Designation: F 2042 – 00ε1

Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II — Crosslinking and Fabrication[1]

This standard is issued under the fixed designation F 2042; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε[1] NOTE—Figs. 1-3 and Figs. 5-9 were editorially revised in June 2001.

1. Scope

1.1 This guide is intended to educate potential users of silicone elastomers, gels and foams relative to their fabrication and processing. It does not provide information relative to silicone powders, fluids, pressure sensitive adhesives, or other types of silicone products.

1.2 The information provided is offered to guide users in the selection of appropriate processing conditions for specific medical device applications.

1.3 Formulation and selection of appropriate starting materials is covered in the companion document, F 2038 Part I. This monograph addresses only the curing, post-curing, and processing of elastomers, gels and foams as well as how the resulting product is evaluated.

1.4 Silicone biocompatibility issues can be addressed at several levels, but ultimately the device manufacturer must assess biological suitability relative to intended use. Biocompatibility testing may be done on cured elastomers prior to final fabrication, but the most relevant data are those obtained on the finished device. Data on selected lots of material are only representative when compounding, and fabrication are performed under accepted quality systems such as ISO 9001 and current Good Manufacturing Practice Regulations. Extractables analyses may also be of interest for investigation of biocompatibility, and the procedures for obtaining such data depend on the goal of the study (see F 619, the HIMA Memorandum 7/14/93, and USP 23, for examples of extraction methods).

2. Referenced Documents

2.1 *ASTM Standards:*

D 395 Test Methods for Rubber Property—Compression Set[2]

D 412 Test Methods for Rubber Properties in Tension[2]

D 430 Test Methods for Rubber Deterioration—Dynamic Fatigue[2]

D 624 Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers [2]

D 792 Test Methods for Specific Gravity (Relative Density) and Density of Plastics by Displacement [3]

D 813 Test Method for Rubber Deterioration—Crack Growth[2]

D 814 Test Method for Rubber Property—Vapor Transmission of Volatile Liquids[2]

D 926 Test Method for Rubber Property—Plasticity and Recovery (Parallel Plate Method) [2]

D 955 Test Method of Measuring Shrinkage from Mold Dimensions of Molded Plastics[3]

D 1349 Practice for Rubber—Standard Temperatures for Testing[2]

D 1566 Terminology Relating to Rubber[2]

D 2240 Test Method for Rubber Property—Durometer Hardness[2]

F 619 Practice for Extraction of Medical Plastics[4]

F 719 Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation[4]

F 720 Practice for Testing Guinea Pigs for Contact Allergens—Guinea Pig Maximization Test[4]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[4]

F 813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices[4]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implantation With Respect to Effect of Materials on Muscle and Bone[4]

F 1905 Practice for Selecting Tests for Determining the Propensity of Materials to Cause Immunotoxicity [4]

F 1906 Practice for Evaluation of Immunological Responses in Biocompatibility Testing Using ELISA Tests, Lymphocyte Proliferation, and Cell Migration[4]

F 1984 Practice for Testing Whole Complement Activation in Scrum by Solid Materials[4]

F 2038 Guide for Silicone Elastomers, Gels and Foams Used in Medical applications Part I: Formulations and Uncured Materials[4]

2.2 *Other Biocompatibility Standards:*

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F4.11 on Polymeric Materials.

Current edition approved July 10, 2000. Published October 2000.

[2] *Annual Book of ASTM Standards,* Vol 09.01.

[3] *Annual Book of ASTM Standards,* Vol 08.01.

[4] *Annual Book of ASTM Standards,* Vol 13.01.

United States Pharmacopeia, current edition (appropriate monographs may include: <87>, <88>, <151>, <381>) [5]

FDA Department of Health and Human Services General Program Memorandum #G95–1, May 1, 1995: Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part I: Evaluation and Testing[6]

ANSI/AAMI 10993–1 Biological Evaluation of Medical Devices, Part I: Guidance on Selection of Tests[7]

HIMA Memorandum Guidance for Manufacturers of Silicone Devices Affected by Withdrawal of Dow Corning Silastic Materials, 7/14/93[8]

2.3 *Sterilization Standards:*

ANSI/AAMI ST46 Good Hospital Practice: Steam Sterilization and Sterility Assurance[7]

ANSI/AAMI ST41 Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance[7]

