**經濟部標準檢驗局**

**品質管理驗證機構認可申請書**

# Application Form for Quality Management System Certification Bodies to be recognized by the Bureau of Standards, Metrology and Inspection, M.O.E.A., R.O.C.

**1. 基本資料：**

**Basic Information:**

|  |  |
| --- | --- |
| 申請驗證機構名稱(中文)： |  |
| Applicant Organization Title (in English) ： |  |
| 機構簡稱：Abbreviation of Applicant Organization： |  |
| 地 址：Address： |  |
| 負 責 人:Name of Head of Applicant Organization： |  |
| 電 話 號 碼：Telephone No. ： |  |
| 傳 真 號 碼：Fax No. ： |  |
| 機構網址:Organization Website Address： |  |
| 聯 絡 人：Name of contact Person： |  |
| 電 話 號 碼：Telephone No. ： |  |
| 傳 真 號 碼：Fax No. ： |  |
| 電子郵件信箱：E-mail Address： |  |
| 其他分支機構包含於申請範圍：Other branches included in the application： | [ ] 無 (No)[ ] 有, 請填下表(Yes, please fill in the following table) |

包含於申請認可範圍內之其他地址：

Other branches included in the application scope：

|  |  |  |
| --- | --- | --- |
| 部門/單位名稱Name of Department/Unit | 業務項目Scope of Operation | 地　址Address |
|  |  |  |
|  |  |  |
| [ ] 已閱讀並瞭解「6.注意事項」。 I hereby acknowledge that I have read and understood the contents of the “6.notes”. |
| 申請日期：Date of Application： |  | 申請驗證機構負責人簽章：Signature of Head of Applicant Organization： |
| 按一下這裡以輸入日期。 |  |  |

**2.申請認可類別及範圍(請勾選適當項目)：**

 **Application category and scope (please check and click on those appropriate boxes)** **：**

|  |  |
| --- | --- |
| 類 別Category | 範 圍\*Scope\* |
| 商品驗證登錄、自願性產品驗證及度量衡業自行檢定許可RPC、VPC and Self- Verification Conducted by Measuring Instrument Enterprises | 正字標記CNS Mark |
|  | [ ]  | 01 農業、林業及漁業 (Agriculture, forestry and fishing) |
|  | [ ]  | 02 礦業、採石業 (Mining and quarrying) |
|  | [ ]  | 03 食品、飲料及煙草 (Food products, beverages and tobacco) |
| [ ]  | [ ]  | 04 紡織及紡織製品 (Textiles and textile products) |
| [ ]  | [ ]  | 05 皮革及其製品 (Leather and leather products) |
| [ ]  | [ ]  | 06 木材及其製品 (Wood and wood products) |
| [ ]  | [ ]  | 07 紙漿、紙及紙製品 (Pulp, paper and paper products) |
| [ ]  | [ ]  | 10 焦炭及石油煉製品之製造 (Manufacture of coke and refined petroleum products) |
| [ ]  | [ ]  | 12 化學品、化學製品及纖維 (Chemicals, chemical products and fibers) |
| [ ]  | [ ]  | 14 橡膠及塑膠製品 (Rubber and plastic products) |
| [ ]  | [ ]  |  15 非金屬礦物製品 (Non-metallic mineral products) |
| [ ]  | [ ]  |  16 水泥、混凝土、石灰、石膏等 (Concrete, cement, lime, plaster etc.) |
| [ ]  | [ ]  |  17 基礎金屬及加工金屬製品 (Basic metals and fabricated metals) |
| [ ]  | [ ]  |  18 機械及設備 (Machinery and equipment) |
| [ ]  | [ ]  |  19 電機及光學設備 (Electrical and optical equipment) |
|  | [ ]  |  20 造船業 (Shipbuilding) |
|  | [ ]  |  21 航太業 (Aerospace) |
|  | [ ]  |  22 其他運輸業 (Other transport equipment) |
| [ ]  | [ ]  |  23 其他製造業 (Manufacturing not elsewhere classified) |

