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A Draft Code of Practice for Analytical Quality Control in National Rivers Authority Laboratories

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NRA

National Rivers Authority

A DRAFT CODE OF PRACTICE FOR ANALYTICAL QUALITY CONTROL IN NATIONAL RIVERS AUTHORITY LABORATORIES

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Authors: V W Truesdale and M J Gardner

Contract Manager: M J Gardner

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Any enquiries relating to this report should be referred to the author at the following address:

Water Research Centre (1989) plc, Medmenham, Henley Road, Medmenham, PO Box 16, Marlow, Buckinghamshire SL7 2HD. Telephone: Henley (0491) 571531

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SUMMARY

I BACKGROUND

The Water Research Centre has been contracted by the National Rivers Authority (NRA) to produce a Code of Practice for Analytical Quality Control (AQC) for use in its laboratories. The draft Code provided in this report is being circulated for comment and subsequent revision.

II RESUME OF CONTENTS

The draft code of practice deals with the approach to AQC with respect to setting analytical requirements, sample handling, and within- and between-laboratory quality control.

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SECTION 1 - BACKGROUND

The Water Research Centre has been contracted by the National Rivers Authority (NRA) to produce a Code of Practice for Analytical Quality Control (AQC) in its laboratories. The draft Code provided in this report is being circulated for comment and subsequent revision.

SECTION 2 - APPROACH TO DRAFTING THE CODE OF PRACTICE

So much attention has already been devoted to AQC in water laboratories that we felt it was essential, in drafting a Code of Practice, to take into account existing approaches to AQC and to explore the variety of opinions on the likely future development of QC activity. With this in mind, WRc arranged for an independent consultant, Dr V Truesdale, to visit NRA Regions to discuss both current practices and any developments which NRA staff felt would be needed for the future. Dr Truesdale was chosen for the job as an experienced analyst from outside the water industry who was familiar with the technical aspects of water analysis. His brief was to discuss any relevant topic with senior NRA staff and to summarise these discussions as a basis for drafting a Code of Practice. His summary of his visits to NRA Regions is Appendix A of this report.

The draft Code of Practice given below is based on the information obtained by Dr Truesdale, supplemented where necessary to cover what are seen as all the important points relating to AQC.

The draft Code contains two main extensions to what is presently seen as "laboratory AQC". These are:

- i) recommendations concerning the relationship between analytical laboratories and the users of analytical data and
- ii) AQC in sample collection.

The former recommendations arise from the comments of the NRA personnel who were consulted. The aim is to encourage action to increase the

awareness of data users of the issues of analytical accuracy, with respect to both defining appropriate analytical requirements and appreciating the existence and possible importance of analytical errors. The guidance on AQC in sampling is included in order to draw attention to sample collection in the control of data quality. The demonstration of the quality and reliability of sampling is seen as of equal importance to control over the analytical stage in providing data of known accuracy.

SECTION 3 - DRAFT AQC CODE OF PRACTICE

3.1 INTRODUCTION

During the last decade it has become generally understood that the quality of analytical data generated by laboratories may not be adequate unless appropriate attention is given to certain, key factors. This code of practice is designed to ensure that data produced by the laboratories of the newly formed National Rivers Authority (NRA) meet the needs for which they are intended. At the same time the code should help in rationalising, or unifying, the approaches to quality control that are currently in use within the component laboratories of the NRA.

The basic philosophy underlying the code is that analytical data generated by the NRA should be of known quality. Measurements of any kind involve errors, and good practice calls for knowledge of, and (where necessary) control over uncertainty, such that the objectives of making the measurement can be fulfilled. This approach of seeking data of an accuracy appropriate to the task in hand, has two important implications.

Firstly, those designing projects (the data users) need to be clear as to what they consider are the acceptable levels of error for each measurement within their project. They will wish to choose analysis which meets their needs without asking for undue accuracy which, in turn, may incur unnecessary costs.

Secondly, if later the analytical results are used for another purpose, it is essential that knowledge of their quality also accompanies them to avoid their being used inappropriately. A given degree of control over error, which is satisfactory for one application, may not be adequate for another. Also, with the continuing trend of banking data there is an increasing opportunity for misinterpretation when data of differing quality are unknowingly compared. Features identified in mixed data can relate to the errors within the measurements rather than to real phenomena.

