QUALITY MANAGEMENT IN SOIL AND PLANT ANALYTICAL LABORATORIES

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ABSTRACT

Quality management in analytical laboratories, irrespective of the discipline, is considered a matter of course. However, many laboratories find it very difficult to effectively and systematically implement the necessary procedures of quality assurance, and implementation leaves much to be desired in many places. Particularly, laboratories with marginal budgets, or smaller research laboratories working without much competition, often do not have the necessary resources and incentives to engage in a comprehensive effort as done by laboratories seeking accreditation. Proper training and refresher courses may be neglected or, all too often, properly trained staff resign to take up a better position elsewhere. Much neglected aspects of laboratory work also include keeping of full, systematic records and drafting and implementation of proper operating procedures and protocols.

To assist soil and plant laboratories with the mentioned constraints, ISRIC, with the support of FAO, developed practical guidelines for effective quality management: *Guidelines for Quality Management in Soil and Plant Laboratories* (FAO Soils Bull. 74, 1998). Emphasis was placed on achieving an improvement of performance by adopting a limited number of relatively simple rules and inexpensive measures based on the principles of Good Laboratory Practice. The many examples and model documents included in these guidelines should facilitate the adaptation and adoption of specific procedures and documents.

INTRODUCTION

Analytical data produced by different soil and plant laboratories appear to show an often distressingly large variability. Soil parameters are, amongst others, used for soil classification and correlation, land evaluation, soil quality, fertility, and pollution assessment. Erroneous data may lead to very costly mistakes by administrators and other authorities and also hamper technology transfer. In an attempt to reduce the observed variability, laboratory cross-checking programmes conducted in the recent past, notably ISRIC's Laboratory Methods and Data Exchange Programme *(LABEX),* have indicated that this phenomenon can, amongst others, to a large extent be attributed to essentially two causes:

1. High inaccuracy (bias) through lack of standardization of analytical procedures.
2. High imprecision (scattering) caused by lack of within-laboratory consistency.

Efforts to standardize soil analytical procedures on an international level are at present being undertaken by working groups of ISO (International Standardization Organization, Technical Committee 190). The solution of within-laboratory problems has been left to the initiatives of individual institutes. Therefore, particularly commercial laboratories whose success is directly related to the quality of their product, often have a lead here.

It is generally accepted that the quality of the output of laboratories strongly depends on the quality of the organization of the work, not only at the level of execution of the analysis but also at management level ('good tree, good fruits'). To achieve optimal performance, the concept of *"Good Laboratory Practice"* (GLP) was developed and has been practised now for quite some time by a number of categories of laboratories where the quality of the work is of vital importance, e.g. in the fields of food, medicine, toxicology, pollution, etc.

Implementation of GLP in soil and plant analytical laboratories in a consequent manner has not been done on a large scale yet, particularly not in developing countries, but it seems to be the only way to significantly and structurally improve the laboratory performance.

It is somewhat unfortunate and confusing that GLP as a descriptive general term is in fact, by origin, a rather strict set of regulations for test laboratories. Of late, the wider term *"Quality Management"* has come into fashion.

In many countries governments are introducing the rule that orders for environmental and ecological analyses should only be given to laboratories that are accredited for this type of work. For accreditation, consequent Quality Management is an essential aspect. Accreditation is a ponderous and expensive major undertaking often involving the hiring of specialist consultants and the employment of (extra) personnel trained in laboratory organization and quality assurance. Yet, even if accreditation is not a prime objective, then still a tremendous improvement of the lab performance can be achieved by implementation of a number of basic rules in a simple way at relatively little cost. The objective of the recently published *Guidelines for Quality Management in Soil and Plant Laboratories* (FAO Soils Bull. 74) is to

introduce a number of basic measures in the laboratory which do not necessarily require asubstantial input of capital but may involve a change in attitude and practice of all laboratory personnel. On the other hand, where costs are involved the justification can perhaps be found in an analogy with advertising: 'advertising is expensive, not advertising is more expensive'.