**\*** 所列範圍依據NACE Rev. 2 (The lists of scopes are based on the NACE Rev. 2)

**3.申請性質(請勾選)：**

 **Application Status (please check and click on those appropriate boxes) ：**

|  |  |
| --- | --- |
| [ ]  新申請案 (4.1, 4.2/4.3, 4.4, 5.1, 5.2, 5.3)New application (4.1, 4.2/4.3, 4.4, 5.1, 5.2, 5.3) | [ ]  延展申請 (4.1, 4.2/4.3, 4.4, 5.2, 5.3)Application for extension of the validity period (4.1, 4.2/4.3, 4.4, 5.1, 5.2, 5.3) |
| [ ]  認可範圍異動 (請續勾選下列選項，並敘明) Changes in the scope of recognition (please check the following items and elaborate) |
|  | [ ]  增列，範圍：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(4.2/4.3, 5.3) Increase of recognition scopes |
|  | [ ]  減列，範圍：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Reduction of recognition scopes1. 原因Reason

[ ] 經認證機構減列範圍(Reduced by the accreditation body)[ ] 機構內部業務調整(Internal business adjustment)[ ] 其他(請敘明)： Others (Please elaborate) |
|  |  |
| 1. 對同時具RPC/VPC/正字標記/度量衡業自行檢定業者資格等客戶是否提供驗證移轉措施?Is there any mechanism to assist clients with RPC/VPC/CNS mark/ Self-verification conducted by measuring instrument enterprises qualifications to transfer certification?

[ ] 是，說明：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_。 Yes, please elaborate: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.[ ] 無具RPC/VPC/正字標記/度量衡業自行檢定業者資格之客戶。There is no RPC/VPC/CNS mark/ Self-verification conducted by measuring instrument enterprises clients.[ ] 其他(請敘明)：Others (Please specify): |
|  |  |
| [ ]  認證證書登載事項變更(請續勾選下列選項，並敘明) Changes in the registered items in accreditation certificate (Please check the following and elaborate)[ ] 地址 (4.2/4.3, 4.4, 5.2) Address (4.2/4.3,4.4, 5.2)[ ] 機構名稱 (4.2/4.3, 4.4, 5.2) Organization Title (4.2/4.3,4.4, 5.2)[ ] 認證效期 (4.2/4.3) Expiry date of accreditation (4.2/4.3)[ ] 其他，請敘明：Others (Please specify)： |
|  |  |
| [ ]  代理人變更Agent change (4.1) 變更日期 Change date from:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  屆期不延展。請敘明對同時具RPC/VPC/正字標記/度量衡業自行檢定業者資格等客戶之後續處置)：No need for extension. Please elaborate the follow-up treatments for the clients with RPC/VPC/CNS mark/ Self-verification conducted by measuring instrument enterprises qualifications: |
|  |  |
| [ ]  其他(請敘明)： Others (Please specify): |
|  |  |

**4.檢附文件(請勾選)：**

 **List of Attachments (please check and click on those appropriate boxes) ：**

|  |
| --- |
| [ ]  4.1委任書(國外申請者適用) Letter of Authorization for the recognized Quality Management System Certification Body Application (applicable to foreign applicants)*註：國外之驗證機構應填具委任書，委任在中華民國境內有住所或營業所之代理人辦理**Note：A foreign applicant shall authorize an agent who has a domicile or business place within the territory of Taiwan, the Republic of China to submit the application. In such cases, the letter of authorization from the applicant shall also be provided.* |
| [ ]  4.2財團法人全國認證基金會核發之認證證書影本A copy of an accreditation certificate issued by Taiwan Accreditation Foundation |
| [ ]  4.3簽署國際認證論壇(IAF)或亞太認證聯盟(APAC)多邊承認協定之當地國認證機構核發認證證書英文影本，或符合「品質管理驗證機構認可作業要點」第2點第2項規定由第三國已簽署國際認證論壇或亞太認證聯盟多邊承認協定之認證機構核發認證證書影本，或符合同要點第4點第2款規定之佐證文件A copy of an English version accreditation certificate issued by other accreditation body which is a member of the Multilateral Recognition Arrangements of the International Accreditation Forum or the Asia Pacific Accreditation Cooperation or a copy of accreditation certificate issued by an certification body in the third country which has been accredited as a member of the Multilateral Recognition Arrangements (MLA) of the International Accreditation Forum, Inc. (IAF) or the Asia Pacific Accreditation Cooperation (APAC) in accordance with Paragraph 2 of Article 2 as well as Paragraph 2 of Article 4 of the Directions for Recognition of Quality Management Certification Bodies. |
| 認證機構： Accreditation body：  |
|  |  |
| 認證期限(倘認證證書未記載有效期限，請提供由認證機構出具之說明文件)：Expiry date of accreditation (if there is no expiration on the accreditation certificate, please provide the explanatory documents submitted by the accreditation body): |
|  |  |
| [ ]  4.4申請者核發之ISO 9001證書原文版樣本及英文版樣本A sample of issued ISO 9001 certificate with bilanguages of the applicant’s language version and English version.*註：經本局認可後，當所核發之ISO 9001證書樣本有任何異動時(如格式、標記、圖形、簽署人等)，貴機構應及時通知本局，以避免未報備的證書有效性受質疑。**Note：After being recognized by BSMI, you should notify BSMI in time when there is any change in the ISO 9001 certificate sample (such as format, marking, graphics, signatory, etc.) to avoid the validity of the unfiled certificate being questioned.* |

