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Clothing for protection against infectious agents — Test method for resistance to penetration by biologically contaminated aerosols

Vêtements de protection contre les agents infectieux - Méthode d'essai de la résistance à la pénétration par des aérosols contaminés biologiquement

ICS 13.340.10

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

ISO 22611 was prepared by Technical Committee ISO/TC 94, *Personal safety -- Protective clothing and equipment*, Subcommittee SC 13, *Protective clothing*.

Introduction

The protection of persons from contact with biological infectious agents often requires clothing that provides a barrier against the various means for exposure to infectious agents. Infectious agents include different types of microorganisms such as bacteria, viruses, and fungi. Infectious agents can be carried by both liquids (contaminated fluids, liquid imbibed solids, aerosols) and solids (dust particles). These potential routes of exposure led to the investigation and development of four test methods considered representative for the following major risk situations:

— contact with contaminated liquids (ISO 16603 and 16604);

— contact with embedded contaminated solids (ISO 22610);

— exposure to liquid aerosols (ISO 22611);

— exposure to solid particles (ISO 22612).

Barrier materials are available in a variety of forms, including woven and knitted fabrics, nonwovens, plastic sheets, coated materials, and microporous laminates. Often these materials may be tested in different ways to demonstrate barrier performance. For this reason, a project was supported by the European Commission to develop and to validate test methods for the assessment of the barrier properties of materials against biological hazards, encountered both in occupational safety and in health care situations. The test method in this International Standard, and related test methods are the result of this project (known as the BioBar Project). These test methods are intended to provide the basis of a classification system, which would offer, in conjunction with a risk analysis, a tool to decision makers and specification writers for basing their product specifications on.

This specific test is intended for measuring the resistance of protective clothing materials to penetration by biologically contaminated aerosols. The test method addresses only the performance of materials or certain material constructions (e.g., seams) used in protective clothing and not the design, overall construction and components, or interfaces of garments or other factors that may affect the protection offered by the protective clothing.

It is emphasized that the test does not necessarily simulate conditions that clothing materials are like to be exposed to in practice. The use of test data should therefore be restricted to broad comparative assessment of such material according to their bacterial penetration resistance characteristics.

Testing prior to degradation by physical, chemical, and thermal stresses, which could negatively impact the performance of the protective barrier, could lead to a false sense of security. Tests that assess the impact of storage conditions and shelf life on the penetration resistance for disposable products, and the effects of laundering and sterilization on the penetration resistance for reusable products should also be considered. The integrity of the protective barrier can also be compromised during use by such effects as flexing and abrasion. [1] It is also possible that pre-wetting by contaminating materials such as alcohol and perspiration also compromises the integrity of the protective barrier. If these conditions are of concern, the performance of protective clothing materials should be assessed following an appropriate preconditioning technique representative of the expected conditions of use..

Clothing for protection against infectious agents — Test method for resistance to penetration by biologically contaminated aerosols

1 Scope

This International Standard describes a laboratory test method for measuring the penetration resistance of protective clothing materials to a contaminated aerosol. This test method exposes material specimens to a specific bacterium suspended in an aerosol at a specified set of conditions.

This test method is not always effective in testing protective clothing materials having thick, inner liners which readily absorb the challenge liquid.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3801, *Textiles - Woven fabrics - Determination of mass per unit length and mass per unit area*

ISO 5084, *Textiles - Determination of thickness of woven and knitted fabrics (other than textile floor coverings)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply

3.1
blood-borne pathogen
infectious secreted or excreted bacterium, virus, or other disease inducing microbe carried in blood or other body fluids

3.2
body fluid
any liquid produced (secreted or excreted) by the body

NOTE For the purpose of this International Standard, body fluids include those liquids potentially infected with blood-borne pathogens, including, but not limited to, blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid and peritoneal fluid, amniotic fluid, saliva in dental procedures, and any body fluid that is visibly contaminated with blood, and all body fluids in situation where it is difficult or impossible to differentiate between body fluids.

