European cooperation for Accreditation

Paul Stennett – Chief Executive
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UKAS – who we are

- The National Accreditation Body (“NAB”)
- Accreditation – the recognition of competence of organisations to perform specific tasks – calibration, inspection, testing and certification
- UKAS assesses for compliance against criteria of competence (international standards)

UKAS – who we are

- Established 1995 by Ministers as a private company limited by guarantee
- Operates under an MoU with BIS
- Duty to act in the public interest:
  commercially aware, but not commercially driven
- EU Regulation 765/2008 provided legal framework for accreditation
- Accreditation recognised as a public authority activity
- UKAS appointed as National Accreditation Body by The Accreditation Regulations 2009

European cooperation for Accreditation

- The European co-operation for Accreditation, (“EA”) is a non profit association established November 1997 and registered as an association in the Netherlands.
- EA is the European network of nationally recognised accreditation bodies located in the European geographical area.
- EA has been established by the European Commission as the official European accreditation infrastructure. This became effective on 1st April 2009 .
- The appointment of EA as the official European accreditation infrastructure follows the adoption of Regulation (EC) no 765/2008 of the European Parliament and the Council of 9 July 2008 establishing a legal framework for accreditation in the EU/EFTA member states. This regulation came into effect as of 1st January 2010.

Purpose of EA

- Provide Europe with an effective, reliable accreditation infrastructure
- Develop accreditation criteria and guidelines supporting harmonisation of practices
- Operate a sound, robust, reliable peer evaluation process
- Ensure equivalence of accreditation and equal reliability of accredited results
- Cooperate with the European Commission and other European, international stakeholders

Regional Cooperation Bodies

The IAF and ILAC Arrangements are structured to build on existing and developing regional MLAs/MRAs established around the world.

European Cooperation for Accreditation (EA)

Pacific Accreditation Cooperation (PAC)

Inter-American Accreditation Cooperation (IAAC)

Asia Pacific Laboratory Accreditation Cooperation (APLAC)

Southern African Development Community Accreditation (SADCA)

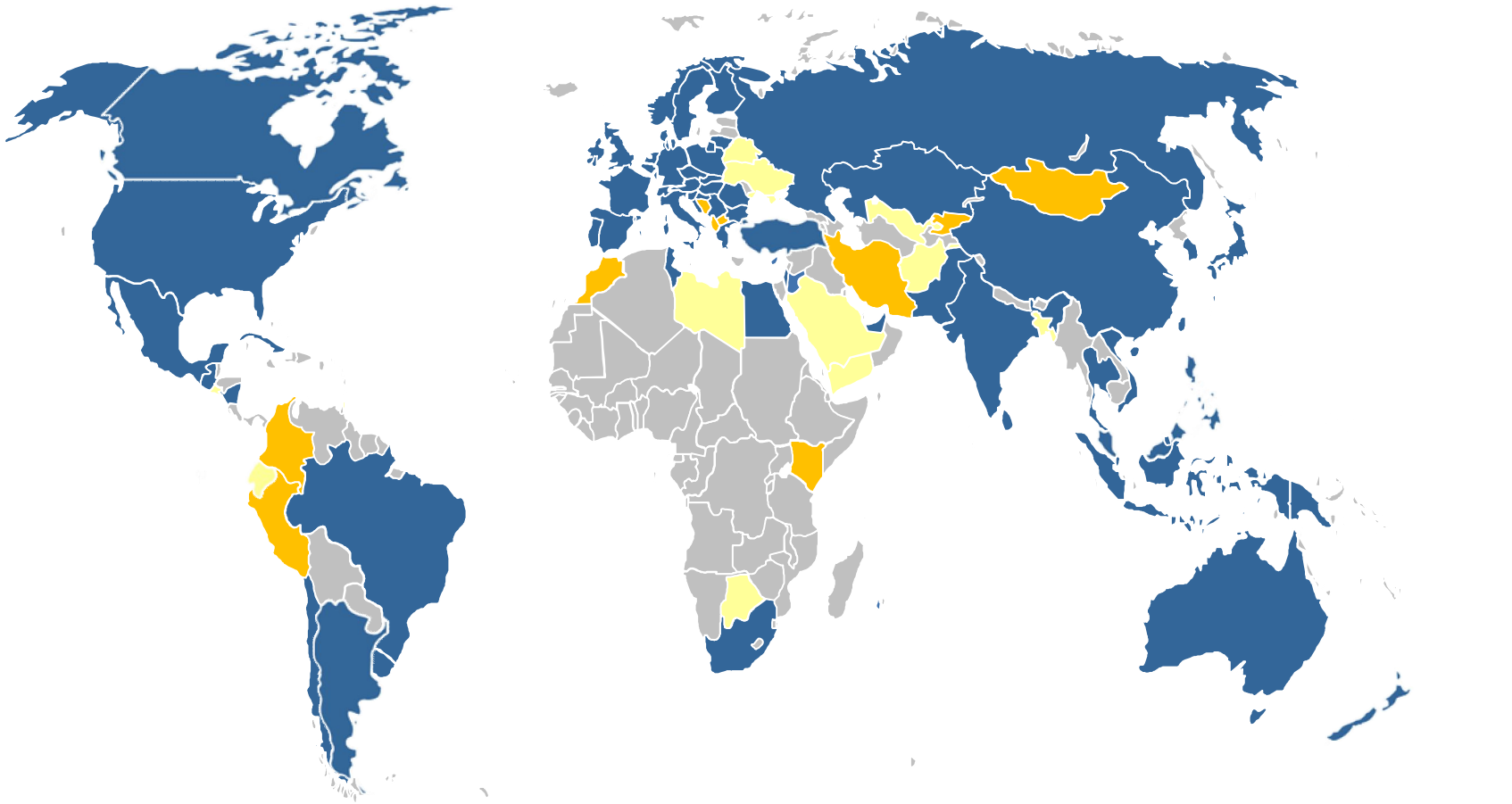
African Accreditation Cooperation (AFRAC)

