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CLARIFICATION ON THE DIFFERENCE BETWEEN OECD PRINCIPLES OF GOOD LABORATORY PRACTICE, GOOD CLINICAL PRACTICE, SMALL glp AND ISO/IEC 17025

Over the past 12 months, we have had numerous requests for the clarification on the differences between OECD Principles of Good Laboratory Practice (henceforth referred to as GLP), ISO/IEC 17025, small glp (good laboratory practice) and Good Clinical Practice (GCP).

It has come to our attention that there is confusion about the different quality systems, and this article is aimed at dissipating the confusion. Following is the clarification of the aforementioned:

1. OECD PRINCIPLES OF GOOD LABORATORY PRACTICE:

OECD Principles of Good Laboratory Practice (henceforth referred to as GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, monitored, recorded, archived and reported. Non-clinical studies are those studies in which a test item contained in various chemical products is examined under laboratory conditions or in the environment to obtain data on its chemical and physical properties and/or its safety, intended for submission to regulatory authorities for the purpose of registration or licensing. This studies and/or experiments could be conducted in laboratory, animal house, greenhouse and field (crops or animals). These principles were developed by group of experts in 1979 and 1980. GLP helps to avoid the creation of technical barriers to trade and further improve the protection of human health and environment. It also provides an assurance to regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making registration or licensing decisions.

2. GOOD CLINICAL PRACTICE (GCP):

GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well being of trials subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and

that the trial data are credible. The difference between GLP and GCP is that the former is for non-clinical health and environmental safety studies whereas latter is for clinical studies.

3. SMALL glp:

Every laboratory interested in producing quality results is interested in maintaining sound laboratory management practices. Sometimes these practices are referred to, in general terms, as **good laboratory practice** ("small or lower case glp"). In simple terms, small glp is a code of good laboratory practice. Small glp covers issues like proper use of chemicals and lab instruments, laboratory techniques, dress code, storage and transport, spillages and etc. Thus, small glp is not equivalent to GLP.

4. ISO/IEC 17025:

ISO/IEC 17025 is an international standard that specifies the requirements for the competence to carry out tests and/or calibrations. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory developed methods. ISO/IEC 17025 relates to testing laboratories and it is not applicable to non-testing laboratory activities. However, ISO 17025 quality system elements can be used to interpret elements of GLP such as: management responsibility; QA program and SOP documentation. The following elements of GLP are not specifically covered by the system elements of ISO/IEC 17025: study plans; Study Director; Principal Investigator; study report format; archiving and some QA personnel responsibilities.

DATES FOR THE 2011 ILAC AND IAF PEER EVALUATION

The ILAC, IAF and EA Peer Evaluation of SANAS will take place from **Monday, August 01 to Friday, August 05, 2011**.

As SANAS relies on the availability of Assessors coming from accredited facilities, we request the assistance of the facilities to make the identified staff member available during this period.

SANAS CLIENT QUESTIONNAIRE

In preparation of the 2011 Communication Meeting and World Accreditation day celebration, we will be conducting a survey to solicit views from our stakeholders on the format of the envisaged events.

During November, the SANAS Corporate Services

division will distribute a questionnaire which will take approximately five minutes for completion.

We would appreciate your feedback **by 02 December 2010**, to ensure that the changes meet the needs and expectations of our valued customers.

WORKSHOP ON THE ACCREDITATION PROCESS FOR ENERGY EFFICIENCY SAVINGS

The recent challenges in the Electricity Supply Industry has necessitated the Department of Energy to encourage consumers of Electrical energy to use energy more efficiently by providing a tax incentive to those that can prove objectively that they have made a saving in terms of energy consumed over a specified period of time.

This objective evidence will be provided by Accredited Measurement and Verification Bodies (M&Vs).

SANAS hosted a workshop where the requirements for Accreditation in this area were discussed. All interested parties and potential M&Vs seeking to become accredited were invited to attend the workshop.

Presentation for this workshop will be made available on the SANAS website.

IAF NOTICE FROM IAF CHAIR

One of IAF member Accreditation Bodies (ABs) recently identified a website that plagiarizes the IAF website to the extent of replacing references to IAF with references to CNAB. The website address is www.cnab-global.org.

The website also lists a number of IAF member ABs that it claims are members of CNAB. Following is the wording of a public notice that will be published prominently on the IAF website, and we encourage other IAF members to publish this notice.

IAF Website Message:

“An organization identified as the Commonwealth of Nations Accreditation Board (CNAB) hosts a website (<http://www.cnab-global.org/>) that plagiarizes the website of the International Accreditation Forum (www.iaf.nu), presenting IAF information as its own and inserting the name CNAB in place of IAF. The organization further falsely identifies many IAF member accreditation bodies as members of CNAB.”

The IAF is trying to identify the owner of the domain as well as the host for the website in order to try to get the website shutdown.

INTERNATIONAL HAPPENINGS OF INTEREST

INTERNATIONAL CONGRESS OF METROLOGY

The 15th International Congress of Metrology will be held from 03 - 06 October 2011 in Paris (France). The deadline for papers proposal is 15th December

2010. Information can be obtained from info@cfmetrologie.com - www.metrologie2011.com



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OUR MISSION

To create an impartial and transparent mechanism for organisations to independently demonstrate their competence and facilitate the beneficial exchange of goods, services and knowledge and provide a service that is recognised as equitable to best international practice while reflecting the demographics of South Africa in all that we do.

We issue our report monthly and if you would like to receive future copies, please forward your particulars to Tshenolo Molamu to enable us to add your details to the distribution list.