

GSO Procedure for

Designation of the Conformity Assessment

Bodies

- Version 4 -

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HISTORY OF MODIFICATIONS

Revision No	Date	Responsible	Object of modification
01	01/05/2014	Moteb Al-Meezani	First issue
02	14/02/2016	Ibrahim Al-Hashaf	General revision
03	01/06/2016	Ibrahim Al-Hashaf	Updating Article 18 to match the certification tracking process as per the electronic system Add Annex (8) Rules for the use of the Gulf Logo to track conformity Add definitions (26-27-28-29) to Article 4 (Tracking - Gulf Tracking Certificate - Gulf Certificate Tracking System - QR Code) Add paragraph (b) in Article (16) on the contribution of the designated bodies to provide free services to the Authority Updating Article (32) paragraph (2) for the costs of implementation of the preliminary or periodic assessments, by adding the technical assessment and the technical committee for the final review and recommending the appointment and updating Annex 4 of these costs. Updating Paragraph (f) of Article (1) of Article (14) by removing the words when the Commission so requests, Updating paragraph (a) of Article (1) of Article (28) by making regular technical follow-up evaluations (3 months) for periodic evaluations from the date of the previous evaluation. Add responsibilities to the appointment chart in Annex(1)
04	23/12/2018	Ibrahim Al-Hashaf	 Article 4: Update the definitions Article 5/2: Add the clause of non-discrimination + obligation of GSO to update NBs about changes in its policies Article 7: Deletion of article "Use third party for technical assessment" Article 8/5: Add the possibility of unannounced visits from GSO to NBs Article 9: Update "Impartiality" as per the common elements of new ISO/CASCO standards + add the specific requirements of ISO/IEC 17065 Article 13/1: Remove the requirement of annual report + Add other mandatory information to be communicated in case of changes related to the NB Article 14: Update "Confidentiality" as per the common elements of new ISO/CASCO standards Article 15: Rephrase the article "Participation in standardization activities" Article 19: New article about required profile and duties of Legal Representative Article 21/3: Consider the signed application for notification a formal commitment to undergo GSO rules Article 23/8: For applicant already designated for another TR and having the required technical competencies, the notification could be granted based on documentary assessment (with condition to conduct early surveillance within 6 months) Article 24: Replace "Technical assessment" by "Assessment" and align the requirements to the new ISO/IEC 17011 statement Article 25: Replace "Review" by "Final review and recommendation"



GSO Procedure for Designation of the Conformity

Assessment bodies (NP-01)

Revision No	Date	Responsible	Object of modification
			 Article 26: The decision-maker for designation is the Director of GSO conformity assessment department Article 28: Set GSO rules for considering extension requests for notification scope Article 28: Define margins for notification cycle + set conditions for extending the validity of notification / Replace the term 'follow-up visit' by 'surveillance visit' Article 30: Define the period of suspension (3 months renewed once) Remove Annex 2 (Chart of the technical evaluation procedure) and Annex 4 (Notification and Registration Costs) Remove annex 8 (Rules for use the GSO Conformity Tracking Symbol (GCTS) from NP-01), as it is issued as separate document.

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Date of issue: 23-12-2018



CONTENTS

CHAPTER ONE: Framework – Definitions	6
Article (1): Objective	6
Article (2): scope	6
Article (3) Complementary Reference	6
Article (4): Definitions	7
CHAPTER TWO: General requirements for designation of the conformity assessment bodies	11
Article (5): General	11
Article (6): Information obligation on GSO for Member States	11
CHAPTER THREE: Requirements for Notified bodies	12
Article (7): General	12
Article (8): Impartiality for Notified Body	12
Article (9): Resources for the notified body	13
Article (10): Presumption of conformity for CAB	14
Article (11): The operational obligations of the conformity assessment procedures for the notified body	14
Article (12): Subsidiaries of and subcontracting by notified bodies	15
Article (13): Information obligation on notified bodies to the GSO and the relevant bodies	15
Article (14): Confidentiality	16
Article (15): Participation in standardization activities	16
Article (16): The multi-branches applicant bodies	16
Article (17): Tracking of certificates issued by the notified body	17
Article (18): Insurance and Bank Guarantee	18
Article (19): Legal Representative	18
CHAPTER FOUR: Procedures for the designation process	19
Article (20): General	19
Article (21): Submit Application for Notification	19
Article (22): Initial review of the application and announcement to Member States	19
Article (23): Application and document review	20
Article (24): Assessment	22
Article (25): Final Revie and Recommendation	22
Article (26): Designation Decision	23
Article (27): Registration of the Notified Body	23
Article (28): Follow-up of the efficiency of the notified bodies	23

 Revision: 4
 Date of issue: 23-12-2018
 Page: 4 of 37



GSO Procedure for Designation of the Conformity

Assessment bodies (NP-01)

Article (29): Changes Affecting Designation	25
Article (30): Withdrawal, Reduction or Suspension of Notification	26
Article (31): Complaints and Appeal	26
CHAPTER FIVE: Costs of Notification and Registration	27
Article (32): Notification costs	27
Article (33): Registration costs	28
CHAPTER SIX: Final Provisions	29
Article (34): Coordination with the competent authorities of Member States to implement this procedure	29
Article (35): Cancellation	29
Article (36): Effective Date	29
Annex 1/ Chart of designation process procedures	30
Annex 2/ Notification Cycle	31
Annex 3/Insurance requirements	32
Annex 4/Mechanism of dealing with bank guarantee	34
Annex 5/Appeals	36

Revision: 4	Date of issue: 23-12-2018	Page: 5 of 37



CHAPTER ONE

Framework - Definitions

Article (1):

Objective

The aim of this procedure is to identify the criteria and mechanism for the designation of conformity assessment bodies which submitted to become notified bodies in order to provide conformity assessment services in accordance with the approved GSO technical regulations.

Article (2):

Scope

This procedure is concerned with the designation of conformity assessment bodies for products subject to the GCC scheme to control the safety of products in the markets of the GSO member states.

