ORLAB Technical Note

Ophthalmic Product Series

Issue 7

A series of technical notes to aid understanding of standards, reasons for failure to comply and hints on avoiding the problem.

Accreditation number 1923

Accredited since 1985

Non-prescription eye protectors with powered lenses.

Scope

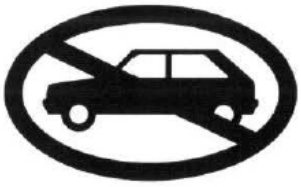
The Technical Note covers the issue of eye protectors, sunglasses and fashion spectacles into which the manufacturer has intentionally included refractive power over all or part of the lens that was not prescribed by an eyecare professional. "sunglasses" should be taken to mean "sunglasses and fashion spectacles" in this note.

Background

Historically, the eye protection and sunglass industries have supplied products with nominally zero power ("plano" or "afocal"). These are the subject of AS/NZS 1337.1 and AS/NZS 1067 respectively. Eye protection and sunglasses that incorporate a prescribed optical correction are the subject of AS/NZS 1337.6 and AS/NZS ISO 21987. For lenses that have intentional power, the distinction needs to be made between those whose power is set by prescription from an eyecare professional.

More recently, the borderline has been blurred by marketing of ready-to-wear reading spectacles. While it is often claimed that these are simply magnifiers and that they do not correct a defect of sight, the fact of the matter is that the magnification that they provide is minimal and their real function is to allow the wearer to overcome the progressive loss of ability to focus at near (presbyopia) that affects us all (like death and taxes!). They are the subject of AS/NZS ISO 16034. The standard "specifies the minimum requirements for complete single-vision ready-to-wear near-vision spectacles." It also states (Clause 1) "These spectacles are not intended for regular use without the approval of an eyecare professional." The standard also requires the following warning symbol and working on a label or swing-tag.

WARNING



- For near-vision and reading use only
- Not for regular use without the approval of an eyecare professional
- Not for driving or vehicle operation
- Not for distance vision
- Not for use as eye protection

The current situation

It seems that there are now available ready-made (not to prescription) bifocal eye protectors and sunglasses, progressive addition and degressive eye protectors. Bifocal lenses have a plano distance portion and a segment with positive power, usually a D shaped segment. Progressive addition lenses gradually increase in power going from plano at the distance visual point to the addition at the near visual point. Degressive lenses have a power that is intended for near vision and the power gradually reduces going from the near visual point to the distance visual point. They do not normally reach zero power in the distance portion so they are usually for intermediate and near distances and will not provide clear vision in the distance.

Dilemma no.1: existing standards

In AS/NZS 1067 the scope includes

> *This Standard specifies minimum requirements for sunglasses and sunglass lenses of nominal plano power, and which are not prescription lenses, intended for protection against solar radiation for general use, for social and domestic purposes, including road use and driving.*
>
> *This Standard applies to the following:*
>
> *(a) Spectacles comprising tinted lenses of nominal zero power mounted in a spectacle frame.*
>
> *(b) Individual tinted lenses of nominal zero power intended for use in sunglasses.*
>
> *(c) Rimless sunshields and one piece visors.*
>
> *(d) Clip-on and slip-on type sunglasses.*
>
> *(e) Children's sunglasses.*

This means that lenses with power unambiguously do not come within the scope of this standard.

In AS/NZS 1337.1 the scope includes

> *This Standard specifies minimum requirements for non-prescription eye and face protectors and associated oculars. They are designed to provide protection for the eyes and faces of persons against common occupational hazards such as flying particles and fragments, dusts, splashing materials and molten metals, harmful gases, vapours and aerosols. Requirements for optical qualities and low,*

medium, high and very high impact resistance are given and appendices describing appropriate test methods are included in this Standard.

Requirements for prescription-eye protectors against low and medium impact are given in AS/NZS 1337.6. Requirements for eye protectors against laser radiation are given in AS/NZS 1337, Parts 4 and 5.

While the requirement to be nominally plano is not explicitly in the scope, it is contained in the requirements of Clause 2.4.7 and means that lenses with power do not come within the scope of this standard either.

In AS/NZS 1337.6 the Scope includes

This Standard specifies minimum requirements for eye protectors fitted with prescription lenses intended to provide low or medium impact eye protection from flying particles and fragments in occupational situations.

This means that lenses that are not prescribed do not come within the scope of this standard.

AS/NZS ISO 16034, as indicated earlier, only applies to single vision lenses.

So we are left with the situation that we have no standard that is applicable to these products.

Dilemma no. 2: test methods

It is possible to use (and adapt if necessary) the test methods and acceptance criteria from the standards and apply them to such products. A testing authority (such as ORLAB) is permitted to report that a method has been used and the acceptance criteria met. It may not, however, report compliance with the standard if the product is not in the scope or the test method has been varied.

