LENS IMPACT RESISTANCE COMPLIANCE GUIDE

FOR STREET/DRESS EYEWEAR (NOT FOR INDUSTRIAL EYEWEAR)

DECEMBER 2013

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TVC Lens Impact Resistance Compliance Guide Introduction

Spectacle lens materials, fabrication, and delivery have taken on many new forms over the last several years. When the FDA impact regulations took effect the only lens materials available were glass and hard resin. Today the choice of materials is much broader. Production of finished lenses takes many forms; from traditional surfacing methods to in-office casting or lamination. The definition of manufacturer has been expanded to include such operations as grinding, coating or rendering a lens impact resistant. These new manufacturers as well as the traditional manufacturers must know and understand their responsibilities for impact testing. Lastly, the FDA regulation (CFR 801.410), adopted in 1971, has provided the industry with a successful method of protecting the eyewear consumer. Considering the accelerating state of the art, The Vision Council maintains this guide to address the issues of new materials, new processes, and new delivery systems.

Purpose

The purpose of this guide is to provide the ophthalmic industry with a document detailing the rules, regulations, and practices necessary to ensure a manufacturer's compliance with the FDA Impact Resistance Standard. This guide was prepared by the Lens Technical Committee of The Vision Council. It is intended that this book contains up-to-date information, to ensure a manufacturer's knowledge of FDA's impact compliance regulations.

This 2012 printing contains some slight editing changes for consistency. There are no substantive changes to the guidelines presented in this edition of this work. It is the intent of the committee to make revisions as regulations and practices change. This guide is provided for information only, and is not a standard or a required method of compliance.

New Materials

New materials such as polycarbonate, hard-resin-like high-index plastics, and new types of glass have also entered the market. Many of these materials require modified surfacing processes and coatings and, as a result, have their surfaces altered by the processor during coating. The materials also have different relative impact strengths and are affected differently by processing, scratch resistant and/or anti-reflection coating. Therefore, the original manufacturer cannot warrant the final lens' impact resistance via factory impact testing. In this case, the secondary processor becomes the manufacturer and must assume manufacturer's responsibilities. State or local laws may also impose additional restrictions on the impact performance of spectacle lens materials. This guide lists some statutes where special impact resistance is required, but each manufacturer should check relevant state laws to ensure compliance.

Background

The FDA impact-resistance regulation has been, and continues to be, a quiet success. It has protected consumers, minimized the need for manufacturers to wrestle with more detailed government regulations, and carried out the government's duty to protect its citizens. It is worthwhile examining how this happened. Impact-resistance dress wear lenses were in the market long before the FDA regulation of l971. The first type of ophthalmic lenses to be heat-treated for impact resistance were industrial safety lenses of 3mm thickness which was taking place for plano lenses long before World War II. During the 1940's, the first "air-quenching" (a.k.a., "air-tempering" or "air-hardening") machinery was developed, which allowed changing cycle parameters, depending on Rx and lens configuration: so "Safety-Rx" lenses became important protectors. By 1950, strengthened finished single vision (FSV) dress wear lenses were being offered under trade names like "Tempross," with statements that they should be used for children, athletes, etc., since they were more difficult

to break than regular lenses, and would not break or shatter into “sharply-pointed splinters.” Warnings made it clear that they were not for industrial safety use. Remembering that finished single vision, minus lenses were routinely made at an average center thickness of 0.6mm, we know that they possessed much less strength than those which we deal with today. As knowledge of the heat-treating process increased, factory-finished glass lens series were designed and 2mm center thickness to allow better strengthening, as impact strength which can be obtained by air-quenching varies approximately as the square of the thickness. At the time the United States of America Standards Institute (later ANSI) published USAS Z80.1-l 964, “Prescription Requirements for First Quality Glass Ophthalmic Lenses” the “Dress Eyewear Heat-Treated Lens” was defined as “a lens of 2mm minimum thickness that has been heat treated to withstand a specific impact test.” The impact test was a 1/2 inch steel ball dropped 50 inches for notched or drilled lenses and a 5/8 inch ball for other lenses. So, a 5/8 inch dropped-ball test was established practice, and the FDA wished to set a floor under the impact resistance of spectacle lenses.

When the FDA regulation went into effect in 1971, it gave a tremendous boost to the use of hard-resin lenses for two reasons. First, fashion was calling for larger lenses, and second, the FDA regulations were written so that drop-ball test compliance for hard-resin lenses could be accomplished by testing a significant sample from each production batch (which was the procedure used by the large-volume primary lens manufacturers), and most glass lenses had to be “100% drop-balled” at the laboratory. A new chemical strengthening method for glass lenses was introduced which was much more effective than heat-treating for thin lenses. Because of liability consideration however, labs were reluctant to drop below the 2mm minimum thickness. It is interesting to note that this minimum thickness was never used in FDA regulations, but was required in ANSI Z80.1-1972, recommended in ANSI Z80.1-1979, and dropped from ANSI Z80.1- 1987.

