies and granting Certificates of Conformity, approved by the Chief Executive Officer of the Authority.

Certificate of Product Conformity: means a certificate issued for products subject to technical regulations, confirming that samples have been periodically tested and meet the Authority's approved regulations and technical specifications. The product is sampled by the certificate-issuing body.

Certificate of Consignment Conformity: means a certificate confirming that the product included in the shipment, identified by the invoice number and batch number indicated on the certificate, meets the Authority's requirements and specifications. The product is sampled by the certificate-issuing body.

Article Three: Purpose

This Regulation aims to:

a. Define the general framework, requirements, and prerequisites for designating and authorizing Conformity Assessment Bodies to carry out procedures and tests specified in the regulations and technical specifications for product categories and processes within the Authority's scope of work.

b. Determine the rights, obligations, and legal responsibilities of the Authority and Conformity Assessment Bodies.

Article Four: Scope

This Regulation applies to all Conformity Assessment Bodies operating within the scope of the Authority's work, whether located within or outside the Kingdom.

Chapter Two: Designation of Conformity Assessment Bodies

Article Five: Requirements for Designating Conformity Assessment Bodies for Inspection and Certification Activities

- Submission of a commercial registration for conducting the relevant activity.
- Accreditation by the Saudi Accreditation Center, with the scope of designation covered by the accreditation scope, or by an accreditation body that is a member of international accreditation organizations (ILAC-IAF).
- Possession of a legal entity status within the Kingdom.
- Maintenance of an electronic system that documents all procedures related to granting Certificates of Conformity, issuing technical and financial reports, and any other actions related to certificate issuance procedures (for areas that require it). This system must grant the Authority full access and electronic connectivity. At a minimum, the system should include:

  a. The number of applications submitted, categorized by country of origin or source.

  b. The number of applications granted Certificates of Conformity, with verification of certificate statuses.

  c. The number of the rejected applications.

  d. The number of applications requiring corrective actions.

  e. Corrective actions taken and their documentation.

  f. The number of objections submitted by clients regarding verification results.

  g. Any specific reports or statistics required by the Authority.

- Payment of the applicable fee for "Requesting Evaluation of a Conformity Assessment Body Designation File" as detailed in the Guidance Manual.
- Submission of a conformity assessment program to be implemented, encompassing the requirements and procedures specific to each field of application.
- Provision of necessary information and documents for each field, according to the requirements outlined in the Guidance Manual.

Article Six: Scopes of Designation for Conformity Assessment Bodies for Inspection and Certification Activities

Conformity Assessment Bodies are designated for a period of three (3) years in the fields outlined below for each scope. Sub-activities are determined as per the Guidance Manual for the Requirements of Designating Conformity Assessment Bodies.

Activity	Scope of Designation	Fees (SAR)	
		Designation & Renewal	Adding a Country
Inspection	Verification of establishment's compliance with the Authority's regulations, procedures, and systems	20,000	1000
Certification	Certificates of Consignments Conformity	20,000	1000
	Certificates of Products Conformity	20,000	1000
	Quality Management System Certificates for Establishments	40,000	———

- The Authority will collect a fee for each Certificate of Conformity, with a maximum of (1,000 SAR/certificate) per shipment.
- The designated body will collect a fee for each Certificate of Products Conformity, with a maximum of (1,000 SAR/certificate).
- ** The validity of the certificates issued for each scope is specified in the Guidance Manual for Designating Conformity Assessment Bodies. The validity period shall not be less than one month and not more than 3 years for each certificate (except for the Certificate of Consignment Conformity).

Article Seven: Requirements for Designating Conformity Assessment Bodies for Testing Activities

- Hold a valid private laboratory license issued by the Authority for the relevant activity and field, as detailed in the Guidance Manual for Licensing Private Laboratories.
- Be accredited by the Saudi Accreditation Center (SAC) for the designated scope of testing. Accreditation by a member body of international accreditation organizations (ILAC-IAF) covering the designated scope is also acceptable.
- Maintain its primary operational headquarters within the Kingdom of Saudi Arabia.
- Successfully participate in relevant proficiency testing programs as required by the Authority. These programs may be administered by the Authority or by an accredited third party. Participation must align with the requirements of the international standard ISO/IEC 17043.
- Utilize laboratory methods compliant with the Authority's approved standard procedures.
- Submit all required documentation as specified for designation in the Guidance Manual.
- Remit the applicable fee for "Requesting Evaluation of a Private Laboratory Designation File" as outlined in the Guidance Manual.

