



財團法人全國認證基金會
Taiwan Accreditation Foundation

跨境認證合作原則
(中英對照版)

指引與報告

TAF-CNLA-G14(3)

TAF

說明

財團法人全國認證基金會(Taiwan Accreditation Foundation, TAF, 以下簡稱本會)是一個提供全方位專業認證服務的非營利性機構,也是我國唯一獲得國際認證組織承認之認證機構。本會建構符合國際標準之符合性評鑑制度,並且結合國內相關技術團體,運用專業的評鑑人力,以提供公正、獨立與透明之認證服務。推動國內符合性評鑑機構(實驗室、檢驗機構、能力試驗執行機構、參考物質生產機構及驗證機構)各領域之國際認證,提昇其品質與技術能力,並致力於人才培訓與資訊推廣,強化認證公信力,以滿足顧客(政府、工商業、消費者等)之需求,促進與提昇產業、國家競爭力及民生消費福祉。

本會為國際實驗室認證聯盟(International Laboratory Accreditation Cooperation; 簡稱 ILAC)及亞太認證聯盟(Asia Pacific Accreditation Cooperation; 簡稱 APAC)的正會員,並代表我國簽署國際相互承認協議(Mutual Recognition Arrangement; 簡稱 MRA)。本會認可實驗室與檢驗機構所出具試驗/校正/檢驗報告(或證書),可為國際間簽署相互承認協議之認證機構所接受。

本會為公正、獨立與透明之認證機構,對於認證相關文件之規劃、制訂與審查透過公開意見徵詢,包括公告於本會網站、TAF 會員網之會員專區進行公開徵詢意見、邀請本會技術委員或外部專家制訂與/或審查等,依各類文件性質不同而採用上述必要的審查方式,以廣納各界意見。新文件的發行與實施事宜亦於本會網站、認證服務資訊系統會員專區公告。

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目 錄

介紹.....	1
前言.....	1
目的.....	1
授權.....	1
1. 跨境認證合作原則.....	1
2. 申請認證與資源審查.....	2
3. 與國內認證機構合作.....	3

介 紹

ILAC-G21:2002 這份文件是由 ILAC 技術委員會(ILAC Technical Accreditation Issues Committee)擬定且經 2001 年 ILAC 會員大會首度核准發行。
ILAC-G21:09/2012 經由 ILAC 會員大會通過後進行修訂且核准出版，本會決議以中英文對照方式直接採用，以作為未來處理跨境認證議題之指引。

PREAMBLE

This guidance document was first endorsed by the ILAC General Assembly in 2001, as a code of good practice for ILAC member bodies (ILAC Decision GA 5.19). This document has been revised and approved for publication after being endorsed by the ILAC membership.

PURPOSE

1. The ILAC Mutual Recognition Arrangement (the Arrangement) is designed to ensure that endorsed test reports and calibration certificates issued by laboratories, and endorsed inspection reports issued by inspection bodies accredited by ILAC Full Members (i.e. signatories to the ILAC Arrangement) under their defined scopes of accreditation, can be accepted worldwide.
2. ILAC's objective is to offer the benefits of the Arrangement to the market so that duplicate accreditations will not be necessary.
3. For this to be achieved, each accreditation body which is a signatory to the Arrangement provides an equivalent accreditation service. This equivalence is ensured by a peer evaluation process managed under the ILAC Arrangement.
4. The principles set out in this document serve to strengthen the international network of accreditation bodies through the ILAC Arrangement. These accreditation bodies accredit laboratories and inspection bodies that provide conformity assessment activities in different economies. The principles seek to assist the objective of facilitating international trade by removing technical barriers to trade.

AUTHORSHIP

This document has been prepared by the ILAC Arrangement Committee (ARC).

