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**Standardization Organization  
for the Cooperation Council for the Arab States of the Gulf  
GSO**

**GUIDE FOR NOTIFIED BODIES**

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**Note:**

This release represents the eighth draft and is issued for review by the GCC Committee for Conformity Assessment and for presentation of its comments thereon within two weeks of its publication date

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### **Article 1:**

The purpose of this Guide is to set minimum criteria used in the assessment and appointment of conformity assessment bodies which will participate in activities necessary for compliance with the requirements of Gulf Technical Standards, as well as:

- to provide explanations and clarification to conformity assessment bodies wishing to work as notified bodies in Member States of the Cooperation Council for the Arab States of the Gulf (GCC) as regards technical regulations applicable in GCC Member States;
- to specify the method used in the assessment and appointment of notified conformity assessment bodies and their subsequent assessment and registration methods.

Adherence to the requirements of this Guide shall constitute the basis for any recommendations for the appointment of any conformity assessment body wishing to work as a notified body.

This Guide is also a supplement to laws, regulations and technical standards issued by the Organization in this respect.

### **Article 2: Definitions**

Unless otherwise indicated by the context, the following terms – wherever used in this Regulation – shall have the meaning set out below:

#### **Gulf Cooperation Council (GCC)**

The Cooperation Council for the Arab States of the Gulf.

#### **Organization**

The Standardization Organization for the Cooperation Council for the Arab States of the Gulf.

#### **Member States**

GCC Member states (The State of United Arab Emirates, The Kingdom of Bahrain, The Kingdom of Saudi Arabia, The Sultanate of Oman, The State of Qatar, The State of Kuwait).

#### **Board of Directors**

The board of directors of the Organization.

#### **Technical Council**

The technical council of the Organization.

#### **Gulf Technical Regulation**

A document approved by the Board of Directors that lays down the specifications of the products and the relevant processing operations and the production methods, including the applicable administrative provisions to be adhered to. The Regulation may include or examine in particular the terms, definitions, packing and the marking or labelling requirements to be applied to the products, operations or the methods of production.

#### **National legislation**

A mandatory document issued by competent authorities of GCC Member States laying down essential requirements for products or specific product categories.

### **Conformity Marking**

Conformity marking used by GCC Member States which has a specific shape and is attached to the relevant product and/or a declaration of conformity which documents that the product fulfils essential requirements laid down in the relevant Gulf Technical Regulation.

### **Essential requirements**

Binding safety, health and environmental requirements applicable to products.

### **Gulf Standards**

A document approved by the Board of Directors that lays down, for normal and frequent use, the rules and instructions or characteristics of the products, operations or relevant methods of production thereof, the adherence to which shall not be compulsory. This document may include or examine in particular the terms, definitions, packing and the marking or labelling requirements to be applied to the products, operations or the methods of production.

### **ISO**

International Organization for Standardization.

### **IEC**

International Electrotechnical Commission.

### **Conformity assessment**

Confirmation that the requirements relating to a product, process, system, person or body are fulfilled.

### **Applicant**

A conformity assessment body wishing to work as a notified body in GCC Member States, which submits an application for such purpose. Any such body must be accredited in accordance with the accreditation definition set forth in ISO 17000 (or need not be accredited subject to special terms of this Guide).

### **Notified body**

An applicant who has been appointed as a conformity assessment body capable of implementing all conformity assessment measures at a certain level specified in Gulf Technical Regulations (usually an accredited body).

### **Appointing body**

A governmental authority in each Member State to which the State has delegated powers to decide on the appointment of an applicant as a notified body (sometimes referred to as “the assessor”). Each of the Member States shall provide the Organization with information about its authorized appointing body.

### **Accreditation**\*

An official certification by a third party that a conformity assessment body is qualified and capable of performing specific conformity assessment tasks.

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\* Source: ISO/IEC 17000

### **Accreditation body**

An authorized body confirming the competence of a conformity assessment body.

### **Identification number**

A unified number allocated at the relevant Member State's level and issued by the Organization to notified bodies after their appointment.

### **Conformity assessment module**

A defined conformity assessment measure which has certain limits, inputs and outputs and is used directly or indirectly to assess adherence to specified requirements of technical regulations or standards. Each module comprises sampling, testing and inspection, evaluation, verification and assurance of conformity, certification and any other related measures.

### **Type**

A set of variations of a single product whose mutual differences do not affect the safety level and other requirements relating to their use.

### **Product**

A product or process.

