

EN ISO 15189, the Standard for Accreditation in Laboratory Medicine

Desmond Kenny and David Burnett

The publication of EN ISO 15189 is an important step towards universal acceptance by medical laboratory professionals of the need for accreditation as a means of demonstrating to the public, to governments, regulatory bodies and other interested parties that a laboratory possesses the competence necessary to ensure the high standards of service which patients and clinicians should be able to take for granted.

Before ISO 15189 existed, accreditation of medical laboratories was notable for the lack of uniformity in how it was implemented in different countries and regions. In many countries, medical laboratory accreditation did not exist at all. This lack of uniformity made it difficult for medical laboratory professionals in different countries to learn from one another's experience. In particular, it made it difficult for those who wished to start new medical laboratory accreditation programmes to decide which of the various existing models to follow.

When work began on the writing of ISO 15189 the desire of medical laboratory professionals throughout the world to have such a standard soon became apparent. The need for this standard was amply demonstrated when several countries began to use drafts of the standard to establish accreditation schemes for the first time. Even while still in draft form, ISO 15189 was accepted as a suitable basis for medical laboratory accreditation by international and national accreditation bodies.

Now that the standard has been published it is possible to make meaningful use of the experiences of others in improving our understanding of the issues involved and in ensuring a greater uniformity of approach to medical laboratory accreditation throughout the world. It is hoped that this special issue of eJIFCC will contribute to this process.