Kimberly-Clark PROFESSIONAL*

KIMTECH* BRAND

Technical Glossary

Question/Topic	Discussion
AAMI	Association for the Advancement of Medical Instrumentation. This organization is composed of a number of specialized task forces, with volunteer experts from government, industry and academia, that develop standards and guidelines as needed.
Abrasion Resistance, Gloves	The ability of the glove or finger cot to resist abrasion while in use, judged by one of the following criteria: 1) retention of barrier integrity, or 2) particle generation.
Abscess	A cavity filled with pus (dead white blood cells and broken down tissues) and surrounded by inflamed tissue. Sterile abscesses are caused by a non-bacterial inflammatory response which may occur in acute or chronic inflammatory conditions.
Absorbable Dusting Powder (ADP)	A glove donning powder consisting of modified (cross-linked) cornstarch and less than 2% magnesium oxide as defined in the United States Pharmacopeia (USP). Phosphorous oxychloride or epichlorhydrin are utilized in the surface cross-linking.
Absorbent	Pull within the material (e.g. a sponge absorbs).
Accelerator	A chemical used as a catalyst to accelerate the cross-linking of liquid latex into a usable solid film. Primary accelerators used for making gloves are thiazoles (MBTs), thiurams, carbamates and thioureas.
Activated Carbon (Charcoal)	An absorbent of porous structure manufactured by carbonization of organic material and treated by controlled oxidation to increase its adsorptive properties.
Activated cells	Transformed cells that have achieved the capacity to exercise their full functional potential (e.g. activated macrophages, T-cells and mast cells). They activate, or turn on, when something in the environment triggers their need.
Adsorb	Adhere to the surface of a material (e.g. salt adsorbs to the surface of popcorn).
Adsorption	A surface phenomenon involving the removal of a substance from the atmosphere or liquids into an adsorbent's pore structure where it is held via electrostatic forces. Commercial adsorbent materials have enormous internal surfaces.
Aerosol	A gaseous suspension of solid or liquid particles about 100 µm or smaller in size.
Aerosol Photometer	A light scattering mass concentration indicator. (Instruments of this type have a threshold sensitivity of at least 10-3 microgram per liter for 0.3 micrometer diameter DOP particles and are capable of measuring concentrations over a range of 105 times)
Agar Diffusion	The Agar Diffusion or Overlay test is one of the many assays used by medical device manufacturers and pharmaceuticals to screen biomaterials for cytotoxicity.
Agar Overlay	See " Agar Diffusion."
Airborne Particulate	Airborne particulate are discrete particles having measurable physical boundaries in all directions and of such size and mass as to remain suspended in air indefinitely until their path allows adherence to a solid material.
Allergen	A substance, usually a protein, that is able to elicit an IgE antibody response and activate mast cells. Every allergen is a type of antigen but not every antigen is an allergen.
Allergic contact dermatitis	An allergic rash (Type IV) with physiological memory to the chemical sensitizer which caused it (meaning it will cause it again with subsequent exposure).
Allergy	The immunologic state induced in a susceptible individual by an allergen characterized by a marked change in the subject's reactivity. Both Type I and Type IV hypersensitivities are allergies (e.g. Type I = latex protein allergy, hay fever, penicillin) An allergy is a physical response to specific substances. Examples are food allergies (i.e. milk, peanuts and seafood), flowers and weeds (i.e. ragweed), mold, animal dander (i.e. dog, cat and rabbit) and bee stings.
Anaphylaxis	An immediate systemic allergic reaction to a foreign protein or other substance. The reaction results from the release of histamine and other substances when allergen combines with IgE antibodies on mast cell surfaces.
Angioedema	Diffuse swelling. In Type I reactions, swelling of the lips and periorbital (around the eyes) often occurs.
Anion	The ion in an electrolyzed solution that migrates to the anode when voltage is generated; broadly: a negatively charged ion. Typical examples include Chloride (Cl-), Phosphate (PO4-3), Sulfate (SO4-2), Nitrate (NO3-).
ANSI	American National Standards Institute. ANSI endorses standards and guidelines for the U.S. but does not actively create them.
Antibody	A substance formed in the body that reacts specifically with a protein or allergen which causes Type I hypersensitivity (IgE)or resistance to infection (IgA, IgD, IgE, IgG, IgM).

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Antigen	Any substance that is capable of eliciting an immune (antibody or cellular) response; a molecule that causes the creation of and subsequently combines with the antibody or antigen-specific receptor on a T-cell.
Antigenic chemicals	Chemical contact sensitizers that can elevate the level of sensitization for patient and healthcare provider, potentially resulting in allergic contact dermatitis (Type IV, delayed type hypersensitivity) externally or granulomas internally.
Antioxidant	A substance added to latex and synthetic gloves to prevent or delay deterioration of the glove by the oxygen in air.
Antistatic	Usually refers to the property of a material that inhibits triboelectric charging. Do we have "antistatic gloves" or more specifically, do we apply antistatic agents on any of our gloves: The answer is No.
Antrhax/bioterrorism	
AQL	Acceptable Quality Level. Applies to product attributes and defines the allowable number of defects for various sample sizes. For example, AQL 1.5 means that the sample must demonstrate that it exceeds 1.5% defects in order to reject the sample.
Are our gloves silicone-free?	Currently, all our cleanroom nonsterile products are silicone free. We do not make the same claim with our boxed products. Some of them have silicone in them.
Asthma	A condition of the lungs in which there is widespread narrowing of the airways. Most cases represent a chronic form of allergy due to IgE antibodies. Irritant asthma is activated by irritants such as a chemicals or particles.