The situation was still relatively simple until about 1980 when new types of plastic lenses and abrasion-resistant coatings began to appear. While the first new plastic lens material of consequence was polycarbonate, which had high impact resistance when coated, it was found that some types of scratch resistant coatings could weaken hard-resin lenses to the point where they would fail the FDA test. The reason appeared to be that good scratch resistance coatings were made of hard, brittle materials which, if cracked by impact, could in turn initiate cracking in the substrate lens. A great deal of work was done to overcome this problem while retaining the benefit of much-improved scratch resistance.
However, as the decade of the 1980’s passed the situation became still more complicated. New products, new coatings, and new processes were appearing at a more rapid rate than ever before. These included a large variety of “high-index” lens materials designed to process like hard resin while offering the potential for thinner centers or edges that accompanies high refractive index. These lens materials had different impact-resistance properties than hard resin. Many of these new materials were imported.
Some manufacturers were not initially aware of the complications involved in making sure impact-resistant lenses reached the consumer. Anti-reflection coatings became more popular in this country because scientists learned how to make AR coatings adhere to plastic lenses. These were being applied over scratch resistant coatings in some cases. New processes being used today often include small-scale “in-house” casting and/or coating operations. Since these operations affect the impact resistance of the finished spectacle lens, those employing them become “manufacturers” as far as the FDA regulations are concerned and are required to follow the FDA rules. The problems mentioned in the previous paragraphs have been or are being successfully solved, but there has been substantial confusion and wasted effort in some cases because of misunderstanding of FDA regulations and their detailed implementation.

Optical Standards

Any manufacturer of ophthalmic lenses must follow specific criteria regarding both the quality and safety of lenses. Some of the standards for ophthalmic lenses are voluntary but are sufficiently recognized and would be cited in a court of law for either the plaintiff or defendant as the desired level of industry practice. The FDA regulation CFR801.410, however, is the law and must be followed.

ANSI Z80.1

"Recommendations for Prescription Ophthalmic Lenses" or lenses worn under normal conditions rather than for safety or protection from the sun. This standard addresses the aspects of lens optical and cosmetic quality, as well as the definition of optical terms used in conjunction with lenses. Definitions and some procedures are given which will allow measurement to the tolerances specified for each optical characteristic. The impact-resistance recommendations are equal to the FDA regulation. The minimum impact resistance can only be altered by the FDA.

ANSI Z80.3

This standard covers the same information as Z80.1 in relation to "Nonprescription Sunglasses and Fashion Eyewear." Like the Z80.1 standard, the requirements and recommendations for impact resistance can only be altered by the FDA.

ANSI Z87.1

This standard covers very specific rules and recommendations for "Occupational and Educational Eye and Face Protection." It also incorporates the specific prescription requirements and recommendations of the Z80.1 standard. The standard is used by OSHA in their regulations for the protection of workers. The minimum impact resistance can only be altered by the FDA.

ASTM F803

The American Society for Testing and Materials (ASTM) has provided F803-86 as a standard for "Eye Protectors for Use by Players of Racket Sports." This standard specifies the type of eye protectors to be used by players of racquetball, squash, handball, tennis, and badminton. Optical test methods, product marking specifications, performance requirements and mechanical test methods are included in this standard.

ANSI Ophthalmic Standards Summary

For your information, ophthalmic subjects covered by the American National Standards Institute (ANSI) include:

Z80.1 - Recommendations for Prescription Ophthalmic Lenses
Z80.2 - Prescription Requirements for First Quality Rigid Contact Lenses
Z80.3 - Nonprescription Sunglasses and Fashion Eyewear Requirements
Z80.4 - Accessory Solution Use with Contact Lenses made of Conventional Hard Plastic such as Polymethyl Methacrylate
Z80.5 - Dress Ophthalmic Frames
Z80.6 - Physiochemical Properties of Conventional Hard Plastic Contact Lenses
Z80.7 - Ophthalmic - Intraocular Lenses - Optical and Physical Requirements
Z80.8 - Ophthalmics - Soft Contact Lenses - Prescription Requirements
Z80.9 - Low Vision Aids
Z87.1 - Occupational and Educational Eye and Face Protection

Where to Get Standards

The **ANSI** standards may be ordered from: American National Standards Institute, Inc. 11 West 42nd Street New York, NY 10036 Phone: (212) 642-4900, Fax: (212) 302 – 1286, www.ansi.org	The **ASTM** standards may be ordered from: American Society for Testing & Materials 100 Bar Harbor Drive West Conshocken, PA, USA 19428-2959 Phone: (610) 832-9585, Fax: (610) 839-9555, www.astm.org

Federal Regulations

FDA – Good Manufacturing Practices

The Good Manufacturing Practices (GMP) for medical devices[1], which have been promulgated by and are enforced by the Food and Drug Administration, which is part of the United States Department of Health and Human Services. Lens manufacturers must comply with these regulations because FDA has classified ophthalmic lenses as Class I medical devices. The regulations concerning good manufacturing practices are extensive. They set forth the practices for methods used, and the facilities and controls used for the manufacture, packaging, storage, and installation of all finished devices intended for human use.[2] Compliance is mandatory and requires the establishment of specific controls and written record keeping. A complete detailed description of compliance procedures which meet the Good Manufacturing Practice regulations is beyond the scope of this guide.