Article (3)

Complementary References

- General Product Safety Regulation BD09100504
- Conformity Marking for the GCC Countries BD09100501
- GSO ISO/IEC 17020: Conformity assessment Requirements for the operation of various types of bodies performing inspection.
- GSO ISO/IEC 17025: General requirements for the competence of testingand calibration laboratories.
- GSO ISO/IEC 17065: Conformity Assessment requirements for bodies certifying products, processes and services
- GSO ISO/IEC 17067: Conformity assessment Fundamentals of product certification and guidelines for product certification schemes

Note: Consider the final versions of the complementary references referred to above.

Revision: 4	Date of issue: 23-12-2018	Page: 6 of 37
-------------	---------------------------	---------------



Article (4):

Definitions

For the implementation of the rules of this procedure, the following terms shall have the meanings assigned to each of them unless the context requires otherwise

1. The Cooperation Council

The Gulf Cooperation Council countries.

2. The Organization

The GCC Standardization Organization "GSO" of the Cooperation Council.

3. The Member States

The Member States of the Standardization Organization for the Cooperation Council for the Arab States of the Gulf (United Arab Emirates, Kingdom of Bahrain, Saudi Arabia, Sultanate of Oman, State of Qatar, State of Kuwait and Republic of Yemen).

4. Gulf standard

A document approved by the Board of Directors which, for normal and repeated use, establishes the rules, instructions, or characteristics of the products, processes and methods of production that are not mandatory and may include or specifically consider terms, definitions and packaging, and requirements for placing badges or marks applicable to products Services, operations, production methods or otherwise.

5. Gulf Technical Regulations

A document approved by the Board of Directors that provides the characteristics of the products and the related processes and their production methods, includes the administrative provisions in force, with which the compliance is mandatory. It could include in particular terminology and definitions, packaging and labeling requirements or labels that apply to the products or services, processes or production methods.

6. Conformity

The fulfilment is for specific requirements. This means that the requirements product, service, process, system, body or person are fulfilled. These requirements may be standards, technical regulations, contractual clauses, consumer requirements, etc.

7. Conformity assessment

Demonstration that specified requirements related to a product, process, system, person or body are fulfilled.



GSO Procedure for Designation of the Conformity

Assessment bodies (NP-01)

8. conformity assessment bodies

Bodies that perform conformity assessment activities, including testing, calibration, certification and inspection.

9. Designation

Acceptance of the applicant body that applicate to perform conformity assessment services in specific field in accordance with the rules of this procedure.

10. Applicant bodies

A conformity assessment body that applies for Designation to the GSO in accordance with the rules of this procedure.

11. Notified body

The body designated in accordance with the rules of this procedure to provide conformity assessment services contained in the adopted GCC technical regulations, within a specific technical regulation, or a specific list of products, risks or categories of products in accordance with this procedure.

12. Accreditation

Third-party attestation related to a conformity assessment body (8) conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

13. GCC Accreditation Center

Center for Accreditation of the GSO member states.

14. Gulf Conformity Marking

A specific marking of the Cooperation Council for the Arab States of the Gulf which is affixed on the product or/and the Declaration of Conformity to indicate that the product is in conformity with the requirements set out in the applicable Gulf Technical Regulations.

15. Place on the market

Means put the product for the first time on the Gulf Common Market.

16. Manufacturer

Any natural or legal person who manufactures a product, design or mandates another natural or legal person to do it, and then markets it under its own name or under its own trademark.

17. Authorized Representative

A natural or legal person based in one of the Member States who has received a written mandate from a Manufacturer to act on his behalf.

Revision: 4	Date of issue: 23-12-2018	Page: 8 of 37
-------------	---------------------------	---------------



18. Importer

Any natural or legal person within one of the Member states who places a product on the market from a third country outside the Member states.

19. Distributor

Any natural or legal person in the supply chain, other than the Manufacturer or the Importer, who makes a product available on the market.

20. Economic Operator

This includes manufacturer, official representative, importer, and distributor.

21. The multi-branch applicant body

Is a conformity assessment body with one legal entity, one head office and multiple branches involved in conformity assessment activities Some specific activities may be implemented or managed, in whole or in part, within a network of sites. All sites need to have direct or contractual legal contact with the head office of the entity and are subject to a common quality system, within the specific geographical area.

22. Branch

Anybody that conduct conformity assessment activity on a temporary or permanent basis and administratively or legally is following the main conformity assessment body.

23. Main branch

Is a branch in which one or more of the main activities of the conformity assessment are carried out (policy development, conformity assessment processes, management review, decision making of conformity assessment processes).

24. Appeal

A request submitted by the applicant body or the notified body to the Gulf Steering Committee for notification to review the decisions taken by the GSO regarding the designation for CAB in accordance with the provision of this regulation.

25. The appellant

The applicant or the notified body that submitted the complaint to the Gulf Committee for notification.

26. Surveillance

All subsequent actions carried out by the notified body to ensure that the conformity of the products to which identical certificates have been granted is continued.

27. GSO Certificate Tracking System

An electronic system in which all products bearing the Gulf conformity marking, that subject to the notified body, are registered.

Revision: 4	Date of issue: 23-12-2018	Page: 9 of 37



28. GSO Conformity Tracking Symbol (GCTS)

A symbol provided by the GSO, consisting of the Gulf Conformity Marking, with four-digits notified body number, located below it, and the QR Code. This symbol is generated by GSO Certificate Tracking System.

Revision: 4



CHAPTER TWO

General requirements for designation of the conformity assessment bodies

Article (5):

General

1. Responsibility for designation a notified body:

The General Secretariat of GSO is responsible for the designation of the applicant bodies that have fulfilled the requirements stipulated in the rules of this procedure.

2. General obligations of the GSO:

- 1. The GSO shall ensure transparency, impartiality and objectivity in the procedures of notification activities and shall take all measures to ensure that there is no conflict of interest. The GSO's policies, processes and procedures are non-discriminatory and shall be applied in a non-discriminatory way. The GSO makes its services accessible to all applicants whose application for notification falls within the scope of its notification activities as defined within its policies and rules. Access shall not be conditional upon the size of the applicant conformity assessment body or membership of any association or group, nor shall designation be conditional upon the number of conformity assessment bodies already designated.
- 2. The GSO shall ensure the confidentiality of the information obtained through the designation process.
- 3. The GSO shall establish a documented system of procedures for such action.
- 4. The GSO encourages the notified bodies to participate in the sectorial cooperation groups in the fields of Gulf technical regulations facilitating the exchange of information and experiences among them.
- 5. The GSO shall undertake the coordination of the experience exchange among Member States with regard to the notification activities and capacity building for the national staff with competence in the field of the notification.
- 6. The GSO shall inform the applicants and the notified bodies about any relevant decision pertaining to its status as notifying authority.

