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Standard Terminology Relating to Antimicrobial and Antiviral Agents¹

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1. Scope*

1.1 The purpose of this terminology standard is to establish uniformity in terms used in the field of antimicrobial and antiviral agent testing. Terms are adapted from related fields such as regulatory terms defined by law and definitions as supported by test requirements.

1.2 The terms are appropriate to the wide range of interest related to standards developed in the area of antimicrobial and antiviral testing.

1.3 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

- E645 Practice for Evaluation of Microbicides Used in Cooling Water Systems
- E723 Practice for Evaluation of Antimicrobials as Preservatives for Aqueous-Based Products Used in the Paper Industry (Bacterial Spoilage)
- E875 Practice for Evaluation of Fungal Control Agents as Preservatives for Aqueous-Based Products Used in the Paper Industry
- E1052 Practice to Assess the Activity of Microbicides against Viruses in Suspension
- E1153 Test Method for Efficacy of Sanitizers Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces
- E2111 Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporidical

Potencies of Liquid Chemicals

- E2180 Test Method for Determining the Activity of Incorporated Antimicrobial Agent(s) In Polymeric or Hydrophobic Materials
- E2196 Test Method for Quantification of *Pseudomonas aeruginosa* Biofilm Grown with Medium Shear and Continuous Flow Using Rotating Disk Reactor
- E2197 Quantitative Disk Carrier Test Method for Determining Bactericidal, Virucidal, Fungicidal, Mycobactericidal, and Sporidical Activities of Chemicals
- E2362 Practice for Evaluation of Pre-saturated or Impregnated Towelettes for Hard Surface Disinfection
- E2562 Test Method for Quantification of *Pseudomonas aeruginosa* Biofilm Grown with High Shear and Continuous Flow using CDC Biofilm Reactor
- E2614 Guide for Evaluation of Cleanroom Disinfectants
- E2647 Test Method for Quantification of *Pseudomonas aeruginosa* Biofilm Grown Using Drip Flow Biofilm Reactor with Low Shear and Continuous Flow
- E2783 Test Method for Assessment of Antimicrobial Activity for Water Miscible Compounds Using a Time-Kill Procedure
- E2784 Test Method for Evaluation of the Effectiveness of Handwash Formulations Using the Paper Towel (Palmar) Method of Hand Contamination
- E2799 Test Method for Testing Disinfectant Efficacy against *Pseudomonas aeruginosa* Biofilm using the MBEC Assay
- E2871 Test Method for Determining Disinfectant Efficacy Against Biofilm Grown in the CDC Biofilm Reactor Using the Single Tube Method
- E2897 Guide for Evaluation of the Effectiveness of Hand Hygiene Topical Antimicrobial Products using *ex vivo* Porcine Skin
- E2966 Test Method for Quantitative Assessment of Sanitizing Solutions for Carpet
- E3058 Test Method for Determining the Residual Kill Activity of Hand Antiseptic Formulations
- E3092 Practice for Evaluating Efficacy of Vaporous Decontaminants on Materials Contaminated with *Bacillus* Spores and Contained Within 0.2µm Filter-Capped Tubes
- E3135 Practice for Determining Antimicrobial Efficacy of Ultraviolet Germicidal Irradiation Against Microorganisms on Carriers with Simulated Soil

¹ This terminology is under the jurisdiction of ASTM Committee E35 on Pesticides, Antimicrobials, and Alternative Control Agents and is the direct responsibility of Subcommittee E35.15 on Antimicrobial Agents.

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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.

*A Summary of Changes section appears at the end of this standard

- E3161** Practice for Preparing a *Pseudomonas aeruginosa* or *Staphylococcus aureus* Biofilm using the CDC Biofilm Reactor
- E3178** Practice for Evaluating Static and Cidal Chemical Decontaminants against *Bacillus* Spores using Centrifugal Filtration Tubes
- E3179** Test Method for Determining Antimicrobial Efficacy of Ultraviolet Germicidal Irradiation against Influenza Virus on Fabric Carriers with Simulated Soil
- E3180** Test Method for Quantification of a *Bacillus subtilis* Biofilm Comprised of Vegetative Cells and Spores Grown Using the Colony Biofilm Model
- E3273** Practice to Assess Microbial Decontamination of Indoor Air using an Aerobiology Chamber
- E3276** Test Method for Assessing Impact Energy and Precision of Direct-fire, Single-projectile Less Lethal Impact Rounds Used by Public Safety Officers
- E3285** Test Method for Evaluation of Contact-Mediated Microbial Transference
- E3286** Practice for Preparation Of Cell Monolayers on Glass Surfaces for Evaluation of Microbicidal Properties of Non-Chemical Based Antimicrobial Treatment Technologies
- E3364** Test Method for Evaluating the Performance of Antimicrobials in or on Polymeric Porous and Nonporous Materials Against Staining by *Streptomyces* species (A Pink Stain Organism)
- E3371** Test Method for Measuring the Ability of a Synthetic Polymeric Material to Resist Bacterial Adherence

