In the 1960s, external quality assurances were organized to arrive at a standardization of medical laboratory analyses. Building on those experiences, the first “Guideline of the German Medical Association for the Implementation of Statistical Quality Control and of External Quality Assurance Studies in the Field of Medicine” was promulgated on July 12, 1971.

In the Calibration Exception Directive of June 26, 1970, there was a provision for compliance with the directive from the German Medical Association when using measuring devices. Over the years, this directive has been subject to supplements and modifications. The first major reform occurred at the end of the 1980s. In the mid-1990s, analytical systems with pre-measured reagent doses were integrated into the quality assurance requirement.

With the promulgation of the EU directives on medical products, national medical product law was reformed, and in 2002 the Medical Devices Marketing Regulations finally adopted an obligation to perform regular quality assurance of medical laboratory analyses. In 2004, a working group formed which developed an overall concept for quality assurance of all medical laboratory tests – the new “Guideline of the German Medical Association for Quality Assurance of Medical Laboratory Analyses”, or in German, “Rili-BAEK” for short.

The Rili-BAEK 2007 guideline contains a fundamental new orientation of basic requirements for quality assurance of all medical laboratory analyses. It is divided up into Section A with general requirements for a quality assurance/quality management system in preparing, conducting and assessing medical laboratory tests, along with five other special sections.

It is prefaced by a segment containing important term definitions.

There are special sections for:
- Qualitative medical laboratory analyses
- The direct detection and characterization of infectious agents
- Ejaculate tests
- Molecular genetic and cytogenetic medical laboratory analyses

The special sections also “only” specify basic requirements for regularly conducting internal quality measures, in order to allow those responsible for conducting medical laboratory analyses a degree of latitude in sufficiently implementing the state of the art and technology.

The Rili-BAEK guideline was created not only in close cooperation with the competent medical research institutions but also with the Deutsche Krankenhaus Gesellschaft (DKG), with the Kassenärztliche Bundesvereinigung (KBV) and with the Dachverband für Technologen/-innen und Analytiker/-innen in der Medizin Deutschland e.V. (dvta), the regional agencies responsible for monitoring medical product regulations, the Verband der Diagnostikakersteller (VDGH) as well as the relevant top-level Federal agencies, such as Physikalisch Technische Bundesanstalt [Germany’s National Metrology Institute] (PTB), the Robert Koch Institute (RKI) and the Paul Ehrlich Institute (PEI).

With the Rili-BAEK guideline, uniform requirements for conducting all medical laboratory analyses in clinics and physicians’ surgeries have been established on the one hand, and independent of the insurance status of the relevant patients on the other hand.

In this context, external quality assurance tests have also been established as a system of market supervision. Current external quality assurance tests indicate that there still remains a considerable need for standardization with respect to the screening procedure in the field of drug-use testing. Here the external quality assurance testing organizations are gaining insights into how reliable and comparable results can be achieved through more stringent rules.

Overall, external quality assurance tests demonstrate a strong educative character. In the many external quality assurance tests, especially for the field of qualitative analyses, but also for infectious agent diagnostics, ejaculate analyses and molecular genetic and cytogenetic

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*Correspondence: Martin Brüggemann, Referent im Dezernat 3, Bundesärztekammer, Herbert-Lewin-Platz 1, 10623 Berlin, Germany, Tel.: +49 30 400456-436, Fax: +49 30 400456-378, E-Mail: manfred.brueggemann@baek.de

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diagnoses, the object is not merely to determine a measured value but to also document the steps towards classification of the measured value and to discuss the overall findings during the evaluation of the external quality assurance test with those heading up the external quality assurance testing. For this purpose, external quality assurance testing is very often followed up by comprehensive recommendations on how to improve diagnostics, but also on the assessments of the analyses.

In Germany, quality assurance is not only confined to participation in external quality assurance testing but also emphasises routine daily internal quality assurance as an important aspect, in order to regularly approve the measuring system for patient measurements and to respond early to negative trends.

With the Rili-BAEK guideline, a concept emerging from a corporatist model has established itself towards improving patient care.