A good many of protocols and instructions are usually already in practice in one way or the other. Therefore, making an inventory of existing documents should always be a first step. In many cases, however, these concern half-way measures, not properly written up (or filed somewhere and never seen) and the interpretation of which varies from person to person and from time to time. In many cases, notes and calculations are made on odd pieces of paper which happen to lie around. Rejected analytical results or readings are thrown away and malfunctioning apparatus is left to colleagues without notification. Good Laboratory Practice tries to avoid these engrained habits by consequent documentation of all relevant actions ('what isn't written, isn't done'). Cynics sometimes tauntingly refer to GLP as 'Generates Lots of Paper'. Obviously, documentation can be overdone and then it may be counterproductive. In the present *Guidelines,* too much documentation is consciously avoided. A workable approach is preferred to a fully elaborated procedure involving a drastic change in prevailing practice which may cause evading tactics or an attitude of rejection. Stricter or more comprehensive measures can always be implemented later when the need arises.

A step-by-step approach should in any case be practised with the implementation of all new Quality Management rules and measures. There is a limit to what personnel and a laboratory as a whole can handle, absorb or digest in a limited span of time with a certain budget.

Success depends on the fulfilment of three major preconditions:

1. The directorate of the institute supports (or rather demands) the improvement.
2. The necessary means and time are made available.
3. Participation of all personnel who should be made aware and be involved from the outset.

The first two items are the responsibility of the management of the institute, the third is mainly (but not only) the concern of the laboratory staff. The third condition underscores once again the importance of the cooperation, participation, involvement and contribution of all laboratory staff throughout the implementation of consequent Quality Management.

Since the *Guidelines for Quality Management* are aimed at improving the performance of a laboratory, the activities involved focus on the term "quality". The quality of the product, in the present case analytical results, should obviously be acceptable. To establish whether the product fulfils the quality requirements these have to be defined first. Only after that it can be decided if the product is satisfactory or if and what corrective actions need to be taken.

WHAT IS QUALITY ?

The term "quality" has a relative meaning. This is expressed by the ISO definition: *"The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs"*. In simpler words, one can say that a product has good quality when it *"complies with the requirements specified by the client"*. When projected on analytical work, quality can be defined as *"delivery of reliable information within an agreed span of time under agreed conditions, at agreed costs, and with necessary aftercare"*. The "agreed conditions" should include a specification as to the precision and accuracy of the data which is directly related to "fitness of use" and which may differ for different applications. Yet, in many cases the reliability of data is not questioned and the request for specifications omitted. Many laboratories work according to established methods and procedures which are not readily changed and have inherent default specifications. Moreover, not all future uses of the data and reports can be foreseen so that specifications about required precision and accuracy cannot even be given. Consequently, this aspect of quality is usually left to the discretion of the laboratory. However, all too often the embarrassing situation exists that a laboratory cannot evaluate and account for its quality simply because the necessary documentation is lacking.

In the *Guidelines for Quality Management* numerous activities aimed at maintaining the production of quality are dealt with. In principle, three levels of organization of these activities can be distinguished. From the top down these levels are:

1. Quality Management (QM)
2. Quality Assurance (QA)
3. Quality Control (QC)

QUALITY MANAGEMENT

Quality Management is the assembly and management of all activities aimed at the production of quality by organizations of various kinds. In the present case this implies the introduction and proper running of a "Quality System" in laboratories. A statement of objectives and policy to produce quality should be made for the organization or department concerned (by the institute's directorate). This statement also identifies the internal organization and responsibilities for the effective operation of the Quality System.

Quality Management can be considered a somewhat wider interpretation of the concept of "Good Laboratory Practice" (GLP). Therefore, inevitably the basics of the present Guidelines largely coincide with those of GLP. These are discussed below in the Section GLP.

Note. An even wider concept of quality management is presently coming into vogue: "Total Quality Management" (TQM). This concept includes additional aspects such as leadership style, ethics of the work, social aspects, relation to society, etc.

QUALITY ASSURANCE

Proper Quality Management implies consequent implementation of the next level: *Quality Assurance.* The ISO definition reads: *"the assembly of all planned and systematic actions necessary to provide adequate confidence that a product, process, or service will satisfy given quality requirements."* The result of these actions aimed at the production of quality, should ideally be checked by someone independent of the work: the Quality Assurance Officer. If no QA officer is available, then usually the Head of Laboratory performs this job as part of his quality management task. In case of special projects, customers may require special quality assurance measures or a Quality Plan.

QUALITY CONTROL

A major part of the quality assurance is the *Quality Control* defined by ISO as *"the operational techniques and activities that are used to satisfy quality requirements."* An important part of the quality control is the *Quality Assessment:* the system of activities to verify if the quality control activities are effective, in other words: an evaluation of the products themselves.

