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

1. 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.

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

B. Evaluation of Medical Supplies' Materials shall be carried out according to the following:

1. 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 Ministers’ Council for G.C.C Countries.

2. Every company should coordinate with the Gulf Health Council for Cooperation Council States for specifying the items it desires to evaluate.

3. The company products shall not be evaluated unless the company qualification process is completed.

4. Evaluation of the company products and its affiliated branches, independently, according to the following:
   a. The accredited company products according to the factory visit report.
   b. The accredited company products according to the list submitted along with the qualification dossier, in case the company is exempted from factory visit.

5. The case the company desires to evaluate new items; it should submit a request, during the specified period, which shall be present to the SGH Qualification Committee to take the appropriate decision.

أ) يعتبر الصنف مجازياً في إحدى الحالتين التاليةتين:

1. أن يكون سبق ترسيمته وتوثيقه خلال إحدى أربع مناقصات سابقة ولم يكن عليه أي ملاحظات فنية من الدول الأعضاء.

2. أن يكون تم تقييمه وفقّاً ل sistem تقييم المنتجات المعتمدة وكانت نتائج التقييم مقبولة.

(ب) يتم تقييم منتجات المواد الطبية وفق ما يلي:

1. يبدأ قبول طلبات تقييم المنتجات بعد الانتهاء من تسريحة كل مناقصة وتنتهي عند طرح المناقصة القادمة.

2. تقوم كل شركة بتحديد الأصناف التي ترغب في تقديمها بالتنسيق مع مجلس الصحة لدول مجلس التعاون.

3. لا يتم تقييم منتجات الشركة إلا بعد تأهيلها.

4. يتم تقييم منتجات الشركات وفروعها كل على حدة حسب التالي:
   a) الأصناف المعتمدة لكل شركة من واقع تقارير الزيارة.

   b) الأصناف المعتمدة لكل شركة من واقع ملف التأهيل للشركات المستثمرة من الزيارة.

5. عند رغبة الشركة في تقديم أصناف جديدة، فيجب أن تتقدم بطلبات حسب المواعد المحددة، لكي يتم عرض الطلبات على لجنة تأهيل الشركات.
6. In case there are new added items to the SGH manual after the company factory visit, the company should undertake the following procedures in case of desire to shift these new added items, which were unlisted at visit time, to the list of its accredited factory products:

a. The company should present a request for adding the new items with their code numbers within one month from the date of launching the updated manual on the Gulf Health Council official website. The requested items should be among the accredited items in the factory visit report.

b. The Gulf Health Council shall communicate with the GCC Member Countries to ensure that the SGH auditors had inspected the production lines of the items in question, and to make sure that these items are among the accredited unlisted factory products at the time of factory visit.

c. Based on the approval of the GCC Member Countries, the Gulf Health Council 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 Gulf Health Council for evaluating these new added items.

e. The Gulf Health Council shall conduct product evaluation for these items in accordance to the applied regulations and Product Evaluation Mechanism.

f. In case the company requests adding new items which are neither in the list submitted along with the qualification dossier nor in any list submitted along with the factory visit report, the company should undertake the following procedures in case of desire to shift these new added items, which were unlisted at visit time, to the list of its accredited factory products:

a) The company should present a request for adding the new items with their code numbers within one month from the date of launching the updated manual on the Gulf Health Council official website. The requested items should be among the accredited items in the factory visit report.

b) The Gulf Health Council shall communicate with the GCC Member Countries to ensure that the SGH auditors had inspected the production lines of the items in question, and to make sure that these items are among the accredited unlisted factory products at the time of factory visit.

c) Based on the approval of the GCC Member Countries, the Gulf Health Council 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.

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f) In case the company requests adding new items which are neither in the list submitted along with the qualification dossier nor in any list submitted along with the factory visit report, the company should undertake the following procedures in case of desire to shift these new added items, which were unlisted at visit time, to the list of its accredited factory products:

a) The company should present a request for adding the new items with their code numbers within one month from the date of launching the updated manual on the Gulf Health Council official website. The requested items should be among the accredited items in the factory visit report.

b) The Gulf Health Council shall communicate with the GCC Member Countries to ensure that the SGH auditors had inspected the production lines of the items in question, and to make sure that these items are among the accredited unlisted factory products at the time of factory visit.

c) Based on the approval of the GCC Member Countries, the Gulf Health Council 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.
7. The company shall be committed to present a request for evaluating the different item’s sizes included in the SGH manual which are the among the list of the accredited factory products at the Gulf Health Council which it intends to participate with in the SGH tenders, and should not restrict evaluation of only one or two sizes.

