National Standard of the People's Republic of China

GB 19082—XXXX to replace GB 19082-2003

Technical requirements for single-use protective clothing for medical use

(Draft standard for approval)

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Preface

Within this Standard, Sections 4.2, 4.3, 4.6, 4.8 and 4.10 are commendatory while the others are compulsory.

This Standard is to replace the GB 19082-2003, *Technical Requirements for Single-use Protective Clothing for Medical Use*. The major changes made to GB 19082-2003 are as follows:

- Revision to the application scope of the Standard
- Update and revision of the normative references
- Edit of the terminologies and definitions
- Addition of requirements and test methods for static decay performance
- Revision of the technical requirements for skin irritation with reference to GB/T 16886.10-2005 and clarification of the test methods
- Replacement of the test method for ethylene oxide residual quantity, from the original method in GB 15980-1995 to the gas chromatography mediation method in GB/T 14233.1-1998
- Revision of the normative appendix A into the corresponding test methods in ISO 16603:2004, to replace the original reference method ASTM F1670:1998
- Addition of background information

Appendix A of this standard is a normative appendix.

This Standard was proposed by the State Food & Drug Administration.

This Standard is placed under the centralised management of the Clinical Test Laboratory and the In-Vitro Diagnostic Test Systems Technical Committee for Standardization. This Standard is drafted by Beijing Medical Instrument Examination Centre. Persons who were primarily involved in the preparation of this Standard include Yue Weihua, Su Jian, Zhang Xiaoli and Yuan Xiuhong. The versions of the original Standards to be replaced by this Standard are as follows:
Technical Requirements for Single-use Protective Clothing for Medical Use

1 Scope

This Standard specifies the requirements, test methods, markings, instructions, packaging and storage of single-use protective clothing for medical use.

This Standard is applicable to single-use protective clothing (hereafter referred as Protective Clothing for simplicity) with obstruction or protection functions against potential infectious substances such as patient blood, body fluids, secretions and particulate matter in air, with which the medical staff may come into contact as part of their work.

2 Normative References

The provisions of the following documents, through reference in this text, constitute provisions of this Standard. All dated references are subject to edition, and earlier versions (not including corrections) are not applicable to this Standard. However, parties to agreements based on this Standard are encouraged to investigate the possibility of applying the most recent version of such documents. The latest versions of all undated references are applicable to this Standard.

GB/T 191 Graphic Labels for Packing, Storage and Transportation
GB/T 3923.1-1997 Textiles - Tensile properties of fabrics - Part 1: Determination of breaking force and elongation at breaking force - Strip method
GB/T 4744-1997 Textile fabrics - Determination of resistance to water penetration - Hydrostatic pressure test
GB/T 4745-1997 Textile fabrics - Determination of resistance to surface wetting - Spray test
GB/T 5455-1997 Textile fabrics - Determination of resistance to water penetration - Hydrostatic pressure test
GB/T 5549-1990 Surface active agents - Determination of surface tension by drawing up liquid films
GB/T 12703-1991 Electrostatic test methods for textiles
GB/T 12704-1991 Fabrics - Determination of vapour transmission rate--Dish method.
GB/T 14233.1-1998 Infusion, transfusion, injection equipment for medical use - Part 1: Chemical analysis methods
GB/T 14233.2-2005 Infusion, transfusion, injection equipment for medical use - Part 2: Biological test methods
GB 15979-2002 Hygienic standard for disposable sanitary products
GB/T 16886.10-2005 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 16603:2004 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
IST 40.2 (1) Standard Test Method for Electrostatic Decay of Nonwoven Fabrics
Pharmacopoeia of the People's Republic of China, 2005
3 Terms and Definitions

The following terms and definitions apply to this specification.

3.1 Particulate matter
Granular materials suspended in air in their solid state, liquid state or mixed solid-liquid state, such as animalcules, dust, smoke or fog.

