Designation: F 640 – 79 (Reapproved 2000)

Standard Test Methods for Radiopacity of Plastics for Medical Use[1]

This standard is issued under the fixed designation F 640; 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.

This standard has been approved for use by agencies of the Department of Defense.

1. Scope

1.1 These test methods cover the determination, by radiography, of the radiopacity of plastic in the form of film, sheet, rod, tube, and moldings. The results of these measurements are an indication of the likelihood of locating the plastic part within the human body.

1.2 *Types of Tests*— There are three methods of tests described, differing in the method of calculating radiopacity.

1.2.1 *Method A*—Radiopacity is determined as a specific difference in optical density between the image of the plastic and the background on the X-ray film or equivalent.

1.2.2 *Method B*—Radiopacity is determined by comparing the images of the test piece and of a standard piece simulating the medical device.

1.2.3 *Method C*—The intrinsic radiopacity of a plastic is determined by measurements made on the image of a slab of a specific thickness of the formulation.

1.3 The values stated in SI units are to be regarded as the standard.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

B 209 Specification for Aluminum and Aluminum-Alloy Sheet and Plate[2]

D 1898 Practice for Sampling of Plastics[3]

D 3182 Practice for Rubber—Materials, Equipment, and Procedures for Mixing Standard Compounds and Preparing Standard Vulcanized Sheets[4]

E 7 Terminology Relating to Metallography[5]

E 94 Guide for Radiographic Testing[6]

E 135 Terminology Relating to Analytical Chemistry for Metals, Ores, and Related Materials[7]

E 142 Test Method for Controlling Quality of Radiographic Testing[8]

F 647 Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application[9]

3. Terminology

3.1 *Definitions*—For definitions of terms relating to X-ray procedures, refer to Guide E 94 and Test Method E 142.

3.2 *Descriptions of Terms:*

3.2.1 *optical density*—in photographic photometry, the logarithm to the base 10 of the ratio of the incident light to the transmitted light (see Terminology E 135). The range of values of optical density expected in this test method is 0.5 to 1.5.

3.2.2 *contrast*—in this test method, contrast is the difference between optical density measurements made on the background (nominally 1.0 optical density) and on the test specimen.

3.2.3 *penetrameter*—a device employed to obtain evidence on a radiograph that the technique used is satisfactory. It is not intended for use in judging the size of discontinuities nor for establishing acceptance limits for materials or products.

3.2.4 *intrinsic radiopacity*—for this application, where the plastic is part of a medical device, the X-ray linear absorption coefficient is important. The following definition is excerpted from Terminology E 7:

absorption coefficient—specific factor characteristic of a substance on which its absorption radiation depends. The rate of decrease of the natural logarithm of the intensity of a parallel beam per unit distance traversed in a substance. For X rays, the linear absorption coefficient is the natural logarithm of the ratio of the incident intensity of an X-ray beam incident intensity of

[1] These test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are the direct responsibility of Subcommittee F04.15 on Material Test Methods.

Current edition approved Oct. 26, 1979. Published January 1980.

[2] *Annual Book of ASTM Standards*, Vol 02.02.

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

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

[5] *Annual Book of ASTM Standards*, Vol 03.01.

[6] *Annual Book of ASTM Standards*, Vol 03.03.

[7] *Annual Book of ASTM Standards*, Vol 03.05.

[8] *Annual Book of ASTM Standards*, Vol 03.03.

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

a beam of X rays, I_t the transmitted intensity, and X the thickness of the absorbing material, then:

$$I_t = I_e \exp(-\mu X).$$

Here μ is the linear absorption coefficient. The mass absorption is given by μ/ρ where ρ is the density.

3.2.5 *attenuation*—loss of energy per unit distance.

4. Summary of Test Methods

4.1 The plastic specimen is laid on the cassette in the Xray apparatus and a 10-mm thick sheet of aluminum is placed on top of the specimen (or 15-mm thick, if so specified). The apparatus is equivalent to that used in a hospital. Radiographs are made at specified voltages, times, and currents that are typical of those used in the X-ray diagnosis of humans. The radiopacity of the material or medical device is evaluated in terms of the criteria described for the test method selected. Calibration is achieved by using both a standard specimen and an X-ray optical density standard.

