LENS IMPACT RESISTANCE TESTING PLAN
FOR STREET/DRESS EYEWEAR (NOT FOR INDUSTRIAL EYEWEAR)

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THE VISION COUNCIL

Lens Impact Resistance Testing Plan

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Forward

The Vision Council (TVC) has developed a plan for labs that need to impact test plastic lenses in accordance with FDA requirements. The step-by-step procedures may be used to test dress wear plastic prescription lenses. This plan should not be used for glass or industrial safety lenses.

TVC discussions with the FDA have resulted in the simplified testing plan. This sampling method will make testing even easier than before. In addition, for some labs the number of lenses tested will be reduced.

The program is based on FDA regulation 21 CFR 801.410 and the FDA Q&A on lens impact resistance (dated 1987 and Sept 2010). The plan uses recognized sampling methods for assuring desired LTPD and AQL. FDA expects all sampling plans to assure ongoing consumer protection by providing 15% LTPD. This revision of the TVC Testing Plan includes sampling to achieve that goal.

Please be aware that although this program has been reviewed by the FDA, the FDA does not provide specific acceptance or approval. The FDA requirement can be met by methods other than those discussed here. Each manufacturer or lab must choose the method that best serves their business. The VC has produced a document that comments on the FDA Q&A of 2010.

Comments about or suggested changes to this document should be sent to:

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The Testing Plan

Assuring lens impact resistance means more than drop-ball testing a few lenses. How you select those test lenses and how you respond to any failures are critical parts of any testing program. In addition, you should have routine quality controls in place that will find most non-conforming lenses before they reach the shipping department. Thickness measurement and cosmetic flaw inspection are excellent controls.

The sampling plan presented here is based on achieving 15% LTPD and AQL better than 6.5. LTPD stands for Lot Tolerance Percent Defective and is intended to measure the level of consumer protection. AQL stands for Acceptance Quality Limit and measures the product quality produced by the lab. Experience has shown that very few lenses will fail the drop-ball test. During testing, lens failure should be infrequent. You should expect to produce passing batches of lenses using either sampling plan.

Part I of this document tells you how to conduct testing under the TVC plan.

Part II provides sample quantities and acceptance criteria.

Part I – How to Test

1. Define a batch
A batch is defined as one day or one week of production of all processed plastic lenses. This is further explained in Part II. The testing plan and the batch definition are intended for use by the majority of lens labs. If your business is significantly different you should evaluate the appropriateness of these plans before using them.
Both sampling plans require collecting samples from your lab's entire plastic lens production including all materials, configurations and processes. The inclusion all lens types in the batch assures that, over time, all of your production is tested. Weak lenses caused by changes anywhere in the lab will eventually be detected.

2. Selecting the lenses you will test
The test samples should be representative of your lab's typical production mix of Rx powers, materials, coating options, etc. You may accomplish this by randomly selecting sample lenses from your entire production or by selecting random sample lenses from each product type in accordance with your sales mix. For example, if certain products take different routes through the lab the second approach may result in a more representative selection from all product types. Most lenses are not cosmetically marked or weakened by the drop-ball test. AR coated lenses, however, may be marked by the test. Another source of lenses for test is from yield loss lenses that do not have visible defects such as cracks or scratches or are too thin (off-power or off-axis would be good candidates).

3. What about AR coated lenses?
The outside coating services you use for anti-reflection, mirror, etc. are, by FDA definition, a "manufacturer" and have a responsibility for assuring impact resistance. Either they test for you or you test their work. You can have cosmetic or power reject lenses coated by your service provider and then test these rather than customer's lenses. This is advisable because the impact test will likely damage the coating and a tested lens might not be saleable. The number and type of lenses should be in accordance with your normal AR sales mix.

