Secretariat of ISO/TC131/SC 6
Contamination control

Re. ISO 11171 Revision Status Report to SC 6

Dear Member

I have received the below message from the Project Leaders Mr Barry Verdegan and Mr Michael Schumacher:-

"The purpose of this note is to apprise members of ISO/TC 131/SC 6 of the current progress and status of the ISO 11171 revision. At the October 2017 meetings in Winterthur, plans were discussed to conduct a WG1 internal consultation of the draft document prior to sending it out the CD for ballot. This was to be closely followed by a round robin to:

• measure intra-company repeatability and inter-company reproducibility of particle count data obtained using automatic particle counters calibrated with ISO CD 11171:2018 and the new batch of NIST SRM2806 calibration fluid;
• generate particle count data to be used by NIST to certify consensus standard SRM 2806d [that will report sizes in units of µm(c)]; and
• generate particle count data for NIST RM 8632a that will be used to update Table A.1 in the standard.

The internal consultation has been completed and a number of changes made (refer to document ISO/TC 131/SC 6/WG 1 N310) to address these issues. The CD ballot N 750 has been launched to keep the project on schedule.

Unfortunately, the round robin has been delayed because primary candidate material for SRM 2806d is not yet available. Please see the joint statement below from NIST and IFTS which provides the background to this situation. There are a number of implications which the committee should be aware of:

• The earliest that the round robin can now begin is early September.
• Certification of SRM 2806d cannot begin until qualified candidate material is received. Certification requires that the round robin be completed. This delays the release of SRM 2806d to the market.
• NIST is limiting sales of SRM 2806b to extend the availability of the material. In addition, we are encouraging the industry to rely on secondary calibration suspensions purchased from legitimate suppliers for calibration purposes. Together, these actions are intended to lengthen the availability of SRM 2806b until SRM 2806d becomes available.
• At our October meeting 2018 in Xinxiang, we will be unable to discuss round robin results, as the round robin should be taking place at that time. We will discuss the CD comments and any actions required to move the SRM and ISO standard forward."
• Once the round robin begins, participants will be asked to complete their calibration and analysis with 4 months and submit their data for analysis by the PL and NIST.
• To avoid disruption to the industry due to lack of SRM or an updated ISO calibration standard, SC 6 may want to consider an off-cycle (spring) or teleconference meeting to discuss the round robin results and changes to the document. Although not anticipated, if there is further delay in securing primary candidate material, a review of the material specification and consideration of alternative suppliers may be in order. These questions can be discussed in Xinxiang.

The following joint statement regarding the delay was provided by NIST and IFTS on 29 May 2018:
“The interlaboratory comparison will be delayed by 3 to 4 months because the primary candidate material for the SRM 2806d is still being fabricated. The delay is caused by some technical difficulties. A batch of candidate material was offered to NIST, but unfortunately the material had lower particle concentrations than required and there was a systematic variation found in the bottle-to-bottle particle concentrations. The coefficient of variation was within specification. IFTS is working on preventing the systematic variation and further optimizing the bottle counting process. Within a week, IFTS will have in-line data for NIST to analyze followed by bottled candidate SRM 2806d material. If these data are complying with the NIST requirement, IFTS will start with the bottle filling process in the two coming weeks. IFTS will then have to confirm the bottle counting data”.

Yours sincerely

Anita Attra
Secretary of ISO/TC 131/SC 6