FDA - Lens Impact Resistance

Testing for impact-resistance is governed by FDA regulations[3] (21 CFR 801.410) and the responsibility for the testing is placed on the manufacturer. Originally created for glass, the “drop-ball” test was believed to be potentially harmful to the surface of plastic lenses. For this reason, the FDA allowed plastic lenses to be impact tested by testing a statistically significant sample of each production “batch” at the factory level. There is a specific protocol for the test method and for the means of arriving at the sample size (number of lenses) for testing a batch of lenses.

FDA 21 CFR 801.410 Definitions

The Manufacturer Is:

“Manufacturer is defined under 21 CFR 820.3(o) and would include the person (or firm) who puts the lens in the form ready for its intended use or who alters the physical or chemical characteristics of the lens by grinding, heat treating, beveling, applying scratch resistant coating, applying anti-reflection coating, cutting, or other pertinent actions. Manufactures of all plastic lenses and non-prescription glass lenses may test at the uncut-finished or finished stage while glass prescription lenses must be tested at the finished stage. Retail laboratories that perform some or all of these processes are manufacturers. For the purpose of 21 CFR 801.410, the term "manufacturer" also includes a company that imports impact resistant lenses for eyeglasses, or who imports finished eyeglasses or sunglasses for resale. (21 CFR 801.410(g))”

The FDA rules required the impact resistance test to be done by the manufacturer. [8]
Applying FDA regulations, the following would fit the definitions of a manufacturer and are subject to the law:

Plastic Lens Casters

Large volume lens manufacturers producing lenses in any variety of materials and laboratories and/or individual dispensers with lens casting equipment.

Lens Molders
Manufacturers producing lenses by using thermoplastic forming methods.

Importer
Finished lenses, Rx lenses and plano lenses (mounted or un-mounted), which are manufactured outside the US are sold routinely in the U.S. The importer or distributor must assume the responsibility of manufacturer and ensure FDA compliance. [9]

Scratch Resistant or Anti-Reflection Coaters
Coatings or surface treatments alter lens surfaces and may affect impact resistance. Therefore, a coater must assume the role and responsibilities of a lens manufacturer; whether domestic or imported.

Plastic and Glass Processor
Producers of plastic or glass lenses to finished prescriptions. The term also includes processing operations that affect the surface quality or the impact strength of lenses; for example surfacing, glass edging, heat, or chemical tempering.

Lamination
Lamination, while not a new technique to produce lenses finished to prescriptions, has become more commercialized today. Lens components may or may not meet impact requirements by themselves. However, those who bond them together are manufacturers and still must comply with FDA regulations.

Other
The term manufacturer may not be limited to the categories listed on the previous page because of continually changing technology.

Impact Resistant Lens:
"A lens capable of withstanding, or having withstood, the drop-ball test, as described in the regulation."

In the Guidance for Industry and FDA Staff - Impact Resistant Lenses: Questions and Answers published by the FDA September 2nd, 2010, Question 51 asks: "Do the impact test regulations apply to retail stores that fabricate lenses?

The FDA Answer is:

> "FDA considers retail stores that fabricate lenses by coating and/or surfacing to be manufacturers of impact-resistant lenses. Therefore, such retailers must document impact resistance (21 CFR 801.410(c)(3)). You may perform impact testing on site or you may contract with a third party testing lab. Retail stores that only perform edging are not considered manufacturers."

What Constitutes an FDA Impact Failure?
"A lens will be considered to have fractured (failed) if it cracks through its entire thickness, including a laminar layer, if any, and across its complete diameter into two or more pieces as if any lens material visible to the naked eye becomes detached from the ocular surface." [10]

FDA Lens Testing Requirements

Who Must Test
All manufacturers must test.

When to Test Lenses
The intent of the regulation is to ensure that all lenses are impact resistant after the lens is finished.
Does testing by the semi-finished lens manufacturer or previous processing manufacturer exempt you from testing? The answer is No. In fact, it is generally felt that you should also inform subsequent processors about the regulation and their responsibility.
A manufacturer furnishing lenses to a subsequent processor who will render the lens impact resistant in its finished form, need not impact test the lenses. This decision should be considered carefully, given legal and implied impact responsibilities. Ensuring that the lenses have left your possession in an impact resistant condition may be prudent if technology allows.