Using the methods of AS/NZS 1067 or AS/NZS 1337.1 to assess robustness and lens retention or impact strength, respectively, is straightforward.

However, the methods of AS/NZS ISO 21987 as applied to refractive power are more problematic.

With bifocals, the checking of the location of the segment compared with the supplied parameters is part of the method in the standard. This means that the manufacturer needs to supply the test laboratory with those parameters as well as the inter-pupillary distance.

This situation is also true of the progressive addition lenses except that the checking of the power requires knowledge of the location of the distance and near reference points and the checking of the position of the top of the progression all require observation of reference points and design identifiers marked on the lenses (as required in AS/NZS ISO 21987). In our experience the reference points may be absent or difficult to observe, particularly if the lens was marked before hard coating because the hard coat tends to fill in the marking.

Degressive lenses have no markings by which to identify a distance reference point and there is no part of the lens that is plano for distance anyway. There is no way of checking that the lens is as specified, you get what the manufacturer says it is. In addition, the wearer who needs to see clearly in the distance and be protected will have to take them off and carry a pair of plano eye protectors to replace them so they are not left without protection.

Dilemma no. 3: testing and compliance

It could be commented that Europe seems to have overcome these problems and such products have been marked as complying with EN 166. This is true. Our interpretation is that they fall outside the scope of EN 166 too.

However, the testing and compliance infrastructure in Europe is somewhat different from Australia. In Australia there is a clear distinction between compliance authorities (such as SAIGlobal and BSI Benchmark) and testing authorities (such as ORLAB). The compliance authorities do have some testing facilities but mainly subcontract that work to testing authorities such as ORLAB and they are expected to use ISO 17025 accredited laboratories unless none is available. Since ORLAB is accredited (by NATA http://www.nata.com.au) to test to AS/NZS 1067, AS/NZS 1337.1 & .6, AS/NZS ISO 21987 and AS/NZS ISO 16034, an accredited laboratory is available. Compliance authorities are accredited by JAS-ANZ (www.jas-anz.com.au) to ISO/IEC 17065.

ISO 17025 places restrictions on how accredited labs operate, which includes stating compliance to a standard only when the test method has been followed without amendment. In other words, ORLAB cannot unilaterally amend a test method and then report compliance. Compliance authorities have more latitude to vary things.

In Europe there is a system of notified bodies. These often combine the functions of compliance and test authorities and, as such, have the extra latitude for interpretation. Not all notified bodies are ISO 17025 accredited. In addition, the notified bodies that do their own personal protective equipment testing, do communicate with one another about difficulties with standards and may agree on an interpretation or variation of a test method amongst themselves (Secret European Business??).

We also get the strong impression, from discussion with other testing laboratories in Europe and the USA, that the NATA interpretation of ISO 17025 is generally more stringent than that of some overseas accreditation authorities.

Issues and concerns

There are some issues and concerns that eyecare and workplace safety professionals have about these products. We have taken the view that this Technote is not the place to air that discussion.

Summary and resolution

If it seems that, on occasions, ORLAB appears dogmatic or inflexible on matters, this is not of our making but a consequence of the Australian accreditation system.

The most satisfactory solution would be for someone to propose a project to Standards Australia to prepare a standard for such products.
http://www.standards.org.au/StandardsDevelopment/Developing_Standards/Pages/Proposing-a-project.aspx

This is the forum for the discussion of the issues and concerns. Until such a process has been undertaken, the guide to selection and use of eye protection (AS/NZS 1336) cannot be amended to provide guidance on the selection and use of such products and any labelling and/or warning requirements applied (as in the other standards). At this stage AS/NZS 1336 is silent on the matter.

In the meantime, we understand that there is an option with, at least, SAI Global to have such products tested against your own technical specification, which may include the test methods and compliance requirements of these standards. ORLAB can undertake the testing with the nominated methods for such a process, it is only the statement of compliance with the standard(s) that will be absent from the report.

References

AS/NZS 1336:2014 Eye and face protection–Guidelines.

AS/NZS 1337.1:2010 Personal eye protection Part 1: Eye and face protectors for occupational applications.

AS/NZS 1337.6:2012 Personal eye protection Part 6: Prescription eye protectors against low and medium impact.

AS/NZS ISO 16034:2011 Ophthalmic optics-Specifications for single-vision ready-to-wear near-vision spectacles.

AS/NZS ISO 21987:2011 Ophthalmic optics-Mounted spectacle lens.

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories.

ISO/IEC 17065:2012 Conformity assessment - Requirements for bodies certifying products, processes and services.