## **Article 3: General Provisions**

### **3.1 Submission of applications for the appointment of conformity assessment bodies**

Applicants shall present their applications to the appointing body in any Member State. The Member States shall notify the Organization of the conformity assessment body/bodies that has/have been appointed by them as a notified body/notified bodies for the purpose of the completion of their registration with the Organization, the issue of an identification number to each of them and publication of a list of the notified bodies of GCC Member States.

### **3.2 Responsibilities of notified bodies**

Notified bodies in each GCC Member State shall perform conformity assessment activities necessary to prove that a product submitted by a manufacturer or his representative fulfils all essential requirements of the applicable Gulf Technical Regulation(s) (and shall perform periodic inspections) whenever one or more Gulf Technical Regulations require a third party's intervention or upon request of the manufacturer or his representative, and shall award Conformity Markings to products.

## **Article 4: Terms and Conditions of Appointment**

### **4.1 Introduction**

The appointing body in a Member State shall review the application on the basis of the following key principles: **independence, integrity, competence, permanent capacity**. Details of these principles are specified in the set of international standards issued by

ISO/CASCO concerning the use and competence of conformity assessment service providers. Every applicant must also have in place the following:

- (1) employees having sufficient knowledge and experience relating to the performance of conformity assessment activities in accordance with the requirements of the relevant regulation;
- (2) necessary arrangements and measures to keep confidential all information obtained by it during its performance of conformity assessment activities;
- (3) sufficient insurance covering its professional activities, unless covered by national legislation of the Member States.

The appointment procedure shall be based on:

- (1) essential requirements laid down in the relevant Gulf Technical Regulation(s) under which the conformity assessment body has submitted its application for appointment;
- (2) the field in which the applicant has been accredited, which must cover the field in respect of which the applicant has filed its application, the body which has awarded accreditation to the applicant or, if the applicant is not accredited, the field in which the applicant purports to perform conformity assessment activities;
- (3) other conditions that may be specified by the Organization.

In case of a non-accredited applicant, the appointing body is also required to carry out detailed assurance processes and personal interviews with highly skilled experts and technicians and to review all activities performed by the applicant in order to issue a recommendation indicating that the applicant meets the required conditions.

Obtaining accreditation from the GCC Accreditation Center (or from bodies included in the list published by the Organization) is a mandatory prerequisite for the applicant's appointment as a notified body. In the transition period until the start-up of the operation of the GCC Accreditation Center (or the grace period after the start of the Center's operations), priority shall be given to applicants accredited by bodies published by the Organization or to those fulfilling the requirements of this Guide.

**Accreditation does not necessarily mean that the applicant will be appointed as a notified body; the final decision on appointment/commissioning of a notified body in the Member States is solely at the discretion of the Member States acting through their respective official appointing authorities.**

#### 4.2 Designated field

The applicant shall be appointed as a notified body in a specific area of conformity assessment activities (according to his application) and in a technical field specified in the relevant Gulf Technical Regulation(s), which is defined as “designated field”.

Each applicant shall specify in its application submitted to the appointing body the field in which it wishes to be appointed by referring to the applicable Gulf Technical Regulation(s), measures and conformity assessment modules which it is capable of implementing.

## **Article 5: Assessment and Appointment Procedure**

### **5.1 Introduction**

This part explains various steps of the process of assessment of the applicants in the light of requirements specified in Article 4 of this Guide.

In order that the appointing body may perform its task, particularly if the applicant is not accredited, the appointing body must rely on its experience and use a set of measures including inspection of documents, revision, assurance and interviews. It may also assess the results of prior conformity assessment activities performed by the applicant in previous phases. In this case, the appointing bodies shall prepare the necessary reports clarifying the result of assessment or periodic monitoring or re-assessment carried out by them in order to substantiate their appointment. Such reports shall concern solely the field where the applicant wishes to be appointed. **If, however, the applicant is accredited in the required conformity assessment field, the appointing body shall complete the phases described in Article 5.2 only to the extent it deems fit and shall be satisfied with the applicant's accreditation documents and their assessment, unless indicated otherwise.**

### **5.2 Phases of the assessment process**

The applicant's assessment process is composed of the following four main phases:

- assessment of compliance;
- assessment of adequacy (followed by a recommendation to appoint or not to appoint the applicant).

If the applicant is appointed, the above phases are followed by:

- periodic survey/assessment (at least once a year), including quality systems and performance assessment;
- overall re-assessment (at least once every four years), including quality systems and performance assessment.

The evaluating body may agree with the applicant on the performance of an unofficial assessment before the actual assessment to provide some time for assessment of the situation and adjusting the applicant's situation to the relevant requirements. This unofficial assessment is recommended particularly to new applicants.

