International Consortium for Harmonization of Clinical Laboratory Results Harmonization Oversight Group / Council Conference Call Meeting

DATE: 15 December 2016 TIME: 7:00 a.m. to 8:00 a.m. EST

HOG Members:

Dr. Greg Miller (Chair) Dr. Eunice Lee (Vice-Chair) Mr. Joseph Passarelli Dr. Tony Killeen Dr. Amy Saenger

ICHCLR Council Members:

Dr. Gary Myers (chair) Mr. Hirofumi Koide Dr. Katsuyuki Nakajima

Council Members Absent:

HOG Members Absent:

Dr. Junghan Song

Dr. Ian Young Dr. Steve Master

AACC Staff:

Ms. Stefanie Kleinman (Scientific and Practice Affairs Coordinator)

Minutes:

1. New HOG Member

Greg Miller welcomed Dr. Amy Saenger as the newest member of the HOG.

2. Council dues for 2017 and restructuring of ICHCLR

Gary Myers provided an update on the situation regarding AACC's decision to not include funds in the 2017 operating budget for the ICHCLR and to recommend as a Council member that the ICHCLR consider restructuring its organization.

Greg and Gary provided a report on the history and activities of the ICHCLR for the AACC Board of Directors (BOD) July 2016 meeting.

Greg and Gary received the following e-mail from Patti Jones, AACC President on 21 November 2106 following further deliberations by the BOD at their November meeting.

Hi gentlemen,

I'm catching up on emails today and just wanted to let you guys know the gist of the Board's discussion late last week.

Basically, the AACC will have no funds in the 2017 operating budget for ICHCLR, but we won't pull out of it immediately either. Thus as we spoke about, Greg, as AACC president I am officially requesting that the AACC representative to the ICHCLR Council ask the Council to wave dues for 2017. The AACC BOD understands that ICHCLR will visit a restructuring during 2017, to dues structure, to website base and possibly to secretariat home, working with the IFCC. AACC Finance Committee and BOD will revisit dues to ICHCLR next Fall.

Let me know if you guys have any additional questions.

Best regards, Patti

Following the July AACC BOD discussion, Greg spoke to Patti Jones, Mike Bennett, AACC President-Elect, and Corinne Fantz, AACC Treasurer, regarding this BOD decision. In the end, the current BOD does not feel the ICHCLR is a good use of \$50,000 per year and as a Council member AACC requested us to revisit the organization and funding of the ICHCLR.

Gary indicated the goals of the ICHCLR have changed since the organization was established in 2013. The ICHCLR is now focused on (1) creating a prioritized list of measurands in need of harmonization, (2) creating a list of what organizations throughout the world have active harmonization or standardization initiatives to promote cooperation and best use of resources; (3) working with regulatory and standards organizations to develop tools and procedures for harmonization especially when there are no reference methods or certified reference materials available. He reminded everyone the ICHCLR has not pursued creation of HIGs to conduct harmonization activities because the AACC had concerns that it would be financially liable for a project that lost funding partway through. Since the ICHCLR is not starting HIGs, we have not spent money to support the initial HIG meetings and project development costs. Consequently, the ICHCLR has a substantial balance in its account (approximately \$165,000) and does not need to have the Council members contribute \$50,000 per year.

Gary asked the JCCLS and HOG members present to consider and comment on the following proposal for the ICHCLR going forward.

- A. Waive the 2017 annual \$50,000 contribution for all Council members, the 2017 annual \$10,000 contribution for the one Organizational member, and the \$500 contribution from members of the Strategic Partners Group.
- B. Review the organizational structure of ICHCLR for current and future goals.
- C. Establish new Council and other participation annual contributions.
- D. Consider moving the secretariat role to another organization such as the IFCC. Gary and Greg have had preliminary discussions with IFCC leadership about this possibility. IFCC has been receptive to consideration. Note that there is a natural synergy in the goals of each organization. ICHCLR provides prioritization of measurands in need of harmonization and a portal for what different organizations are doing. IFCC has a well-established program for organizing specific harmonization projects through its Scientific Division.

Dr. Nakajima, on behalf of JCCLS, indicated support by JCCLS for the steps outlined above. Since Dr. Song could not be on the conference call, Greg recommended that Gary and he call Dr. Song and Eunice to obtain input from KSLM on this issue. Dr. Killeen indicated that CAP would also support the plan as outlined.

Following an e-mail to Dr. Song on 15 December after the ICHCLR conference call, Dr. Song responded on behalf of KSLM as follows:

KSLM's opinion on the following issues are;

A. Waive 2017 annual \$50K contribution for all Council members; what about our one Organizational member at \$10K.; KSLM agrees

B. Review the organizational structure of ICHCLR for current and future goals. KSLM agrees

C. Establish new Council and other participation annual contributions. Financially it is a little bit large annually for a professional society like KSLM to pay or contribute.

First, operating cost of Council or full ICHCLR should be analyzed.

If ICHCLR could entice some of the industry members, it would ease much of the financial pressure off.

D. Consider moving the secretariat role to another organization such as the IFCC.

KSLM is neutral on this issue. And we think IFCC is fine if it is interested in our cause.

Further discussion and planning on this issue will occur on subsequent conference calls.

3. Web site update

Greg provided a brief update on efforts to move the ICHCLR website from AACC to a new web developer. On the recommendation of Dr. Graham Beastall, IFCC Past -President, Greg contacted a firm called Insoft located in Denmark. This computer firm has done work for IFCC and the JCTLM and was well recommended. After several e-mail exchanges we decided to contract with Insoft to develop a new website for the ICHCLR. The initial cost was estimated to be \$7000 USD and annual hosting and support cost is estimated to be \$3500 USD. Insoft anticipates the new web site to be operational sometime in January 2017.

4. Progress on prioritization of measurands spreadsheet.

Greg indicated there was not sufficient time on this call to discuss the current status of measurand prioritization. He will send out the most recent spreadsheet with the conference call minutes.

5. Schedule next calls

A doodle poll will be sent to determine dates for the next series of conference calls.