The European Commission's science and knowledge service

Joint Research Centre

The role of the accreditation legal framework in the *European QA scheme*

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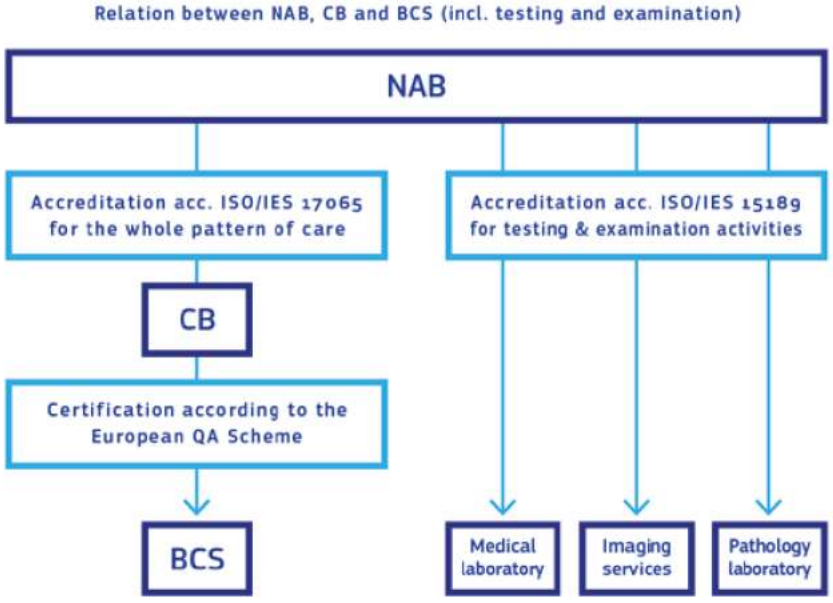
European Commission

European QA scheme and accreditation legal framework - 1



Legal entities will be certified or accredited individually according to the parts of care provided (according to the modules described at chapter 3 of this document) and specific interface requirements will be incorporated to grant continuity of care across BCSs when needed.

NAB=National Accreditation Body
CB= Certification Body
BCS=Breast Cancer Service

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European QA scheme and accreditation legal framework - 2

Scheme (European QA Scheme)

Scheme owner runs a scheme

Stakeholders ⟷ Scheme owner (EC)

CB's client (BCSs)

CB & Conformity Assessment

Requeriments for certification bodies are given in ISO/IEC 17065

Customers of clients (patients / BCS users)

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Standards that will be used – ISO/IEC 17065

ISO/IEC 17065 – "Requirements for bodies certifying products, processes and services"

It was published in 2012 while its predecessor, ISO/IEC Guide 65, had been in existence since the mid-1990s and was referenced and used by industries and regulators around the world.

Many of these industries and governments are shifting towards requiring third-party accreditation of the Certification Bodies which certify the products, processes, or services entering or being used in the country or region where the regulators have oversight responsibilities.

Standards that will be used – ISO/IEC 17065

The overall aim of certifying Product, Process and Service is to give confidence to all interested parties that a Product, Process and Service fulfills specified requirements.

***…is to confirm that a product (or service) complies with specified requirements found in standards, authority regulations or voluntary specifications*.**

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Standards that will be used – ISO/IEC 17065

ISO/IEC 17065 specifies requirements, the observance of which is intended to ensure that certification bodies operate certification schemes in a competent , consistent and impartial manner.

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Standards that will be used – ISO 15189

ISO 15189 – "Medical laboratories -- Requirements for quality and competence"

It was prepared by ISO/TC212 – "Clinical laboratory testing and in vitro diagnostic test systems". Its first edition was in 2003, second in 2007 and the current one in 2012.

Standards that will be used – ISO 15189

ISO 15189, which has been developed with strong involvement from the *medical*, *scientific* and *clinical community*, is for the use of medical laboratories in *developing* their management systems and maintaining their own competence;

and for accreditation bodies to *confirm* or *recognize* the competence of these laboratories through Accreditation.

Standards that will be used – ISO 15189

Since its publication, it has been recognized officially by the *International Laboratory Accreditation Cooperation (ILAC)* to be used as the international standard for the accreditation of medical laboratories *worldwide*.

While this International Standard is intended for use throughout the currently recognized disciplines of medical laboratory services, those working in other services and disciplines such as clinical physiology, medical imaging and medical physics could also find it *useful* and *appropriate*.

Standards that will be used – ISO 15189

Accreditation to ISO 15189 involves the independent assessment of a laboratory to determine competence, impartiality and consistency.