What to Test
Testing for impact resistance compliance must be carried out on lenses “in uncut-finished or finished form.” (21 C. F. R. 801.410(c)(3))

Registration

Medical Device Manufacturer
The FDA requires a manufacturer to register as a Medical Device Manufacturer (MDM) because spectacle lenses are classified as a Class 1 medical device. Additionally, Medical Device Manufacturers must also comply with the regulations for Medical Device Reporting (MDR).[11]

The medical device reporting regulations[12] require device manufacturers to report to the FDA “whenever the manufacturer becomes aware that (1) one of its marketed devices may have caused or (2) contributed to a death or serious injury or has malfunctioned and that the device or any other device marketed by the importer would be likely to cause or contribute to a death or serious injury.” [13]

These reports must be made to the FDA as soon as possible after the information has been obtained, but no later than 5 days of initial receipt by telephone, and follow up with a written report to the FDA within 15 working days of initial receipt of the information (21 C.F.R. 803.24(b)(1)-(b)(2)).

It should be noted that these reports become available to the public and should be submitted only after consultation with legal counsel.

The following publications are valuable sources of information for manufacturers and importers of lenses to assist in compliance with the Medical Device Regulations.

FDA 85-4160
Import/Export - Regulatory Requirements for Medical Devices
(PB 86-102480)

FDA 85-4194
An Overview of the Medical Device Reporting Regulation
(PB 86109709/AS)
FDA 85-4196
Medical Device Reporting and the Health Care Professional (pamphlet)
FDA 87-4199
Medical Device Establishment Registration: Information and Instructions
(PB 88-123666/AS (Supersedes FDA 85-4199))
FDA 86-4203
Labeling - Regulatory Requirements for Medical Devices
(GPO 017-012-00327-3 (PB 86-184349/AS))
FDA 87-4002
Guidance for Industry and Staff - Impact Resistant Lenses - Questions and Answers
(Revised September 2nd, 2010))
FDA 87-4179
Device Good Manufacturing Practices manual, Nov. 1985
(Revised November 1987 [(GPO 017-012-00330-3 (PB 88-132139)])
FDA 87-4222
An Introduction to Medical Device Regulations
FDA 88-4226
Medical Device Reporting Questions and Answers

Where to Get FDA Documents

The Government Printing Office (GPO) documents may be ordered from: Superintendent of Documents U.S. Government Printing Office Washington, DC 20402 www.access.gpo.gov	The PB Documents may be ordered from: Center for Devices and Radiological Health Food and Drug Administration (HFZ-265) 5600 Fishers Lane Rockville, MD 20857 www.fda.gov/cdrh

The Center for Devices and Radiological Health (CDRH) was formed in 1982 and implements national programs to assure the safety, effectiveness and proper labeling of medical devices.

State Requirements
Individual states also may require registration. For example, in the state of California, a laboratory grinding and finishing lenses must register with the California State Health Services. Please contact the state agency in your state to assure proper registration and compliance.

Importers

Off-shore manufactured lenses must also conform to the import compliance laws of the U.S., and foreign manufacturers are required - to register with FDA. The importer must also be registered with the FDA[14] and assumes responsibility for the impact compliance of imported lenses. [15]

Types of Test Plans

The test plan required will depend upon the raw material from which the lens is manufactured and the type of lens to be tested.

A. 100% of all finished impact resistant glass lens for prescription use must be tested. [16]

B. A statistically significant sample of a production batch may be tested for the following types of lenses:

1. Plastic lenses in uncut-finished or finished form after all processing is completed.
2. Mass produced plano glass lenses for sunglasses in uncut-finished or finished form.

Exceptions

Glass lenses which do not require impact testing are: "prism segment, multifocals, slab-off prisms, lenticular cataracts, iseikonic, depressed segment one-piece multifocal, biconcave, myodisc and minus lenticulars, and custom laminated and cemented assemblies. In addition, raised multifocal lenses need not be tested beyond design testing. Note however, that all of these lenses are required to be made of impact resistant materials or be treated for impact resistance." [17]

Statistical Testing

FDA does not limit manufacturers to any specific sampling plan; however, you should use a valid statistical sampling plan. FDA has recognized the standards below. You may use either of these standards or an equivalent standard.

FDA Regulation 21 C.F.R. 801.410(c)(3) allows the manufacturer to choose a sampling plan like the ANSI/ASQC Z1.4, or other sampling plans shown to be statistically significant. Recently, MIL 105E has been replaced by the near identical ANSI/ASQ C Z1.4. The FDA booklet, "Guidance for Industry and FDA Staff - Impact Resistant Lenses: Questions and Answers published by the FDA September 2nd, 2010", states that a 6.5 AQL with a sampling level of General Level II is an acceptable sampling plan. A statistical test, therefore, is recommended to be at least this stringent.

The following examples are based on ANSI/ASQC Z1.4, Sampling Procedures and Tables for Inspection by Attributes. This procedure is intended for use by the layman and is an introduction to statistical testing.

