UNITED STATES ACCREDITATION BOARD

SUMMARY PROCEDURE FOR PRODUCT CERTIFICATION ACCREDITATION

1 Make a formal application for accreditation. The applicant will then be listed on United States Accreditation Board (USAB) web site as “APPLICANT BODY”.

2 The applicant organization is required to comply with the requirements of ISO/IEC17065 and to maintain a Quality Management System that meets ISO 9001:2015.

3 The applicant sends to USAB the Manuals and procedures for operation as a product certifier.

4 USAB shall review and comment. If necessary, USAB will require the applicant to amend and respond before the next step.

5 USAB shall issue a provisional accreditation certificate when satisfied that the document structure is adequate. The applicant is listed on USAB web site as “PROVISIONAL BODY”

6 The applicant conducts the product certification activities. The applicant sends USAB photocopies or scanned or electronic records of all the documents related to that work. These shall be in accordance with the documents that USAB had earlier reviewed.

7 USAB will as soon as is convenient conduct site witness of the applicant’s product certification activity. The applicant is required to pay USAB travel and accommodation expenses.

8 The applicant’s accreditation becomes firm. Applicant is listed on USAB web site without caveat.

9 The applicant continues to conduct product activities but does not need tosend paperwork.

10 The applicant must advise USAB at month end, on Form, of the value of all product certification activity invoiced. A fee is due to USAB for each certificate issued and on the anniversary of each issue should the Product Certifier maintain surveillance of the product.

11 USAB will monitor the level of the product certification activity and conduct accreditation reviews to suit.

12 The product certifier must inform USAB of all invoice-able activity.

13 USAB will arrange listing of the product certifier at www.usab-us.org .

NOTES

1. Organizations seeking accreditation as product certifiers shall demonstrate awareness, knowledge and intimacy with relevant product standards and legal requirements of the nations that such products may be distributed to. Predominantly, this applies to the European Union andthe various documents published by the European Parliament and Commission with regard to Conformity Assessment.

2. Organizations shall be cognizant of the role of Notified Bodies and their sole role and authority within the European Union with regard to the authorization of CE Marks to defined products.

3. As a general rule only Notified Bodies may authorize the placing of a CE Mark on a product.Some products however, have several categories and the very low risk products may be 'self-certified by producers who may prefer to employ the services of independent third-party organizations. Such organizations should be wary, especially in view of the UK (and probably other European states), initiative in this area.

4. It is most important that the applicant clients are given the opportunity to understand the relationship between USAB and government etc. The product certifier is therefore instructed not toimply or cause to be inferred that USAB act with the approval of the government. That is why Terms and Conditions are so important. USAB guide is also useful and USAB has no objection to the applicant issuing one to each of the applicant clients.

5. USAB revenue comes from a levy on the income of the product certifier. This is defined in contract between USAB and the product certifier. The arrangement is designed to enable theproduct certifier to achieve initial accreditation at minimal cost and to budget ongoing costs of accreditation in proportion to the test and calibration laboratory's own revenue and growth.

6. Currently USAB accredit product certifiers with regard to ISO/IEC 17065 who may also meetother standards.

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Product certification is indicative of a product's ability to meet (i) the general safety requirement and (ii) the specific requirements of a product standard. In order to issue a certificate, there shall be evidence of the following: -

- Adequate design
- Adequate manufacture & manufacturing environment
- Adequate inspection and test

The demonstration of adequacy is via the following means:

- Design evaluation: Technical Construction File for the product.
- Manufacturing assurance: Quality assurance records of manufacture and quality management system (typically ISO 9001 but also other standards depending upon the product)
- Inspection and Test: Certification that the product meets a documented product standard and the requirements of applicable directives and regulations. Typically, this will be achieved via meeting the requirements of ISO/IEC 17065 but, depending upon the regulatory regime, may invoke other standards as well such as ISO 17021 or ISO 17025.

Unless the above three activities, as a minimum, are demonstrated then conformity assessment cannot be assured and product certification cannot follow. Moreover, even if these three activities are assured, and even with the very best of available records, a CE mark may still not be applied under the auspices of USAB. This is because the European Commission has defined restrictive measures for CE Marking such that as a general rule, only Notified Bodies may authorize the placing of a CE mark on a product. There are no Notified Bodies within the USAB regime and whilst Notified Bodies are not essential in all cases it is a matter of policy that USAB abstain from authorizing CE Marking and this is clarified in its Advisory Notice.

END