

SC 6 Agenda

August 21, 2017 meeting of ASC SC6 – Instruments and Low Vision Devices

Topics to cover:

ANSI Standards in progress

- 1) ANSI Z80.28 – Methods of reporting optical aberrations of eyes- This revised standard is in the final process of editing the copy by the parent ANSI organization prior to publication.
- 2) ANSI Z80.37 – Slit- lamp Microscopes – Currently out for Z80 Parent Committee final voting, closes 8/29/17.
- 3) ANSI Z80.38 - Light Hazard From Operation Microscopes Used in Ocular Surgery - This standard has been voted on and passed. It was approved by ANSI on 7/28/17. Next step is submission to ANSI for editing prior to publication.

ANSI Standards currently under review

- 1) ANSI Z80.17 – Focimeters - At present there is no specific plan to alter this standard
- 2) ANSI Z80. 23 – Corneal topographers - For this meeting there are several items to cover on this standard
 - a) Currently the standard only covers corneal topographers that measure the anterior surface of the cornea. For some time, however, there have been systems that measure both the anterior and posterior surfaces of the cornea. The sub-committee must decide if the scope of this standard should be enlarged to include those systems that can measure both surfaces. If it is decided to enlarge the scope of include measurement of the posterior corneal surface, requirements of the quality of measurement and methods to insure compliance with any requirement agreed upon will be needed.
 - b) Currently there are 3 types of corneal topographers covered by the standard, i) reflection based instruments (Placido disk, etc.) ii) optical cross-sectioning based instruments, and iii) luminous surface based instruments (the luminous surface usually created with the use of fluorescein). For some time now systems employing a fourth method, optical coherence tomography (OCT), have been available in the clinical market. The sub-committee must decide whether to include these OCT systems in the standard. If it is decided to include OCT systems, test devices to insure compliance with measurement required will be needed that are applicable to OCT systems. A definition item would also needed to be drafted and added to the Definitions clause.
 - c) The sub-committee needs to determine if there if any change is needed in the displays recommended by the standard. This can only be determined by soliciting the opinions of the interested parties – clinicians and manufacturers.

International Standards

- 1) Dr. Brown is not in a position to continue as the project leader for the merging of the ISO 15253:2006 and ISO 15254:2002 into ISO 15253. Dr. Citek has been proposed as the new project leader.
- 2) ISO/DIS 8596 (Ed 3): Ophthalmic optics -- Visual acuity testing -- Standard and clinical optotypes received sufficient support in the voting process to proceed to the next level. It is unclear if the FDIS stage will be bypassed in this case. The United States abstained in this voting process because the standard, in our opinion is not complete for use in this country.
- 3) Dr. Bruce Drum will report to sub-committee on the progress of the project group for revision of ISO 15004-2 - Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection.