

Guide on Notified Bodies

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

Guide on Approved Bodies

Draft No. (8) – Date: (November-26th-2008)

Note

This Publication is the 8th draft issued in order for the Gulf Conformity Verification Committee to review it and make observations about its content, within 2 weeks from the date of its publication.

Guide on Notified Bodies

Contents:

| Section | Subject | Page Number |
|----------------|---|--------------------|
| 1 | | 3 |
| 2 | Definitions | 4 |
| 3 | General Principles | 5 |
| 4 | Conditions and Basis for Appointment | 9 |
| 5 | Process of Assessment and Appointment of Applicants | 10 |
| 6 | Withdrawal of Appointment of notified bodies | |
| 7 | Transitional Procedures | 12 |
| 8 | 7- References | 18 |
| | | |

Guide on Notified Bodies

Section 1

The purpose of this Guide is to specify a minimum level of criteria to be used in the assessment and appointment of conformity verification bodies to undertake duties and functions as set out in the Gulf Technical Regulations. This Guide is also aimed at:

- Providing explanations and clarifications to conformity verification bodies wishing to act as notified bodies within the jurisdiction of Cooperation Council States subject to the GCC Technical Regulations in force in the Member States.
- Laying down the method of registration, evaluation and appointment of notified conformity verification bodies as well as information on how to follow up such evaluation.
- Meeting the criteria of this Guide will serve as basis to any recommendations made about the appointment of any conformity verification body wishing to carry out the functions of a notified body.

This guide should be seen as complementary to legal texts, legislations and technical regulations issued by the Organization to that effect.

Section 2. **Definitions**

When used in this Guide, the following terms shall have the meanings assigned to them hereunder unless the context otherwise requires:

The Cooperation Council

The Cooperation Council for the Arab States of the Gulf

Guide on Notified Bodies

The Organization

The Standardization Organization for the States of the Cooperation Council

The Member States

The Member States of the Cooperation Council (The United Arab Emirates, the Kingdom of Bahrain, The Kingdom of Saudi Arabia, The Sultanate of Oman, Qatar, and Kuwait)

The Technical Council

The Technical Council of the Organization

The Board of Directors

The Board of Directors of the Organization

The Gulf Technical Regulation

A document approved by the Board of Directors, which lays down product characteristics and their related processes and production methods including the applicable (in force) administrative provisions, with which compliance is mandatory. It may include or deal exclusively with terminology, definitions, packing or marking and labeling requirements as they apply to a product, process, or production method.

National legislations

A mandatory document issued by relevant authorities in the Member States of the Council which lays down the essential requirements of a product or of a specific category of products.

Conformity Mark

The conformity mark of the GCC States which shall take a special form and shall be affixed to a product and/or a conformity declaration to demonstrate that a product complies with the essential requirements prescribed in the relevant Gulf Technical Regulations.

Guide on Notified Bodies

Essential Requirements

Special requirements related to products which may affect the health, safety and environment, with which compliance is mandatory.

Gulf Standards

A document adopted by the Board of Directors, that provides for common and repeated use, rules, guidelines, or product characteristics or related processes and production method, with which compliance is not mandatory. It may include or deal exclusively with terminology, definitions, packing or marking and labeling requirements as they apply to a product, process, or production method.

ISO

International Standardization Organization.

IEC

International Electro technical Commission.

Conformity Assessment*

A demonstration whether specific requirements relating to a product, process, service, system, person or body have been fulfilled.

Applicant

Conformity verification body seeking to act as a notified body in the Council States and submits an application to be appointed for this purpose. It must be accredited according to the definition of ISO Standard 17000 (A conformity verification body may be non-accredited under special conditions laid down in this Guide).

Notified Body

An applicant appointed as conformity verification body which can perform within a specific scope all conformity assessment procedures described in the Gulf Technical Regulations. Notified bodies are usually accredited bodies.

* Reference ISO/IEC 17000

Guide on Notified Bodies

Appointment authority

The government entity in each of the Member States, having authority derived from the State to designate an applicant as an approved body and may be sometimes called assessment bodies. Member States shall inform the Organization of their authorized appointment authorities.

Accreditation

A formal attestation by a third party that a conformity verification body is competent and eligible to perform specific conformity verification functions.

Accreditation body

An authoritative body which verify the competence of conformity assessment bodies

Identification Number

A single number used by all Member States and given by the Organization to the notified body after it has been appointed as a notified body.

Conformity assessment form

Specific conformity verification procedure which has specific limits, specific input and specific output. It may be used directly or indirectly, to ensure that specific requirements in technical regulations or standards are fulfilled. Conformity assessment procedures include procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration and approval, as well as their combinations.