3. Terminology

3.1 Definitions:

- accuracy**, *n*—a measure of the degree of conformity of a value generated by a specific procedure to the assumed or accepted true value, and includes both precision and bias. **E1153**
- ambient temperature**, *n*—temperature of the environment in which a test method is performed. **E1153**
- anti-adherence**, *n*—term describing a state where the attachment of bacteria to the surface of products is suppressed or describing the effect of an agent which reduces the ability of bacteria to attach to product surfaces. **E3371**
- anti-adherent**, *adj*—term describing a state where the attachment of bacteria to the surface of products is suppressed or describing the effect of an agent which reduces the ability of bacteria to attach to product surfaces. **E3371**
- antibacterial**, *adj*—describes an agent that kills bacteria or suppresses their growth or reproduction.
- antimicrobial**, *adj*—describes an agent that kills or inactivates microorganisms or suppresses their growth or reproduction. **E1153, E2783**
- antiseptic**, *n*—a material for use on living tissue that either destroys microorganisms or suppresses their growth.
- asperity**, *n*—a protuberance in the small-scale topographical irregularities of a solid surface.

DISCUSSION—In materials science, smooth surfaces are rough on a microscopic scale. The surface topology of even highly polished surfaces is similar to that of mountain ranges.

DISCUSSION—Depending on the material and its surface finish, the distance between asperity peaks and valleys can range from $<0.1 \mu\text{m}$ to $>100 \mu\text{m}$. When this distance is $\geq 1 \mu\text{m}$, the peak can create a shadow between an irradiation source and microbes located on the peak's distal side. When a cavity is $\geq 1 \mu\text{m}$ deep, microbes can reside inside the cavity and be partly or fully protected from exposure. **E3286**

bias, *n*—a systematic error that contributes to the difference between the mean of a large number of test results and an accepted reference value (ASTM Form and Style Manual).

DISCUSSION—A statement of bias is not possible because standard reference materials are not available for most microbiological methods.

biofilm, *n*—microorganisms living in a self-organized community attached to surfaces, interfaces, or each other, embedded in a matrix of extracellular polymeric substances of microbial origin, while exhibiting altered phenotypes with respect to growth rate and gene transcription.

E2196, E2562, E2647, E2799, E2871, E3161, E3180

biofouling, *n*—the unwanted accumulation of organisms and/or their products on surfaces.

cleaner-sanitizer, *n*—a physical or chemical agent that removes soil from an object and reduces numbers of microorganisms on non-food contact surfaces. **E1153**

carrier, *n*—a surrogate surface or matrix that facilitates the interaction of test microorganisms and treatment(s).

E1153, E3135, E3179

carrier, *n*—inanimate surface or object inoculated with the test organism. **E2111, E2197, E3276, E3286**

cell monolayer, *n*—a single layer of eukaryotic cells typically propagated on a glass or plastic surface to which they are securely attached.

cleansing wash, *n*—a procedure intended to remove soil or residue. **E3161**

clastogen, *n*—an agent that reduces chromosomal breakage.

composite sample, *n*—a series of grab samples integrated into a single sample or samples collected at specific times and integrated into a single sample.

cooling system, *n*—equipment and coolant used for the removal of heat from processes, equipment, or both. **E645**

cooling water, *n*—any water-based solution that absorbs and transfers heat in a heat exchange system. **E645**

cumulative effect, *n*—a progressively additive reduction in the numbers of viable microorganisms measured from an established baseline following repeated applications of a material or procedure.

