Laenade Tahwil al-Sharokat

Laenade Tahwil Sharokat/Masann Mawazum al-Sharokat

Qualification Bylaws for Medical Supplies Companies, and appendixes: (Application Form, Mechanism of Visiting the Company Production Site, Mechanism of Product Evaluation and the Site Visit Checklist).

First Article:
Companies/factories that would be eligible to participate in the Group Purchasing Medical Supplies Tenders (Pool Procurement Tenders) launched by the Health Council for Cooperation Council States must complete Prequalification procedures.

Second Article:
The requests for prequalification and registration shall only be honored if they satisfy the following conditions:
1) The application form should be filled up, printed, stamped and signed by the person authorized by the company/factory.
2) The prequalification dossier shall be submitted with a covering letter to be delivered personally by hand via the company’s local authorized agent together with payment of fees.

Third Article:
The company/factory should notify the Health Council in the following cases:
1) In the event of change in the company/factory ownership, certificate issued by a competent authority at the country of origin should be presented to authenticate/prove this change.
2) In the event of changing the local agent.

Article Four:
The qualification of the company/factory or its branch shall be cancelled in the following cases:
1) In case the company/factory certificates are proved to be falsified or tampered with.
2) In case the company/factory is being listed among the banned/boycotted companies/factories.
3. إذا ثبت تكرار مخالفتها أو عدم تطبيق أسس الممارسة الجيدة للصناعة.
4. إذا الغي تسجيل الشركة/المصنع أو وقف إنتاجها في بلد المنتج، أو منع تداول منتجاتها في أحد البلدان لأسباب فنية.
5. في حال تبين عدم صحة البيانات المقدمة في استمارة وملف طلب التأهيل.
6. الغش التجاري.
7. يتم إلغاء طلب تأهيل الشركات التي طلبت منها استكمال النواقص والشركات التي طلبت منها زيادة مصانعها أو كلاهما ولم تستجب للطلب مجلس الصحة بعد مرور سنة أشهر من مخاطبتها.

المادة الخامسة:
يحق لمجلس الصحة رفض أو تجاهل تأهيل أي شركة أو مصنع أو منتج مع إيضاح الأسباب لذلك.

المادة السادسة:
1. يجب على الشركة/المصنع تسديد رسوم التأهيل على النحو التالي:
   a) الشركات الجديدة: تسديد مبلغ (1,500) دولار أمريكي عند تقديم ملف طلب التأهيل.
   b) الشركات المؤهلة سابقاً: تسديد مبلغ (1,000) دولار أمريكي عند تقديم ملف إعادة التأهيل.
2. يسري تأهيل الشركة/المصنع لمدة (خمس سنوات) من تاريخ إبلاغها بقرار تأهيلها من قبل مجلس الصحة لدول مجلس التعاون، وتلتزم الشركة/المصنع بتقديم ملف (ملف إعادة التأهيل) قبل عام على الأقل من تاريخ انتهاء الفترة المحددة لتأهيلها (السنة الرابعة).

Article Five :
The Health Council shall have the right to decline or suspend the qualification of any company, factory or a product. Reasons for decline or suspension shall be declared.

Article Six :
1. The prequalification fees should be paid as follows:
   a) New companies: US $1500 upon submission of the qualification dossier.
   b) Previously qualified companies: US$1,000 upon submission of the requalification dossier.

2. The qualification period lasts for (five years) as from the date of notification by the Health Council. However, the company/factory is committed to present an updated qualification dossier, for requalification, by the end of the fourth year from qualification date.
Article Seven:
The Health Council shall register the company/factory and issue a registration number and qualification Certificate after settlement of the necessary fees.

Article Eight:
The company/factory whose qualification is declined, suspended and the companies whose lines of production are declined and the company whose registration is cancelled could apply, by submitting a new qualification dossier, asking for qualification after the lapse of one year from the decline or cancellation dated.

Article Nine:
The GCC Qualification Committee is authorized to decline qualification of any new applicant, likewise, the committee shall cancel registration of any previously qualified company/factory in case adverse technical reports from the GCC Member States show incompetency of the company/factory products after usage and experiment.

Article Ten:
Should any of the duly qualified companies at the Gulf Health Council wishes to participate in another tender, then it's should present copy of the company qualification dossier and settle the required fees. The Gulf Health Council shall provide all Member Countries with copy of the following documents: (Quality Certificate, Free Sale Certificate and list of the company products); on condition that these items are included in the main qualification dossier for approval. Based on the above, the company shall be invited to participate in the tender, and the qualification dossier shall be presented to the Qualification Committee.