Quality control is primarily aimed at the *prevention* of errors. Yet, despite all efforts, it remains inevitable that errors are made. Therefore, the control system should have checks to *detect* them. When errors or mistakes are suspected or discovered it is essential that the "Five *W*s" are trailed:

- what error was made?
- where was it made?
- when was it made?
- who made it?
- why was it made?

Only when all these questions are answered, proper action can be taken to correct the error and prevent the same mistake being repeated.
The techniques and activities involved in Quality Control can be divided into four levels of operation:

1. *First-line control*: Instrument performance check.
2. *Second-line control*: Check of calibration or standardization.
3. *Third-line control*: Batch control (control sample, identity check).
4. *Fourth-line control*: Overall check (external checks: reference samples, interlaboratory exchange programmes).

Because the first two control levels both apply to the correct functioning of the instruments they are often taken together and then only three levels are distinguished. This designation is used throughout the Guidelines:

1. *First-line control:* Instrument check / calibration.
2. *Second-line control:* Batch control
3. *Third-line control:* External check

It will be clear that producing quality in the laboratory is a major enterprise requiring a continuous human effort and input of money. The rule-of-fist is that 10-20% of the total costs of analysis should be spent on quality control. Therefore, for quality work at least four conditions should be fulfilled:

- means are available (adequate personnel and facilities)
- efficient use of time and means (costs aspect)
- expertise is available (answering questions; aftercare)
- upholding and improving level of output (continuity)

In quality work, management aspects and technical aspects are inherently cobbled together and for a clear insight and proper functioning of the laboratory these aspects have to be broken down into their components. This is done in the respective chapters of the Guidelines.

GOOD LABORATORY PRACTICE (GLP)

As mentioned earlier, Quality Management in the present context can be considered a modern version of the hitherto much used concept "Good Laboratory Practice" (GLP) with a somewhat wider interpretation. The OECD Document defines GLP as follows: *"Good Laboratory Practice (GLP) is concerned with the organizational process and the conditions under which laboratory studies are planned, performed, monitored, recorded, and reported."*

Thus, GLP prescribes a laboratory to work according to a system of procedures and protocols. This implies the organization of the activities and the conditions under which these take place are controlled, reported and filed. GLP is a policy for all aspects of the laboratory which influence the quality of the analytical work. When properly applied, GLP should then:

- allow better laboratory management (including quality management)
- improve efficiency (thus reducing costs)
- minimize errors
- allow quality control (including tracking of errors and their cause)
- stimulate and motivate all personnel
- improve safety
- improve communication possibilities, both internally and externally.

The result of GLP is that the performance of a laboratory is improved and its working effectively controlled. An important aspect is also that the standards of quality are documented and can be demonstrated to authorities and clients. This results in an improved reputation for the laboratory (and for the institute as a whole). In short, the message is:

- say what you do
- do what you say
- do it better
- be able to show what you have done

The basic rule is that all relevant plans, activities, conditions and situations are recorded and that these records are

safely filed and can be produced or retrieved when necessary. These aspects differ strongly in character and need to be attended to individually.

As an assembly, the involved documents constitute a so-called *Quality Manual*. This comprises then all relevant information on:

- Organization and Personnel
- Facilities
- Equipment and Working materials
- Analytical or testing systems
- Quality control
- Reporting and filing of results.

Since institutions having a laboratory are of divergent natures, there is no standard format and each has to make its own Quality Manual. The Guidelines contain examples of forms, protocols, procedures and artificial situations. They need at least to be adapted and many new ones will have to be made according to the specific needs, but all have to fulfil the basic requirement of usefulness and verifiability.

The principles of Good Laboratory Practice which are used for the present Guidelines are laid down in various documents such as ISO and ISO/IEC guides, ISO 9000 series, OECD and CEN (EN 45000 series) documents, national standards (e.g. NEN standards)*, as well as a number of text books. The consulted documents are listed in the Literature. (This list can be very useful for further reading). Use is also made of documents developed by institutes which have obtained accreditation or are working towards this. This concerns mainly so-called Standard Operating Procedures (SOPs) and Protocols. Sometimes these documents are hard to acquire as they are classified information for reasons of competitiveness.

* ISO: International Standardization Organization; IEC: International Electrical Commission; OECD: Organization for Economic Cooperation and Development; CEN: European Committee for Standardization, EN: European Standard; NEN: Dutch Standard.

Reference:

Van Reeuwijk, L.P. (1998) *Guidelines for Quality Management in Soil and Plant Laboratories*. FAO Soils Bull. no. 74. FAO, Rome; ISRIC, Wageningen.