

## **Příloha č.2**

### **Statement from EC4 to the appropriate persons in ISO/TC 212, CEN/TC 140 and ILAC**

#### **The application of ISO EN 15189:2003 by Accreditation Bodies**

This statement is intended to reiterate and clarify the concern presented at the recent meeting of ISO/TC 212 in Berlin on behalf of the European Communities Confederation for Clinical Chemistry and Laboratory Medicine (EC4) by Simone Zerah (France). The concern relates to the manner in which ISO EN 15189 is being used, particularly by some National Accreditation Bodies (NABs), who are members of the European Co-operation for Accreditation (EA), in their assessment of medical laboratories.

By way of background it is helpful to understand that the EC4 is a grouping of Clinical Chemists and other laboratory professionals with membership from all countries in the European Community. Among the working groups of EC4 are groups which participate in the development of international and regional standards (ISO/CEN Working Group, chaired by Des Kenny, Ireland) and accreditation systems (Accreditation Working Group, chaired by Wim Huisman, The Netherlands). Members of these groups have a distinguished record of contributing to the development of Standards<sup>1</sup> and to the development of accreditation systems particularly in the UK, The Netherlands and Italy. The EC4 through its membership of the EA working group on Medical Laboratories has promoted the acceptance of ISO EN 15189 and has encouraged members to participate in the development of accreditation as a means of ensuring quality and competence in medical laboratories. In countries such as the UK and The Netherlands, individual members have supported partnership between the professionally led accreditation bodies, (CPA(UK)Ltd and CCKLTest), and the corresponding NABs, (UKAS and RvA), and recently encouraged members to be involved in their country's NABs rather than develop separate professionally led accreditation bodies.

For a considerable period there was strong resistance in EA to the use of ISO EN 15189 as the International Standard of choice for assessment of medical laboratories with a strong feeling that ISO/IEC 17025 was a suitable standard for application to any type of laboratory. The view of EC4 is that it is from this background that our current problems arise. Many NABs in Europe that use ISO CEN 15189 as the basis for assessment of Medical Laboratories, apply it as if they were applying ISO/CEN 17025 without an understanding that medical laboratories are fundamentally different in many respects from laboratories involved in conformity assessment. ISO CEN 15189, which was written by medical laboratory professionals, sets out the requirements for quality and competence that have to be met in order to provide a medical laboratory service. This service is far wider in scope and implication than the performance of individual tests (examinations) and encompasses pre examination and post examination phases. These include clinical advice to the doctors on the choice of tests and investigation strategy, patient preparation, appropriateness of tests, information for patients, followed by the clinical interpretation of test results in individual patients and advice on management of the patient and provision of information (as well as data). Medical laboratories in underpinning the diagnosis, treatment and monitoring of disease provide a crucial essential component of modern healthcare.

The centre of EC4's concern is the way in which the scope of an assessment is being defined by many accreditation bodies in Europe. Laboratories are being accredited for a limited number of tests or examinations from their repertoire rather than for the service they provide. This means, for example, that instead of a biochemistry service being accredited, only certain tests in the repertoire are being accredited and others, equally important for patient care, are not being accredited. There are three separate concerns that arise from this situation, firstly that it is contrary to the intent of ISO EN 15189 that it is used in this

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manner, secondly, that already hard pressed laboratory professionals will not be prepared to continue to participate as technical assessors in these circumstances and thirdly, it will bring the accreditation process into disrepute. This disrepute will stem from the public's perception that an 'accreditation certificate' means that the laboratory service is accredited whereas in fact only certain tests are being accredited. In many countries, such as the UK, that has a proud record of voluntary participation in accreditation, it is clearly understood by the laboratory professionals involved and by Government that accreditation means and is accreditation of a medical laboratory service.

EC4 through its participation in the EA Medical Laboratory Working Group, since its inception, has sought to achieve better understanding of these issues and it is only because of its continuing concern that ISO EN 15189 is not be applied correctly that has caused it to bring the issues to the attention of ISO/TC 212, CEN/TC 140 and ILAC in the hope that resolution can be achieved in the interests of all parties. EC4 believes that the proper application of ISO EN 15189 by NABs is of paramount importance to laboratory professionals and the patients we serve. This can only be achieved in partnership and through constructive dialogue and it is this that we invite through this statement.

*Signed*

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- [1] <sup>1</sup> JANSEN, R.T.P., BLATON, V., BURNETT, D., HUISMAN, W., QUERALTO, J.M., ZÉRAH, S. and ALLMAN, B., European Communities Confederation of Clinical Chemistry, Essential criteria for quality systems of medical laboratories, *European Journal of Clinical Chemistry and Clinical Biochemistry*; **35**: 121-132, 1997
- [2] JANSEN, R.T.P., BLATON, V., BURNETT, D., HUISMAN, W., QUERALTO, J.M., ZÉRAH, S. and ALLMAN, B., European Communities Confederation of Clinical Chemistry, Additional essential criteria for quality systems of medical laboratories, *Clinical Chemistry and Laboratory Medicine*; **36**: 249-252, 1998