First: Qualification Review Documents required for the qualification request file.
The company or factory must submit a file containing all the required documents as follows:

المادة السابعة:
يقوم مجلس الصحة بتسجيل الشركة أو المصدر وإعطاءها رقم تسجيل وشهادة التأهيل بعد دفع كافة الرسوم اللازمة.

المادة الثامنة:
يحق للشركات التي تم رفض أو إلغاء تأهيلها أو عدم تأهيل بعض خطوط الإنتاج إعداد طلب التأهيل من خلال تقديم ملف جديد وذلك بعد مرور عام من قرار لجنة تأهيل الشركات.

المادة التاسعة:
يحق للجنة تأهيل الشركات عدم تأهيل شركة جديدة أو إلغاء تأهيل شركة مؤهلة سابقاً بناءً على التقارير الفنية وخبرات الدول الأعضاء من واقع استخدامها وتجربتها لمنتجاتها.

المادة العاشرة:
على الشركات المسجلة والمؤهلة في إحدى مناقصات اللوائح الطبية بمجلس الصحة لدول مجلس التعاون إذا رغبت في المشاركة في مناقصة أخرى، فيجب عليها تقديم صورة من ملف المؤهل ودفع رسوم التأهيل، وعلى مجلس الصحة لدول مجلس التعاون تزويدها بالأعضاء بصورة من شهادة الجودة وحرية البيع وقائمة منتجات الشركة خريطة أن تكون هذه المنتجات مدرجة بالملف الأساسي لها لاعتمادها، ليتم دعوتها للمشاركة في المناقصة ومن ثم عرض ملف التأهيل على لجنة تأهيل الشركات.

أولاً: متطلبات التأهيل:
المستندات المطلوبة لملف طلب التأهيل يجب على الشركة أو المصدر أن تقدم ملفاً يحتوي على جميع المستندات المطلوبة وهي:
1) Application Form

Download the designated “Application Form” from the website of the Health Council. Fill up all the particulars make a print out (on plain paper) get it signed and stamped.

2) Quality Certificate:

a. Accredited quality certificates such as (CE, ISO, TUV, FDA etc.). The quality certificates must be duly attested by the consulate of any of the GCC Member States at the country of origin. The quality certificates should indicate that the factory is applying Good Manufacturing Practice (GMP) and it is subject to periodical technical inspection by competent authorities at the country of origin. Moreover, the following points worth to consider:

b. Manufacturers of medical diagnostic devices and reagents, and the manufacturers of medical rehabilitation supplies should ensure to submit the following documents:

• Quality Certificate: To ensure GMP by providing the following certificates: (ISO 9001-2000 & ISO 13485).

• Product Quality Certificate CE mark or FDA certificate.

• Manufacturers of implantable products (Items that would be implanted into human body (Either permanent, or temporary) must be a researching company rather than being a generic (similar). The manufacturers of such items are committed to present clinical studies issued at the country of origin and by accredited research centers about the result of usage and ensure guarantee safety of using these products.

c. Should a manufacturing agreement exist between the company and another party in terms of (designing, manufacturing, filling & packaging) the applicant must present an evidence- based certificate to declare the scope of the relationship between the two parties.

d. The companies that manufacture sterilized items shall submit GMP certificate.

1) طلب التأهيل

تребعة طلب التأهيل طباعة حسب نموذج طلب التأهيل

الموقع الرسمي مجلس الصحة.

2) شهادة الجودة:

- شهادة الجودة المعتمدة مثل: CE, ISO, TUV

الخليج العربي في بلد المنشأ توضح أن الشركة/المصنع تتبع أسس الممارسة الجيدة لتصنيع المواد وأنها تخضع للتفتيش الفني بصفة دورية من قبل السلطات المختصة في بلد المنشأ، مع مراعاة ما يلي:

- الشركات التي تقوم بتصنيع الأجهزة والكواشف التشخيصية الطبية، ولوازم التأهيل الطبي أن تقدم شهادات التالية:

  • شهادة جودة المصنعين من خلال شهادة (GMP) من خلال شهادة (ISO 9001:2000& EN 46001 & ISO 13485)

  • شهادة جودة المنتج من خلال شهادة: FDA أو CE Mark

  • يجب تقديم الشهادات والدراسات السريرية والكلينيكية من بلد المناشدة والدولة المقدمة ومركز الإبحاث العالمية المعتمدة عن نتائج استخدام المنتجات التي تزرع أو تستخدم داخل جسم الإنسان بشكل دائم أو مؤقت وسلامتها على أن تكون الشركة مصنعة وذات أبحاث وليست مجمعة أو مشتقة.