**5.其他應檢附文件(請勾選)：**

 **Designated related information (please check and click on those appropriate boxes):**

|  |
| --- |
| [ ]  5.1 申請者公司簡介(含位置圖)、年報及稽核業務說明A brochure of the applicant (include site location map), annual report and/or explanation of audit business |
| [ ]  5.2 (預定)認可後相關作業說明書(中文或英文版)(Intended) related operating instructions after being recognized by BSMI (Traditional Chinese version or English version) |
| [ ]  5.3 (預定)執行欲申請或已取得商品驗證登錄、自願性產品驗證、度量衡業自行檢定許可或正字標記等工廠之品質管理系統驗證人員名單(Intended) lists of personnel on executing quality management system certification of factories that want to apply for or have obtained RPC, VPC, Self-Verification Conducted by Measuring Instrument Enterprises or CNS mark |

**6.注意事項 Notes:**

**申請認可作業**

**Application for recognition**

6.1 申請認可之品質管理驗證機構（以下簡稱申請者），應具備下列資格之一：

A quality management certification body (CB) that applies for recognition (hereinafter referred to as “applicant”) shall meet one of the following requirements:

6.1.1 取得財團法人全國認證基金會認證；

 Being accredited by Taiwan Accreditation Foundation, the Republic of China; or

6.1.2 取得**當地國**認證機構之認證，且該認證機構必須已簽署國際認證論壇( International Accreditation Forum, Inc.)或亞太認證聯盟(Asia Pacific Accreditation Cooperation)之多邊承認協定。當地國無認證機構或已有認證機構而尚未簽署國際認證論壇或亞太認證聯盟之多邊承認協定者，得經由第三國已簽署任一該等協定之認證機構認證；但當地國認證機構嗣後簽署前述多邊承認協定者，申請者須於1年內取得該認證機構之認證。

Being accredited by an accreditation body (AB) that is **located in the same country** as the applicant and is a member of the Multilateral Recognition Arrangements (MLA) of the International Accreditation Forum, Inc. (IAF) or the Asia Pacific Accreditation Cooperation (APAC). If there is no AB in the applicant’s country, or if the AB located in the applicant’s country has not yet become a member of the IAF MLA or APAC MLA, the accreditation can be obtained from any IAF MLA or APAC MLA member AB located in other countries. When an AB located in an applicant’s country becomes a member of the IAF MLA or PAC MLA, the applicant is required to obtain accreditation from the AB within one year in order to retain recognition by the Bureau of Standards, Metrology and Inspection (BSMI).

6.2 申請認可範圍以實施商品驗證登錄、自願性產品驗證、度量衡業自行檢定許可或正字標記產品驗證且經認證機構認證之範圍為限。

The scope of recognition for application is only under the schemes of the Registration of Product Certification (RPC), Voluntary Product Certification (VPC), Self-verification Conducted by Measuring Instrument Enterprises or Chinese National Standards product Certification (CNS Mark) and limited to the range accredited by the AB.

