SLOVENSKI STANDARD
SIST EN 14136:2004

01-november-2004

Uporaba shem zunanje ocene kakovosti za oceno delovanja postopkov diagnostiļ nih preiskav in vitro

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

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

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

Ta slovenski standard je istoveten z: **EN 14136:2004**

ICS:

11.100.10	Diagnostiļ ni preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN 14136:2004 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14136

May 2004

ICS 11.100

English version

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 14136:2004: E

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of an identical text or by endorsement, at the latest by November 2004, and conflicting national standards shall be withdrawn at the latest by November 2004.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.

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.

3.1
assigned value
value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose [ISO/IEC Guide 43-1:1997]

3.2
external quality assessment
EQA
determination of individual and collective laboratory performance, and performance characteristics of examination procedures by means of interlaboratory comparison

NOTE The primary objectives of EQA are educational, and can be supported by additional elements.

3.3
nominal scale
scale with a set of possible values, for a given kind-of-property, that are each designated by a word or symbol without any relation to magnitude

EXAMPLE Blood group (A, B, AB, 0)

NOTE The values can be listed in any arbitrary order according to practical considerations and convention.

3.4
ordinal scale
scale with an ordered set of possible values, for properties of a given kind-of-property, that are each designated by a word or symbol used for ranking according to magnitude, but where differences or ratios between values have no arithmetic meaning

EXAMPLES Wording such as "not detected", "weakly positive"," "positive", "strongly positive" or figures such as 0, 1, 2, 3.

3.5
target value
accepted reference value

NOTE Examples of target values are assigned values, reference procedure values, and consensus values.

3.6
reference measurement procedure
thoroughly investigated measurement procedure shown to yield values having an uncertainty of measurement commensurate with its intended use, especially in assessing the trueness of other measurement procedures for the same quantity and in characterizing reference materials [EN 12286:1998, 3.7]

3.7
reference procedure value
value obtained by a reference measurement procedure

3.8
survey sample
sample sent to participants for selected examination, where the result is returned to the EQAS organisation for independent assessment of performance

4 Design requirements for EQAS

4.1 The EQAS organisation shall formulate the objectives of its surveys at its start.

4.2 The EQAS organisation shall provide survey samples composed in such a way that they simulate as closely as possible the relevant properties of the samples on which the examination procedures are intended to be used.

NOTE 1 For assigning target values to survey samples see EN ISO 17511.

NOTE 2 For some evaluations it can be appropriate to use a set of survey samples with different target values.

NOTE 3 The responsibility of the EQAS organisation for providing survey samples with appropriate properties is set out in ISO/IEC Guide 43-1.

NOTE 4 EQAS organisations should not select survey samples containing unphysiological additives which may disadvantage an individual IVD MD.

4.3 The frequency of surveys shall be appropriate for the investigation, and preferably at least 6 times per year. In order to allow evaluation of recent IVD MD performance the survey data shall be available as soon as feasible after return of results.

4.4 In order to assess the performance of a particular IVD MD, the design of the EQAS shall enable a device- or procedure-specific evaluation of results.

NOTE Examination can comprise a combination of IVD MDs, e.g. instrument, reagent and calibration material.

4.5 For each IVD MD supplied by an individual manufacturer, frequency distributions, measures of central tendency (e.g. median) and measures of dispersion (e.g. standard deviation, quantiles) of the participants' results shall be reported when the number of participants is appropriate for statistical evaluation.

NOTE 1 When different IVD MDs, that are intended to examine the same quantity, claim metrological traceability of their calibration to the same reference measurement procedure the central tendencies of their distributions should converge towards the target value obtained by applying the reference measurement procedure to the same samples.

NOTE 2 The EQAS organisation should have, if appropriate, access to laboratories approved according to EN ISO 15195 which can assign reference procedure values with stated uncertainty and metrological traceability.

4.6 The EQAS shall be designed such that the EQAS organisation shall be able to distinguish the performance of the individual participants from the performance of the procedure as it is done in general.

4.7 The choice of the technique employed for assigning values to the survey samples shall be appropriate for the intended investigation.

