ACCREDITATION EXAMPLES OF SOME LABORATORIES

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ABSTRACT: How to build up the quality system in practise? Because all permanent development can only be carried out by the staff members of the laboratory, the key factor is the personnel. All the steps should be co-ordinated by a skilled quality manager and it is important that enough time is available for quality work. However, development of quality system contains some pitfalls that one should be aware.

KEY WORDS: Quality system; Forensic laboratory; Accreditation.

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TYPICAL STARTING SITUATIONS

The worst case situation

The worst case situation can be found in laboratories that have suffered from severe financial problems over the years. This can be illustrated with the examples including:

- complete absence of the quality system;
- major deficiencies in basic instrumentation, e.g. microscopes, balances, chromatographs, computers, etc.;
- total lack of high-tech instruments, e.g. SEM, bullet speedometer, CE (for DNA), etc.;
- deficiencies in availability of consumables;
- improper calibration or no calibration of equipment;
- lack of (reliable) reference materials;
- deficiencies in participation with proficiency tests;
- no control over competence of personnel;
- absence of documentation (personnel register, methods, SOP's, instrument register, maintenance, etc.

The worst case situation is, however, becoming increasingly rare as a consequence of greater awareness of needs of technical crime investigation amongst decision making bodies. Laboratories still being in this level are advised to seek external funding e.g. from EC programmes.

The "usual" situation

Much more often laboratories are in a level in which major resources are relatively well-balanced with their duties and commissions. The quality system, however, may still be relatively primitive. The following problems typically illustrate the state of the art of these laboratories:

- management is not committed to the quality system;
- laboratory does not function according to the quality system;
- the quality system covers only a part of activities of the lab;
- familiarisation and training is not systematically documented;
- no corrective action has been carried out to the non-compliance found in the internal audits;
- validation is insufficient;
- measurement uncertainty has not been estimated or it is unrealistic;
- no corrective action has been carried out after deviation from acceptance criteria;
- proficiency test results are not fully exploited;
- calibrations have not been performed according to the plan.

Development of these laboratories can usually be achieved without significant extra funding. Typically better co-ordination solve most of the problems.

STARTING TO BUILD UP A QUALITY SYSTEM

When building up a quality system the key factor is personnel. This is because all permanent development can only be carried out by the staff members of the laboratory. Moreover, this should be done together.

How to build up the quality system in practise? The first prerequisite is to get the management committed to quality. Commitment in this context means that the management has reserve enough recourses for the needs of the quality system. Very often this has a temporary impact on the overall performance of the laboratory. On the other hand, any significant development becomes impossible if this element fails. Secondly, a quality manager has to be nominated and sufficient resources has to be given to her/him. Numerous duties require a person who is dedicated to the quality projeect. Finally, the personnel has to be motivated by sufficient training and by fair sharing of responsibilities regarding the quality system.

NEXT STEPS

The following actions include internal audits, which have to be started ASAP to open everyone's eyes. The practice has shown that the belief on the general quality of scientist's own laboratory is unrealistically great. Internal audits show in an effective way what the real state of the art is.

It is equally important that enough time is available for quality work, i.e. nothing comes for free! Achievements in development of quality system provide a good means to control efficiency of the laboratory. It should however be noted that some extra funding is usually required e.g. for buying reference materials, for getting traceable calibrations made, etc.

The work should proceed in preparing the quality manual, SOP's and other documents. Again, the work should be shared between a representative group of staff members.

All these steps should be co-ordinated by the quality manager to avoid duplication of work.

BEFORE SENDING OUT THE APPLICATION

There is no need to try to make the quality system perfect before sending out the application to the accreditation body. On the contrary, assessment carried out by the accreditation body provides an effective means to identify areas where further development should first be carried out. This however requires that the main elements of the quality system have been finalised. Thus, one should make sure that:

- internal audits are frequently carried out according to a known timetable;
- quality manual is available for and adopted by each member of staff;
- competence of all staff members have been registered;
- all equipment have been registered;
- proficiency test results are available and properly utilised;
- measurement uncertainty is estimated – when relevant;
- clients' requirements are fully taken into consideration;
- everything is well-documented, dated and signed, and systematically archived.

POTENTIAL PITFALLS

Development of quality system, like any development project, contains some pitfalls that one should be aware.

It has most often been found that any deficiencies in the commitment of the management to quality system seriously jeopardise the project. Other pitfalls have been illustrated below.

Skills of the quality manager becomes significant as she/he has to make sure that the duties, responsibilities and authorities of all staff members are properly defined. Development of the quality system is typically so laborious project that the balance between the "real work" and the quality work cannot easily be found. Thus, co-ordination is important: if the project timetable fails due to the lack of resources, people become frustrated, sceptic and angry. The same applies if the personnel is not sufficiently motivated.

Finally, development should be made such that the quality system does not become too complex. This would only lead to a situation in which quality has become a facade.

FINAL CONCLUSION

All achievements are entirely up to the laboratory itself. Excessive external aid, "spoon feeding", does not guarantee any success.