



Standard Guide for Assessment of Adventitious Agents in Tissue Engineered Medical Products (TEMPs)¹

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1. Scope

1.1 This guide is intended as a resource for individuals and organizations involved in the production, delivery, and regulation of tissue engineered medical products (TEMPs). The safety from contamination by potentially infectious adventitious agents is important in the development of all TEMPs as well as their components. This guide addresses how to assess safety risks associated with adventitious agents and their byproducts. These agents currently include bacteria, fungi, mycoplasma, viruses, endotoxins, transmissible spongiform encephalopathies (TSEs), and parasitic organisms. This guide does not address TEMPs with live animal cells, tissues or organs, or human cells, including stem cells, grown on any animal feeder cells. Also excluded is patient follow-up testing.

1.2 This guide does not apply to any medical products of human origin regulated by the U.S. Food and Drug Administration under 21 CFR Parts 16 and 1270 and 21 CFR Parts 207, 807 and 1271. This guide does apply to cellular therapies regulated under the PHS (Public Health Service) act.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this 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 to determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

E1873 Guide for Detection of Nucleic Acid Sequences by the Polymerase Chain Reaction Technique

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 F04.45 on Adventitious Agents Safety.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

F2210 Guide for Processing Cells, Tissues, and Organs for Use in Tissue Engineered Medical Products

F2211 Classification for Tissue Engineered Medical Products (TEMPs)

F2312 Terminology Relating to Tissue Engineered Medical Products

F2386 Guide for Preservation of Tissue Engineered Medical Products (TEMPs)

2.2 *ANSI/AAMI Standard:*

ST72 Bacterial Endotoxin—Test Methodologies, Routine Monitoring and Alternatives to Batch Testing³

2.3 *Federal Regulations:*⁴

9 CFR Animals and Animal Products

21 CFR 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs, General

21 CFR 211 Current Good Manufacturing Practice for Finished Pharmaceuticals

21 CFR 610.12 General Biological Products Standards—Sterility

21 CFR 610.13 (b) General Biological Products Standards—Purity Test for Pyrogenic Substances

21 CFR 820 Quality System Regulation

21 CFR 1270 Human Tissue Intended for Transplantation

21 CFR 1271 Human Cells, Tissues, and Cellular and Tissue-Based Products

2.4 *MDA Standard:*

Code of Practice for the Production of Human-Derived Therapeutic Products⁵

2.5 *U. S. Pharmacopeia Document:*

United States Pharmacopeia (USP), Edition XXIV (24)⁶

3. Terminology

3.1 Definitions:

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

⁴ Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, <http://www.access.gpo.gov>.

⁵ Available from Medicines and Healthcare Products Regulatory Agency (MHRA), Hannibal House, Elephant & Castle, London SE1 6TQ, U.K.

⁶ Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, <http://www.usp.org>.