8. The company shall be committed to present a request for evaluating the different item’s sizes included in the SGH manual which are the among the list of the accredited factory products at the Gulf Health Council which it intends to participate with in the SGH tenders, and should not restrict evaluation of only one or two sizes.

9. 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.

10. The GCC Member States should notify the Gulf 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.

11. The Member Countries shall provide the Gulf Health Council with the evaluation results according to the designated program via electronic connectivity.

12. Items that need pre-evaluation must be evaluated in three GCC Member countries; the Saudi Ministry of Health shall be one of them. Evaluation result shall be considered from two countries, including the country that has biggest required quantity.
12/a. 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 countries is accepted.

12/b. In the event of delay in receiving evaluation result from the GCC Member Country with the largest quantity due to negligence of the company, then the offered bid by the company for such item shall be eliminated.

12/c. The item that has different sizes, it shall be sufficient to evaluate one size except (pediatric or adult).

13. Manufacturers of renal dialysis supplies should provide samples for evaluation, at the GCC Member Countries, well before the due date for launching the tender.

14. Manufacturers of linens and medical uniforms should provide samples for evaluation at the time of offering their bids.

15. Every company shall be informed about the evaluation result of its factory products.

16. The company observations about the evaluation results of its factory products shall be accepted within a period not exceeding one month from date of providing such result.

17. 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. The Gulf Health Council shall have the right not to consider evaluation result of any item without catalogue number.

18. In case adverse technical observations on any item are reported by the GCC Member Countries, minimum two of the member countries, then all previous evaluations of such item(s) shall be void and must be re-evaluated.

19. Items that are not used or tried and tested for four consecutive years should be re-evaluated. But, items relating to the following tenders: (Orthopedic & Spine, Rehabilitation supplies, Pediatric, or adult Adult)

13. مناقصة لوازم الكلية الصناعية : على الشركات أن تقوم بتقديم عيناتها قبل وقت كاف من طرح المناقصة حتى يتم تقييمها في الدول الأعضاء.

14. مناقصة الملابس والأكسسوارات الطبية : على الشركات أن تقوم بتقديم عيناتها عند تقديم عروضها.

15. يتم إبلاغ كل شركة بنتيجة التقييم.

16. تقبل ملاحظات الشركة حول نتيجة التقييم في مدة أقصاها شهر من تاريخ إبلاغها بالنتيجة.

17. تلزم الشركة ذكر رقم الكاتالووج لكل بند تقدمه طلب تقييمه. وعلى الدول الأعضاء عند اتخاذ نتيجة التقييم في برنامج الربط الإلكتروني ضرورة ذكر رقم الكاتالووج لكل بند، ولمجلس الصحة لدول مجلس التعاون الحف والجهة الرئيسية لانتقادات التقييم لا يُنفث دفع رقم الكاتالووج.

18. عند ورد ملاحظات فنية من الدول الأعضاء (دولتين على الأقل) على أي صف تقييم مقبول، فلتلغى نتيجة التقييم السابقة، ويجب إعادة تقييمه من جديد.

19. يتم إعادة تقييم منتجات الشركات التي سبق تقييماً ولم تستخدم أو تجرب أربع سنوات
Ophthalmic Supplies, ENT Supplies tenders must be re-evaluated in case the item is not tried and tested in the last two tenders.

20. The Executive Board Office shall have the right to take the necessary action against any company that presents any item(s) for evaluation not included in the company qualification dossier or with the factory visit report.

21. While asking for product evaluation for the items manufactured by Gulf companies, the country of origin of the manufacture must be one of the three Member Countries that shall perform evaluation.

22. If specification of any item is amended, then all previous evaluation results of such item will be cancelled. And the company must ask and proceed for product evaluation according to the newly amended specifications. However, this condition does not apply if the amendment in the sizes or the package which do not affect usage of the product.

23. Manufacturers of orthopedic and spine are committed to abide by the following:

a. Present "Clinical Studies" performed on the company products, and should present either "FDA/CE Certificate", as well as, "Declaration of Conformity Certificate". The company should provide evidence that its products are marketed, with commercial quantities, in the developed countries.

b. Present a certificate issued by "Registry Center" confirming that the product has been safely used during the past five years.

c. The company is committed to conduct product demonstration and technical support to the concerned technicians, at the GCC Member Countries, during evaluation process.

24. The Executive Board Office shall have the right to take the necessary action against any company that presents any item(s) for evaluation not included in the company qualification dossier or with the factory visit report.

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