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New Guidelines of the German Medical Association for Quality Assurance of Medical Laboratory Tests

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Laboratory medicine is the medical discipline that has been practising legally prescribed quality control and assurance for over 45 years. From 1969/1970 on, up until 2002, the legal requirement for *quality control* in laboratory medicine was firmly established in the Calibration Act [1, 2].

Since 2002, quality assurance in medical laboratory tests has belonged to the field of medical product law [3].

A *quality management system (QMS)* is the basis of all professional management and mandated by law for several years now in the medical field [4].

As a rule, quality initiatives in laboratory medicine have two aspects, namely the obligation towards patients, especially in light of lump-sum remuneration with the resulting tendency towards reducing services. In order to counter this trend, minimum standards must be defined and monitored by public agencies, and major breaches must be sanctioned. Safeguarding one's own future, on the other hand, requires efforts far beyond these initiatives, and calls for the orientation towards a model of business excellence [5].

The minimum quality that government or empowered bodies (self-administration) can and must require relates to structures, processes, and results. These rules must be justiciable, i.e., formulated in a detailed and non-ambiguous manner, as they are subject to sanctions. However, it is also important to be aware of problems of such sets of rules, and the fact that they involve strict requirements, which in large part are no longer individually adaptable. That is why in the interest of patients, regulation should be limited to what is absolutely necessary, according to the principle: As much as necessary, but as little as possible, to allow latitude for individual decisions.

The new 2008 Rili-BAEK is the fourth set of rules issued by the German Medical Association, after the guidelines of the years 1971, 1987 and 2001, prescribing minimum standards for quality assurance in medical laboratories. Whereas the rules in effect up to that time pertained exclusively to the quality of results of a definitive list of quantitative tests, the Rili-BAEK in (general) Section A is concerned with the essential elements of quality management, geared towards the protection of the patient. Section A applies to *all users* of medical laboratory procedures, independent of whether a special Section B (B1–B5) exists for them or not. The implementation of Section A of the Rili-BAEK guideline fulfils the statutory rules. Additional orientation can also be provided in the latest QM standard ISO 9000.

Sections B (B1–B5) specify the quality criteria for the quality of results and the evaluation of the individual test procedures.

Using Section B1 as an example, which went into effect first together with Section A in 2008 [6], below we shall attempt to explain the basic principles of the new Rili-BAEK guideline. The fundamental revision of the guidelines existing up to 2008 became necessary for several reasons. For quite some time, a large gap had emerged between the reality of modern device technology and the resulting medical laboratory practice on the one hand, and the rules of Rili-BAEK on the other hand. The fundamental consequence from the use of devices with considerably higher measurement stability was the shift from approving measurement *results after* the measurement towards the measurement *procedure for* the measurement. The most conspicuous change compared to the existing guidelines is that *all* quantitative medical laboratory tests performed by a medical laboratory are subject to internal quality control.

Additional essential changes compared to the existing guidelines include: the term "series" is no longer used, instead explicit instructions were formulated in terms of time and event control as to when single control sample measurements (SCSM) are to be performed; the internal limits for the parameters in the table are prescribed, as they serve as an early warning; for evaluation of the error of measurement, instead of precision and accuracy the new statistical parameter of the root mean square of the error of measurement was introduced; to support laboratories, critical events

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are to be reported to the higher Federal authority (Federal Institute for Drugs and Medical Devices – BfArM), and the terms were precisely defined in detail.

The fundamental precepts for drafting Sections B were to be formulate provisions as specifically as possible, to largely do away with exceptions and simply to require internal quality control for all measurement parameters. As a proven methodology, the principle of the tracer analyte was retained for tables.

Great emphasis was placed on timely control, as this allows an opportunity to intervene and avert harm to the patient. Whilst retrospective controls are indispensable elements to methodology, the damage has already long occurred in case of faulty measurements.

In determining ranges of tolerance in the tables of B1, clinical relevance and technical feasibility were to be observed. The requirements for accuracy of measurement, however, depend on the context. For the examinations in the field of outpatient care, the inter-individual variance with respect to the reference range of those not clinically sick remains important. For assessing the permissible error, biological variance [7] can be used as a guide. In order to separate two consecutive test results in daily clinic routine with the prescribed probability of error, the limits derived in this manner would be too far apart. Unfortunately, technically achievable accuracy of measurement is not even sufficient in most cases. Prescribing general medically-relevant error limits is thus not possible, that is why one (unfortunately) has to choose among what is technically and realistically feasible as a limit.

Concerns and apprehensions towards the new Rili-BAEK appear to have subsided in the meantime. However, the level of implementation for the rules in different types of medical laboratories still differs widely, as revealed by the results of state regulatory authorities [8–10]. The greatest deficits are in the practices of non-laboratory physicians. It is public knowledge that the rules of Social Code V are not observed.

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