- على الشركة/المصنع تقديم الشهادات الدالة في حال وجود اتفاق بينها وبين مصنع/مصنعين أخر من حيث التصميم، التصنيع، التعبيئة والتغليف مع توضيح اسم المصنع/المصنع بلد المناشدة والعناوين والعلاقات بينهما.

- على الشركات التي تقوم بتصنيع الأصناف المعقمة تقديم شهادة GMP.
3) Free Sale Certificate:

This certificate must be issued by the health authority or accredited authority at the country of origin. It must be duly attested by the consulate of any of the GCC Member States at the country of origin. The FSC should clearly indicate the following:

1) The company should be a manufacturing or assembling company and it is licensed to manufacture medical supplies in the country of origin. (The license number and date are to be stated on the certificate).

2) The company/factory products are circulating in the country of origin. The company should submit a written undertaking letter stating that the materials that will be exported to the importing country should be of the same quality circulating in the country of origin, and should submit evidence that the company products are marketed in one of the developed countries, if any. However, manufactures of Medical Uniforms are exempted from this condition.

3) Manufactures of The items within (T-Toxic) Group in the Laboratory Supplies Manual are exempted from providing Free Sale Certificate, but they must submit Quality Certificate, as well as, product licenses along with the other documents in the qualification dossier.

4) The Company that have Contract Manufacturing or Legal Manufacturing with other company, should present Free Sale Certificate issue at the country of origin and/or issued at the country wherein the company products are marketed.

4) Marketing activities:

a. List of the countries where the company products are marketed. The company should present evidence to prove recurrent marketing activities in these countries with considerable quantities, and should present supporting documents such as: AWB approved by the consignee, purchase orders etc...

b. Manufacturing of orthopedic and spine surgery supplies should submit a certificate stating that the company/factory products are marketed in

3) شهادة حرية البيع:

شهادة حرية البيع صادرة من السلطات الصحية في بلد المنشأ ومصدقة من سفارة إحدى دول الخليج العربية أو من يقوم مقامها على أن تثبت هذه الشهادات بوضوح ما يلي:

1. أن الشركة مصنعة أو مجمعة ومصرح لها بصنع اللوازم الطبية في بلد المنشأ (يذكر رقم الترخيص وتاريخه).

2. أن منتجات الشركة/المصنعين متداولة في بلد المنشأ، وعلى الشركة تقديم تعهد خطي بأن المواد التي سيتم تصديرها للدولة المستورة ستكون نفس النوعيات المتداولة في بلد المنشأ، مع تقديم ما يثبت تسويق منتجاتها في إحدى البلدان المتقدمة أو وجود وسيلة من تلك الشركات المختصصة في تصنيع الكسائي الطبية.

3. إعطاء شركات مجموعة السوم ضمن مناقصة لوازم المختبرات الطبية وخدمات نقل الدم من شرط تقديم شهادة حرية البيع، على أن تقدم هذه الشركات شهادة الجودة والترخيص الخاصة بالمنتج ضمن ملف طلب التأهيل.

4. بالنسبة للشركات التي تقوم بالتصنيع بنظام (Contract) التصنيع التعاقدي مع شركة أخرى، أن تقدم شهادة حرية البيع صادرة من بلد المنشأ أو من البلد المستورد فيها منتجات الشركة.

4) قائمة بأسماء الدول المستوردة بها الصفن أو أصناف الشركة/المصنع

- تقديم ما يثبت تسويق منتجاتها في تلك الدول بكميات معقولة مع تكاليف طبب مثالي، صورة من بوليصة الشحن المعتمدة من جهة الشراء، صورة من أمر الشراء. الخ.

- فيما يخص شركات لوازم جراحة العظام والعمود الفقري أن تقدم شهادة بان منتجات
one of the developed countries such as Europe or USA with considerable quantities.

5) Factory Products:

The company should submit a list of its factory products along with the original catalogue that illustrates these products. The company must provide a (CD) that includes the items which intends to participate with in the SGH Tender. The company must use the designated program, in the Health Council official website, for presenting its factory products. The (CD) should contain the following information:

a. Whether the product is (partially) or (completely) manufactured.

b. The company catalogue number for each item.

Gulf Companies should present Registration Certificate, issued by the country of origin, for the items it wishes to participate with in the SGH Tenders.

6) Local Agents:

A list containing names and addresses of the company/factory local agents in the in the GCC Member Countries.

7) Factory Site Master File: factory Layout

Manufacturers of Linens & Medical Uniforms should provide the following information in the qualification dossier together with the above mentioned items.

a. Copy of valid industrial license for the producing medical textiles.

b. A list of the number of works in the factory according to their specialties.

c. A list of types and numbers of the available machineries and tools in the factory including sewing and preparation machines.
1) General Provisions for Qualification Requirements:
Companies/factories should take the following requirements into consideration when submitting qualification dossier:

**Article # One:**

a. The company/factory is committed to submit a complete qualification dossier which must include all above mentioned requirements.

b. To submit a duly signed and stamped Covering Letter this should include the factory name and address. It should specify the provided documents i.e. the contents of the qualification dossier.

c. The qualification dossier should have numerical separators between the provided documents, which are to be arranged according to the above mentioned sequence.

d. All the applicant’s information is to be mentioned on the Application Form which must be printed on plain paper rather than on the company letter head paper.

**Article # Two:**

List of the items that need pre-evaluation could be obtained from the official website of the Health Council.

**Article # Three:**

The GCC Qualification Committee shall have the right to decide the company that needs to conduct inspection visit to their production site to ensure that the factory is applying (GMP) and to audit the production line.

**Article # Four:**

The Group Purchasing Department at the Health Council shall have the right not to receive incomplete qualification dossier.

**Article # Five:**

The applicant is committed to complete the missing documents, declare acceptance to the site visit and pay the required visit costs during six-month period from notification date by the Health Council. In case of delay...
and/or refrain after the lead time, the applicant must be subject to point number (7) of the Fourth Article.

Article # Six:
The Head of Group Purchasing department at the Health Council is authorized to notify the successful applicants who satisfy all qualification requirements, based on recommendations of the GCC Qualification Committee and GCC auditors who conduct site visits.

Article # Seven:
In case the manufacturer owns many factories/branches, then he should present a separate qualification dossier for each factory/branch. The qualification rules shall be applied on each and every factory/branch.

Article # Eight:
List of duly qualified companies/factories shall be presented by the Health Council to the Tender Preparation Committee.

Article # Nine:
Manufacturers of implantable items relating to cardiovascular surgery supplies, cardiac catheterization, interventional radiology, and producers of items that contain biological materials as mentioned hereunder must be (Researching) Company rather than (Generic):
- Aortic & mitral valves, vascular patches/grafts, tube grafts, pericardial membranes, intracoronary shunts, bare metal drug eluted stents.
- ASD, VSD/PDA occludes angiography/angioplasty balloons, embolic particles or system, thoracic abdominal stent, pacemakers and sutures, biological glue.

Article # Ten:
Manufacturers of Orthopedic & Spine Surgery Supplies must be (Researching) Company rather than (Generic). They should present clinical studies issued by the accredited international research centers on the results of using these items and to submit evidence-based certificates such as "FDA or CE certificates" and "Declaration of Conformity Certificate".
Article # Eleven:
Companies should present clinical studies issued at the country of origin and international research centers about the result of using the above mentioned items (the implantable items, and the items that contain biological materials) after marketing such materials in the country of origin for, at least, one year and to submit the product accreditation certificate (FDA/CE) for these items.

Article # Twelve:
Manufacturers of (Haemostatic Oxidized Regenerated Cellulose) are subject to a site visit to the plant, where these items are manufactured, so as to ensure that the factory is applying the accredited method for producing these items.

Article # Thirteen:
Sterilization method of all items relating to Renal Dialysis Supplies must be either (Steam) or (GAMA).

Article # Fourteen:
Manufacturers of the unlisted items in the SGH manuals could apply for prequalification. But they shall have no right to apply for pre-evaluation of the unlisted items unless these items are approved by the GCC Member Countries to be included on the SGH tender’s manuals in accordance to the applied rules and regulations.

Article # Fifteen:
The SGH Auditors should specify, on their visit report, the source of the items that are (partially) manufactured, so as to ensure that the specified source is prequalified at the Health Council and, accordingly, take the necessary procedure.