3.2 Filtering efficiency
Percentage of granular materials filtered out in air by the protective clothing under specified conditions.

3.3 Synthetic blood
A kind of synthetic liquid for test purposes which is equivalent to blood in terms of surface tension and viscosity.

3.4 Protective clothing critical area
Locations on the left and right foreparts, left and right arms and back part of the protective clothing.

3.5 Electrostatic decay
Capability of the material to eliminate the charges induced on the material surfaces when grounded.

3.6 Decay time
Time taken by induced charge to decay to 10% of the original level, in seconds.

4 Requirements

4.1 Appearance
4.1.1 The protective clothing shall be dry, clean and free of mildew stain, and have no defects such as conglutination, slits or holes in its surface.

4.1.2 The connecting parts of the protective clothing may be made using a process of stitching, gluing or heat-sealing. For a stitching process, the eyeholes shall be sealed, with a needle pitch of 8-14 every 3cm. The stitching shall be even and straight, with no skipped stitches allowed. For a gluing or heat-sealing process, the processed parts shall be smooth and tight, with no bubbles allowed.

4.1.3 For protective clothing with slide fasteners, the slide fasteners shall be hidden, and the zipper heads shall be self-lockable.

4.2 Structure
4.2.1 Protective clothing consists of a hooded frock and trousers, in either coverall or two-piece suit form, as shown in Figures 1 and 2.

![Figure 1 Coverall protective clothing](image1)

![Figure 2 Two-piece suit protective clothing](image2)

4.2.2 The protective clothing shall be well structured for easy wear and removal as well as excellent tightness.

4.2.3 The sleeve and ankle openings shall be elasticated. The hood facial opening and the waist shall be elasticated, with a draw cord or hasps.

4.3 Size designation

The sizes of the protective clothing shall be 160, 165, 170, 175, 180 and 185, with specifications detailed in Tables 1 and 2.

<table>
<thead>
<tr>
<th>Table 1 Specifications for coverall type sizes</th>
<th>Units: cm</th>
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<tr>
<td>Size</td>
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<td>160</td>
<td>165</td>
</tr>
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<td>165</td>
<td>169</td>
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<td>170</td>
<td>173</td>
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</table>
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<table>
<thead>
<tr>
<th>Size</th>
<th>Frock length</th>
<th>Chest circumference</th>
<th>Pants length</th>
<th>Waistline</th>
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<tbody>
<tr>
<td>160</td>
<td>76</td>
<td>120</td>
<td>105</td>
<td>100±105</td>
</tr>
<tr>
<td>165</td>
<td>78</td>
<td>125</td>
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<td>80</td>
<td>130</td>
<td>111</td>
<td>110±115</td>
</tr>
<tr>
<td>175</td>
<td>82</td>
<td>135</td>
<td>114</td>
<td>115±120</td>
</tr>
<tr>
<td>180</td>
<td>84</td>
<td>140</td>
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<td>185</td>
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<tr>
<td>Deviation</td>
<td>±2</td>
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</table>

**Table 2 Specifications for two-piece suit sizes**

<table>
<thead>
<tr>
<th>Size</th>
<th>Frock length</th>
<th>Chest circumference</th>
<th>Pants length</th>
<th>Waistline</th>
</tr>
</thead>
<tbody>
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<td>105</td>
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</tr>
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<td>165</td>
<td>78</td>
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<td>108</td>
<td>105±110</td>
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<td>180</td>
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<td>185</td>
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<tr>
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<tr>
<td>Deviation</td>
<td>±2</td>
<td>±2</td>
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</tr>
</tbody>
</table>

4.4 **Liquid obstruction function**

4.4.1 Permeability to water

The hydrostatic pressure for critical parts of the protective clothing shall not be below 1.67kPa (17cmH2O).

4.4.2 Moisture infiltration level

The wetting infiltrating level of the protective clothing shall not be less than 2500g/(m²·d).

4.4.3 Penetration of synthetic blood

The penetration of synthetic blood into the protective clothing shall not be below Level 2 requirements listed in Table 3.

**Table 3 Levels of penetration of synthetic blood**

<table>
<thead>
<tr>
<th>Level</th>
<th>Pressure, kPa</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>20</td>
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<tr>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>3</td>
<td>3.5</td>
</tr>
<tr>
<td>2</td>
<td>1.75</td>
</tr>
<tr>
<td>1</td>
<td>0*</td>
</tr>
</tbody>
</table>

*a* Indicates that the pressure on the material is only the pressure applied by the synthetic blood in the basin.

4.4.4 Surface moisture resistance

The spray rating for the outside surface of the protective clothing shall not be below Level 3 requirements.

4.5 **Breaking strength**

The breaking strength of the critical parts of the protective clothing shall be no less than 45N.

4.6 **Crack elongation rate**

The crack elongation rate in the critical parts of the protective clothing shall be no less than 15%.

4.7 **Filtering efficiency**

The filtering efficiency for non-oily particles at the critical parts and seams of the protective clothing shall be no less than 70%.

4.8 **Flame retardant properties**

Protective clothing with flame retardant features shall meet the following requirements:

4.8.1 The length of damage shall not exceed 200mm.

4.8.2 The burn time shall not exceed 15s.
4.8.3 The smouldering time shall not exceed 10s.

4.9 Antistatic properties
The static charge on the protective clothing shall not exceed 0.6μC/piece.

4.10 Electrostatic decay performance
The electrostatic decay time of the protective clothing shall not exceed 0.5s.

4.11 Skin irritation
The primary irritation scoring shall not exceed 1.

4.12 Microbiological specifications
4.12.1 The protective clothing shall meet the microbiological specifications defined in GB 15979-2002, as shown in Table 4.
4.12.2 Protective clothing marked with Sterilised or Asepsis text or graphics shall be free of bacteria.

<table>
<thead>
<tr>
<th>Total numbers of bacteria colony</th>
<th>Coli group</th>
<th>Bacillus aeruginosus</th>
<th>Staphylococcus aureus</th>
<th>Streptococcus hemolyticus</th>
<th>Total numbers of epiphyte colony</th>
</tr>
</thead>
<tbody>
<tr>
<td>cfu/g</td>
<td>No finding</td>
<td>No finding</td>
<td>No finding</td>
<td>No finding</td>
<td>≤100</td>
</tr>
</tbody>
</table>

4.13 Ethylene oxide residual quantities
For protective clothing sterilised with ethylene oxide, the quantity of residual ethylene oxide shall not exceed 10μg/g.

5 Test Method

5.1 Appearance
5.1.1 Visual check; requirements in 4.1.1 shall be met.
5.1.2 Visual check and measurement of needle pitch with a general gauge; the requirements in 4.1.2 shall be met.
5.1.3 The slider fasteners of each piece of protective clothing shall be operated five times, with a total of three pieces tested; the requirements in 4.1.3 shall be met for all of the pieces.

5.2 Structure
Visual check; the requirements in 4.2 shall be met.

5.3 Size designation
A sample of each size shall be measured using general measuring tools, with a total of 3 pieces tested; the requirements in 4.3 shall be met for all.

5.4 Liquid obstruction function
5.4.1 Permeability to water
The critical parts of the protective clothing shall be tested at the hydrostatic pressure specified in GB/T 4744-1997; the requirements in 4.4.1 shall be met.
5.4.2 Moisture infiltration level
The materials of protective clothing shall be tested in accordance with method A - moisture adsorption defined in GB/T 12704-1991; the requirements in 4.4.2 shall be met.
5.4.3 Penetration against synthetic blood
The materials of the protective clothing shall be tested in accordance with the method described in Appendix A; the requirements in 4.4.3 shall be met.

5.4.4 Surface moisture resistance
The outside surfaces of the protective clothing materials shall be tested with the spray test defined in GB/T 4745-1997; the requirements in 4.4.4 shall be met.

5.5 Breaking strength
The critical parts of the protective clothing shall be tested with the strip method specified in GB/T 3923.1-1997; the requirements in 4.5 shall be met.

5.6 Crack elongation rate
The critical parts of the protective clothing shall be tested with the strip method specified in GB/T 3923.1-1997; the requirements in 4.6 shall be met.

5.7 Filtering efficiency
At least three samples of protective clothing shall be tested; the requirements in 4.7 shall be met for all. Perform the test using a sodium chloride or similar solid aerosol particle count mean diameter (CMD): 0.075μm±0.020μm; particle distribution geometric standard deviation ≤1.86; concentration ≤200mg/m³ under relative humidity 30%±10% and temperature 25°C±5°C. The air flow rate shall be set as 15 L/min±2L/min; air flow through a sectional area of 100cm².

5.8 Flame retardant properties
The flame retardant properties of the protective clothing shall be tested with the vertical method specified in GB/T 5455-1997; the requirements in 4.8.1 4.8.3 shall be met.

5.9 Antistatic properties
The test shall be performed in accordance with the method specified in Section 7.2 of GB/T 12703-1991; the requirements in 4.9 shall be met.

5.10 Electrostatic decay performance
The test shall be performed in accordance with the method specified in IST 40.2-01.

5.10.1 Test environment
Before the test, the sample shall be placed for 24h under relative humidity 50%±3% and temperature 23°C±1°C. The test shall also be performed under the same conditions.

5.10.2 Sampling
A sample shall be taken from each of the critical parts of the protective clothing, 89mmX(152±6)mm in size. During the sampling process, latex or cotton gloves should be worn to prevent pollution on the sample surfaces.

5.10.3 Test
The samples under test should be mounted onto an accurate meter that can generate at least 5,000V positive and negative voltages. A 5000V voltage should be applied to the sample and the charge decay time then measured. The requirements in 4.10 shall be met for all five samples.

5.11 Skin irritation
5.11.1 Leaching media
0.9% sodium chloride injection

5.11.2 Preparation of leaching solution
Under aseptic conditions, two samples sized 2.5cm×2.5cm should be cut from the protective clothing. The leaching solution should be added at a ratio of 1mL/cm², and leach for 72h at 37°C. A leaching solution containing no sample under test should be using the same method to act as a negative contrast solution.

5.11.3 Test
The test should be performed in accordance with the method specified in Section 6.3 of GB/T 16886.10-2005; the requirements in 4.11 shall be met.

5.12 Microbiological specifications
5.12.1 The protective clothing should be tested in accordance with the method specified in Appendix B of GB 15979-2002; the requirements in 4.12.1 shall be met.
5.12.2 The asepsis test should be performed in accordance with the method specified in Section 3 of GB/T 14233.2-2005; the requirements in 4.12.2 shall be met.

5.13 Ethylene oxide residual quantity
The test should be performed in accordance with the method specified in Section 9, Part 3 of GB/T 14233.1-1998; the requirements in 4.13 shall be met.

6 Signs and Instructions

6.1 Labels
6.1.1 The minimum packaging of the protective clothing shall be marked with the following labels, which shall be clear and readable. If the packaging is transparent, the following labels shall be legible through the packaging:
   a) Product name
   b) Name and address of the manufacturer or supplier
   c) Product model and specifications
   d) Applicable standard
   e) Registration number of the product
   f) Sterilisation method specified (for sterilised product)
   g) “For single use” or equivalent indication
   h) Production date
   i) Storage and valid period
   j) “Instructions before use” or equivalent indication

6.1.2 The protective clothing packaging shall bear at least the following signs:
   a) Product name
   b) Name and address of the manufacturer or supplier
   c) Product model and specifications
   d) Applicable standard
   e) Registration number of the product
   f) Packaging quantity
6.2 Instructions

6.2.1 A Chinese version of the instructions is required.
6.2.2 The instructions shall be clear and understandable. Illustrations are allowed.
6.2.3 The instructions shall include at least the following contents:
   a) Product name
   b) Name, address and contact of the manufacturer
   c) Usage and limit of the product
   d) Applicable standard
   e) Registration number of the product
   f) Flame retardant description
   g) Inspection before use
   h) Table of size specifications
   i) Use method and recommended use period
   j) Storage and validity period
   k) Meanings of the signs/marks used
   l) Precautions

7 Packaging and storage

7.1 Packaging

7.1.1 The pictorial markings for the handling of packages on the outer package shall meet the requirements in GB/T 191.
7.1.2 The protective clothing packaging shall be able to prevent mechanical damage and pollution prior to use.
7.1.3 The innermost packaging for the protective clothing shall contain a copy of the instructions and inspection certificate of the product.

7.2 Storage
As per the Instructions.
Appendix A
(Normative appendix)
Test method for penetration of synthetic blood

A.1 Scope
This test aims to determine the ability of protective clothing to resist penetration by synthetic blood under different test pressures.

A.2 Method
The test is performed on the materials of the protective clothing using synthetic blood under continuous pressures, and the penetration of synthetic blood into the material is then checked visually.

A.3 Instruments
The following instruments are required for the test:

a) Penetration basin shown in Figure A.1 and test instruments shown in Figure A.2, stainless steel materials preferred
b) A square-form retaining screen with the following specifications:
   » Hole rate >50
   » Inflection ≤5mm under pressure 14 kPa
c) Compressed air source that can produce 14 kPa±1 kPa pressure
d) Stopwatch, with accuracy ±1s
e) Analytical balance, with accuracy ±0.01g
f) Pincers that can produce torque 13.5N·m
g) Surface tension meter

A.4 Synthetic blood
A.4.1 Elements
Prepare 1L synthetic blood by following the preparation method specified in Appendix A of ISO 16603:2004,

- Sodium carboxymethylcellulose (such as CMC- Sigma 9004-32-4, medium viscosity) 2g
- Polyethylene glycol (20) Emulsifier S-20 (such as Tween 20 [Fluka 9377]) 0.04g
- Sodium chloride (analytically pure) 2.4g
- Amaranth dye (such as Sigma 915-67-3) 1.0g
- Monobasic potassium phosphate (KH₂PO₄) 1.2g
- Disodium hydrogen phosphate (Na₂HPO₄) 4.3g
- Distilled water or de-ionised water Added to 1L

1) 2-Methyl-4-isothiazolin-3-one hydrochloride (MIT) (0.5g/L) can be added into the synthetic blood to prolong the storage life of the solution.
2) Sigma 9004-32-4, Fluka 9377, Sigma 915-67-3 and Fluka 9377 are only examples of appropriate commercial products. They are provided only for informational purposes and not intended to indicate the ISO's recognition thereof.

A.4.2 Preparation method
Dissolve the sodium carboxymethylcellulose into 0.5L water and stir for 60 minutes with a magnetic stirrer. Weigh out the proper amount of Tween 20 in a small flask. Add water and mix evenly.
Add the Tween 20 solution into the solution of sodium carboxymethylcellulose. Wash the flask with distilled water several times and add the above solution into it. Dissolve NaCl into the solution. Dissolve KH₂PO₄ and Na₂HPO₄ into the solution.
Add the MIT (if applicable) and the amaranth dye. Dilute the solution with water to nearly 1000 ml.
Use phosphate to adjust the pH value of the synthetic blood to 7.3±0.1 and make up to volume 1000 ml.
Measure the surface tension of the synthetic blood according to GB/T 5549-1990; the results should fall within 0.042 N/m±0.002N/m.

A.5 Preparation of the test sample
Cut off three pieces of 75mmX75mm parts randomly from each piece of the protective clothing as the test samples. For testing of composite materials or multilayer materials, the edges shall be sealed properly. An area with a diameter above 57mm shall be reserved for test purposes.

A.6  Test steps
A.6.1  Assemble the test basin according to the illustration in Figure A.1:
   a)  Place the test basin flat on the test bed. Face the normal outer surface of the protective clothing material to the basin and then place it into the basin.
   b)  Place a washer, a retaining screen and another washer on the test basin. Mount the flange cover and transparent cover and screw to tighten them.
   c)  Mount the penetration test basin vertically into the test instruments, with the drain valve facing downward.
   d)  Screw the bolt of the penetration test basin slowly to 13.5N-m.
   e)  Close the drain valve.
A.6.2  Use a funnel or injector and add 50~55 ml synthetic blood slowly from the top inlet into the penetration test basin. Observe for 5 minutes. If the synthetic blood penetrates the test sample, stop the test.
A.6.3  Otherwise, connect the air pipe of the test instrument as shown in Figure A.2. Input air of a determined pressure through the top inlet into the penetration test basin. Increase the pressure gradually to 1.75kPa. Maintain the pressure for 5 minutes and observe the visible surface of the sample for any liquid penetration. If synthetic blood penetrates the test sample, stop the test. The synthetic blood penetration of the sample is now Level 1.
A.6.4  If no synthetic blood penetration is observed, increase the pressure slowly to 3.5kPa and maintain the pressure for 5 minutes. Observe the visible surface of the sample for any liquid penetration. If synthetic blood penetrates the test sample, stop the test. The synthetic blood penetration of the sample is now Level 2.
A.6.5  If no synthetic blood penetration is observed, increase the pressure slowly to 7kPa and maintain the pressure for 5 minutes. Observe the visible surface of the sample for any liquid penetration. If synthetic blood penetrates the test sample, stop the test. The synthetic blood penetration of the sample is now Level 3.
A.6.6  If no synthetic blood penetration is observed, increase the pressure slowly to 14kPa and maintain the pressure for 5 minutes. Observe the visible surface of the sample for any liquid penetration. If synthetic blood penetrates the test sample, stop the test. The synthetic blood penetration of the sample is now Level 4.
A.6.7  If no synthetic blood penetration is observed, increase the pressure slowly to 20kPa and maintain the pressure for 5 minutes. Observe the visible surface of the sample for any liquid penetration. If synthetic blood penetrates the test sample, stop the test. The synthetic blood penetration of the sample is Level 5. If no penetration of synthetic blood is observed, the synthetic blood penetration of the sample is Level 6.
A.6.8  At the end of the test, close the air source, and turn the valve of the penetration test basin to the ventilation position.
A.6.9  Open the drain valve to drain the synthetic blood. Rinse the test basin with an appropriate detergent to remove bloodstains. Remove the sample and washers from the test basin. Clean the outer surfaces of the test basin and all other parts that have come into contact with the synthetic blood.
1 - Transparent cover
2 - Flange cover
3 - Washer
4 - Retaining screen
5 - Washer
6 - Test sample
7 - Top inlet
8 - Drainage valve
9 - PTFE washer material
10 - Test basin
11 - Test basin bracket

Figure A.1 Structure of the test basin
1 - Pincers
2 - Pressure regulator
3 - Air pressure gauge
4 - Supply valve
5 - To the test basin
6 - Test basin
7 - Drain valve

Figure A.2  Schematic diagram of the test instrument
References

2. EN 149-2001 Respiratory protective devices: Filtering half-masks to protect against particles: Requirements, testing, marking
3. NIOSH 42 CFR 84 Regulation Tests and Requirements for Certification and Approval of Respiratory Protective Devices
4. prEN 14126 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
6. AAMI TIR11:2005 Selection and use of protective apparel and surgical drapes in health care facilities