Publication of the English version of the Rili-BAEK guideline – the diagnostics industry’s view on the Rili-BAEK guideline and its ramifications on laboratory medicine in Germany

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With the publication of the first major amendment of the guideline of the German Medical Association for quality assurance of medical laboratory analyses in the year 2003, all the participating stakeholders from the ranks of physicians and medical self-governance, societies and professional associations, public agencies and German states, have achieved a milestone in creating a unified quality standard in laboratory medicine.

Already in previous years, specifically since 1972, various precursor projects had taken up the cause of quality assurance in medical laboratory services. In many instances, however, these initiatives eschewed a generally accepted standard and were instead geared towards various special-case scenarios, such as the so-called “lex kodak” in the guideline of 1988, which provided exemptions for dry chemistry.

Individual subsections, such as microbiology (Section B 3 of the current guideline), not contained in the previous versions, were only made part of today’s version of the unified guideline.

From the viewpoint of the diagnostics industry, the Rili-BAEK guideline currently in effect has ushered in a noticeable improvement in the quality of medical laboratory services provided. In particular, this work has accomplished what was so difficult for all the previous initiatives, namely to create an awareness among laboratory operators for the necessity of a unified quality standard in medical laboratories. Today, no traditional medical laboratory can ignore the requirements of the Rili-BAEK guideline. Unlike mandatory accreditation according to DIN ISO EN 15189, as was implemented in France, the requirements are not leading to the mass extinction of laboratories – smaller labs in particular – nor is it accelerating the existing trend towards industry concentration.

With the introduction of the Rili-BAEK guidelines, all the stakeholders came together to establish a rational and logical set of rules for a high uniform quality standard in laboratory medicine, thus avoiding the creation of a de facto useless “paper tiger” riddled with compromises.

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