6.3 申請認可中之驗證機構，本局得視需要要求提供相關資料，必要時並得派員前往查核。**經認可之驗證機構，本局每年得定期或不定期實施查核1次。**驗證機構無正當理由者，不得規避、妨礙或拒絕。

The BSMI may request the applicant to provide the related documents and dispatch staffs to conduct on-site inspections when it is necessary. **The BSMI may also conduct regular or random inspections annually.** The CB shall not deny, impede or evade these inspections without any justifiable reasons.

**認可後對生產廠場的管理**

**Management for production premises after recognition**

6.4 當認可驗證機構所核發之ISO 9001證書被用於申請驗證登錄商品、自願性驗證產品或正字標記等產品驗證時，該認可驗證機構將收到本局或相關單位之通知。認可驗證機構應**維持該類生產廠場名單**，並於執行該廠商例行追查作業時確實稽核其品質管理系統及**每年依「產品驗證生產廠場品質管理系統查核表」或「正字標記認可品質管理驗證機構ISO 9001品質管理系統追查查檢表」之填表說明進行查核**，以確認下列事項：

When an ISO 9001 certificate issued by a recognized CB is used to apply for either the certification of RPC products, VPC products, or CNS products, the recognized CB will receive a notification from the BSMI or the related authorities. The recognized CB shall **maintain a list of such organizations**, audit the quality management system seriously and fulfill the related checklist according to the form description to **confirm the following items when conduct surveillance every year**:

|  |  |  |
| --- | --- | --- |
| **對象****Subject** | 驗證登錄商品或自願性驗證產品登錄之廠場Obtained RPC/VPC production premises | 核准使用正字標記之廠場Obtained CNS production premises |
| **檢查項目****Inspection Items** | 1. 是否持續營運或已經主管機關登記歇業？

Is the production premise in operation or registered as closed by the competent authority?1. 能否持續符合ISO 9001標準之要求？

Does the production premise continuously meet the requirements of ISO 9001?1. ISO 9001證書內容是否異動？

Is there any changed content in the ISO 9001 certificate?1. 產製過程所依據規範為何，以使產品能滿足商品驗證登錄或自願性產品驗證商品公告適用之法規、法令及檢驗標準？

What specifications does the production premise abide by through the manufacturing process so that the products can meet with the applicable regulations and inspection standards covered in RPC or VPC certificate?1. 產製過程如何管理，以使後續產製產品能與商品驗證登錄或自願性產品驗證登錄型式一致？

How does the production premise manage the manufacturing processes to ensure the subsequently manufactured products are in compliance with the product type registered in the RPC or VPC certificate? | 1. 持續符合指定品管制度之要求;

Ensure that the quality management of these organizations continues to comply with the requirements of specified quality management systems;1. 持有正字標記產品適用之最新版次相關法規及國家標準;

Ensure that the manufacturers maintain the most up-to-date versions of regulations and national standards applicable to the CNS Mark;1. 依國家標準建立適切之檢驗計畫予以執行，並提供適當資源使品質管理系統持續有效運作。

Ensure that the organizations establish adequate inspection plans for the CNS Mark products in accordance with related inspection standards and devote adequate resources for the continuous compliance of their quality management systems with the requirements. |
| **查核表****Checklist** | [產品驗證生產廠場品質管理系統查核表](https://www.bsmi.gov.tw/wSite/lp?ctNode=9347&CtUnit=3807&BaseDSD=7&mp=1)Inspection Checklist for Quality Management System of Product Certification Production Premise Registered by the Bureau of Standards, Metrology and Inspection, Ministry of Economic Affairs, R.O.C. | [正字標記認可品質管理驗證機構ISO 9001品質管理系統追查查檢表](https://www.bsmi.gov.tw/wSite/lp?ctNode=9166&CtUnit=1704&BaseDSD=7&mp=1)Recognized QM certification body for CNS MarkISO 9001 Quality Management System Surveillance Checklist |
| **查核表****回饋方式****Ways for Checklist feedback** | 於每次稽核作業完成後3個月內，將該查核表上傳至本局「品管驗證機構系統」。Upload the Inspection Checklist to the quality certification body system within 3 months after audited. | 於每次稽核作業完成後3個月內，將該查檢表依廠商所在區域別分別寄送本局第六組或轄區分局。Sending the Inspection Checklist to Section 6 or branches of the BSMI. |

6.5 前點追查作業，本局得視需要派員進行實地查核，驗證機構無正當理由者不得規避、妨礙或拒絕。

The BSMI may arrange the witnessing of the recognized CB carrying on the above audit activity, when necessary and the CB shall not evade, impede or deny without any justifiable reasons.