- The IAF MLA recognises EA, PAC, IAAC
- The ILAC MRA recognises EA, APLAC, IAAC

ILAC MRA

- The ILAC network of members includes 139 bodies covering a total of 92 different economies
- There are 67 Signatories to the ILAC MRA, representing 55 economies
- The number of accredited laboratories has increased significantly in the last five years. There are currently almost 40,000 accredited laboratories, representing growth of over 50% since 2004
- The number of accredited Inspection Bodies has increased from 1842 in 2004 to 6734 in 2010

ILAC MRA



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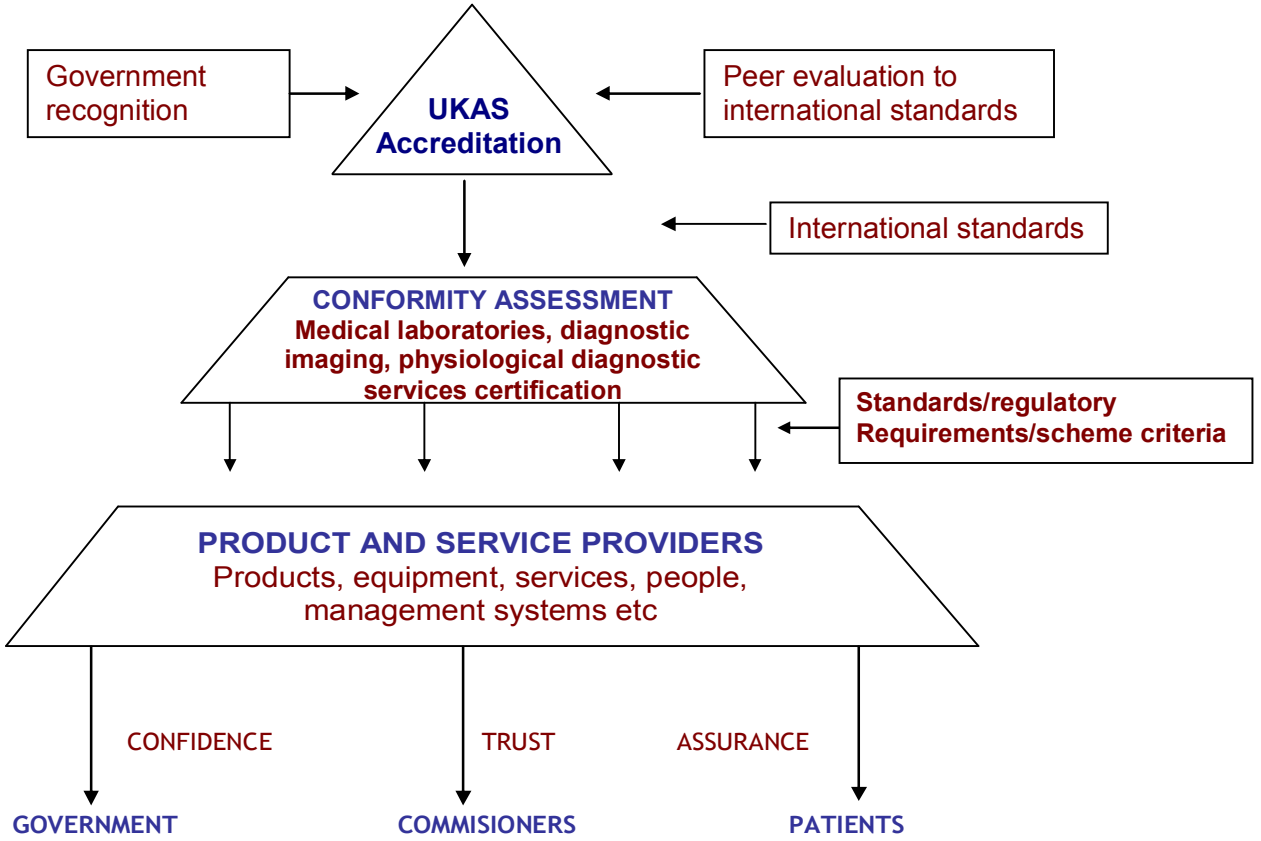
International Accreditation Organisations