Batch Size

Some flexibility is allowed by 21 C.F.R. 801.410(c)(3) by the fact that the tester is allowed to define what constitutes a batch of lenses from which a statistically significant sampling can be tested.

For instance, a batch might be:

- A batch of raw material
- Set-up of processing equipment
- Shipment or source of lenses

A batch may also be established based on a convenient time interval for testing such as; shift, a day, a week, etc.

Inspection Level
The Inspection Level is determined by the relationship between the batch size and the sample size. The batch size selected is used to find the "sample size code letter" of the Inspection Level (See sample size code letters table ANSI/ASQC Z1.4,). This letter is then used in other tables. As previously stated, General Inspection Level II is an acceptable plan per the FDA handbook.

Sample Plan Confidence
Three sampling plans are provided by ANSI/ASQC Z1.4: Normal, Tightened and Reduced. They are designed to provide the manufacturer with a constant level of confidence (at one value of AQL) that the sample is truly representative of the product, taking into account the history of previous batches.
It is typical for the Normal level to be used initially and when appropriate one might switch to Tightened or reduced sampling plans. ANSI/ASQC Z1.4, Refer to Table of Contents for; Single Sampling Plan for Normal Inspection of General Level II.

Acceptable Quality Level (AQL)
Next, the Acceptable Quality Level (AQL) to ensure compliance with the regulation is selected. As noted previously, the 6.5 AQL is acceptable. Individual circumstances may warrant lower, more stringent AQL levels.

Pass or Fail
From the test results, determine if the number of rejects is within an acceptable or reject able level. (See Appendix D)

Example
Using your copy of ANSI …The following example illustrates a simple case of approximately 1,000 units per shift where the shift has been designated as a batch.
From table, Sample Size Code Letters
Batch size: 1,000 units (See 501 to 1200; General Level II, find "J" as the Sample Size Code Letter)
From Appendix D, Single Sampling Plan for Normal Inspection (See Sample Size Code Letter "J")

1. Find 80 unit sample size
2. Under column heading AQL (normal inspection) 6.5. Accept batch on 10 or fewer rejects. Reject batch on 11 or more rejects. Therefore, if from this 1,000 unit batch, there were 5 impact failures in the 80 unit sample size, the batch would pass the FDA requirement for impact resistance.

Another example of a Sampling Plan can be found in The Vision Council Document: Lens Impact Resistance Testing Plan

Routine Testing

If batches of lenses are passing consistently at the normal size plan it may be prudent to proceed to the Reduced Sampling Plan, provided that the requirements of the switching procedures are met. Appendix E, Single Sampling Plan for Reduced Inspection in the Master Table shows that a sample size of 32 units would replace the 80 unit sample in the previous example.

It may be possible or necessary to further reduce testing for financial or logistical reasons. This is possible if failure rates are low enough~~,~~. The user should consider the use of "special inspection levels" and the Sample Size Code Letters when special inspection levels are being considered.

Example:

From Appendix C, Sample Size Code Letters, (under Special Inspection levels, level S-3 is chosen for the example batch size of 1,000 units)

1. Find the sample size code letter "E," refer to Single Sampling Plan for Normal Inspection (Master Table).
2. Find "E" and the corresponding sample size of 13, under a 6.5 AQL, the batch would be accepted with 2 failures and rejected on 3 failures.

Batch Failure

Although this document cannot make absolute statements concerning what to do when a batch fails, certain options seem reasonable:

1. Determine if a pattern of increasing lens failures has been developing over time. This may indicate that a processing problem has developed or testing procedures are not consistent.
2. Look for obvious lens surface and edge flaws, or flaws with the test device such as an irregular surface on the steel balls or neoprene gasket.
3. If obvious flaws on the lenses are observed, consider having the batch re-inspected or reworked and retest the remaining batch.
4. If the testing device is flawed, correct the testing device and retest the batch.
5. If no obvious reason for lens failure is found, you should 100% test the batch or scrap it.

Documentation

The FDA requires that records concerning the testing results and a description of the methods and testing apparatus must be maintained for a period of three years. [18] Further, copies of invoices, shipping documents, and records of sale or distribution of all impact resistance lenses, including finished eyeglasses and sunglasses must be kept for a period of three years. [19]

Statistical Testing Summary

The ANSI/ASQC Z1.4 Standard can be purchased from: http://www.ansi.org

Another example of a Sampling Plan can be found in The Vision Council Document: Lens Impact Resistance Testing Plan

New Lens Processing and Materials

Should you be unable to determine if a new product or process requires impact testing, consult your trade association.

Future Issues

The technology involved in making a pair of spectacles, along with other new materials or delivery systems will surely go through changes. This guide will be updated as the need arises to provide the manufacturer with a resource for compliance.

