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Cleaning and Disinfection Quality

Guidance standards for establishing and assessing cleaning and disinfection in UK Hospitals and other healthcare facilities.

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Preface

This guidance is intended to set environmental cleaning and disinfection standards for healthcare facilities in the UK. It is the result of a collaborative effort, with representatives from, public and private healthcare providers, research institutes, cleaning contractors and medical device companies in the UK, North America and the Republic of South Africa. The decision to develop joint healthcare guidance and standards for a system to describe and evaluate disinfection and cleaning quality arose after the Environmental Network SIG meeting lead by Dr Elaine Cloutman-Green in London on the 30th of May 2017.

This guidance is intended to reflect and improve UK practice, but should be available for any similar group anywhere in the world. It is intended for use to help achieve pre-determined standards for their own healthcare facilities. It also takes into account the fact that healthcare providers may have different cleaning and disinfection challenges due to local circumstance.

It is essential that all cleaning operatives and their supervisors understand the Health and Safety and Control of Substances Hazardous to Health implications of the chemicals they are using. All cleaning operatives and their supervisors should be fully aware of the manufacturers recommendations for suitable Personal Protective Equipment that is to be worn with their individual chemistries. This information should be available to all based on the local requirements and protocols/ procedures. Risk assessments should be carried out prior to exposure to any chemical disinfectants.

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Introduction

This guidance describes a system for establishing a standard, which includes assessing disinfection and cleaning quality and includes guidance on laboratory testing.

The guidance provides suppliers and providers with the opportunity to verify standards and agree the levels of quality that have to attained and maintained.

The guidance provides customers with the opportunity to unambiguously specify their quality standard requirements.

The guidance makes it possible to inform the users of the facilities of the standards of disinfection and cleaning quality maintained in the facilities.

The guidance makes it easier for customers to make comparisons between different tenders, and it makes it easier for suppliers to prepare tenders, as quality standards required are defined unambiguously.

The standard provides a common basis for cleaning quality, facilitating the co-operation and communication between the customers and suppliers within the field of cleaning. A common language minimises the risk of misunderstandings.

The standard offers the prospect of unambiguous documentation of a predetermined level of quality.

The standard makes it possible for employees to inspect their own work against predetermined quality profiles. Thus, the standard enables employees to assess their own work performance.

The standard includes objective measuring criteria, leaving no room for doubt as to the quality selected.

Clinicians should not alter their use of surface disinfectants or cleaning regimes on the basis of testing methodologies that do not simulate actual disinfection and cleaning practices.

1 Scope

This Guidance describes a standard system for establishing and assessing disinfection and cleaning quality. It is based on the general principles of a Boyd cycle, where assessment of the environment, is followed by decision on actions required, followed by verification that the action has produced the required cleaning and/or disinfection standard. At this time, it is impossible to know the full impact of hand hygiene amongst other potential contributors to bio burden on healthcare facility surfaces. Until this is fully understood, it has to be assumed that the more effective the hand hygiene is for everyone entering healthcare premises, including staff, the lesser the effect of microbial contamination on surfaces will be from hands. The safety of patients and staff is the primary consideration in this document. It also recommends the type of chemicals used for disinfection with recommendations on the various tests that should be used in high, medium and low risk areas of healthcare facilities.

The guidance describes two main principles: visual inspection for cleaning of macroscopic particles, soling, dust etc, and testing of the efficiency of disinfection, using measuring instruments.

In addition, quantification and semi-quantification methods can be used within specialised areas, such as production of electronics, pharmaceutical, food or general laboratory environments where enhanced quality or statutory requirements are observed.

The indoor air quality is already described in the UK Healthcare Technical Memoranda HTM 03-01, but in order to achieve an acceptable indoor air quality, it may become necessary to stipulate special requirements as regards dust and lint. This is done by using dust measurements. Customers have the option of defining dust measurements as a supplement to the visual inspection. Customers have to specify when measurements shall be taken and the dust level acceptable, which will change from area to area in most healthcare establishments.

The system can be used in various ways:

- For inspecting the disinfecting and cleaning quality achieved;
- For assessing the soiling level and/or the rate of re-soiling;
- As an outcome requirement in connection with conducting, ordering, offering, and/or tendering cleaning services, without the need for external quality standards.
- For assessing the disinfecting and cleaning activity necessary to achieve a given level of quality.
- For establishing the disinfecting and cleaning quality achieved in relation to the activity.
- This standard describes the application of the measuring system for specifying a required quality and for inspecting the disinfection and cleaning quality achieved.

The standard may be adapted for use in various types of buildings and localities, e.g. in office buildings, hospitals, schools, nursery schools, shopping centres, shops, production halls, ships, buses, trains, aircraft, hotels and restaurants, irrespective of the cleaning methods, frequency or system used. The standard describes the result achieved immediately after disinfection and cleaning has been completed.

Note 1 – The standard does not include the measurement and control of cleaning-related services, such as replenishing lavatory articles, emptying waste paper bins, dealing with recyclable articles, etc. If any such tasks are to be undertaken, it shall be stated specifically in the cleaning contract, included the system for assessing and rating the quality of this part of the services.

Note 2 – The standard does not discuss the use of disinfection systems such as UV-C light. These systems are seen as an opportunity to enhance standard short term chemical cleaning and disinfection techniques and it is left to local risk assessment to determine the need for such enhancements.

2 Glossary of Terms Relating to Surface Disinfection:

2.1 Action Level:
Concentration of a regulated substance (e.g., ethylene oxide, formaldehyde) within the employee breathing zone, above which OSHA requirements apply.

2.2 Activation of a Sterilant:
Process of mixing the contents of a chemical sterilant that come in two containers (small vial with the activator solution; container of the chemical) Keeping the two chemicals separate until use extends the shelf life of the chemicals.

2.3 Antimicrobial Agent:
Any agent that kills or suppresses the growth of microorganisms.

2.4 Antiseptic:
Substance that prevents or arrests the growth or action of microorganisms by inhibiting their activity or by destroying them. The term is used especially for preparations applied topically to living tissue.

2.5 Asepsis:
Prevention of contact with microorganisms.

2.6 Bacterial Count:
Method of measuring the number of bacteria per unit sample. The term also refers to the estimated number of bacteria per unit sample, usually expressed as number of colony-forming units.

2.7 Bactericide:
Agent that kills bacteria.

2.8 Bio Burden:
Number and types of viable microorganisms with which an item is contaminated; also called *bio load* or *microbial load*.

2.9 Biocide or Biocidal:
Terms with the suffix *cide* or *cidal* for killing action also are commonly used. For example, a Biocide is an agent that can kill any and all living cells including microorganisms. The term *germicide* includes both antiseptics and disinfectants. *Antiseptics* are germicides applied to living tissue and skin; *disinfectants* are antimicrobials applied only to inanimate objects. In general, antiseptics are used only on the skin and not for surface disinfection, and disinfectants are not used for skin antisepsis because they can injure skin and other tissues. Virucide, fungicide, bactericide, sporicide, and tuberculocide can kill the type of microorganism identified by the prefix. For example, a bactericide is an agent that kills bacteria.

2.10 Biofilm:
Accumulated mass of bacteria and extracellular material that is tightly adhered to a surface and cannot be easily removed.

2.11 Ceiling Limit:
Concentration of an airborne chemical contaminant that should not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling must be assessed as a 15-minute time-weighted average exposure.

2.12 Centigrade or Celsius:
A temperature scale (0oC = freezing point of water; 100oC = boiling point of water at sea level). Equivalents mentioned in the guideline are as follows: 20 ºC = 68oF; 25 ºC = 77oF; 121 ºC = 250 ºF; 132oC = 270 ºF; 134 ºC = 273 ºF. For other temperatures, the formula is: Fo = (Co x 9/5) + 32 *or* Co = (Fo –32) x 5/9.

2.13 Cleaning:
Cleaning is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the

effectiveness of these processes. *Decontamination* removes pathogenic microorganisms from objects so they are safe to handle, use, or discard.

2.14 Cleaning:
Removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

2.15 Contact Time:
Time a disinfectant is in direct contact with the surface or item to be disinfected. For surface disinfection, this period is framed by the application to the surface until complete drying has occurred.

2.16 Contaminated:
State of having actual or potential contact with microorganisms. As used in health care, the term generally refers to the presence of microorganisms that could produce disease or infection.

2.17 Critical Items/ Areas (High Risk):
Critical items/ areas confer a high risk for infection if they are contaminated with any microorganism. Thus, objects that enter sterile tissue or the vascular system must be sterile because any microbial contamination could transmit disease. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. Most of the items in this category should be purchased as sterile or be sterilized with steam if possible. Heat-sensitive objects can be treated with EtO, hydrogen peroxide gas plasma; or if other methods are unsuitable, by liquid chemical sterilants. Germicides categorized as chemical sterilants include ≥2.4% glutaraldehyde-based formulations, 0.95% glutaraldehyde with 1.64% phenol/phenate, 7.5% stabilized hydrogen peroxide, 7.35% hydrogen peroxide with 0.23% peracetic acid, 0.2% peracetic acid, and 0.08% peracetic acid with 1.0% hydrogen peroxide. Liquid chemical sterilants reliably produce sterility only if cleaning precedes treatment and if proper guidelines are followed regarding concentration, contact time, temperature, and ph.

2.18 Culture:
Growth of microorganisms in or on a nutrient medium; to grow microorganisms in or on such a medium.

2.19 D Value:
Time UC-V radiation dose required to inactivate 90% of a population of the test microorganism under stated exposure conditions.

2.20 Decontamination:
According to OSHA, “the use of physical or chemical means to remove, inactivate, or destroy blood borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal”. In health-care facilities, the term generally refers to all pathogenic organisms.

2.21 Decontamination Area:
Area of a health-care facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

2.22 Detergent:
Cleaning agent that makes no antimicrobial claims on the label. They comprise a hydrophilic component and a lipophilic component and can be divided into four types: anionic, cationic, amphoteric, and non-ionic detergents.

2.23 Disinfectant:
Usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects. Disinfectants are grouped by product label claims of “limited,” “general,” or “hospital” disinfection.

2.24 Disinfection:
Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects. In health-care settings, objects usually are disinfected by liquid chemicals or wet pasteurization. Each of the various factors that affect the efficacy of disinfection can nullify or limit the efficacy of the process.

Factors that affect the efficacy of both disinfection and sterilization include prior cleaning of the object; organic and inorganic load present; type and level of microbial contamination; concentration of and exposure time to the germicide; physical nature of the object (e.g., crevices, hinges, and lumens); presence of biofilms; temperature and pH of the disinfection process; and in some cases, relative humidity of the sterilization process (e.g., ethylene oxide).

Unlike sterilization, disinfection is not sporicidal. A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called *chemical sterilants*. At similar concentrations but with shorter exposure periods (e.g., 20 minutes for 2% glutaraldehyde), these same disinfectants will kill all microorganisms except large numbers of bacterial spores; they are called *high-level disinfectants*. *Low-level disinfectants* can kill most vegetative bacteria, some fungi, and some viruses in a practical period of time (≤10 minutes). *Intermediate-level disinfectants* might be cidal for mycobacteria, vegetative bacteria, most viruses, and most fungi but do not necessarily kill bacterial spores. Germicides differ markedly, primarily in their antimicrobial spectrum and rapidity of action

2.25 Disinfection:
Thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

2.26 Fungicide:
Agent that destroys fungi (including yeasts) and/or fungal spores pathogenic to humans or other animals in the inanimate environment.

2.27 General Disinfectant:
Registered disinfectant labelled for use against both gram-negative and gram-positive bacteria. Efficacy is demonstrated against both *Salmonella choleraesuis* and *Staphylococcus aureus*. Also called *broad-spectrum disinfectant*.

2.28 Germicidal Detergent:
Detergent that also is registered as a disinfectant.

2.29 Germicide:
Agent that destroys microorganisms, especially pathogenic organisms.

2.30 High-level Disinfectant:
Agent capable of killing bacterial spores when used in sufficient concentration under suitable conditions for a predictable period of time. It therefore is expected to kill all other microorganisms.

2.31 Hospital Disinfectant:
Disinfectant registered for use in hospitals, clinics, dental offices, and any other medical-related facility. Efficacy is demonstrated against *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa.* There are approximately 1,200 registered hospital disinfectants.

2.32 Inanimate Surface:
Non-living surface (e.g., floors, walls, furniture).

2.33 Infectious Microorganisms:
Microorganisms capable of producing disease in appropriate hosts.

2.34 Inorganic and Organic Load:
Naturally occurring or artificially placed inorganic (e.g., metal salts) or organic (e.g., proteins) contaminants on a medical device before exposure to a microbicidal process.

2.35 Intermediate-Level Disinfectant:
Agent that destroys all vegetative bacteria, including tubercle bacilli, lipid and some nonlipid viruses, and fungi, but not bacterial spores.

2.36 Kill Time/ Exposure Time:
Time a disinfectant takes to kill an organism including spores. In the case of hospital disinfectants, a log 4 kill would be the minimum acceptable for a persistent disinfectant and a log 5 kill for a non-persistent disinfectant.

2.37 Limited Disinfectant:
Disinfectant registered for use against a specific major group of organisms (gram-negative or gram-positive bacteria). Efficacy has been demonstrated in laboratory tests against either *Salmonella choleraesuis* or *Staphylococcus aureus* bacteria.

2.38 Lipid Virus:
Virus surrounded by an envelope of lipoprotein in addition to the usual core of nucleic acid surrounded by a coat of protein. This type of virus (e.g., HIV) is generally easily inactivated by many types of disinfectants. Also called *enveloped* or *lipophilic virus*.

2.39 Low-Level Disinfectant: agent that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some nonlipid viruses, and some fungi, but not bacterial spores.

2.40 Medical Device:
Instrument, apparatus, material, or other article, whether used alone or in combination, including software necessary for its application, intended by the manufacturer to be used for human beings for diagnosis, prevention, monitoring treatment, or alleviation of disease;
diagnosis, monitoring, treatment, or alleviation of or compensation for an injury or handicap;
investigation, replacement, or modification of the anatomy or of a physiologic process; or
control of conception and that does not achieve its primary intended action in or on the human body by pharmacologic, immunologic, or metabolic means but might be assisted in its function by such means.

2.41 Microbicide:
Any substance or mixture of substances that effectively kills microorganisms.

2.42 Microorganisms:
A microorganism or microbe is a microscopic organism, which may be single-celled or multicellular. As used in health care, generally refers to bacteria, fungi, viruses, and bacterial spores.

2.43 Minimum Effective Concentration (MEC):
The minimum concentration of a liquid chemical germicide needed to achieve the claimed microbicidal activity as determined by dose-response testing. Sometimes used interchangeably with *minimum recommended concentration*.

2.44 Mycobacteria:
Mycobacterium is a genus of Actinobacteria, given its own family, the Mycobacteriaceae. Over 190 species are recognized in this genus. This genus includes pathogens known to cause serious diseases in mammals, including tuberculosis (Mycobacterium tuberculosis) and leprosy (Mycobacterium leprae) in humans. Bacteria with a thick, waxy coat that makes them more resistant to chemical germicides than other types of vegetative bacteria.

2.45 Noncritical Items/ Areas (Low Risk)
Noncritical items/ areas are those that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin is "not critical." In this guideline, noncritical items are divided into noncritical patient care items and noncritical environmental surfaces. Examples of noncritical patient-care items are bedpans, blood pressure cuffs, crutches and computers. In contrast to critical and some semi critical items, most noncritical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. To date no risk has been documented for transmission of infectious agents to patients through noncritical items when they are used as noncritical items and do not contact non-intact skin and/or mucous membranes. Several low-level disinfectants may be used for noncritical items. Most registered disinfectants have a 10-minute label claim. However, multiple investigators have demonstrated the effectiveness of these disinfectants against vegetative bacteria (e.g., *Listeria*, *Escherichia coli*, *Salmonella*, vancomycin-resistant Enterococci, methicillin-resistant *Staphylococcus aureus*), yeasts (e.g., *Candida*), mycobacteria (e.g., *Mycobacterium tuberculosis*), and viruses (e.g. poliovirus) at exposure times of 30–60 seconds. UK law requires all applicable label instructions on registered products to be followed (e.g., use-dilution, shelf life, storage, material compatibility, safe use, and disposal). If the user selects exposure conditions (e.g., exposure time) that differ from those on the registered products label, the user assumes liability for any injuries resulting from off-label use and is potentially subject to enforcement action under the Insecticide, Fungicide, and Rodenticide Act (IFRA).

Non-critical environmental surfaces include, some food utensils, bedside tables, patient furniture and floors. Noncritical environmental surfaces frequently touched by hand (e.g., bedside tables, bed rails) potentially could contribute to secondary transmission by contaminating hands of health-care workers or by contacting medical equipment that subsequently contacts patients. Mops and reusable cleaning

cloths are regularly used to achieve low-level disinfection on environmental surfaces. However, they often are not adequately cleaned and disinfected, and if the water-disinfectant mixture is not changed regularly (e.g., after every three to four rooms, at no longer than 60-minute intervals), the mopping procedure actually can spread heavy microbial contamination throughout the health-care facility. In one study, standard laundering provided acceptable decontamination of heavily contaminated mop heads but chemical disinfection with a phenolic was less effective. Frequent laundering of mops (e.g., daily), therefore, is recommended. Single-use mops and disposable towels impregnated with a disinfectant also can be used for low-level disinfection when spot-cleaning of noncritical surfaces is needed.

2.46 Nonlipid Viruses:
Generally considered more resistant to inactivation than lipid viruses. Also called non-enveloped or hydrophilic viruses e.g. Norovirus.

2.47 Non-Persistent:
For the purposes of this guidance document, a non-persistent sterilant or disinfectant is any chemical that reduces its efficacy within 1 hour after application.

2.48 One-Step Disinfection Process:
Simultaneous cleaning and disinfection of a noncritical surface or item.

2.49 Parts Per Million (ppm):
Common measurement for concentrations by volume of trace contaminant gases in the air (or chemicals in a liquid); 1 volume of contaminated gas per 1 million volumes of contaminated air or 1¢ in 10,000 both equal 1 ppm. Parts per million = µg/mL or mg/L.

2.50 Permissible Exposure Limit (PEL):
Time-weighted average maximum concentration of an air contaminant to which a worker can be exposed, according to OSHA standards. Usually calculated over 8 hours, with exposure considered over a 40-hour work week.

2.51 Persistent:
Dictionary version - continuing to exist or occur over a prolonged period. For the purposes of this paper a persistent sterilant or disinfectant is any chemical that does not reduce its efficacy within 1 hour after application.

2.52 Personal Protective Equipment (PPE):
Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts) not intended to function as protection against a hazard are not considered to be PPE.

2.53 Prions:
Transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including sheep and goats, bovine spongiform encephalopathy in cattle, and Creutzfeldt-Jakob disease in humans. They are unlike any other infectious pathogens because they are composed of an abnormal conformational isoform of a normal cellular protein, the prion protein (PrP). Prions are extremely resistant to inactivation by sterilization processes and disinfecting agents.

2.54 QUAT: (See Annex C Page 66 for more information)
Abbreviation for *quaternary ammonium compound*, a surface-active, water-soluble disinfecting substance that has four carbon atoms linked to a nitrogen atom through covalent bonds.

2.55 Recommended Exposure Limit (REL):
Occupational exposure limit recommended by NIOSH as being protective of worker health and safety over a working lifetime. Frequently expressed as a 40-hour time-weighted-average exposure for up to 10 hours per day during a 40-work week.

2.56 Sanitizer:
Agent that reduces the number of bacterial contaminants to safe levels as judged by public health requirements. Commonly used with substances applied to inanimate objects. According to the protocol for the official sanitizer test, a sanitizer is a chemical that kills 99.999% (log 5) for non-persistent and 99.99% (log4) for persistent, of the specific test bacteria in 60 seconds under the conditions of the test.

2.57 Semi Critical Items/ Areas (Medium Risk)

Semi critical items/areas contact mucous membranes or nonintact skin. This category includes respiratory therapy and anaesthesia equipment, some endoscopes, laryngoscope blades, oesophageal manometer probes, cystoscopes, anorectal manometer catheters, and diaphragm fitting rings. These medical devices should be free from all microorganisms; however, small numbers of bacterial spores are permissible. Intact mucous membranes, such as those of the lungs and the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms, such as bacteria, mycobacteria, and viruses. Semi critical items minimally require high-level disinfection using chemical disinfectants. Glutaraldehyde, hydrogen peroxide, *ortho*-phthalaldehyde, and peracetic acid with hydrogen peroxide are accepted as dependable high-level disinfectants provided the factors influencing germicidal procedures are met. When a disinfectant is selected for use with certain patient-care items, the chemical compatibility after extended use with the items to be disinfected also must be considered.

High-level disinfection traditionally is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. The definition of high-level disinfection is a sterilant used for a shorter contact time to achieve a 6-log kill of an appropriate *Mycobacterium* species. Cleaning followed by high-level disinfection should eliminate enough pathogens to prevent transmission of infection.

Laparoscopes and arthroscopies entering sterile tissue ideally should be sterilized between patients. However, in the UK, this equipment sometimes undergoes only high-level disinfection between patients. As with flexible endoscopes, these devices can be difficult to clean and high-level disinfect or sterilize because of intricate device design (e.g., long narrow lumens, hinges).

2.58 SiQUAT: (See Annex C Page 66 for more information)

Abbreviation for *quaternary ammonium compound* that has an addition silane compound to bond the molecule to surfaces. The surface-active, water-soluble disinfecting substance that has four carbon atoms linked to a nitrogen atom through covalent bonds will remain actively bonded to the surface until the surface is damaged.

2.59 Shelf Life:

Length of time an undiluted or use dilution of a product can remain active and effective. Also refers to the length of time a sterilized product (e.g., sterile instrument set) is expected to remain sterile.

2.60 Spore:

Relatively water-poor round or elliptical resting cell consisting of condensed cytoplasm and nucleus surrounded by an impervious cell wall or coat. Spores are relatively resistant to disinfectant and sterilant activity and drying conditions (specifically in the genera *Bacillus* and *Clostridium*).

2.61 Sterile or Sterility:

State of being free from all living microorganisms. In practice, usually described as a probability function, e.g., as the probability of a microorganism surviving sterilization being one in one million.

2.62 Sterilisation:

Validated process used to render a product free of all forms of viable microorganisms. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.

2.63 Sterilisation:

Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Steam under pressure, dry heat, EtO gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in health-care facilities. Sterilization is intended to convey an absolute meaning; unfortunately, however, some health professionals and the technical and commercial literature refer to “disinfection” as “sterilization” and items as “partially sterile.” When chemicals are used to destroy all forms of microbiologic life, they can be called chemical sterilant. These same germicides used for shorter exposure periods also can be part of the disinfection process (i.e., high-level disinfection).

2.64 Sterility Assurance Level (SAL): probability of a viable microorganism being present on a product unit after sterilization. Usually expressed as 10–6; a SAL of 10-6 means $\leq$1/1 million chance that a single viable microorganism is present on a sterilized item. A SAL of 10-6 generally is accepted as appropriate for items intended to contact compromised tissue (i.e., tissue that has lost the integrity of the natural body barriers). The sterilizer manufacturer is responsible for ensuring the sterilizer can achieve the desired SAL. The user is responsible for monitoring the performance of the sterilizer to ensure it is operating in conformance to the manufacturer’s recommendations.

2.65 Surfactant: agent that reduces the surface tension of water or the tension at the interface between water and another liquid; a wetting agent found in many sterilants and disinfectants.

2.66 Tuberculocide:
A registered hospital disinfectant that also kills *Mycobacterium tuberculosis* (tubercle bacilli). There are approximately 200 tuberculocides registered. Such agents also are called *mycobactericides*.

2.67 Use-Life:
The length of time a diluted product can remain active and effective. The stability of the chemical and the storage conditions (e.g., temperature and presence of air, light, organic matter, or metals) determine the use-life of antimicrobial products.

2.68 Vegetative bacteria:
Bacteria that are devoid of spores and usually can be readily inactivated by many types of germicides.

2.69 Virucide:
An agent that kills viruses to make them noninfective.

3 Glossary of Terms Relating to Surface Cleaning

3.1 Soiling

3.1.1 Dust and Lint
Fine, small particles or fibres from clothing, that can form a layer on the object surface and that can be stirred up becoming airborne.

3.1.2 Loose Dirt
Fairly small particles that are not easily stirred up.

Examples: Gravel, sand, soil, ash, fibres, hair, spiders' webs, insects and crumbs.

Note – In this standard, "waste" and "loose dirt" are treated as one and the same type of soiling.

3.1.3 Stain
Dried-in or wet soiling that is not caused by damage or lack of maintenance of the building.

Examples: any type of spillage (blood, secretion, excreta, coffee, fizzy drink, oil, etc.) blotches, condensation rings, trodden-in chewing gum, lines, skid marks and finger marks.

3.1.4 Surface Soiling
Dried-in or wet soiling on unlimited areas of a surface that is not caused by damage or lack of maintenance.

Examples: continuous areas of soiling on a larger area such as accumulated or trodden-in soiling, lime scale and rust deposits, greasy film, or cleaning fluids/water, nicotine, skid and finger marks covering extensive areas as well as areas of unevenness in finish treatment.

Note – Spillages or dust are not surface soiling. Extensive occurrence of spillage is always counted as accumulations of stains.

3.1.5 Waste
Soiling that can be picked up.

Examples: bits of paper, leaves and cigarette butts.

Note – In this standard, "waste" and "loose dirt" are treated as one and the same type of soiling.

3.2 Acceptance Number (Ac)
The largest number of nonconforming lots permitted in the sample.

Example: If 13 rooms are to be inspected and Ac = 1, it means that one of the inspected rooms is permitted to fail the inspection for the sample – in overall terms – to be accepted.
This will vary dependant on risk. It is possible that this number may be set at 0 for some areas such as operating theatres and any other number for administration offices.

3.3 Acceptance Quality Level (AQL)
The quality level which, for the purposes of sampling inspection, is the limit of a satisfactory process average.

Note - AQL indicates the acceptance quality level, defined as the lower limit for the disinfection and cleaning services that is considered acceptable.

3.4 Accessible (A) Area
Surface, irrespective of size, which is immediately accessible.

3.5 Accumulation of Soiling
Occurrences of the same soiling type.

Note - If there are accumulations of soiling of the same soiling type covering a large area on an individual object, it may be broken down into smaller areas for assessment. Every 1m x 1m section should be counted as one accumulation of soiling on the object.

Example: dust or spillage on a table.

3.6 Close to Body Surfaces
Horizontal surfaces of furniture/fixtures within a one-metre radius around the user.

3.7 Contract
Agreement, public or private, that a caller for tenders (customer) and a supplier enter into in relation to cleaning services and possibly also cleaning-related service tasks

3.8 Dust Coverage Percentage
The percentage of the adhesive foil that – after having taken samples from hard and semi-hard sur-faces – is covered by dust and other loose dirt.

3.9 Dust Fall Rate
The increase of the dust coverage percentage as a function of time.

3.10 Dust Index
The percentage of the adhesive foil that – after having taken samples from the carpet – is covered by dust and other loose dirt.

3.11 Dynamic Friction Coefficient
Quotient of horizontal frictional force and vertical load during a constant motion of a glider over a horizontal surface.

3.12 Electrostatic Charge Tendency
Static electric charge generated by a person who, as part of an experiment, walks across a floor.

3.13 Glider
Measuring probe with a given weight and surface to determine the dynamic friction coefficient.

3.14 Lot
A set type of inspections or tests.

3.15 Not Immediately Accessible (NA) Area
Surface which is not easy to access.

Example: Behind locked door or in a clinical area that cannot be accessed during normal working hours.

3.16 Object Group
Group of different cleaning surfaces.

3.17 Point-to-Point Resistance
Electrical resistance measured between two electrodes placed on the use-surface

3.18 Quality Profile
The agreed quality for a given inspection.

3.19 Rejection Number (Re)
The smallest number of nonconforming inspections or tests in the sample that will lead to a rejection of the sample.

3.20 Sample Size (*n*)
A set number of lots.

3.21 Sampling Plan
A specific plan which indicates the number of inspection units from a lot which are to be inspected (sample size) and the associated criteria for determining the acceptability of the lot (acceptance and rejection numbers).

3.22 Specular Gloss
The ratio of the luminous flux reflected from an object in the specular direction for a specified source and receptor angle to the luminous flux reflected from glass with a refractive index of 1,567 in specular direction

Note – To define the specular gloss scale, polished black glass with a refractive index of 1,567 is assigned the value of 100.

Note - In this standard the term “surface resistance” is used for “point-to-point resistance”

Guidance

4 Principles and Processes for Surface Cleaning and Disinfection (with no measuring instruments)

4.1 Choice of Chemical Disinfectant

This choice should be made based on several factors:

According to the level of disinfection required in the room, or area to be disinfected.

Risk assessment of persistent or non-persistent effect required.

Potential harm to patients.

Potential for harm to staff – requirement for PPE.

Specialist staff training required.

Potential for harm to fixtures, fittings and environment (manufacturers recommendations).

A list of disinfecting chemicals, with mode of action, contact time, Kill time, precautions etc is attached at annex H to this document.

The efficacy of chemical disinfectants may be enhanced by the use of systems such as steam pre cleaning and UVC light emitters. The need for “extra measures” prior to disinfection will depend on the results of local risk assessments.

4.2 Choice of Chemical Detergent

Detergents are generally less toxic and harmful than disinfectants, however this choice should still be made based on the same factors above:

According to the level of disinfection required in the room, or area to be disinfected.

Risk assessment of persistent or non-persistent effect required.

Potential harm to patients.

Potential for harm to staff – requirement for PPE.

Specialist staff training required.

Potential for harm to fixtures, fittings and environment (manufacturers recommendations).

4.3 Main Principles for Visual Inspection and Chemical Disinfection

The standard is based on the following main principles:

Description of 5 different quality levels, where level 1 is the lowest level of quality and level 5 is the highest;

Division into 4 object groups: furniture & fixtures, walls, floors and ceilings;

Description of quality profiles with quality requirements and any supplementary requirements;

Division into 4 soiling types: waste and loose dirt, dust, stains and surface soiling;

The soiling types are divided into 2 soiling groups: Group 1. waste and loose dirt, dust, lint and stains *and* Group 2. surface soiling;

The soiling groups are assessed at accessible (A) and not immediately accessible (NA) areas;

Inspection takes place after cleaning, before the room is used;

At the inspection, the occurrence of soiling is registered separately for the 4 object groups;

The cleaning of the room is accepted, if the amount of accumulations of soiling for every object group is below or equal to the numbers permitted for the quality levels in question;

Note – Every quality level is defined by the amount of accumulations of soiling permitted, the occurrence of which is acceptable within the different object groups and in different risk areas, after cleaning has been completed. It is taken into account whether the accumulations of soiling are found in accessible or not immediately accessible areas.

The customer selects the quality profile appropriate for the room in question.

Inspection interval shall be conducted with agreement from both customer and provider.

The result of the inspections shall always be documented and communicated to the customer.

Standards

5 Principles and Processes for Surface Cleaning and Disinfection (with no measuring instruments) - Description of the System Based on Visual Inspection

5.1 The Structure of the System

The system is based on a description of five different quality levels, all of which are defined by a number of outcome requirements.

The outcome requirements specify the amount of soiling that can acceptably be left behind after the cleaning has been completed in both accessible (A) and not immediately accessible (NA) areas (see Table 1) within the four different object groups (see Table 2).

5.1.1 Soiling Groups

The accumulations of soiling are divided into two soiling groups and four different soiling types:

Soiling group 1:

Waste and loose dirt

Dust

Stains (wet and dry). Soiling group 2:

Surface soiling (wet and dry).

5.1.2 Division into Inspection Areas

A room can be divided into several separate inspection areas, if they constitute a natural entity. For instance, every individual compartment in a large sanitary room can constitute one inspection area.

Note 1 – New inspection areas generated by dividing large (above100 m^2) or other rooms (i.e. sanitary divided by compartments/closets) into two or more separate inspection areas must be given a unique identity. The new inspection areas must be added into the lot in such a way that they can be selected for inspection.

Note 2 – Large rooms that cannot be divided into smaller natural entities (i.e. the floor in a physiotherapy gym), can be divided into a number of smaller theoretical inspection units (as large as possible, up to 100 m^2) which each are given a unique identity. If one or more of these inspection units are selected for inspection, the whole area shall be inspected.

Example 1: A physiotherapy gym with a floor of area 520 m^2 can be divided into 6 theoretical inspection units with 5 at 100m^2 area and 1 at 20 m^2 area.

5.1.3 Quality Levels

The quality levels are expression of the cleaning quality that customers want to experience visually.

The five levels are described in Table 3.

The quality level is specified at object group level.

The number of accumulations of soiling for the different quality levels is considered in relation to the size of the inspection area or unit and its risk/ location in the facility.

Within soiling group 1 (waste and loose dirt, dust and stains), the number of permitted accumulations of soiling is stated for the different quality levels, whereas within soiling group 2, surface soiling is stated as a percentage of permitted soiling of the cleanable surfaces within the different object groups.

For each quality level and object group the highest number of accumulations of soiling (waste and loose dirt, dust and stains) and the highest percentage of surface soiling permitted should be agreed by both customer and provider.

5.1.4 Supplementary Requirements

Supplementary requirements can be used for stipulating special requirements as regards the occurrence of individual soiling types.

Example 1: no occurrences of dust on furniture & fixtures and on ceilings in an operating room.

Example 2: no occurrences of residue from bodily fluids in sanitary rooms, wards and other areas with high hygiene demands.

5.1.5 Quality Profile

The individual types of rooms are described by quality profiles, consisting of a maximum of eight quality requirements (requirements relating to maximum levels for two soiling groups of soiling types on four object groups), and any supplementary requirements.

6 Assessing the Cleaning Quality

6.1 Procedure for Assessing Cleaning Quality

The cleaning quality shall be assessed based on data collected from inspections performed according to clause 7.

6.1.1 Assessment of Soiling in Group 1 (7.3.2)

In connection with the assessment, the inspector counts the number of accumulations of soiling within the different soiling types for both accessible and not immediately accessible areas on the different object groups.

The numbers of accumulations of soiling for the soiling types waste and loose dirt, dust and stains are added up before the results are compared with the requirements for the contract level.

The requirements for the quality level have been fulfilled when the total number of accumulations of soiling per object group is below or equal to the number of permitted accumulations of soiling for the level agreed and the size of the inspection unit.

6.1.2 Assessment of Soiling in Group 2 (7.3.3)

At the assessment, the inspector makes a rough estimate of the percentage of the cleanable surface of the particular object group that is covered by soiling.

The requirements for the quality level have been fulfilled when the percentage of surface soiling on the object group is below or equal to the percentage stated in the contract.

6.1.3 Assessment of the Inspection Areas or Units

The quality assessment is performed at room level, and an inspection unit is accepted or rejected on the basis of a comparison between the level of quality reached and the quality profile. The inspection unit is accepted when the agreed quality levels for all the object groups included any supplementary requirements are fulfilled.

6.1.4 Assessment of the Sample

The assessment shall be performed when all inspection units in the sample (n) have been inspected. The sample is accepted if the number of rejected inspection units in the sample is less than or equal to the acceptance number in the contract.

7 Procedures and conditions for Inspection of Cleaning

7.1 Performing Inspection

7.1.1 Visual Inspection by Walking Around

Inspection is performed after cleaning has been completed, visually by the inspector walking around in the room/inspection unit and observing and registering soiling on all the surfaces covered by the contract, under conditions as close as possible to normal conditions. “Walking around” the room shall be taken to mean walking around the natural walking route of the room to conduct the assessment.

In order to avoid re-soiling of the surfaces in a room start with inspection of the floor, then move on to furniture and fixtures starting with the lover parts, and then inspect walls and ceiling.

It is permitted to look straight or at a slant at the surfaces to be inspected. It is also permitted for the inspector to bend down to check for soiling under furniture & fixtures and to pull out chairs. When assessing surfaces that are high up, the inspector is permitted to use a ladder or similar.

7.1.2 Registration of Results

For counting the data, the inspector may use an assessment form which is given to the customer and kept for data comparison.

7.1.3 Who Performs the Assessment/ Inspection?

The inspection and assessment can be performed by:

The cleaners themselves inspecting their work on completion,

The cleaners and their supervisors either alone or in cooperation with the customer,

The customer or a person appointed by the customer.

The contract shall describe who performs the periodic inspections.

7.2 Using the System to Inspect the Cleaning Quality Achieved

When this system is used to inspect the cleaning provided in accordance with the contract, the following procedures shall be observed.

7.2.1 Conditions for Using the System

In order to ensure a uniform quality over time, routine inspections should be at regular pre-agreed times. It is also recommended that unannounced inspections should also take place at irregular intervals to ensure a reduction in the Hawthorne effect.

When the system is used to inspect the cleaning quality achieved, the inspection of the rooms shall be conducted:

Immediately after the cleaning has been completed; or

At the latest, before the room is used again

If the selected inspection area or unit has already been used, the procedure for selecting a new inspection area/ unit shall be agreed with the customer, choosing between the following alternatives:

Extension of the inspection period, e.g. divided over several days and/or at different times of the day/night until the selected number of inspection rooms, areas and units has been inspected.

If the selected inspection room, area or unit has been used, another unused inspection room, area or unit close by within the same lot is selected for inspection.

A combination of these two alternatives.

7.2.2 Requirements for the Contract

It shall appear clearly what is covered by the inspection. As a consequence, the following points shall be stated in the contract:

The buildings, rooms, areas and the division into inspection units.

The extent of the cleaning to be provided, materials/ chemicals to be used within the individual object groups.

Quality profiles for room types and object groups. (Annex A can be used to specify quality pro-files.)

Any supplementary requirements regarding one or several soiling types.

Example: There may be customers who, out of consideration for the indoor air quality, will make special stipulations regarding dust and lint, or others who have special requirements as regards stains for aesthetic or hygiene reasons.

Possible division of rooms into several separate inspection areas and units.

Specification of type of sampling plan.

The person or persons performing the inspection and the time of the inspection.

The extent and frequency of the inspection.

Specification of method for selection of inspection rooms, areas and units.

Actions to be taken in the case of discontinuation of inspection.

When instrument measuring methods are used, the type, extent, frequency and the required quality levels shall be stated.

The chemicals, concentrations and frequency of use. Cleaning providers are expected to follow manufacturers health and safety PPE guidance for any chemicals required by the customer for use by the cleaners.

Note – The extent of cleaning-related service tasks and criteria for the measurement of the quality of these shall be agreed separately.

The purpose of the inspection is to assess the quality of the cleaning of rooms with a given quality profile as either acceptable or not acceptable.

A prerequisite is that the cleaners perform the cleaning in a uniform manner and in accordance with the same instructions. This means that the cleanliness of all the objects has the same probability of diverging from the stipulated levels of the quality profile. In other words, the element of uncertainty connected with the inspection is primarily caused by the fact that only a proportion of the overall number of rooms is inspected during the sampling inspection.

If a higher number of accumulations of soiling are observed in a room/inspection unit than permitted by the contract, this particular room is not accepted and remedial action taken.

7.3 Inspection Method

A lot can consist of all the inspection units in the building or parts of all the inspection units, for in-stance all the inspection units on a certain floor, all the inspection units with a certain quality profile, or all the inspection units on a certain floor with a certain quality profile, or all the rooms of a specific type.

When total inspection is used all the inspection units of the lot are selected for inspection.

When sampling inspection is used inspection units (rooms or room parts) are selected from the lot.

Inspection units are inspected by assessing all objects from all object groups in the inspection unit.

7.3.1 Selection of Rooms, Areas and Units for Inspection

The rooms can be selected by simple random sampling or by stratified sampling.

7.3.2 Simple Random Sampling (Group 1)

The inspection areas, units and rooms for inspection are selected by simple random sampling from the lot. Each inspection unit has an equal probability of selection.

7.3.3 Stratified Sampling (Group2)

Stratified sampling means that within the lot all the inspection rooms, areas and units are divided into a number of non-overlapping “strata” (groups), for instance risk profiles. A specified proportion from each strata is selected by simple random sampling for the inspection.

7.3.4 Not Acceptable Lots – Additional Inspection

If the sampling inspection result does not meet the acceptance criteria, the lot is rejected and it is classified as not acceptable.

All parties shall be immediately notified if a lot is found not acceptable.

If a lot is found not acceptable, agreed remedial action and an additional sampling inspection must be carried out and completed within an agreed time after the notification date/ time, under the same conditions as the first sampling inspection. Sampling inspection must be selected from the same lot and with the same sample size.

7.3.5 Discontinuation of Inspection

If a lot is found not acceptable after the second sampling inspection described in 7.3.2 the inspection procedures of this standard shall be discontinued. Remedial actions will be undertaken and supervised by the provider and the customer. Inspection shall not be resumed until remedial actions, described in the contract between the customer and the supplier, have been taken. A financial penalty for no conformance can be agreed in the contract. The customer must complete a risk assessment of the suitability of the room for its intended use.

8 Requirements on Feedback to Customers

In the report on the inspection of the cleaning quality, the following general data shall be included:

- The purpose of the inspection
- The name(s) of the individual(s) conducting the inspection, and the name(s) of the individual(s) in charge
- The area of the inspection: company, address, floor, room/ area ID
- The date and time of the inspection
- Any special arrangements regarding the inspection.
- The following data relating to the inspection shall be included:
- The number of inspection units in the different lots (*N*)
- The number of inspection units selected for inspection (*n*)
- Acceptance number (Ac)
- Rejection number
- As a minimum, the inspection result shall consist of the following:
- Results for all samples (accepted/rejected)
- The number of accepted/rejected inspection units within every sample
- The consequences of the above information, possibly an additional remedial action or a discontinuation of inspection
- The report may also describe the numbers of accumulations of soiling within the individual object groups for every soiling type.
- The areas of the individual divergences shall be included, so the result can be used to undertake corrective remedial actions.

Guidance

9 Inspection with Measuring Instruments

9.1 General

If instrument measurements shall be used to assess the quality of the disinfection and in certain cases the cleaning provided, information on the types of measurements and their frequency shall be included in the contract.

The following parameters can be inspected using instrument measurements:

Dust/ lint on surfaces

Microbial bio burden

Friction

Gloss

Static electricity

Surface resistance.

The principles of instrument measurements are described in brief below.

