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Standard Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials¹

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1. Scope

1.1 This guide is intended to assist the biomaterials testing laboratory in the conduct and evaluation of tumorigenicity tests to evaluate the potential for new materials to evoke a neoplastic response. The procedure is generally reserved only for those materials which have not previously been used for human implantation for a significant period of time.

1.2 Assessment of tumorigenicity is one of several procedures employed in determining the biological response to a material as recommended in Practice F 748. It is assumed that the investigator has already determined that this type of testing is necessary for a particular material before consulting this guide. The recommendations of Practice F 748 should be considered before a study is commenced.

1.3 Whenever possible, it is recommended that a battery of genotoxicity procedures be initiated and proposed as an alternative to an *in-vivo* tumorigenicity bioassay. Genotoxicity assays may also be considered as initial screening procedures due to the sensitivity of the assays, the significant reduction in time to gain valuable data, and the desire to reduce the use of animals for testing. Genotoxicity assays that may be considered are outlined in Guides E 1262, E 1263, E 1280, and E 2186, and Practices E 1397 and E 1398. Additionally, other genotoxicity testing which might be considered (but which do not yet have ASTM test methods) include Salmonella/Mammalian-Microsomal Plate Incorporation Mutagenicity Assay, In Vivo Cytogenetics Bone Marrow Chromosomal Damage Assay, BALB/3T3 Morphological Transformation of Mouse Embryo Cells, and the Mouse Micronucleus Assay. The investigator is advised to consider carefully the appropriateness of a particular method for his application after a review of the published literature.

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.*

¹ This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.16 on Biocompatibility Test Methods.

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