ASTM	American Society of Testing and Materials. The ASTM issues testing standards and specifications. The FDA utilizes many of the standards developed by the ASTM to establish medical device requirements.
Asymptomatic	Without symptoms. An asymptomatic individual has not displayed reactions.
Atopic individual	A person with a hereditary tendency to develop IgE-mediated hypersensitivity, usually having multiple allergies to ragweed, cat dander, dust mites, pollens and foods.
Average	The sum of individual observations divided by the total number of observations. Average represents the central tendency of a "sample" group. The sample group can be used to make inferences about the entire population.
Bacteria	One-celled, microscopic plant-like organisms lacking chlorophyll that multiply by fission. Bacteria typically measure from 0.2 to 50 um in diameter.
Bacterial Filtration Efficiency (BFE) (face mask)	Bacterial Filtration Efficiency (BFE) tests are commonly performed on various types of filtration media, which are designed to provide a level of protection against biological aerosols. The BFE test procedure was designed after Military Specification 369.
Basophil	A cell in the blood stream functioning in a similar manner as mast cells, which reside in the tissues. See Mast cells. IgE antibodies can attach to its outer surface.
Bioburden	Bioburden is the population of viable microorganisms on a raw material, component, a finished product and/or a package. When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item.
Biocompatibility	The property of not causing cytological change when introduced to a biological system or model.
Biotech	Biotechnology can be broadly defined as "using living organisms or their products for commercial purposes." As such, biotechnology has been practiced by human society since the beginning of recorded history in such activities as baking bread.
B-Lymphocyte (B-cell)	Responsible for the production of immunoglobulins (antibodies) of all types: IgA, IgD, IgE, IgG, IgM. As the B-cell is activated or transformed and begins production of antibodies, it becomes known as a plasma cell.
Breakthrough Detection Time (BDT)	Breakthrough detection time –"elapsed time measured from the start of the test to the sampling time that immediately precedes the sampling time at which the test chemical is first detected".
Brink of Chaos	A process that is capable but not in a state of statistical control.
Calcium carbonate	A mold-release agent often used that facilitates the release of latex gloves from their porcelain molds (formers). Calcium carbonate is a non water-soluble crystal. It occurs in nature as oyster shells, chalk and limestone.
Calibration	Comparison of a measurement standard or instrument of unknown accuracy with another standard or instrument of known accuracy to detect, correlate, report, or eliminate by adjustment, any variation in the accuracy of the unknown standard or instrument.
Can I have an allergic reaction if I breathe the air from incinerated gloves?	There should be no allergic response to breathing the products of combustion. Healthcare and laboratory services should always confirm that incineration temperatures and practices comply with optimal performance guidelines.
Can latex gloves be incinerated	Yes, latex gloves can be incinerated. Near total combustion occurs as a result of the extremely high temperatures used in incinerators. Any residual by-products such as sulfur dioxide and ash are minimal.
Can nitrile gloves be disposed of in a landfill?	Nitrile gloves can be disposed of in a landfill, however, they are not biodegradable any residual chemicals may leach out over time.
Can nitrile gloves be incinerated?	Yes, nitrile gloves can be incinerated. Total combustion occurs as a result of the extremely high temperatures used for incineration. Any resulting sulfur dioxide, nitrogen or carbon dioxide by-products are minimal.
Can vinyl gloves be disposed of in a landfill?	Vinyl gloves can be disposed of in a landfill, however vinyl is not readily biodegradable. Disposal of gloves contaminated with infectious or other hazardous materials must follow local, state and federal regulations for treatment of such waste.
Can vinyl gloves be incinerated?	Yes, vinyl gloves can be incinerated. Before choosing incineration for vinyl gloves, users should ensure compliance with local safety practices.

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CAS Number	The CAS Registry number is a unique number assigned to a chemical by the Chemical Abstracts Service.
Cation	The ion in an electrolyzed solution that migrates to the cathode when voltage is generated; broadly: a positively charged ion. Typical examples include: Sodium (Na+), Calcium (Ca2+), Magnesium (Mg2+), Potassium (K+).
CE Mark	What is CE Marking? CE Marking is the symbol as shown on the top of this page. The letters "CE" are the abbreviation of French phrase "Conformité Européene" which literaturely means "European Conformity".
Certificate of Compliance (or Conformance)	A written statement, signed by a qualified party, attesting that the items or services are in accordance with specified requirements, and accompanied by additional information to substantiate the statement.
CFU (colony forming units)	Either one or an aggregate of many microbial cells which, when cultivated on solid media, will develop into a single visual colony. The unit of measure used for reporting bioburden (CFU/product).
Chaos	A process that is neither in control, nor statistically capable.
Charge Decay	The decreased and/or neutralization of a net electrostatic charge. A measure of how rapidly a material can dissipate an applied charge. In essence, it is a measure of how well a material can conduct electricity or the movement of electrons.
Chemical Compatibility	The interaction of a material with a chemical substance with which it has come into contact. A minimum interaction is desirable.
Chemical Degradation	Changes in material when in contact with chemicals. Undesirable forms of degradation are swelling, loss of tensile strength, deformation, and loss of abrasion resistance. See also: Permeability.
Chromatography	Chromatography is a separations method that relies on differences in partitioning behavior between a flowing mobile phase and a stationary phase to separate the components in a mixture.
Circumscribed	Within a well-defined area or in one with definite boundaries or limits. A hive has a circumscribed region of swelling.
Clean Area	A defined space within which the airborne particulate level is controlled to specified limits.