10 Measuring Dust

Measuring the dust level on surfaces provides a good instrument measurement of the amount of dust on the surfaces. On carpets, measurements can be taken of the amount of dust that is re suspended in connection with sampling (dust index). Thus, unambiguous limits shall be set for the maximum amounts of dust that are acceptable on the various types of surfaces. Dust as an indicator of potential microbial contamination becomes of greater importance when using a persistent chemical disinfectant.

To ensure a good indoor air quality in terms of dust, these measurements shall be taken immediately before the cleaning as a means of inspecting the cleaning activity (frequency and performance) and dust level 4 shall be used.

The use of measurements of dust on surfaces is recommended for rooms with an even and known soiling level, such as offices, meeting rooms, class rooms, hospital wards, laboratories, passageways and similar.

Measurements of dust on surfaces are not recommended for wet rooms, kitchens, entrances and similar areas where resoiling is heavily activity-dependent.

Measuring dust levels on hard/semi-hard floors is only recommended as quality control for floors with floor polish or other hard surface treatments.

Procedures for measuring dust on surfaces and the associated quality levels are described in section 16.

11 Measuring Microbial Contamination

Microbial contamination measurements are used to measure the number of living bacteria on all types of even, hard and semi-hard surfaces. The purpose of taking the measurements is to inspect that the cleaning of the surfaces is satisfactory compared to the requirements agreed for high, medium and low risk areas. This standard only deals with measuring the total number of microorganisms. If determination of types and numbers of specific microorganisms is required (During an outbreak), choice of test method, procedures and quality level shall be agreed at that time.

It is not necessary to measure levels of microbial contamination routinely in every area of a healthcare facility, and should be done based on local risk assessment. Areas that require regular testing are;

- Operating rooms
- Oncology wards
- Dialysis units
- ICU
- HDU
- Other areas with a patient population that are at high or medium risk.

It is important to note that microbial testing should take place within 1 hour of cleaning/ disinfection and between 1 hour and within 4 hours of the next scheduled cleaning and disinfection. This will ensure that cleaning/ disinfection interventions are frequent enough to meet the target contamination levels. The following aspects can be inspected when measuring microbial contamination:

Total number of microorganisms

Species of microorganism (As required by local risk assessment). It is recommended that at least two different culture media are used to capture a greater proportion of bacteria with the propensity to cause harm. Also, it is recommended to perform tests in duplicate, and to culture plates under aerobic and anaerobic conditions.

12 Measuring Friction

Friction measurements can be used on all types of hard and semi-hard floors to assess whether the skid-resistance is acceptable. Measurements of this type are primarily used in environments with raised demands on walking safety.

Friction level 5 is recommended for use in catering kitchens, industrial premises and other areas where there are spillages of fat and oil.

Friction level 4 is recommended for use at hospitals, nursing homes and other areas where there are walking-impaired people.

Friction level 4 is recommended as the lowest level for shopping centres, supermarkets, schools and other areas with high levels of traffic and periods with damp floors.

Friction level 3 is recommended as the lowest level for office environments. Level 3 can provide poor walking safety for people wearing shoes with a small heel surface (e.g. high-heeled shoes) and smooth sole materials (e.g. leather soles).

Friction level 2 is only recommended for use in connection with maintenance with soft floor finishes in completely dry environments. Level 2 makes heavy demands on the use of correct footwear.

Friction level 1 is not recommended for use in rooms with normal traffic.

Friction level 1 should only be prescribed, if, for special reasons, slippery floors are required.

Procedures for measuring friction and the associated quality levels are described in section 20.

13 Measuring Gloss

Gloss measurements are used to establish the gloss level of all types of even, hard and semi-hard floors. Such measurements are used primarily in rooms where high-gloss floors are required.

Gloss measurements are only recommended for use as quality control in rooms where the contract includes maintenance of the floor. The measurements can be carried out in connection with the establishment of a polishing system or as a monitoring system in connection with ongoing floor maintenance.

Gloss level 5 is only recommended for use in connection with completely even floors entirely with-out surface texture.

Gloss level 4 can be used for floors that are uneven but without surface texture.

Gloss level 3 is the highest recommended level for floors with minor surface texture, such as linoleum.

Gloss levels 1 and 2 are levels that can be recommended if the floors in question are maintained with soft floor finishes (soap or wash-and-wax/shine-systems

Procedures for measuring gloss and the associated quality levels are described in section 21.

14 Measuring Static Electricity

Static electricity from floors is determined by measuring the charge transfer to a person walking across the floor.

Such measurements are only recommended for use as quality control in rooms where the contract includes maintenance of the floor's anti-static.

Static electricity levels 5 and 4 are recommended for use in rooms with volatile/ flammable liquids or gases and particularly sensitive electronics.

Static electricity level 3 is recommended as the lowest level for office premises and other areas where electronic equipment is used.

Static electricity level 1 sufficiently prevents uncomfortable electric shocks and is a reasonable level for passageways and similar places.

Procedures for measuring static electricity and the associated quality levels are only to be regarded as momentary values and are described in 22.

15 Measuring Surface Resistance

With measurements of surface resistance, it is possible to monitor the ability of the floor to conduct away static electricity generated by people walking on the floor. Such measurements are primarily employed in rooms with sensitive electronics or in environments where there is a danger of explosion.

The type of flooring should be taken into account when choosing quality level.

Surface resistance level 4 is only used for very special rooms where electrical shielding is required or where there are particularly stringent demands on securing the safety of the staff (earthing). In the latter instance, it may be preferable to set a lower supplementary limit for surface resistance, e.g. $10^4\Omega$.

Surface resistance level 3 is only used where dissipative flooring is used, while level 2 can be used for areas where there is anti-static flooring or where the surface resistance of the floor has been improved by the use of anti-static floor polish.

Surface resistance level 3 should be used in surgical theatres, laboratories and other rooms where people are working with flammable liquids and in other areas where there is a danger of explosion.

Procedures for measuring surface resistance and the associated quality levels are described in 23.

Standards

16 Measuring Dust on Surfaces

16.1 Scope and Field of Application

Measurements of dust are taken to obtain instrument measurements of the amount of dust on all types of hard and semi-hard floorings as well as the horizontal surfaces of furniture & fixtures. These measurements can also be used to examine the amount of loose dust in carpets. The purpose of the measurements can be:

Inspection of completed cleaning and comparison with agreed outcome requirements (measurements are taken immediately after completed cleaning)

Inspection of the cleaning system and comparison with agreed outcome requirements (measurements can be taken at any time)

Measuring the resoiling rate, “dust fall rate” (the surface is set to zero and then measured; subsequent measurements are taken at regular intervals).

The areas of use are primarily environments where there is a requirement for good cleaning quality and low dust levels.

16.2 Method

16.2.1 Principle

Dust accumulations are sampled using adhesive foil. The total area of the collected particles (projected) is measured by reduction of laser light (laser extinction, e.g. the Dust Detector Method). Alternatively, the area is measured using optical microscopy. Dust accumulations on hard and semi-hard surfaces are measured in dust coverage percentage.

Loose dirt in carpets is measured by vacuum-cleaning using a standardised mouthpiece and standardised vacuuming conditions (The Carpet Tester Method) or by standardised beating of the carpet and vacuuming of the dust (The STEPP Tester Method) and with subsequent collection of the dust on adhesive foil using standardised equipment. The collected dust is stated as dust index.

16.2.2 Sampling Procedures

The dust accumulations are collected using BM Dust lifters or adhesive foil with corresponding elastic and optical properties and adhesive power. The collection efficiency shall be above 0.95.

A pressure roller is used for sampling from hard and semi-hard surfaces; the roller shall be 32 mm long, a diameter of 40 mm and have a pressure of 1 kp against the surface of the adhesive foil. The foil is pressed against the surface with the roller, which is rolled over the foil three times. Before the samples are taken, it is essential that the surface of the pressure roller is clean and free of dust, loose dirt, grease and oils.

Samples from carpets are taken with a standardised sampling mouthpiece and a vacuum cleaner. The internal surfaces of the sampling equipment, where the sampling air passes, shall be clean and free from dust and fibres. Immediately beyond the mouthpiece, proportion of the dust is collected using adhesive foil with a well-defined collection efficiency. The quality levels specified in Table 1.

16.2.3 Sampling Procedures, Carpet Tester

A measuring rule of 2.0 m is placed on the area that is being tested and the sampling equipment is moved with a speed of 10 cm/sec. First used along one side and then along the other side of the rule, providing a total sampling length of 4.0 metres.

16.2.4 Sampling Procedures, STEPP Tester

A rule measuring 2.5 m is placed on the area that shall be measured and the sampling equipment is moved first down along one side and then back along the other side of the rule, so that the weight drops 25 times in all, providing a total sampling length of about 5.0 metres.

16.2.5 Measuring Instruments

The foil is measured before and after sampling in the BM Dust detector or similar instrument or an optical microscope with corresponding reproducibility. The instrument shall be calibrated

with a glass plate, upon which black discs are placed with a diameter of 10 µm, covering a total of the area of 10%, or by a corresponding method.

16.2.6 Quality Levels

The dust accumulations are assessed in relation to five quality levels as shown in Table 1. For a given room, the parties can agree different quality levels for the 4–5 surface categories. The quality levels describe the quality profile of the particular room.

16.2.7 Measurement Frequency

Inspection of the cleaning using this method should be conducted at least twice a year. The measurement frequency shall appear from the contract.

16.2.8 Measurement Objects

Hard and semi-hard surfaces for sampling shall measure at least 20 cm x 30

Carpets for sampling shall have a freely accessible length of at least 2/2.5 metres and a width of at least 50 cm. As a consequence, measurements are not taken on not immediately accessible carpet surfaces. Measurements can be taken on the following surface categories:

Close to body surfaces: e.g. desk or PC table

Accessible furniture & fixtures: e.g. beds, trolleys, cupboard surfaces and window sills

Not immediately accessible furniture & fixtures: e.g. shelf or cupboard surfaces that are high up, the top side of a pendant ceiling lamp or ventilation duct

Accessible hard floors: e.g. in walking zones

Not immediately accessible hard floors: e.g. under beds, desks, cupboards and book cases

Accessible carpets: e.g. in walking zones

The surface categories to be measured shall appear from the contract.

16.2.9 Selection of Inspection Rooms, Areas and Units

Inspection units are selected at random. The number of inspection rooms, areas or units for which measurements shall be taken at an inspection of the cleaning quality should be agreed in the contract.

16.2.10 Number of Samples per Room

Between one and three adhesive foil samples are collected from each surface category. The number of samples per surface category depends as follows on the size of the inspection unit in question:

Rooms measuring 15 m^2 or below 1 sample
Rooms above 15 m^2 and up to and including 35 m^2 samples
Rooms above 35 m^2 and up to and including 100 m^2 3 samples.

If the number of inspection areas is below five, the necessary number of samples per inspection area and surface category shall be increased, so that the total number of samples per surface category is at least five. Extra samples are distributed as evenly as possible between the inspection areas.

16.3 Inspection of Completed Cleaning

As described in 4.3 of this standard.

16.4 Inspection of the Cleaning System

Measurements may be carried out at any time but preferably as close as possible to the time of a subsequent cleaning.

16.5 Measuring Resoiling Rate

The first measurements are taken (on dry surfaces) immediately after the surfaces have been cleaned. Then the measurements are repeated at least twice at regular intervals, e.g. one week and two weeks after the cleaning.

16.6 Measurement

The reference value of the adhesive foil (light transmission when clean) is measured prior to taking the sample. It is essential to ensure that the sampling surface of the adhesive foil is not contaminated by finger marks or any other unwanted soiling after the measurement of the reference value has been taken.

When taking measurements with adhesive foil on hard and semi-hard surfaces, it is necessary to wait at least 30 seconds between sampling and performing the measurement.

Make a careful visual inspection of the adhesive foil after sampling, so that any high results as a consequence of damage to the material surface can be detected and the sample discarded.

Measurements are taken consecutively with registration of all individual results for every inspection unit and surface category.

It is essential to ensure that samples are not taken from the same place on the surface.

Adhesive foil is for single use only.

16.7 Assessing the measurement results

When inspecting a cleaning activity, the result is assessed as accepted when the following two requirements are met for every surface category:

1. The average result of all measurements shall be lower than or equal to the maximum requirement for the agreed level. The average shall always be calculated on the basis of at least five adhesive foil samples.

2. The number of instances of non-conformance in relation to a ceiling value of 1.5 x the maximum requirement for the agreed level shall not be higher than the agreed amount in table 2.

16.8 Recommendations

Measurements of dust accumulations on hard/semi-hard floors are only recommended for quality inspections of floors treated with floor polish or another hard surface treatment. The method is not recommended for floors that are maintained with soft floor finishes, soap or wash-and wax/shine systems.

Routine inspection of the cleaning system against stipulated outcome requirements is only recommended for rooms with an even and known resoiling rate. Such requirements are not recommended to be set for wet rooms, such as operating rooms, entrances and similar areas where resoiling is heavily activity-dependent.

Note – In such areas, outcome requirements should only be used for completed cleaning.

17 Measuring of Bio Burden on Surfaces

17.1 Scope and Field of Application

Measurements of microbial contamination or Bio Burden are taken to obtain instrument measurements of the number of bacterial colonies on all types of hard and semi-hard surfaces including floorings and horizontal surfaces of furniture & fixtures after cleaning/ disinfection and over extended time periods prior to the next cleaning intervention. These measurements can also be used to determine which bacterial species are present, when that information is relevant to the area tested and the requirements of the facility at the time.

The purpose of the measurements can be:

Inspection of completed cleaning and comparison with short term agreed outcome requirements (measurements are taken immediately after completed cleaning)

Inspection of the cleaning system and comparison with agreed long term outcome requirements. Measurements can be taken at any time between 1 and no more than 4 hours or the next scheduled clean. In the case of areas such as operating rooms, post cleaning within 1 hour and prior to the start of the next surgery.

Measuring the re contamination rate, (the surface is set to zero and then measured; subsequent measurements are taken at regular intervals).

The areas of use are primarily environments where there is a requirement for good cleaning/ disinfection quality and low bacterial levels.

17.2 Method

17.2.1 Principle

Procedures for measuring microorganisms and the associated quality levels are described below: The areas of use for assessments of numbers of microorganisms are determined by known or perceived risk associated with the type of room being assessed.

There are three acceptable methods of testing surfaces available:

Culture
Polymerase Chain Reaction
Live Bacteria Specific Metabolic Assay

Each of these has its own capabilities and limitations. Sampling is similar for each test when testing surfaces. Where possible a “wet swab test” should be considered however, manufacturers recommendations should be adhered to. No one test “fits all” requirements in every type of room and area risk profile.

In case of an outbreak, the measuring of viral load on surfaces and skin is covered in Annex D.

17.2.2 Test Methods Available

Culture is useful for identifying species and approximate level of contamination, even though only around 35% of the available bacteria will grow on a standard blood agar culture plate. It is not accurate enough to gauge efficacy of a cleaning and disinfection.

PCR is useful for detection (presence/absence), however it will not confirm quantity of viable/live organisms. The sensitivity and specificity of PCR is dependent on the targets used. It is also not accurate enough to reliably gauge efficacy of a cleaning and disinfection. In addition, the test can be complex and requires highly trained individuals to support.

Live bacteria specific metabolic assay (LBSRMA) is a very accurate method of counting numbers of total bacterial contamination. It does not identify any specific bacteria species. It is the first choice for determining efficacy of cleaning and disinfection in high risk areas such as Operating rooms, ICU’s, HDU’s, oncology wards, transplant units and dialysis units.

Note 2: Microbial contamination may not be measured by measurements using a total adenosine-tri-phosphate (ATP) test. ATP is the energy carrier in all organic cells and a total count therefore contains ATP from many other cells and may include some bacteria. To date no correlation has been made between live bacteria and total ATP, therefore it is not a relevant test. Live bacteria specific metabolic tests may be used to measure microbial contamination as they give an accurate measure of the amount of live bacteria present on a given surface. Measurements are performed by use of enzymes and a luminometer, and the result is given in relative light units (RLU). RLU relates at 1:1 with colony forming units (CFU) and is more accurate at determining total contamination levels than either culture or Polymerase Chain Reaction (PCR).

17.2.3 Sample procedures and processing

All samples should be taken and processed by a suitably trained individual and line with manufacturers recommended method of sampling for the particular type of surface to be sampled from. All samples that are to be processed away from the area tested, should be labelled with date, time, Room/ area/ unit ID and place in the area where taken.

17.2.4 Measurement Objects

Hard and semi-hard surfaces for sampling shall measure at least 1 cm x 1 cm and include;

Close to body surfaces: e.g. desk or PC table

Accessible furniture & fixtures: e.g. beds, trolleys, cupboard surfaces and window sills

Not immediately accessible furniture & fixtures: e.g. shelf or cupboard surfaces that are high up, the top side of a pendant ceiling lamp or ventilation duct

Accessible hard floors: e.g. in walking zones

Not immediately accessible hard floors: e.g. under beds, desks, cupboards and book cases

Accessible carpets: e.g. in walking zones

The surface categories to be measured shall appear from the contract.

17.2.5 Selection of Rooms Areas and Units for Sampling

As previously stated healthcare facilities are separated into high, medium and low risk areas in respect to risk of Hospital Acquired Infections (HAI's) including Surgical Site Infections (SSI's). The decision of which method to use is based on the specific needs of the area, frequency is based on risk. Samples of an area greater than 1 cm^2 may be taken, however all quality levels will be judged per 1 cm^2. The total bacteria count for a room may be calculated by measuring the room surface area giving a m^2 total. Multiply the 1cm^2 bacterial CFU count x 10,000 then by the total surface area.

Example: Operating Room = 208m^2 with an individual bacterial count of 20 per cm^2 = 20 x 10,000 x 208 = 41,600,000.

In some rooms, individual equipment may be sampled, e.g. an electro surgical unit inside an operating room, or an operating lamp head. Individual equipment is sampled per cm^2.

17.2.6 Frequency of Testing

High risk areas should be tested weekly, medium risk monthly and low risk bi annually. Multiple samples should be taken in each area within 1 hour after cleaning has taken place and between 1 and 4 hours after cleaning or before the next cleaning has taken place and processed as quickly as possible, see table 3a for acceptable bacterial counts for each test type. Additional samples may be taken if decided locally to be of relevance. Feedback to both the customer and cleaning provider should be given again as quickly as possible dependent on the type of test and distance (in time) to the testing facility. Random testing is encouraged to reduce the Hawthorn effect.

17.2.7 Quality Levels

Requirements for either species specific or numeric test standards will be set on a room by room, area by area, room by room basis. These will be agreed in the contract. Guidance on number of tests per room type is in table 3b. The required area microbial test standard should not be adjusted dependant on time after cleaning that the sample is taken.

17.2.8 Reporting

In the report on the measurement of bacterial CFU counts in connection with an inspection of the disinfection activity, regardless of where or how quickly the samples are to be processed, the following data shall be included:

Date and time of the tests

Date and time of the most recent cleaning/ disinfection of the rooms and individual equipment or surfaces to be sampled

Sampling method and type of test used (Culture, PCR, RMA)

Number of samples taken

The areas where the samples were taken (address, floor, inspection units)

The test results for all samples

The name(s) of the individual(s) conducting the inspection (the name of the individual in charge and any other participants)

The agreed quality levels

Assessment of the measurement results, quality level achieved – Yes/ No

Any comments on further recommended tests/ cleaning/ disinfection

All individual results should be recorded separately for every sample

The number of instances of non-conformance in relation to the maximum number or species specifically, allowable.

17.3 Inspection of the Cleaning and Disinfection System

Measurements may be carried out at any time but preferably as close as possible to the time of a subsequent cleaning.

17.4 Measuring Re-contamination Rate

The first measurements are taken (on dry surfaces) immediately after the surfaces have been cleaned. Then the measurements are repeated at least twice at regular intervals, e.g. one hour and four hours after the cleaning. Additional measurements may be taken if a longer persistence of kill is claimed.

17.5 Assessing the measurement results

When inspecting a cleaning activity, the result is assessed as accepted when the following two requirements are met for every surface category:

The average result of all measurements shall be lower than or equal to the maximum requirement for the agreed level. The average shall always be calculated on the basis of at least five samples.

17.6 Recommendations

If culture is the test available to the healthcare facility, it is suggested that the following is taken into consideration;

1) Non-selective media such as Nutrient Agar (NA) or Brain Heart Infusion (BHI) agar, should be used for both Total Aerobic Counts (TAC) and total anaerobic counts. Should specific microorganisms need to be identified for further investigation selective media and/or PCR should be used.
2) For TAC inoculated media should be incubated at an appropriate temperature between 30-37C for a minimum of 24 hours
3) The number of acceptable microorganisms will almost certainly change as more data becomes available. Currently the standard of <5 cfu/cm2 using (as per table 3a) BSRMA will show inadequate disinfection at hand contact sites. This is the standard set by US Department of Agriculture for food processing equipment/surfaces, this can be amended over time when more evidence is available.
4) Indicator species for contaminated/very contaminated could be outlined as S. aureus/MRSA, Salmonella, VRE and Gram-ve multiply resistant bacilli (not inclusive list).

Measurements of bacterial bio burden can be done by any one of the 3 tests available. The main areas for use of assessments of numbers of microorganisms, are determined by known or perceived risk associated with the type of room being assessed. Local risk assessments should therefore be carried out in healthcare facilities to determine if perceived areas of risk in the document should be moved into a different category of risk, due to locally identified differences. Healthcare facilities that have specialist clinical areas such as transplant, oncology or renal units (amongst others) should carry out risk assessments in each area to determine which risk category they should fall into.