5. Significance and Use

5.1 Plastics, being composed principally of chemical elements of low atomic weight, have little opacity to X rays. Compounds of elements of higher atomic weight are deliberately mixed into plastics to obtain radiopacity.

5.2 These methods are intended to determine whether the plastic part has the degree of radiopacity specified for its application as a medical device in the human body.

5.3 *Degree of Contrast*:

5.3.1 Using Method A, it is recommended that a specific difference in optical density between the background of 0.8 to 1.2 optical density (3.2.1) and the image of the test specimen be required in any specification for a radiopaque medical device.

5.3.2 Method B requires that the image of the medical device, or the image of the section of the medical device that is radiopaque, give as much contrast (same background optical density as above) as the image of a comparison standard simulating the medical device.

NOTE 1—It is expected that the dimensions and composition of the comparison standard will be specified in the standard for the medical device (see Appendix X1).

5.3.3 In Method C, the intrinsic radiopacity of a plastic is determined by comparison with an equal thickness of aluminum, and by the calculation of the relative linear X-ray attenuation (3.2.5) of the plastic based on measurements of optical density of the image of the sample, and of the image of the comparison aluminum piece.

6. Apparatus

6.1 *X-Ray Machine*, a medical-type (minimally full wave rectified).

6.2 *Inherent X-Ray Beam Filtration*, 2.5-mm aluminum equivalent minimum.

6.3 *X-Ray Film*, par-speed grade, used with par-speed intensifying screens. A grid may be used.

6.4 *Penetrameters*:

6.4.1 *Material*—The aluminum sheet on top of the test specimen and the step wedge (if used) shall be 99+ % aluminum in accordance with Specification B 209 (typically, 1100 alloy). The comparison standard of Method B (7.1) shall be of the same metal, unless otherwise specified.

6.4.2 *Aluminum Sheet*— A 10.0 ± 0.15-mm thick aluminum sheet shall be used on top of the test specimen for all tests. If so specified in the standard for the medical device, a 15.0 ± 0.15-mm thick sheet shall be placed on top of the test specimen.

6.4.3 *Step Wedge*—A step wedge may be used instead of the aluminum sheet specified in 6.4.2, if it has the requisite thickness steps.

6.5 *Rubber Blankets*— Blankets incorporating X-ray absorbers may be used to mask areas outside that covered by the penetrameter (this prevents undercutting). Lead sheets may also be used for masking.

6.6 *Back-Scatter Protection*, as described in Guide E 94.

6.7 *Densitometer*— The densitometer shall be capable of measuring the optical density over the range from 0.0 to 3.0 optical density units, minimum. It shall have a measuring accuracy of ± 0.02 optical density units or better. The densitometer shall have been calibrated within 6 months previously by a method and calibration standard traceable to the U.S. National Bureau of Standards.

6.8 *Step Tablet*, [10] for calibrating densitometers.

7. Comparison Standards

7.1 *Method B*—The comparison standard shall be of similar dimensions to the medical device. Its exact dimensions and composition (see 6.4.1) shall be specified in the standard for the medical device.

7.2 *Method C*—The material of the comparison standard shall be Type 1100 aluminum (6.4.1), 2.0 mm thick, 25 mm wide, and 150 mm long.

8. Sampling

8.1 Sample fabricated stock shapes or molded items in accordance with Practice D 1898.

9. Test Specimens

9.1 *Film or Sheet*— The specimen shall be at least 150 mm long and 25 ± 1 mm wide. (For this specimen and the following it is assumed that the penetrameter covers an area of approximately 150 by 50 mm.)

9.2 *Rod or Tubing*— The specimen shall be at least 150 mm long.

9.3 *Molded Parts*— If the molded part has dimensions small with respect to the area covered by the penetrameter, then several moldings shall be placed under the penetrameter.

9.4 *Slab for Method C*—The dimensions of the specimen of the plastic shall be 2.0 by 25 by 150 mm.

NOTE 2—A 2.0-mm thick sheet is often molded especially for testing: for example, the description of sample in Practice D 3182.

[10] SRM 1001 has been found suitable for this purpose and is available from National Bureau of Standards, Office of Standard Reference Materials, Washington, DC 20234.