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## **PROPOSAL FOR ANOTHER STEP ON THE PATH TO TOTAL QUALITY MANAGEMENT**

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In 1992 the first clinical chemistry laboratory was accredited in Sweden to take a holistic view on quality and not only focus on the quality of measurements and observations in the laboratory. About 80 % of the Swedish clinical chemistry laboratories have since been accredited as well as many other laboratories in laboratory medicine. Accreditation was performed according to the ISO Guide 25 'General requirements for the competence of calibration and testing laboratories' and the EN 45001 'General criteria for the operation of testing laboratories'. In the following years accreditation of medical laboratories was introduced in many countries. The ISO Guide 25 and EN 45001 deal mainly with analytical quality and organisation of the laboratory and it was soon realized that none of the available standards was entirely suitable for medical laboratories. Therefore, a number of application notes were published e.g. in the Scandinavian countries, Holland and Switzerland. The European Confederation of Laboratory Medicine (ECLM) produced an application document to ISO Guide 25 that was recognised by EA (European Accreditation) and widely used. The European Communities Confederation of Clinical Chemistry (EC4) has published "Essential Criteria for Quality Systems in Laboratory Medicine" (2). The Project Group Good Medical Laboratory Services of the ECLM proposed a model for the future development of the concept of total quality management (ref) focusing more on patient outcome.

The IFCC in its policy statement on clinical laboratory accreditation states 'Adherence to high standards, such as those related to timeliness of test results, laboratory trueness and precision, clinical relevance of tests performed, qualifications and training of personnel, and prevention of errors, is an ethical responsibility of all clinical laboratory staff' (1). To meet this statement, the previously available standards need to be substituted by something new.

The new ISO Standard 17025 that substitutes the ISO Guide 25 is still centered on analytical performance in addition to complying with the ISO 9000 series for quality systems. The ISO TC 212, therefore proposed to write an accreditation standard specially for medical laboratories. This has become the ISO/FDIS 15189. This standard will, when it is finally released, take us a good step nearer total quality management of medical laboratories.

A working group of the Swedish Society for Clinical Chemistry has worked out a protocol for a medical audit of accredited medical laboratories. The proposed protocol is now studied by the various sub-specialties of laboratory medicine. We believe it would be of interest to invite the international community to comment on the protocol at an early stage and to initiate a presentation and discussion of what is happening in other countries in this Journal.

Is your laboratory accredited? In that case, which Standard do you use? (ISO guide 25/ EN45001, ISO 17025, ISO 15189 or a national standard). Do you have peer visits or other forms of medical audits? If you want to participate in a discussion about these topics do so by going to the web forum entitled "[Forms of medical laboratory accreditation](#)"

This protocol is planned to fill the gap between EN 45001/ISO 17025 and the forthcoming ISO 15189.

### **MEDICAL AUDIT**

This recommendation is intended for self-sustaining (stand alone) laboratories

### **Competence and education**

1. The executive shall be sufficiently competent to make all necessary decisions. The competence can be divided between several persons. In that case there shall be a clear description of who is responsible for what. A physician, specialist in the field of the laboratory, shall be medically responsible.
2. Physicians, working in the laboratory and not under training, shall be specialists in the appropriate field.
3. Continued education shall meet the needs of all staff within their field of responsibility.

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**Note:** Funds should be budgeted for internal and external education and the plan for education and training reviewed annually.

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The laboratory shall have access to an adequate reference library and electronic or other sufficient library service.

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**Note:** It is assumed that the personnel have received the necessary education to use the library and other library or electronic information services.

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## Selection of analytes

1. The selection of analytes shall be a joint concern for the laboratory and its customers and regularly reviewed to meet the needs of health care.

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**Note 1 :** Consequences of prospective changes should be discussed. Economic reasons alone should, as far as possible, not influence the selection of investigations.

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**Note 2 :** Attention should be paid to the need for and to the laboratory's ability to provide interpretation and evaluation of the results.

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2. There shall be established routines for how to accomplish changes in the selection of analytes and how to distribute new information about important changes in the services of the laboratory.

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**Note 1 :** Information about new analytes and their use could be; change of reference intervals, upgrading of patient instructions, deletion of old and introduction of new methods.

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**Note 2 :** Analytical work can be decentralized to hospital units as well as primary care units. Transferability of results should be the leading principle in the choice of measurement procedures.

