



Standard Test Methods for Radiopacity of Plastics for Medical Use¹

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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 Plate²

D 1898 Practice for Sampling of Plastics³

D 3182 Practice for Rubber—Materials, Equipment, and Procedures for Mixing Standard Compounds and Preparing Standard Vulcanized Sheets⁴

E 7 Terminology Relating to Metallography⁵

E 94 Guide for Radiographic Testing⁶

E 135 Terminology Relating to Analytical Chemistry for Metals, Ores, and Related Materials⁷

E 142 Test Method for Controlling Quality of Radiographic Testing⁸

F 647 Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application⁹

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 a beam of X rays, I_t the transmitted intensity, and X the

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.

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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.