Type

A group of a particular product category having differences that does not affect the level of safety and other performance related requirements.

Product

The produce of any process

Guide on Notified Bodies

Guide on Notified Bodies

Section 3 General Principles

3.1 Submission of Applications by Conformity Verification Bodies Seeking Appointment

An applicant shall lodge an application for appointment to the appointment authority in any of the Member States. The Member State shall notify the Organization of the conformity verification body/bodies which have been designated as notified body/bodies within its jurisdiction, in order to complete their registration procedures at the Organization and allocate an identification number for each body and publish a list of notified bodies in the GCC States.

3.2 Functions of Notified Bodies

Notified bodies in each of the GCC States shall perform the necessary conformity verification procedures to demonstrate that the product of a manufacturer or his representative comply with the essential requirements set out in the relevant Gulf Technical Regulation/Regulations (including periodical inspection), either when the Gulf Technical Regulation/Regulations requires the intervention of a third party or at the request of the manufacturer or his representative who shall affix a conformity mark on such products.

Section 4 Conditions and Basis for Appointment

The appointment authority in the Member State shall assess an applicant based on essential principles: **Independence, integrity, competence, and continuous capability**. These principles are described in details in the ISO/CASCO International Standards and Guidelines on the operation and competence of bodies providing conformity verification services. An applicant shall also have the following:

Guide on Notified Bodies

- (1) The personnel, who have sufficient and relevant knowledge and experience relating to conformity verification procedures in accordance with the requirements of the relevant Regulation;
- (2) The necessary procedures and arrangements to ensure the privacy and confidentiality of the information obtained in the course of conformity verification activities;
- (3) The adequate insurance liability to cover its professional activities, unless such liability is covered by national laws and legislations of Member States.

The assessment process shall be based on the following:

- (1) The essential requirements described in the Gulf technical regulation/regulations within the jurisdiction of which the conformity verification body has applied for appointment;
- (2) The scope of accreditation of the applicant body, provided that the scope for which the applicant body applied covers the purpose of its accreditation, or the scope defined by the applicant body for the performance of conformity verification activities, in case of a non-accredited body.
- (3) Other conditions that may be issued by the Organization.

Where an applicant is non- accredited, the nature of assessment requires also from the appointment authority thorough audit operations and personal interviews with experts and technicians having a high level of expertise, and surveillance of all the activities carried out by the applicant until a recommendation is made that it fulfills the necessary conditions.

Accreditation by the Accreditation Center of the Cooperation Council States (or by the bodies published by the Organization) constitutes a mandatory condition for the appointment of an applicant as an approved body.

Guide on Notified Bodies

However, during the transitional period and until the Accreditation Center of the Cooperation Council States has launched his activities (or during the grace period granted following the operation of the Center), preference shall be given to applicants accredited by the bodies published by the Organization or to applicants which fulfill the requirements of this Guide.

Accreditation will not necessarily lead to the appointment of the applicant as an approved body. The final decision of appointment/designation as an approved body in the Council States remains at the discretion of the Member States via the official appointment authority in each of the Council States.

4.2 Scope of Notification

An applicant shall be notified for a specific scope of conformity verification activities (for which it has been appointed) and a technical scope specified in Gulf technical regulation/regulations known as “Appointment Scope”.

Where an application is submitted to the appointment authority, the applicant shall specify the scope for which appointment is sought by determining the relevant Gulf technical regulation/regulations, as well as conformity verification procedures and forms that the body is technically capable of performing.

Section 5 Process of Assessment and Appointment of Applicants

5.1 Introduction

This section describes the various steps of the assessment process for applicants subject to the criteria set out in Section 4 of this Guide.

To enable the appointment authority to perform its tasks, especially when the applicant is not accredited, it will apply its experience and employ a

Guide on Notified Bodies

number of processes such as document examinations, reviews, audits and interviews etc.... It may also verify previous results of conformity verification procedures previously carried out by the applicant. In such a case, the appointment authority will make necessary reports on its assessment, periodical follow up or reassessment, to justify the appointment. Such reports will relate only to the scope for which appointment is sought by the applicant. **If the applicant is accredited in the scope of conformity verification for which appointment is sought, the appointment authority is not required to implement the stages described in 5.2 unless within the limits set out for each stage. The documents of accreditation of the applicant would be sufficient, unless otherwise required.**

5.2 Assessment Process Stages

A four-stage assessment process is to be applied to all applicants as follows:

- Compliance assessment stage;
- Adequacy assessment stage (followed by the recommendation to appoint or not appoint);

If the applicant is appointed, the following stages apply:

- Periodical surveillance /assessment stage (undertaken yearly at least), which will include both management systems and performance assessments;
- Full re-assessment (four-yearly at least) stage, which will include both management systems and performance assessments.