ANSI/AAMI ST50 Dry Heat (Heated Air) Sterilizers[7]

ANSI/AAMI ST29 Recommended Practice for Determining Ethylene Oxide in Medical Devices[7]

ANSI/AAMI ST30 Determining Residual Ethylene Chlorohydrin and Ethylene Glycol in Medical Devices[7]

AAMI 13409–251 Sterilization of Health Care Products—Radiation Sterilization—Substantiation of 25kGy as a Sterilization Dose for Small or Infrequent Production Batches[9]

AAMI TIR8–251 Microbiological Methods for Gamma Irradiation Sterilization of Medical Devices[9]

2.4 *Quality Standards:*

ANSI/ASQC Q9001 Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation and Servicing[7]

21 CFR 820 Quality System Regulation (current revision)[10]

21 CFR 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs: General (current revision)[10]

21 CFR 211 Current Good Manufacturing Practice for Finished Pharmaceuticals (current revision)[10]

2.5 *Other Standards:*

Dow Corning CTM 0155 (Gel-Like Materials With Modified Penetrometer)

Dow Corning CTM 0813 (Gel-Like Materials With One Inch Diameter Head Penetrometer)

PCB Test Methods such as those used for MRI project No. 4473, 1/24/97, [11]

Biological Performance of Materials: J. Black, Marcel Dekker, NY 1992

3. Terminology

3.1 The classification of silicone elastomers is based upon a number of interrelated factors which include the chemical system used to crosslink the elastomer, the physical characteristics of the uncured elastomer, and the methods used to fabricate the elastomers. Additional pertinent terms are defined in standard D 1566.

3.2 *Definitions:*

3.2.1 *manufacture*—the process which occurs in the supplier's facility in which the various components of the elastomer are brought together, allowed to interact, and are packaged to provide the uncured elastomer for sale.

3.2.2 *fabrication*—the process by which the uncured elastomer is converted into a fully vulcanized elastomer of the desired size and shape. This process may occur in the same facility as the manufacture of the uncured elastomer but is more typically performed at the facility of a customer of the silicone manufacturer.

3.2.2.1 *injection molding*—fabrication of elastomers into forms defined by molds constructed so that the uncured elastomer can be transferred by pumping into the closed mold. This method requires venting of the mold in some manner. The elastomer may be vulcanized by heating the mold after it is filled but more typically the molding conditions (temperature and filling rate) are adjusted so that uncured elastomer can be added to a pre-heated mold in which it will then cure. The mold is than opened and the part removed and post-cured, if necessary.

3.2.2.2 *compression molding*—a process in which the uncured elastomer is placed in an open mold. The mold is closed and pressure applied to the mold to fill the cavity. Heat is applied to vulcanize the elstomer, the mold is than opened and the fabricated part is removed.

3.2.2.3 *freshening*—because of the interaction that can occur between the fumed silica and silicone polymers, thick uncured high consistency elastomers can become so stiff over time that they are very difficult to process. To overcome this problem, a 2–roll mill is used to disrupt this interaction, resulting in a material which is easier to fabricate. This process is called freshening and is typically done immediately before catalyzation.

3.2.2.4 *transfer molding*—a process in which the mixed, uncured elastomer is placed in a compartment connected to the mold. The compartment is then closed, pressure is applied to transfer the uncured elastomer to the mold, filling the cavity. Heat and pressure are applied to the mold to vulcanize the elastomer, the mold is then opened, and the fabricated part is removed.

3.2.2.5 *extrusion*—a continuous process in which the mixed, uncured elastomer is forced through an orifice having the desired cross-sectional profile. The elastomer is then vulcanized by passing it through either a hot air or radiant heat oven. The most common application of extrusion processing is the fabrication of tubing but it can be used to produce other items as well.

3.2.2.6 *post-cure*—the process of subjecting a vulcanized elastomer to elevated temperature, usually in a hot-air oven, after its initial fabrication. This process step is done to

[5] Available from United States Pharmacopeia 12601 Twinbrook Parkway Rockville, MD 20852.

[6] Available from Food and Drug Administration HFI-40, Rockville, MD 20857.

[7] Available from American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036.

[8] Available from Advanced Medical Technology Association, 1200 G St. N.W. Suite 400 Washington, D.C. 20005–3814.