4. Documentation is required
You should record how you have defined your batch. If you change the batch definition, record the change and your reasons for doing so. For example: "The Acme Optical lab defines its production batch for the purposes of impact testing as one day's production of all dress-wear plastic prescription lenses for which the FDA defines our lab as the manufacturer." Another example is: "We include in this batch lenses sent to outside coating services that are returned to us for shipment to our customers." Test results for each batch should be recorded showing the date, the name of the person that performed the test, the quantity of lenses tested and if the batch was accepted or rejected. It is not necessary to record the lens power, lens type or other attributes of individual test samples. We recommend recording the required information on a simple form. This information is useful in determining how well your process is operating.

5. Individual lens failures
You will on occasion break a lens. The sampling plan you select specifies how many lenses can fail in an acceptable batch. If an individual lens fails the impact test, it does not automatically mean the batch failed. Although the batch may not have failed, it is important to immediately investigate the cause of the lens failure. Make a note as to what product type failed and the center thickness and coatings. This is for your own reference and is not part of the required documentation. If the thickness is below your minimum the cause of failure is obvious. If the cause is not obvious you may wish to impact test a few more lenses of the same configuration. Do this testing separate from your normal sample. If additional lenses break contact the manufacturers of the lens, coating and processing equipment involved. Occasionally, a combination of material, coating and processing technique can result in reduced impact resistance. Such occurrences are rare. When they do occur you must find and correct the problem.

6. What to do if a batch fails
Do not simply draw a second set of samples and repeat the test. Find the cause of the failure and take corrective action. First verify that the failed lenses were in an appropriate condition to be tested, i.e. the lens center thickness, average thickness, edge quality, rear surface quality were all normal for shipment to customers. If the failed lenses were obviously unsuitable, select a second set of sample lenses and retest the batch. Failure of a batch without an obvious reason is extremely unlikely. Should this happen, you must investigate immediately. Identify common attributes of the failed lens samples such as material and work. Contact the manufacturer of the lens substrate, the processing equipment and of any coating applied. Retain the broken lenses for more in-depth inspection. Recall and 100% inspection of the batch is one option if your investigation indicates this is necessary for consumer protection.

A leading expert on FDA-required testing of medical devices offers the following advice: “When a lot is rejected, it is not expected that the entire lot will automatically be recalled or inspected. Instead an investigation as to the nature and cause of the failure(s) should be performed. Sometimes additional testing is performed as part of this investigation. A key consideration on how to proceed is whether a root cause can be identified which isolates the problem to a subset of the material. The FDA looks for a decision process that is driven by logic, is performed consistently, and is well documented. Of course, if warranted, actions like recalls of the affected product should be taken.”

7. Isolating problematic products
It would be atypical for a lens type to be unable to meet the FDA impact resistance regulation. If, however, it appears this may be the case, the product should be excluded from your impact batch and shipments of this lens type held until the problem is resolved. If you choose to continue producing this product after the problem is corrected, we recommend you set up a separate batch, either daily or weekly depending on the quantity produced until confidence in the product is high. Only then should you include this product in your regular impact test batch.

Part II – Sampling

1. Introduction
The plan is based on 15% LTPD (lot tolerance percent defective). All sample sizes in the plan provide better than 6.5 AQL.

2. Determining the sample size for your batch
Use a one-week batch and test every week. The same sample size is used for any batch size making administration easy. The Accept number is the number of sample failures that are permitted in an acceptable batch. All five sample sizes provide 15% LTPD. However the smaller sample sizes are more likely to result in rejection of some batches because the number of lens failures allowed is very low. If you are comfortable dealing with the possibility of a rejected batch, you might select one of the smaller sample sizes. Note that if you select a 15 lens sample a single lens failure means the one week batch is rejected. Review paragraph number 6 in Part I above for advice on what to do if a batch fails.

Samples	Accept
15	0
25	1
34	2
43	3
52	4

*__An Example__
A lab chooses to use the 15 lens sample size. This requires testing 15 sample lenses each week. The impact test samples may be drawn from normal process lens ‘breakage’ if they are representative of production. The batch is accepted with zero failed lenses. It is rejected if 1 or more of the 15 samples fail. Batch rejection requires an immediate investigation of the cause and corrective action. Recall of the batch is not mandated.