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## Point of Care testing

1. Decentralization of investigations to units within the hospital or to primary care units shall meet the needs of the health care as far as is technically and practically possible. Routines and arguments for decentralization shall be documented.

2. The laboratory shall have a quality system to guarantee consistency and transferability of results.

## Methods and measurement procedures

1. The laboratory shall provide clinically relevant quality specifications for each investigation. (3).

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**Note :** The analytical goals shall be suitable for the purpose of the investigation and may be different depending on the intended use, e.g. screening, emergency, monitoring.

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2. The laboratory shall state the clinical performance, e.g. patient outcome or usefulness of offered investigations.

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**Note:** The performance can be given as diagnostic specificity, sensitivity or ROC diagrams for different purposes.

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3. Reference intervals, therapeutic intervals and clinical decision levels shall be traceable to an authoritative source.

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**Note:** The basis for this information may be scientific literature or suitable local or regional studies

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## Consultations

1. On call responsibilities shall be as extensive as required by the health care system.

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**Note 1:** The extent of on call service varies between different specialties within laboratory medicine.

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**Note 2:** On call service can be organised on a local or on a regional basis.

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2. The laboratory shall give consultative service to the extent required by the health care system.

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**Note 1:** The laboratory should actively seek contact with its customers e.g. through participation in clinical rounds or through the organisation and participation in conferences etc.

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**Note 2:** The laboratory should participate in establishing diagnostic and therapeutic programs. This could be done through defining diagnostic strategies based on, or including results of laboratory measurements.

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3. The laboratory shall be able to suggest appropriate investigations on the basis of available information (reflex testing).

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**Note:** There should be established ways to referral laboratories .

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## Request-and report routines

1. Requests shall include specific questions and anamnesis information to allow informed Notes of the results Note if requested.
2. The report forms (paper or electronic) shall allow for comments.
3. Routines shall be described to assure a safe transfer of results. Special attention should be given to routines using telephone, fax and other electronic means.
4. The laboratory shall state the turn-around-time for measurements including those that are not carried out frequently or on a regular basis.
5. The laboratory shall specify the maximum “turn-around-time” for acute analyses.

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**Note:** The laboratory should have routines that make it possible to register the time the sample arrived and the time when the final report was issued.

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1. The laboratory shall have documented rules for which information and how this information is assessable for its customers.

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**Note:** It might be critical how information is made available and distributed within the health care system, e.g. between clinics and different levels of the health care system as well as over time.

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## Responsibility for equipment

1. The laboratory shall participate in purchasing of all equipment that the laboratory will eventually be responsible for.

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**Note:** This includes installation and validation of all equipment and training of the staff to carry out measurement procedures within its field.

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2. Maintenance and control of all equipment used for diagnostic purposes but not accredited shall follow the same rules as accredited equipment.

## Health care related information

1. The laboratory shall issue and update information to clinical staff and patients to ensure adequate sampling and sample treatment outside the laboratory.

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**Note:** This information can also contain information about the clinical performance and indications for specific investigations.

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2. The laboratory shall inform its customers about essential changes in its operations, technical and organisational.

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**Note:** This will create a heavy administrative burden and an appropriate information system should be in place to meet the needs.

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3. A dedicated body shall regularly review the service and take new initiatives to promote a smooth collaboration between the laboratory and its users.

## Research and development

1. The laboratory shall specify its willingness and ability (personal and physical) to participate in health care related research.
2. The laboratory shall inform about its research profile, and scientific publications when applicable.
3. The laboratory shall describe routines for handling of research samples.
4. The laboratory shall describe resources for developmental work i.e. method and instrument validation.

## Customer satisfaction

1. The laboratory shall actively, e.g. through the use of questionnaires, explore the degree of customer satisfaction.

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**Note:** Questionnaires should be performed repeatedly and be aimed at specific groups or routines.

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2. The laboratory shall react quickly and adequately on information obtained from customers Actions taken shall be followed up, documented and presented at the internal revision of the laboratory.

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**Note:** Incidence reports and other incoming complaints should be taken into account when deciding the need and type of action.

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## Ethics

1. The laboratory shall have a documented policy for ethical aspects of sampling, sample handling and storage, investigations, results of investigations and the care of patients. The policy shall be endorsed on the highest available level. (4)
2. Information about the ethical rules and policy shall be distributed to patients, laboratory staff, clinical staff and other relevant parties.