The tests used by each healthcare facility in each area, will depend upon availability of the tests, cost and local risk assessment.

Each of the three test methods available has its own capabilities and limitations (already outlined in this document). As no single test “fits all” requirements in every type of room and area risk profile the table 3b gives recommendations at the number of test samples to be taken and from which surfaces in each area type. The table 3a gives the recommendations on numbers of CFU per cm^2 permitted in each risk category area. As this is a guide only, local risk assessment should be continuous and acceptable levels reduced when appropriate to do so, perhaps during an outbreak. It is recommended that local risk assessment is used to advance an area to the next level of risk, and only in exceptional circumstance would the risk be reduced for an area from the recommended level.

Performance and quality standards in table 3a and table 3b can be monitored using form 5. This form should be used to report and record microbiological contamination levels in each area.

18 Measurement of friction

18.1 Scope and field of application

Friction measurements are used to measure skid-resistance on all types of dry, even, hard and semi-hard floorings, such as stone, terrazzo, vinyl and linoleum. The purpose of the measurements is to inspect whether the cleaning and maintenance of the floors fulfils the requirements as regards skid-resistance. The areas of use are primarily environments with raised demands on walking safety, such as rehabilitation wards, operating theatres and corridors.

18.2 Method

18.2.1 Principle

Friction is measured by registering the force needed to pull a glider over the flooring at a constant speed. Tractive force divided by gravity provides the friction coefficient (gliding resistance) between the glider and the flooring. Friction is measured on a scale from 0.00 to 1.00.

18.2.2 Measuring Instruments

Friction is measured with a Sellmaier Floor Slide Control FSC 2000 or another instrument with a corresponding measuring principle, measuring scale, glider and sensitivity. A glider made from plastic shall be used for the measurements. The instrument shall be calibrated in accordance with the supplier's or manufacturer's directions.

18.2.3 Quality levels

Friction is assessed in relation to five quality levels as shown in Table 4:

18.2.4 Performance

Friction measurements are performed when prescribed by the contract.

18.2.5 Measurement Frequency

To ensure that the customer gets an impression of the quality delivered over a period of time, measurements should be taken at least once a quarter. However, measurements could be taken more often. If so, the details thereof shall be included in the contract.

18.2.6 Measurement Objects

It is essential that measurements are only taken on dry, hard and semi-hard floorings. For all floors (entire area) with the same agreed quality level, a collective result is calculated.

18.2.7 Number of Measurement Points per Inspection room

Measurements are taken at 1–5 randomly selected measurement points equally distributed over the floor. The number of measurement points depends as follows on the size of the inspection room in question:

Rooms measuring 15 m^2 or below	1 measurement point
Rooms > 15 m^2 and up to and including 35 m^2	3 measurement points
Rooms > 35 m^2 and up to and including 100 m^2	5 measurement points.

If the number of inspection units is below five, the necessary number of measurements per inspection unit shall be increased, so that the total number of measurement points is at least five. Extra measurement points are distributed as evenly as possible between the inspection units.

18.2.8 Time of Measurements

Measurements shall be taken relatively shortly after cleaning and maintenance have been completed.

18.2.9 Measurement

Before any measurement is taken, the floor shall be clean and dry.

Note – There shall be no grease or oils on the floor.

Note – The glider shall be clean and dry and the plastic surface shall be intact.

The measurements shall be taken using a glider made from plastic.

Note – If needed, other glider materials can be used. This shall be agreed in the contract.

At every measurement, the average friction shall be registered over a two-metre distance on the floor.

Measurements are taken consecutively with registration of all individual results for every inspection unit, so that an average for the inspection unit can be calculated.

18.2.10 Assessment of Measurement Results

The result is assessed as accepted when the following two requirements are met:

1. The average result of all measurements shall be higher than or equal to the minimum requirement for the agreed level.
2. The poorest individual result (average for two metre floor) shall not be poorer than the minimum requirement for the nearest lower level. For level 2, values below 0.15 are not accepted.

18.3 Reporting

In the report on friction measurements for floors, the following data shall be included:

Date and time of measurements

Date and time of the most recent cleaning and maintenance of the floors

The type of measuring instrument and glider used for the measurements

The name(s) of the individual(s) conducting the inspection (the name of the individual in charge and any other participants)

The areas where the measurements were taken (address, floor, inspection unit)

Measurement results, friction coefficient given with two decimal points

The agreed quality levels

Assessment of the measurement results compared to the agreed quality level (accepted/not accepted)

The measurement results shall be presented as:

Average result per inspection room, area or unit

The average result of all individual measurements

The lowest individual result (for two-metre floor)

If measurements are taken with more than one type of glider, the results for every glider shall be presented separately.

18.4 Recommendations

Friction level should be selected on the basis of the functional demands for the floor.

Friction level 5 is recommended for use in Catering kitchens, Operating theatres, ICU/ HDU's

Friction level 4 is recommended for use in wards and corridors, and other areas where there are walking-impaired people.

Friction level 3 is recommended as the lowest level for office environments. Level 3 can provide walking safety for people wearing shoes with a small heel surface (e.g. high-heeled shoes) and slippery sole materials (e.g. leather soles).

Friction level 2 is only recommended for use in connection with maintenance with soft floor finishes in completely dry environments. Level 2 makes strong demands on the use of correct footwear.

Friction level 1 is not recommended for use in rooms with normal traffic and should only be prescribed, if, for special reasons, slippery floors are required.

19 Measuring Gloss

19.1 Scope and Field of Application

Gloss measurements are used to measure the gloss rate on all types of even, hard and semi-hard floorings, such as stone, terrazzo, vinyl and linoleum when the contract includes maintenance of floors. The purpose of the measurements is to inspect whether the maintenance of the floors provides the agreed gloss level. The areas of use are primarily areas where high-gloss floors are required, such as Executive Offices.

19.2 Method

19.2.1 Principle

Mirror reflective properties are measured by sending a beam of light down towards the floor at an angle of 60 degrees. The light reflected at an angle 60 degrees to the perpendicular of the floor represents the gloss of the surface. Gloss is measured in units on a scale from 0 to 100, where 0 describes dead mat (no reflection).

Note - The gloss level of a polished floor, for instance, can be as high as 85 units.

19.2.2 Measuring instruments

It is essential to use measuring instruments that satisfy the requirements given in EN 2813.
The instrument shall be calibrated in accordance with the supplier's or manufacturer's directions.

19.3 Quality levels

Gloss level is assessed in relation to five quality levels as shown in Table 5:

19.4 Performance

Gloss measurements are performed when prescribed by the contract.

19.5 Measurement Frequency

To ensure that the customer gets an impression of the quality delivered over a given period of time, measurements should be taken at least once a quarter. However, measurements could be taken more often. If so, the details thereof shall be included in the contract (4.3 of this standard).

19.6 Measurement Objects

It is essential that measurements are only taken on hard and semi-hard floorings. For all floors (entire area) with the same agreed quality level, a collective result is calculated.

19.7 Selection of Inspection Rooms, Areas or Units

Inspection of rooms, areas or units are selected at random. The number of inspection rooms, areas or units shall be agreed in the contract.

19.8 Number of Measurement Points per Room, Area or Unit

Measurements are taken at 10–15 randomly selected measurement points equally distributed over the floor. The number of measurement points depends as follows on the size of the inspection room:

Rooms measuring 15 m^2 or below	10 measurement points
Rooms > 15 m^2 and up to and including 35 m^2	15 measurement points
Rooms > 35 m^2 and up to and including 100 m^2	25 measurement points.

If the number of inspection units is below five, the necessary number of measurements per inspection unit shall be increased, so that the total number of measurement points is at least 50. Extra measurement points are distributed as evenly as possible between the inspection rooms.

19.9 Time of Measurements

Measurements shall be taken immediately after cleaning and maintenance have been completed and no later than just before the floors are used again.

19.10 Measurement

Before any measurement is taken, the floor shall be clean and dry.

The measuring instrument shall be calibrated prior to the measurements being taken, and later as required. Please ensure that the calibration plate is completely clean before use.

Measurements are taken consecutively with registration of all individual results for every inspection unit, making it possible to calculate an average for the entire inspection unit.

19.11 Assessment of Measurement Results

Results are assessed as accepted when the following three requirements are met:

The average results of all measurements shall be higher than or equal to the minimum requirement for the agreed level.

The poorest result (average of 10–25 measurements) shall not be poorer than the minimum requirement for the level below.

In one inspection unit, the difference between the average of the five lowest measurement results and the five highest measurement results shall not be any greater than stated in Table 6.

19.12 Reporting

In the report on gloss measurements for floors, the following data shall be included:

Date and time of measurements

Date and time of the most recent cleaning and maintenance of the floors

The type of measuring instrument used for the measurements

The name(s) of the individual(s) conducting the inspection (the name of the individual in charge and any other participants)

The areas where the measurements were taken (address, floor, inspection unit)

The number of measurements per inspection unit

Measurement results in complete gloss units

The agreed quality levels

Assessment of the measurement results compared to the agreed quality level (accepted/not accepted).

The measurement results shall be presented as:

Average result per inspection unit

The average value of the five lowest gloss results for every inspection unit

The average value of the five highest gloss results for every inspection unit

The average result of all individual measurements.

19.13 Recommendations

Gloss measurements are only recommended for use as quality control in connection with use of floor polish either for inspection of completed resurfacing or treatment with polish or as a monitoring system in connection with ongoing floor maintenance.

Gloss level 5 is only recommended for use in connection with completely even floors entirely without surface texture.

Gloss level 4 can be used for floors that are uneven but without surface texture.

Gloss level 3 is the highest recommended level for floors with minor surface texture, such as linoleum.

Gloss levels 1 and 2 are levels that can be recommended if the floors in question are maintained with soft floor finishes (soap or wash-and-wax/shine-systems)

20 Measuring static electricity

20.1 Scope and Field of Application

Measurements of static electricity are used to investigate the degree of electrostatic charge generated from walking on floors. The purpose of the measurements is to inspect that the cleaning and the anti-static treatment meet the requirement for maximum electrostatic charge generated from traffic on the floor. The areas of use are all areas that require low electrostatic charge from people or from traffic on the floor, preventing damage to electronic equipment and uncomfortable electric shocks. Examples are offices, IT rooms, control rooms, passageways, electronics workshops, etc. The object is merely to assess the momentary condition.

20.2 Method

20.2.1 Principle

A floor is assessed as regards its tendency to develop an electrostatic charge with the aid of a person walking across the floor wearing a pair of standardised sandals.

20.2.2 Test sandals

Test sandals with soles of conductive rubber are used for the experiment. The resistance between a metal plate and a person standing on it wearing the above-mentioned sandals shall meet the requirements described in EN 1815 (10^8–10^9 Ω).

20.2.3 Measuring Instruments

It is essential to use the measuring instruments and set-up as described in EN 1815. The instrument shall be calibrated in accordance with the supplier's or manufacturer's directions.

20.2.4 Quality levels

In this standard, static electricity levels are assessed in relation to five quality levels as shown in Table 7.

20.2.5 Performance

Measurements of static electricity are performed when prescribed by the contract.

20.3 Measurement Frequency

To ensure that the customer gets an impression of the quality delivered over a given period of time, measurements should be taken at least once a quarter. However, measurements could be taken more often. If so, the details thereof shall be included in the contract.

20.3.1 Measurement objects

Measurements shall be taken on easily accessible sections of the floor. Measurements are only taken on fully covering floorings. It is also possible to take measurements on small floor installations, provided they were installed as an ESD measure.

20.3.2 Selection of Inspection Rooms, Area and Units

Inspection units are selected at random. The number of inspection units for which measurements shall be taken will be agreed in the contract.

20.3.4 Number of Measurement Points per Inspection Room

Measurements are taken at 1–5 randomly selected areas of the floor equally distributed over the total area. The number of areas that the floor is to be divided into depends as follows on the total size of the inspection room in question:

Rooms measuring 15 m^2 or below	1 area
Rooms > 15 m^2 and up to and including 35 m^2	3 areas
Rooms > 35 m^2 and up to and including 100 m^2	5 areas.

If the number of inspection units is below five, the necessary number of measurements per inspection unit shall be increased, so that the total number of measurements is at least 5. Extra measurements are distributed as evenly as possible between the inspection units.

20.4 Time of Measurements

Measurements can be taken at any time.

20.4.1 Measurement

Measurements shall be taken on dry surfaces.

The test sandals shall be clean and dry. See EN 1815 for suitable cleaning methods.

The measuring equipment and the person taking the measurements shall – before every single measurement – be set to zero (discharged to earth).

Walking experiments are conducted as described in EN 1815. The person being measured puts on cleaned footwear with a vertical resistance of $10^8 – 10^9$ Ω/cm^2, holds on to the hand electrode, which is discharged to earth, and walks across the floor with a pace speed of two paces per second, forwards and backwards but always with the body in the same direction. Dragging or rolling (heel to toe) walk shall be avoided. The sandals are lifted 5–8 cm above the floor at every pace and the sole is lowered down again at a level parallel to the floor. Measurements continue until the voltage cannot be increased any further, though a maximum of 60 seconds (120 paces). The measurement result is read as the average of the five highest voltage minimums (the voltage will decrease to a minimum every time the foot is in contact with the floor). The person being measured is discharged to earth before every single experiment. It is essential to avoid contact with other surfaces than the floor during the walk and while the measurements are taken as well as when removing the sandals.

In connection with taking measurements of static electricity, the relative humidity shall also be measured using a calibrated hygrometer or psychrometer.

22.4.2 Assessment of Measurement Results

The result is assessed as accepted when the following two requirements are met:

The average result of all measurements shall be lower than or equal to the maximum requirement for the agreed level.

The poorest individual result shall not be higher than the maximum requirement for the nearest higher level and never higher than 2999 volt.

22.4.3 Reporting

In the report on measurements of static electricity, the following data shall be included:

Date and time of measurements

Date and time of the most recent cleaning and anti-static treatment of the surfaces

The type of measuring instrument used for the measurements

The name(s) of the individual(s) conducting the inspection (the name of the individual in charge and any other participants)

The areas where the measurements were taken (address, floor, inspection unit)

The number of measurements per inspection unit

Measurement results, static electricity given in whole volts

The agreed quality levels

The relative humidity of the rooms

Assessment of the measurement results compared to the agreed quality level (accepted/ accepted).

The measurement results shall be presented as:

Average result per inspection unit

The average result of all individual measurements

The highest individual result.

20.5 Recommendations

Static electricity levels 5 and 4 are recommended for use in rooms with particularly sensitive electronics.

Static electricity level 3 is recommended as the lowest level for office premises and other areas where electronic equipment is used.

Static electricity level 1 sufficiently prevents uncomfortable electric shocks and is a reasonable level for hotel passageways and similar places.

21 Measuring Surface Resistance (point-to-point resistance)

21.1 Scope and Field of Application

Measuring surface resistance is used to investigate the capacity of hard and semi-hard floors to conduct away static electricity. The purpose of the measurements is to inspect that the cleaning and maintenance of the floors take due account of the agreed requirements as regards surface resistance. The areas of use are all areas that require low electrostatic charge due to the presence of electronic equipment or danger of explosion, for instance in Operating rooms, Anaesthetic rooms, ICU/ HDU's and laboratories.

21.2 Method

21.2.1 Principle

Two standardised electrodes are placed at a certain distance (0.30 ± 0.01 m) and, with the aid of a weight (5 kg), they are pressed against a section of the material surface exerting constant pressure. The surface resistance in ohm is measured by applying voltage (10 or 100 V) to the material surface via the two electrodes.

21.2.2 Measuring Instruments

An ohmmeter and measuring electrodes are required to carry out the tests, and the equipment shall comply with the requirements stipulated in EN 61340-4-1:2005, Annex A. The instrument shall be calibrated in accordance with the supplier's or manufacturer's directions.

21.2.3 Quality Levels

Surface resistance is divided into three levels as shown in Table 8

21.2.5 Performance

Surface resistance measurements are performed when prescribed by the contract.

21.3 Measuring Frequency

To ensure that the customer gets an impression of the quality delivered over a given period of time, measurements should be taken at least once a quarter. However, measurements could be taken more often. If so, the details thereof shall be included in the contract (4.3 of this standard).

21.3.1 Measurement Objects

It is essential that measurements are only taken on hard and semi-hard floorings. For all floors (entire area) with the same agreed quality level, a collective result is calculated.

21.3.2 Selection of Inspection Units

Inspection units are selected at random.

21.3.3 Number of Measurement Points per Inspection Room

Measurements are taken at 5–20 randomly selected measurement points equally distributed over the floor. The number of measurement points depends as follows on the size of the inspection unit in question:

Rooms measuring 15 m^2 or below	5 measurement points
Rooms > 15 m^2 and up to and including 35 m^2	10 measurement points
Rooms > 35 m^2 and up to and including 100 m^2	20 measurement points.

If the number of inspection units is below five, the necessary number of measurements per inspection unit shall be increased, so that the total number of measurement points is at least 25. Extra measurement points are distributed as evenly as possible between the inspection units.

21.3.4 Time of measurements

Measurements can be taken at any time. When inspecting the surface resistance of the floor finish, the measurements shall be taken relatively shortly after cleaning and/or maintenance.

21.3.5 Measurement

The floor shall be clean and dry before any measurements are taken.

Measurements are taken as described in EN 61340-4-1:2005. An output voltage of 10 V is used for measuring the floor, which shall have a surface resistance below or equal to 10^5 Ω. If the measured

value is above 10^5 Ω, the output voltage shall be changed to 100 V, and the results of the measurements at this voltage shall be declared. For floors with a requirement for surface resistance higher than 10^5 Ω, an output voltage of 100 V is always used, and the measurement result obtained from this voltage is stated irrespective of whether the result is below 10^5 Ω.

The electrodes shall be placed at least 10 cm from the wall, door sills or any other conclusion of the flooring. The distance between the electrodes shall be 30 ± 1 cm.

The measurements are distributed evenly over the floor in randomly selected directions and in such a way that approximately one measurement is taken per 2–4 m^2.

Measurements are taken consecutively with registration of all individual results for every inspection unit, so that an average for the inspection unit can be calculated.

In connection with the measurements, the relative humidity shall also be measured using a calibrated hygrometer or psychrometer.

21.4 Assessment of Measurement Results

The result is assessed as accepted when the following three requirements are met:

1. The average result of all measurements shall be equal to or within the limit values for the agreed level. If level 2 has been agreed, individual results within the requirements for level 3 are also accepted.
2. For surface resistance levels 4, 3 and 2: The highest individual result shall be lower than or equal to the maximum requirement for the level.
3. For surface resistance level 3: The lowest individual result shall be higher than the minimum requirement for the level.

21.5 Reporting

In the report on surface resistance on floors, the following data shall be included:

Date and time of measurements

Date and time of the most recent cleaning and maintenance of the floors

The type of measuring instrument used for the measurements

The name(s) of the individual(s) conducting the inspection (the name of the individual in charge and any other participants)

The areas where the measurements were taken (address, floor, inspection unit)

The number of measurements per inspection unit

Measurement results given in Ω (one decimal)

The agreed quality levels

The relative humidity of the rooms

Assessment of the measurement results compared to the agreed quality level (accepted/not accepted).

The measurement results shall be presented as:

Average result per inspection unit

The average result of all individual measurements

The lowest individual result

The highest individual result.

21.6 Recommendations

The quality level should be adapted to the flooring. Surface resistance level 4 is only used for very special rooms where electrical shielding is required or where there are particularly stringent demands on securing the safety of the staff (earthing). In the latter instance, it may be preferable to set a lower supplementary limit for surface resistance, e.g. 10^4 Ω (see requirements in EN 61350-5-1). Surface resistance level 3 is only used, where dissipative flooring is used, while level 2 can be used for areas where there is anti-static flooring or where the surface resistance of the floor has been improved by the use of anti-static floor polish.

Surface resistance level 3 should be used in surgical theatres, laboratories and other rooms where people are working with flammable liquids and in other areas where there is a danger of explosion.

Tables

Table 1 – Not immediately accessible (NA) areas

Examples
Horizontal surfaces that are out of normal reach or in locked rooms
Areas with furniture & fixtures that are inconveniently positioned or areas with a great deal of furniture.
Surfaces at a height of above 180 cm (i.e. cleaners are required to work with their arms in or above shoulder height, or areas that require cleaners to stand on something including ceilings).
Areas where cleaners are required to work at a distance of more than one metre away from the body or with their backs bent forwards or in a twisted position.
Areas where, irrespective of method, cleaners cannot do the work without bending their knee and hip joints more than 90 degrees.

