

SC 6 Agenda

February 26, 2018 meeting of ASC SC6 – Instruments and Low Vision Devices

ANSI Standards published since the last meeting

Z80.37-2017 – Slit-lamp microscopes

Z80.38-2017 – Light hazards for operation microscopes

Other ANSI Standard under consideration

Z80.17-2013 – Focimeters (re-issued without revision; review due in 2018)

Topics to cover:

ANSI Standards currently under review

1) ANSI Z80.10 – Tonometers

A PINS has been filed for this work item and the committee can work on any revisions it considers appropriate. The committee members are invited to submit to all other members their suggestions for revision.

2) ANSI Z80.23 – Corneal topographers - At the last meeting these proposed new items for this standard were discussed;

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 need 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.

The attached document is a revised version of ANSI Z80.23 that includes the additions recommended by the committee to this standard to covering the above items. At this meeting we will consider if this revision can be submitted as a revision to the standard.

A PINS document has been filed for this work item.

International Standards

1) Revision of ISO 15004-2

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.

Several technical matters having to do with the setting of limits for photochemical hazard to the retinal and thermal hazard to the retina will be discussed. These topics also apply to ANSI Z80.36 – 2016 (which is not currently under review) and so will also have to be considered with respect to this standard. They include;

- a) Wavelength weighting table values for thermal retinal hazard, $R(\lambda)$, with consideration for the ocular transmission and retinal pigment epithelial (RPE) absorption in the visible and near infrared portion of the spectrum
- b) Area weighting for radiant exposure of the RPE cells for beam areas less than the area of a cell and for exposure times for which no eye movement is likely. This includes scanning system where the eye can move during the scan but due to the speed of the scan the exposure time for an individual RPE cell is very short.
- c) Group 1 continuous source instrument limit for retinal photochemical hazard – This limit is currently is not in accord with the use of a maximum expected exposure time of 1 hour and a radiant exposure limit of 2.2 J/cm^2
- d) Wavelength weighting table values for retinal photochemical hazard limits for aphakic eyes, $A(\lambda)$. Currently the weighting at 440 nm, the reference wavelength, is the same for aphakic and phakic eyes whereas it is known that the ocular transmission value is quite different at 440 nm for these two cases in that there is no crystalline lens in the aphakic eye.
- e) Methods to assess the retinal exposure for an instrument whose source cannot be considered conceptually as having a radiance – such as certain laser sources where it is better to use a model eye and measure the expected retinal irradiance directly.