MGZ
Medizinisch Genetisches Zentrum

Position Paper to Accreditation by DAkkS and CAP

1 European Regulation Setting out the Requirements for Accreditation and Market Surveillance

The European Regulation (EC) No. 765/2008 requires the designation of a single national accreditation body for all EU Member States since January 1st, 2010.
Performance of accreditation and issuing of certificates (confirmation of conformity with standards) are therefore carried out e.g. in Germany by DAkkS (Deutsche Akkreditierungsstelle), in France by COFRAC (Comité Francais d´Accréditation), in Italy by ACCREDIA (Ente Italiano di Accreditamento), in the Netherlands by RvA (Raad voor Accreditatie), in Spain by ENAC (Entidad Nacional de Acreditación), etc.

2 DAkkS Accreditation Program

2.1 About DAkkS

DAkkS is the national accreditation body for the Federal Republic of Germany. According to the regulation no. 765/2008 of the European parliament and council as well as the German Accreditation Body Act, it acts in the public interest and as the sole exclusive provider of accreditation in Germany.
DAkkS is subject to the government's technical, legal and financial supervisory authority. DAkkS applies German administrative law and other administrative requirements as part of its public/official authority accreditation activities.
The DAkkS is a private non-profit organization that performs sovereign tasks.

2.2 Tasks of DAkkS

DAkkS is legally responsible for the accreditation of conformity assessment bodies (laboratories, inspection and certification bodies). As part of approximately 4,000 accreditation procedures, DAkkS, in its role as an independent institution, assesses, attests and monitors the technical competence of these bodies.
DAkkS carries out its sovereign activities for all accreditation procedures within Germany and within the member states of European Economic Area (EEA) and its non-sovereign activities outside the EEA, respectively.
All accreditation activities are carried out in compliance with applicable provisions of EC no. 765/2008 as well as the relevant regulations from the international accreditation organizations *European co-operation for Accreditation* (EA), *International Accreditation Forum* (IAF), and *International Laboratory Accreditation Cooperation* (ILAC).

2.3 International Membership

DAkkS is a member of the international accreditation organizations EA (association of European Accreditation bodies), IAF (global network of accreditation bodies that provide accreditations for products, management systems, and persons) and ILAC (worldwide association for the cooperation of accreditation bodies in the field of laboratories and inspection bodies).
DAkkS assumes responsible positions in these international accreditation organizations, supports the "peer evaluation process" of EA, and actively participates internationally in the development of new documents and standards.
The central objective of the international accreditation network is the mutual recognition of services and results of accredited bodies.

This is made possible by multilateral trade agreements (MRA or MLA) between the national accreditation bodies and the international accreditation organizations.

The EA Multilateral Agreement (EA MLA) is an agreement between EA full members which guarantees the equivalence and reliability of accreditations and the accredited conformity assessment results from the signatory states.

2.4 Accreditation Activities

DAkkS provides accreditations to laboratories, certification and inspection bodies, providers of proficiency tests and reference material producers, which must meet the requirements of the corresponding international standards:

Laboratories	ISO/IEC 17025 (Testing and Calibration Laboratories)
	ISO 15189 (Medical Laboratories) ⇨ MGZ
Inspection Bodies	ISO/IEC 17020
Certification Bodies	ISO/IEC 17065 (or EN 45011) for products
	ISO/IEC 17021 for Management Systems
	ISO/IEC 17024 for persons
Validation and Verification Bodies	ISO 14065
Providers of Proficiency Tests	ISO/IEC 17043
Producers of Reference Materials	ISO Guide 34

The international harmonization of these standards ensures that accreditations take place under a global basis according to the same criteria. As a result of these harmonized standards, and due to international agreements, the assessment services of bodies accredited in Germany are accepted in many European and non-European countries.

2.5 Validity of Accreditation and Surveillance Phase

Accreditation is valid for five years. Within this period of time, three surveillance procedures covering the areas of quality management system, cytogenetics, and molecular genetics of the MGZ are carried out every 1.5 years. The accreditation cycle ends after five years with the expiry of the accreditation or re-accreditation.

