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STANDARD

I.S. EN 14136:2004

ICS 11.100

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USE OF EXTERNAL QUALITY ASSESSMENT SCHEMES IN THE ASSESSMENT OF THE PERFORMANCE OF IN VITRO DIAGNOSTIC EXAMINATION PROCEDURES

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EUROPEAN STANDARD

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EN 14136

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English version

Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures

Utilisation des programmes d'évaluation externe de la qualité dans l'évaluation de la performance des procédures de diagnostic in vitro

Verwendung externer Qualitätssicherungsprogramme bei der Bewertung der Durchführung von Untersuchungsverfahren in der In-vitro-Diagnostik

This European Standard was approved by CEN on 2 March 2004.

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Foreword

This document (EN 14136:2004) has been prepared by Technical Committee CEN/TC 140 “In vitro diagnostic medical devices”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2004, and conflicting national standards shall be withdrawn at the latest by November 2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

This document includes a Bibliography.

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Introduction

External quality assessment schemes (EQAS) are an essential feature of mechanisms designed to maintain and improve the analytical quality and medical appropriateness of clinical laboratory data. EQAS are most highly developed in fields in which mostly quantitative, numerical data are generated; notably in clinical chemistry, haematology, immunology, etc. However, EQAS can also be extended to qualitative or more subjective investigations such as in microbiology and parasitology, as well as in histo- or cytopathology.

Participation and acceptable performance in EQAS serve a valuable function in raising standards in laboratory medicine and in educating providers and users about the potential benefits and limitations of laboratory examinations. Objective data provided by EQAS are an essential component of efforts to relate the current state of the art of laboratory performance to medical needs.

EQAS are already essential parts of laboratory accreditation systems, whether mandatory or not, in member states of the European Union. Good clinical laboratory practice includes both external quality assessment and internal quality control as complementary components of quality assurance.

In addition to the major objectives of EQAS (see ISO/IEC Guide 43-1), data from EQAS can also provide a valuable resource in enabling comparisons to be made between alternative new or established analytical procedures (including in vitro diagnostic medical devices hereafter called IVD MDs), or in demonstrating the transferability of procedures between laboratories, or in disclosing difficulties or deficiencies in their operation that can only become apparent during long-term and widespread use. An EQAS in which the survey samples have reference procedure values can provide evidence of the trueness of results obtained by using different procedures; an EQAS in which the same survey samples are circulated repeatedly and frequently can demonstrate reproducibility and, e. g., the possible effects of changes in the properties of an IVD MD.

The major objectives of individual EQAS differ, ranging from those that are directed principally towards ensuring compliance with specific proficiency targets, to those that are aimed at a general survey and improvement of particular services: e. g., in developing a network of participation, or in establishing criteria for evaluating performance of more subjective investigations. Thus, details of schemes such as organisation (e.g., by regulatory authorities, professional societies or industrial concerns), nature and frequency of sample distribution, and assessment of results, differ from one scheme to another.

Because of the differing functions and objectives of EQAS, it is neither possible nor desirable to impose a single pattern of organisation on all such schemes, and this European Standard does not intend to do so. The general principles for the design and the operation of EQAS are outlined in ISO/IEC Guide 43-1 and include:

— use of appropriate survey samples;

— effective distribution to participants (e. g. laboratories and/or point-of-care testing sites);

— rapid processing of survey data ;

— return to participants of reports that are clearly interpreted with respect to stated criteria;

— mechanisms for follow-up of unsatisfactory performance (e.g. through advice services).

In order to enable EQAS to provide data that are useful in monitoring the analytical performance of specific procedures (including IVD MDs), additional features are used. For example, EQAS should unequivocally identify individual procedures (devices) used in statistically significant numbers, and above all, they should be able to distinguish performance characteristics inherent in a particular procedure (device) from those attributable to its users.

This European Standard specifies ways in which EQAS can meet these procedure (device)-related criteria. Thus, EQAS is able to contribute to the post-marketing monitoring of IVD MDs as mentioned in Directive 98/79/EC on in vitro diagnostic medical devices to the benefit of both their manufacturers and users.

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1 Scope

This European Standard applies to external quality assessment schemes, hereafter called EQAS, that include in their functions the assessment and evaluation of the performance of specified in vitro diagnostic procedures (including in vitro diagnostic medical devices, hereafter called IVD MDs). It sets out the requirements that are necessary to enable EQAS to fulfil this function relating to:

— scheme design and organisation;

— identification of procedures (IVD MDs) used by the participant;

— classification and evaluation of data.

NOTE External quality assessment data generated according to these criteria will help manufacturers, users or competent authorities to monitor independently the post-marketing performance of IVD MDs.

This European Standard does not specify ways in which EQAS themselves are organised, nor how the individual or collective performance of clinical laboratories is evaluated.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 375:2001, *Information supplied by the manufacturer with in vitro diagnostic reagents for professional use.*

EN 12286:1998, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Presentation of reference measurement procedures.*

EN 45003:1995, *Calibration and testing laboratory accreditation system — General requirements for operation and recognition.*

EN ISO 15195*, Laboratory medicine - Requirements for reference measurement laboratories (ISO/FDIS 15195:2003).*

EN ISO 17511, *In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003).*

EN ISO 18153, *In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials (ISO 18153:2003).*

ISO 3534-1:1993, *Statistics — Vocabulary and symbols — Part 1: Probability and general statistical terms.*

International Vocabulary of Basic and General Terms in Metrology (VIM), 2nd edition, Geneva: ISO, 1993

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 375:2001, EN 12286:1998, EN ISO 17511:2003, EN 45003:1995, ISO 3534-1:1993, the International Vocabulary of Basic and General Terms in Metrology (VIM) and the following apply.

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