



ISO, ILAC and IAF streamline quality management requirements for medical laboratories

ISO、ILAC 與 IAF 共同發表簡要 醫學實驗室品質管理要求

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Medical laboratories accredited to ISO 15189:2012 (a sector-specific technical competence and management system standard) are recognized as meeting the management system principles of ISO 9001:2008.

通過 ISO 15189:2012(特定行業的技術能力與管理系統標準)認證的醫學實驗室，經承認符合 ISO 9001:2008 管理系統原則。

The move was announced in a joint communiqué by ISO (the International Organization for Standardization), ILAC (the International Laboratory Accreditation Cooperation) and the IAF (the International Accreditation Forum) in September 2009 and updated in January 2015 as a result of the revision of ISO15189 in 2012.

國際標準化組織(ISO)、國際實驗室認證聯盟(ILAC)與國際認證論壇(IAF)於 2009 年 9 月的聯合公報上正式宣佈這項發展，並依據 ISO 15189 標準 2012 年修訂版於 2015 年 1 月進行更新。

The ISO-IAF-ILAC communiqué was issued to address the misconception in the market that medical laboratories accredited to ISO 15189:2012 do not operate a recognized management system.

ISO-IAF-ILAC 聯合公報的發行宗旨在於釐清市場上對於通過 ISO 15189:2012 認證的醫學實驗室並未實施公認的管理系統的錯誤觀念。

Until now, accredited medical laboratories were often requested by their customers to undertake the additional step of obtaining certification to ISO 9001:2008 to demonstrate that they are in full control of their processes.

至今，通過認證的醫學實驗室仍時常接到顧客的要求，追加進行 ISO 9001:2008 驗證步驟，以證明其完全掌控內部流程。

Medical laboratories accredited to ISO 15189 have demonstrated that they also meet the management systems principles of ISO 9001:2008. Accredited medical laboratories that are included in the scope of a larger organization's certification to ISO 9001 should only need to be assessed according to ISO 15189, and these results will be accepted as meeting the principles of the management system requirements (ISO 9001:2008).

This recognition will improve the efficiency of audits and enable medical laboratories to better meet their customers' needs.

NOTE to editors: ISO is the developer and publisher of ISO 15189 and ISO 9001, but does not itself carry out auditing/assessing, accreditation and certification. These services are performed independently of ISO by accreditation and certification bodies. ISO does not control such bodies, but does develop voluntary International Standards to encourage good practice in their activities on a worldwide basis.

ILAC is the world's principal international forum for the development of laboratory accreditation practices and procedures and the promotion of calibration and testing laboratory and inspection accreditation. This accreditation ensures that decisions on international trade, public health and

通過 ISO 15189 認證的醫學實驗室已證明亦符合 ISO 9001:2008 管理系統原則。獲認證的醫學實驗室，若隸屬於通過 ISO 9001 驗證的大型組織旗下，僅須按照 ISO 15189 進行評鑑即可，這些結果將視為符合管理系統要求原則(ISO 9001:2008)之證明。

此項承認將增進稽核效率，同時讓醫學實驗室更能滿足顧客需求。

給編輯：ISO 為 ISO 15189 與 ISO 9001 標準之發展者暨出版者，本身不從事稽核/評鑑、認證與驗證工作。這些服務由認證及驗證機構自行進行，與 ISO 並無關連。ISO 不負責管制這些機構，不過，ISO 確實著手規劃自願性質的國際標準，鼓勵全球機構採用優良操作實務。

ILAC 為全球主要國際論壇之一，旨在發展實驗室認證操作實務及程序，並提倡校正與測試實驗室以及檢驗認證。這項認證確保國際貿易、公共衛生與環保議題的相關決策，皆以可靠、可重現且精準的資料為依據。除了在其他領域的工作外，身為 ILAC 會員的國家認證機

environmental issues are based on reliable, reproducible and accurate data. As well as working in other fields, national accreditation bodies that are members of ILAC assess and declare the competence of medical laboratories against the requirements of ISO 15189.

IAF is the world association of accreditation bodies and other bodies interested in the accreditation of conformity assessment bodies providing certification services. Its primary function is to develop world wide programs of accreditation that promote the elimination of non tariff barriers to trade. Accreditation bodies declare the competence of conformity assessment bodies in the fields of management systems, products, services, personnel and other similar programs of conformity assessment.

構，負責評鑑與宣布醫學實驗室的能力，是否符合 ISO 15189 的要求。

IAF 是一個全球性質的協會，由認證機構以及其他有意從事符合性評鑑機構之認證的機構所組成，上述之符合性評鑑機構係指提供驗證及檢驗服務的機構。其主要職責為發展全球認證計畫，以推動非關稅貿易障礙之消除。認證機構得宣告符合性評鑑機構在管理系統、產品、服務、人員和其他類似符合性評鑑計畫領域具有充分的能力。