Article (6): Commitment to inform member states

The GSO shall inform Member States of the following:

- 1. Lists of notified bodies and continuous updating of these lists and making them available to the public.
- 2. The applicant bodies that have not designated or the notified bodies for which any action has been taken in accordance with the rules of section (2) of article (26) and article (30) of this procedure.
- 3. Non-conforming products within the scope of the notification that are ensured to be Non-conforming further the results of the surveillance according to section (5) of article (12) of this procedure.

Revision: 4Date of issue: 23-12-2018Page: 11 of 37
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CHAPTER THREE

Requirements for Notified Bodies

Article (7):

General

- The Notified body shall be of a legal personality or a specific part of a legal entity in any of the Member States. Government applicant bodies in the GSO member states shall be considered a legal entity on the basis of their governmental status. The conformity assessment bodies outside the Member States may open offices or delegate legal representation of the entity in any Member States.
- 2. The notified body shall have the necessary technical, financial and professional qualifications to assess the conformity of the product within the scope of the required notification scope.
- 3. The notified body shall have the financial stability and the resources required to cover the liabilities arising from its notification scope and geographical location operations and shall prove that it has the appropriate arrangements (insurance and reserves) to meet these obligations.
- 4. The notified body shall be capable of carrying out all the conformity assessment tasks assigned to such body by the provisions of the relevant scope for which it has been notified, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility and provides evidence that it meets all the requirements of this procedure at all times.
- 5. At any time, the notified bodies shall provide all necessary facilities to the GSO and provide it with all information required to implement the designation procedures. This includes the facilitation of the on-site visits, even unannounced.

Article (8):

Impartiality for Notified Body

- A notified body shall be a third-party body independent of the organization or the product it assesses. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.
- 2. Conformity assessment activities of Notified Body shall be undertaken impartially.
- 3. The Notified Body shall be responsible for the impartiality of its conformity assessment activities and shall not allow commercial, financial or other pressures to compromise impartiality.
- 4. The Notified Body shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a body with a risk to impartiality.



- 5. If a risk to impartiality is identified, the Notified Body shall be able to demonstrate how it eliminates or minimizes such risk.
- 6. The Notified Body shall have top management commitment to impartiality.
- 7. The Notified Body and any part of the same legal entity and entities under its organizational control shall not:
 - be the designer, manufacturer, installer, distributer or maintainer of the certified product;
 - be the designer, implementer, operator or maintainer of the certified process;
 - be the designer, implementer, provider or maintainer of the certified service;
 - offer or provide consultancy to its clients;
 - offer or provide management system consultancy or internal auditing to its clients where the certification scheme requires the evaluation of the client's management system.

Article (9):

Resources for the notified body

- 1. The notified body at all times, for all conformity assessment procedures and for each kind or category of products in relation to which it has been notified, shall have:
 - a. Enough personnel with sufficient technical knowledge and experience to perform conformity assessment tasks.
 - b. Description of the procedures according to which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of these procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as notified body and other activities.
 - c. The necessary procedures to perform their activities taking into consideration the size, the sector, the structure of the undertakings, the degree of complexity of the product technology in question and the mass or serial nature of the production process.
 - d. The necessary means to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.
- 2. The personnel responsible for carrying out conformity assessment activities shall have the following:
 - a. Sound technical and vocational training covering all conformity assessment activities of the relevant scope for which the Conformity Assessment Body has been notified.
 - b. Satisfactory knowledge of the requirements of the assessment they carry out and adequate authority to carry out such operations.
 - c. Appropriate knowledge and understanding of the essential requirements of GSO standards, and Technical Regulations and its implementing rules.
 - d. The ability to draw up certificates, records and reports to demonstrate that assessments have been carried out.



Article (10):

Presumption of conformity for CAB

- 1. Where a conformity assessment body shall demonstrate its conformity with the criteria laid down in the relevant GSO standards or parts thereof, it shall be presumed to comply with the requirements set out in the applicable GSO standards or parts thereof cover those requirements.
- 2. Accreditation granted by the GCC Accreditation Center "GAC" or any accreditation body signatory of ILAC-MRA / IAF-MLA is considered as one tool to prove the competency in the covered scope.

Article (11):

Operational obligations of the conformity assessment procedures for the notified body

- 1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for the scope of notification, in accordance with the requirements of this procedure and the GSO technical regulations and standards.
- 2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.
- 3. Where a notified body finds that requirements laid down in the GSO technical regulations or those mentioned in relevant GSO Standards and included in the scope of the notification have not been met by a manufacturer or the importer responsible for putting the products into the market, it shall require taking appropriate corrective measures and shall not issue a conformity certificate for non-complying products and to inform the GSO accordingly.
- 4. The notified body shall implement all tracking procedures to ensure continuous compliance of the products that have been awarded conformity certificates according to their designation in accordance with the requirements of the GSO technical regulations.
- 5. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies, it shall require the manufacturer or the importer responsible for putting products into the market to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary, and immediately inform the GSO with a copy of all file documents.
- 6. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate, and advise GSO as per point (3)

Revision: 4	Date of issue: 23-12-2018	Page: 14 of 37



Article (12):

Subsidiaries of and outsourcing by notified bodies

- 1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in this procedure.
- 2. The notified body shall take full responsibility for the tasks performed by the subcontractor and Subsidiaries, wherever these are established. Subcontracting all services within the scope of notification is not acceptable.
- 3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.
- 4. Notified bodies shall keep at the disposal of the GSO the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this procedure.