INTERNATIONAL

REGIONAL

NATIONAL

Where do we fit in?



UKAS underpins the credibility and robustness
of a wide spectrum of standards and services, ranging across:

- Quality management - “CE” Marking – BIS
- National measurement system - NMO
- Drinking water quality – DEFRA
- Environmental Management - DEFRA
- Food safety & quality – DEFRA/FSA
- Forensic laboratories – Home Office
- National DNA database – Home Office
- Gas safe register – HSE
- Medical laboratories – UK Dept of Health
- Imaging Services – UK Dept of Health
- Physiological Diagnostic Services -DoH

Certification or Accreditation

- In the U.S. the term “accreditation” is used to describe both certification and accreditation activities, as defined by EU 765/08
- Examples of this difference in application of terms are the College of American Pathologists (CAP) and Joint Commission (TJC), which “accredit” clinical laboratory testing
- According to ISO’s definitions, CAP and TJC would be certification not accreditation programmes

Libeer JC, Ehrmeyer SS: ISO 15189: A Worldwide Standard for Medical Laboratories. Point of Care 3.1; 5-7, 2004

- Expected publication of paper by Charles Shaw helps to clarify definitions

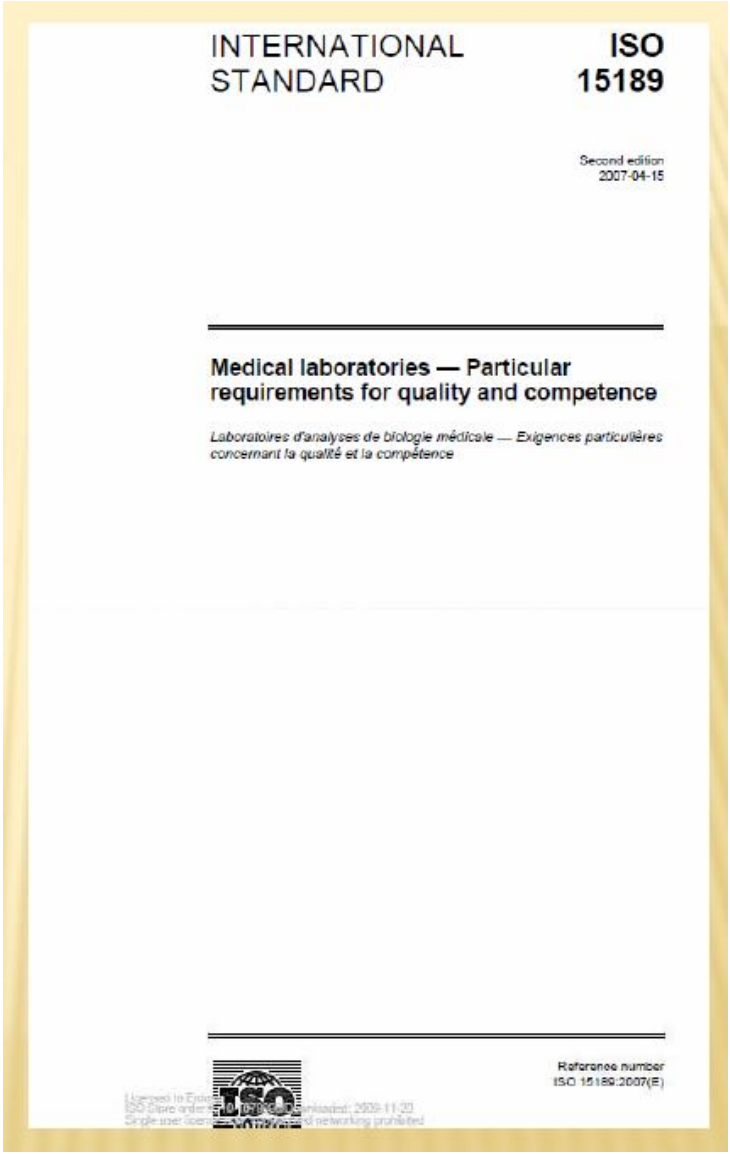
www.iso.org

- ISO, from the Greek *ISOS,* means “equal”
- ISO is a non governmental worldwide federation of national standards institutes, established in 1947
  - *161 countries (1 member/country); secretariat in Geneva*
- ISO develops cooperation and international standardisation
- ISO facilitates exchange of goods and services
  - *18,500 International Standards on many subjects*
  - *1,100 new ISO standards are published every year*

ISO 15189 (2007) *

- Medical Laboratories
  - Particular requirements for quality and competence

* Will be updated in 2012



Developed by ISO/TC 212: (33 member countries + observers)

- Argentina (IRAM)
- Australia (SAI)
- Austria (ON)
- Belgium (IBN)
- Brazil (ABNT)
- Canada (SCC)
- Chile (INN)
- China (SAC)
- Czech republic (CSNI)
- Denmark (DS)
- Finland (SFS)
- France (AFNOR)
- Germany (DIN)
- Iran (ISIRI)
- Ireland (NSAI)
- Israel (SII)
- Italy (UNI)
- Jamaica (JBS)