3.2 STAFF ISSUES

The senior analysts within the NRA shall meet to establish a system of unified training objectives for the various laboratory staff under their control.

Each analyst will be provided with a personal training log-book which indicates their acceptability for carrying out particular analyses, according to both local and national procedure within the above. For example, lack of any certification by an analyst of appropriate seniority might mean a junior analyst is, as yet, unsuited for a particular analytical task.

3.3 USER ISSUES

3.3.1 Appreciation of AQC

The senior scientist at each NRA laboratory will ensure that NRA Users of the laboratory's data are invited to meetings designed to improve User's appreciation of Analytical Quality Control, and its implication to the user. Such meetings should draw attention to systematic and random errors and possibly include a demonstration determination with accompanying discussion of the sources of error, and the use of control charts. Also, the users should be made aware of the difficulties and costs associated with the development of new methods.

The Senior Scientist will also ensure that seminars similar, in principle, to those mentioned above should be established for sampling staff. In these emphasis should be put on sampling and storage errors, and the need for vigilance in overcoming them.

3.3.2 Arranging analysis

Each NRA laboratory will maintain an up-to-date directory of available methods. For each determinand this should contain estimates of analytical performance, detection limits and an estimate of the frequency that the analysis is currently undertaken in the laboratory.

In collaboration with users each NRA laboratory should design a means of coding analytical data which will act as a guide to its accuracy. This procedure will identify the performance of the analytical system used to produce a given result. It is essential that the code draws attention to any data obtained from an analytical system over which statistical control has not been established.

Users should be asked to disclose and discuss the criteria involved in their definition of their requirements so that agreement between analyst and user, as to which methods are suitable, can be reached. The use of unnecessarily accurate methodology can be expensive; the achievement of insufficient accuracy is likely to jeopardise the project.

Users should be made aware that the sporadic use of an analytical system is likely to contribute to a decrease in the overall accuracy of data produced. Additionally, the effort required to establish and maintain effective AQC is proportionately larger for each sample. Alternative actions, such as using another laboratory which operates the same system, but on a more frequent basis, may be preferable.

Where methods of sufficient accuracy are not readily available it will be necessary to develop existing methods and/or consult other NRA laboratories, and/or abandon the determinations as impracticable.

In planning projects with users analysts will raise the question of sampling errors, emphasising that these are additional to any analytical errors.

3.4 GENERAL LABORATORY PRACTICE

3.4.1 Method instruction sheets

Each analytical method in use in the laboratory will be equipped with a written instruction sheet.

Instruction sheets will be up-dated at required intervals. All earlier versions will be withdrawn into secured storage or disposed of. Each version will be numbered and labelled with the date of issue.

Only a limited number of method instruction sheets, the number appropriate for a particular laboratory to be determined by the senior analyst, will be issued to the laboratory. Copying of instruction sheets is to be discouraged. These measures are required to reduce the chances of re-introducing older methodology which has been superseded.

No new methods, or modifications to existing ones, should be permitted without the authorisation of the Senior Analyst.

3.4.2 Equipment

All analytical equipment will be subject to regular maintenance, according to a scheme devised by each Senior analyst.

All analytical equipment will be subject to appropriate calibration checking, according to a scheme drawn up the the Senior analyst.

Each Senior Analyst will do their utmost to maintain degrees of cleanliness and tidiness within laboratory areas consistent with effective analytical practice.

3.5 ANALYTICAL ISSUES

3.5.1 Sampling, storage and transportation of samples

Although much quality control activity has been directed towards the assessment of errors arising during analysis, the evaluation and control of errors occurring during sampling is, by comparison, not so advanced. The situation can be complicated because this area of activity can fall between the responsibilities of users, samplers and the analyst. For the purposes of this CODE OF PRACTICE the user (eg project manager) is assumed to take responsibility for the design of the sampling programme, covering such factors as location and frequency of sampling. It is the analyst's responsibility to ensure quality control over sample collection, transportation and storage. This involves three areas:

- i) Adoption of sampling methods and sampling equipment which are recognised to be appropriate. All sampling staff should be provided with written protocols giving detailed instructions of how samples should be collected. The location of sampling sites should also be documented.
- ii) Initial testing of the chosen approach to sampling to confirm its suitability. This should include tests to examine
 - a) contamination during sampling or sample transport (for example, by the sampling equipment or containers) and
 - b) any losses or gains of determinand, or other important changes in the sample in the interval between sample collection and analysis.
- iii) Routine checks on sample collection and transport. These demonstrate the day to day efficacy of sampling. The exact approach is best decided on a case by case basis; the following recommendations are given as a guide to what should be required:

- a) Where it is recognised to be important, 'field blank' samples (ideally, real samples containing no determinand) should be taken into the field and treated as 'real' samples with respect to contact with sampling devices, filtration, preserving reagents, transport, storage, etc. These field blanks should be analysed with their corresponding 'real' samples, as members of the same batch. Whenever it is considered that sample contamination might be an important source of error (eg with trace metals, organics) field blanks should constitute a significant proportion (at least 5%) of all samples analysed.
- b) As a check on the possible loss of unstable determinands, and on the effectiveness of sample preservation, field control samples (field blanks spiked at the time of sampling) should also be collected.
- iv) A written programme for routine quality control of sampling, with protocols for sampling staff, must be produced if the approach is to be effective.

3.5.2 Introduction and maintenance of methods

Only properly tested methods will enter routine use in NRA laboratories.

New methods will be drawn from reliable sources, eg SCA Blue books, journals etc as judged by designated officers of appropriate seniority.

Before a method is used routinely it will have been evaluated for the following characteristics:

- a. Concentration range
- b. Calibration; sensitivity and linearity
- c. Precision of analysis over its range
- d. Spiking recovery on real samples
- e. Satisfactory 'blank' determination
- f. Interferences

New or modified methods, as sanctioned by the appropriate designated officer (see above), will be rigorously validated for AQC on 5-10 batch period before being used for routine operational work. The tests carried out during this 'running in' period will be used to set the Performance limits (warning and action limits) for succeeding analysis, as well as the precision limits for use by users.

Where substantial changes are made to an analytical system it will be necessary to re-establish its performance characteristics.

After establishing their performance characteristics, analytical systems can be put into routine use. The Shewart chart and associated statistics rely upon control measurements being made on each batch. Although a minimum frequency for analysis is not prescribed, care must be taken that the frequency of use is not so low that, essentially, a new analytical system is used on each occasion.

The Senior analyst at each NRA laboratory will take all reasonable steps to ensure that his staff understand that there is nothing to substitute for the establishment of statistical control over the methods in use in the laboratory.

Wherever possible Shewart or Cusum charts, or their derivatives, will be used to monitor analytical quality for each analytical system in the laboratory. These charts may be computer generated or hand drawn. In each case it is essential that the analyst is able to inspect them.

Analysts will choose the optimum control chart for each given method. The nature of each analytical procedure should be examined to determine which type, or types, of error are most likely to occur and which it is most desirable to detect. For example, if, as is often the case, matrix interferences or poor recoveries are likely, a chart of spiking recovery may be the best choice. Alternatively, if calibration problems are the most likely source of systematic error, a control chart involving analyses of an independent standard solution (see below) would provide a check on long term precision (provided precision for samples and standards is not materially different) and bias.

Standard solutions for use in generating the Shevart or Cusum charts (AQC standards) will be drawn from a different primary source than the ordinary 'calibration standards' used for each method.

It is recommended that AQC standards will be prepared by someone other than the person carrying out the routine analysis.

The glass-ware and associated diluting equipment used for preparation of AQC standards will be different from that used for calibration standards.

3.5.3 Warning and action for AQC failure

The senior analyst is responsible for setting up a laboratory information system that identifies any method that has ceased to remain 'in control' during use. It is preferable that such systems are automatic, for example by being triggered by introduction of inadequate AQC data to a computer data file.

The senior analyst is responsible for introducing and policing a formal system of graded actions, for use when methods become 'out of control'. So, for example, a junior analyst receives as an instruction, the need to inform an identified person of requisite seniority, both verbally and in writing on a standardised form, when he or she first becomes acquainted with an AQC problem. In contrast, a more senior staff member might be allowed greater freedom of action to sort out the problem, although they would still have their action prescribed.

It is desirable that the Senior Analyst should arrange for his staff to have restricted access to AQC data banks. Thus, only senior personnel should be able to correct or change AQC data which the information systems designates problematic.

Each NRA laboratory should operate a formal system for reporting and recording the actions taken, and reasons for breakdown of control on any method.