Article (13):

Information obligation on notified bodies to the GSO and the relevant bodies

- 1. The notified body shall inform the GSO of the following:
 - a. Any rejection, restriction, suspension, termination or withdrawal of a certificate;
 - b. any circumstances affecting the scope of and conditions for notification.;
 - c. When requesting corrective measures from the manufacturer or importer responsible for the place on market;
 - d. Any request for information which they have received from market surveillance authorities or the relevant authorities of Member States regarding conformity assessment activities.
 - e. Conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting;
 - f. The results of its surveillance procedures as implementation of the provisions of this procedure;
 - g. Change in key positions (authorized representative, owners),
 - h. Change in the legal status of the Notified Body or its legal representative,
 - i. Change in accreditation status,
 - j. Change of location/office where conformity assessment activities are performed.
- Notified bodies shall provide the other notified bodies under this same scope of notification and carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative conformity assessment results after recording the information on the GSO Certificate Tracking System, and on request, positive conformity assessment results.

Revision: 4 Date of issue: 23-12-2018	Page: 15 of 37
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Article (14):

Confidentiality

- 1. The Notified Body shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of conformity assessment activities. The Notified Body shall inform the client, in advance, of the information it intends to place in the public domain. Except for information that the client makes publicly available, or when agreed between the Notified Body and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.
- 2. When the Notified Body is required by law or authorized by contractual arrangements to release confidential information, the client or individual concerned shall, unless prohibited by law, be notified of the information provided.
- 3. Information about the client obtained from sources other than the client (e.g. complainant, regulators) shall be confidential between the client and the Notified Body. The provider (source) of this information shall be confidential to the Notified Body and shall not be shared with the client, unless agreed by the source.

Article (15):

Participation in Standardization Activities

- Conformity assessment bodies shall participate actively in the cooperative groups, known as GNBCG (GSO Notified Bodies Cooperative Groups), created by GSO for each Technical Regulation, and attend their periodic meetings. The notified bodies must ensure that the concerned personnel are informed of the relevant standardization activities established under the relevant legislation in its field of notification and implement the decisions and documents produced as a result of the work of the relevant cooperative group.
- 2. Notified bodies shall provide free of charge to the GSO technical services in the field of notification, including not more than ten files per year.

Article (16):

The multi-branches applicant bodies

1. The applicant body who operates from one head office and has several branches within the same legal entity may submit one application, and the branches to be added shall meet the requirements specified in this procedure.

Revision: 4	Date of issue: 23-12-2018	Page: 16 of 37
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- 2. The notified body who need to add branches within the same application shall adhere to the following:
 - a. These branches shall be within the same geographic range and according to the following distribution:
 - 1st Field: Middle East and North Africa
 - 2nd Field: Europe
 - 3rd Field: America
 - 4th Field: Asia
 - 5th Field: Africa
 - 6th Field: Australia and New Zealand
 - b. The number of branches that applicate for designation as GSO notified body within the same geographical area shall not exceed ten branches.
- 3. The branches shall be subject to initial assessment before embarking on any major activity within the scope of the notification.
- 4. The applicant body shall subject all its facilities (even those in which the main activities are not performed) to the assessment at least once during the designation cycle as provided for in it section (7) of article (24).
- 5. Notified body shall ensure the competency of its subsidiaries and failure of any branch to meet the requirements of designation shall result in the removal of the branch from the designation. If the reason for non-compliance with the requirements is due to the central control, then the notification for the head office designation is subject to surveillance by the GSO and may lead to the suspension or withdrawal of designation for all branches.

Article (17):

Tracking of certificates issued by the notified body

- The notified body shall register the certificates issued by it for the products bearing the G Marking, which have been subject to conformity assessment procedures in accordance with these regulations in the electronic system for tracking the certificates and paying the fees thereof in accordance with section (2) Article (33) of this procedure.
- 2. Notified body shall register all certificates issued by it in the electronic system to generate the GSO Conformity Tracking Symbol (GCTS) for each type/model according to the following:
 - a. For the manufacturer: The model/type is registered and the GSO Conformity Tracking Symbol (GCTS) is registered once during the validity period of the model/type certificate of conformity unless it is changed, and it should be reactivated annually or as defined by GSO.
 - b. For the importer: Each model is registered and the GSO Conformity Tracking Symbol (GCTS) is generated by the system for each consignment.



- 3. Notified body shall affix the GSO Conformity Tracking Symbol (GCTS) as described in "GSO Rules for the use of GCTS" for each model/type according to the following:
 - a. Affix GSO Conformity Tracking Symbol (GCTS) in a prominent place on the certificate issued by the notified body.
 - b. The GSO Conformity Tracking Symbol (GCTS) shall be affixed by stamping or casting to the product or to its data plate, it must be visible, legible, indelibly and impossible to remove, However, where this is not possible or not warranted on account of the nature of the product, it must be affixed by stamping or casting by any manner approved by GSO and in accordance with "GSO Rules for the use of GCTS".

Article (18):

Insurance and Bank Guarantee

The notified bodies shall take out bank guarantee or liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment and according to Annexes (3, 4) of this procedure.

Article (19):

Legal Representative

- 1. The legal representative shall be a legal entity in any GSO member state.
- 2. The field of work must be in a field related to notification activities.
- 3. The legal representative shall have satisfactory understanding of the notification requirements.
- 4. The legal representative shall sign an agreement to bear all legal responsibility related to the implementation of notification activities by the designated body.
- 5. When the notified body decides to change the legal representative, the designated body shall notice GSO within a period not exceeding two weeks and provide evidences that all the obligations of this article are properly documented and applied.

Revision: 4	Date of issue: 23-12-2018	Page: 18 of 37



CHAPTER FOUR

Procedures for the designation Process

Article (20):

General

- 1. GSO may notify only conformity assessment bodies which have satisfied the requirements laid down in this procedure.
- A conformity assessment body shall submit an application for notification to the GSO, whether in the Member States or abroad and shall meet the requirements of the legal entity mentioned in section (1) of article (8) of this procedure.
- 3. The requirements for designation as GSO notified body shall include the technical requirements contained in the GSO Technical Regulations related to the scope of notification in addition to the ones stated in this procedure, as well as any additional requirements that may be determined by the GSO.
- 4. The GSO shall have the right to request any additional documents or procedures if the results of the assessment indicate the need for such.