Questions or comments should be forwarded to:

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Footnotes

1. 21 C.F.R. 820
2. 21 C.F.R. 820.1
3. 21 C.F.R. 801.410 (See attached Appendix A)
4. From FDA DEFINITIONS - Manufacturer Is, Question 2, Q&A Pamphlet #1, Page 1; (FDA) 72-4002
5. Question 12, Q&A, Page 7; 21 C.F.R. 801.410
6. Question 12, Q&A, Page 7; 21 C.F.R. 801.410(g)
7. From FDA DEFINITIONS, Manufacturer Is, Point 4; 21 C.F.R. 801.410(f)
8. 21 C.F.R. 801.410(c)(3)
9. 21 C.F.R. 801.410(g)
10. From FDA DEFINITIONS, What Constitutes an Impact Failure, Title 21 C.F.R. 801.410(d)(2)
11. FDA Regulation 21 C.F.R. 807.20 defines who must register as “any owner or operator of an establishment who is engaged in the manufacture, preparation, propagation, compounding or assembly of a device intended for human use is required to register.”
12. 21 C.F.R. 803
13. 21 C.F.R. 803.1
14. 21 C.F.R. 801.40
15. 21 C.F.R. 801.410(g)
16. 21 C.F.R. 801.410(c)(3)
17. 21 C.F.R. 801.410(c)(3)
18. 21 C.F.R. 80l.4l0(f)
19. 21 C. F R 801.410(e)

Appendix A

Federal Regulation on Impact-Resistant Lenses
Code of Federal Regulations
Title 21 - Food and Drugs
Chapter 1 - Food and Drug Administration
PART 801 - Labeling
Subpart H - Special Requirements for Specific Devices

§801.410 Use of impact-resistant lenses in eyeglasses and sunglasses.

(a) Examination of data available on the frequency of eye injuries resulting from the shattering of ordinary crown glass lenses indicates that the use of such lenses constitutes an avoidable hazard to the eye of the wearer.

(b) The consensus of the ophthalmic community is that the number of eye injuries would be substantially reduced by the use in eyeglasses and sunglasses of impact-resistant lenses.

(c) **(1)** To protect the public more adequately from potential eye injury, eyeglasses and sunglasses must be fitted with impact-resistant lenses, except in those cases where the physician or optometrist finds that such lenses will not fulfill the visual requirements of the particular patient, directs in writing the use of other lenses, and gives written notification thereof to the patient.

(2) The physician or optometrist shall have the option of ordering glass lenses, plastic lenses, or laminated glass lenses made impact resistant by any method; however, all such lenses shall be capable of withstanding the impact test described in paragraph (d)(2) of this section.

(3) Each finished impact-resistant glass lens for prescription use shall be individually tested for impact resistance and shall be capable of withstanding the impact test described in paragraph (d)(2) of this section. Raised multifocal lenses shall be impact resistant but need not be tested beyond initial design testing. Prism segment multifocal, slab-off prism, lenticular cataract, iseikonic, depressed segment one-piece multifocal, biconcave, myodisc and minus lenticular, custom laminate and cemented assembly lenses shall be impact resistant but need not be subjected to impact testing. To demonstrate that all other types of impact-resistant lenses, including impact-resistant laminated glass lenses (i.e., lenses other than those described in the three preceding sentences of this paragraph (c)(3)), are capable of withstanding the impact test described in this regulation, the manufacturer of these lenses shall subject to an impact test a statistically significant sampling of lenses from each production batch, and the lenses so tested shall be representative of the finished forms as worn by the wearer, including finished forms that are of minimal lens thickness and have been subjected to any treatment used to impart impact resistance. All nonprescription lenses and plastic prescription lenses tested on the basis of statistical significance shall be tested in uncut finished or finished form.

(d) **(1)** For the purpose of this regulation, the impact test described in paragraph (d)(2) of this section shall be the “referee test,” defined as “one which will be utilized to determine compliance with a regulation.” The referee test provides the Food and Drug Administration with the means of examining a medical device for performance and does not inhibit the manufacturer from using equal or superior test methods. A lens manufacturer shall conduct tests of lenses using the impact test described in paragraph (d)(2) of this section or any equal or superior test. Whatever test is used, the lenses shall be capable of withstanding the impact test described in paragraph (d)(2) of this section if the Food and Drug Administration examines them for performance.