Cleanroom	A room in which the concentration of airborne particles is controlled to specified limits. Federal Standard 209E - A document that establishes standard classes of air cleanliness for airborne particulate levels in cleanrooms and clean zones.
CleanRoom – Laminar Airflow	A cleanroom in which the filtered air makes a single pass through the work area in a parallel flow pattern with a minimum of turbulent flow areas. Laminar airflow rooms have a minimum of 80% of the ceiling (vertical flow) or one wall (horizontal flow).
CleanRoom – Mixed Flow	A hybrid cleanroom consisting of a combination of laminar airflow clean room and turbulent flow clean room.
CleanRoom (Clean Facility)	A room (facility) in which the air supply, air distribution, filtration of air supply, materials of construction, and operating procedures are regulated to control airborne particle concentrations to meet appropriate cleanliness levels.
CleanRoom (Facility) – As Built	A cleanroom (facility) that is complete and ready for operation, with all services connected and functional, but without production equipment or personnel within the facility.
CleanRoom (Facility) – At Rest	A cleanroom (facility) that is complete and has the production equipment installed, but without personnel within the facility.
CleanRoom (Facility) – Operating	A cleanroom (facility) in normal operation with all services functioning and with production equipment and personnel present in the facility.
Conductive Material	A material that has a surface resistance less than 1.0 x 105 OHMs per square. Able to conduct or transmit electricity. The movement of electricity is so rapid that the material is considered to "conduct" electricity.
Contact sensitizer (other keywords: accelerators, MBT, carbamate, thiurams, mercaptobenzothiazole)	A chemical agent used in the manufacturing process of gloves that may elicit a delayed type allergic reaction (Type IV) after repeatedly exposing the substance to a susceptible individual.
Contact urticaria	Contact urticaria or hives may appear within minutes to an hour after a sensitized individual comes in contact with allergens to which he/she is allergic. It is a Type I hypersensitivity reaction.
Contaminant	Any unwanted substance present in or on a material.
Control Chart	A specific process monitoring chart that will graphically show whether a process is in control or out of control. In control means that all sample groups produced are from the same population.
Cp	A measure of a process' ability to meet specification and equals the total spec tolerance divided by six standard deviations. The larger the number, the greater a process' ability to meet spec. Cp = Total Spec Tolerance / 6 x Standard Deviation.
Cpk	Similar to Cp, except it considers that the process may not be on target and calculates the process capability considering only one side of the specification tolerance. Cpk is equal to the average minus the closest spec tolerance (average minus the min).
Cross-reactive proteins	Antigens which differ from one another but are similar enough that they can react with antibodies raised against either one of them.
Cytokines	Cytokines are chemicals, released from cells, that signal other cells to the area, activate specific cell types, "turn off" cells, and regulate other activities as needed.
Cytotoxic	Injures cells. Demonstrated using tests such as hemolysis, medium eluate method (MEM), agar overlay and embryo toxicity.
Cytotoxicity	See "Agar Diffusion."
Decontamination	The removal of contamination from air, other gases, surfaces, or liquids.
Decontamination Factor	The ratio of the concentration of a contaminant in the uncleaned (untreated) air to its concentration in the clean (treated) air.

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Degradation	Deleterious effects that liquid chemicals, extreme heat, ozone, fatigue, oil or other substances have on the physical properties of gloves. Tell-tell signs of degradation may include softening and tackiness, brittleness, loss of elasticity and growth.
Degranulation	The release of granules from a sensitized mast cell when triggered by an allergen (Type I reaction). Granules include stored substances such as histamine. The cells then re-synthesize new stores of mediators and continue their patrol.
Deionize	To remove ions. Deionization is generally the removal of ions from water by a process called ion exchange. Water is passed over a resin (plastic) exchange bed. The ions in the water have a greater attraction to the exchange bed than to the water.
Delayed hypersensitivity (Type IV or chemical allergy)	Initiated by antigenic chemicals (chemical contact sensitizers) on the skin, this delayed hypersensitivity causes the symptoms of allergic contact dermatitis such as itching, red appearance; small blisters; dry, thickened skin; crusting; scabbing sores.
Dermatitis	A general term referring to any inflammation of the skin; may be caused by irritation or Type IV (delayed type hypersensitivity). Characterized by erythema (redness), pain, pruritus (itching), vesicles (tiny blisters) and papules (hard bumps).
Differential pressure (Delta P) (mask)	The differential pressure test evaluates the air flow resistance of filtration media. The differential pressure is defined in Military Specification 36954C.
Disease	A departure from health or normal function (e.g. a broken bone, chicken pox, a sprained ankle, an allergy).
D-Max	The maximum radiation dose that can be delivered to a product before unacceptable damage occurs.
D-Min	The minimal radiation dose required to sterilize the product to the desired sterilization assurance level (SAL).
DNAse	An enzyme that breaks down DNA. Present on standard gloves, additional processing is required for its removal. Should be considered when running laboratory DNA isolation, purification and characterization studies.
Do we have sulfur in our gloves?	All latex (both NRL and Nitrile) use native S as a cross link element. Vinyl gloves do not typically have sulfur.
DOP Aerosol	A dispersion of dioctyl phthalate (DOP) droplets in air.
Dose audit	A check to make sure the dose is still correct. The population and sterilization resistance of microorganisms vary with environmental conditions such as temperature and moisture.
Dose mapping	Product dose mapping is conducted to identify the zones of minimum and maximum dose, within the product load with the specified loading pattern, and to assess the reproducibility of the process.