**These phases are similar to phases of the accreditation process; however, in case of an accredited applicant, the appointing body shall only make sure of the scope of the accreditation and that the accreditation clearly covers all requirements of the relevant Gulf Technical Standard(s).**

### **5.2.1 Phase One: assessment of compliance (non-accredited applicants)**

This phase includes an assessment of the applicant's application, including the draft contract, and review of supporting documents. The applicant must submit an official application to the appointing body.

The compliance assessment is largely intended as a documentary evaluation focusing on an examination of documents and some inspection visits to the applicant. Before the start of the adequacy assessment, the applicant may be asked to provide any additional information. This phase is concentrated on an examination of accreditation certificates, of the scope of accreditation and the accreditation body.

Bodies which have successfully passed the compliance assessment phase shall proceed to the following phase:

### **5.2.2 Phase Two: assessment of adequacy (non-accredited applicants)**

This phase includes assessment of activities and employees, as well as a review of whether the non-conformities revealed during the first assessment phase have been remedied.

This assessment phase is intended to determine whether the applicant is capable of applying its skills practically in the performance of a conformity assessment under the relevant Gulf Technical Standard.

The appointing body shall concentrate on an examination and assessment of the effectiveness of the applicant's internal regulations, measures and activities pertaining to conformity assessment. This phase shall be based on a number of interviews and assurance and may also include a review of the applicant's previous activities in the examined and tested fields.

The appointing body may organize personal interviews with all competent persons and employees involved in conformity assessment activities, who are required to prove their capabilities and practical experience.

The purpose of such personal interviews is to determine the technical capacities of such employees and to assess the extent of compliance and effectiveness of the applicant's internal system of competencies (whether the persons in charge of the relevant responsibilities and tasks possess technical skills to perform such tasks).

The governmental authority may request any information or the performance of any additional assessment measures before issuing its decision.



**In all cases,**

**Member States, acting through their appointing bodies, are ultimately responsible for the applicant's appointment as a notified body.**

**If the appointing body appoints an applicant as a notified body, the appointing body shall issue a letter of appointment, which shall be sent to the Organization for completion of the registration process and the issue of the applicant's identification number. The letter of appointment shall include the following:**

**The notified body's name, address, contact data and designated field.**

**A copy of the appointment letter shall be sent to the notified body, which shall present it in turn to the Organization for entry in the register of notified bodies and for the issue of an identification number. The Organization shall inform the other Member States of the notified bodies and identification numbers allocated to them.**

**If an appointing body in a Member State withdraws or cancels an appointment, it shall notify the Organization, which shall take the appropriate steps and shall inform the other Member States.**

### **5.2.3 Phases Three and Four: periodic survey and re-assessment (non-accredited bodies)**

The recommendation relating to the appointment phase shall be upheld by an annual periodic survey and assessment plus an overall re-assessment carried out every four years. This periodic assessment and re-assessment shall be focused on confirming that quality systems and operating measures used by the notified body continue to conform to the relevant requirements and on an evaluation of the conformity assessment activities based on a review of implemented contracts and monitoring of practical steps taken at various sites as required.

The first periodic assessment visit shall take place four months after the date of the appointment decision. Subsequent visits shall take place every year until the overall re-assessment date four years later. If necessary, the appointing body may seek to make periodic assessments in shorter than annual intervals.

Appointing bodies shall inform the notified body of the results of the periodic assessment or re-assessment and, where any non-conforming elements are identified, shall provide the notified body with an opportunity to remedy them. If any non-conformity persists, the appointing body may suspend or cancel the appointment decision and notify the Organization, which shall notify the other Member States.

A notified body that is not accredited from the outset and obtains accreditation shall be treated as an accredited body as regards periodic survey and re-assessment.

**Appointed accredited notified bodies must maintain the force of their accreditation in order to keep their status.**

#### **5.2.4 Remediating non-conformities (non-accredited bodies)**

Identified non-conformities which have been remedied shall not be assessed on a case-by-case basis; the remediation process of non-conformities shall be assessed after the completion of remediation of all such cases. Due to the foregoing, the time limits granted by the appointing body to the applicant for remediation of such non-conformities shall vary and the review date shall be subject to agreement by the parties.

The normal time limit granted to the applicant for correction of non-conformities during the first assessment phase is three months (taking into account that the applicant cannot start its work as a notified body because the appointment decision has not yet been issued). The time limit granted for remediating non-conformities identified during subsequent visits shall be one month.

In cases where non-conformity results in a safety and health risk, the appointing body may withdraw the appointment with immediate effect until the internal situation in the notified body/applicant is remedied and confidence in the conformity assessment activities performed by the notified body/applicant is reinstated.