(2) In the impact test, a 5/8-inch steel ball weighing approximately 0.56 ounce is dropped from a height of 50 inches upon the horizontal upper surface of the lens. The ball shall strike within a 5/8-inch diameter circle located at the geometric center of the lens. The ball may be guided but not restricted in its fall by being dropped through a tube extending to within approximately 4 inches of the lens. To pass the test, the lens

must not fracture; for the purpose of this section, a lens will be considered to have fractured if it cracks through its entire thickness, including a laminar layer, if any, and across a complete diameter into two or more separate pieces; or if any lens material visible to the naked eyes becomes detached from the ocular surface. The test shall be conducted with the lens supported by a tube (1-inch inside diameter, 1-1/4 inch outside diameter, and approximately 1-inch high) affixed to a rigid iron or steel base plate. The total weight of the base plate and its rigidly attached fixtures shall be not less than 27 pounds. For lenses of small minimum diameter, a support tube having an outside diameter of less than 1-1/4- inches may be used. The support tube shall be made of rigid acrylic plastic, steel, or other
suitable substance and shall have securely bonded on the top edge a 1/8 by 1/8-inch neoprene gasket having a hardness of 40+5, as determined by ASTM Method D 1415;1 a minimum tensile strength of 1,200 pounds, as determined by ASTM Method D 412; and a minimum ultimate elongation of 400 percent, as determined by ASTM Method D 412 (ASTM Methods D 412 and D 1415 are incorporated by reference). The diameter or contour of the lens support may be modified as necessary so that the 1/8- by 1/8-inch neoprene gasket supports the lens at its periphery.

(e) Copies of invoice(s), shipping document(s), and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, shall be kept and maintained for a period of 3 years; however, the names and addresses of individuals purchasing nonprescription eyeglasses and sunglasses at the retail level need not be kept and maintained by the retailer. The records kept in compliance with this paragraph shall be made available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration or by any other officer or employee acting on behalf of the Secretary of Health and Human Services and such officer or employee shall be permitted to inspect and copy such records, to make such inventories of stock as he deems necessary, and otherwise to check the correctness of such inventories.

(f) In addition, those persons conducting tests in accordance with paragraph (d) of this section shall maintain the results thereof and a description of the test method and of the test apparatus for a period of 3 years. These records shall be made available upon request at any reasonable hour by any officer or employee acting on behalf of the Secretary of Health and Human Services. The persons conducting tests shall permit the officer or employee to inspect and copy the records, to make such inventories of stock as the officer or employee deems necessary, and otherwise to check the correctness of the inventories.

(g) For the purpose of this section, the term “manufacturer” includes an importer for resale. Such importer may have the tests required by paragraph (d) of this section conducted in the country of origin but must make the results thereof available, upon request, to the Food and Drug Administration, as soon as practicable.

(h) All lenses must be impact-resistant except when the physician or optometrist finds that impact resistant lenses will not fulfill the visual requirements for a particular patient.

(i) This statement of policy does not apply to contact lenses.

[1]Copies may be obtained from: American Society for Testing Materials (ASTM), 100 Bar Harbor Drive, West Conshohocken, PA U.S.A. 19428-2959 www.astm.org (Secs. 201, 501, 502, 519, 701(a), 52 Stat. 1040-1042 as amended, 1049-1051 as amended 1055, 90 Stat. 564-565 (21 U.S.C. 321, 351, 352, 3601, 371(a))) [41 FR 6896, Feb. 13, 1976, as amended at 44 FR 20678, Apr. 6, 1979]

Appendix B

Excerpts from ANSI Z1.4

7. Drawing of Samples
When representative sampling is used, the units from each part of the lot or batch shall be selected at random.

7.3 TIME OF SAMPLING
Samples may be drawn after all the units comprising the lot of batch have been assembled, or samples may be drawn during assembly of the lot or batch.

7.4 DOUBLE OR MULTIPLE SAMPLING
When double or multiple sampling is to be used, each sample shall be selected over the entire lot or batch.

8. Normal, Tightened and Reduced Inspection
8.1 INITIATION OF INSPECTION
Normal inspection will be used at the start of inspection unless otherwise directed by the responsible authority.

8.2 CONTINUATION OF INSPECTION
Normal, tightened or reduced inspection shall continue unchanged for each class of defects or defectives on successive lots or batches except where the switching procedures given below require change. The switching procedures shall be applied to each class of defects or defectives independently.

8.3 Switching Procedures
8.3.1 NORMAL TO TIGHTENED
When normal inspection is in effect, tightened inspection shall be instituted when 2 out of 5 consecutive lots or batches have been rejected on original inspection (i.e., ignoring resubmitted lots or batches for this procedure).

8.3.2 TIGHTENED TO NORMAL
When tightened inspection is in effect, normal inspection shall be instituted when 5 consecutive lots or batches have been considered acceptable on original inspection.

8.3.3 NORMAL TO REDUCED
When normal inspection is in effect, reduced inspection shall be instituted providing that all of the following conditions are satisfied:
a. The preceding 10 lots or batches (or more, as indicated by the note to Table VIII) have been on normal inspection and none has been rejected on original inspection; and
b. The total number of defectives (or defects) in the samples from the preceding 10 lots or batches (or such number as was used for condition “a” above) is equal to or less than the applicable number given in table VIII. If double or multiple sampling is in use, all samples inspected should be included, not “first” samples only; and
c. Production is at a steady rate; and
d. Reduced inspection is considered desirable by the responsible authority.