Dose setting	Method 1, "Dose Setting using Bioburden Information." Determine the number of organisms on the packaged, pre-sterilized gloves.
Dosimeter	A device that measures the amount of radiation which reaches the position where the dosimeter is placed.
Draize Test (200 Person Modified Draize Test)	200-person challenge test utilized to determine hypoallergenicity (irritant or dermal reactions caused by chemicals) of a given product. Samples of the test glove are patch tested on each of the individuals repeatedly over a 6-week period.
Dust	Small, solid particles that may be present on a surface or in a gas.
Dyshydrosis	A condition of dermal breakdown (irritation) aggravated by constant, long-term contact with sweat in an occlusive environment, as under a glove without frequent changing. Vesicles, or tiny blisters, which are very painful often appear.
Dyspnea	Difficulty breathing; shortness of breath.
e. T-cells (Tc) which release cytokines (chemical signals) and assist phago-cytes	
Eczema	Dermatitis of the skin, often of unknown origin, marked early by redness, itching, minute papules and vesicles, weeping, oozing, and crusting; and later by scaling, thickening and hardening of the skin. Causes may be allergic or non-allergic.
Edema	Swelling.
Element	Any of more than 100 fundamental substances that consist of atoms of only one kind.
Elongation	Measurement in percent of the length a glove material can be stretched before it breaks.
Endotoxic shock	Physiologic response resulting from a high dose of endotoxins into the blood stream. There is a sudden outflow of fluid from the blood vessels resulting in blood pressure drop (hypotension) which can be sufficient to cause the body to go into shock.
Endotoxin	Pieces off the cell wall of dead bacteria, capable of causing multiple local and systemic pathological problems, including fever, complement activation, cell lysis, tissue inflammation, diarrhea, microthrombi formation (clots) and disseminated intravascula.
Enzyme-Linked Immunosorbent Assay (ELISA)	A highly sensitive immunoassay for specific antibodies or antigens (including allergens) depending on how the test is set up. Results expressed as mg/g or mL; ppm; Au/g or mL.
Erythema	Inflammatory redness of the skin.
EtO Sterilization	Ethylene oxide (EtO), formaldehyde and glutaraldehyde, the most commonly used low-temperature sterilizing agents, interact with microorganisms by replacing available hydrogen atoms with alkyl groups.
Fiber	A particle having a length 100 micrometers or greater and an aspect ratio of at least 1:10.

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Fissure	Horizontal cracks in the skin most notable in irritation reactions.
Flammability test for face masks (medical)	Flammability is evaluated according to 16 CFR1610 and requires a minimum performance level of Class 1.
Flare	A diffuse area of redness on the skin due to increased dilation of the local blood vessels. Flares are usually present surrounding the wheals of a hive, projecting outward like rays.
Fluid Penetration Resistance (face mask)	Healthcare workers who are involved in treating and caring for individuals who are injured or sick can be exposed to biological liquids capable of transmitting diseases.
Fomite	An inanimate object that serves to transmit or carry an infectious agent from one person to another. A recently used nose tissue from a child with a cold is a fomite.
Gamma Irradiation	The process of product sterilization utilizing gamma wave radiation. It is the most compatible sterilization process for latex gloves.
Garments, CleanRoom	Special items of clothing designed to be worn to protect clean room atmosphere from contaminants released by workers. Special clothing apparel includes footwear, or shoe covers, and head covers.
Gas Chromatograph	An analytical instrument used for quantitative analysis of extremely small quantities or organic compounds. The chromagraph's operation is based upon the adsorption and partitioning of a gaseous phase within a column of granular material.
Gas Plasma	Gas Plasma Sterilization. Oxidizing sterilants, such as chlorine dioxide, hydrogen peroxide, ozone, and peracedic acid, are reactive and readily decompose into more unstable species called free radicals.
Genetically predisposed	This describes an individual with the DNA capability to physiologically act in a particular way.
Gloves and Dimethylmercury	
Gloves for use repeated contact in food manufacturing	The blue nitrile exam gloves (Safeskin® and Fisher Blue®) have been evaluated to pass the regulatory requirements for repeated food contact.
Gnotobiotics	Gnotobiotics, «NOH toh by AHT ihks,» is the scientific study of animals or other organisms raised in environments that are free of germs or that contain only specifically known germs.
Good Manufacturing Practices (GMPs)	What are GMPs? Good Manufacturing Practices (GMPs) are regulations that describe the methods, equipment, facilities, and controls required for producing: human and veterinary products (21 CFR 210-211), medical devices (21 CFR 820), processed food.
Granuloma	Calcified nodules formed by the body as a protective, walling-off of foreign bodies or chronic inflammatory conditions caused by long-term irritants, infections or the presence of particles triggering a Type IV response.
Hapten	A small biochemical group that initially, by itself, cannot elicit an allergic response. It must conjugate (join) to a carrier (usually protein) to be recognized by the body. Once the body reacts to the two together, it may recognize the hapten alone.
Hemolysis	A hemolysis test measures the ability of the glove material to cause red blood cells to rupture. Glove extracts are placed in direct contact with blood by exposure to an aliquot of saline containing rabbit red blood cells.
Hemolytic	Destructive to (rupturing) red blood cells.
HEPA (High Efficiency Particulate Air) Filter	A replaceable extended-media dry-type filter in a rigid frame, having minimum particle collection efficiency of 99.97% for 0.3 micrometer thermally-generated dioctyl phthalate (DOP) (or specified alternative aerosol) particles, and a maximum clean-filter.