[9] Available from Association for the Advancement of Medical Devices, 1110 North Glebe Rd., Suite 220, Arlington, VA 22201–4795.

[10] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robins Ave., Philadelphia PA 19111–5094, Attn: NPODS

[11] Available from Midwest Research Institute, 425 Volker Blvd., Kansas City, MO 64110–2299

complete cross-linking of the object, remove peroxide by-products, and eliminate changes in its physical properties. Post-cure is often necessary when the component is only partially cross-liked by molding; it is performed in an attempt to accelerate molding process, and increase its output.

3.2.2.7 *calendaring*—the process of forming an uncured, mixed elastomer into a thin sheet or film by passing it between two rolls.

3.2.2.8 *dispersion*—the process of placing an uncured elastomer in a solvent. This lowers the viscosity of the material and is usually done to allow the fabrication of thinner films that can be obtained by calendaring or to form coatings. Following dispersion use, the solvent must be removed either before or during the vulcanization process. Care must be taken to assure that the solvent is compatible with the elastomer, to prevent preferential settling of the components of the formulation by excessive dilution of the elastomer.

3.2.3 *one-part elastomer*—an elastomer supplied in the uncured form in one package containing all of the formulation components. It does not require mixing before fabrication.

3.2.4 *two-part elastomer*—an elastomer supplied in two packages which must be mixed in specified proportions before fabrication.

3.2.5 *liquid silicone rubber or low consistency silicone rubber (LSR)*—an elastomer having a viscosity such that it can be moved or transferred by readily available pumping equipment. LSRs are typically used in injection molding operations.

3.2.6 *high consistency rubber (HCR)*—an elastomer having a viscosity such that it cannot be moved or transferred by readily available pumping equipment. These elastomers are fabricated using high shear equipment such as a two-roll mill and cannot be injection molded. They are typically used in compression or transfer molding and extrusion processes.

3.2.7 *RTV (room temperature vulcanization)*—a one-part elastomer which cures in the presence of atmospheric moisture. Little, if any, acceleration of cure rate is realized by increasing temperature. Because cure is dependent upon diffusion of water into the elastomer, cure in depths of greater than 0.64 cm is not recommended.

3.2.8 *gel*—a lightly crosslinked material having no or relatively low levels of reinforcement beyond that provided by the crosslinked polymer. Gels are usually two-part formulations utilizing a platinum catalyzed addition cure system. The hardness of the gel can be adjusted within wide limits. The material is not usually designed to bear a heavy load but rather to conform to an irregular surface providing intimate contact. As a result, loads are distributed over a wider area. These materials may also be used to provide protection from environmental contaminants.

3.2.9 *foam*—a crosslinked material which has a component added to it which generates a volatile gas as the material is being vulcanized. This vulcanization process results in a material with a relatively low density. Foams are usually two-part formulations utilizing a platinum catalyzed addition cure system. They conform as they expand to irregular surfaces just as gels do to provide intimate contact and protection from the environment but are more rigid and provide more strength than gels. Since foams are expanded elastomers, on a weight basis, they are highly crosslinked relative to gels. Most cure conditions will result in a closed cell foam.

4. Significance and Use

4.1 This standard is intended to provide guidance for the specification and selection of fabrication methods for silicones used in medical devices. It also provides guidance relative to testing that might be done to qualify lots of acceptable material, based on desired performance properties.

4.2 Silicone manufacturers supplying material to the medical device industry should readily provide information regarding non-proprietary product formulation to their customers either directly or through the US FDA Master File program.

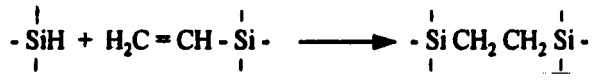
5. Crosslinking Chemistry

5.1 Silicone elastomers used in medical applications are typically crosslinked by one of three commonly used cure systems. These involve the platinum catalyzed addition of a silylhydride to an unsaturated site, the generation of free radicals by a peroxide or the reaction of an easily hydrolyzable group of silicon.

5.1.1 *addition cure*—this cure system utilizes the addition of a silylhydride to a site of unsaturation, usually a vinyl group. As shown in Fig. 1, this reaction is catalyzed by a platinum complex. The catalyst will be present at a level such that the concentration of platinum is in the range of 5 to 20 ppm but is more typically present at a level of about 7.5 ppm. When multiple silylhydrides are present in the same molecule, for example, in a crosslinker molecule, and they react with vinyl groups attached to a silicon in a silicone polymer, a crosslinked network results.