Article (21):

Submit Application for Notification

- Applicants body shall submit a formal request to the GSO for each GSO technical regulation that seeking to be designated in its scope. It shall provide all necessary data for the completion of the designation procedure and shall attach to the application all necessary administrative and technical documents as stated in article (23) of this procedure.
- The applicant shall pay the fees incurred in the process (administrative and technical) as stated in article (32) of this procedure.
- 3. The application is considered a formal commitment from the CAB to undergo GSO rules and conditions for notification.

Article (22):

Initial review of the application and announcement to Member States

1. The GSO shall notify the Member States about the application through the electronic designation system for the purpose of receiving the opinion of the Member States if they have any objection to the applicant and explain the justification within two weeks from the date of publication on the system at the maximum.

Revision: 4 Date of issue: 23-12-2018	Page: 19 of 37
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2. If there is no any objection in accordance with section (1) of this article, the GSO shall review as initial review the application, documents and information obtained in accordance with section (1) of article (21), to verify that the basic documents for the commencement of the designation are fulfilled.

Article (23):

Application and documents review

The application and document review phase shall be carried out by the GSO in accordance with the chart of the designation procedure in Annex 1, during which the application shall be evaluated, and the completeness and validity of all documents required by this procedure shall be demonstrated as a minimum:

- 1. It shall be verified that the formal application submitted by the applicant is formally stamped and authenticated, the identity of the person responsible for issuing it is determined, and that he/she is the official representative of the applicant throughout the designation procedure and has the authority to bear all the consequences resulting from the designation process, as well as ensuring the compliance with all relevant procedures and legislation of the GSO and bearing all the fees resulting from the designation procedure, without any conditions or guarantees regarding the final result.
- 2. It shall be verified that the application for multi- branches show the number of sites under their management or central administrative systems, as well as the scope and field of their respective activities. It also specifies all the sites where conformity assessment activities are conducted, implemented by each branch and that the application is completed and stamped.
- 3. Verification of the documents proving that the legal entity of the applicant meets the requirements of section (1) of Article (8) of this procedures, accompanied by an official registration document or a replacement thereof (e.g. commercial license) proving that the applicant is actually a legally registered entity in one of the Member States, with a description of the scope of services, the address of the body, and for the applicant bodies not located in one of the Member States and seeking to open an office or designate a legal representative in any of the Member States , the proof thereof shall be to attached (commercial license of the office or legal representative).and an evidence of the nature of the legal relationship between the applicant and the legal representative shall be attached.
- 4. Verification that the legal entity of the branches required to be added falls within the same legal entity as the notified body that the designation has been granted to, in addition to the requirements contained in section (1) Article (8) and Article (17).
- 5. Verification of the bank guarantee or insurance policy is valid and meets the requirements of Article (19).



- 6. Verification that the attached documents contain sufficient information regarding the exact identification of the applicant, particularly with regard to the seeking scope of notification, including the following information, for example, but not limited to:
 - a. Name of owner/owners of the applicant body.
 - b. Officials and sufficient data on the buildings, equipment and human resources of the applicant body.
 - c. Services currently performed by the applicant body.
 - d. The branch (s) covered by the application and all related thereto.
 - e. Accreditation certificates, with a detailed statement of accreditation scopes and their relationship with the conformity assessment fields required for notification activities. This statement shall show the conformity assessment services and standards applied in both fields (the field of accreditation and the required scope of notification) And clearly indicate the required scope of notification covered by accreditation.
 - f. The exact identification of the conformity assessment work required for designation, which includes, in particular, the following:
 - i. The relevant GSO Technical Regulations.
 - ii. Designated products.
 - iii. Provide a summary of the conformity assessment services that the applicant intends to undertake and experience in this field.
 - iv. Procedures for conformity assessment in the field of notification.
 - g. A report on the circumstances that may conflict with independence and impartiality.
 - h. Documents and technical documents that provide the necessary evidence to evaluate and prove the competence of the applicant Body.
 - i. Names and addresses of the external contracting bodies, including the external branches of the applicant body (which is not applicant for designation).
- 7 If the results of the document review show that the information or any of the documents is missing or incomplete, the GSO shall inform the applicant body to address the issue.
- 8 Upon completion of the application and document review, the GSO shall issue a report with its recommendations. In case of Conformity Assessment Body which is already notified for any of GSO Technical Regulation and holding the necessary technical competence proved by recognized accreditations. The Document review can lead to a direct recommendation of notification, since the applicant has the required experience with the notification process; the effectiveness of implementation must be verified during the next planned on-site assessment.

Revision: 4	Date of issue: 23-12-2018	Page: 21 of 37



Article (24):

Assessment

- 1. The assessment phase shall be carried out after completion of the application and document review. In case of need for on-site assessment, the GSO may undertake or delegate the task to the GCC Accreditation Center "GAC" via formal assignment.
- 2. The assessment process, including the on-site assessment, shall be carried out as determined by GSO in Annex (2), and upon completion, a report gathering findings and recommendations shall be issued.
- 3. Assessment procedures shall be carried out in accordance with international practice and guidance in this scope (In particular ISO/IEC 17011).
- 4. The assessment of the accredited bodies that are accredited by the GCC Accreditation Center or any ILAC-MRA / IAF-MLA signatory accreditation body shall be limited to the specific aspects of GSO Technical Regulation, with the necessity to assess the relevant technical evidences.
- 5. For applicants' bodies, which are not accredited by the GCC Accreditation Center or any ILAC-MRA / IAF-MLA signatory accreditation body, in addition to the rules of section (2) of this article, they shall prove their competence through a comprehensive on-site assessment to evaluate suitability, verification of technical evidences and determination of efficiency.
- 6. Assessment of the multi-branches' applicant bodies shall be subject to the following procedures:
 - a. The central quality system of the multi-branches applicant is subject to the assessment annually, as well as the assessment of all the main branches in the initial assessment and surveillance stage.
 - b. All branches shall be subject to visit during the period of notification and may be frequent in certain circumstances provided that such branches are informed of the reasons for such frequent visits.
 - c. All facilities of the applicant where the conformity assessment activities are conducted shall be subject to assessment at least once during the notification cycle.
 - d. Temporary sites are subject to the same requirements and assessment on a sampling basis as part of the designation process to provide evidence of their technical competence.
- 7. If the results of the assessment of the multi-branch applicant body have proved the lack of conformity in the Central Office or in any of the branches of the notified body, corrective action(s) shall be taken on all the sites of the application. GSO shall review the assessment program and this may increase the number of onsite assessments.