8.3.4 Reduced to Normal

When reduced inspection is in effect, normal inspection shall be instituted if any of the following occur on the original inspection.

a. A lot or batch is rejected.
b. A lot or batch is considered acceptable under the procedures of 10.1.4;or
c. Production becomes irregular or delayed; or
d. Other conditions warrant that normal inspection shall be instituted.

8.4 Discontinuation of Inspection

In the event that 10 consecutive lots or batches remain on tightened inspection (or such other number as many be designated by the responsible authority), inspection under the provisions of this document should be discontinued pending action to improve the quality of submitted material.

Appendix C

Table I-Sample Size Code Letters

See 9.2 and 9.3

Lot Size			Special inspection level				General inspection level		
			S-1	S-2	S-3	S-4	I	II	III
2	to	8	A	A	A	A	A	A	B
9	to	15	A	A	A	A	A	B	C
16	to	25	A	A	B	B	B	C	D
26	to	50	A	B	B	C	C	D	E
51	to	90	B	B	C	C	C	E	F
91	to	150	B	B	C	D	D	F	G
151	to	280	B	C	D	E	E	G	H
281	to	500	B	C	D	E	F	H	J
501	to	1200	C	C	E	F	G	J	K
1201	to	3200	C	D	E	G	H	K	L
3201	to	10000	C	D	F	G	J	L	M
10001	to	35000	C	D	F	H	K	M	N
35001	to	150000	D	E	G	J	L	N	P
150001	to	500000	D	E	G	J	M	P	Q
500001	to	over	D	E	H	K	N	Q	R

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Appendix D

Table II-A - Single sampling plan for normal inspection (Master table)

See 9.4 and 9.5

Sample size code letter	Sample size	0.010	0.015	0.025	0.040	0.065	0.10	0.15	0.25	0.40	0.65	1.0	1.5	2.5	4.0	6.5	10	15	25	40	65	100	150	250	400	650	1000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↓	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31
B	3	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	⇕	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45
C	5	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	⇕	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	↑
D	8	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	⇕	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	↑	↑
E	13	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	⇕	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	↑	↑	↑
F	20	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	⇕	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑
G	32	↓	↓	↓	↓	↓	↓	↓	↓	0 1	⇕	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑
H	50	↓	↓	↓	↓	↓	↓	↓	0 1	⇕	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑
J	80	↓	↓	↓	↓	↓	↓	0 1	⇕	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑
K	125	↓	↓	↓	↓	↓	0 1	⇕	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
L	200	↓	↓	↓	↓	0 1	⇕	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
M	315	↓	↓	↓	0 1	⇕	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
N	500	↓	↓	0 1	⇕	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
P	800	↓	0 1	⇕	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Q	1250	0 1	↑	⇕	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
R	2000	↑	↑	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑

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Single Normal Plan

↓ Use first sampling plan below arrow. If sample size equals, or exceeds, lot or batch size, Do 100% inspection

↑ Use first sample plan above arrow.

Ac Acceptance Number

Re Rejection Number

Appendix E

Table II-C - Single sampling plan for reduced inspection (Master table)

See 9.4 and 9.5

Sample size code letter	Sample size	Acceptable Quality Levels (Reduced Inspection)[t]																									
		0.010	0.015	0.025	0.040	0.065	0.10	0.15	0.25	0.40	0.65	1.0	1.5	2.5	4.0	6.5	10	15	25	40	65	100	150	250	400	650	1000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↓	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31
B	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↕	↓	0 2	1 3	2 4	3 5	5 6	7 8	10 11	14 15	21 22	30 31
C	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↕	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	14 17	21 24	↑
D	3	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↕	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	14 17	21 24	↑	↑
E	5	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↕	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	14 17	21 24	↑	↑	↑
F	8	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↕	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	↑	↑	↑	↑	↑	↑
G	13	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↕	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	↑	↑	↑	↑	↑	↑	↑
H	20	↓	↓	↓	↓	↓	↓	↓	0 1	↕	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	↑	↑	↑	↑	↑	↑	↑	↑
J	32	↓	↓	↓	↓	↓	↓	0 1	↕	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	↑	↑	↑	↑	↑	↑	↑	↑	↑
K	50	↓	↓	↓	↓	↓	0 1	↕	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
L	80	↓	↓	↓	↓	0 1	↕	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
M	125	↓	↓	↓	0 1	↕	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
N	200	↓	↓	0 1	↕	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
P	315	↓	0 1	↕	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Q	500	0 1	↑	↕	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
R	800	↑	↑	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑

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Single Normal Plan

↓ Use first sampling plan below arrow. If sample size equals, or exceeds, lot or batch size, Do 100% inspection

↑ Use first sample plan above arrow.

Ac Acceptance Number

Re Rejection Number

[t] If the exeptance number has been exceeded, but the rejection number has not been reached, accept the lot, but reinstate the normal inspection (See 10.1.4).