Table 2 –
Object Groups

Object group	Examples
Furniture & fixtures	Tables, chairs, waste paper bins, lamps including pendant ceiling lamps, sanitary installations, white goods, lamella curtains, venetian blinds, radiators, blackboards and chalk grooves, movable partition walls, book cases, cupboards, pictures, loose mirrors and window sills
Walls	Wall surfaces, pipes on walls, doors (incl. kick plates), internal glass/interior glass walls, door frames, window frames, switches, ventilation grids, wall lamps, fillets, railings, hand rails, handles, panels and radiator cabinets
Floors	Floor surfaces, floor grates, convector pits, doorsteps and stairs both vertical and horizontal surfaces
Ceilings	Ceiling finishes, light shafts and frames in ceiling windows, rafters, exterior part of ventilation ducts, pipes below ceilings, sloping beams, ceiling grates, ceiling hatches, lamps in or on the ceiling and the underside of internal stairs

Table 3a – Quality levels for measurement of numbers of microorganisms on surfaces within healthcare facilities

Acceptable Risk levels	Culture Per cm^2	PCR Per cm^2 Log conversion	RMA Per cm^2
Low risk	10 plus	> 2.41	250 plus
Medium risk	5 - <10	2.15 – 2.41	50 - <250
High risk	0 - <5	< 1.65	0 - < 50

Table 3b – Quality levels for measurement of numbers of samples per area per room

Room type	**Number of samples per test**		
	Floor	**Horizontal surface**	**Vertical surface**
Low Risk	**2**	**2**	**2**
Medium Risk	**3**	**4**	**3**
High Risk	4	12	4

Table 4 – Quality levels for friction measurements

Quality level	Description	Friction coefficient, μ
Friction level 1	Very unsafe floor	< 0.20
Friction level 2	Unsafe floor	0.20 – 0.29
Friction level 3	Conditionally skid-resistant	0.30 – 0.39
Friction level 4	Skid-resistant	0.40 – 0.59
Friction level 5	Very skid-resistant	0.60 – 1.00

Table 5 – Quality levels for gloss measurements

Quality level	Description	Gloss in units
Gloss level 1	Mat	0 – 19
Gloss level 2	Silk mat	20 – 34
Gloss level 3	Semi-gloss	35 – 49
Gloss level 4	Gloss	50 – 65
Gloss level 5	Wet-look	> 65

Table 6 – Maximum gloss differences, the average of the five highest values minus the average of the five lowest values

Quality level	Description	Maximum gloss difference
Gloss level 1	Mat	10
Gloss level 2	Silk mat	15
Gloss level 3	Semi-gloss	20
Gloss level 4	Gloss	25
Gloss level 5	Wet-look	30

Table 7 – Quality levels for static electricity given in volt

Quality levels	Description	Field strength in volt
Static electricity level 1	Minor anti-static effect	2000 – 2999
Static electricity level 2	Fairly good anti-static effect	1000 – 1999
Static electricity level 3	Good anti-static effect	500 – 999
Static electricity level 4	Very good anti-static effect	100 – 499
Static electricity level 5	Extremely good anti-static effect	0 – 99

Table 8 – Quality levels for surface resistance

Quality levels	Description	Resistance in Ω
Surface resistance level 1	Insulating floors	$> 10^{12}$
Surface resistance level 2	Anti-static floors	$> 10^{9} – \leq 10^{12}$
Surface resistance level 3	Dissipative floors	$> 10^{6} – \leq 10^{9}$***
Surface resistance level 4	Conductive floors	$\leq 10^{6}$

Forms

Form 1

Quality profiles

Customer	Address/department										Date									Signature
Group of rooms																				Comments
Description/Profile																				
Quality Level	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
FURNITURE AND FIXTURES																				
Waste and loose dirt, dust and stains																				
Surface soiling																				
WALLS																				
Waste and loose dirt, dust and stains																				
Surface soiling																				
FLOORS																				
Waste and loose dirt, dust and stains																				
Surface soiling																				
CEILINGS																				
Waste and loose dirt, dust and stains																				
Surface soiling																				
Supplementary requirements																				

Form 2
Assessment form

PERFORMED BY:												
Organisation:		Customer:										
Address												
Building/storey							Room ID.					
Quality profile A ☐ B ☐ C ☐ D ☐ E ☐ F ☐ Inspection unit size 0-15m^2☐ 15-35m^2☐ 35-60m^2☐ 60-100m^2☐												
Object group	Waste and loose dirt		Dust		Stains		Total number of accumulations			Surface soiling %		
	A	NA	A	NA	A	NA	A	NA	Level 0 - 5	A	NA	Level 0 - 5
Furniture & fixtures												
Walls												
Floors												
Ceilings												
Tick off if dominating occurrences on/of ☐ Lamps up high ☐ Uneven floor treatment ☐ Textile furniture ☐ Dust on high levels							Chemicals used					
Signature							Date					

Form 3
Report form for inspection of cleaning quality

Report on inspection of cleaning quality for units with different quality profiles

Company:			Address:			
The purpose of the inspection:			Inspection conducted by:		Person in charge of the inspection:	
Date:			Sampling plan: Single	Double	Total	
Sample: (Quality profile or another name)						
Number of inspection areas/units in the lot (N)						
Type of inspection (Normal or additional)						
Sample size *(n)*						
Acceptance number (Ac) Rejection number (Re) Number of accepted inspection areas Number of not accepted inspection areas						
Sample accepted/not accepted (A/NA)						
Consequences: (additional inspection, discontinuation or any actions)						

Signature

Form 4

REGISTRATION FORM FOR A SPECIFIC AGREED QUALITY LEVEL - DUST ON SURFACES

Customer:							
Address:							
Time of cleaning	Date:		Time.:				
Time of measuring	Date:		Time:				
Purpose of the measurements, see D.1.1:							
Inspection unit (IU)	Close to body	Furniture and fixtures		Hard floors		Carpets	COMMENTS
	A	A	NA	A	NA	A	
Average*							
Agreed quality level							
Requirement (dust cov. %)							
Ceiling value of 1.5 x the requirement							
Number of results higher than the ceiling value							
Allowed number of results higher than the ceiling value							
Approved/not approved (Ap/NAp)							

Tot. num. IU (N)	6	7 - 9	10 - 14	15 - 26	27 - 50	>50	
Num. units for insp. (n)	5	6	7	8	9	11	
1-3 samples shall be collected pr. surface category depending on the IU size, see D.1.6.5							
*Average of 5 to 33 measurements per surface category depending on the total number of inspection units and the size of the units inspected							

Quality level	Close to body surfaces	Furniture and fixtures		Hard floors		Carpets Method A	Carpets Method B
	A	A	NA	A	NA	A	
Dust level 1	>4,0	>5,0	>15,0	>12,0	>18,0	>20,0	>1.0
Dust level 2	4,0	5,0	15,0	12,0	18,0	20,0	1.0
Dust level 3	2,0	2,5	10,0	7,0	10,0	10,0	0.5
Dust level 4	1,0	1,5	5,0	3,0	5,0	5,0	0.25
Dust level 5	0,7	1,0	3,0	1,5	2,5	3,0	0,15
Values for dust levels 2 - 5 are maximum values.							
Date:		Sign.:					

Form 5 -Report form for testing of microbial contamination levels

Address:			**Floor:**	
Date:	**Time of measurement:**		**Time of cleaning:** **Most recent disinfection:**	
Object:			**Person in charge of taking measurements:**	
Inspection unit and inspection object	**Agreed quality**	**Individual results**	**Average**	**Comments (including sampling method)**

Form 6

REGISTRATION FORM FOR A SPECIFIC AGREED QUALITY LEVEL- FRICTION MEASUREMENT												
Customer												
Address:												
Time of cleaning				Date					Time:			
Time of measurement				Date:					Time:			
Inspection unit (IU)												
IU size												
Flooring												
Measuring result												
Measuring result												
Measuring result												
Measuring result												
Measuring result												
COMMENTS												
Average of all results												
Agreed quality level												
Requirement (μ)												
Lowest result > min. requirement for the level below the agreed level (Yes/No)												
Approved/not approved (Ap/NAp)												
Number of inspection units for inspection (n) as a function of the total number of inspection units (N)												
Tot. num. IU (N)	6		7 - 9		10 - 14		15 - 26		27 - 50		>50	
Num. units for insp. (n)	5		6		7		8		9		11	
Depending on the size of the IU, 1–5 measurements shall be performed on randomly selected measurement points equally distributed over the floor, see D.3.6.5												
Date:						Signature:						
Quality level												

Quality level	Description	Friction coefficient, μ
Friction level 1	Very unsafe floor	< 0.20
Friction level 2	Unsafe floor	0.20–0.29
Friction level 3	Conditionally skid-	0.30–0.39
Friction level 4	Skid-resistant	0.40–0.59
Friction level 5	Very skid-resistant	0.60–1.00

Form 7

REGISTRATION FORM FOR ONE INSPECTION UNIT - GLOSS MEASUREMENTS

Customer:						
Address:						
Time of cleaning	Date:		Time:			
Time of measurement	Date:		Time:			
Inspection unit (IU)	Flooring	Measuring result	5 highest (H)	5 lowest (L)	H - L	COMMENTS
Average*						
Agreed quality level						
Requirement (gloss un.)						
Approved/not approved (Ap/NAp)						

Tot. num. IU (N)	6	7 - 9	10 - 14	15 - 26	27 - 50	>50
Num. units for insp. (n)	5	6	7	8	9	11

* Average of 10-25 measurements per unit depending on the IU size, see D.4.6.5, and average og the 5 highest and 5 lowest results respectively

Quality level	**Description**	**Gloss in units**	**Maximum gloss difference** (H - L)
Gloss level 1	Mat	0–19	10
Gloss level 2	Silk mat	20–34	15
Gloss level 3	Semi-gloss	35–49	20
Gloss level 4	Gloss	50–65	25
Gloss level 5	Wet-look	> 65	30

Date:		Sign.				

Form 8

REGISTRATION FORM – STATIC ELECTRICITY

Address:			**Floor:**	
Date:	**Time of measurement:**		**Time of cleaning:** **Most recent anti-static treatment:**	
Object:			**Person taking measurements:**	
Inspection unit and inspection object	**Agreed quality**	**Individual results**	**Average (1–5 measurements)**	**Comments**

Form 9

REGISTRATION FORM – SURFACE RESISTANCE

Address:			**Floor:**	
Date:	**Time of measurement:**		**Time of cleaning:** **Time of maintenance:**	
Object:			**Person taking measurements:**	
Inspection unit and flooring	**Agreed quality**	**Individual results**	**Average (5–20 measurements)**	**Comments**

Annex A

Competence required for using Environmental cleaning and disinfection standards.

A.1 Skills in general

The customers, suppliers and the users of the rooms where this HTM is used, have different needs when it comes to knowledge and skills about the guidance and standard required. The different needs of knowledge are based on what position the person has within the organization.

A.2 Knowledge levels

Four knowledge levels are defined, where the two highest levels can be used as basis for claiming conformity for operators:

- Knowledge level 1 – Some knowledge about details in this guidance document.
- Knowledge level 2 – Uses parts of guidance document in their work.
- Knowledge level 3 – Has detailed knowledge about the whole or a large part of guidance document.
- Knowledge level 4 – Masters the use of guidance document in all aspects.

Persons with higher knowledge levels will always have the knowledge needed for the lower levels.

Knowledge required for different levels of employers at the contractor and the customer:

PART	FUNCTION	LEVEL OF KNOWLEDGE			
		1	2	3	4
Contractor	Cleaner		X		
	Work leader/ Supervisor			X	
	Planner				X
	Management			X	
Customer	Buyer			X	
	Contact person/ Cleaning responsible				X
Consultants	Performing inspections			X	
	Working out tenders, planning cleaning services				X

A.2.1 Knowledge level 1

Knowledge level 1 comprises knowledge about the object groups, the two sets of measuring methods (visual and instrumental) and the quality profiles which can be established for the rooms, with different requirements for object groups according to measurable criteria. The management team at the supplier is the target group for this knowledge level.

A.2.2 Knowledge level 2

Knowledge level 2 comprises knowledge about the terms and definitions in this guidance document and the meaning of those, e.g. the terms A and NA, object groups, soiling groups, accumulation of soiling and quality profiles. Some knowledge on how to measure and rate performance is needed, and also knowledge about how to bring a room up to the agreed quality profile. The cleaning employees should have this level of knowledge.

A.2.3 Knowledge level 3

Knowledge level 3 comprises thorough knowledge about the visual inspection, and knowledge about instrumental measurement methods. In addition to this, knowledge level 3 comprises thorough knowledge of the statistical conditions for quality measurement. In practice, this means how often an inspection must take place, the measuring scheme and sample method etc. This knowledge level is for persons who perform inspections, e.g. team leaders, inspectors and consultants who are responsible for assessments.

A.2.4 Knowledge level 4

Knowledge level 4 implies thorough knowledge of the entire standard thus to be able to work out procurement documents and offers, carry out assessments visual as well as with instruments, report

the results and use these to adjust the cleaning effort etc. The planners at the supplier of cleaning services and the customers purchasing manager for cleaning services, or the consultant used by the customer for working out procurement documents, should have this knowledge level.

A.2.5 Documentation of knowledge

Knowledge level 3 and 4 can be documented from exam related training courses or equivalent documentation issued from a third-party evaluation body. Maintenance of knowledge shall be documented regularly.

Annex B

Recommendations regarding inspection

In order to avoid re-soiling of the surfaces that has been cleaned, inspection of the inspection units shall be carried out immediately after the cleaning has been completed, or at the latest, before the room is used again. This can be difficult to achieve if the areas is in continuously use (i.e. hospitals), or if the cleaning is carried out during the normal business hours of the premises.

The following clauses give some examples on special arrangements for inspection. By using these procedures or mixes of the procedures it should be possible to cover most eventualities of special cases.

NORMATIVE: Any special arrangements used during inspection, as some of the procedures described below, shall be described in the report from the inspection.

B.1 Cleaning during business hours

For areas which are not used continuously (i.e. single offices, hotel rooms) it will normally be possible to find other similar inspection units nearby, which can be inspected if the inspection unit has been taken into use. In such cases the procedures already described, can be used.

For areas which are more or less continuously in use (i.e. toilets, meeting and conference rooms, receptions, corridors and other common areas) it is recommended to organise the cleaning in such a way that these areas are cleaned close to the start/end of the day, starting/finishing with the areas most exposed to re-soiling. If the inspection unit has been exposed to re-soiling by the time of inspection, it will normally be possible to find other similar inspection units which have not been re-soiled, and use the procedures described.

In large common areas parts of the area, for instance the main pathway may be re-soiled. In such cases the parts that have been re-soiled can be excluded from the inspection, and the rest of the area can be inspected. If the exclusion causes change of size group for the inspection unit (see table 4) this has to be taken into account when evaluating the result.

For open-plan offices it is recommended to divide the area into smaller inspection units, and give each inspection unit a unique identity, which can be selected for inspection. For instance, can each work station be a separate inspection unit. If the inspection unit selected for inspection has been exposed to re-soiling by the time of inspection, it will normally be possible to find other similar inspection units which have not been re-soiled, and use the procedures described.

If it is impossible to find an inspection unit which have not been taken into use (i.e. an office which is cleaned when the occupant is working in the room), the surfaces that has obviously been taken into use may be excluded from the inspection.

For areas with heavy traffic or a large group of people on a small area, i.e. schools, it is recommended to use the procedure described in G.2.

B.2 Areas in continuously use

In areas which are more or less continuously in use, or where re-soiling is likely to occur almost immediately after cleaning, inspection must be carried out immediately after cleaning. Examples are:

Entrances, toilets and common areas in airports, train and bus stations, hospitals etc.

Hospital wards, ICU/ HDU’s

Hospital corridors

Inspection must be carried out in close cooperation with the cleaner and his/her supervisor, and performed immediately after the cleaner has left the room. In such cases it is important to inform the

cleaner that cleaning shall be performed “as usual” (within the normal time limits for the task), and that the inspection is a control of the quality of the total cleaning services, and not his/her work in special.

Rooms/areas that are closed for cleaning can remain closed until inspection has been performed. In other areas (i.e. large common areas) parts of the area (i.e. an inspection unit) may be closed for the users/public until inspection has been performed. Hospital wards can be closed for other than the occupants during inspection (may be opened in emergency situations), and the occupants can be asked to stay in bed until inspection has been performed.

In security centres, wards and other rooms where it is difficult to avoid that some of the surfaces are taken into use by the occupants before inspection, the surfaces that has obviously been taken into use may be excluded from the inspection.

Annex C

Information on disinfecting chemicals and other agents

Chemical Disinfectants

Formaldehyde

Overview. Formaldehyde is used as a disinfectant and sterilant in both its liquid and gaseous states. Liquid formaldehyde will be considered briefly in this section, and the gaseous form is reviewed elsewhere. Formaldehyde is sold and used principally as a water-based solution called formalin, which is 37% formaldehyde by weight. The aqueous solution is a bactericide, tuberculocide, fungicide, viricide and sporicide. OSHA indicated that formaldehyde should be handled in the workplace as a potential carcinogen and set an employee exposure standard for formaldehyde that limits an 8-hour time-weighted average exposure concentration of 0.75 ppm. The standard includes a second permissible exposure limit in the form of a short-term exposure limit (STEL) of 2 ppm that is the maximum exposure allowed during a 15-minute period. Ingestion of formaldehyde can be fatal, and long-term exposure to low levels in the air or on the skin can cause asthma-like respiratory problems and skin irritation, such as dermatitis and itching. For these reasons, employees should have limited direct contact with formaldehyde, and these considerations limit its role in sterilization and disinfection processes. Key provisions of the OSHA standard that protects workers from exposure to formaldehyde appear in Title 29 of the Regulations (CR) Part 1910.1048 (and equivalent regulations in OSHA approved plans).

Mode of Action. Formaldehyde inactivates microorganisms by alkylating the amino and sulfhydryl groups of proteins and ring nitrogen atoms of purine bases.

Microbicidal Activity. Varying concentrations of aqueous formaldehyde solutions destroy a wide range of microorganisms. Inactivation of poliovirus in 10 minutes required an 8% concentration of formalin, but all other viruses tested were inactivated with 2% formalin. Four percent formaldehyde is a tuberculocidal agent, inactivating 104 *M*. *tuberculosis* in 2 minutes 82, and 2.5% formaldehyde inactivated about 107 *Salmonella* Typhi in 10 minutes in the presence of organic matter. The sporicidal action of formaldehyde was slower than that of glutaraldehyde in comparative tests with 4% aqueous formaldehyde and 2% glutaraldehyde against the spores of *B. anthracis*. The formaldehyde solution required 2 hours of contact to achieve an inactivation factor of 104, whereas glutaraldehyde required only 15 minutes.

Uses. Although formaldehyde-alcohol is a chemical sterilant and formaldehyde is a high-level disinfectant, the health-care uses of formaldehyde are limited by its irritating fumes and its pungent odour even at very low levels (<1 ppm). For these reasons and others—such as its role as a suspected human carcinogen linked to nasal cancer and lung cancer. When it is used, direct exposure to employees generally is limited; however, excessive exposures to formaldehyde have been documented for employees of renal transplant units, and students in a gross anatomy laboratory. Formaldehyde is used in the health-care setting to prepare viral vaccines (e.g., poliovirus and influenza); as an embalming agent; and to preserve anatomic specimens; and historically has been used to sterilize surgical instruments, especially when mixed with ethanol. A 1997 survey found that formaldehyde was used for reprocessing haemodialyzers by 34% of U.S. haemodialysis centres—a 60% decrease from 1983. If used at room temperature, a concentration of 4% with a minimum exposure of 24 hours is required to disinfect disposable haemodialyzers reused on the same patient. Aqueous formaldehyde solutions (1%–2%) also have been used to disinfect the internal fluid pathways of dialysis machines. To minimize a potential health hazard to dialysis patients, the dialysis equipment must be thoroughly rinsed and tested for residual formaldehyde before use.
Paraformaldehyde, a solid polymer of formaldehyde, can be vaporized by heat for the gaseous decontamination of laminar flow biologic safety cabinets when maintenance work or filter changes require access to the sealed portion of the cabinet.

Glutaraldehyde

Overview. Glutaraldehyde is a saturated dialdehyde that has gained wide acceptance as a high-level disinfectant and chemical sterilant. Aqueous solutions of glutaraldehyde are acidic and generally in this state are not sporicidal. Only when the solution is “activated” (made alkaline) by use of alkalinating agents to pH 7.5–8.5 does the solution become sporicidal. Once activated, these solutions have a shelf-life of minimally 14 days because of the polymerization of the glutaraldehyde molecules at alkaline pH levels. This polymerization blocks the active sites (aldehyde groups) of the glutaraldehyde molecules that are responsible for its biocidal activity.

Novel glutaraldehyde formulations (e.g., glutaraldehyde-phenol-sodium phenate, potentiated acid glutaraldehyde, stabilized alkaline glutaraldehyde) produced in the past 30 years have overcome the problem of rapid loss of activity (e.g., use-life 28–30 days) while generally maintaining excellent microbicidal activity. However, antimicrobial activity depends not only on age but also on use conditions, such as dilution and organic stress. Manufacturers' literature for these preparations suggests the neutral or alkaline glutaraldehyde's possess microbicidal and anticorrosion properties superior to those of acid glutaraldehyde's, and a few published reports substantiate these claims. However, two studies found no difference in the microbicidal activity of alkaline and acid glutaraldehyde's. The use of glutaraldehyde-based solutions in health-care facilities is widespread because of their advantages, including excellent biocidal properties; activity in the presence of organic matter (20% bovine serum); and noncorrosive action to endoscopic equipment, thermometers, rubber, or plastic equipment.

Mode of Action. The biocidal activity of glutaraldehyde results from its alkylation of sulfhydryl, hydroxyl, carboxyl, and amino groups of microorganisms, which alters RNA, DNA, and protein synthesis. The mechanism of action of glutaraldehyde's are reviewed extensively elsewhere.