Article (25):

Final Review and recommendation

GSO Notification Section appoints a committee to review the results of the assessment and all information obtained and issues its recommendation on designation after making sure that the applicant has met all the requirements mentioned in this procedure.

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GSO Procedure for Designation of the Conformity

Assessment bodies (NP-01)

Article (26):

Designation Decision

- 1. The Director of GSO Conformity Assessment Department is responsible of making decision to designate or reject the notification based on the recommendation issued by the Notification section mentioned in article (25).
- 2. GSO shall formally inform the applicant of its decision to designate or reject the notification, which shall be justified, within fifteen working days.

Article (27):

Registration of the Notified Body

- GSO shall register the notified body after the decision of designation and paying the fees so that one designation number for each notified body (one legal entity) shall be issued regardless of the number of technical regulations assigned to it. The branches participating in the scope of notification shall be mentioned in the designation document. This shall not preclude the issuance of several documents for the designation of the number of branches participating in the same notification number.
- 2. The notification period shall be set at four years from the date of designation of the body and it's renewable after approval by the GSO.
- 3. The notified body shall be informed of its designation number, the date of termination of the designation and the necessary information.
- 4. The notified body may commence its business from the date of announcement of the designation number.
- The notified body who is seeking to renew the notification shall submit the application (Application Form NF.01) three months prior to the end of the designation period granted to it under section 3 of this article.
- 6. The GSO shall inform Member States of the notified bodies and any update thereof.

Article (28):

Follow-up of the competence of the Notified Bodies

The notified bodies shall be subject to follow-up to monitor and maintain the confidence in the competence of designated bodies according the following system:

1. Notification cycle:

A- After the initial assessment and during the designation period, the notified body shall be subject to three surveillance assessments (at least one of them conducted on-site) and a renewal assessment as follows:

Revision: 4	Date of issue: 23-12-2018	Page: 23 of 37

- 1. Surveillance Assessment I: After 12 months (<u>+</u> 3 months) from the date of designation. When the designation is granted without carrying out an initial on-site assessment, the surveillance assessment must be performed on-site after 6 months from the date of designation;
- 2. Surveillance Assessment II: After 24 months (+3 months) from the date of designation;
- 3. Surveillance assessment III: After 36 months (+3 months) of the date of designation;
- 4. Renewal Assessment: At least 3 months before the expiry of the designation.
- B- GSO shall determine the appropriate mechanism for surveillance assessments according to the available cases and evidences on compliance. GSO could limit the mechanism to office assessment of the documents proving the continuity of competency with the same requirements that led to its notification or based on the onsite assessment. This does not preclude any additional assessment when needed.
- C- The continuity of accreditation of notified body obtaining accreditation from the GCC Accreditation Center or any recognized accreditation body, is an evidence for the progress of assessments and the notified body shall provide all necessary data to GSO for verification in appropriate time. GSO is entitled to take any additional appropriate actions to guarantee the competence of its notified bodies.
- D- When an extension of the notification scope is requested for adding/updating new products' categories and standards, the notified body shall duly fill out the relevant parts of the Application Form NF.01 and send it to GSO along with the supportive evidences proving the competence for the requested extension. GSO evaluates the request and determines whether an on-site visit is required, or the extension can be granted by carrying out an office assessment of submitted evidences; in this case, the effectiveness of implementation of extended scope should be appraised during the next visit.

The periodic revisions of the notification scopes during planned assessments does not require the submission of application.

E- The validity of notification can be extended, for three months term, in case of delay in conducting renewal assessment and making the decision. This exemption is restricted to the case of force majeure that shall be subject of formal approval from GSO. The extension can be renewed only once.

2. Market Surveillance:

- A- Results of the market surveillance is carried out by the competent market surveillance authorities in the Member States.
- B- GSO follows up the performance of notified bodies through the results of the tracking carried out by these entities according to what is stated in sections (4, 5) of article (12) of this procedure.



3. Exchange of information, complaints and reports on the performance of notified bodies:

- A Information and complaints are received by the GSO through the exchange of information on the performance of the notified bodies with the Member States.
- B- GSO shall investigate all cases where it casts doubt, or doubt is brought to its attention from external parties regarding the competence of a notified body and its fulfilment of the requirements and responsibilities to which it is subject.

4. Verification of continued confidentiality:

GSO shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

Article (29):

Changes Affecting Notification

1. Changes relating to the notified body:

- In case of request from the notified body to extend its scope of notification, the requirement in clause (1-D) of Article (28) shall be met.
- In the event of restriction, suspension, termination or withdrawal of notification, or where the notified body has ceased its activity, GSO shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.
- Changes in the ownership, the key staff, the legal status, the accreditation and the legal representative must be communicated in timely manner to GSO.

2. Changes relating to the products:

- Results of the competence follow-up mentioned in Article (28) of this procedure.
- Any change in the requirements for the products stated in the GSO technical regulations or standards affecting the product. The notified body shall verify the implementation by the concerned parties, taking into account the necessity of giving the transition period for the mandatory implementation.