6.6 憑認可驗證機構所核發ISO 9001證書，經登錄為驗證登錄或自願性產品驗證生產廠場、經度量衡專責機關許可為度量衡業自行檢定業者或核准使用正字標記之廠場，其**證書登載事項有所異動時（含減列、註銷、廢止及重評換證）**，核發證書之驗證機構於通知生產廠場時，**應同時副知本局商品驗證機關（構）或度量衡專責機關**。

Where changes (including reduction of scope, cancellation and rescission of certificates, and issuance of certificates after re-assessment) are made to the content of ISO 9001 certificates, which were issued by the recognized CB and used for registering production premises under the RPC or VPC scheme by the BSMI (or its commissioned certification bodies), for obtaining the approval from the BSMI to conduct self-verification of measuring instruments, or the CNS Mark certified manufacturers, the recognized CB **shall also inform the BSMI (or its commissioned commodity certification bodies) when the new certificates are issued.**

**認可後的自我管理**

**Self-management after recognition**

6.7 經認可之驗證機構，其認證範圍被減列且影響認可範圍時，應於收到認證機構通知後**1個月內**檢具申請書及認證證書影本或佐證文件向本局申請變更，其認可證書登載事項有異動時，亦同。

A CB recognized by the BSMI (hereinafter referred to as recognized CB) shall apply to change the scope of registration within one month after the notice of CBs with this application form copy or related documents, if the accredited scope has been reduced or any change of the content specified in the recognition certificate is made.

6.8 為加強經認可之品質管理驗證機構驗證人員熟悉商品驗證登錄、自願性產品驗證、度量衡業自行檢定許可與正字標記相關法規與技術，驗證人員**每年應參加本局或本局指（核）定機構舉辦之驗證人員訓練課程活動至少1次**。

The staff members of the recognized CB shall be required to participate in training courses delivered by the BSMI or designated institutes at least once per year to enhance their familiarity with the relevant regulations and techniques of the RPC Scheme, the VPC Scheme, Self-verification Conducted by Measuring Instrument Enterprises and the CNS Mark Scheme.

6.9 **前一年度或當年度已參加前點之訓練課程活動者，始得執行**擬申請或已取得本局商品驗證登錄、自願性產品驗證、度量衡業自行檢定許可或正字標記生產廠場之ISO 9001品質管理系統驗證作業。

The ISO 9001 quality management system certification of the organization newly applying for or registered the RPC, VPC, Self-verification Conducted by Measuring Instrument Enterprises or CNS Mark Scheme shall only be performed by staff members who have completed the training courses of the year or of the preceding year.

6.10 經認可之驗證機構有下列情形之一者，本局得撤銷或廢止其全部或部分之認可：

All or parts of qualification of a recognized CB will be revoked or rescinded by the BSMI under one of the following situations:

6.10.1 認證證書被終止者；

The accreditation certificate of the recognized CB has been withdrawn;

6.10.2 認證範圍被減列者；

The accredited scope of the recognized CB has been reduced;

6.10.3 違反「品質管理驗證機構認可作業要點」第6點、第8點或第10點規定者；

The recognized CB violates the Clauses 6, 8 or 10 of the “Directions for Recognition of Quality Management Systems Certification Bodies”;

6.10.4 違反「正字標記管理規則」第36條至第39條規定之一者；

 The recognized CB violates one of the Articles 36 to 39 of the “Regulations Governing of CNS Mark”;

6.10.5 所發驗證證書或相關文件有虛偽不實之情事者。

There is evidence of fraudulent behavior on issuing certificates or offering documents.

6.10.6 以詐偽方法取得認可者。

Obtain the certification with a fraud method.