External Quality Assessment Schemes (EQAS)

Revision May 2001

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EDMA believes that External Quality Assessment Schemes (EQAS) provide an effective and useful **monitor of the analytical performance of clinical laboratories** and as such are to be welcomed and supported. Together with effective laboratory procedures and internal quality control, EQAS contribute to the maintenance and improvement of the quality of clinical laboratory analysis.

The results of EQAS depend on many factors that reflect day to day practice in the clinical laboratory. These include the reagent, the instrument (incl. its maintenance), the user (incl. skill and training) as well the characteristics of the sample material supplied. The consolidated data from EQAS represent the results of a population of laboratories, as determined in the samples submitted.

THE IN VITRO DIAGNOSTICS DIRECTIVE 98/79/EC

The IVD Directive is concerned with the regulation of products and not with the analytical performance of clinical laboratories. Mainly for this reason, EQAS are therefore mentioned only four times in the text of the IVD Directive.

- Recital 9 excludes materials used in EQAS from the Directive
- Recital 29 mentions that information obtained from EQAS is useful for decision-making on the classification of devices.
- Article 11 section 2 mentions that Member States can require EQAS organisers to report incidents as defined in section 1.
- Article 14 section 2(a) also mentions that information from EQAS should receive due consideration in assessment of classification of devices.

In these references EQAS is clearly not considered to be part of the device vigilance procedure

However, information from EQAS is of value to manufacturers as one element in post- production review (Annex III section 5)

In the IVD Directive the analytical performance evaluation of the product[1] is part of the technical documentation that the manufacturer must prepare **before a product is placed on the market**. Such an evaluation should not be confused with the evaluation of the analytical performance of clinical laboratories, which is the aim of EQAS. Thus External Quality Assessment is not a post-marketing tool, but in some cases it may provide useful post-marketing information.

EQAS: PRESENT SITUATION

At present, EQAS (at the national or regional levels - or both) are operated in most member states and used in all states. The basic principles of these schemes are similar, but there are many national and regional differences:

- in the nature of participation (compulsory or voluntary);
- in the organisation and design of the schemes;
- in the extent to which schemes are run (or funded) by health agencies,

[1] CEN TC140 WG1 is developing a standard for this: prEN 13612

scientific societies, individuals or companies;
- in the cost of participation;
- in the criteria against which laboratory results are judged;
- in the follow-up and consequences of unsatisfactory performance of individual laboratories.

There are also differences in the scope of the schemes - the analytes that are assessed and the frequency of assessment. Although most analytes are now included in EQAS, some (which are routinely determined in clinical laboratories) are not included in the schemes of any member state.

EDMA CONCERNS

EDMA is concerned that some of the differences between national or regional EQAS, especially differences in national assessment criteria, may lead to market segmentation and counter the beneficial effects of the Single European Market for IVD products. EDMA is concerned that EQAS may impose, in practice, national or regional technical guidelines blocking the dissemination of new and beneficial technologies, especially when schemes distribute specimens of low commutability (not representative of clinical specimens) that are not appropriate to all routine analytical methods, or if they use comparison values not linked to objective or state-of-the-art criteria of accuracy.

EDMA SUGGESTIONS

EDMA suggests that the possibility of trade barriers arising from EQAS can be minimised by a series of measures:

1. Institutions organising EQAS should have a documented and certified Quality System
2. A European Standard for EQAS should be developed between Professionals, Industry and Health Agencies. This standard should give recommendations for:
   - description, preparation and distribution of EQAS materials with high degree of commutability;
   - statistical models and data reduction;
   - definition criteria to evaluate the performance of participants;
   - support or guidance to be provided to unsatisfactory performers.
   - scientific advisory panels to be provided to scheme Organisers;

   The standard should also define the criteria to establish the values, against which results are compared, and their links to reference measurement procedures and/or certified reference material where appropriate.

3. An extended programme should be set up involving bodies such as BCR, WHO, IFCC, ICSH to define and develop reference measurement procedures and materials, for selected analytes - where the state of technology allows this.

4. Current EQAS should be progressively extended to more analytes.

5. Mechanisms should be developed to ensure regular and effective dialogue between Organisers of EQAS and other interested parties including Industry.

6. EDMA suggests that in most cases existing national or regional schemes should be maintained, aiming however at a harmonisation of the basic approach on a European level.

7. EDMA suggests that European EQAS should be developed for those analytes for which there are insufficient laboratories at the national level to ensure statistical validity.

CONCLUSIONS

In EDMA's view, laboratories and other clinical testing sites should be strongly

encouraged to participate in EQAS. Schemes should be based upon support and education. Performance criteria should be those of a European wide concept which would facilitate the organisation of schemes on a regional basis. This would harmonise the routine practice of EQAS and permit the operation of schemes even across National boundaries. Thus, a laboratory could participate in any scheme following the approach of the proposed harmonised European Standard.

EDMA believes that these proposals will stimulate continuous improvement in the quality of clinical laboratory analysis and in patient care.

Standardisation Working Party
February 1995: revision May 2001