Microbicidal Activity. The in vitro inactivation of microorganisms by glutaraldehyde's has been extensively investigated and reviewed. Several investigators showed that ≥2% aqueous solutions of glutaraldehyde, buffered to pH 7.5–8.5 with sodium bicarbonate effectively killed vegetative bacteria in <2 minutes; *M. tuberculosis*, fungi, and viruses in <10 minutes; and spores of *Bacillus* and *Clostridium* species in 3 hours. Spores of *C. difficile* are more rapidly killed by 2% glutaraldehyde than are spores of other species of *Clostridium* and *Bacillus*. Microorganisms with substantial resistance to glutaraldehyde have been reported, including some mycobacteria (*M. chelonae*, *Mycobacterium avium-intracellulare, M. xenopi*), *Methylobacterium mesophilicum*, *Trichosporon*, fungal ascospores (e.g., *Microascus cinereus*, *Cheatomium globosum*), and *Cryptosporidium*. *M. chelonae* persisted in a 0.2% glutaraldehyde solution used to store porcine prosthetic heart valves.

Two percent alkaline glutaraldehyde solution inactivated 105 *M. tuberculosis* cells on the surface of penicylinders within 5 minutes at 18ºC. However, subsequent studies questioned the mycobactericidal prowess of glutaraldehyde's. Two percent alkaline glutaraldehyde has slow action (20 to >30 minutes) against *M. tuberculosis* and compares unfavourably with alcohols, formaldehydes, iodine, and phenol. Suspensions of *M. avium, M. intracellulare,* and *M. gordonae* were more resistant to inactivation by a 2% alkaline glutaraldehyde (estimated time to complete inactivation: ~60 minutes) than were virulent *M. tuberculosis* (estimated time to complete inactivation ~25 minutes) 605. The rate of kill was directly proportional to the temperature, and a standardized suspension of *M. tuberculosis* could not be sterilized within 10 minutes. An FDA-cleared chemical sterilant containing 2.5% glutaraldehyde uses increased temperature (35ºC) to reduce the time required to achieve high-level disinfection (5 minutes), but its use is limited to automatic endoscope repressors equipped with a heater. In another study employing membrane filters for measurement of mycobactericidal activity of 2% alkaline glutaraldehyde, complete inactivation was achieved within 20 minutes at 20ºC when the test inoculum was 106 *M. tuberculosis* per membrane. Several investigators have demonstrated that glutaraldehyde solutions inactivate 2.4 to >5.0 log10 of *M. tuberculosis* in 10 minutes (including multidrug-resistant *M. tuberculosis*) and 4.0–6.4 log10 of *M. tuberculosis* in 20 minutes. On the basis of these data and other studies, 20 minutes at room temperature is considered the minimum exposure time needed to reliably kill *Mycobacteria* and other vegetative bacteria with ≥2% glutaraldehyde.

Glutaraldehyde is commonly diluted during use, and studies showed a glutaraldehyde concentration decline after a few days of use in an automatic endoscope washer. The decline occurs because instruments are not thoroughly dried and water is carried in with the instrument, which increases the solution's volume and dilutes its effective concentration. This emphasizes the need to ensure that semi critical equipment is disinfected with an acceptable concentration of glutaraldehyde. Data suggest that 1.0%–1.5% glutaraldehyde is the minimum effective concentration for >2% glutaraldehyde solutions when used as a high-level disinfectant. Chemical test strips or liquid chemical monitors are available for determining whether an effective concentration of glutaraldehyde is present despite repeated use and dilution. The frequency of testing should be based on how frequently the solutions are used (e.g., used daily, test daily; used weekly, test before use; used 30 times per day, test each 10th use), but the strips should not be used to extend the use life beyond the expiration date. Data suggest the chemicals in the test strip deteriorate with time and a manufacturer's expiration date should be placed on the bottles. The bottle of test strips should be dated when opened and used for the period of time indicated on the bottle (e.g., 120 days). The results of test strip monitoring should be documented. The glutaraldehyde test kits have been preliminarily evaluated for accuracy and range but the reliability has been questioned. To ensure the presence of minimum effective concentration of the high-level disinfectant, manufacturers of some chemical test strips recommend the use of quality-control procedures to ensure the strips perform properly. If the manufacturer of the chemical test strip recommends a quality-control procedure, users should comply with the manufacturer's recommendations. The concentration should be considered unacceptable or unsafe when the test

indicates a dilution below the product's minimum effective concentration (MEC) (generally to ≤1.0%–1.5% glutaraldehyde) by the indicator not changing colour.

A 2.0% glutaraldehyde–7.05% phenol–1.20% sodium phenate product that contained 0.125% glutaraldehyde–0.44% phenol–0.075% sodium phenate when diluted 1:16 is not recommended as a high-level disinfectant because it lacks bactericidal activity in the presence of organic matter and lacks tuberculocidal, fungicidal, viricidal, and sporicidal activity. In December 1991, the US EPA issued an order to stop the sale of all batches of this product because of efficacy data showing the product is not effective against spores and possibly other microorganisms or inanimate objects as claimed on the label. The US FDA has cleared a glutaraldehyde–phenol/phenate concentrate as a high-level disinfectant that contains 1.12% glutaraldehyde with 1.93% phenol/phenate at its use concentration. Other US FDA cleared glutaraldehyde sterilants that contain 2.4%–3.4% glutaraldehyde are used undiluted.

Uses. Glutaraldehyde is used most commonly as a high-level disinfectant for medical equipment such as endoscopes, spirometry tubing, dialyzers, transducers, anaesthesia and respiratory therapy equipment, haemodialysis proportioning and dialysate delivery systems, and reuse of laparoscopic disposable plastic trocars. Glutaraldehyde is noncorrosive to metal and does not damage lensed instruments, rubber. or plastics. Glutaraldehyde should not be used for cleaning noncritical surfaces because it is too toxic and expensive.
Colitis believed caused by glutaraldehyde exposure from residual disinfecting solution in endoscope solution channels has been reported and is preventable by careful endoscope rinsing. One study found that residual glutaraldehyde levels were higher and more variable after manual disinfection (<0.2 mg/L to 5 mg/L) than after automatic disinfection (0.2–6.3 mg/L). Similarly, keratopathy and corneal decompensation were caused by ophthalmic instruments that were inadequately rinsed after soaking in 2% glutaraldehyde.
Healthcare personnel can be exposed to elevated levels of glutaraldehyde vapour when equipment is processed in poorly ventilated rooms, when spills occur, when glutaraldehyde solutions are activated or changed, or when open immersion baths are used. Acute or chronic exposure can result in skin irritation or dermatitis, mucous membrane irritation (eye, nose, mouth), or pulmonary symptoms. Epistaxis, allergic contact dermatitis, asthma, and rhinitis also have been reported in healthcare workers exposed to glutaraldehyde.

Glutaraldehyde exposure should be monitored to ensure a safe work environment. Testing can be done by four techniques: a silica gel tube/gas chromatography with a flame ionization detector, dinitrophenylhydrazine (DNPH)-impregnated filter cassette/high-performance liquid chromatography (HPLC) with an ultraviolet (UV) detector, a passive badge/HPLC, or a handheld glutaraldehyde air monitor. The silica gel tube and the DNPH-impregnated cassette are suitable for monitoring the 0.05 ppm ceiling limit. The passive badge, with a 0.02 ppm limit of detection, is considered marginal at the American Council of Governmental Industrial Hygienists (ACGIH) ceiling level. The ceiling level is considered too close to the glutaraldehyde meter's 0.03 ppm limit of detection to provide confidence in the readings. ACGIH does not require a specific monitoring schedule for glutaraldehyde; however, a monitoring schedule is needed to ensure the level is less than the ceiling limit. For example, monitoring should be done initially to determine glutaraldehyde levels, after procedural or equipment changes, and in response to worker complaints. In the absence of an OSHA permissible exposure limit, if the glutaraldehyde level is higher than the ACGIH ceiling limit of 0.05 ppm, corrective action and repeat monitoring would be prudent.

Engineering and work-practice controls that can be used to resolve these problems include ducted exhaust hoods, air systems that provide 12 – 24 air exchanges per hour, ductless fume hoods with absorbents for the glutaraldehyde vapour, tight-fitting lids on immersion baths, personal protection (e.g., nitrile or butyl rubber gloves but not natural latex gloves, goggles) to minimize skin or mucous membrane contact, and automated endoscope processors. If engineering controls fail to maintain levels below the ceiling limit, institutions can consider the use of respirators (e.g., a half-face respirator with organic vapour cartridge or a type "C" supplied air respirator with a full face piece operated in a positive pressure mode). In general, engineering controls are preferred over work-practice and administrative controls because they do not require active participation by the health-care worker. Even though enforcement of the OSHA ceiling limit was suspended in 1993 by the U.S. Court of Appeals, limiting employee exposure to 0.05 ppm (according to ACGIH) is prudent because, at this level, glutaraldehyde can irritate the eyes, throat, and nose. If glutaraldehyde disposal through the sanitary sewer system is restricted, sodium bisulfate can be used to neutralize the glutaraldehyde and make it safe for disposal.

Hydrogen Peroxide

Overview. The literature contains several accounts of the properties, germicidal effectiveness, and potential uses for stabilized hydrogen peroxide in the health-care setting. Published reports ascribe good germicidal activity to hydrogen peroxide and attest to its bactericidal, viricidal, sporicidal, and

fungicidal properties. Manufacturers MSDS sheets list liquid chemical sterilants and high-level disinfectants containing hydrogen peroxide and their cleared contact conditions.

Mode of Action. Hydrogen peroxide works by producing destructive hydroxyl free radicals that can attack membrane lipids, DNA, and other essential cell components. Catalase, produced by aerobic organisms and facultative anaerobes that possess cytochrome systems, can protect cells from metabolically produced hydrogen peroxide by degrading hydrogen peroxide to water and oxygen. This defence is overwhelmed by the concentrations used for disinfection.

Microbicidal Activity. Hydrogen peroxide is active against a wide range of microorganisms, including bacteria, yeasts, fungi, viruses, and spores. A 0.5% accelerated hydrogen peroxide demonstrated bactericidal and viricidal activity in 1 minute and mycobactericidal and fungicidal activity in 5 minutes. Bactericidal effectiveness and stability of hydrogen peroxide in urine has been demonstrated against a variety of health-care–associated pathogens; organisms with high cellular catalase activity (e.g., *S. aureus*, *S. marcescens*, and *Proteus mirabilis*) required 30–60 minutes of exposure to 0.6% hydrogen peroxide for a reduction in cell counts, whereas organisms with lower catalase activity (e.g., *E. coli*, *Streptococcus* species, and *Pseudomonas* species) required only 15 minutes' exposure. In an investigation of 3%, 10%, and 15% hydrogen peroxide for reducing spacecraft bacterial populations, a complete kill of 106 spores (i.e., *Bacillus* species) occurred with a 10% concentration and a 60-minute exposure time. A 3% concentration for 150 minutes killed 106 spores in six of seven exposure trials. A 10% hydrogen peroxide solution resulted in a 103 decrease in *B. atrophaeus* spores, and a $\geq$105 decrease when tested against 13 other pathogens in 30 minutes at 20ºC. A 3.0% hydrogen peroxide solution was ineffective against VRE after 3 and 10 minutes exposure times and caused only a 2-log10 reduction in the number of *Acanthamoeba* cysts in approximately 2 hours. A 7% stabilized hydrogen peroxide proved to be sporicidal (6 hours of exposure), mycobactericidal (20 minutes), fungicidal (5 minutes) at full strength, viricidal (5 minutes) and bactericidal (3 minutes) at a 1:16 dilution when a quantitative carrier test was used. The 7% solution of hydrogen peroxide, tested after 14 days of stress (in the form of germ-loaded carriers and respiratory therapy equipment), was sporicidal (>7 log10 reduction in 6 hours), mycobactericidal (>6.5 log10 reduction in 25 minutes), fungicidal (>5 log10 reduction in 20 minutes), bactericidal (>6 log10 reduction in 5 minutes) and viricidal (5 log10 reduction in 5 minutes). Synergistic sporicidal effects were observed when spores were exposed to a combination of hydrogen peroxide (5.9%–23.6%) and peracetic acid. Other studies demonstrated the antiviral activity of hydrogen peroxide against rhinovirus. The time required for inactivating three serotypes of rhinovirus using a 3% hydrogen peroxide solution was 6–8 minutes; this time increased with decreasing concentrations (18-20 minutes at 1.5%, 50–60 minutes at 0.75%).

Concentrations of hydrogen peroxide from 6% to 25% show promise as chemical sterilants. The product marketed as a sterilant is a premixed, ready-to-use chemical that contains 7.5% hydrogen peroxide and 0.85% phosphoric acid (to maintain a low pH). The mycobactericidal activity of 7.5% hydrogen peroxide has been corroborated in a study showing the inactivation of >105 multidrug-resistant *M. tuberculosis* after a 10-minute exposure. Thirty minutes were required for >99.9% inactivation of poliovirus and HAV. Three percent and 6% hydrogen peroxide were unable to inactivate HAV in 1 minute in a carrier test. When the effectiveness of 7.5% hydrogen peroxide at 10 minutes was compared with 2% alkaline glutaraldehyde at 20 minutes in manual disinfection of endoscopes, no significant difference in germicidal activity was observed). No complaints were received from the nursing or medical staff regarding odour or toxicity. In one study, 6% hydrogen peroxide (unused product was 7.5%) was more effective in the high-level disinfection of flexible endoscopes than was the 2% glutaraldehyde solution. A new, rapid-acting 13.4% hydrogen peroxide formulation (that is not yet MHRA cleared) has demonstrated sporicidal, mycobactericidal, fungicidal, and viricidal efficacy. Manufacturer data demonstrate that this solution sterilizes in 30 minutes and provides high-level disinfection in 5 minutes. This product has not been used long enough to evaluate material compatibility to endoscopes and other semi critical devices, and further assessment by instrument manufacturers is needed.
Under normal conditions, hydrogen peroxide is extremely stable when properly stored (e.g., in dark containers). The decomposition or loss of potency in small containers is less than 2% per year at ambient temperatures.

Uses. Commercially available 3% hydrogen peroxide is a stable and effective disinfectant when used on inanimate surfaces. It has been used in concentrations from 3% to 6% for disinfecting soft contact lenses (e.g., 3% for 2–3 hrs), tonometer biprisms, ventilators, fabrics, and endoscopes. Hydrogen peroxide was effective in spot-disinfecting fabrics in patients' rooms. Corneal damage from a hydrogen peroxide-soaked tonometer tip that was not properly rinsed has been reported. Hydrogen peroxide also has been instilled into urinary drainage bags in an attempt to eliminate the bag as a source of bladder bacteriuria and environmental contamination. Although the instillation of hydrogen peroxide into the bag reduced microbial contamination of the bag, this procedure did not reduce the incidence of catheter-associated bacteriuria.

A chemical irritation resembling pseudomembranous colitis caused by either 3% hydrogen peroxide or a 2% glutaraldehyde has been reported. An epidemic of pseudo membrane-like enteritis and colitis in seven patients in a gastrointestinal endoscopy unit also has been associated with inadequate rinsing of 3% hydrogen peroxide from the endoscope.

As with other chemical sterilants, dilution of the hydrogen peroxide must be monitored by regularly testing the minimum effective concentration (i.e., 7.5%–6.0%). Compatibility testing by Olympus of the 7.5% hydrogen peroxide found both cosmetic changes (e.g., discoloration of black anodized metal finishes) and functional changes with the tested endoscopes (Olympus, written communication, October 15, 1999).

Alcohol

***Overview*.** In the healthcare setting, “alcohol” refers to two water-soluble chemical compounds—ethyl alcohol and isopropyl alcohol—that have generally germicidal characteristics. MHRA has not cleared any liquid chemical sterilant or high-level disinfectant with alcohol as the main active ingredient. These alcohols are rapidly bactericidal rather than bacteriostatic against vegetative forms of bacteria; they also are tuberculocidal, fungicidal, and viricidal but do not destroy bacterial spores. Their cidal activity drops sharply when diluted below 50% concentration, and the optimum bactericidal concentration is 60%–90% solutions in water (volume/volume).

***Mode of Action*.** The most feasible explanation for the antimicrobial action of alcohol is denaturation of proteins. This mechanism is supported by the observation that absolute ethyl alcohol, a dehydrating agent, is less bactericidal than mixtures of alcohol and water because proteins are denatured more quickly in the presence of water. Protein denaturation also is consistent with observations that alcohol destroys the dehydrogenases of *Escherichia coli*, and that ethyl alcohol increases the lag phase of *Enterobacter aerogenes* and that the lag phase effect could be reversed by adding certain amino acids. The bacteriostatic action was believed caused by inhibition of the production of metabolites essential for rapid cell division.

***Microbicidal Activity*.** Methyl alcohol (methanol) has the weakest bactericidal action of the alcohols and thus seldom is used in healthcare. The bactericidal activity of various concentrations of ethyl alcohol (ethanol) was examined against a variety of microorganisms in exposure periods ranging from 10 seconds to 1 hour. *Pseudomonas aeruginosa* was killed in 10 seconds by all concentrations of ethanol from 30% to 100% (v/v), and *Serratia marcescens, E, coli* and *Salmonella typhosa* were killed in 10 seconds by all concentrations of ethanol from 40% to 100%. The gram-positive organisms *Staphylococcus aureus* and *Streptococcus pyogenes* were slightly more resistant, being killed in 10 seconds by ethyl alcohol concentrations of 60%–95%. Isopropyl alcohol (isopropanol) was slightly more bactericidal than ethyl alcohol for *E. coli* and *S. aureus.*

Ethyl alcohol, at concentrations of 60%–80%, is a potent viricidal agent inactivating all of the lipophilic viruses (e.g., herpes, vaccinia, and influenza virus) and many hydrophilic viruses (e.g., adenovirus, enterovirus, rhinovirus, and rotaviruses but not hepatitis A virus (HAV), Norovirus or poliovirus). Isopropyl alcohol is not active against the nonlipid enteroviruses but is fully active against the lipid viruses. Studies also have demonstrated the ability of ethyl and isopropyl alcohol to inactivate the hepatitis B virus(HBV) and the herpes virus, and ethyl alcohol to inactivate human immunodeficiency virus (HIV), rotavirus, echovirus, and astrovirus.

In tests of the effect of ethyl alcohol against *M. tuberculosis*, 95% ethanol killed the tubercle bacilli in sputum or water suspension within 15 seconds. In 1964, Spaulding stated that alcohols were the germicide of choice for tuberculocidal activity, and they should be the standard by which all other tuberculocides are compared. For example, he compared the tuberculocidal activity of iodophor (450 ppm), a substituted phenol (3%), and isopropanol (70%/volume) using the mucin-loop test (106 *M. tuberculosis* per loop) and determined the contact times needed for complete destruction were 120–180 minutes, 45–60 minutes, and 5 minutes, respectively. The mucin-loop test is a severe test developed to produce long survival times. Thus, these figures should not be extrapolated to the exposure times needed when these germicides are used on medical or surgical material.
Ethyl alcohol (70%) was the most effective concentration for killing the tissue phase of *Cryptococcus neoformans*, *Blastomyces dermatitidis*, *Coccidioides immitis*, and *Histoplasma capsulatum* and the culture phases of the latter three organisms aerosolized onto various surfaces. The culture phase was more resistant to the action of ethyl alcohol and required about 20 minutes to disinfect the contaminated surface, compared with <1 minute for the tissue phase.
Isopropyl alcohol (20%) is effective in killing the cysts of *Acanthamoeba culbertsoni* as are chlorhexidine, hydrogen peroxide, and thimerosal.

Uses. Alcohols are not recommended for sterilizing medical and surgical materials principally because they lack sporicidal action and they cannot penetrate protein-rich materials. Fatal postoperative wound infections with *Clostridium* have occurred when alcohols were used to sterilize surgical instruments contaminated with bacterial spores. Alcohols have been used effectively to disinfect oral and rectal thermometers, hospital pagers, scissors, and stethoscopes. Alcohols have been used to disinfect fibreoptic endoscopes but failure of this disinfectant have led to infection. Alcohol towelettes have been used for years to disinfect small surfaces such as rubber stoppers of multiple-dose medication vials or vaccine bottles. Furthermore, alcohol occasionally is used to disinfect external surfaces of equipment (e.g., stethoscopes, ventilators, manual ventilation bags), CPR manikins, ultrasound instruments or medication preparation areas. Two studies demonstrated the effectiveness of 70% isopropyl alcohol to disinfect reusable transducer heads in a controlled environment. In contrast, three bloodstream infection outbreaks have been described when alcohol was used to disinfect transducer heads in an intensive-care setting.

The documented shortcomings of alcohols on equipment are that they damage the shellac mountings of lensed instruments, tend to swell and harden rubber and certain plastic tubing after prolonged and repeated use, bleach rubber and plastic tiles and damage tonometer tips (by deterioration of the glue) after the equivalent of 1 working year of routine use. Tonometer biprisms soaked in alcohol for 4 days developed rough front surfaces that potentially could cause corneal damage; this appeared to be caused by weakening of the cementing substances used to fabricate the biprisms. Corneal opacification has been reported when tonometer tips were swabbed with alcohol immediately before measurement of intraocular pressure. Alcohols are flammable and consequently must be stored in a cool, well-ventilated area. They also evaporate rapidly, making extended exposure time difficult to achieve unless the items are immersed.

