Editorial

1982: A new start for the Journal

Many of you will have noticed in the fourth issue of Volume 3 that the *Journal* has recently been acquired by Taylor & Francis Ltd. This will add the considerable experience of a scientific publisher, founded in 1798 with over 30 journals already in their portfolio, to the active editorial team established by myself and United Trade Press. During its first three years, *Journal of Automatic Chemistry* has grown at a steady rate, both in terms of content and subscription and advertising income. I am grateful to United Trade Press for their support in founding the *Journal*.

Taylor & Francis Ltd, together with the existing Editorial Board, aim to increase the subscription level by introducing the Journal to a wider audience. The content will continue to be vigorously refereed, although the turn round time from receipt of paper to publication will be improved. The size of the Journal and its frequency will also be reviewed over the ensuing year. In order to cater for the real needs of the readership, it is important for you, the reader, to let us know either directly or through members of the Corresponding Editorial Board your views of the Journal. Are there areas that you would like covered, but at present are not being addressed?

What has the Journal achieved?

In its short life, the *Journal* has achieved some success and status—recently in *Nature* (October 1981) Professor T. S. West wrote:

Each issue contains about eight or nine articles, many of them devoted to microprocessors and a smaller number to improvements to commercial automated systems or the construction of miscellaneous ancillary devices to improve their performance. In addition there are useful and informative articles on meetings, new products and literature, and a running calendar of current and forthcoming events. There are also occasional book reviews.

The standard of the papers is usually good, even excellent, and the 'virtual' A4 format allows good use to be made of illustrations. The generally high quality of the articles read in the sample issues suggests that this journal has so far done an excellent job and should be scanned on a regular basis by all who are concerned with automation. It is not possible, since the dates are not given, to establish publication times, but the journal gives the impression of being very much 'on the ball'.

This shows that the aims and objectives the Editorial Board set out to achieve when *Journal of Automatic Chemistry* was launched have been met. However, in such a changing area it is important to keep abreast of the technology. This we will endeavour to do by submitted articles, by evocative and informative commentaries, both from Editorial Board members and from invited specialists, and by review articles. The enthusiasm and experience of our new publisher will be a considerable asset as the *Journal* develops.

Peter B. Stockwell

Commentary

Acceptable performance standards for clinical laboratory methods

Many of the instruments and methods used in clinical laboratories have been selected for somewhat subjective reasons, such as low cost and ease of performance, rather than as a result of objective evaluation of their analytical performance. The usual clinical laboratory quality-control procedures monitor performance characteristics such as imprecision and inaccuracy in order to detect changes in performance, but they cannot improve an analytical instrument or method which is basically unsound [1]. Therefore, an essential part and first step of a *total* laboratory quality-control programme should be the evaluation of analytical instruments or methods before their introduction into the routine diagnostic service laboratory.

New analytical instruments and reagent kits are introduced each year. Evaluation of their performance characteristics is a complex procedure which requires considerable expertise, skilled staff, ample space and time resources, and suitable patient samples and comparative methods. There are many published protocols for evaluation; these have been recently discussed in detail by Westgard [2]. Although no protocol is universally applicable, most protocols proposed in the literature follow a similar pattern. The majority of published evaluations conform, in general experimental design, to this pattern. Therefore, evaluations cannot be performed by *all* potential purchasers and many must rely for guidance on objective reports in the literature, or the experience of professional colleagues.

A major problem with published evaluation protocols is that definitive criteria for acceptability of the performance characteristics are not delineated. Indeed, many evaluations of instruments, reagent kits, and methods document in great detail all aspects of analytical performance, but fail to assess in an objective manner whether the performance found is truly suitable for clinical laboratory use.

It has been stated that one of the major current philosophical problems in clinical biochemistry is the assessment of the standard of analytical performance that is actually required to provide optimal patient care at least expense [3]. Such standards have been termed analytical goals. One of the major difficulties in the setting of such goals is that clinical biochemistry tests are used in many different clinical settings, such as in aiding diagnosis, in screening, in assessment of the efficacy of therapy and in emergency situations. This has led some clinical biochemists to consider the definition of numerical analytical goals to be an insoluble problem; for example, the Expert Panel on Nomenclature and Principles of Quality Control of the International Federation of Clinical Chemistry state that a single set of performance characteristics is unlikely to be applicable to all of the situations in which tests are used [1]. However, analytical goals for a number of performance characteristics have been documented in the literature; this subject has been recently reviewed [4].

Most work has been concerned with the delineation of analytical goals for imprecision; this is considered to be appropriate since analytical imprecision cannot be avoided. Strategies for the derivation of goals for imprecision have been classified as being based on (1) the reference range; (2) biological variation; (3) the views of clinicians; (4) the state of the art; (5) the