When an analytical system ceases to be 'in control' the results from that batch will not be reported; the samples will be re-analysed only after control has been re-established. The record of failure will, however, be logged and retained for longer term surveillance of the system's behaviour.

3.6 INTER-LABORATORY CHECKS

It is recommended that NRA should establish an interlaboratory calibration group to ensure that the NRA laboratories are not only adequately 'cross-linked', but also bracketed into other laboratory systems both within and outside the UK. Inter-laboratory calibration represents one of the most effective tools for demonstrating the accuracy of results and all possible must be done to make effective use of it.

The Interlaboratory calibration group should consider (and review) the following points:

- a. The numbers of laboratories which should participate in interlaboratory tests.
- b. The determinands to be addressed, the required accuracy and range of concentrations of interest.
- c. The frequency of checks for each determinand.
- e. The various sample matrices to be covered.
- f. The action to be taken in response to the check sample results.
- g. The minimum time between analysis of check samples, and any consequent remedial action.
- h. The confidentiality of results.

Note

As part of another contract with the NRA WRC has been asked to make proposals for a check sample service (separate from but along similar lines to the AQUACHECK Scheme for drinking water analysis) which would meet the needs of the NRA.

APPENDIX A

SUMMARY OF CONSULTATIONS WITH NRA STAFF ON CURRENT AQC PRACTICE IN NRA LABORATORIES - V W TRUESDALE

SECTION A1 - INTRODUCTION

This report describes the results of consultations with staff of the newly formed NRA (National Rivers Authority) laboratories on the subject of AQC (Analytical Quality Control).

The staff and laboratories visited (in chronological order) were:

Mr Ian Fox	Thames, Reading
Mr Mike Jessup	Anglia, Peterborough
Mr Keith Foster	Severn Trent, Nottingham
Mr Geoff Firth	Yorkshire, Leeds
Mr John Mitchell	Northumbrian, Newcastle*
Mr Steve Smith	North West, Warrington*
Mr Ron West	Welsh, Llanelli
Mr John Hendry	Southern, Worthing
Mr David Palmer	Wessex, Bridgewater**
Mr Chris Triner	South West, Exeter**

* Seen together at Warrington ** Seen together at Bridgewater

At the time of visiting laboratories were operating at Peterborough, Nottingham, Warrington and Llanelli. The Warrington laboratory was to move to new premises. The Leeds laboratory was being re-furbished. It will be commissioned in the Autumn. Laboratories are planned for the remaining NRA regions at Reading, Newcastle, Worthing and Bridgewater. The latter will serve both Wessex and South West regions.

At each venue the meeting started with my outlining the nature of this project, its relationship to WRc and NRA and the likely outcomes.

Through the use of 'open questions' the staff were then encouraged to speak about AQC in the way that suited them best. This enabled me to understand basic attitudes to AQC, and minimised the extent to which I could impose my own view or assumptions upon the conversation. Although different starting points were chosen by different people the conversations were, nevertheless, very similar in content. Typically, the topics covered were, staffing structure, general approach to AQC, Interlaboratory calibration, Control charts, background development (from Water Authority to NRA), Contracting-back, NAMAS, TR 66, Training profiles for lab staff, tours of laboratories.

SECTION A2 - RESULTS

A2.1 CURRENT THINKING

Although there are some differences of details between the ways the different laboratories work I was impressed with the degree of concurrence on this important subject to AQC. The statement made by several of the staff, that AQC is an all-pervading philosophy rather than something to be tagged upon the end (of analytical work), seems to sum up current thinking at the laboratories. These analysts have all experienced the changes in approach to AQC that have swept the water industry over the last 1-2 decades, and all are convinced of its own value. Most, if not all, mentioned the work of Cheeseman and Wilson. Indeed, many remarked that it was sad that neither of those scientists is alive to see the benefits of their earlier interventions.

Several of the staff recalled that AQC was not welcomed at its inception. It seemed to many in those days that so much attention given to AQC was simply time switched from the 'real' job of 'getting results out'. In contrast, AQC is now seen as relating to EVERYTHING one does in the laboratory, as well as to specific measures to keep analysis 'in control'; hence the 'philosophy' label.

