UNICEF Industry Consultation on Personal Protective Equipment needs in Ebola response
Technical specifications, standards and norms

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We need to protect against:
EVD Virus-Infectious liquid

**Liquid**: amount, disease progress

- 5-10 L of fluid lost daily at a critical stage of their illness. consumed 4.5 L of ORS daily

**Liquid-tight**

**Blood (RBCs)**:

- RBCs 10,000 nm in diameter

**Resist blood penetration**

**Virus**:

- Ebola: diameter approx. 80 nm, length can be quite variable

**Tested against Viral penetration**

other bloodborne virus HIV: 80 ng in diameter
Biohazard elements

- ØX174 25 - 27 nm
- HBV 42 - 47 nm
- Adenovirus 70-90 nm
- HIV 80 to 110 nm
- Filoviruses 80 nm
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Context of use
- Used for Isolation high risk areas within ETU/ Holding Center

Short specifications
- Disposable, single-use liquid-penetration resistant, biohazard-protective coverall with hood, for use in EVD patient-isolation units suitable for stringent infection prevention and control practices and tested against viral penetration. Protective seams providing barrier equal to fabric.

Standards
- CE 89/686/EEC, Category III: Chemical protective coverall, Type 3B / Type 4B comply with EN14605:2005 +A1:2009 (or equivalent) marketing approval certificate
- Compliance with the EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)
Full Body protection: Coveralls (2)

Context of use
- Used for Isolation high risk areas within ETU/ Holding Center

Short specifications
- Coverall: Disposable, single-use, liquid-penetration resistant, biohazard protective coverall, co-packed with an apron/gown for use in EVD patient-isolation units suitable for infection prevention and control practices.
- Apron: Gown designed with sleeves, for front protection with complete closure from the back and wrap around-waist ties. Elasticated cuffs. Shin length and below-Knee height.
Both Coverall and Apron are made of fabric that is infective agent tested against viral penetration at minimum 1.75kPa

Standards
- Confirmation of compliance with the EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)
Full Body protection:

**Specific issues:**

Limited global capacity for immediate supply
limited supplier base
Relatively Long lead-time (in terms of emergency response)
Partial Body protection: Hood

Context of use
- Used for Isolation high risk areas within ETU/ Holding Center / CCC

Short specifications
- Disposable, single-use, liquid-penetration resistant, biohazard-protective Hood with or without surgical mask Type IIR, for use in EVD patient-isolation units suitable for infection prevention and control practices and tested against microbial penetration. Cape hood covering full neck and parts of shoulders

Standards
- CE 89/686/EEC marketing approval certificate
- Mask: conform to EN 14683:2005 for type IIR mask (or equivalent standard)
- Compliance with the EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard) (Preferred)
Partial Body protection: Protective Gown/Apron

Context of use
- Used for Isolation high risk areas within ETU/ Holding Center / CCC

Short specifications
- Disposable, single-use, liquid-penetration resistant, biohazard-partial-body protective gown/apron with sleeves for use in EVD patient-isolation units and CCC suitable for infection prevention and control practices and tested against viral penetration.

Standards
- CE 89/686/EEC, Category III Type 3PB or 4PB or 6PB comply with EN14605:2005+A1:2009 or EN 13034:2005 + A1:2009 (or equivalent) marketing approval certificate
- Comply with EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)
Partial body protection: Surgical gowns (1)
AAMI Level 4, fully reinforced

Context of use
- Higher risk areas such as CCCs, clinical care – wet areas

Short specifications
- Surgical gown with long sleeves and a waist tie that binds at side or back
- Non-woven material (SMS, SMMS, etc.), reinforced material throughout
gown that passes ASTM F1671
- Size approx. 150 cm (W) x 130 cm (L)
- Single use, disposable

Standards
- Meets requirements for ANSI/AAMI PB70 (US) classification Level 4
  → Only AAMI Level 4 gowns pass test for resistance to penetration by a blood-borne viral
  pathogen (ASTM F1671)
- May also have CE 93/42: EN 13795 (EU)
- Or equivalent
Partial body protection: Surgical gowns (2)
Standard/high performance EN 13795

**Context of use**
- Lower risk areas such as CCCs, clinical care - dry area, other lower risk areas in HC facilities

**Short specifications**
- Surgical gown with long sleeves and a waist tie that binds at side or back
- Non-woven material (SMS, SMMS, etc.), reinforced in critical areas if HP gown
- Size approx. 150 cm (W) x 130 cm (L)
- Single use, disposable

**Standards**
- CE 93/42: EN 13795 standard performance (SP) or high performance (HP)
- Or equivalent
Partial body protection: Surgical gowns

**Specific issues:** PPE for Ebola is not the intended use of the product

**Supply challenges**
- Limited global capacity for immediate supply
- Relatively long lead-time for quantities requested

**Tests and standards not equivalent across stringent national regulatory authorities**

- EN 13795 (EU) does not include test for resistance to penetration by a blood-borne viral pathogen
- Only AAMI Level 4 gowns pass test for resistance to penetration by a blood-borne viral pathogen (ASTM F1671) in the gown’s critical zones

**Product limitations**
- Definition of ‘critical area’ not as relevant, not adequate for high-risk
- Sleeves require taping
- Sterility – not necessary
Partial body protection: Aprons (disposable)

**Context**
- ETUs and CCCs over full or partial body protection

**Short specifications**
- Single use, sleeveless apron with adjustable back- and neck-band
- Seamless, liquid proof and stain resistant
- Material: durable environmentally friendly plastic, polyethylene (PE)
- Size, approx.: 85 x 130 cm (w x l)
- Thickness: approx. 50 µ

**Standards**
- None yet identified

**Specific issues**
- Size and thickness
- Sourcing
Partial body protection: Aprons (reusable)

**Context**
- Heavy duty (cleaning activities)

**Short specifications**
- Reusable sleeveless protective apron with adjustable back- and neck-band
- Seamless liquid proof and stain resistant
- Material: durable environmentally friendly plastic
- Size, approx.: 120 x 145 cm (w x l)
- Thickness, approx.: 300 µ

**Standards**
- None yet identified

**Specific issues**
- Size, sourcing
Thank you

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