Chlorine and Chlorine Compounds

Overview. Hypochlorite's, the most widely used of the chlorine disinfectants, are available as liquid (e.g., sodium hypochlorite) or solid (e.g., calcium hypochlorite). The most prevalent chlorine products in the United States are aqueous solutions of 5.25%–6.15% sodium hypochlorite, usually called household bleach. They have a broad spectrum of antimicrobial activity, do not leave toxic residues, are unaffected by water hardness, are inexpensive and fast acting, remove dried or fixed organisms and biofilms from surfaces, and have a low incidence of serious toxicity. Sodium hypochlorite at the concentration used in household bleach (5.25-6.15%) can produce ocular irritation or oropharyngeal, oesophageal, and gastric burns. Other disadvantages of hypochlorite's include corrosiveness to metals in high concentrations (>500 ppm), inactivation by organic matter, discolouring or "bleaching" of fabrics, release of toxic chlorine gas when mixed with ammonia or acid (e.g., household cleaning agents), and relative stability. The microbicidal activity of chlorine is attributed largely to undissociated hypochlorous acid (HOCl). The dissociation of HOCI to the less microbicidal form (hypochlorite ion OCl) depends on ph. The disinfecting efficacy of chlorine decreases with an increase in ph that parallels the conversion of undissociated HOCI to OCl. A potential hazard is production of the carcinogen bis(chloromethyl) ether when hypochlorite solutions contact formaldehyde and the production of the animal carcinogen trihalomethane when hot water is hyperchlorinated. After reviewing environmental fate and ecologic data, MHRA has determined the currently registered uses of hypochlorite's will not result in unreasonable adverse effects to the environment.
Alternative compounds that release chlorine and are used in the health-care setting include demand-release chlorine dioxide, sodium dichloroisocyanurate, and chloramine-T. The advantage of these compounds over the hypochlorite's is that they retain chlorine longer and so exert a more prolonged bactericidal effect. Sodium dichloroisocyanurate tablets are stable, and for two reasons, the microbicidal activity of solutions prepared from sodium dichloroisocyanurate tablets might be greater than that of sodium hypochlorite solutions containing the same total available chlorine. First, with sodium dichloroisocyanurate, only 50% of the total available chlorine is free (HOCl and OCl), whereas the remainder is combined (monochloroisocyanurate or dichloroisocyanurate), and as free available chlorine is used up, the latter is released to restore the equilibrium. Second, solutions of sodium dichloroisocyanurate are acidic, whereas sodium hypochlorite solutions are alkaline, and the more microbicidal type of chlorine (HOCl) is believed to predominate. Chlorine dioxide-based disinfectants are prepared fresh as required by mixing the two components (base solution [citric acid with preservatives and corrosion inhibitors] and the activator solution [sodium chlorite]). In vitro suspension tests showed that solutions containing about 140 ppm chlorine dioxide achieved a reduction factor exceeding 106 of *S. aureus* in 1 minute and of *Bacillus atrophaeus* spores in 2.5 minutes in the presence of 3 g/L bovine albumin. The potential for damaging equipment requires consideration because long-term use can damage the outer plastic coat of the insertion tube. In another study, chlorine dioxide solutions at either 600 ppm or 30 ppm killed *Mycobacterium avium-intracellulare* within 60 seconds after contact but contamination by organic material significantly affected the microbicidal properties.

The microbicidal activity of a new disinfectant, "superoxidized water," has been examined. The concept of electrolyzing saline to create a disinfectant or antiseptics is appealing because the basic

materials of saline and electricity are inexpensive and the end product (i.e., water) does not damage the environment. The main products of this water are hypochlorous acid (e.g., at a concentration of about 144 mg/L) and chlorine. As with any germicide, the antimicrobial activity of superoxidized water is strongly affected by the concentration of the active ingredient (available free chlorine). One manufacturer generates the disinfectant at the point of use by passing a saline solution over coated titanium electrodes at 9 amps. The product generated has a pH of 5.0–6.5 and an oxidation-reduction potential (redox) of >950 mV. Although superoxidized water is intended to be generated fresh at the point of use, when tested under clean conditions the disinfectant was effective within 5 minutes when 48 hours old. Unfortunately, the equipment required to produce the product can be expensive because parameters such as ph, current, and redox potential must be closely monitored. The solution is nontoxic to biologic tissues. Although the United Kingdom manufacturer claims the solution is noncorrosive and nondamaging to endoscopes and processing equipment, one flexible endoscope manufacturer (Olympus Key-Med, United Kingdom) has voided the warranty on the endoscopes if superoxidized water is used to disinfect them. As with any germicide formulation, the user should check with the device manufacturer for compatibility with the germicide. Additional studies are needed to determine whether this solution could be used as an alternative to other disinfectants or antiseptics for hand washing, skin antisepsis, room cleaning, or equipment disinfection (e.g., endoscopes, dialyzers). In October 2002, the FDA cleared superoxidized water as a high-level disinfectant (FDA, personal communication, September 18, 2002).

Mode of Action. The exact mechanism by which free chlorine destroys microorganisms has not been elucidated. Inactivation by chlorine can result from a number of factors: oxidation of sulfhydryl enzymes and amino acids; ring chlorination of amino acids; loss of intracellular contents; decreased uptake of nutrients; inhibition of protein synthesis; decreased oxygen uptake; oxidation of respiratory components; decreased adenosine triphosphate production; breaks in DNA; and depressed DNA synthesis. The actual microbicidal mechanism of chlorine might involve a combination of these factors or the effect of chlorine on critical sites.

Microbicidal Activity. Low concentrations of free available chlorine (e.g., HOCl, OCl, and elemental chlorine-Cl2) have a biocidal effect on mycoplasma (25 ppm) and vegetative bacteria (<5 ppm) in seconds in the absence of an organic load. Higher concentrations (1,000 ppm) of chlorine are required to kill *M. tuberculosis* using the Association of Official Analytical Chemists (AOAC) tuberculocidal test. A concentration of 100 ppm will kill ≥99.9% of *B. atrophaeus* spores within 5 minutes and destroy mycotic agents in <1 hour. Acidified bleach and regular bleach (5,000 ppm chlorine) can inactivate 106 *Clostridium difficile* spores in ≤10 minutes 262. One study reported that 25 different viruses were inactivated in 10 minutes with 200 ppm available chlorine. Several studies have demonstrated the effectiveness of diluted sodium hypochlorite and other disinfectants to inactivate HIV. Chlorine (500 ppm) showed inhibition of *Candida* after 30 seconds of exposure. In experiments using the AOAC Use-Dilution Method, 100 ppm of free chlorine killed 106–107 *S. aureus*, *Salmonella choleraesuis*, and *P. aeruginosa* in <10 minutes. Because household bleach contains 5.25%–6.15% sodium hypochlorite, or 52,500–61,500 ppm available chlorine, a 1: 1,000 dilution provides about 53–62 ppm available chlorine, and a 1:10 dilution of household bleach provides about 5250–6150 ppm.
Data are available for chlorine dioxide that support manufacturers' bactericidal, fungicidal, sporicidal, tuberculocidal, and viricidal label claims. A chlorine dioxide generator has been shown effective for decontaminating flexible endoscopes but it is not currently FDA-cleared for use as a high-level disinfectant. Chlorine dioxide can be produced by mixing solutions, such as a solution of chlorine with a solution of sodium chlorite. In 1986, a chlorine dioxide product was voluntarily removed from the market when its use caused leakage of cellulose-based dialyzer membranes, which allowed bacteria to migrate from the dialysis fluid side of the dialyzer to the blood side.

Sodium dichloroisocyanurate at 2,500 ppm available chlorine is effective against bacteria in the presence of up to 20% plasma, compared with 10% plasma for sodium hypochlorite at 2,500 ppm. “Superoxidized water” has been tested against bacteria, mycobacteria, viruses, fungi, and spores. Freshly generated superoxidized water is rapidly effective (<2 minutes) in achieving a 5-log reduction of pathogenic microorganisms (i.e., *M. tuberculosis*, *M. chelonae*, poliovirus, HIV, multidrug-resistant *S. aureus*, *E. coli, Candida albicans*, *Enterococcus faecalis, P. aeruginosa*) in the absence of organic loading. However, the biocidal activity of this disinfectant decreased substantially in the presence of organic material (e.g., 5% horse serum). No bacteria or viruses were detected on artificially contaminated endoscopes after a 5-minute exposure to superoxidized water and HBV-DNA was not detected from any endoscope experimentally contaminated with HBV-positive mixed sera after a disinfectant exposure time of 7 minutes.

Uses. Hypochlorite’s are widely used in healthcare facilities in a variety of settings. Inorganic chlorine solution is used for disinfecting tonometer heads and for spot-disinfection of countertops and floors. A 1:10–1:100 dilution of 5.25%–6.15% sodium hypochlorite (i.e., household bleach) or a registered tuberculocidal disinfectant has been recommended for decontaminating blood spills. For small spills of blood (i.e., drops of blood) on noncritical surfaces, the area can be disinfected with a 1:100 dilution of

5.25%-6.15% sodium hypochlorite or a registered tuberculocidal disinfectant. Because hypochlorite's and other germicides are substantially inactivated in the presence of blood, large spills of blood require that the surface be cleaned before a registered disinfectant or a 1:10 (final concentration) solution of household bleach is applied. If a sharps injury is possible, the surface initially should be decontaminated, then cleaned and disinfected (1:10 final concentration). Extreme care always should be taken to prevent percutaneous injury. At least 500 ppm available chlorine for 10 minutes is recommended for decontaminating CPR training manikins. Full-strength bleach has been recommended for self-disinfection of needles and syringes used for illicit-drug injection when needle-exchange programs are not available. The difference in the recommended concentrations of bleach reflects the difficulty of cleaning the interior of needles and syringes and the use of needles and syringes for parenteral injection. Clinicians should not alter their use of chlorine on environmental surfaces on the basis of testing methodologies that do not simulate actual disinfection practices. Other uses in healthcare include as an irrigating agent in endodontic treatment and as a disinfectant for manikins, laundry, dental appliances, hydrotherapy tanks, regulated medical waste before disposal, and the water distribution system in haemodialysis centres and haemodialysis machines.
Chlorine long has been used as the disinfectant in water treatment. Hyperchlorination of a *Legionella*-contaminated hospital water system resulted in a dramatic decrease (from 30% to 1.5%) in the isolation of *L. pneumophila* from water outlets and a cessation of healthcare-associated Legionnaires' disease in an affected unit. Water disinfection with monochloramine by municipal water-treatment plants substantially reduced the risk for healthcare–associated Legionnaires disease. Chlorine dioxide also has been used to control *Legionella* in a hospital water supply. Chloramine T and hypochlorite's have been used to disinfect hydrotherapy equipment.

Hypochlorite solutions in tap water at a ph >8 stored at room temperature (23ºC) in closed, opaque plastic containers can lose up to 40%–50% of their free available chlorine level over 1 month. Thus, if a user wished to have a solution containing 500 ppm of available chlorine at day 30, he or she should prepare a solution containing 1,000 ppm of chlorine at time 0. Sodium hypochlorite solution does not decompose after 30 days when stored in a closed brown bottle.

The use of powders, composed of a mixture of a chlorine-releasing agent with highly absorbent resin, for disinfecting spills of body fluids has been evaluated by laboratory tests and hospital ward trials. The inclusion of acrylic resin particles in formulations markedly increases the volume of fluid that can be soaked up because the resin can absorb 200–300 times its own weight of fluid, depending on the fluid consistency. When experimental formulations containing 1%, 5%, and 10% available chlorine were evaluated by a standardized surface test, those containing 10% demonstrated bactericidal activity. One problem with chlorine-releasing granules is that they can generate chlorine fumes when applied to urine.

Iodophors

Overview. Iodine solutions or tinctures long have been used by health professionals primarily as antiseptics on skin or tissue. Iodophors, on the other hand, have been used both as antiseptics and disinfectants. MHRA has not cleared any liquid chemical sterilant or high-level disinfectants with iodophors as the main active ingredient. An iodophor is a combination of iodine and a solubilizing agent or carrier; the resulting complex provides a sustained-release reservoir of iodine and releases small amounts of free iodine in aqueous solution. The best-known and most widely used iodophor is povidone-iodine, a compound of polyvinylpyrrolidone with iodine. This product and other iodophors retain the germicidal efficacy of iodine but unlike iodine generally are nonstaining and relatively free of toxicity and irritancy.

Several reports that documented intrinsic microbial contamination of antiseptic formulations of povidone-iodine and poloxamer-iodine caused a reappraisal of the chemistry and use of iodophors. "Free" iodine contributes to the bactericidal activity of iodophors and dilutions of iodophors demonstrate more rapid bactericidal action than does a full-strength povidone-iodine solution. The reason for the observation that dilution increases bactericidal activity is unclear, but dilution of povidone-iodine might weaken the iodine linkage to the carrier polymer with an accompanying increase of free iodine in solution. Therefore, iodophors must be diluted according to the manufacturers' directions to achieve antimicrobial activity.

Mode of Action. Iodine can penetrate the cell wall of microorganisms quickly, and the lethal effects are believed to result from disruption of protein and nucleic acid structure and synthesis.

Microbicidal Activity. Published reports on the in vitro antimicrobial efficacy of iodophors demonstrate that iodophors are bactericidal, mycobactericidal, and viricidal but can require prolonged contact times to kill certain fungi and bacterial spores. Three brands of povidone-iodine solution have demonstrated more rapid kill (seconds to minutes) of *S. aureus* and *M. chelonae* at a 1:100 dilution than did the stock solution. The viricidal activity of 75–150 ppm available iodine was demonstrated against seven viruses. Other investigators have questioned the efficacy of iodophors against poliovirus

in the presence of organic matter and rotavirus SA-11 in distilled or tap water. Manufacturers' data demonstrate that commercial iodophors are not sporicidal, but they are tuberculocidal, fungicidal, viricidal, and bactericidal at their recommended use-dilution.

Uses. Besides their use as an antiseptic, iodophors have been used for disinfecting blood culture bottles and medical equipment, such as hydrotherapy tanks, thermometers, and endoscopes. Antiseptic iodophors are not suitable for use as hard-surface disinfectants because of concentration differences. Iodophors formulated as antiseptics contain less free iodine than do those formulated as disinfectants. Iodine or iodine-based antiseptics should not be used on silicone catheters because they can adversely affect the silicone tubing.

Ortho-phthalaldehyde (OPA)

Overview. Ortho-phthalaldehyde is a high-level disinfectant that received FDA clearance in October 1999. It contains 0.55% 1,2-benzenedicarboxaldehyde (OPA). OPA solution is a clear, pale-blue liquid with a pH of 7.5.

Mode of Action. Preliminary studies on the mode of action of OPA suggest that both OPA and glutaraldehyde interact with amino acids, proteins, and microorganisms. However, OPA is a less potent cross-linking agent. This is compensated for by the lipophilic aromatic nature of OPA that is likely to assist its uptake through the outer layers of mycobacteria and gram-negative bacteria. OPA appears to kill spores by blocking the spore germination process.

Microbicidal Activity. Studies have demonstrated excellent microbicidal activity in vitro. For example, OPA has superior mycobactericidal activity (5-log10 reduction in 5 minutes) to glutaraldehyde. The mean times required to produce a 6-log10 reduction for *M. bovis* using 0.21% OPA was 6 minutes, compared with 32 minutes using 1.5% glutaraldehyde. OPA showed good activity against the mycobacteria tested, including the glutaraldehyde-resistant strains, but 0.5% OPA was not sporicidal with 270 minutes of exposure. Increasing the ph from its unadjusted level (about 6.5) to ph 8 improved the sporicidal activity of OPA. The level of biocidal activity was directly related to the temperature. A greater than 5-log reduction of *B. atrophaeus* spores was observed in 3 hours at 35ºC, than in 24 hours at 20ºC. Also, with an exposure time $\leq$5 minutes, biocidal activity decreased with increasing serum concentration. However, efficacy did not differ when the exposure time was $\geq$10 minutes. In addition, OPA is effective (>5-log10 reduction) against a wide range of microorganisms, including glutaraldehyde-resistant mycobacteria and *B. atrophaeus* spores.

The influence of laboratory adaptation of test strains, such as *P. aeruginosa*, to 0.55% OPA has been evaluated. Resistant and multiresistant strains increased substantially in susceptibility to OPA after laboratory adaptation (log10 reduction factors increased by 0.54 and 0.91 for resistant and multiresistant strains, respectively). Other studies have found naturally occurring cells of *P. aeruginosa* were more resistant to a variety of disinfectants than were sub cultured cells.

Uses. OPA has several potential advantages over glutaraldehyde. It has excellent stability over a wide ph range (ph 3–9), is not a known irritant to the eyes and nasal passages, does not require exposure monitoring, has a barely perceptible odour, and requires no activation. OPA, like glutaraldehyde, has excellent material compatibility. A potential disadvantage of OPA is that it stains proteins grey (including unprotected skin) and thus must be handled with caution. However, skin staining would indicate improper handling that requires additional training and/or personal protective equipment (e.g., gloves, eye and mouth protection, and fluid-resistant gowns). OPA residues remaining on inadequately water-rinsed transoesophageal echo probes can stain the patient's mouth. Meticulous cleaning, using the correct OPA exposure time (e.g., 12 minutes) and copious rinsing of the probe with water should eliminate this problem. The results of one study provided a basis for a recommendation that rinsing of instruments disinfected with OPA will require at least 250 mL of water per channel to reduce the chemical residue to a level that will not compromise patient or staff safety (<1 ppm). Personal protective equipment should be worn when contaminated instruments, equipment, and chemicals are handled. In addition, equipment must be thoroughly rinsed to prevent discoloration of a patient's skin or mucous membrane.

In April 2004, the manufacturer of OPA disseminated information to users about patients who reportedly experienced an anaphylaxis-like reaction after cystoscopy where the scope had been reprocessed using OPA. Of approximately 1 million urologic procedures performed using instruments reprocessed using OPA, 24 cases (17 cases in the United States, six in Japan, one in the United Kingdom) of anaphylaxis-like reactions have been reported after repeated cystoscopy (typically after four to nine treatments). Preventive measures include removal of OPA residues by thorough rinsing and not using OPA for reprocessing urologic instrumentation used to treat patients with a history of bladder cancer (Nevine Erian, personal communication, June 4, 2004; Product Notification, Advanced

Sterilization Products, April 23, 2004).
A few OPA clinical studies are available. In a clinical-use study, OPA exposure of 100 endoscopes for 5 minutes resulted in a >5-log reduction in bacterial load. Furthermore, OPA was effective over a 14-day use cycle. Manufacturer data show that OPA will last longer in an automatic endoscope reprocessor before reaching its MEC limit (MEC after 82 cycles) than will glutaraldehyde (MEC after 40 cycles). High-pressure liquid chromatography confirmed that OPA levels are maintained above 0.3% for at least 50 cycles. OPA must be disposed in accordance with UK regulations. If OPA disposal through the sanitary sewer system is restricted, glycine (25 grams/gallon) can be used to neutralize the OPA and make it safe for disposal.

The high-level disinfectant label claims for OPA solution at 20ºC vary worldwide (e.g., 5 minutes in Europe, Asia, and Latin America; 10 minutes in Canada and Australia; and 12 minutes in the United States). These label claims differ worldwide because of differences in the test methodology and requirements for licensure. In an automated endoscope reprocessor with an MHRA cleared capability to maintain solution temperatures at 25ºC, the contact time for OPA is 5 minutes.

Peracetic Acid

Overview. Peracetic, or peroxyacetic, acid is characterized by rapid action against all microorganisms. Special advantages of peracetic acid are that it lacks harmful decomposition products (i.e., acetic acid, water, oxygen, hydrogen peroxide), enhances removal of organic material, and leaves no residue. It remains effective in the presence of organic matter and is sporicidal even at low temperatures. Peracetic acid can corrode copper, brass, bronze, plain steel, and galvanized iron but these effects can be reduced by additives and ph modifications. It is considered unstable, particularly when diluted; for example, a 1% solution loses half its strength through hydrolysis in 6 days, whereas 40% peracetic acid loses 1%–2% of its active ingredients per month.

Mode of Action. Little is known about the mechanism of action of peracetic acid, but it is believed to function similarly to other oxidizing agents—that is, it denatures proteins, disrupts the cell wall permeability, and oxidizes sulfhydryl and sulphur bonds in proteins, enzymes, and other metabolites.

Microbicidal Activity. Peracetic acid will inactivate gram-positive and gram-negative bacteria, fungi, and yeasts in ≤5 minutes at <100 ppm. In the presence of organic matter, 200–500 ppm is required. For viruses, the dosage range is wide (12–2250 ppm), with poliovirus inactivated in yeast extract in 15 minutes with 1,500–2,250 ppm. In one study, 3.5% peracetic acid was ineffective against HAV after 1-minute exposure using a carrier test. Peracetic acid (0.26%) was effective (log10 reduction factor >5) against all test strains of mycobacteria (*M. tuberculosis, M. avium-intracellulare, M. chelonae, and M. fortuitum*) within 20–30 minutes in the presence or absence of an organic load. With bacterial spores, 500–10,000 ppm (0.05%–1%) inactivates spores in 15 seconds to 30 minutes using a spore suspension test.