#### **5.3 Change of the designated field (all cases)**

If the notified body wishes to expand the field of its activities (i.e. its designated field), such request shall be considered as a new application and shall not mean re-assessment of the scope of work with respect to which the notified body has been originally appointed. To assist the new assessment procedure, the same evidence and materials previously submitted by the notified body shall be used in this respect.

A change of the designated field shall not require the issue of a new letter of appointment to set the periodic assessment or re-assessment dates (according to Article 6.5), but the date of periodic assessment of the new designated field shall be included in the previously determined schedule (in relation to the previous field).

#### **5.4 Changes affecting activities performed by the notified body**

The notified body is obliged to immediately inform the appointing body in case of any change relating to the management structure, employees or any other conditions which may affect its ability to fulfil its tasks as a notified conformity assessment body within its specified designated field.

#### **5.5 Conditions of appointment**

The conditions of appointment shall be included in the relevant notices issued by the appointing bodies. Such notices shall include the **notified body's consent** to the following conditions:

- (1) the corporate status of the notified body in a GCC Member State;

- (2) the performance of assessments by the appointing body, whether at periodic, annual or any other intervals determined by the appointing body (however, periodic inspection may not start earlier than four months after the appointment) (**non-accredited bodies**);
- (3) another condition for maintaining the appointment shall be the performance of complete re-assessment 3.5 years (42 months) after the appointment date and every four years thereafter or at any other time which the appointing body deems fit (**non-accredited bodies**);
- (4) the acceptance of any additional controlling measures required by the appointing body (**non-accredited bodies**);
- (5) neither the appointing body nor the Organization bears any responsibility for errors committed by the notified body in the determination of the scope of product assessment;
- (6) provision of information about its insurance coverage. Such insurance must include public liability and professional indemnity insurance and must cover all GCC Member States.

None of the GCC Member States shall assume any responsibility for or provide any insurance coverage for the activities of notified bodies. The insurance coverage value shall be determined by the Member States, shall be notified to the Organization and shall be reviewed from time to time.

#### **Article 6: Withdrawal of Appointment**

- 6.1. The Organization and appointing bodies in the GCC Member States are responsible for carrying out necessary measures in respect of notified bodies in case of any doubt about their activities performed since their appointment as notified bodies.
- 6.2. If the Organization concludes (whether *ex officio* or based on a complaint) that a notified body does not comply with the requirements or does not fulfil its responsibilities, it shall notify the appointing body in the relevant Member State and ask it for the documents and materials on which it relied in its assessment of the notified body's competence. If the relevant Member State fails to provide this evidence, the Organization shall invite the other Member States to discuss the matter and to decide whether to withdraw or not to withdraw the appointment or to issue any other decision.
- 6.3. If the notified body does not fulfil its obligations, the appointing body in the relevant Member State shall notify it of such failure and shall take the necessary steps, such as suspension or withdrawal of the appointment, and shall notify the Organization thereof. In such cases and in order to maintain continuity, the appointing body shall arrange for the appointment of another body as a notified body to perform the activities of the body whose appointment has been withdrawn. At the same time, the appointing body shall seek the suspension of certificates which might have been issued to the body prior to the withdrawal of its appointment.

- 6.4 It is necessary to take into account that the appointment of notified bodies and the withdrawal of appointment **fall within the competencies of the appointing body in each GCC Member State, which is responsible for such decision**, except for cases referred to in clause 2 above.

#### **Article 7: Transitional Provisions**

The following arrangements shall be made in the transitional period when all parties (the GCC Member States' Accreditation Centre, the governmental appointing body, the applicant, etc.) have not yet begun their operations:

- 7.1 The Organization shall coordinate with Member States the presentation of a list of international and foreign bodies which shall be considered recognized accreditation bodies and whose certificates can be accepted.
- 7.2 The Organization shall present a list of international and foreign bodies which shall be considered notified bodies and which have been assessed by the accreditation bodies included in the above-mentioned list. Those bodies shall have the authority to work in the GCC Member States in the designated fields determined for them, taking into account that such bodies must also fulfil the conditions set forth in this Guide.

#### **Article 8: Sources**

- (1) Regulation on Conformity Marking of GCC Member States;
- (2) Guide to Conformity Assessment Modules;
- (3) Gulf Technical Regulations;
- (4) ISO/IEC conformity assessment standards and documents published by ISO Conformity Assessment Committee (CASCO);
- (5) EC documents and guidelines concerning the Global Approach for Certification and Testing, particularly Council Decision 93/465/EEC of 22 July 1999.