NOTE 1 Examples of assigned values are:

— reference procedure value,

— value derived from known composition,

— procedure-dependent or -independent consensus value.

NOTE 2 It is preferable to use assigned values with defined uncertainties.

4.8 When values are assigned by an internationally accepted reference measurement procedure the requirements of EN 12286, EN ISO 15195 and EN ISO 17511 shall be followed.

4.9 The EQAS organisation shall document how assigned values have been determined.

5 Requirements for organisations conducting EQAS

5.1 An EQAS shall be conducted by a competent organisation established in the field of medical laboratory examinations.

5.2 The EQAS organisation shall have an independent medical and scientific advisory committee.

5.3 The EQAS organisation shall be free from any commercial, financial or other conflicting interests - whether internal or external - which might influence its independent judgement or adversely affect the quality of work.

NOTE National authorities can state additional requirements for the qualification of the EQAS organisation.

5.4 The EQAS shall be organised in such a way that all parties involved maintain confidence in its independent judgement at all times.

5.5 The EQAS organisation shall establish and maintain a quality management system.

NOTE 1 ISO/IEC Guide 43-1 and ILAC–G13:2000 give examples for a quality management system.

NOTE 2 The organisation should be accredited by a national or European accreditation body and/or acknowledged by a national authority.

6 Assessment of analytical examination procedures

6.1 General

6.1.1 The nature of the survey samples and the assigned values, where applicable, shall be appropriate to the objectives of the particular EQA round and to the IVD MDs assessed.

6.1.2 Results shall be reported for each individual in vitro diagnostic examination procedure and assessed according to the claims made for the procedure.

6.1.3 If a value assigned to a survey sample is claimed to be traceable to a specified metrological level the requirements of EN ISO 17511 and EN ISO 18153 shall apply.

6.1.4 Data from an EQA survey shall be assessed by applying statistical techniques, appropriate for the type of property examined. The statistical technique(s), including outlier identification procedures, shall be described by the EQA organisation and made available to the participants of the scheme.

NOTE 1 See also ISO/IEC Guide 43-1.

NOTE 2 Performance assessment which is based on data from more than one sample as well as more than one user should be more reliable, and is recommended. The number of samples and/or frequency of surveys will depend on the EQAS design.

NOTE 3 See also ISO/DIS 13528.

6.1.5 The results obtained by EQAS shall be interpreted according to criteria for acceptable performance, and in relation to the claims of the manufacturer for that IVD MD.

NOTE 1 Criteria for acceptable performance should reflect the medical use (e.g. based on biological variation or other means) and the "state-of-the-art" of the quality of the IVD MDs. In some countries national legislation, rules or guidelines provide such criteria. EQA organisers, at a national or regional level, should seek consensus on the criteria applied, taking into account 6.1.4.

NOTE 2 For quantities which are not traceable to SI units, fitness for purpose, i.e. medical requirements, should be emphasised, while awaiting internationally-agreed consensus-based reference measurement systems. A 95 % centile performance criterion applied on the data of *all* laboratories reporting on the same quantity does not take into account the understanding that each procedure may generate a unique answer. In these cases, a single assigned value for *all* IVD MDs purporting to measure the same substance, is not appropriate. Therefore, a survey report should give results of each procedure separately for the group of laboratories employing that procedure. An unvalidated all-laboratory mean should be avoided for assessment of performance of products measuring these substances. When international consensus has been reached on a reference measurement system for such a substance an assigned value or a reference procedure value can be established.

6.1.6 The EQA organiser shall gather sufficient information linked to the results, for reliable assessment of the results (e.g. kit identification, calibrator, measuring equipment).

6.1.7 Conclusions on the performance of a particular IVD MD shall only be made if obtained when using the operating procedures recommended by the manufacturer (e.g. reagent-calibrator-instrument setting combinations).

NOTE 1 The user should be requested to declare whether the IVD MD was used in accordance with the instructions for use.

NOTE 2 Results from participants who are known or identified not to use the IVD MD in accordance with the manufacturer's instructions should not be included in the performance monitoring of that product.