Optical Manufacturers Association

OPHTHALMIC GLASS RADIOLOGICAL STANDARD

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OPTICAL MANUFACTURERS ASSOCIATION

OPHTHALMIC GLASS RADIOLOGICAL STANDARD

A. General Provisions

1. Nature

The Standard is a voluntary performance standard developed by the Optical Manufacturers Association.

2. Denomination

The Standard is to be referred to as the "Optical Manufacturers Association Ophthalmic Glass Radiological Standard."

3. Purpose

The purpose of the Standard is to establish a uniform maximum level for radioactive emissions from ophthalmic glass manufactured to conform to the Standard. The Standard is intended to provide producers, distributors, dispensers and users with a common understanding of the radioactivity levels of ophthalmic glass which complies with the Standard.

4. Adoption and Use

The adoption and use of the Standard for any purpose is strictly voluntary. Reference made to the Standard in contracts, labels, invoices or advertising materials may, however, be enforceable through legal channels of federal, state or local laws and regulations. The Optical Manufacturers Association specifically disclaims any and all claim, responsibility or liability arising in any way, or alleged to arise in any way, from the development, promulgation, advertising promotion or use of the Standard.

5. Effective Date

The provisions of the Standard are applicable to ophthalmic glass manufactured in conformity with the Standard subsequent to November 1, 1975.

6. Amendment

The Standard is subject to amendment or revocation and additional related standards may also be developed at the sole discretion of the Optical Manufacturers Association.

B. Definitions

1. Ophthalmic Glass

"Ophthalmic Glass" is all glass intended for sale or use in the United States in ophthalmic lens components

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used in direct proximity to the eye such as in eyeglasses or sunglasses. This would exclude from the regulation the segment glass of multifocals. ?

2. Manufacturer

"Manufacturer" is a producer from raw materials, subsequent to the effective date of the Standard, of ophthalmic glass for lens blanks intended for further processing. "Manufacturer" is not limited to those producing in the United States.

3. Alpha-Particle Emission Rate

"Alpha-particle emission rate" is the number of alpha-particles per minute per square centimeter emitted from the surface of a lens which is in closest proximity to the eye.

C. Requirements

1. Rationale

The radioactive decay chains of thorium and uranium produce alpha, beta and gamma radiation. Of the three types of radiation at the low levels of activity which are addressed by the Standard, alpha radiation has the highest potential for ionization, and hence the greatest biological significance. The Standard therefore provides a limit upon the emission of alpha radiation from ophthalmic glass.

2. Alpha Limit

All ophthalmic glass covered by the Standard shall have at all times alpha-particle emission rate of less than 0.45 alphas/cm^2/min. from the ophthalmic glass lens surface in direct proximity to the eye.

D. Measurement

1. Methods of Measurement

In order to reach the limit of alpha-particle emission rate specified in the Standard, manufacturers may employ a combination of measurements of both raw materials and manufactured ophthalmic glass using integral alpha and/or gamma counting as well as gamma spectroscopy.

Measurements shall be performed upon raw materials and/or manufactured ophthalmic glass such that a statistically valid sampling of the manufactured ophthalmic glass conforms at all times to the limit of alpha-particle emission rate specified in the Standard.

Contact-hard lenses ?

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For the purposes of identifying the sources of alpha-particles, observation of the gamma ray activity of specified isotopes is to be used.

2. Identification of Alpha-Particle Emission

Because of possible changes in the equilibrium concentrations of daughter products in the thorium and uranium chains, arising from the chemical processing of rare earth and/or zirconium oxides occasionally used in the manufacture of ophthalmic glass, measurements of other than alpha-particle emission rate may be used to achieve acceptable radioactivity levels. Such measurement shall be referred to the manufactured ophthalmic glass such that the disintegration rate per unit mass (disintegrations per minute per gram - dpm/gm) of the manufactured ophthalmic glass does not exceed the limits as set forth below for the activity of specified isotopes which are convenient to measure:

1) Actinium 228 activity - 30 dpm/gm.
2) Lead 212 activity - 30 dpm/gm.
3) Lead 214 activity (or Bismuth 214) - 30 dpm/gm.

Actinium 228 and Lead 212 are radionuclides within

the thorium chain; and the measurement of the activity of both is necessary to determine the significant alpha activity in the glass due to the thorium series. Measurement of Lead 214 (or Bismuth 214) activity can be used to determine the significant alpha activity in the glass due to the uranium series.

In addition, the sum of 3) and 1) or 2), whichever is larger, shall not exceed 30 dpm/gm.

D. Declarations of Compliance

If they desire to assure purchasers that ophthalmic glass has been manufactured in compliance with the Standard, it is recommended that sellers include the following statement in connection with their names and addresses on contracts, labels, invoices or advertising materials:

"This ophthalmic glass conforms to all requirements of the Optical Manufacturers Association Ophthalmic Glass Radiological Standard."