Elastomers using this cure system are two-part elastomers and are utilized in both LSRs and HCRs. In practice, the platinum catalyst, an inhibitor, and vinyl functionality on the silicone backbone are present in one part of the formulation and the crosslinker in the presence of vinyl functionality on the silicone backbone is present in the other. These two parts are intimately mixed shortly before they are intended to be used. At room temperature a certain amount of working time (time before the crosslink network builds to unacceptable levels) is provided to allow time to fabricate the silicone part. Heat is then applied to activate the platinum, the crosslinking reaction occurs, and the elastomer is vulcanized. The amount of working time and rate of cure are determined by the amount of crosslinker, catalyst, and inhibitors used in the formulation.

Mixing of LSRs of this type is usually accomplished by pumping the material in the prescribed ratios through a static mixer. HCRs are usually mixed by placing the prescribed ratios of the two parts on a two-roll mill and crossblending until adequately mixed. Mixing of the two components of the formulation at other than the ratio prescribed by the vendor is



NOTE—Si=Silicon
Pt=Platinum

FIG. 1

likely to result in changes in the cure characteristics, cured physical properties, or both, and may result in changes in the extractables profile.

5.1.2 *peroxide cure*—this cure system utilizes the decomposition of an organic peroxide, as shown in Fig. 2.

Radicals A and B then form organic radicals on the alkyl groups attached to silicon atoms along the polymer chain by abstracting hydrogen atoms as shown in Fig. 3.

These elastomers may be provided as two-part materials but are more commonly supplied as one-part materials where the peroxide is already present in the elastomer. Alternatively, only a base material may be supplied to which the fabricator can add the peroxide of his choice. The elastomers will usually be HCRs but some LSRs also employ this cure system.

The peroxide used will determine the shelf-life and cure rate of the elastomer at a particular temperature. Because peroxides are used at levels of 0.5–2 wt % and decomposition products form as the organic peroxide breaks down, these elastomers must be post-cured to remove those materials from the elastomer before use in medical applications.

Peroxides are classified as either non-vinyl specific, depending upon the type of radical reaction they promote.

5.1.2.1 *non-vinyl specific peroxides*—these peroxides promote the combination of two radicals on adjacent chains as shown in Fig. 4, resulting in an ethylene linkage between the polymer chains.

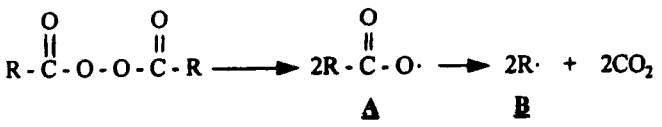
5.1.2.2 *vinyl-specific peroxides*—these peroxides promote the addition of the radical to a vinyl group attached to silicon on a polymer chain as shown in Fig. 5, resulting in a propylene linkage between the polymer chains. As these reactions are repeated, the crosslink network results.

5.1.3 *condensation cure*—elastomers of those type may be either one-part or two-part RTVs and contain hydroyzable groups on the crosslinker and on the polymer ends.

5.1.3.1 *one-part RTV*—elastomers of this type must be packaged in containers that are impermeable to moisture. When extruded from the container, they react with moisture from the atmosphere which diffuses through the elastomer. This results in the hydrolysis of the reactive groups on a crosslinker molecule as shown in Fig. 6.

The silanol species formed can then react with a hydrolyzable group attached to the end of a polymer chain as shown in Fig. 7. As this reaction is repeated on the same crosslinker molecule, the crosslink network results.

RTV formulations normally contain an organometallic compound to facilitate the reaction. Because they rely on the permeation of moisture through the elastomer to cure, use in applications where thicknesses of greater than 0.64 cm are desired are not normally recommended because of the long cure times necessary. RTVs are normally used in adhesive applications where two silicones, or other substrates, are being bonded together.