High pressure liquid chromatography (HPLC)	Chromatography is a separations method that relies on differences in partitioning behavior between a flowing mobile phase and a stationary phase to separate the components in a mixture.
Histamine	A highly vasoactive (acts on the blood vessels) substance liberated in large amounts from basophils and mast cells during allergic (immediate type hypersensitivity - Type I) reactions.
Histogram	A bar graph in which the area of each bar is proportional to the frequency or relative frequency represented.
How are polymers classified?	Polymers are broadly classified in two types: Thermoplastics & Thermosets. Thermoset materials undergo chemical change (crosslink) with the application of heat which results in permanent and non-reversible setting of the material.
Hyper	Above, higher than normal, as in hyperactive, hypertension (high blood pressure), or hypersensitivity.
Hypersensitivity	Term used to describe an exaggerated response to a substance (i.e. an antigen), developed after repeated exposure, causing a genetically predisposed individual to become sensitized or allergic (Type I or Type IV).
Hypo	Below, under, deficient, containing less than usual such as in hypodermic, hypotension (low blood pressure).
Hypoallergenic	Generally used as a term to describe a product's reduced potential for developing a skin response to residual chemicals. A modified Draize test performed on 200 subjects is used to substantiate a hypoallergenic claim. After producing product to meet these requirements, manufacturers were allowed to utilize the term hypoallergenic as an identifier for the product (a claim).
Iatrogenic	An adverse patient condition caused by the treatment or diagnostic procedures. An iatrogenic disorder is a condition caused by medical personnel or procedures or through exposure to the environment of a health-care facility.
Ideal State	A process that is both in control and statistically capable.

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IEST	Institute of Environmental Standards and Technology. A consortium that develops standards and recommended practices and provides training by industry experts. The standards and recommended practices are developed by committees comprised of scientists.
Ig	Antibodies (immunoglobulin) of any of the five classes.
IgE	Immunoglobulin E (IgE Antibodies). IgE antibodies are the hallmark of a Type I allergy (e.g. penicillin, peanut, latex protein).
IgG	Attaches to foreign bodies as well as bacteria to incapacitate and assist in their destruction. These are the antibodies created when individuals are inoculated with vaccines.
Induration	Hardness, caused by inflammatory swelling with an excessive number of white blood cells.
Infection	Multiplication of organisms in the body that may or may not result in disease.
Inflammation	Cellular or systemic response to physiological, chemical or biologic injury. Inflammation occurs as a part of irritation, Type I and Type IV reactions.
Investigation of airborne molecular base and ammonium off-gassed from cleanroom gloves (Outgassing)	
Ion	An atom or group of atoms that carries a positive or negative electric charge.
Irritant contact dermatitis	Dermatitis develops when a substance repeatedly chemically injures, physically abrades or otherwise damages the skin.
Irritation	An inflammatory reaction of tissues to an injury. An irritation is not an allergic response, it possesses no physiological memory of the substance that caused it. Repeated contact or long-term exposure can result in irritant contact dermatitis.
Is the filter media for 62476 (Value Mask) the same as that of 62694 (Voltec mask)?	Yes
Is there any data on problems associated with burning latex gloves?	The Environmental Protection Agency (EPA) gives data on problems associated with rubber tires and pollution evaluation criteria in regards to tire burning but not specifically on latex gloves.
ISO	The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. ISO has developed a series of standards relating to Quality Systems known as the ISO 9000 family standards.
ISO 9002	A quality system model for quality assurance in production and installation. I would skip ISO 9003 because it implies like 9002 doesn't cover inspection and testing.
kGy	The International System of Units (SI) for absorbed dose where 1 gray (Gy) equals 1 joule per kilogram. This measurement of the amount of radiation exposure was formerly expressed in megarads (Mrad).
LAL	
Laminar Air Flow	Air flow in which essentially the entire body of air within a confined area moves with uniform velocity along parallel flow lines.
Latex	Commonly, it is a milky, usually whitish fluid obtained from over 1,000 species of trees and plants. Relating to gloves, it is natural rubber latex, the raw material which comes from the Hevea brasiliensis tree.
Leaching	Process applied in the production of gloves by which chemicals or contaminants are dissolved and carried away by water to reduce chemical residual levels. Wet gel leaching occurs right after latex is dipped onto the mold.
LEAP	An ELISA utilizing rabbit IgG antibodies made to latex proteins. The advantages include specificity for latex proteins and a heightened sensitivity or detection capability over the Modified Lowry assay for total protein.
Leukocyte	White blood cells, the body's major cellular defense system.
Lichenification	Thickening and hardening of the skin with exaggeration of its normal markings, like lines and creases, resembling elephant skin in appearance.
Lowry	Determines the concentration of total protein present in a sample. A Modified Lowry assay was developed for use with latex products.
Lymphocyte	A white blood cell, either B-cell or T-cell.
Lymphokine	A soluble chemical released by sensitized lymphocytes on contact with a specific antigen. Lymphokines help stimulate the activity of other lymphocytes and macrophages. Lymphokines are specific forms of cytokines.
Lysed	Ruptured or broken open as in lysed red blood cells during the hemolysis test.
Maceration	Softening of tissues by the action of a liquid, making it more vulnerable to abrasive injury. Hands can become macerated after hours of sweating under a glove, potentially resulting in irritant contact dermatitis.
Magnesium oxide	A very fine, white, odorless powder added to modified cornstarch to prevent caking in the production of USP absorbable dusting powder. No more than 2% is allowed.