In addition, arrangements can be made between the assessment body and the applicant for an informal pre-assessment, to allow assessment and enable the applicant to comply with the criteria and requirements. Informal assessment visits are strongly recommended for new applicants.

Guide on Notified Bodies

These stages are similar to the stages of the accreditation process. However, if the applicant is accredited, the appointment authority will only check the scope of accreditation and ensure that it expressly covers the requirements of the relevant Gulf Technical Regulation/Regulations.

5.2.1 Stage 1: Compliance assessment (Non-accredited bodies)

This stage comprises assessment of the application lodged, contract review and document review. The applicant has to submit a formal written application for appointment to the appointment authority.

The compliance assessment is largely a desk-based exercise, focused on documents examinations and supplemented by visits to the applicant. Additional information may be required from the applicant prior to the commencement of adequacy assessment. This stage focuses on the examination of certificates, scope and purpose of accreditation.

Applicants who satisfy the compliance assessment are next subject to the next stage.

5.2.2 Stage 2: Adequacy assessment (Non-accredited bodies)

This stage comprises assessment of activities and staff, and clearance of non-conformities found out during the initial assessment stage.

This stage focuses on the assessment of the ability of the applicant to translate its capabilities into effective conformity verification performance in the scope of the relevant Gulf Technical Regulation/Regulations.

The appointment body will be more concerned with examination and evaluation of the effectiveness of the applicant's laws, procedures and processes annexed to conformity verification. The methodology used at this stage will include a number of interviews and audits. It may also include the

Guide on Notified Bodies

review of previous activities undertaken by the applicant in the areas of examination and testing.

All persons with responsibility for conformity verification may be the subject of interview by the appointment authority. These persons shall be able to demonstrate their capabilities and practical expertise.

Personal interviews are directed at determining the individual technical competencies of staff and determining to which extent the applicant's system for the authorization of staff is appropriate and effective.

The government authority may request any additional information or assessments to be made prior to a decision on appointment.

The Member States shall be responsible for the appointment of applicants as notified bodies via their appointment authorities.

Where an applicant is appointed as a notified body, the appointment authority will issue a letter of appointment that will be sent to the Organization for the completion of the registration procedures and assignment of an identification number. The letter of appointment shall include the following:

Name, address, contact numbers and scope of appointment of the notified body.

A copy of the letter of appointment will be submitted to the notified body, which shall also have recourse to the Organization to register in the register of notified bodies and receive an identification number. The Organization will notify other states of notified bodies and their identification numbers.

If the appointment is withdrawn or revoked by an appointment authority in the Member States, the Organization must be notified to initiate the necessary procedures in this regard and notify other

Guide on Notified Bodies

Member States.

5.2.3 Stages 3 and 4: Periodical Surveillance and reassessment (Non-accredited bodies)

The appointment recommendation is maintained by periodical annual surveillances and four yearly full reassessments. Periodical assessments and reassessments will be directed at ensuring continued compliance of the Notified Bodies' management systems and work procedures and at assessing the performance of Notified Bodies' conformity verification activities by reference to contract records and observation of practical work, if necessary, at a range of relevant locations.

The first periodical assessment visit becomes due four months following a decision of appointment. Surveillances take place annually thereafter until the fourth visit when a full reassessment will be undertaken.

Periodical assessment visits may be carried out at intervals less than one year, at the discretion of the appointment authority, if needed.

The appointment authority will advise the notified body of the outcome of all periodical assessment and reassessment visits. Where compliance is found to be inadequate opportunities for corrective action will be provided. Where compliance remains inadequate the appointment authority may cease or revoke the appointment decision and inform the Organization of its decision. The Organization will then notify the other Member States.

Guide on Notified Bodies

If accreditation is granted to a notified body which had not been previously accredited, it shall receive the same treatment accorded to accredited bodies with regard to the two stages of periodical survey and re-assessment.

Where bodies are accredited, the continuity of appointment depends on the continuity of accreditation of the notified body.

5.2.4 Clearance of non-conformities

Corrected non-conformities are not judged in isolation but are considered in the overall context of the assessment after all non-conformities are corrected. The time periods allowed by the appointment body to the applicant for the correction of non-conformities will therefore vary. The date for review shall be agreed between the applicant and the Notified Body.

Normally, in cases of non-conformities, up to three months is allowed to the applicant at the initial stage of assessment (a body is not at this stage appointed and therefore cannot do Notified Body work) and up to one month for subsequent visits.