Article Eight: Scopes of Designation for Conformity Assessment Bodies for Testing Activities

The Authority designates Conformity Assessment Bodies to perform testing activities for analyzing products under its control for a period of three (3) years. These designations are based on the availability of relevant and validated tests for each specific activity, as detailed in the Guidance Manual for the Requirements of Designating Conformity Assessment Bodies.

Activity	Scope of Designation	Fees (SAR)
Testing	Imported and locally manufactured products are tested and analyzed at the expense of the importer, manufacturing company, or any party in the product supply chain.	1.000 per designated activity, with the Authority retaining 300 for issuing a clearance certificate based on sampling and risk assessment.

Chapter Three: Final Provisions

Article Nine: Final Provisions of the Regulation

First: The Authority will take appropriate action if a Conformity Assessment Body violates any provision of this Regulation. Such actions may include, but are not limited to, the penalties outlined below:

1. In the event of proven explicit violation or transgression by a Conformity Assessment Body against the Authority's regulations and/or its technical and/or administrative requirements related to this Regulation, the Authority shall have the right to take appropriate punitive action, which includes the following penalties:

A. **Suspension or Reduction of Designation Scope**
The Authority reserves the right to partially or fully suspend a Conformity Assessment Body's authorized scope of operation if any of the following occur:

- At the request of the Conformity Assessment Body, Voluntarily, to a partial or complete suspension due to its inability to continue meeting the required designation field partially or fully.
- The Conformity Assessment Body's inability to close non-conformance cases related to designation requirements within the timeframe specified by the Authority.
- The Conformity Assessment Body's inability to address any reason for suspension of the scope of designation within the specified timeframe, only affecting a specific part of the scope.
- Submission of any information or data that is false or misrepresents the facts.
- The Conformity Assessment Body fails to maintain the required accreditation for its designated scope of operations.
- Inability to continuously meet the requirements of accreditation for part of the scope.
- Non-payment of designation fees.
- Non-payment of fees owed to the designated body.

B. Cancellation of Designation:

The Authority reserves the right to permanently cancel the scope of designation of a Conformity Assessment Body (CAB) in accordance with specific procedures it establishes under the following circumstances:

- At the request of the Conformity Assessment Body, Voluntarily, due to its inability to continuously meet the requirements of designation or for any other reason.
- Inability of the Conformity Assessment Body to address any of the reasons for suspension of the scope of designation.
- In the event of evidence of fraudulent behavior that directly or indirectly affects the safety, security, or availability of the product, or the commitment to the existence of operating factories, or if the Conformity Assessment Body has provided false or misleading information.
- Engaging in illegal activities that compromise the principles of impartiality, integrity, objectivity, non-discrimination, or fair competition by the Conformity Assessment Body or any of its personnel (auditors, experts, employees, subcontracted laboratories, etc.).
- Failure of the Conformity Assessment Body to fulfill its defined obligations.
- Upon discovering discrepancies in the reports issued by the Conformity Assessment Body.
- In the event of observations or if the Authority finds that the designated Conformity Assessment Body is ineffective.
- Failure to maintain accreditation in the field of acceptance.

2. In the event of proven negligence or non-compliance in the performance of the Conformity Assessment Body.

   The Authority has the right to impose penalties and claim compensation for all damages incurred by the Authority as a result of negligence by the Conformity Assessment Bodies in performing their work.

Second: Rights and Obligations of the Authority

- The Authority has the right to adjust the fees in accordance with any issued resolutions.
- The Authority has the right to modify the list of required tests and the maximum price limit for each test.
- The Authority has the right to use and disseminate the information obtained from the Conformity Assessment Body in any manner it deems appropriate.
- The Authority has the right to verify the accuracy of the submitted information using any method it deems appropriate.
- The Authority shall periodically monitor and supervise the performance of Conformity Assessment Bodies to ensure their compliance with its regulations, requirements, and specifications. This includes conducting inspection visits according to the Authority's approved mechanisms. The Authority may delegate a third party to carry out these tasks.
- The Authority shall not be held liable for any errors made by a Conformity Assessment Body or for any financial or legal obligations arising therefrom.
- The Authority is obligated to maintain the confidentiality of information it accesses, or that is accessed by its employees or contractors, during the designation process of a Conformity Assessment Body.
- The Authority is obligated to objectively review and address any complaints submitted by a Conformity Assessment Body or its clients, taking necessary actions to resolve them in accordance with established procedures.
- The Authority is obligated to publish a list of designated Conformity Assessment Bodies on its website.
- The Authority has the right to make exceptions to these requirements, when necessary, with providing justification.