NOTE—R=any organic group

FIG. 2

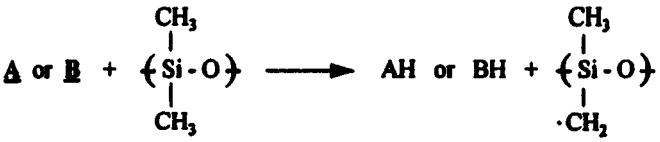


FIG. 3

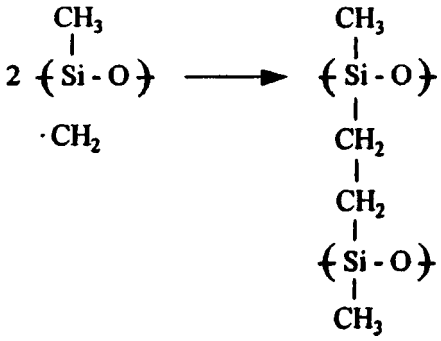


FIG. 4

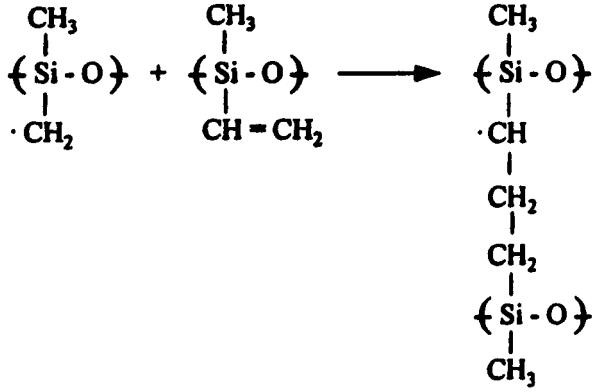


FIG. 5

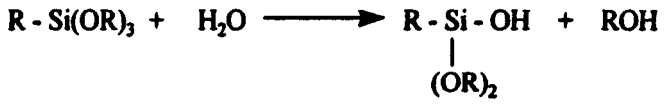


FIG. 6

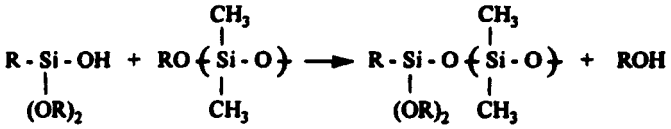
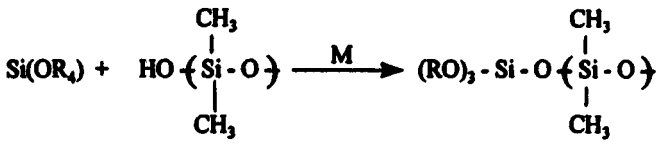


FIG. 7

5.1.3.2 *two-part RTVs (deep section condensation cure)*—another cure system which has found some utility in medical applications involves the reaction of an alkoxy crosslinker with a silanol ended polymer in the presence of an organometallic compound as shown in Fig. 8. The system results in rapid cures in deep-section because it does not rely upon the diffusion of water through the silicone. The organometalic compound is usually a tin compound.

5.2 Silicone gels are supplied as two-part formulations which are intimately mixed shortly before use and are cured using the chemistry shown in Fig. 1. However the relative ratio of SiH to SiVi is adjusted so that only a fraction of the total



NOTE—M=Metal

FIG. 8

vinyl groups present react.

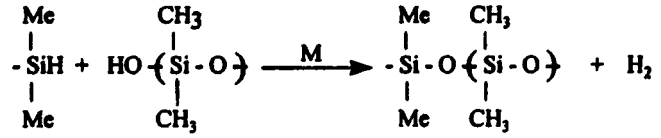
5.3 Silicone foams are supplied as two-part formulations which are intimately mixed shortly before use and are typically vulcanized by one of two commonly used cure systems depending on whether the blowing agent is generated by the curing reaction or by the decomposition of a separate component of the formulation.

5.3.1 *blowing agent generated by the curing reaction*—to crosslink the foam the reaction of a silylhydride with a silanol catalyzed by an organometallic compound is utilized. Typically the catalyst will be an organotin compound. This reaction is shown in Fig. 9 and results in the formation of a siloxane bond and the generation of a molecule of hydrogen. When two or more silylhydrides are present in the same molecule, i.e. a crosslinker molecule, as they react with successive silanol groups attached to silicone polymers, a crosslinked network results. As the crosslinked network is formed, with the simultaneous release of hydrogen, the volume of material expands. Eventually enough crosslinking occurs to allow the elastomer to retain its shape and the hydrogen rapidly diffuses from the silicone resulting in a low density material which has filled the void in which it was placed.