Where non-conformity was such as to compromise safety and health, the appointment body could immediately withdraw the appointment until such time as corrective action is made at the applying body/notified body and confidence is regained in the body in terms of performing conformity verification activities.

5.3 Changing the scope of notification

Where a notified body wishes to extend its scope of work (the scope for which it has been appointed), it is to submit a new application and does not have to undergo a re-examination of the scope of work for which it has been already appointed. The arguments and presumptions that have been previously submitted on the part of the applicant will be used in the new assessment process.

Guide on Notified Bodies

Where changes are made to the scope of notification, the new letter of appointment will not be considered in relation to the due date of the periodical assessment or re-assessment (under Section 6.5). With respect to the periodical assessment of the new scope of notification, it will be incorporated within the timing of the overall assessment process in place (the previous scope).

4/5 **Changes having bearing upon the functions of a notified body**

A notified body is required to promptly notify the appointment authority of any changes relating to its organizational chart, staff, or any other circumstances that might affect its ability to perform its duties as a notified conformity verification body, within its scope of notification.

5/5 **Terms of Appointment**

The terms and conditions of appointment will be set out in special letters issued by the appointment authority, but it will be a condition that the notified body agrees to each of the following conditions:

- (1) to be a legal entity established on the territory of a GCC country;
- (2) to assessment regularly or annually or at such intervals as may be deemed appropriate by the appointment authority (provided that regular inspection is undergone four months after the date of appointment), **(non-accredited bodies)**;
- (3) That continued appointment will be subject to a full re-assessment 3.5 years (42 months) after initial appointment and every 4 years thereafter, or at such intervals as may be deemed appropriate by the appointment authority **(non-accredited bodies)**;

Guide on Notified Bodies

(4) To acceptance of any further monitoring procedure requested by the appointment authority (**non-accredited bodies**);

(5) That the appointment authority or the Organization shall not be held responsible for any mistakes made by a notified body in determining the level of product conformity.

(6) To provide information on the available insurance cover. Such insurance must include “public liability” and “professional indemnity” insurance and cover all the GCC countries.

Member states shall not retain responsibility to provide an insurance to cover the activities of notified bodies. The value of insurance cover shall be determined by Member States and shall be notified to the Organization. The value shall also be revised from time to time.

Section 6 Withdrawal of appointment

1/6 The Organization and the appointment bodies in the Member States have the responsibility to act when doubt arises about the competence of a notified body, as from the moment of notification.

2/6 Should the Organization consider, on its own initiative or after complaint, that a notified body does not comply with the requirements or fulfill its responsibilities, it will inform the appointment authority in the concerned state and ask for appropriate documented evidence concerning the basis for the verification of the competence of the notified body. Should the concerned Member State not provide such information, the Organization may bring this to the attention of the other Member States for discussion or take a decision either to withdraw the appointment or not withdraw it or initiate any other decision.

3/6 When a notified body ceases to fulfill its obligations, the appointment authority in the state concerned shall bring this to the knowledge of

Guide on Notified Bodies

the notified body and initiate the adequate necessary procedures such as the suspension or withdrawal of appointment and inform the Organization. In such a case and to ensure continuity the appointment authority shall take appropriate steps to ensure that another body is designated as notified body to perform the tasks of the de-notified body. The appointment authority shall also discuss the status of certificates issued by the de-notified body before the decision of withdrawal has been made.

- 4/6 It should be taken into consideration that the appointment of a notified body and the withdrawal of such appointment shall be vested in the appointment authority in each of the GCC States, the appointment authority shall retain the responsibility of such decision, except for the cases mentioned in Section 6.2.

Section 7 Transitional Provisions

During the transitional phase, while all concerned parties are being mobilized (The accredited Council of the GSS States, government appointment body/applicant...), the following arrangements shall be taken into consideration:

- 1/7 The Organization shall, in collaboration with the Member States, provide a list of international and foreign bodies considered as recognized accreditation bodies, the accreditation certificates of which may be accepted.
- 2/7 The Organization shall provide a list of the international and foreign bodies considered as notified bodies which have been assessed by accreditation bodies mentioned in the preceding list. Such bodies shall be entitled to pursue their activities within the GCC states in the scope of work for which they have been notified, taking into consideration that such bodies must also meet the criteria described in this guide.

Guide on Notified Bodies

Section 8 References

| | |
|---|--|
| 1 | Regulation on the GCC Conformity Mark |
| 2 | Guide on Conformity Assessment Forms |
| 3 | Gulf Technical Regulations |
| 4 | ISO/IEC International Standards on Conformity Assessment – Code of Good Practice |
| 5 | Files and Guidelines issued by the European Commission on the Global Approach for Certification and Testing in particular EC Resolution 93/465/EEC |