1. CROSS-FRONTIER ACCREDITATION – PRINCIPLES FOR COOPERATION

- 1.1 ILAC is the international forum for accreditation bodies providing accreditation of laboratories

前言

本指引文件首度於 2001 年經 ILAC 會員大會通過，作為 ILAC 會員組織優良操作之準則 (ILAC 決議 GA5.19)。本文件於 ILAC 會員大會通過後進行修訂且核准出版。

目的

1. ILAC 相互承認協議旨在確保 ILAC 正會員認證實驗室出具之測試報告及校正證書，以及認證檢驗機構出具之檢驗報告，在全世界均獲得接受。
2. ILAC 欲將該相互承認協議所具益處，提供給市場以減少非必要之重複認證。
3. 為達成此目的，簽署相互承認協議之各認證機構，將提供等同之認證服務。此項等同性將依 ILAC 相互承認協議同儕評鑑過程給予保證。
4. 本文件制定原則將透過 ILAC 相互承認協議，強化 ILAC 建立之認證機構國際網絡。這些認證機構將承辦各國或經濟體之符合性評鑑服務實驗室及檢驗機構認證工作。本文件制定原則藉由消瀾貿易技術障礙，進而協助達成促進國際貿易之目標。

授權

本文件經 ILAC 相互承認協議委員會 (ARC) 擬定。

1. 跨境認證合作原則

- 1.1 ILAC 為實驗室與檢驗機構之認證機構國際論壇，其提供全球觀點與基礎架構，協助證明 ILAC



and inspection bodies. ILAC provides the global perspective and infrastructure that supports the demonstration of technical competence and the equivalence of the accreditation worldwide performed by signatories to the ILAC Arrangement.

- 1.2 The signatories to the ILAC Arrangement generally provide laboratory and/or inspection body accreditation to their domestic markets. Accreditation bodies may, however, have a policy to meet the demand for accreditation from a broader market that may arise in exceptional cases.

2. APPLICATION FOR ACCREDITATION AND RESOURCE REVIEW

- 2.1 Some examples of when a laboratory or inspection body might apply for accreditation from a body outside its country (economy) are:
 - a. There is no domestic accreditation body.
 - b. The domestic accreditation body does not offer accreditation for the required scope.
 - c. The domestic accreditation body is not a signatory to the ILAC Arrangement.
 - d. The laboratory or inspection body's clients require accreditation by a specific accreditation body, and will not be persuaded to accept the domestic equivalent.
 - e. The laboratories or inspection bodies are part of a group who wants all their laboratories or inspection bodies to be accredited by the same accreditation body.
- 2.2 Where one or more domestic accreditation bodies that are ILAC Arrangement signatories for the requested scope of accreditation exist in the country (economy) of the applicant, and the applicant still elects to apply for accreditation from the foreign accreditation body, the foreign accreditation body should in accordance with the requirements to have a program to promote the ILAC Arrangement with major stakeholders (as specified in IAF/ILAC A2) take the following steps before accepting the application:

相互承認協議簽署者，在全球皆能提供具備技術能力之等同認證服務。

- 1.2 ILAC 協議簽署者通常提供國內市場實驗室/檢驗機構認證。然而，認證機構可制定相關政策，以便在發生特例情況時，因應外國市場認證服務之需求。

2. 申請認證與資源審查

- 2.1 實驗室或檢驗機構尋求本國或所在經濟體以外機構提供認證服務之部分原因，包括：
 - a. 國內並無認證機構。
 - b. 國內認證機構並無提供所需之認證範圍。
 - c. 國內認證機構並非 ILAC 協議簽署會員。
 - d. 其客戶要求由特定認證機構提供認證，而且無法被說服以接受國內等同認證。
 - e. 其為連鎖實驗室或檢驗機構集團之一部分，該集團要求旗下全體實驗室或檢驗機構，由同一認證機構進行認證。
- 2.2 當申請者國內或所在經濟體有一至數家 ILAC 協議簽署認證機構，提供其所需認證範圍，但是仍選擇向他國認證機構申請認證時，該國外認證機構應依照制定計畫，向主要關係者(如 IAF/ILAC A2 文件所述)推廣 ILAC 協議之益處，並在接受申請前採取下列步驟：



- a. Enquire if the applicant is aware of the domestic accreditation body.
 - b. Suggest that accreditation provided by a domestic accreditation body would better take account of local factors and conditions, where relevant.
 - c. Point out the equivalence of the domestic accreditation body's accreditations as demonstrated through the ILAC Arrangement.
 - d. Point out that, according to the principles in part 3 of this document, and even if the application is accepted, the local accreditation body may be involved in the accreditation process.
- 2.3 The foreign accreditation body should proceed with the application only if the applicant persists in requiring accreditation by the foreign accreditation body.