3.3
infectious agent
micro organisms, including those that have been genetically modified, cell culture and human endoparasites, which may be able to provoke any infection, allergy, or toxicity. [2]

NOTE infectious agents include blood borne pathogens that may be carried in blood or body fluids.

3.4
penetration
transfer of a bacteria through closures, porous materials, seams and holes or other imperfections in a protective clothing material

NOTE In this International Standard, the bacterium is a suspension of *S. aureus*.

3.5
protective clothing material
any material or combination of materials used in an item of clothing for the purpose of isolating parts of the wearer's body from contact with a potential hazard, e.g. infectious biological agents.

NOTE The primary intended use of this clothing should be to protect the wearer; protection of people and goods in the environment of the wearer can be possible as a secondary non-essential effect.

4 Principle

A solution, containing micro organisms is sprayed into a box. Underpressure is used to collect the droplets of the contaminated aerosol on two membrane filters. One of these filters is shielded by the protective clothing material.

The ratio of bacteria found on the shielded and the unshielded filter is used to assess the barrier properties of the protective clothing material.

5 Equipment and reagents

5.1 Test chamber

The test chamber consists of a cubic box (ca. 280 mm side) made from a transparent synthetic material, e.g. 8 mm thick polymethylmethacrylate. A schematic representation and indicative dimensions are shown in Figure 1.

NOTE There is no outlet to the box as the diameter of the atomizer and the spray entrance to the box ensure that a tight fit does not occur, thus preventing a pressure build-up in the box.

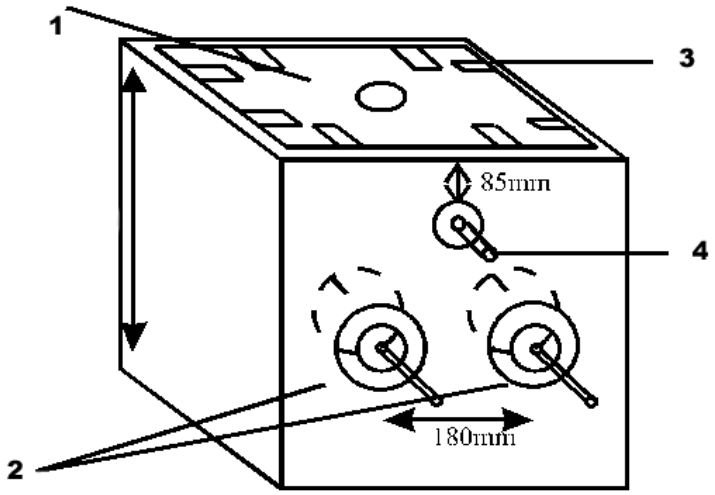

Figure 1 — Schematic representation of the test apparatus

Key

1 lid
2 stainless steel sample holders (threaded to fit delrin filter)
3 right angle fixing toggle latch (zinc plated steel)
4 stainless steel inlet tube to fit collison atomiser (inner diameter 10 mm, outer diameter 14,5 mm)

5.2 Other equipment

Following items of equipment are needed for this test method:

5.2.1 Collison atomiser (see Figure 3);

5.2.2 controllable vacuum pump, with a maximum air flow rate of 34 l/min, and an obtainable vacuum of < 8 mbar. A vacuum controller allows the vacuum to be set between 1000 mbar and 8 mbar, and, once the vacuum has been achieved, the percentage rise in pressure before the pump activates again can also be specified;

5.2.3 sample filter assembly (see Figure 2) that employs a Delrin open filter, a support grid and silicone washers to prevent leakage;

5.2.4 Thoma bacterial counting chamber;

5.2.5 stopwatch, or electronic timer;

5.2.6 analytical balance, capable of weighing accurately to 0,01 g;

5.2.7 air pressure source, capable of providing air at (138 ± 10) kPa;

5.2.8 incubator, capable of maintaining a temperature of (37 ± 1) °C, containing an orbital shaker;

5.2.9 water bath, capable of maintaining a temperature of (45 ± 1) °C;

5.2.10 autoclave, capable of maintaining a temperature of (121 ± 2) °C;

5.2.11 thickness gauge, suitable for measuring specimen thickness to the nearest 0,02 mm.