Article # Sixteen:
The SGH Qualification Committee, during its annual meeting, shall take the appropriate decision with regard to the requests presented by the manufacturers for adding new items to their factory products.

المادة الحادية عشرة:
على الشركات تقديم دراسات إكلينيكيّة من بلد المنشأ ومراكز البحوث العالمية المعتمدة عن نتائج استخدام الأصناف المزروعة داخل جسم الإنسان والبنود التي تحتوي مواد بيوحولية بعد تسويقها في بلد المنشأ لمدة عام على الأقل مع تقديم الشهادات الدالة على اعتماد المنتج (FDA / CE) للبنود التي تستوجب ذلك، والتي ورد ذكرها أعلاه.

المادة الثانية عشرة:
ينتم زيارة مصانع الشركات التي تنتج الصنف Haemostatic Oxidized Regenerate Cellulose للتحقق من طريقة التصنيع الخاصة بهذا المنتج وحسب الآلية المعتمدة.

المادة الثالثة عشرة:
تكون وسيلة التقييم المستخدمة للكيفية بنود لوازم الكليّة الصناعية بالبخار أو بخار جاما، (GAMA).

المادة الرابعة عشرة:
بخصوص الشركة / المصانع تقديم ملف طلب التأهيل في حال قيامها بتصنيع بنود غير مدرجة في دليل مناقصات اللوازم الطبية، ولا يحق للشركة المطلوبة بتقديم هذه البند إلا بعد الموافقة على إدراجها في القائمة من قبل الدول الاعضاء طبقًا للنظام المنبع.

المادة الخامسة عشرة:
على الفريق الرائد لمصنع الشركة تحديد مصدر الجزء الأساسي للبنود التي تصنف بشكل (جرئي) ليتم التحقق إذا كان مؤهلاً من قبل مجلس الصحة لتطبيق الإجراءات اللازم.

المادة السادسة عشرة:
يتم اعتماد إضافة بنود جديدة إلى قائمة منتجات المصنع بناءً على طلب الشركة المصنعة من قبل لجنة تأهيل الشركات التي تقد اجتماعها في الربع الأخير من كل عام.
Article # Seventeen:

Due to the sensitive nature of the chemical substances in the SGH Manual for Medical Laboratory Supplies, the tendered chemical items in group (F) would be awarded to the manufacturing companies only.

Secondly: Factory Visit:

First Article:

1. The Health Council shall coordinate with the GCC Member Countries, and the medical supplies companies to complete procedures pertaining to the site visits that would be conducted to their factories for checking the production lines and to ensure that they are applying Good Manufacturing Practice (GMP). These procedures shall be completed in accordance to annexed "Site Visit Mechanism" which regulates visiting the company's production plants.

2. The Health Council Board Office shall have the right to hold qualification of any company in case such company fails to provide the required missing documents, or delay/refrain to complete the necessary procedures for visiting the company production site after the lapse of the six-month period from the notification date by the Health Council.

3. The company/factory shall be committed to complete the procedures and bear all the costs of the site visit to its production site, as stipulated on the "Site Visit Mechanism" annexed to these bylaws.

4. In the event a single audit team is commissioned to visit two or more factories in one or more than one country, the audit team members shall be entitled to receive the amount of the visit costs paid by each factory.

5. The terms of the "Factory Visit Mechanism" shall be applied on each factory (individually) irrespective of the number of factories that would be visited in the same country, city or during the same period.

6. In case the factory has different production lines for items related to different tenders, and the company presented a separate qualification file for each tender, then one audit team shall visit the factory to inspect the production lines of the different tenders.
7. The Health Council shall transfer the costs of the factory visit to the bank account of each audit team member.

8. The stipulation of item number (4) and (5) above shall apply on factory visit conducted to Gulf, as well as, international factories.

9. The Health Council Board Office shall deduct (10%) as administrative fees from the total amount deposited by the company for visit costs, and transfer the balance amount to the audit team members.

10. The Health Council shall not incur any expenses resulting from factory visit.

11. During visit period, the company should provide statement to the audit team. The statement should include sources of supply and methods of analyzing raw materials used in manufacturing its products. Moreover, the company should present accreditation certificates issued by accredited supervisory authorities.