Revision: 4	Date of issue: 23-12-2018	Page: 25 of 37
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GSO Procedure for Designation of the Conformity

Assessment bodies (NP-01)

Article (30):

Withdrawal, Reduction, or Suspension of Notification

- 1. Where GSO has ascertained or has been informed that a notified body no longer meets the requirements laid down in this procedure, or that it is failing to fulfil its obligations as a result of the follow-up of the competence as mentioned in Article (28) of this procedure or otherwise, the GSO shall take an appropriate decisions depending on the seriousness of the failure to fulfil those obligations, and the notified body bear all the fees resulting from these procedures. Such decisions may be one of the following:
 - a. Continuation of notification with increased monitoring over the notified body.
 - b. To reduce the scope of notification by removing the part where the non-conformity is raised.
 - c. Suspension of the notification of the notified body until the adoption of suitable corrective action(s).
 The suspension is allowed for a period of three months, renewed only once before withdrawal.
 - d. Withdrawal of the notification of the notified body.
- 2. In the event of restriction, suspension or withdrawal of notification, notified body shall take full legal responsibility arising therefrom. The GSO shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article (31):

Complaints and Appeals

- 1. GSO shall establish a documented system of complaints and Appeal.
- 2. The applicant body or the notified body have a right to make appeal against the decision taken by the GSO and submit a request to the GCC Steering Committee for Notification within 30 days from the date of announcement of the decision, in accordance with the Appeal procedure mentioned in Annex 5.

Revision: 4	Date of issue: 23-12-2018	Page: 26 of 37
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CHAPTER FIVE

Costs of Notification and Registration

Article (32):

Notification costs

The applicant body under this procedure shall bear all costs resulting from the designation process as follows:

1. Administrative costs:

- 5000 Saudi Riyals for each application to be submitted. The designation of each GSO Technical Regulation shall be considered as a separate application.
- SR 2500 per branch to be added to the same scope of notification of the main branch of each GSO technical regulation.

2. Initial, surveillance and correctional assessment costs:

- 2-1 (SR 3500/expert/day), the costs of implementing the initial or surveillance assessment
 - 2-1-1 (SR 3500/expert/day), the costs of the initial technical assessment office assessor.

2-1-2 (SR 3500/expert/day), the costs of carrying out the initial or surveillance assessment, provided that the GSO estimate the number of experts (expert/day) required.

- 2-1-3 (SR 3500/half day), the costs of final technical review committee and notification decision.
- 2-1-4 (SR 3500/expert/half day), initial or surveillance technical office assessment costs.
- 2-2 (SR 2000/expert/day) when conducting the assessment to verify corrective action, provided that the GSO shall estimate the number of experts (expert/day) required to carry out the task.

3. Renewal costs:

(SR 3500/expert/day), and the GSO shall estimate the number of experts to carry out the necessary assessment to renew the designation of the notified body. The applicant shall bear the costs of travel, accommodation and transportation of the assessment teams in accordance with a recommendation by the GSO specifying the travel and subsistence costs for the members of the technical teams based on their grades or any opinion by GSO.



Article (33):

Registration costs

The notified body, upon announcement of its notification by the GSO, shall pay all costs resulting from the registration as follows (Annex 4):

1. Costs of registration of the notified body and giving it an identification number:

- SR 1000/ the decision of designation to work within technical regulation scope.
- SR 1000/ the decision of renewal designation to work within technical regulation for the same.

2. Licensing costs for the notified body to grant the right to use the G Marking for the supplier:

• SR 500/product/supplier and license renews annually.

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Page: 28 of 37

Date of issue: 23-12-2018

Revision: 4



CHAPTER SIX

Final Provisions

Article (34):

Coordination with the competent authorities of Member States to implement this procedure

The national standardization bodies of the Member States shall coordinate with the competent authorities of the Member States and exchange information on the performance of the notified bodies and conformity assessment procedures for the certified products.

Article (35):

Cancellation

Any text which conflicts with the provisions of this procedure shall be null.

Article (36):

Effective Date

This procedure shall enter into force upon adoption.

Revision: 4	Date of issue: 23-12-2018	Page: 29 of 37



Annex 1/Chart of designation process procedures [Informative]



	Revision: 4	Date of issue: 23-12-2018	Page: 30 of 37
Note: Only the Arabic version of this Regulation is authentic in law and is applicable where there are differences with this translation.			



GSO Procedure for Designation of the Conformity

Assessment bodies (NP-01)





	Revision: 4	Date of issue: 23-12-2018	Page: 31 of 37
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Annex 3/Insurance requirements [Mandatory]

Insurance requirements for conformity assessment activity:

1. Accurate description of the activities involved and potential risks.

1.1. The conformity assessment body shall provide documents that give a precise description of the activities covered and the possible risks involved.

1.2. The adequacy of the insurance for the potential risks from the relevant activities shall be assessed during the consideration of the application, the assessment of the body, and sufficient material resources provided to cover the liability arising from its activities.

2. The availability of sufficient material resources to cover the liability arising from this activity.

2.1. The conformity assessment body shall have sufficient funds (such as insurance or bank reserves) to cover the liabilities arising from its operations.

2.2. As a result of the legal entity of the conformity assessment, and the obligations associated with it, the body shall prove its ownership of an insurance policy from an insurance company or the provision of a bank guarantee covering its professional, civil and criminal liability and not less than twice the annual income of the conformity assessment authority in the activities concerned.

2.3. The adequacy of the insurance for the risks arising from the relevant activities is evaluated during the application study and the assessment of the body.

2.4. "Self-insurance" shall be in the form of a physical reserve, and the conformity assessment shall verify that the amount is available as soon as it is needed, and the guarantees made accordingly.

2.5. If the amount of the required compensation exceeds the resources available in the bank guarantee or the insurance policy, this does not vacate the body of the conformity assessment and remains a claim to provide the necessary compensation and the conformity assessment body shall pay the missing amount in addition to the deposit of the bank guarantee.

2.6. Government agencies other than Member States shall prove the State's insurance for their activities in accordance with the requirements mentioned in this procedure to be excluded.

2.7. The insurance policy and "self-insurance" shall cover the civil liability and professional responsibility of the conformity assessment body and the following:

- Responsibility for permanent human resources;
- Responsibility of the members of the technical and administrative committees for the activities concerned;

Revision: 4	Date of issue: 23-12-2018	Page: 32 of 37



• Responsibility of inspectors, evaluators, experts and temporary human resources to be assigned within the relevant conformity assessment activities;

• Responsibility for the activities of the subcontractors to carry out conformity assessment processes;

• Responsibility for all accidents that may occur during the insurance period;

• Responsibility for other activities carried out by the same legal entity if they have a direct impact on the continuation of the activities involved;

2.8. Must be clear within the insurance policies (whether insurance contract documents or self-insurance policies) cover civil liability, professional liability and criminal liability (or equivalent phrases in national laws);

2.9. Insurance coverage shall be continuous for the duration of the designation and shall be ended after 180 days from the end of the designation.

