Comments on	Title	Date of Comments
Draft ANSI Z80.35 Rev 05	EDF Lenses	January 23, 2018

Clause	Proposed Change	Technical Rationale Supporting Change	Source	Meeting Notes	Comments
Section 4.1, 6.1, 7.1	Delete the word “assembled”	“Final form” should suffice	Dr. Carl Tubbs		
General	Change word “Distance” to “far” throughout document	“Far” is a more specific term	Dr. Carl Tubbs		
Section 5.2.1	Limit comparison to Multifocal IOL to only bullet (c) unwanted optical/ visual effects.	Only the unwanted optical/ visual effects evaluation needs a multifocal IOL as an upper bound comparison.	October 2017 Optical Teleconference meeting		
Section 5.2.2	Suggest removing “Note 2”. If EDF powers are labelled inconsistently across IOL companies (instead of defined as in Note 1), this will certainly lead to errors in IOL power selection by clinicians and may make bench and clinical testing more confusing when IOLs are compared.	To ensure consistency of dioptric power labelling across EDF lenses.	Dr. Carl Tubbs		
Section 5.2.3	In the last paragraph, add MTF requirement as follows: “The MTF shall be greater than or equal to 70 % of the maximum theoretically attainable modulation for the specific IOL design.”	MTF requirement per ISO 11979-2, 4.3.4.1.	Alcon	Editorial: Does the first sentence referencing 11979-2 cover this proposal?	
Section 5.2.4	Add ISO 11979-2 for requirement	Harmonize with ISO	Alcon	Editorial: ANSI Z80.7, section 5.2.3 includes references to ISO 11979-2.	

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Section 7	Can we harmonize these requirements with ISO?	Harmonization with ISO	Alcon	Editorial: ANSI Z80.7 refers to ISO 11979-5, but the information is organized differently between the two documents. We can add ISO 11979-5 to Section 7 requirements.	
7.2 (Technical)	Replace with: "The general guidelines in 7.2 of ANSI Z80.7 shall apply."	Simplify and align with other standards.	J&J	Editorial: Recommend to accept proposal as the ANSI Z80.7 section 7.2 has the same information as the EDF Z80.35 section 7.2.	
Section 7.4	Add ISO 11979-5 to requirements	Harmonize with ISO	Alcon		
Section 7.4	*"Consideration shall be given to methods that use solvents that dissolve the contaminating materials and that have a detection limit of 0.2 µg/lens or 10µg/g. "* Does the	Clarification	Dr. Carl Tubbs	This is the same language in Z80.12 Multifocal IOLs	

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	detection limit apply to the solvent or to the contaminants, should there not be a risk assessment tolerance based on the type and toxicity of the identified contaminant?				
10.2.1 2nd paragraph	Recommend making this a "Note" as the pilot study or phased approach is optional.	Normative sections shall not have optional language, except in notes.	Dr. Carl Tubbs		
Section 11	Can an existing document be referenced rather than creating a separate Annex For EDF?	Simplify standard	Alcon	Editorial: ISO 11979-4 can be referenced, but the following are missing in the ISO document: 1. Spectral transmittance 2. MTF graph for EDF IOLs 3. Power constant 4. US federal law statement 5. Adverse events 6. Clinical investigation	

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				of EDF lens 7. Patient labeling (D.5) in entirety	
B.1.1 last paragraph	Reword *"Additional assessments may be necessary, based upon risk analysis or for unusual designs such as non-rotationally symmetric lenses."* to *"Based on risk analysis, additional clinical assessments may be necessary (such as in cases of non-rotationally symmetric IOLs). "*	For clarity	Dr. Carl Tubbs		
B.2 1st paragraph	Rephrase to "…adverse events tabulated in ISO 11979-7 ~~"grid"~~"; in order to avoid the word "grid" here and in rest of the paragraph.	To avoid the word "grid"	Dr. Carl Tubbs		
B.2 2nd paragraph	Reword to "*Effectiveness should be demonstrated by the assessments listed in B.1.1. The sample size for the study should be adequate to detect adverse events with an expected rate of 1% or greater. If the EDF IOL has no approved monofocal parent, then 300 evaluable investigational device subjects available at all scheduled visits in the EDF IOL group are needed, and if the EDF IOL is a modification of an approved monofocal IOL, a sample size of 100 device subjects may be sufficient for*	For clarity	Dr. Carl Tubbs		

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	the clinical assessments."				
B.3 last paragraph	Change to "*Recruitment should plan for the loss of no more than 10% of the study population at the one year time point."*	For clarity	Dr. Carl Tubbs		
B4.3 Contrast Sensitivity	Change the verbiage "Testing should be performed once and then repeated…" to "To improve repeatability, testing may be performed once and then repeated…"	Not all contrast sensitivity testing system need average of two measurements.	J&J		
B.5.2	Align verbiage for intermediate 10% contrast testing with the FDA-AAO consensus document.	For harmonization with the FDA-AAO consensus document. *"Ophthalmology. 2017 Jan;124(1):139-141."*	FDA		
Annex D	Consider adding how determined, or graphical display of the labelled IOL power on the defocus curve or the MTF curve in D.4.	Need easy way for clinician to select IOL power in consistent fashion.	Dr. Carl Tubbs		