The recent re-accreditation of MGZ by DAkkS was in March 2017 and is now valid until March 2022.

2.6 ISO 15189 and DAkkS Requirements and Checklists

The content of ISO 15189, a system- and process-oriented quality management system, especially for medical laboratories, organized into two parts: a) management requirements, focusing on the QM system structure, function, and management of laboratory operations, its guiding policies, and processes, and b) technical requirements, focusing on the technical competency and related procedures and processes. In addition to the requirements of this standard, DAkkS provides written rules e.g. to the use of computer systems, metrological traceability, and discipline-specific checklists e.g. for cytogenetics, molecular genetics, immunogenetics, hematology etc.

3 CAP Accreditation Program

3.1 About CAP

The College of American Pathologists (CAP) is a member-based physician organization founded in 1946 comprising approximately 18,000 board-certified pathologists. It is the world's largest association composed

exclusively of pathologists certified by the American Board of Pathology, and is considered the leader in laboratory quality assurance and promotion of best practices in pathology and laboratory medicine.
The CAP acts as a Medicare Accreditation Organization (AO) and does accreditation of laboratories under deemed authority by The Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA) program.

3.2 CAP Accreditation Programs

CAP offers several internationally recognized laboratory accreditation/inspection programs, including the core program CAP Laboratory Accreditation Program (CAP LAP), Forensic Drug Testing, Reproductive, Biorepository, and CAP15189.
Most of the laboratories have been accredited under CAP LAP, in 2008 the first laboratory in US became to be officially accredited under CAP15189.

CAP15189 is a quality management program designed for accreditation to the ISO 15189 standard (Medical laboratories-requirements for quality and competence) in U.S., building on the CAP LAP program. As such, the laboratory must first be accredited in the CAP LAP before seeking accreditation to the ISO 15189 standard with CAP15189. Accreditation to the ISO 15189 standard does not meet U.S. CLIA requirements and cannot replace a CLIA-based accreditation for laboratories in U.S.

3.3 Checklists

The CAP LAP program is based on accreditation requirements, comprising documents called checklists. The All Common Checklist contains a core set of requirements that apply to all areas performing laboratory tests and procedures as well as discipline-specific checklists e.g. for cytogenetics, molecular pathology, transfusion medicine, reproductive laboratory etc. The All Common Checklist also describes the requirements for analytical validation/verification of the method performance specifications before the use of methods and instruments in patient testing.

3.4 Inspections

An on-site laboratory inspection occurs every two years. In the years when an on-site inspection does not occur, the laboratory performs a self-inspection using materials provided by the CAP.

Final Appraisal

MGZ has the permission to use the combined MRA mark of DAkkS and ILAC within the scope of accreditation. ILAC's combined MRA mark indicates the international recognition of DAkkS-accredited laboratory services. The basis for this is the signing of the ILAC MRA by DAkkS. This multilateral agreement regulates the mutual recognition of the results of accredited laboratories in all ILAC member states.

The technical requirements of the international standard ISO 15189 according to which medical laboratories are consistently accredited in Europe reflect the elements from CAP LAP accreditation checklists, but in a more generic form.

However, the content of ISO 15189 goes beyond the requirements of the CAP LAP accreditation programs. Both the management requirements and the requirements of the technical part of ISO 15189 demand regular management reviews, internal audits and an established risk based approach procedure to assure the compliance of the laboratory's activities to the QM system and its effectiveness, to meet patient needs and to continuously identify improvement opportunities before issues arise.
A holistic approach is required, including evaluation of the appropriateness, suitability and performance of tests, of relations to suppliers, clinicians, patients, and consultants, and the implementation of an effective CAPA (corrective action and preventive action) system to find causes for deviations/non-conformities, to avoid them in the future, and to realize effective solution strategies.

The CAP accreditation according to CAP LAP program is not only comparable with the requirements of the ISO 15189 requirements and with the role surveillance of DAkkS, but the ISO 15189 accreditation exceeds these regarding the additional requirements of a system- and process-oriented QM system.

28. Aug. 2018

Dr. rer. nat. Petra Hoffmüller
Head of Quality Management
Medical Genetics Center Munich