5.3.2 *blowing agent not generated by the curing reaction*—to crosslink the foam the addition of a silylhydride to a site of unsaturation, usually a vinyl group as shown in Fig. 1, is utilized. During the vulcanization process, as the crosslinked network is being built up, a component of the formulation which decomposes to form a gaseous by-product, generates the blowing agent. Typically this component will be ammonium bicarbonate which decomposes to form ammonia, carbon dioxide, and water as shown in Fig. 10. The ammonia and carbon dioxide that forms as the curing reaction proceeds expands the foam and then diffuses from the silicone resulting in a low density material which has filled the void in which it was placed.

6. Post-Cure and Fabrication Methods

6.1 Fabrication methods will be determined by the type of elastomer being used for the application. High consistency elastomers are generally fabricated using two-roll mills in conjunction with compression and transfer molding or extrusion techniques. Liquid silicone rubber elastomers are generally fabricated by using injection molding processes.



NOTE—Me=Methyl

FIG. 9

FIG. 10

6.2 Vulcanization and post-curing guidelines are usually recommended by the manufacturer but may vary depending upon the detail, configuration and size of the object being fabricated. Peroxide cured elastomers must be post-cured. Platinum catalyzed elastomers may or may not require post-curing, depending on the particular application and/or object being made.

7. Physical Properties

7.1 Physical properties of elastomers are used by manufacturers to insure that the elastomer has been properly formulated and processed and by the fabricator to determine that the elastomer will perform as intended in the application. Properties of both uncured and vulcanized elastomers may be determined. While customer specific testing may be done, the following ASTM methods describe tests that are of general utility and are commonly used in the industry. In addition, standard D 1349 addresses temperatures at which such testing occurs.

D 395 Test Methods for Rubber Property—Compression Set
D 412 Test Methods for Rubber Properties in Tension
D 430 Test Methods for Rubber Deterioration—Dynamic Fatigue
D 624 Test Methods for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers
D 792 Test Methods for Specific Gravity (Relative Density) and Density of Plastics by Displacement
D 813 Test Methods for Rubber Deterioration—Crack Growth
D 926 Test Method for Rubber Property—Plasticity and Recovery (Parallel Plate Method)
D 955 Test Method of Measuring Shrinkage from Mold Dimensions of Molded Plastics
D 2240 Test Method for Rubber Property—Durometer Hardness
Dow Corning CTM 0155 (Gel-Like Materials With Modified Penetrometer)
Dow Corning CTM 0813 (Gel-Like Materials With One Inch Diameter Head Penetrometer)

8. Packaging, Labeling and Storage

8.1 Cured silicone elastomers or components for use in medical applications shall be supplied in proper packaging to prevent their contamination during typical conditions of shipment and storage, as well as their adulteration from the package shelf.

8.2 All packages shall be labeled so as to identify the manufacturer, specific product name, and lot or batch number.

8.3 The material supplier shall provide information regarding recommended storage conditions and product warranties.

9. Biocompatibility

9.1 The biocompatibility of silicone elastomers as a class of materials cannot be categorically established; it depends on formulation, processing conditions and ultimate use. Device manufacturers are ultimately responsible for ensuring the biocompatibility of a device using appropriate state-of-the-art methodology.

9.2 PCBs are generated by the decomposition of 2,4 dichlorobenzoyl peroxide, which is used in some peroxide-cured elastomers. Information on PCB formation and removal from elastomers catalyzed with this peroxide should be available from the manufacturer, or may be obtained by direct testing

(MRI Project No. 4473, Jan 24, 1997; Midwest Research Institute, 425 Volker Boulevard, Kansas City, Missouri 64110–2299; Ph. (816) 753–7600. This method is useful for the determination of PCB levels in cured elastomers only). The user is ultimately responsible for determining acceptable levels of PCBs for their application.

9.3 Biocompatibility testing may be conducted on the silicone materials that are used to manufacture a medical device to guide in the selection of material or manufacturer.

9.4 Biological Test Methods for obtaining information on the biocompatibility of silicone elastomers as part of medical devices can be found in Practices such as F 748, F 813, F 719, F 720, F 981, F 1905, F 1906, and F 1984 and ISO 10993–1 and USP documents (<87>, <88>, <151>, <381>). Considerations for sample preparation and presentation that may impact biological test results are provided in references such as Biological Performance of Materials by J. Black (1992).