Third: Rights and Obligations of Conformity Assessment Bodies

- Conformity Assessment Bodies are obligated to stay informed about and comply with all regulations, bylaws, guidance manuals, requirements, specifications, circulars, and instructions issued by the Authority regarding the scope of their designation, including any amendments or additions.

- Conformity Assessment Bodies must adhere to all requirements outlined in the Authority's approved technical regulations, stay updated on any changes, and refrain from issuing Certificates of Conformity for products banned by the Authority.
- Conformity Assessment Bodies must comply with the Private Laboratories Law, its Executive Regulations, and any future regulations set forth by the Saudi Food and Drug Authority.
- Conformity Assessment Bodies have the right to appeal the Authority's decision regarding designation and submit supporting evidence within sixty (60) days from the date of being notified of the decision, and the appeal shall be submitted in accordance with established procedures.
- Conformity Assessment Bodies must fully cooperate with and facilitate the work of the Authority's officials during inspection and technical assessment visits.
- Conformity Assessment Bodies must implement the Authority's recommendations following inspection visits, develop approved corrective action plans, and set specific timeframes for their implementation.
- Conformity Assessment Bodies are responsible for issuing Certificates of Conformity and analyzing products in accordance with applicable regulations, technical regulations, requirements, and specifications, and shall bear legal liability for any damages resulting from their actions.
- Conformity Assessment Bodies must protect the intellectual property rights of the standards used, as well as any information pertaining to their clients.
- Conformity Assessment Bodies are obligated to maintain independence, impartiality, integrity, and confidentiality regarding information accessed by them, their employees, or their contractors, throughout the designation period and after its termination. They must refrain from disclosing any information related to the services they have provided without prior written consent from the Authority, which will be granted only in specific cases as determined by the Authority.

  Conformity Assessment Bodies must retain client files for a minimum of five (5) years from the expiry date of the Certificates of Conformity, for reference as needed.
- Conformity Assessment Bodies are obligated to immediately notify the Authority if they are unable to continue meeting the requirements and specifications of the designation.

- Conformity Assessment Bodies are responsible for performing all assigned tasks. If a third party is appointed to carry out specific tasks, they must ensure the third party adheres to all requirements and conditions stipulated in the Guidance Manual. The Conformity Assessment Body must obtain written approval from the Authority and provide a copy of the contract signed between them, assuming full responsibility for the services provided by the third party.
- Conformity Assessment Bodies must maintain enough qualified technical and scientific personnel at their headquarters within the Kingdom, in accordance with the Authority's standards.
- Conformity Assessment Bodies must adhere to the service fees outlined in the Guidance Manual and as determined by the Authority.
- Conformity Assessment Bodies are required to provide a bank guarantee upon designation for fields where the designated body collects fees on the Authority's behalf. The bank guarantee amount is specified in the Guidance Manual for Designation.
- Conformity Assessment Bodies are prohibited from sharing any documents or materials belonging to the Authority with any other entity, whether inside or outside the Kingdom, without prior written consent from the Authority. They are fully responsible for the security of the information provided to them for the performance of their duties.
- Conformity Assessment Bodies are prohibited from using the Authority's name, logo, or any other logos on products or final inspection reports for promotional or advertising purposes.
- Conformity Assessment Bodies are obligated to report any suspected or irregular practices to the Authority.
- Conformity Assessment Bodies must provide services for each scope within the timeframes specified by the Authority.
- Conformity Assessment Bodies must provide contact details to the Authority and respond to its inquiries promptly.
- Conformity Assessment Bodies are obligated to establish a Service Level Agreement with their clients that aligns with their designated scopes.

- Conformity Assessment Bodies engaged in testing activities must ensure there are no conflicts of interest between the laboratory and the client.

  If a Conformity Assessment Body wishes to receive sample testing requests from the Authority, it must obtain a designation certificate from the Authority in accordance with the requirements for designating Conformity Assessment Bodies for testing activities.

- Conformity Assessment Bodies engaged in testing activities are obligated to submit test results to the Authority within fifteen (15) days from the date of sample receipt.

- Conformity Assessment Bodies engaged in testing activities must transport samples using scientifically sound methods, adhering to the specific transportation and storage conditions of the product.

- Conformity Assessment Bodies are obligated to establish electronic connectivity with the Authority's systems as directed by the Authority.

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