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Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood

Vêtements de protection contre les contacts avec le sang et les fluides corporels — Détermination de la résistance des matériaux des vêtements de protection à la pénétration par le sang et les fluides corporels — Méthode d'essai utilisant un sang synthétique

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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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 16603 was prepared by Technical Committee ISO/TC 94, *Personal safety — Protective clothing and equipment*, Subcommittee SC 13, *Protective clothing*. It is based on ASTM F1670-98.

Introduction

Workers, primarily those in the health care profession, involved in treating and caring for individuals injured or sick, can be exposed to biological liquids capable of transmitting disease. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. This is especially true of blood-borne viruses which cause hepatitis [hepatitis B virus (HBV) and hepatitis C virus (HCV)] and acquired immune deficiency syndrome (AIDS) [human immunodeficiency viruses (HIV)]. Since engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential of direct skin contact through the use of protective clothing.

This International Standard is concerned with protective clothing and related protective devices designed to protect against the penetration of blood or body fluids. This test method addresses only the performance of materials or certain material constructions (e.g. seams) used in protective clothing. This test method does not address the design, overall construction and components, or interfaces of garments or other factors which can affect the overall protection offered by the protective clothing.

It is emphasized that the test does not necessarily simulate conditions to which clothing materials are likely to be exposed in practice. The use of test data should therefore be restricted to broad comparative assessment of such material according to their synthetic blood 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 which 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 be considered. The integrity of the protective barrier can also be compromised during use by such effects as flexing and abrasion or pre-wetting by contaminating materials such as alcohol and perspiration. If these conditions are of concern, the performance of protective clothing materials for synthetic blood penetration should be evaluated following an appropriate preconditioning technique representative of the expected conditions of use.

Medical protective clothing materials are intended to be a barrier to blood, body fluids, and other potentially infectious materials. Many factors can effect the wetting and penetration characteristics of body fluids, such as surface tension, viscosity and polarity of the fluid, as well as the structure and relative hydrophilicity or, hydrophobicity of the materials. The surface tension range for blood and body fluids (excluding saliva) is approximately 0,042 N/m to 0,060 N/m.[2] In order to help simulate the wetting characteristics of blood and body fluids, the surface tension of the synthetic blood is adjusted to approximate the lower end of this surface tension range, i.e. (0,042 ± 0,002) N/m.

Part of this method for exposing the protective clothing material specimens with synthetic blood involves pressurization of the test cell to 14,0 kPa (in Procedures A and B). This hydrostatic pressure has been documented to produce test results that correlate with a human factors validation.[3] Some studies, however, suggest that mechanical pressures exceeding 345 kPa can occur during actual use.[4] [5] Therefore, it is important to understand that this test method does not simulate all the physical stresses and pressures that are exerted on protective clothing in use. This test method can also be used as a screening test to determine which time and pressure protocol is appropriate for evaluating the viral-resistance-properties of protective apparel with a more sophisticated barrier test method as described in ISO 16604. Procedures C and D use a stepped pressurization approach with pressures up to 20,0 kPa. These procedures simulate a range of possible procedures for ranking material performance.

Given the variety of health care settings, activities, and the potential for exposure to blood or body fluids, the barrier requirements for protective clothing materials will change with the application. The choice of an appropriate test method depends on the specific application of protective clothing and its intended use. A risk assessment should be performed to determine the level of risk for determining the appropriate test method.[1]

Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood

1 Scope

This International Standard describes a laboratory test method for measuring the penetration resistance of clothing materials to blood and body fluids. This test method uses a synthetic blood in continuous contact with the material specimen at specified set of conditions using the ISO 13994 test apparatus.

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

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 textiles and textile products*

ISO 13994, *Clothing for protection against liquid chemicals — Determination of the resistance of protective clothing materials to penetration by liquids under pressure*

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
blood-resistant material
material that restricts blood and body fluid penetration

3.3
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 situations where it is difficult or impossible to differentiate between body fluids.

3.4
body fluid simulant
liquid which is used to act as a model for human body liquids

NOTE In this International Standard, synthetic blood is used as a body fluid simulant.

3.5
penetration
flow of a liquid through closures, porous materials, seams and holes or other imperfections in a protective clothing material on a non-molecular level

NOTE In this International Standard, the penetration liquid is synthetic blood.

3.6
protective clothing
item of clothing that is specifically designed and constructed for the intended purpose of isolating all or part of the body from a potential hazard; or, isolating the external environment from contamination by the wearer of the clothing

3.7
synthetic blood
mixture of an amaranth dye, surfactant, thickening agent, inorganic salts, and distilled water having a surface tension and viscosity representative of blood and some other body fluids

NOTE The synthetic blood in this International Standard does not simulate all of the characteristics of real blood or body fluids, for example, colour, coagulation and content of cell matter.

4 Principle

The resistance of a protective clothing material to penetration by blood and body fluids is determined by subjecting the material to synthetic blood as a body fluid simulant for a specified time and pressure sequence and observing if visible penetration of the liquid occurs.

In the penetration test apparatus, the clothing material acts as a partition separating the body fluid simulant from the viewing side of the test cell.

Any evidence of synthetic blood penetration constitutes failure. Results are reported as “pass/fail”.

5 Synthetic blood

The synthetic blood shall meet the following requirements:

— surface tension: (0,042 ± 0,002) N/m

— pH: (7,3 ± 0,1)

— viscosity: (2,7 ± 0,3) mPa·s

— conductivity: (12,0 ± 1,2) mS/cm

NOTE A suitable method of preparation can be found in Annex A.

6 Apparatus

6.1 Penetration test cell, as specified in ISO 13994, to restrain the specimen during contact with the pressurized test synthetic blood.

In the test cell, the specimen acts as a partition separating synthetic blood from the view side of the test cell. It consists of a cell body that is fastened to a cell support. The cell body has a capacity of approximately 60 ml for synthetic blood. A flange cover, with an open area to allow visual observation and a transparent cover are included. The cell body has a top port for filling and a drain valve for draining the penetration test cell. Other items, such as a fitting to allow attachment of the air line to the top port in the cell body, gaskets, and the retaining screen are also required. A diagram of the penetration test cell and apparatus are shown in Figures 1 and 2. An alternative air pressure controller is listed in Annex B.

6.2 Retaining screen, comprising a smooth finish plastic or metal square mesh screen to support extensible or elastomeric materials, meeting the following specifications:

a) open area of > 50 %;

b) deflection of the test specimen is limited to $\leqslant 5{,}0$ mm.

6.3 Air pressure source, capable of providing air at $\left(20{,}0^{+2}_{0}\right)$ kPa.

6.4 Stopwatch, or electronic timer.

6.5 Balance, with a precision of at least 0,01 g.

6.6 Vessel, or graduated cylinder or vessel, with a precision of 1 ml.

6.7 Thickness gauge, suitable for measuring thickness to the nearest 0,02 mm.

7 Test specimens

7.1 Selection

7.1.1 Select specimens from single material samples or individual protective clothing items, consisting of either a single layer or a composite of multiple layers that is representative of an actual protective clothing construction with all layers arranged in proper order.

If in the design of an item of protective clothing, different materials or thicknesses of material are specified at different locations, select specimens from each location.

If in the design of an item of protective clothing, seams are claimed to offer the same protection as the base materials, test additional specimens containing such seams.

Cut each material specimen into squares with a minimum dimension of 70 mm. A 75 mm square is preferred.

Test three specimens taken at random from each material, composite, area (in the case of heterogeneous design), or other condition.

If this procedure is used for quality control or to support broad product claims concerning the blood-resistant properties of materials used in protective clothing, proper statistical design and analysis of larger data sets than those specified in this test method should be performed. Examples of acceptable sampling plans are found in references such as ISO 2859-1[9].

7.1.2 It is possible that protective clothing materials incorporating an impervious layer between two fabric layers are sensitive to false positive failures by wicking at the edges. Seal the edges of the test specimens to