- Japan (JISC)
- Korea, Republic of (KATS)
- Mexico (DGM)
- The Netherlands(NEN)
- New Zealand (SNZ)
- Norway (SN)
- Portugal (IPQ)
- Singapore (SPRING SG)
- Spain (AENOR)
- Sweden (SIS)
- Switzerland (SNV)
- Turkey (TSE)
- Trinidad and Tobago (TAT)
- United Kingdom (BSI)
- United States (ANSI)

Clin Chem Lab Med 2004;42(6):576–577 © 2004 by Walter de Gruyter • Berlin • New York

Editorial

Towards quality specifications in extra-analytical phases of laboratory activity

Healthcare delivery organizations around the world are focusing considerable attention on the definition and use of quality indicators to identify health care improvement opportunities, to measure the efficacy of specific interventions, and to provide a quantitative link between quality of care and cost effectiveness. Using quality indicators for performance and outcome measurement is a way of measuring, monitoring and improving the quality of care and services.

Laboratory data are an integral part of the physicians' decision-making process and, according to current evidence presented at the CDC meeting "Making the Laboratory a Key Partner in Patient Safety" in Atlanta, they influence 70% of medical diagnoses (1). Therefore, the reduction of laboratory errors and the improvement of quality in medical laboratories play a significant role in programs for assessing and improving quality in health care.

The availability of the definitive edition of the new International Standard "Medical laboratories. Particular requirements for quality and competence" (2), released in February 2003, does not appear to have been followed by a debate on the acceptance of this new International Standard for harmonizing existing accreditation programs worldwide and for further detailing quality indicators.

ance targets should be proposed. In particular, while there is consensus on analytical quality specifications (3), currently there is no agreement on indicators and related quality specifications in pre- and post-analytical phases. The paper by Carmen Ricós and colleagues published in this issue of the journal should therefore be welcomed and its importance acknowledged (4).