3. COOPERATION WITH THE DOMESTIC ACCREDITATION BODY

- 3.1 The foreign accreditation body shall seek acceptance from the applicant before consulting with the domestic accreditation body.
- 3.2 When an accreditation body that is a signatory to the ILAC Arrangement decides to provide accreditation services outside its country (economy), it should ensure that appropriate assessors are used, taking into account factors such as language, local laws and regulations, culture, etc., as well as technical competence requirements. The foreign accreditation body should also consult the domestic accreditation body and take into consideration any relevant accreditation requirements that the domestic accreditation body has set to suit the local conditions.
- 3.3 The preferred ILAC approach to ensure access to relevant competence is to cooperate to the greatest extent practicable with the domestic accreditation body by using its personnel, as appropriate, on the assessment team.
- 3.4 If it is not possible to include personnel from the

- a. 詢問申請者是否知悉有國內認證機構。
 - b. 建議在考量到當地相關因素和條件下，由國內認證機構提供認證為宜。
 - c. 指出國內機構認證透過 ILAC 協議證明具有等同性。
 - d. 依本文件第 3 部分原則指出，即使受理申請，當地認證機構仍可能參與認證流程。
- 2.3 外國認證機構惟在申請者堅持其提供認證下，才得以受理申請。

3. 與國內認證機構合作

- 3.1 國外認證機構需在獲得申請者同意後，才能知會國內認證機構執行認證。
- 3.2 當 ILAC 協議簽署認證機構決定提供認證服務至外國或其他經濟體時，應確保採用適任評鑑員，考量語言、當地法律及法規、文化和技術能力需求等因素。外國認證機構亦應知會國內認證機構，並將國內認證機構為符合當地條件而制定之相關認證要求納入考量。
- 3.3 為確保獲得等同能力，ILAC 推薦優先採用之方法，即是盡量與國內認證機構合作，在評鑑小組適度納入其人員。
- 3.4 無法將國內認證機構人員納入評鑑小組時，應在



domestic accreditation body on the assessment team, cooperation with the domestic accreditation body should be extended to invite the domestic accreditation body to observe the assessment, subject to acceptance by the applicant.

- 3.5 Where the domestic accreditation body is not a signatory to the ILAC Arrangement, or where the scope of the domestic accreditation body does not cover the requested activity, the foreign accreditation body should try to cooperate with the domestic accreditation body according to these principles so as to provide the domestic accreditation body with the opportunity to gain experience to apply for the ILAC Arrangement.
- 3.6 The principles for cooperation among ILAC member bodies stated in this document also apply for reassessment and surveillance activities performed by an accreditation body outside its country (economy).
- 3.7 In all cases, the objective of an eventual change, with the accreditation moving to the relevant domestic accreditation body, should be borne in mind when the domestic accreditation body becomes a signatory to the ILAC Arrangement for the relevant scope, or when the applicant laboratory or inspection body so chooses.

申請者同意下，擴大與國內認證機構之合作範圍，邀請國內認證機構擔任評鑑觀察員。

- 3.5 倘若申請者國內認證機構未簽署 ILAC 協議，或是其認證範圍不含申請者所需活動，國外認證機構應依照本文件原則，試圖給予國內認證機構機會，獲得申請 ILAC 協議所需經驗。
- 3.6 本文件所述之 ILAC 會員機構合作原則，同樣適用向外國或其他經濟體之認證機構提出之重評鑑與監督活動申請。
- 3.7 在這些情況下，不論是國內認證機構加入申請者所需之 ILAC 協議範圍，或者面臨到申請者之可能選擇時，均應牢記終極目標是將認證移交至相關國內認證機構來執行。