Standards that will be used – ISO 15189

ISO 15189 addresses all those factors in the laboratory that affect the production of test data, including:

- **technical competence of staff;**
- **validity and appropriateness of test methods, including pre- and post-analytical elements such as sample collection and reporting;**
- **sample quality, including patient identification, handling and transport to maintain sample integrity;**
- **a review of the history relating to previous patient results and any known clinical diagnoses;**

Standards that will be used – ISO 15189

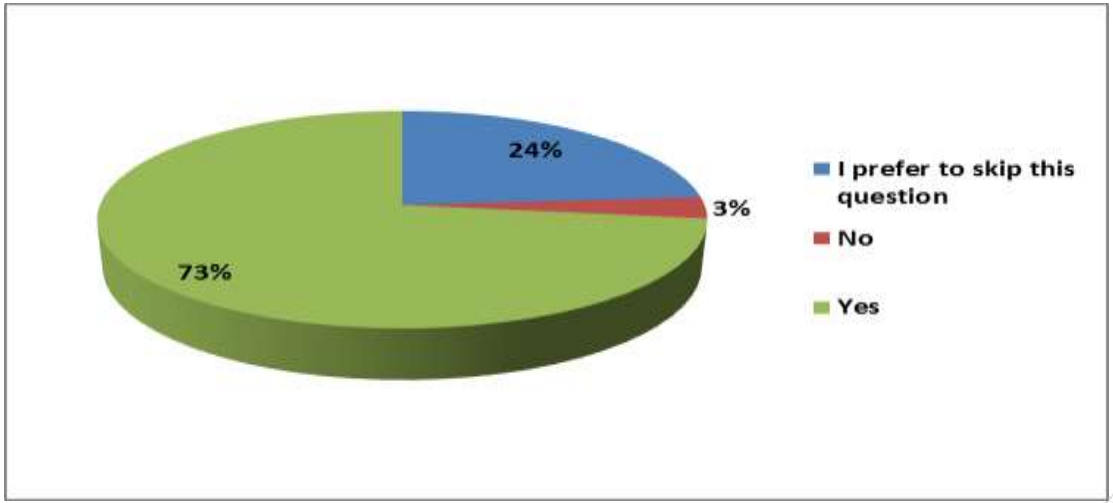
- **procedures relating to the use of "referral laboratories" such as specialised testing centres for specific diseases;**
- **traceability of measurements and calibrations to relevant standards;**
- **suitability, calibration and maintenance of test equipment;**
- **testing environment;**
- **quality assurance of test data;**
- **acceptable turnaround time;**
- **application of appropriate ethical values.**

Standards that will be used – ISO 15189

….ensuring that the accredited medical laboratory meets the needs of all patients, clinical personnel responsible for patient care and any other interested parties;

and provides, as well, not only accurate results, BUT it does so on the right patient, within a meaningful timeframe, as regards clinical management, using appropriate laboratory procedures and with a respect for ethics, confidentiality and the safety of the patient.

Q: Do you agree with the standard ISO17065:2012 for the accreditation of certification bodies?



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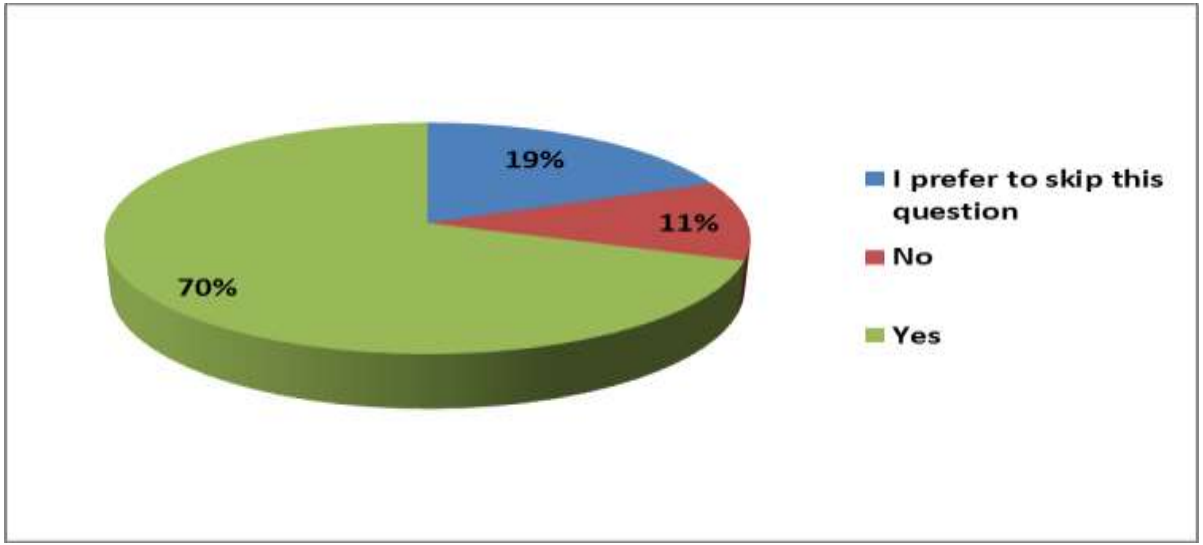
Q: Do you agree with the standard ISO15189:2012 for testing and examination activities?



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Critical issues with ISO 15189:2012

Existence of other standards on medical testing services already in use and appropriate to the context

- ISO/IEC 17020:2012 inspection for pathology laboratories in Germany
- Biomedical Laboratory and Diagnostic Imaging standards (Accreditation Canada's Qmentum International Accreditation Program)
- Screening imaging services in Germany already covered by certification

Direct application of ISO 15189:2012 to imaging services (as this standard was developed for medical laboratories)

New version of the Scope

For testing activities ISO 15189:2012 will be used. Possible time and equivalence derogations will be covered within the Scheme Owner's requirements along the discussion and approval processes of the QASDG.

Thank you and keep in touch!

European Commission Initiative on Breast Cancer

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