Overall then, as a national body, the NRA is staffed by senior analysts who, because they have been drawn from such similar backgrounds are very

like-minded about AQC. Each of the earlier Water Authorities may have approached AQC somewhat differently, but the main point is that by the time NRA was formed AQC was firmly established as a central issue in laboratory work. Such homogeneity of practice bodes well for cohesive practice within the NRA, at least within its chemical work.

A2.2 NAMAS

The desire/need for NAMAS (National Measurement Accreditation Service) accreditation at each of the laboratories offers another measure of the status of AQC in NRA labs. Some laboratories have been accredited for some time, some are almost accredited, but all are seeking accreditation. The prevalent view seems to be that accreditation to NAMAS will provide an external reference point which will be respected by the public. Given that NRA work will be used in court, and sometimes up against NAMAS accredited PLC labs, the staff are keen to have their reliability justified by an external body.

The general perception within the group consulted seems to be that NAMAS accreditation is 'automatically' a good thing. Only one person expressed serious reservations as to the need for it within the NRA. Even so, most on the group volunteered the somewhat contradictory statement that NAMAS, itself, is (or has been) learning its way into designing suitable systems for use in chemical labs; originally NAMAS was 'physics based' and has had to adapt to chemistry. Overall I found these perceptions most interesting, and was left wondering, from time to time, whether the NRA groups might not be well ahead in Quality Assurance but had not appreciated it! Given a deep desire for high standards of AQC, as I believe these people have, and an inherent belief that NAMAS is ahead in the field, it would be all too easy for them to project their own expertise onto NAMAS! Such a trend would be reinforced by the considerable amount of work that seems to be involved in 'transposing' to the NAMAS system. Notwithstanding these thoughts I conclude that the combination of NRA and NAMAS experience must lead to better, rigorous and more visible AQC. Ultimately, then, the really important factor seems to be cost, and it remains a moot point as to whether NRA could not set up its own NAMAS-like monitoring systems,

particularly if the public credibility dimension can be covered by some other means. Most of the labs desired an injection of cash from NRA HQ to cover the not insignificant expenses of introducing the AQC required by NAMAS.

A2.3 AQC AND THE USERS

The major intent behind AQC is that analytical results will be of known quality. Emphasis is put on 'known' particularly because in some cases the quality will not be the best that can be obtained; especially where analysis is expensive one needs to choose an appropriate quality to suit ones objectives, both immediate and longer term. Some determinands can be analysed very precisely and accurately, but others much less so. Also, the same determinand can have a very different error attached to it depending upon the analytical method used. So, for example, some figures are good to within a few percent of the stated value while others to within only plus or minus 50% (or even wider limits) of the stated value.

Obviously users of data should be aware of this spread of possible error. Discussion with the scientists suggests, however, that with certain exceptions users have a patchy understanding of errors; they perceive analysis to be an 'exact' business. Most, including many scientific staff, simply adopt the stated figure and take it for granted. It seemed to be agreed that to always accompany each data with its corresponding error was an unnecessary complication, especially where the general public is concerned. At best it would increase the length and complexity of discussions unreasonably, and at worst it would provoke incredulity amongst the many who have no appreciation of the role of chance in science.

Notwithstanding the above comments there does seem to be room for improving the operation and professionalism of the NRA by training users in error appreciation. NRA users should be supplied with likely error estimates. This would not only eliminate the possibility of a number of embarrassing encounters, possibly in the court-room, but it would increase the likelihood of users obtaining the analysis they actually

require. Thus, an accompanying factor is that, in general, users' judgements as to what analyses are required in a satisfactory survey are usually at variance with what the analysts finally recommend. One particularly vivid example concerns the situation where two analytical methods are available, the one expensive, precise and accurate, the other less so on all three counts. Apparently, users will always go for the former even when rationally the latter is adequate for their purposes! While the scientists addressed in this survey saw themselves as only too pleased to help users, they nevertheless found the lack of error appreciation among users to be an impediment to effective communication.

The problem of archiving data was also identified as a potential problem by most of the staff visited. Data-banking can give the impression that all the components have the same error spread, when in fact, they can be of radically different reliabilities.

A2.4 INTER-LABORATORY CALIBRATION

All of the laboratories visited have participated in inter-lab calibrations (ilc's) and appreciate their value. As part of the earlier Water Authority system some had set up elaborate ilc's involving their several component bodies. At the same time most, if not all, the labs have participated in Aquacheck- the system run by WRc. Interest seems to be growing in Graham Topping's DAFS initiative over AQA in marine monitoring. Some labs also stated that they had been involved, albeit sporadically, with the ICES intercomparison exercises.