The authors have reviewed available scientific evidence and have made a thorough search in the literature (Medline) for quality indicators and related specifications. According to current recommendations, when standards are not established, and this is our case, they must be based on preliminary data collection where benchmarks are available. The authors base their proposal on data in the literature and on state-of-the-art evidence obtained, in particular, in Q-Probes and Q-Tracks studies of the College of American Pathologists and, based on their findings, report a series of indicators related to the three main processes and sub-processes of laboratory activity. For example, the pre-analytical phase includes indicators related to requesting laboratory tests and collecting, transporting and receiving samples. Moreover, the study details the quality specifications, or limits of acceptability, for each indicator.

> The value of the new International Standard is irrefutable. Medical laboratories are the first medical discipline for which a specific International Standard has been elaborated and delivered, linking the needs of quality management systems, according to the ISO 9001:2000 series, with technical requirements that determine competence in clinical laboratories.

of an indicator is different from knowing whether or not the level is acceptable. The acceptability of a performance or an outcome rate must be evaluated in relation to the purpose for which it is to be used. The goal of medical laboratories is to provide an error-free service, but more realistic and achievable perform-

dence by means of a meta-analysis of existing studies. Second, the heterogeneity of data retrieved, due to differences in study designs, types of laboratories, geographical settings, and number and statistical treatment of data compromises the scientific validity of quality specifications for each and every

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Relationships between standards

Accredited certification

- A wide range of ISO *certification* standards exist, each designed for a specific purpose:- for example ISO14000 –environmental standards; ISO27000 – IT/information security, etc.
- However, probably the most well known is ISO9000 which is concerned with quality management systems.
- ISO 9000 is the basis of “modified” standards in Healthcare/hospital certification (“accreditation”) schemes
- UKAS accredited certification schemes are in operation using this approach.
- This approach has been very successfully deployed in other areas; e.g. the “BRC standard” has considerably raised standards of (microbiological) safety and hygiene in food production.
- The use of UKAS accreditation permits systems to be “tested once, accepted everywhere”.

Quality Management System (QMS)

- … a set of interrelated or interacting elements that organisations use to direct and control how quality policies are implemented and quality objectives are achieved (www.praxiom.com/iso-definition.htm)

- In summary, ISO 9000 is a generic system that specifies, in very broad terms, the necessary components of a quality management system. Rather than being specific to any specific area, it details the basic requirements of the quality function for all providers of services and products.

Quality management systems & certification

- In Europe, healthcare certification systems have not been as readily adopted as for example in the USA .
- Several possible reasons could exist for this;-
- Unjustified fear of “ISO9000” inflexibility
- Standards have not been developed with full stakeholder consensus
- Not accredited by the national accreditation body – therefore leading to a fragmented approach in the market and lack of creditability amongst potential users.
- In the USA, the demands of private health insurers require that hospitals are certified.