decontaminant, *n*—a physical or chemical agent or process that destroys pathogenic or potentially pathogenic microorganisms in/on surfaces or objects. **E1153**

decontamination, *n*—a procedure that eliminates or reduces contaminants. The usual reference is to reduce potentially harmful or undesirable microorganisms.

disinfectant, *n*—a physical or chemical agent or process that destroys pathogenic or potentially pathogenic microorganisms in/on surfaces or objects. **E2362, E2871**

D-value (decimal reduction time/log death time), *n*—the time or radiation dose required to achieve inactivation of 90 % of one log₁₀ of a population of the test microorganism under stated exposure conditions.

effectiveness, *n*—a measure of the performance of a product. **E2614**

efficacy, *n*—the proven performance of a product established under defined conditions of testing. **E1153, E2614**

electromagnetic spectrum, *n*—the ordered array of known radiations, extending from the shortest wavelengths, gamma rays, through X rays, ultraviolet radiation, visible radiation, infrared and including microwave and all other wavelengths of radio energy. **E3276, E3286**

endospore, *n*—a dormant, robust and non-metabolically active structure produced by certain bacteria from the Firmicutes phylum. **E3092, E3178**

envelope, *n*—a layer of host cell membrane-deprived lipid that surrounds the capsid of some viruses.

exosporium, *n*—the outermost layer of spores of *Bacillus anthracis* and its close relatives *Bacillus thuringiensis* and *Bacillus cereus*. **E3092**

false negative, *adj*—incorrectly indicating the absence of a finding or condition.

false positive, *adj*—incorrectly indicating the presence of a finding or condition.

fomite (fomes), *n*—an inanimate object that harbors pathogenic microorganisms and may transmit infection.

germ, *n*—microorganisms pathogenic to humans.

glove juice procedure, *n*—a process requiring placement of test subjects' hands into low bioburden plastic bags or sterile gloves that are powder-free and non-antimicrobial. Stripping solution is added to the glove, the hands are massaged, and the stripping solution (glove juice) is sampled to recover microorganisms.

grab sample, *n*—single sample from process stream (flowing) or from source of confined geometry (stagnant) withdrawn at a specific time.

inoculum, *n*—in microbiology, a specimen comprised of living spores, bacteria, yeast or the multicellular filamentous fungi, or combination of two or more types of microorganisms, that are introduced into a test medium or onto a specimen to be tested in order to investigate the ability of the medium or specimen to support microbial growth or to investigate its antimicrobial properties. **E2180, E2783**

intermediate-level disinfectant, *n*—a disinfectant that inactivates mycobacteria, vegetative bacteria, most fungi, and lipid and non-lipid viruses.

irradiance (E), *n*—a radiometric term for the radiant flux that is incident upon a surface (W·m²). **E3135, E3179**

light-emitting diode (LED), *n*—a solid-state electronic device or transistor which emits light.

DISCUSSION—A LED is a p-n junction diode, which emits light when activated. When a suitable voltage is applied to the leads, electrons are able to recombine with electron holes within the device, releasing energy in the form of photons. **E3135, E3179**

low-level disinfectant, *n*—a disinfectant that inactivates vegetative bacteria, lipid viruses, and some fungi.

macrobacillus, *n*—a *Bacillus* endospore that possess an exosporium. **E3092**

mercury vapor lamp—a gas discharge lamp that uses electric arc through vaporized mercury to produce light. **E3135, E3179**

microbacillus, *n*—a *Bacillus* endospore that does not possess an exosporium. **E3092**

microbially induced staining, *n*—undesirable pigmentation or disfiguration of an object due to surface colonization by certain microorganisms. Both bacteria and fungi produce metabolic pigments that can result in surface stains on susceptible objects. **E3364, E3371**

microbial transference, *n*—relocation of a microorganism from a previously contaminated surface to a different surface by contact. **E3285**

minimum inhibitory concentration (MIC), *n*—the lowest concentration of an antimicrobial agent that prevents visible growth of a microorganism in an agar or broth dilution susceptibility test.

nebulizer, *n*—a device used to create an aerosol from a liquid. **E3273**

negative control, *n*—material or procedure used to differentiate the effects of specified treatments from the uncontrolled variables in a test system.

neutralization, *n*—the process for inactivating or quenching the activity of a microbicide, often achieved through physical (for example, filtration or dilution) or chemical means. **E1052, E1153, E2614, E2783, E2897**

persistent effect, *n*—prolonged antimicrobial activity measured after treatment(s) that prevents or inhibits proliferation or survival of microorganisms, or both.

