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Distribution List

Dear

Accreditation Scheme for Medical Testing Laboratories

As you are probably aware, the Hong Kong Accreditation Service will be expanding its scope of accreditation to include medical laboratories. The medical laboratory accreditation programme will be a voluntary scheme and accreditation criteria will be based on ISO 15189:2003, *Medical laboratories – Particular requirements for quality and competence*.

To prepare for the launching of the scheme, a Working Party for Medical Testing under the Accreditation Advisory Board was set up in April 2002. The Working Party comprise experts from different medical testing disciplines and each major discipline was represented by at least one member. The main task of the Working Party was to interpret the requirements of ISO 15189, for different medical testing disciplines and draft detailed accreditation criteria, taking into account local needs. Task Forces for 5 sub-disciplines of medical testing namely Anatomical Pathology, Chemical Pathology, Clinical Microbiology and Infection, Haematology, Immunology and a Task Force for general criteria, each under the chairmanship of one member of the Working Party were set up. To enable members of the Working Party and its Task Forces to act in the best interest of the scheme, these individuals were appointed on an ad personam basis, in their capacity as experts, and not to represent the interests of the various professional groups. Nevertheless, you may wish to know that out of the 13 Working Party members, 8 are pathologists, 3 are technologists and 2 are clinical scientists, with representation from both the public and private sectors.

After more than a year of intensive work by the Working Party and its Task Forces, the final drafts of the supplementary criteria are now available. Although the accreditation scheme is voluntary and not regulatory, we would like the scheme to be widely accepted. Hence we are making available the final draft criteria documents to relevant institutions and professional associations for comment.

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As your association represents an important sector of the medical testing community in Hong Kong, we would like to seek your comments, if any, on the documents.

The Working Party is fully aware that there are differing views regarding the requirements on the qualification of the Laboratory Director and that some would like the qualification to be raised beyond what is set out in the Technical Criteria. The Working Party has agreed to review the requirements for Laboratory Director regularly and the minutes of its meeting on 20 June 2003 state "HKAS will critically review the requirements for Laboratory Director on an annual basis. It is the intention with time to raise the requirements for Laboratory Director such as to aim for Doctoral degree in medical sciences for non-pathologist LD".

I would also like to add that accreditation is about continuous improvement and the Technical Criteria is not cast in stone. A great deal of effort has been spent and more than a year has passed since the Working Party and its Task Forces have been set up. I believe it is time to launch the scheme and review the criteria periodically in the light of experience.

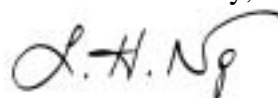
Enclosed please find two copies of CD which contain the following draft documents:

- (i) the Technical Criteria for Laboratory Accreditation (Medical Laboratories) [HOKLAS 015] which is based on the International Standard ISO 15189:2003 for Medical Laboratories;
- (ii) the Assessment/Reassessment Questionnaire (Medical Laboratories) [HOKLAS 016];
- (iii) the Supplementary Criteria for different disciplines; and
- (iv) the Explanatory Notes on Scope of Accreditation.

Should you wish to distribute to your members for wider consultation, please feel free to copy the contents.

As we intend to launch the scheme in the next couple of months, we would be most grateful if your comments could reach us by 26 July 2003.

Yours sincerely,



(Dr. L.H. Ng)
Executive Administrator

Encl.