12. The company should follow these procedures to add its factory products which were included in the visit report, but were unlisted in the SGH manuals at the time of visit. Bearing in mind that the company could take this action only after the unlisted items are recently enrolled in the manuals after the factory visit:

   a) The company shall submit, within one month from the date of launching the updated manual on the website of the Health Council, a request for adding its factory products with their relevant code numbers among the recently added item.

   b) The Health Council shall refer list of the requested items to the audit team members in the GCC Member Countries so as to ensure that the auditors had inspected production lines of the said items during the factory visit, and these items are among the unlisted items at that time.

   c) Based on the approval of the GCC Member Countries, the Executive Board Office shall include these items in the company qualification dossier and them to the company products in the

لا يتحمل مجلس الصحة أي مصاريف مترتبة على الزيارة.

8. The Health Council shall transfer the costs of the factory visit to the bank account of each audit team member.

8. The stipulation of item number (4) and (5) above shall apply on factory visit conducted to Gulf, as well as, international factories.

9. The Health Council Board Office shall deduct (10%) as administrative fees from the total amount deposited by the company for visit costs, and transfer the balance amount to the audit team members.

10. The Health Council shall not incur any expenses resulting from factory visit.

11. During visit period, the company should provide statement to the audit team. The statement should include sources of supply and methods of analyzing raw materials used in manufacturing its products. Moreover, the company should present accreditation certificates issued by accredited supervisory authorities.

12. The company should follow these procedures to add its factory products which were included in the visit report, but were unlisted in the SGH manuals at the time of visit. Bearing in mind that the company could take this action only after the unlisted items are recently enrolled in the manuals after the factory visit:

   a) The company shall submit, within one month from the date of launching the updated manual on the website of the Health Council, a request for adding its factory products with their relevant code numbers among the recently added item.

   b) The Health Council shall refer list of the requested items to the audit team members in the GCC Member Countries so as to ensure that the auditors had inspected production lines of the said items during the factory visit, and these items are among the unlisted items at that time.

   c) Based on the approval of the GCC Member Countries, the Executive Board Office shall include these items in the company qualification dossier and them to the company products in the
designated program with the relevant code number. The company shall be informed with this addition.

d) The company shall present a request to the Health Council for product evaluation for the newly added items.

e) The Health Council shall evaluate these items in accordance with the mechanism and the established regulations.

f) In case the company asks for adding items, (whether they are listed or unlisted in the manual) which are neither within the list of the company products presented along with qualification dossier nor among the list presented along with factory visit report, then the company request shall be presented to SGH Qualification Committee in the next meeting to take the appropriate decision.

13. Upon agreeing on the factory visit date, the company shall satisfy the following requirements:

a) To make sure that the production lines of the factory products are in a working condition.

b) Update the factory products in the qualification dossier delivered to the Health Council by presenting two lists: (first list contains the factory products which are included in the SGH manual; the second list contains other factory products which are unlisted in the SGH manual). The SGH Auditors should only inspect the production lines of the updated lists.

14. The reply and corrective action taken by the company with regard to the remarks and observations mentioned on the factory visit report shall be referred to the SGH Auditors to review and take the appropriate decision. They have to advise the Health Council with their collective decision whether the company has successfully corrected and satisfied the remarks and observations.
Second Article: Factory Visit Program:

1. The travelling dates for the SGH Auditors who visit factories located at the Far East or at the Far West are as follows: Departure date two days before visit date, and the return within two days after visit ends.

2. The factory visit commence on the next day of the SGH Auditors arrival, and ends on the next day of the last visit.

3. In case of visiting two factories, there should be an interval gab between the two visits as follows:

   a) Twenty-four-hour-gab; in case the two factories are located at the same city/state. Terms of factory Visit Mechanism shall be applied on each factory separately.

   b) Forty-eight-hour-gab; in case the two factories are located at two different states/countries. Terms of Factory Visit Mechanism shall be applied on each factory separately.

   c) The Health Council shall provide members of the SGH Qualification Committees, for all tenders and prior scheduled meeting date, with compact discs that contain the soft copy of the qualification dossiers, to enable them study and get ready for the meeting. Then present all qualification dossiers during the meeting, using laptop computers, for study and to take the appropriate decision. However, every committee member should bring a laptop computer.

   d) The Health Council shall provide the SGH Auditors, via e-mail, with copy of the qualification dossier that includes the company product list, as well as, the "Factory visit Check-list". Upon confirming the factory visit date, the Health Council shall communicate with the factories which are located in the same city/state.