pink stain organism, *n*—an Actinomycete such as *Streptomyces* species ATCC 25607 (deposited as *Streptovorticillium reticulum*) that is capable of metabolically producing a light rose to orange-colored discoloring pigment. **E3364**

positive control, *n*—treatment using known material or procedure used to validate a test protocol.

precision, *n*—the closeness of agreement between independent test results obtained under prescribed conditions. **E1153**

preservative, *n*—chemical agent(s) added to a product to reduce or prevent microbial growth. **E723, E875**

radiometer, *n*—a device for measuring the radiant power that has an output proportional to the intensity of the input power. **E3135, E3179**

recovery control, *n*—a procedure that validates that initial population(s) meet the criterion of a method.

reference control, *n*—material or procedure with known performance in a test method.

repeatability, *n*—the precision of test results obtained in the same laboratory under specifically defined conditions.

reproducibility, *n*—the precision of test results obtained in different laboratories performing the same test procedure under specifically defined conditions. **E1153**

resident microbial skin flora, *n*—microorganisms that survive and multiply on the skin, forming a stable population. **E2784**

room temperature, *n*—temperature in the range of 20 to 30°C (68 to 85°F). **E2783, E3058**

sanitizer, *n*—chemical or physical agent(s) used to reduce the number of microorganisms to a level judged to be appropriate for a defined purpose and/or claim. **E1153, E2614, E2966**

shadowing, *v*—creating a dark area or shape by blocking light rays. **E3135, E3179**

slimicide, *n*—chemical agent(s) added to a process to reduce the number of slime-forming microorganisms.

soiling agent, *n*—substance applied either along with or on top of the test microorganism that can reduce the effectiveness of the antimicrobial technology. **E3135, E3179**

soil load, *n*—a solution of one or more organic, or inorganic substances, or both, added to the suspension of the test organism to simulate the presence of body secretions, excretions, or other extraneous substances. **E2111, E2197, E3273**

spore, *n*—a dormant, robust, and non-metabolically active structure produced by certain bacteria enabling prolonged survival and greater resistance to deleterious environmental factors. **E3180**

sterilant, *n*—chemical or physical agent(s) that kill all forms of microorganisms in the inanimate environment.

surrogate microorganism, *n*—microorganism that is tested to estimate responses of other microorganism(s) for which direct testing is impractical.

test substance, *n*—a formulation that incorporates antimicrobial ingredients. **E2197, E3273**

transient microbial skin flora, *n*—microorganisms that contaminate the skin but do not form a stable population. **E2784**

treated materials or articles, *n*—plastic, textile, or other pre-formed articles pretreated with antimicrobial products before first use. The antimicrobial benefit is limited to the material or article to maintain or preserve its chemical and/or physical integrity.

ultraviolet germicidal irradiation (UVGI)—a method that uses short-wavelength ultraviolet (UVC) light to kill or inactivate microorganisms primarily by forming pyrimidine dimers, leaving them unable to perform vital cellular functions. **E3135, E3179**

ultraviolet (UV) light, *n*—radiation having wavelengths shorter than wavelengths of visible light (~400 nm) and longer than those of X-rays (~100 nm). **E3135, E3179**

UV-A, *n*—radiation within the ultraviolet spectrum that extends from approximately 315 to 400 nm in wavelength. **E3135, E3179**

UV-B, *n*—radiation within the ultraviolet spectrum that extends from approximately 280 to 315 nm in wavelength. **E3135, E3179**

UV-C, *n*—radiation within the ultraviolet spectrum which extends from approximately 100 to 280 nm in wavelength. **E3135, E3179**

validation, *n*—the action (or process) or proving that a procedure, process, system, equipment, or method works and achieves its intended purpose under defined conditions.

vapor, *n*—a substance in the gas phase at a temperature lower than its critical temperature, such that it can be condensed back into a liquid by increasing the pressure on it without reducing the temperature. **E3092**

volar aspect of the forearm, *n*—the surface of the forearm on the same side as the palm of the hand.

xenon arc lamp—a specialized type of gas discharge lamp, an electric light that produces light by passing electricity through ionized xenon gas at high pressure. **E3135, E3179**