Mast cell	Mast cells are white cells residing primarily in the tissues which carry receptors for IgE and, together with basophils, participate in immediate type hypersensitivity (Type I) reactions by releasing stored histamine and other vasoactive substances.

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Mean	Represents the "Central Tendency" or average of an entire population. The formula is the same as for the average, except the mean includes the entire population. It is typically impractical to measure every member of any population.
Mediators	Substances that incite, initiate or control such reactions as inflammation, white cell activation or the progress of an allergic reaction.
Medical Device	The definition of a medical device appears in section 201(h) of the FD&C Act. A device is "...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, inc..."
Meningomyelocele (Spina Bifida)	A birth defect of the spinal column, characterized by the absence of vertebral arches (top part of the backbone), through which the spinal membranes may protrude. Thus, this portion of the central nervous system is not adequately protected.
Method 1	Dose setting utilizing the number (bioburden) and resistance of micro-organisms on the products to determine the level of irradiation necessary for sterilization with the desired safety margin (e.g. 10-6).
Micrometer (micron)	A unit of measurement equal to one-millionth of a meter or approximately 0.00003937 inch (e.g. 25 micrometers are approximately 0.001 inch).
Micron	mi•cron also mi•kron (mì¹kròn´) noun plural mi•crons or mi•cra (-kre) also mi•krons or mi•kra (-kre) A unit of length equal to one millionth (10-6) of a meter. No longer in technical use. [Greek mikron, neuter of mikros, small.]
Modified Lowry assay	See Lowry.
Modulus	A measurement of the resistance to stretch. A lower modulus represents a glove in which it is easier to move and thus less fatiguing.
Neutrophils (Polymorphonuclophils – [PMNs])	See leukocytes.
Non-pyrogenic	Non-fever causing. Reflects low levels of endotoxins which cause fever, inflammation, endotoxic shock, elicit micro-thrombi formation and numerous other adverse conditions. (See Endotoxin)
Normalized Breakthrough Detection Time	Normalized breakthrough detection time – Time at which the permeation reaches 0.1 ug/cm2/min. Helps in comparing results that used analytical systems of varying sensitivity levels.
Nosocomial	Infection acquired in a hospital. Nosocomial diseases may be acquired by patients, visitors or hospital staff.
Outgassing (gloves)	Outgassing is like evaporation, only with solid materials. It happens because even the densest solid material isn't really solid. There are spaces between the molecules.
Ozone	An extremely reactive gas (O3) that is produced by the interaction of oxygen and an energy source. Generators, fans, electrocautery units, X-ray machines, etc. produce ozone when running. Ozone exposure can lead to deterioration of latex.
Papules	Small circumscribed, solid, elevated bumps in the skin. Scratching them is usually painful.
Parenteral	Taken into the body or administered in a manner other than through the digestive tract, as by intravenous or intramuscular injection. Parenteral products are defined as those drugs that are injected directly into the blood stream.
Particle	A solid or liquid object, generally between .001 micron and 1000 microns in size.
Particle Counter, Airborne	An instrument for continuous counting of airborne particles larger than a given threshold size. The sensing means may be optical, electrical, aerodynamic, etc.
Particle Counter, Optical	A light scattering instrument with display and/or recording means to count and size discrete particles in air, as defined by ASTM F-50-83.
Particle Filtration Efficiency or Sub-micron Filtration or Latex Particle Challenge test (face mask)	The filtration efficiency of filter media materials against sub-micron particles cannot be determined using viable challenge particles. Although now discontinued, the ASTM F1215 is the standard for conducting the latex particle challenge.
Particle Size	The maximum linear dimension of a particle as observed with an optical microscope or the equivalent diameter of a particle detected by an instrument.
Particle Size Distribution	The relative percentage by weight or number of different particle size fractions.
Particulate	A substance that consists of particles (minute quantities of solid or liquid matter.
Particulate Cleanliness Level, Fluids	The number of particles equal to or larger than a specified size that are present in a unit volume of fluid.
Particulate Filtration Efficiency (PFE)	This is a measure of the ability of a material to screen out airborne particles (usually done at .1 - .3 micron particle size). This test is also known as the Latex Particle Challenge.
PCR (polymerase chain reaction).	PCR is probably the most commonly used technique in molecular biology and it would be difficult to give you a true indication of how much it has changed the field. It would not be an over exaggeration to say that it has completely revolutionised biology.
Penetration	Penetration is usually defined as the flow of a chemical through closures, porous materials, seams, and pinholes or other imperfections in a protective clothing material on a nonmolecular level.
Permeability	The process whereby a fluid or gas passes through a barrier at the molecular level. Passage of these materials through defects such as holes or tears does not constitute permeability.

Technical Glossary

Permeation	Permeation is usually defined as the process by which a chemical migrates through the protective clothing material at a molecular level.
Petroleum Jelly and gloves	Oil and petroleum-based products can cause the deterioration of latex gloves. In fact, OSHA has warned users about this and a standards interpretation and compliance letter on the subject is available on their website.
pH	Hydrogen ion concentration; measurement of how acidic or basic a glove extract is.
Phagocyte	Cells that engulf or take in substances that the body is trying to get rid of, including bacteria, fungi, foreign bodies (e.g. asbestos) and dead cell or tissue debris.
Phagocytic	The ability of a cell to engulf and take in foreign bodies or microorganisms. Phagocytic cells include macrophages and neutrophils (PMNs).
Pharmaceutical Cleanroom	The cleanroom is an integral part of the manufacturing process required to produce sterile drug products.
Population	A set of observations with common traits. In statistics, it usually refers to a Normal distribution (Bell Shaped Curve) to which normal statistics, such as Standard Deviation, apply.