Certification systems-views and comments

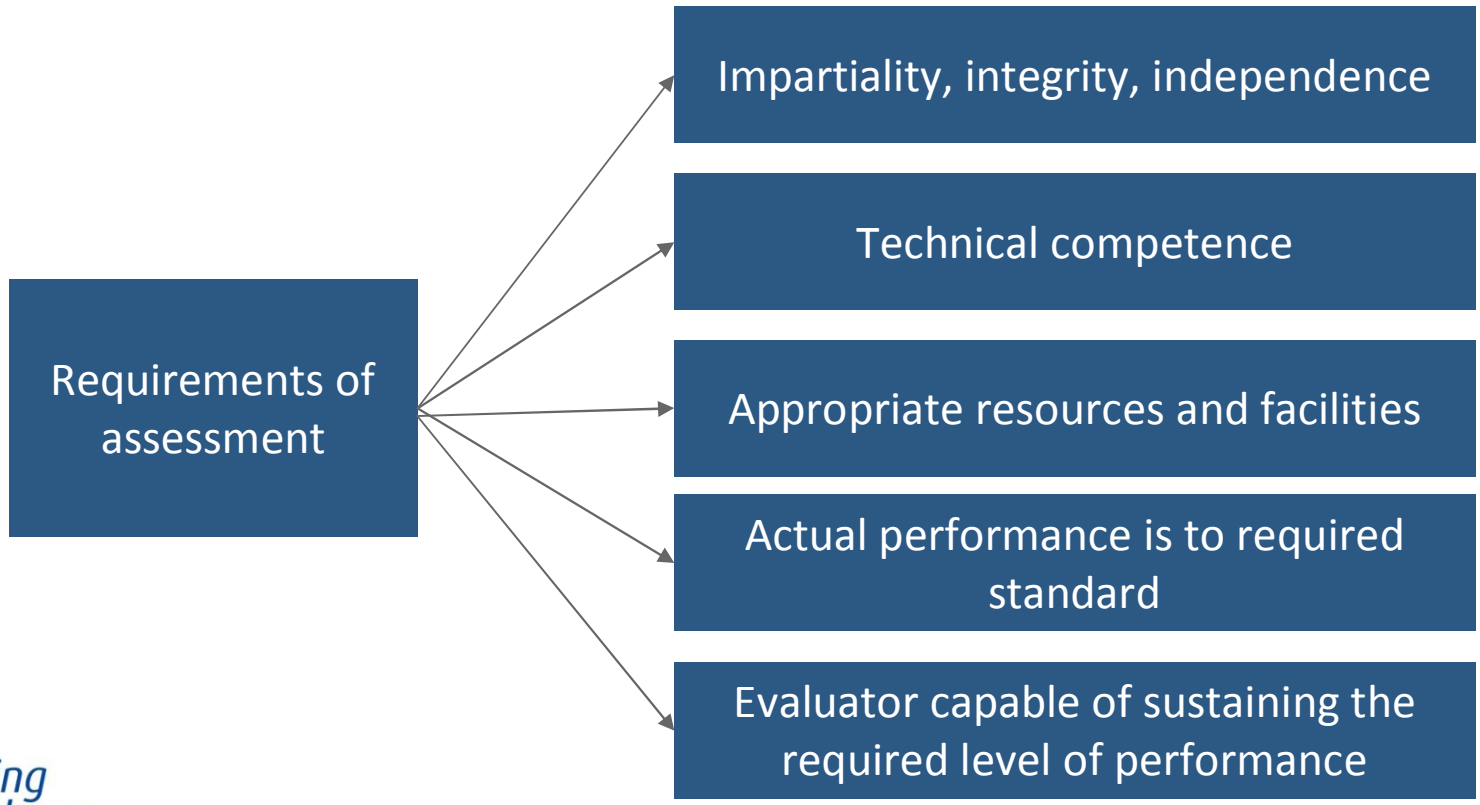
- **Standards and assessment as a strategic tool** “Our standards and assessments examine governance and quality systems, managing infection, clinical and non-clinical risks, medical equipment and the quality of healthcare environments.”
- “Our approach to standards and assessment is to see them as a strategic tool for continuous improvement, to share good practice and innovation, and help improve safety, quality and business performance”.
- “There is growing suite of disease-specific certifications, such as Primary Stroke Centre Certification or infection prevention protocols to provide a process adapted to the bespoke requirements of different types of healthcare organisation”.
- “There are now adaptations to local legislative and functional requirements. This is certification with a global impact and status, having been applied in hospitals from Brazil to Italy to China, and providing a benchmark of quality of care that can be trusted by patients worldwide”.

Certification systems – range and scope

- **Helps organise and strengthen patient safety efforts** – Patient safety and quality of care issues are at the forefront of the standards.
- **Strengthens community confidence** in the quality and safety of care, treatment and services when accreditation has formal recognition.
- **Improves risk management and risk reduction** –standards focus on performance improvement strategies that continuously improve the safety and quality of care, which can reduce the risk of error or low quality care.
- **May reduce liability insurance costs** – By enhancing risk management efforts, accreditation may improve access to and reduce the cost of liability insurance coverage.
- **Enhances staff development** –the standard requires that certified organisations provide additional opportunities for staff to develop their skills and knowledge. Involvement of appropriately qualified clinical Peers in the review process strengthen the relevance and value of assessment
- **Assessments** are regularly carried out.

How does accreditation work?

…..what will UKAS be seeking to determine?



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Conclusions

- Outside of Europe/UK, certification systems are more widely used as a general mark of quality for hospital performance
- May influence the patient's choice of hospital or to conform with requirements of the private health insurer.
- In the UK there would appear to be a greater focus on accreditation of specific clinical areas, such as "JAG" – endoscopy, "ISAS"- diagnostic imaging services, "IQIPS" – physiological diagnostic services and "CPA" – medical laboratories.
- Use of ISO standards as a basis for either certification or accreditation can help improve the effectiveness of the standard and increase acceptance and awareness.
- Similarly, accreditation by the "NAB" will increase the rigour of the processes, ensure impartiality and independence and aid acceptance by Government organisations/agencies.

European Accreditation Network

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