المادة الثانية: برنامج زيارات المصانع:

1) الشركات التي تقع مصانعاً في أقلية الشرق أو أقلية الغرب، يكون تاريخ السفر قبل يومين من موعد الزيارة وتكون الميعود خلال يومين بعد الانتهاء من الزيارة.

2) تبدأ زياره المصانع في اليوم الثاني من وصول أعضاء اللجنة، وتنتهي الزيارة في اليوم الثاني من آخر زيارة أما بالنسبة لزيارة المصانع الخليجية، تكون فترة الزيارة لكل مصنع (3 أيام)، وفي حال وجود أكثر من مصنع في نفس المدينة يكون هناك يوم راحة بعد زيارة كل مصنع. وفي حال اقتضت الضرورة غير ذلك عند زيارة مجموعة المصانع، فعلى اللجنة الرائدة التنسيق مع هذه الشركات ومجلس الصحة.

3) في حالة زيارة مصنعين يكون هناك فترة راحة بين الزيارات على النحو التالي:

   a) إذا كانت المصانع في نفس المدينة / الولاية تكون فترة الزيارة (24) ساعة، وتطبيق شروط الزيارة المصانع لكل مصنع على حدة.

   b) إذا كانت المصانع في دولتين / ولايتين تكون فترة الزيارة (48) ساعة، وتطبيق شروط الزيارة المصانع لكل مصنع على حدة.

ج) يقوم مجلس الصحة بتوذير أعضاء لجان تأهيل شركات اللوامض الطبية بقرار دمج يحتوي على نسخة إلكترونية من ملف طلب التأهيل المقدم من الشركات لجميع المنافقات بها قبل موعد الاجتماع بفترة كافية للإطلاع والتحضير، ثم عرضها أثناء الاجتماع لتقوم اللجنة بدراسةها من خلال جهود الحاسوب المحمول واتخاذ القرار المناسب، وعلى كل عضو من أعضاء اللجنة إحضار جهاز حاسوب محمول.

د) يقوم مجلس الصحة بتزويذ أعضاء اللجنة الرائدة عن طريق البريد الإلكتروني بنسخة من ملف الشركة وقائمة المنتجات المبقولة التي توفرها الشركة. وتزويذ الزيارة. ويتزويد مجلس الصحة بالمطابقة.
companies to update their factory products as follows:

1. The listed items on the SGH Manuals:

2. The company shall present a compact disc, as well as, signed and stamped copy of the company products that are listed in the SGH manual in (Access) format according to the designated program of the Health Council.

3. The Unlisted Items in the SGH Manuals:

4. The company shall present a signed and stamped copy of the company products that are unlisted in the SGH manual in (Excel) format.

The Health Council shall furnish the Audit Team Members with the updated lists along with the visit file, so that the auditors inspect the production lines for these items.

Thirdly: Evaluation of the Company Products:

First Article:

The Health Council shall undertake evaluation of the company/factory products at Ministries of Health in three GCC Member Countries.

Second Article:

The companies should submit an evidence to prove the company classification whether they are: researching, generic (similar), assembling or others.

Third Article:

The item will be deemed as "tried and tested" if it satisfies one of the following cases:

a) In case the items were awarded and supplied in one of the last four tenders without any adverse technical remarks or observations being reported by the GCC Member Countries.

b) Regarding orthopedic and spine surgery supplies, medical rehabilitation supplies, ophthalmological supplies and ENT supplies tenders, the item will be considered as "tried & tested" if it was awarded in the last two tenders with the same catalogue number mentioned on the offered bid and without any adverse
technical remarks or observations reported by the GCC Member Countries.

c) The case the item has been pre-evaluated in accordance to the Product Evaluation Mechanism" with acceptable result.

Article Four:
The company is committed to mention the catalogue number for each item it presents for evaluation. The GCC Member Countries should mention the catalogue number for each item while entering evaluation result in the designated program via electronic link. However, evaluation result of any item without catalogue number shall not be considered.

Article Five:
Item that are not “tried & tested” shall be evaluated in accordance with the following procedures:

a) The company products shall not be evaluated unless the company qualification process is completed.
b) Manufacturers of orthopedic and spine surgery supplies has to submit certificates and clinical studies, issued at the country of origin and developed countries, about the result of using implantable products.
c) The item should be among those items that are subject to prior evaluation.
d) The company should provide sufficient quantity of samples of the item that needs evaluation.
Manufacturers of Medical Laboratories supplies should provide sufficient quantity of samples with minimum quantity (100 tests) for the reagents of, at least, two batches. Quantity of samples to be provided for other consumable items are 30 (thirty) pieces.
e) Items should be evaluated in three GCC Member Countries, including MOH- Saudi Arabia. The acceptable result must be declared by, at least, two countries. However, the GCC Member States with the largest required quantity must be one of the two countries.