Powder	Donning powder on gloves is composed of cornstarch (USP absorbable dusting powder). Some companies have qualified a lactose starch. Powder facilitates donning and absorbs sweat.
Precipitation, Electrostatic	The separation of particulate matter from air or other gases under the influence of an electrostatic field.
Product Dose Mapping	See "Dose Mapping."
Protease	An enzyme that breaks down proteins. Present on standard gloves to varying levels, additional processing is required for its removal. Should be considered when using gloves during laboratory protein isolation and characterization studies.
Protein content	Regarding latex gloves, protein content is the measurement of total protein regardless of allergenic content. The ASTM D5712 Modified Lowry assay is the method recognized by the government for use with gloves.
Proteins	Any of a class of naturally occurring complex combinations of amino acids (containing carbon, hydrogen, oxygen, nitrogen, usually sulfur, occasionally phosphorus) which are essential constituents of all living cells.
Pus	A "creamy" liquid that consists of the remains of dead white blood cells and tissue debris. Its main constituent is an abundance of polymorphonuclear cells.
Pyrogen	A fever-producing substance. Endotoxin is a pyrogen.
Pyrogenic	Capable of eliciting a fever.
Quality System Regulation (QSR)	The Food and Drug Administration (FDA) is revising the current good manufacturing practice (CGMP) requirements for medical devices and incorporating them into a quality system regulation.
Radioallergosorbent Test (RAST)	A radioimmunoassay designed to detect IgE-bound allergens responsible for tissue hypersensitivity. The protein allergen is bound to a surface such as plastic plates or spheres. The patient's serum is added.
Rhinitis	Inflammation of the nasal mucous membrane (runny nose).
RNAse	An enzyme that breaks down RNA. Present on standard gloves, additional processing is required for its removal. It is more ubiquitous than DNAse and thus more difficult to avoid.
Rubber	An elastic substance obtained from the latex of many tropical plants, especially Hevea brasiliensis (rubber tree). It is present in over 40,000 products in the medical and consumer industry.
SAL	See "Sterility Assurance Level."
SAL Dose	The level of radiation delivered to the product to achieve the required SAL (sterility assurance level).
Sampling	A process consisting of the withdrawal or isolation of the fractional part of a whole. In air or gas analysis, the separation of a portion of an ambient atmosphere with or without the simultaneous isolation of selected components.
Sensitization	The physiological process of developing an allergy.
Sensitize	To increase the specific sensitivity of an individual to an antigen or allergen as the result of exposure. Sensitization is an asymptomatic process until an individual's threshold level is reached through repeated exposure.
Shedding	The generation of particles as a result of mechanical action on a material.
Silicone [gloves]	Silicone is a synthetic polymer, or macro-molecule, whose backbone is a repeating chain of Si-O molecules, with various organic groups attached to the silicon. The most common silicone is PDMS, poly-dimethylsiloxane [(CH3)2Si-O).
Solution	A homogenous substance, usually a single phase mixture of two or more materials.
Solvent	A substance which dissolves another to form a solution.
SPC (Statistical Process Control)	Statistical process control is the practice of using statistical methods such as control charts and capability analysis to monitor and control a process. The application of statistics to determine non-random changes in a process. Any changes or "shifts" in the process will be reflected as non-random occurrences and can be studied for root cause.
Specification – Design	A concise document defining technical requirements in sufficient detail to form the basis for a product or process. It indicates when appropriate, the procedure that determines whether or not the given requirements are satisfied.
Specification – Performance	A concise document that details the performance requirements for a product. The performance specification includes procedures and/or references for testing and certification of the product.

Technical Glossary

Spectrophotometer	A photometer for measuring the relative intensities of the light in different parts of a spectrum.
Spina Bifida (Meningomyelocele)	A limited defect in the spinal column, characterized by the absence of vertebral arches, through which the spinal membranes may protrude. Patients with Spina Bifida are at extremely high risk of latex-related hypersensitivity. (See Meningomyelocele)
Standard Deviation	A statistical measurement of variability equal to the square root of the arithmetic average of the squares of the deviations from the mean in a frequency distribution.
Static Decay	The materials ability to dissipate a charge. Normally tested by placing a known charge (5000 volts) on the material (glove). A non-contact meter measures the charge on the material.
Static Dissipative	A property of material having a surface resistivity of at least 105 OHMs per square, but less than 1.0 x 1012 OHMs per square surface resistivity.
Statistical Capability	A process with a Cpk > 1.0 (although this can be defined as > 1.33 as well).
Statistical Control	A process which, when sampled on a regular basis, demonstrates an average that is consistent with the population central tendency and variability. In other words, the sample is statistically from the same population as previous samples.
Sterile	Assurance that a given device is without living organisms.
Sterility indicators for masks (gamma dots)	We had a temporary shortage on indicator dots 2002. During that time, we decided to put the sterility indicators only on the outercases and not on the bags. This started in May and ended in July last year. Product codes affected were: 62483, 6246.
Steriliy Assurance Level (SAL)	The expected probability of an item being non-sterile after exposure to a valid sterilization process. This is a safety factor over and above demonstrating that all microorganisms are killed.
Sterilization	A physical or chemical process that completely destroys or eliminates all forms of microbial life.
Sterilization Dose	Minimum absorbed dose required to achieve the specified sterility assurance level.
Surface Finish, Glove	The surface properties of a glove or finger cot that may be chemically or mechanically applied, affecting the adhesion, abrasivity, hand or feel, or hardness of the covering.