2.10. In order to assess the operational risk of the notified body, the risk analysis, area and quantity of insurance shall be adjusted to the risk analysis result. The insurance guarantee shall cover injuries to persons and damage to property as well as material loss caused by

Revision: 4	Date of issue: 23-12-2018	Page: 33 of 37
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Annex 4/Mechanism of dealing with bank guarantee [Mandatory]

Purpose of bank guarantee:

A bank guarantee is a sum of money allocated by the conformity assessment body as "self-insurance" to cover its professional, civil and criminal liability arising from the errors of the activities in which it is designated, in accordance with the requirements in the "Insurance Requirements of the Applicants".

The bank guarantee does not cover the fees imposed by the organization on the conformity assessment body within the designation procedures. These fees shall be part of the contractual procedures between the organization and the conformity assessment body.

If the amount of the required compensation exceeds the resources available in the bank guarantee, this does not absolve the conformity assessment body and remains required to provide the necessary compensation.

Beneficiaries of bank guarantee:

The bank guarantee is paid to the entities (or individuals) that are proven to have been damaged as a result of the failure of the conformity assessment body to assume its responsibilities within the scope of the activities in which it was assigned.

How to estimate the amount of compensation to be deducted from the bank guarantee:

The compensation is estimated as follows:

Judicial ruling:

If the injured body raises a lawsuit or the Public Prosecution submits a request for compensation to the affected bodies, the judicial authorities shall assess the amount of compensation to be paid and the compensation shall be paid in accordance with the judgment.

Agreement between the concerned parties:

If the compensation process is not covered by the preceding paragraph, the conformity assessment body and the affected body may agree by agreement on the value of the compensation required. Conformity assessment body shall pay the compensation in favor of the affected body.

Role of the Organization:

The role of the Organization is to assess the appropriateness of insurance for the risks arising from the activities involved, and the existence of guarantees for the availability of bank guarantee during the term of designation.

Revision: 4 Date of issue: 23-12-2018	Page: 34 of 37
---------------------------------------	----------------



The Organization shall take the necessary measures to warn, suspend or withdraw the designation and / or impose financial penalties on the conformity assessment body, which violates its responsibilities.

If the Organization is found to have defaulted on the notified body, the Organization shall have the right to deduct any damages, fines or any expenses from the guarantee without the need to give an ultimatum or recourse to the judiciary.

The Organization shall require the conformity assessment body an information in advance of any use of the bank guarantee, either by judicial order or by mutual consent with the affected party. This shall be ascertained during the follow-up operations, provided that the conformity assessment body complies with the guarantee amount within one week of its use and shall notify the Organization accordingly.

	Revision: 4	Date of issue: 23-12-2018	Page: 35 of 37
Note: Only the Arabic version of this Regulation is authentic in law and is applicable where there are differences with this translation.			



GSO Procedure for Designation of the Conformity

Assessment bodies (NP-01)

Annex 5/Appeals [Mandatory]

1- Objective:

The appeal aims at:

1. Preserving the rights of the notified bodies, the applicant bodies and the GSO on the basis of the Gulf legislation in force and international standards.

- 2. To verify the extent to which this procedure and related legislation have been applied.
- 3. Reflecting the principle of transparency in the procedures of the Organization.
- 4. Maintain effective communication relations between the GSO and the applicant and notified bodies.

2- Field:

The Gulf Steering Committee shall be responsible for considering appeals submitted by the applicant bodies or the notified bodies against the final administrative decisions taken by the GSO in accordance with the rules of this procedure I as follows:

- 1. Accepting the appeal and canceling the decision of the GSO.
- 2. Accepting the appeal with partial amendment to the organization's decision.
- 3. Rejection of the appeal.

3- Principles of consideration of an appeal:

1. The appeal shall be submitted to the Gulf Steering Committee for designation in writing within a maximum period of 30 working days from the date of notification or knowledge of the party concerned with the decision of the Organization.

2. The following data shall be available in the appeal:

- 2.1 Name and address of the applicant.
- 2.2 The decision of GSO.

2.3 The subject of the appeal and justifications on which the appeal is based, accompanied by the documents, which it deems necessary.

4- Requirements for considering an appeal:

4.1. General:

1. The appeal shall be submitted to the GCC Steering Committee and shall be justified and shall be based on one or more of the following reasons:

- \checkmark Violate any of the rules of this procedure.
- ✓ Abuse of authority in the application of this measure;
- 2. The GCC Steering Committee provides a documented system of appeal.

4.2. Procedures for submitting and considering appeals:

1. The appellant shall submit its appeal to the Gulf Steering Committee for designation containing the data contained in item (3.2) of the principles of consideration of Grievance and clarifying their applications.

2. The Chairman of the Steering Committee shall determine the date of submission of the appeal to the Gulf Steering Committee for designation.

Revision: 4	Date of issue: 23-12-2018	Page: 36 of 37
-------------	---------------------------	----------------



3. The GCC Steering Committee shall consider the appeal based on the rules of this procedure and the relevant Gulf legislation, and the Gulf Steering Committee for appointment may seek such assistance from outside the Committee as may be necessary. The recommendation issued by any party shall be considered as a guide.

4. The GCC Steering Committee for designation shall meet with the chairman or his assignee, knowing that the meetings of the committee and the transactions between members are confidential and no member may disclose the views or positions of the members.

5. The decisions of the committee shall be justified, and the decision shall be issued within a maximum period of 60 days from the date of registration of the appeal and its decisions are binding on all its members, whether they are approved by them or objectors or conservatives. The committee's decision is final and binding for all parties and follow-up the implementation of its decision.

4.3. Appeal Costs:

The appellant shall pay the Organization a sum of (5000) Saudi Riyals upon submission of the appeal. If the appeal is accepted, the amount shall be returned.

	Revision: 4	Date of issue: 23-12-2018	Page: 37 of 37
Note: Only the Arabic version of this Regulation is authentic in law and is applicable where there are differences with this translation.			