9.5 Toxicological test data on cured silicone materials applies only when all formulating and processing utilizes specified ingredients, and is accomplished in accordance with accepted quality systems such as ISO 9001 and current Quality System Regulations/Good Manufacturing Practices (GMPs) promulgated by the FDA.

9.6 Extraction is a part of most biological screening tests on cured elastomers and on finished medical devices. Typical extraction methods designed for this purpose are described in USP 23 (<88>) and F 619. Other methods may be directed towards specific goals, and should be chosen based on the question addressed, and the selectivity and sensitivity of the methods available for extract analysis. The HIMA Memorandum of 7/14/93 addresses extraction study methods intended to establish equivalency between silicone materials. Extract results will be influenced by sample, extraction, and analysis parameters.

10. Sterilization

10.1 Manufacturers of fabricated silicones elastomers may supply such materials sterile or may want to advise end users (hospitals, clinics and physicians, for example) on sterilization methods. These methods should be validated before use.

10.2 Ethylene oxide is highly soluble in silicone. Those users sterilizing with ethylene oxide must do testing to ensure acceptable levels of harmful residues if sterilized material is used as is (See References). Cell culture tests, such as Practice D 813, may be used to show absence of sterilant residues. Material characteristics may also change as a result of ethylene oxide sterilization.

10.3 Autoclave sterilization is permissible for most silicone elastomers because material characteristics are not significantly altered during autoclave sterilization.

10.4 Radiation sterilization of silicone elastomers results in a dose-related increase in crosslink density that may increase durometer and modulus of elasticity and reduce elongation and flexural durability. When silicone elastomer devices are sterilized by radiation, qualifying performance testing on finished medical devices or reasonable near-finished components subjected to the maximum radiation dosage shall be conducted to ensure that radiation sterilization has not adversely affected expected performance.

11. Quality Control Provisions

11.1 Silicone elastomers should be processed and tested utilizing quality control programs such as that discussed in ANSI/ASQC C1 (Specification of General Requirements for a Quality Program), preferably in consistency/acceptability can also be monitored by matching product performance to lot acceptance requirements, providing these are specific and reasonably narrow.

11.2 Fabricators of silicone elastomer components will inform customers of changes in formulation, test methods, specifications or packaging. Details of the changes with a means to identify when each change occurred shall be provided.

11.3 Sterilization will be performed using quality standards such as:

ANSI/AAMI ST46 Good Hospital Practice: Steam Sterilization and Sterility Assurance
ANSI/AAMI ST 41 Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance
ANSI/AAMI ST50 Dry Heat (Heated Air) Sterilizers
ANSI/AAMI ST29 Recommended Practice for Determining Ethylene Oxide in Medical Devices
ANSI/AAMI ST30 Determining Residual Ethylene Chlorohydrin and Ethylene Glycol in Medical Devices
AAMI 13049–251 Sterilization of Health Care Products—Radiation Sterilization—Substantiation of 25kGy as a Sterilization Dose for Small or Infrequent Production Batches
AAMI TIR8–251 Microbiological Methods for Gamma Irradiation Sterilization of Medical Devices

11.4 Material suppliers shall provide certification to specified product requirements.

12. Keywords

12.1 foam; gel; high consistency rubber; liquid silicone rubber; medical device material; moisture cure; peroxide cure; platinum cure; RTV

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Medical devices made from silicone elastomer are widely used in the care of public health and have a history of biocompatibility in many applications. This standard educates the user as to the fabrication of such elastomers, and tests which can be used to characterize and compare performance of processed materials. Formulation, the first level at which biocompatibilty of the ultimate device is affected, is covered in Part I of this monograph.

X1.2 The previous version of this standard has now been split into two parts, one addressing formulation, and one, fabrication. The codes previously used in this standard were not widely accepted by manufacturers, and therefore the monograph had minimal utility. The information provided here at least provides a starting point from which the user can seek guidance on the biological impact of various processing conditions on silicone devices. Manufacturers' responsibilities as defined here are now or are expected to be practiced in the industry; manufacturers can be differentiated on the basis of the information they provide on the topics discussed herein.