Surface Resistivity	The resistance (ability to impede the flow of current) between the two opposite sides of a unit square of the surface of the material, in OHMs/Square (OHMs x width of path / length of the path).
Synthetic rubber	Not of natural origin; produced by chemical synthesis. Synthetic gloves include, but are not limited to, vinyl (PVC), neoprene(chloroprene), nitrile, viton (fluorocarbon rubber), styrene butadiene (SBR), Tactylon (Styrene-Ethylene-Butadiene-Styrene—SE.
Tachycardia	Rapid heart rate.
Talc	Magnesium silicate, $Mg_3Si_4O_{10}(OH)_2$, used as a solid lubricant. Banned from use on surgical gloves after found to cause granulomas and adhesions in surgical wounds.
Tensile strength	Measurement of the amount of stretch or pull required to rupture or break the glove material. Measurement is in Pa's or MPa's.
Threshold State	A process that is in control, but NOT statistically capable.
T-lymphocyte	The lymphocyte responsible for cell-mediated immunity. When sensitized, T-lymphocytes have a receptor which recognizes a specific chemical antigen (chemical sensitizer).
Tribocharging	The generation of charge when materials are contacted (rubbed) or separated. (One material will retain a positive charge and the other will retain a negative charge.) Some level of charge is always generated during any contact between two objects.
Type I hypersensitivity (Protein allergy)	An IgE-mediated immediate hypersensitivity reaction. Symptoms may include, but are limited to, hives, itching, runny nose, watery eyes, facial swelling, abdominal cramps, diarrhea, nausea, difficulty breathing, rapid heart rate (tachycardia).
Type IV hypersensitivity (Chemical allergy)	A cell-mediated delayed hypersensitivity reaction, characterized by dermatitis, eczema, erythema, vesiculation (blisters), keratosis (overgrowth and thickening of the skin), hyperplasty (thickening of skin) and cracking. The area affected usually sprea
U.S. Pharmacopeia (USP)	What is the U.S. Pharmacopeia? The U.S. Pharmacopeia (USP)—the world's only non-governmental pharmacopeia—establishes state-of-the-art standards to ensure the quality of medicines and other health care technologies.
Universal Precautions	A method of infection control in which all human blood and other bodily fluids are considered infectious for HIV, HBV, and other pathogens, regardless of patient history.
Urticaria	Hives. Symptom of Type I (immediate type hypersensitivity).
Validation	Establishing documented evidence that a system does what it purports to do.
Vasoactive substance	Substances that act on blood vessels; for example, to dilate (expand), constrict or alter blood vessel permeability.
Vesicles	Small, circumscribed elevation of the epidermis containing fluid; small blisters.
Vinyl gloves	Usually refers to synthetic gloves made of polyvinyl chloride (PVC).
Volume Resistivity	The resistance through the volume of metal, in OHMs/square.

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V-tear	Measurement of the amount of force necessary to propagate a tear.
Vulcanization	The process of treating crude latex, subjecting it to heat and sulfur to render it non-sticky, increasing its strength and elasticity.
What is a CAS number?	The CAS Registry number is a unique number assigned to a chemical by the Chemical Abstracts Service.
What is a polymer?	Polymers are primarily made of carbon, hydrogen and oxygen. The structure of polymers is like a chain where repeating units (-mers) are connected many (-poly) times.
What is ESD (Electrostatic Discharge)? [cleanroom gloves]	The rapid, spontaneous transfer of electrostatic charge. Usually the charge flows as a spark between two bodies with differing electrostatic potentials (voltages) as they approach one another. (ESD Assoc.)
What is ISO 17025?	What is ISO 17025? ISO/IEC 17025 - General Requirements for the Competence of Calibration and Testing Laboratories was published by ISO in December 1999.
What is Polypropylene?	What is Polypropylene? Producing a polymer begins with its basic building block: the monomer. A monomer is an individual molecule.
What is PVC (Poly vinyl chloride)?	Poly vinyl chloride popularly known as PVC is one of the most important commodity polymers. The monomer vinyl chloride is produced by reaction of chlorine with ethylene followed by dehydrohalogenation process.
What is the difference between the filter media described as "white, Meltblown polypropylene" an	High Efficiency is 20 gsm versus 15 gsm; the production of the high efficiency is also a different set-up allowing for finer fiber diameter.
What is the effect of steam on masks?	Steam willl impact filtration efficiency. Since we impart an electrostatic charge to enhance filtration that may be diminished with the steam.
What is the melting point of latex and nitrile gloves?	Akron Rubber Development Laboratory has determined that the melting point of nitrile is at 283.4 Celsius.
What is the relationship between non-volatile residue testing and particle counting? (gloves)	NVR is determined by weight, and particles definitely have weight, but not enough to be a measurable part of the NVR for most cleanroom consumables. The weight of particles depends on their volume and what their made of.
Wheal	A circumscribed swelling of the skin, appearing as an urticarial (hive) lesion; slightly reddened, often blanched in the center, changing in size and shape, extending to adjacent areas, and usually accompanied by intense itching.
White cell	Cells of the immune system, also called leukocytes. They received the name white cells because they compose the thin white layer that forms between the red blood cells and the serum when blood separates into layers as it is spun down in a centrifuge.
Why don't we test for heavy metals? (except for Zinc)	Testing of metals is related to equipment type. We use Ion Chromatography (IC).
Work Zone	That volume within the clean room that is designated for clean work and for which testing is required. The volume shall be identified by an entrance and exit plane normal to the air flow (where there is laminar airflow).