The scientists were clear that from both the national and the local perspective of NRA there is a requirement for intercomparison between the NRA labs. So the question is really how and where this should be done, not whether it should be done. Most favoured an extension of Aquacheck to accommodate their special needs. Firstly, a number wanted a faster turn-round of the results so that action could be taken to trace any problems sooner than is currently possible. If results return too long after the analysis it is difficult to trace problems - you therefore know that a given method has gone awry, but you are left not

knowing how. An ilc frequency of one per fortnight was suggested. Secondly, many wanted Aquacheck samples to mimic more closely the concentrations of determinand usually encountered by their lab. Apart from offering tighter control on their own work this would offer two advantages. Firstly, it would allow ilc samples to be treated as routinely as possible, thereby checking the routine method and not the skill of the AQC department! Also it would help to minimise the 'political' dimension that some of the more senior members of departments can introduce when they interpret the exercise as a competition between labs rather than simply a quality safety-mechanism. The scientists judge it unfair to have to suffer failure for 'trivial' reasons which relate to situations outside their normal working range. Opinion as to whether results should be anonymous was divided.

A2.5 DOCUMENTED METHODOLOGY

All the labs recognise the problems that can result from 'corruption' of analytical methods, and the consequent need for limited distribution of copies of officially up-dated method-sheets. All the labs introduce methods direct from the Blue Books or from their senior analytical staff, after initial testing of their operational characteristics.

A2.6 CONTROL CHARTS

The Shewart control chart is currently in greatest use in the NRA. Some laboratories use manual versions, some use the mathematics but not the charts ie 'loss of control' is automatically signalled to the AQC section in the computer read-out, others produce their charts via the computer. Nevertheless, the aim generally is to have computer generated charts since the operator is more involved. Within the more computerised labs it is possible to arrange for AQC standards to vary randomly within a stated range, yet for the 'corrected' value to be displayed on the control chart. This offers yet one more way around the operator sub-consciously 'getting the right answer'.

A2.7 THE MORE DIFFICULT AREAS FOR AQC

There does seem to be anxiety over the determinations which for one reason or another, do not lend themselves easily to rigorous AQC. For example, with some 'organics' determinations the time for analysis is so great that AQC standards effectively compete for resources against real samples. Under these circumstances a compromise has to be made, and its making seems to generate anxiety.

The solution seems to lie in two interacting areas; firstly within the idea of results being of a known quality secondly, within the 'contract' that the analyst sets up with the user, particularly in respect to throughput and accuracy.

Firstly it has to be accepted that reducing AQC from the rigor commensurate with TR 66 means that less is known about the quality. In the extreme, as stated TR 66's quotation from Eisenhart, "until a measurement operation has attained a state of statistical control, it cannot be regarded in any logical sense as measuring anything at all." Accordingly, there is a need to be very determined about retaining AQC even when it seems to sap up substantial parts of the analytical time!

When a determination is lengthy or difficult it is important that the difficulties are made plain to the user so that the consequences are built into the original plan of work. Ideally, it would be the user who stated the limits for error, but as has been suggested the arrangement in operation tends to be the reverse. Consequently, it is even more important for the user to be compelled to appreciate what s/he is requesting when asking for these types of analyses in the first place. Given the opinions expressed about Users' lack of appreciation of errors it is imperative that the analyst assert his/her need to spend time and resources on obtaining the required knowledge about the quality of the out-put. This could involve lengthy method development. In the recent trend toward accountability which has swept Britain's industry, and indeed Society, the user is given fuller knowledge of the costs so that s/he can decide whether there are alternative means by which the

required results can be obtained. This seems a satisfactory approach to adopt with analysis, as TR 66 also suggests.

SECTION A3 - CONCLUSION

Within the newly formed NRA laboratories the Senior analytical staff are convinced of the arguments and methodology of AQC presented in the Manual of Cheeseman and Wilson. Therefore, only small refinements of procedure are necessary to unite the laboratories into a highly professional unit.

By far the greatest gains to be made with respect of AQC seem to reside within the arrangements that are made between user and analyst when work is originally planned. In essence, users need to take more responsibility for setting the levels of accuracy they require.