Uses. An automated machine using peracetic acid to chemically sterilize medical (e.g., endoscopes, arthroscopies), surgical, and dental instruments is used in the UK. As previously noted, dental handpieces should be steam sterilized. The sterilant, 35% peracetic acid, is diluted to 0.2% with filtered water at 50ºC. Simulated-use trials have demonstrated excellent microbicidal activity, and three clinical trials have demonstrated both excellent microbial killing and no clinical failures leading to infection. The high efficacy of the system was demonstrated in a comparison of the efficacies of the system with that of ethylene oxide. Only the peracetic acid system completely killed 6 log10 of *M. chelonae, E. faecalis,* and *B. atrophaeus* spores with both an organic and inorganic challenge. An investigation that compared the costs, performance, and maintenance of urologic endoscopic equipment processed by high-level disinfection (with glutaraldehyde) with those of the peracetic acid system reported no clinical differences between the two systems. However, the use of this system led to higher costs than the high-level disinfection, including costs for processing, purchasing and training, installation, and endoscope repairs. Furthermore, three clusters of infection using the peracetic acid automated endoscope reprocessor were linked to inadequately processed bronchoscopes when inappropriate channel connectors were used with the system. These clusters highlight the importance of training, proper model-specific endoscope connector systems, and quality-control procedures to ensure compliance with endoscope manufacturer recommendations and professional organization guidelines. An alternative high-level disinfectant available in the UK contains 0.35% peracetic acid. Although this product is rapidly effective against a broad range of microorganisms, it tarnishes the metal of endoscopes and is unstable, resulting in only a 24-hour use life.

Peracetic Acid and Hydrogen Peroxide

Overview. Two chemical sterilants are available that contain peracetic acid plus hydrogen peroxide (i.e., 0.08% peracetic acid plus 1.0% hydrogen peroxide [no longer marketed]; and 0.23% peracetic acid plus 7.35% hydrogen peroxide.

Microbicidal Activity. The bactericidal properties of peracetic acid and hydrogen peroxide have been demonstrated. Manufacturer data demonstrated this combination of peracetic acid and hydrogen peroxide inactivated all microorganisms except bacterial spores within 20 minutes. The 0.08% peracetic acid plus 1.0% hydrogen peroxide product effectively inactivated glutaraldehyde-resistant mycobacteria.

Uses. The combination of peracetic acid and hydrogen peroxide has been used for disinfecting haemodialyzers. The percentage of dialysis centres using a peracetic acid-hydrogen peroxide-based disinfectant for reprocessing dialyzers increased from 5% in 1983 to 56% in 1997. Olympus Key-Med does not endorse use of 0.08% peracetic acid plus 1.0% hydrogen on any Olympus endoscope because of cosmetic and functional damage and will not assume liability for chemical damage resulting from use of this product. This product is not currently available. MHRA has cleared a newer chemical sterilant with 0.23% peracetic acid and 7.35% hydrogen peroxide. After testing the 7.35% hydrogen peroxide and 0.23% peracetic acid product, Olympus concluded it was also not compatible with the company's flexible gastrointestinal endoscopes; this conclusion was based on immersion studies where the test insertion tubes had failed because of swelling and loosening of the black polymer layer of the tube.

Phenolics

Overview. Phenol has occupied a prominent place in the field of hospital disinfection since its initial use as a germicide by Lister in his pioneering work on antiseptic surgery. In the past 30 years, however, work has concentrated on the numerous phenol derivatives or phenolics and their antimicrobial properties. Phenol derivatives originate when a functional group (e.g., alkyl, phenyl, benzyl, halogen) replaces one of the hydrogen atoms on the aromatic ring. Two phenol derivatives commonly found as constituents of hospital disinfectants are *ortho*-phenyl phenol and *ortho*-benzyl-*para*-chlorophenol. The antimicrobial properties of these compounds and many other phenol derivatives are much improved over those of the parent chemical. Phenolics are absorbed by porous materials, and the residual disinfectant can irritate tissue. In 1970, depigmentation of the skin was reported to be caused by phenolic germicidal detergents containing *para*-tertiary butylphenol and *para*-tertiary amyl phenol.

Mode of Action. In high concentrations, phenol acts as a gross protoplasmic poison, penetrating and disrupting the cell wall and precipitating the cell proteins. Low concentrations of phenol and higher molecular-weight phenol derivatives cause bacterial death by inactivation of essential enzyme systems and leakage of essential metabolites from the cell wall.

Microbicidal Activity. Published reports on the antimicrobial efficacy of commonly used phenolics showed they were bactericidal, fungicidal, viricidal, and tuberculocidal. One study demonstrated little or no viricidal effect of a phenolic against coxsackie B4, echovirus 11, and poliovirus 1. Similarly, 12% *ortho*-phenyl phenol failed to inactivate any of the three hydrophilic viruses after a 10-minute exposure time, although 5% phenol was lethal for these viruses. A 0.5% dilution of a phenolic (2.8% *ortho*-phenyl phenol and 2.7% *ortho*-benzyl-*para*-chlorophenol) inactivated HIV and a 2% solution of a phenolic (15% ortho-phenyl phenol and 6.3% para-tertiary-amylphenol) inactivated all but one of 11 fungi tested.

Manufacturers' data using the standardized AOAC methods demonstrate that commercial phenolics are not sporicidal but are tuberculocidal, fungicidal, viricidal, and bactericidal at their recommended use-dilution. Attempts to substantiate the bactericidal label claims of phenolics using the AOAC Use-Dilution Method occasionally have failed. However, results from these same studies have varied dramatically among laboratories testing identical products.

Uses. Many phenolic germicides are registered as disinfectants for use on environmental surfaces (e.g., bedside tables, bedrails, and laboratory surfaces) and noncritical medical devices. Phenolics are not cleared as high-level disinfectants for use with semi critical items but could be used to preclean or decontaminate critical and semi critical devices before terminal sterilization or high- level disinfection. The use of phenolics in nurseries has been questioned because of hyperbilirubinemia in infants placed in bassinets where phenolic detergents were used. In addition, bilirubin levels were reported to increase in phenolic-exposed infants, compared with nonphenolic-exposed infants, when the phenolic was prepared according to the manufacturers' recommended dilution. If phenolics are used to clean nursery floors, they must be diluted as recommended on the product label. Phenolics (and other disinfectants) should not be used to clean infant bassinets and incubators while occupied. If phenolics are used to terminally clean infant bassinets and incubators, the surfaces should be rinsed thoroughly with water and dried before reuse of infant bassinets and incubators.

Quaternary Ammonium Compounds

Overview. The quaternary ammonium compounds are widely used as disinfectants. These compounds can be adhered to surfaces through hydrolysis or electrolysis. This gives them a persistent potential, allowing them to remain active on surfaces for days, months or years. Removal from the surface or skin is less difficult with electrolysis bonded Si Quats than Si Quats bonded through hydrolysis, due to the more fragile covalent bond formed with the surface or skin cell. Unique qualities for all Si Quats is that they do not leach or lose efficacy over time.

Healthcare Associated infections have not been reported from contaminated quaternary ammonium compounds used to disinfect patient-care supplies or equipment, such as cystoscopes or cardiac catheters. The quaternaries are good cleaning agents, but high-water hardness and materials such as cotton and gauze pads can make early versions of them less microbicidal because of insoluble precipitates or cotton and gauze pads absorb the active ingredients, respectively. One study showed a significant decline (~40%–50% lower at 1 hour) in the concentration of early generation quaternaries released when cotton rags or cellulose-based wipers were used in the open-bucket system, compared with the nonwoven spun lace wipers in the closed-bucket system**.** As with several other disinfectants (e.g., phenolics, iodophors) gram-negative bacteria can survive or grow in the early versions of these (Generation 1 – 3) compounds.

Chemically, the quaternaries are organically substituted ammonium compounds in which the nitrogen atom has a valence of 5, four of the substituent radicals (R1-R4) are alkyl or heterocyclic radicals of a given size or chain length, and the fifth (X-) is a halide, sulphate, or similar radical. Each compound exhibits its own antimicrobial characteristics, hence the search for one compound with outstanding antimicrobial properties. Some of the chemical names of quaternary ammonium compounds used in healthcare are alkyl dimethyl benzyl ammonium chloride, alkyl didecyl dimethyl ammonium chloride, and dialkyl dimethyl ammonium chloride. The newer quaternary ammonium compounds (i.e., fourth generation), referred to as twin-chain or dialkyl quaternaries (e.g. didecyl dimethyl ammonium bromide and dioctyl dimethyl ammonium bromide), purportedly remain active in hard water and are tolerant of anionic residues.

A few case reports have documented occupational asthma as a result of exposure to benzalkonium chloride. Fifth generation compounds are a combination of multiple Quats or Si Quats as seen in the product 3TSP in Q Shield, are able to covalently bond to fabrics, skin and surfaces through hydrolysis. By combining multiple Quats or Si Quats in compound it is possible to produce final solutions that are active against all gram positive and gram-negative organisms, as well as enveloped and non-enveloped viruses at log 5 or more in 5 mins. This chemical reaction results in a long-term antimicrobial coating on any surface.

Mode of Action. The bactericidal action of the quaternaries has been attributed to the inactivation of energy-producing enzymes, denaturation of essential cell proteins, and disruption of the cell membrane. Evidence exists that supports these and other possibilities.

Microbicidal Activity. Results from manufacturers' data sheets and from published scientific literature indicate that the quaternaries sold as hospital disinfectants are generally fungicidal, bactericidal, and viricidal against lipophilic (enveloped) viruses. Earlier versions are not sporicidal and generally not tuberculocidal or viricidal against hydrophilic (nonenveloped) viruses. Quaternary ammonium compounds (as well as 70% isopropyl alcohol, phenolic, and a chlorine-containing wipe [80 ppm]) effectively (>95%) remove and/or inactivate contaminants (i.e., multidrug-resistant *S. aureus*, vancomycin-resistant *Enterococcus*, *P. aeruginosa*) from computer keyboards with a 5-second application time. No functional damage or cosmetic changes occurred to the computer keyboards after 300 applications of the disinfectants.

Attempts to reproduce the manufacturers' bactericidal and tuberculocidal claims using the AOAC tests with a limited number of quaternary ammonium compounds have occasionally failed probably due to issues in respect to “wet testing” or dry testing”. Quats and Si Quats are most effective when dry. However, test results have varied extensively among laboratories testing identical products, and no account was taken of the 1st to 5th generation of products tested. 5th generation products have been shown to not only have better antimicrobial activity, with no reduction in efficacy over time, but also to adhere to surfaces better and are much more difficult to remove.

Uses. The quaternaries commonly are used in ordinary environmental sanitation of critical and noncritical surfaces, such as floors, furniture, and walls. Registered quaternary ammonium compounds are also appropriate to use for disinfecting medical equipment that contacts intact skin (e.g., blood pressure cuffs), food preparation surfaces. To date they have not been registered for use in Medical device class 2 or 3 and as such should not be used on implantable devices.

MISCELLANEOUS INACTIVATING AGENTS

Other Germicides

Several compounds have antimicrobial activity but for various reasons have not been incorporated into the armamentarium of health-care disinfectants. These include mercurials, sodium hydroxide, β-propiolactone, chlorhexidine gluconate, cetrimide-chlorhexidine, glycols (triethylene and propylene), and the Tego disinfectants. Two authoritative references examine these agents in detail.
A per oxygen-containing formulation had marked bactericidal action when used as a 1% weight/volume solution and viricidal activity at 3%, but did not have mycobactericidal activity at concentrations of 2.3% and 4% and exposure times ranging from 30 to 120 minutes. It also required 20 hours to kill *B. atrophaeus* spores. A powder-based per oxygen compound for disinfecting contaminated spill was strongly and rapidly bactericidal.

In preliminary studies, Nano emulsions (composed of detergents and lipids in water) showed activity against vegetative bacteria, enveloped viruses and *Candida*. This product represents a potential agent for use as a topical biocidal agent.

New disinfectants that require further evaluation include gluco protamin, tertiary amines, and a light-activated antimicrobial coating. Several other new disinfection technologies might have potential applications in the healthcare setting.

Metals as Microbicides

Comprehensive reviews of antisepsis, disinfection, and anti-infective chemotherapy barely mention the antimicrobial activity of heavy metals. Nevertheless, the anti-infective activity of some heavy metals has been known since antiquity. Heavy metals such as silver have been used for prophylaxis of conjunctivitis of the new born, topical therapy for burn wounds, and bonding to indwelling catheters, and the use of heavy metals as antiseptics or disinfectants is again being explored. Inactivation of bacteria on stainless steel surfaces by zeolite ceramic coatings containing silver and zinc ions has also been demonstrated.

Metals such as silver, iron, and copper could be used for environmental control, disinfection of water, or reusable medical devices or incorporated into medical devices (e.g., intravascular catheters), however recent research may point towards antibiotic resistant strains also being resistant to metals. A comparative evaluation of six disinfectant formulations for residual antimicrobial activity demonstrated that only the silver disinfectant demonstrated significant residual activity against *S. aureus* and *P. aeruginosa*. Preliminary data suggest metals are effective against a wide variety of microorganisms. Clinical uses of other heavy metals include copper-8-quinolinolate as a fungicide against *Aspergillus*, copper-silver ionization for *Legionella* disinfection, organic mercurials as an antiseptic (e.g., mercurochrome) and preservative/disinfectant (e.g., thimerosal [currently being removed from vaccines]) in pharmaceuticals and cosmetics.

Ultraviolet Radiation (UV)

The wavelength of UV radiation ranges from 328 nm to 210 nm (3280 A to 2100 A). Its maximum bactericidal effect occurs at 240–280 nm. Mercury vapour lamps emit more than 90% of their radiation at 253.7 nm, which is near the maximum microbicidal activity. Inactivation of microorganisms results from destruction of nucleic acid through induction of thymine dimers. UV radiation has been employed in the disinfection of drinking water, air, titanium implants, and contact lenses. Bacteria and viruses are more easily killed by UV light than are bacterial spores. UV radiation has several potential applications, but unfortunately its germicidal effectiveness and use is influenced by organic matter; wavelength; type of suspension; temperature; type of microorganism; and UV intensity, which is affected by distance and dirty tubes. The application of UV radiation in the health-care environment (i.e., operating rooms, isolation rooms, and biologic safety cabinets) is limited to destruction of airborne organisms or inactivation of microorganisms on surfaces. The effect of UV radiation on postoperative wound infections was investigated in a double-blind, randomized study in five university medical centres. After following 14,854 patients over a 2-year period, the investigators reported the overall wound infection rate was unaffected by UV radiation, although postoperative infection in the “refined clean” surgical procedures decreased significantly (3.8%–2.9%) 780. No data support the use of UV lamps in isolation rooms, and this practice has caused at least one epidemic of UV-induced skin erythema and keratoconjunctivitis in hospital patients and visitors.

Pasteurisation

Pasteurization is not a sterilization process; its purpose is to destroy all pathogenic microorganisms. However, pasteurization does not destroy bacterial spores. The time-temperature relation for hot-water pasteurization is generally ~70 ºC (158oF) for 30 minutes. The water temperature and time should be monitored as part of a quality-assurance program. Pasteurization of respiratory therapy and anaesthesia equipment is a recognized alternative to chemical disinfection. The efficacy of this

process has been tested using an inoculum that the authors believed might simulate contamination by an infected patient. Use of a large inoculum (107) of *P. aeruginosa* or *Acinetobacter calcoaceticus* in sets of respiratory tubing before processing demonstrated that machine-assisted chemical processing was more efficient than machine-assisted pasteurization with a disinfection failure rate of 6% and 83%, respectively. Other investigators found hot water disinfection to be effective (inactivation factor >5 log10) against multiple bacteria, including multidrug-resistant bacteria, for disinfecting reusable anaesthesia or respiratory therapy equipment.

Annex D

Information on detection of viruses on surfaces and skin.

In case of a viral outbreak of either a known pathogen (Norovirus, enterovirus) or a novel virus (SARS, SARS – CoV-2), it may be necessary to test surfaces and skin of staff to determine if sanitisers and disinfectants are effective against the particular pathogen. It is possible to adapt the methodology to test high risk surfaces in healthcare facilities. The Following test methodologies should be used.

The Kemp-Hirschman test for anti-viral efficacy of skin sanitisers on skin.

I. Principle of test procedure

The number of test organisms released from the surface of artificially contaminated pig skin (as a laboratory surrogate of human hands) is assessed before and after the hand sanitizer is applied. The ratio of the two resulting values is called the reduction factor. It represents a measure of the anti-viral activity of the hand sanitizer product tested. Tests should be performed in a clean air cabinet of H14 or greater filtration level. Laboratories undertaking the tests should be aware of the minimum standards of protection level required for the virus to be tested.

II. Experimental procedure:

1) Pre values

A single piece of pig skin or "vitro skin" at least 4cm x 4cm is washed for 1 minute in soft soap to remove natural commensal organisms and dried thoroughly with a clean paper towel. 2 x 1 cm squares are marked in the centre of the piece of pig skin. A sterile dry Dacron swab is rolled over each area to determine if there are any viral units present prior to deliberate contamination. The skin should be handled using sterile gloves and it should remain inside the cabinet until testing is complete. Nothing else should be allowed to come into contact with the skin.

2) Preparation

Each 1 cm square is then contaminated with a minimum of 10^4 viral units in 1 ml of fluid suspension using a sterile pipette. The area is allowed to dry for 5 mins.

3) Hand sanitizer application procedure

The manufacturer's recommended amount of the test sanitizer is applied onto the two marked areas and rubbed vigorously for 30s using a sterile gauze swab. This comprises five strokes backwards and forwards, plus rotational rubbing. Repeat with a further recommended dose to give a total rubbing time of 60s. Allow 3 mins drying time.

4) Post values

Immediately after the 3 min drying time another sterile Dacron swab is used to collect any remaining viable viral particles. Both samples are then neutralized, serially diluted and virus titrated in 96 well tissue culture plates to determine the tissue culture infectious $dose_{50}$ ($TCID_{50}$) of surviving viral particles. $TCID_{50}$ is determined by method of Kärber[1].

This procedure is repeated for as many time points as required. The pig skin must kept under the cabinet and not allowed to touch anything between tests.

When testing the pig skin is completed, it should be discarded in the appropriate waste bin/ receptacle, as per the labs hazardous materials or I.D protocols.

5) Calculation of anti-viral activity

The total number of live viral units recovered from the samples is averaged for the tested pig skin areas. The differences between the individual combined log pre values and the log post values establish a log reduction factor.

6) Pass/ Fail.

As there is no standard value for this laboratory test, therefore, the acceptable mean log reduction factor for the test virus must be decided by the laboratory investigator.

For example, Pass/fail may be determined by the related risk associated with the minimum number of viral units required to cause illness in a normal healthy host dependant on the virus tested. An example of this may be Norovirus, which can require ingestion of as few as 10 viable viral units to cause illness. It would therefore require a minimum of log 4 reduction at each time point to be considered to have reduced a 10^4 solution below dangerous levels.

The Kemp-Hirschman test for anti-viral efficacy of disinfectants on surfaces

I. Principle of test procedure

The number of test organisms released from the surface of artificially contaminated TC-6 well plates is assessed before and after the disinfectant is applied. The ratio of the two resulting values is called the reduction factor. It represents a measure of the anti-viral activity of the disinfectant product tested. Tests should be performed in a clean air cabinet of H14 or greater filtration level. Laboratories undertaking the tests should be aware of the minimum standards of protection level required for the virus to be tested.

The following test methodology is used for disinfectants that are active when dry.

II. Experimental procedure:

1)

Using a standard TC-6 well plate. A Sterile dry Dacron swab is rolled over each area to determine if there are any viral units present prior to deliberate contamination. The TC-6 plate should be handled using sterile gloves and it should remain inside the cabinet until testing is complete. Nothing else should be allowed to come into contact with the well plate.

2) Preparation Hand sanitizer application procedure

Using a pipette spread 100 µl of each product on to the bottom of the wells (leaving 3 wells as blank controls). Leave for 30 mins or until dry at room temperature.

50 µl of the manufacturer's recommended concentration of the test disinfectant is applied into each of the 3 wells and allow 3 mins to dry.

3) Application of contaminate to skin

Each well is then contaminated with a minimum of 10^4 viral units in 50 µl of fluid suspension using a sterile pipette. The area is allowed to dry for a further 5 mins.

4) Post values

Immediately after the 5 min drying time another sterile Dacron swab is used to collect any remaining viable viral particles from all well plates. Both samples are then neutralised, serially diluted and virus titrated in 96 well tissue culture plates to determine the tissue culture infectious $dose_{50}$ ($TCID_{50}$) of surviving viral particles. $TCID_{50}$ is determined by method of Kärber[1]. Polymerase Chain Reaction (PCR) may also be used if available.

This viral collection procedure is repeated for as many time points as required or until the controls no longer show a viable viral load. The well plate must kept under the cabinet and not allowed to touch anything between tests.

When testing the well plate is complete, it should be discarded in the appropriate waste bin/ receptacle, as per the labs hazardous materials or I.D protocols.

5) Calculation of anti-viral activity

The total number of live viral units recovered from the samples is averaged for the three tested wells. The differences between the individual combined log pre values and the log post values establish a log reduction factor.

6) Pass/ Fail.

As there is no standard value for this laboratory test, therefore, the acceptable mean log reduction factor for the test virus must be decided by the laboratory investigator.

For example, Pass/fail may be determined by the related risk associated with the minimum number of viral units required to cause illness in a normal healthy host dependant on the virus tested. An example of this may be Norovirus, which can require ingestion of as few as 10 viable viral units to cause illness. It would therefore require a minimum of log 4 reduction at each time point to be considered to have reduced a 10^4 solution below dangerous levels.