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1. Background

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In May 1946 the Scandinavian Society for Clinical Chemistry and Clinical Physiology was founded in order to promote collaboration between the Nordic countries in laboratory medicine. A main achievement during the years since then has been the organization of biannual congresses.

At such a congress in Otnäs in Finland in 1969 it was decided that a closer Scandinavian cooperation was advisable and a few committees for special tasks were organized. One of these was the "the Nordic Committee on Quality Control" (4). It was soon realized that a more solid financial ground was needed for the committee work. An application for a project was sent to the Nordic Council of Ministers , which provided the necessary funds and after some years of planning the Nordic Project of Clinical Chemistry (NORDKEM) could start working in 1977. As was mentioned in the "Foreword", the main original goals of NORDKEM were to promote quality control activities and collection of reference values (2). Later the discussion of goals for NORDKEM has continued. The process started with a new organization with financial support from both national health authorities *and* owners of hospitals and health care organizations and continued with 1) goal discussions in the Board of NORDKEM, 2) an official evaluation process initiated by the social-political committee of the Nordic Council of Ministers, and has finally been influenced by the increased orientation towards Europe.

Among the great number of projects supported by NORDKEM it is easy to identify one sequence of projects all dealing with improvement of quality. They are characterized by the following key words: 'Quality requirements' (1), 'Design of quality control' (5), 'Clinical goals, and Quality specifications' (6). The last step in this series of projects was started about three years ago and was given the title: 'Medical Need for Quality Specifications in Clinical Laboratories'. As an example of the mutually enriching collaboration between NORDKEM and the Scandinavian Society for Clinical Chemistry this project was to a

large extent influenced by the 'General Scandinavian Recommendations on Quality Control and Quality Assurance' issued by the Society two years earlier (3).

The report of the present NORDKEM project describes:

a) the general approach of the project and guidelines for assessing quality specifications and designing control systems (chapters 1, 2, 4)

b) three main subprojects oriented towards terminology (chapters 3, 10, 11), clinical goals for serum (plasma) protein assays (chapter 5.1), and problems related to improving the transferability of clinical laboratory data (chapter 5.2)

c) a number of associated projects that provide background material indicating that our approach is applicable (chapter 6)

d) practical approaches in order to simplify the work with obtaining quality specifications (chapter 7)

e) discussions and conclusions (chapters 8, 9)

There are - as indicated in Fig. 1 - three basic blocks involved in the work with specifications of analytical quality specifications (AQSpecs):

1. The clinical goals,

2. The characteristics of the measurement procedure, and

3. The design of quality assurance programs.

The word "clinical goal" is often used in a general meaning. In this report, however, it is mostly used with the meaning: "clinical goal for AQSpecs". It is expressed quantitatively as a total error at a defined level. In the world of a practically working clinical laboratory,

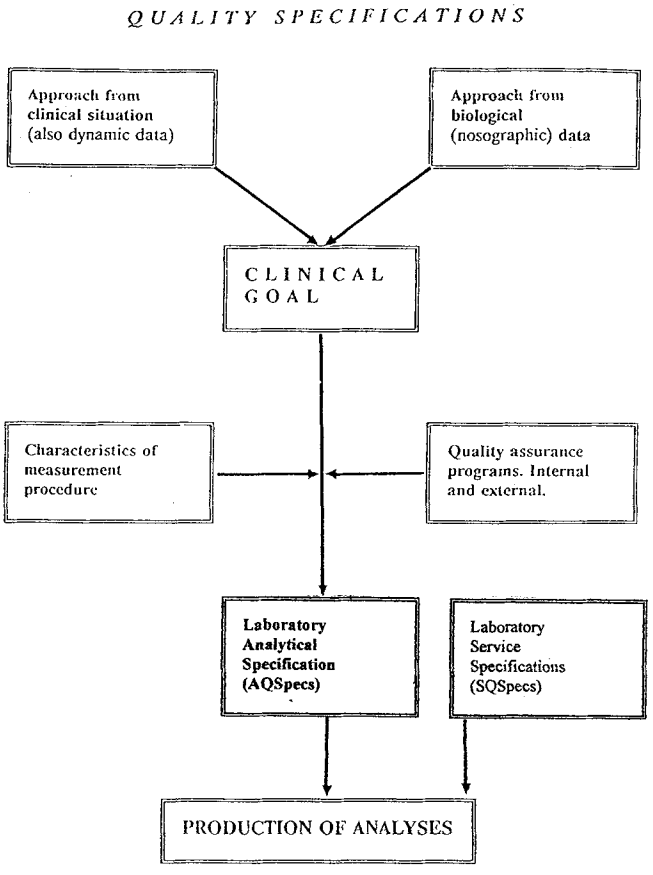

Figure 1.

the three blocks (**1-3**) are interactive and the result of the exercises - the AQSpecs - come out as hopefully useful compromises.

Is it meaningful to spend time specifying the analytical quality of the measurement procedures of the laboratory?

The following motivations are important and relevant:

Quality specifications are required for

1. design of analytical quality control and assurance programs
2. advanced management of the clinical laboratory
3. professional discussions with suppliers of equipment and reagents *etc.*
4. professional discussions with customers and for the billing of services.

It is important to stress that the laboratory - in addition to the AQSpecs - also has to provide specifications for its service (SQSpecs). These include *e.g.* 'request - report time', 'interpretation of laboratory results', availability of services, and costs for services.

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