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Summing up

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INTRODUCTION

Good Laboratory Practice (**GLP**) is a concept that was formulated already in 1978 by the US Food and Drug Administration (FDA) (2) and was taken up in 1981 by the Organisation for Economic Co-operation and Development (OECD)(5). Several recent documents about GLP are of interest to the Nordic countries (1,3,4,6). They describe the meaning of this concept which seems to be equivalent to "Good Laboratory Quality Management" as this term is defined by professor James O Westgard in this publication. The term can be split into several different functions. Production of analytical results is the predominant function of the clinical chemical laboratory and analytical quality control and analytical quality assurance are therefore major tasks for this type of laboratory. There are, however, also other very important quality characteristics for a clinical laboratory in general and a clinical chemical laboratory in particular: **e. g.** turnaround time, optimal selection and utilization of tests and interpretation of results. Particularly nowadays - as stressed by professor Mogens Hørder (the chairman of the NORDKEM Board) and by dr Lars Mellin - it is also important to relate the quality to the costs - both internal ones for the laboratory and external ones for the health care organization and the society.

The title of the project "Medical Need for Quality Specifications in Laboratory Medicine" would indicate that it is not only technical and analytical chemical considerations that should be made in the formulation of the quality specifications. It is important to work together with clinicians and primary care physicians and to merge the knowledge from all sides to define the clinical situations where the test is needed, to evaluate the

need for prompt reporting, to establish guidelines for interpretation of the result and to assess the effect of analytical and preanalytical errors.
An important continuation of this process is to find ways for obtaining the specified quality, whether they are instructions for reducing preanalytical variations or guidelines for improving analytical quality etc. Furthermore, control systems for monitoring quality should be elaborated, either in general terms or as examples.

APPROACHES

If the project is given this broad definition it will need considerable time to conclude and a priority list is desirable as well as assistance from other groups working with similar problems.
There are several problems with proficiency testing as indicated in the communication by professor Ronald Laessig. In a future world of medicine exchange of information and knowledge will be far more dominating than today. Clinical laboratory data must also be transferable from one place to another. That is the reason why the main project group will work with analytical quality specifications for some plasma proteins and low molecular serum hormones as two important applications. It is also important to have ideas about how to recalculate data from one laboratory to another in order to solve the problem of communicating clinical laboratory data between hospitals or other health care centres. This will be a task for the main project group as well as attempts to coordinate terminology, abbreviations and computing procedures.
It is stimulating for the main project group that several research groups working within this area have - after request - announced their interest to participate as associated project groups (see the list in Section 21). We hope that this joint effort will:

* promote the work with establishing clinical laboratory quality specifications in the Nordic countries.
* widen the activities to cover many important areas
* add resources and knowledge to assess, if possible, other quality characteristics as turnaround time, test selection and result interpretation.

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