المادة الرابعة:
تعلزم الشركة بنذر رقم الكتاولج لكل بند تنتقد بطلب تقييمه، وعلى الدول الأعضاء عند إدخال نتيجة التقييم في برنامج الربط الإلكتروني ضرورة ذكر رقم الكتاولج لكل بند، ولن ينظر في تقييم أي بند لم يذكر له رقم كتاولج.

المادة الخامسة:

(أ) أن يتم تقييم منتجات الشركة إلا بعد تأهيلها.
(ب) بالنسبة لمنتجات شركات لوارزم جراحة العظام والعمود الفقري، على الشركة تقديم شهادات ودراسات سريرية من بلد المنشأ والدول المتقدمة عن نتائج استخدام المنتج المزروع داخل جسم المريض.

"Implants"

(د) أن يكون الصفن من البند التي تم التعميم عن ضرورة إجراء تقييم مسبق لها.
(د) على الشركة تقديم عينات كافية من المنتج المراد تقييمه. أما فيما يتعلق بالشركات المتخصصة في لوارزم المختبرات الطبية وخدمات نقل الدم، فعلى الشركة تقديم عينات كافية من المنتج المراد تقييمه وبدأت بالحمالات 100 فحص، على أن لا يقل عن تشغيلتين (2 batches) وبالنسبة للمواد المستهلكة وحدها، 30 وحدة.

(ع) البنود التي تحتاج إلى تقييم، يجب أن تكون مقيمة في ثلاث دول من الدول الأعضاء من بينها وزارة الصحة السعودية، ونتيجة التقييم مقبولة في دولتين بما فيهما الدولة صاحب أعلى كمية مطلوبة.
e/1 In the event of delay in receiving evaluation result from the GCC Member Country with the largest quantity due to delay in performing evaluation, then the evaluation result received from the other two GCC Member Countries shall be considered.

f) The Gulf manufacturer who asks for product evaluation, the GCC Member Country (where this manufacturer is situated) must be one of the GCC Countries to perform evaluation.

g) In case the specification of any item is amended, then all previous evaluation results of the item shall be cancelled. Companies should proceed for evaluation according to the newly amended specification. Except amendment in the item’s size or package size which does not affect usage.

General Provisions for Product Evaluation:

Article One:
Evaluation period of the company products shall not exceed THREE MONTHS from the date of providing sufficient quantity of samples for each item. However, evaluation period of Orthopedic and spine items as well as Oral & maxillofacial items shall not be less than ONE YEAR from the date of performing the surgery.

Article Two:
Items with adverse observations and remarks reported by the GCC member States must be re-evaluated.

Article Three:
The company products that were pre-evaluated but not used or not “tried & tested” for four consecutive years, they must be re-evaluated. Regarding Orthopedic and Spine Surgery Supplies, Rehabilitation Supplies, Ophthalmological Supplies and
ENT Supplies; they must be re-evaluated if they were not used or not “tried & tested” during the last two tenders.

**Article Four:**
The SGH Tender Committee would not accept any item for just being “tried and tested” or pre-evaluated. Acceptance of the offered item shall be based on the quality of the presented sample and how compatible with the “tried and tested” or pre-evaluated sample.

**Article Five:**
The GCC Member States should notify the Health Council with the items that are not used in their hospitals, in case samples for such items are delivered to them for the purpose of evaluation.

**Article Six:**
Evaluation results shall be presented to the SGH Qualification Committee, and the Health Council notifies the company with evaluation result of its products.

**Article Seven:**
Companies are committed to provide samples to the GCC States that are authorized to conduct evaluation via their scientific offices or local agents located at these countries. However, samples delivered via parcel post or express couriers would not be accepted.

**Article Eight:**
The period for receiving products’ evaluation requests commence after completion of the award procedures for each tender. This period ends upon launching the next tender, and according to the announced dates on the official website of the Health Council.

**Article Nine:**
The company shall be committed to submit evaluation request for all item’s sizes as included in the manual, which intends to participate with in the SGH tenders. Evaluation request should not be limited to only one or two sizes, but it must for all the company approved item’s sizes at the Health Council.