Preferred Product Characteristics for Personal Protective Equipment for the Health Worker on the Frontline Responding to Viral Hemorrhagic Fevers in Tropical Climates

World Health Organization

Preferred Product Characteristics for Personal Protective Equipment for the Health Worker on the Frontline Responding to Viral Hemorrhagic Fevers* in Tropical Climates

*Ebola, Marburg and other hemorrhagic fevers that share similar human-to-human transmission characteristics

Preferred product characteristics for personal protective equipment for the health worker on the frontline responding to viral hemorrhagic fevers in tropical climates
ISBN 978-92-4-151415-6

This document was produced jointly by:
Medical Devices, Innovation Access and Use Unit
Essential Medicines and Health Products Department
Access to Medicines, Vaccines and Pharmaceuticals
and
Experts Networks-Clinical Management
Infectious Hazards Management Department
Health Emergencies

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Printed by the WHO Document Production Services, Geneva, Switzerland

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Acknowledgements

This document is the product of technical information and guidance received from subject matter experts, field health workers, administrators and regulatory bodies. Many individuals shared knowledge and expertise, through workshops, conferences and solicited comments. Input was also received from the open consultation period. The WHO Advisory Committee for Innovative Personal Protective Equipment (AC) consisted of four sub groups. AC members, their affiliations and committee subgroup, as well as the WHO staff who provided critical leadership and expertise, are listed in Appendix 1.

WHO thanks the government of Japan and the U.S. Agency for International Development for their contribution to this effort.

Acronyms

AAMI	Association of the Advancement of Medical Instrumentation
AATCC	American Association of Textile Chemists and Colorists
AC	WHO Advisory Committees for Innovative Personal Protective Equipment
AC-WG	WG AC working group
ANSI	American National Standards Institute
ASTM	American Society of Testing Materials International
BS EN	European Standard that is published in United Kingdom
DIN EN	European Standard is published in Germany by German Standards Institute
EBOV	Ebola virus
EN	European Standard-European Norm
ETU	Ebola treatment unit
EVD	Ebola virus disease
HW	Health worker
HW-F	Health worker at the frontline
IPC	Infection prevention and control
ISO	International Organization for Standardization
MSF	Médecins sans Frontières (Doctors without Borders)
N95	Respirator, blocks at least 95% of 0.3 micron test particles
NFPA	National Fire Protection Association
OSH	Occupational safety and health
PAPR	Powered air purifying respirator
PPE	Personal protective equipment
PPC	Preferred product characteristics
R&D	Research and development
RSV	Respiratory Syncytial Virus
SARS	Severe Acute Respiratory Syndrome
TPP	Target product profile
WHO	World Health Organization

Definitions

Health worker at the frontline (HW-F): Clinical health workers tending to Ebola virus disease (EVD) patients and non-clinical staff performing heavy duty services such as transporting symptomatic patients, care-setting cleaning, environment decontamination and removal of deceased for respectful disposition. Together, these workers are at the highest risk of exposure and thus are defined as health workers at the frontline (HW-F). Health worker (HW) is a more generalized term for those personnel who also will use PPE but are not necessarily in direct patient contact or performing high risk activities.

Ebola treatment unit (ETU)s: Treatment units set up for EVD patients, with sections divided into increasing degree of illness from triage to suspect (holding) to confirmed zones (treatment).

Low and middle income countries: As defined using the World Bank country classification.

Preferred product characteristics (PPC): A PPC profile describes the preferred criteria for a product or suite of products that meet the intended unmet public health need in a priority disease area and is structured to drive innovation towards meeting the need. PPC addresses research and development (R&D) therefore its parameters are not static and will be reviewed and updated periodically to meet the public health demand.

Standard precautions: Set of infection control practices used to prevent transmission of diseases and should be applied in a constant basis with all patients, regardless of diagnosis- in all practices and at all times. Standard precautions include: hand hygiene, use of PPE based on risk assessment, prevention of needle-stick or sharps injuries, safe waste management, cleaning, disinfection and sterilization; where applicable, of the equipment, linen used and the patient care environment. This is to protect from contact with blood, body fluids, non-intact skin (including rashes), and mucous membranes.

Target product profile (TPP): May contain similar parameters as PPC and includes a set of desired minimally acceptable technical specifications in addition to preferred criteria. TPP is a technical document detailing specific requirements.

Technical specifications: Refers to the existing local, national, regional and international sets of standards, testing methods and quality control systems for which all individual PPE elements are reviewed or tested before they can be made available in their respective markets. The manufacturers and normative entities take the responsibility to ensure product performance and reliability. Detailed explanations are in Figure 1 in Appendix 3.

Tropical climate: Tropical zones dominated by abundant rainfall with a temperature range of >200 C-380 C and >75-95% humidity. This includes tropical rainforest, monsoon and savanna climate zones (i.e. “hot, humid” conditions).

Work period: Little is known about the ideal amount of time a HW-F can wear PPE and safely provide care for a patient or carry out heavy duty work. This period includes the time needed for donning and doffing PPE. The literature indicates that given existing knowledge about disease transmission, an appropriate period may be between 40 minutes and 4 hours. Beyond this time, the HW-F may become subject to discomfort and be more likely to misuse PPE, thereby increasing the chance of disease transmission. For this reason, we define a work period as being between 40 minutes and 4 hours, subject to IPC protocol.

Intended target

Key explanations and concepts are presented here to guide the reader when viewing this document.

Intended target for this PPC document: Although this document is addressing the unmet public health need for protective PPE for the HW-F when responding to Ebola virus (EBOV) infections, the principles of this guidance may also be applied to other filovirus infections such as Marburg virus. The document may also have applications for other diseases that share human-to-human transmission characteristics which pose a similar risk to the health worker (see explanation in *Definitions*) (Table 1).

Table 1. The target use populations, setting and intended use of this PPC document

Target population, setting and use	
Primary target use population	Heath workers on the frontline providing patient care and heavy duty services in basic facilities under hot, humid conditions.
Secondary target use population	Health workers who will use PPE for protection from high risk exposure in advanced equipped medical facilities.
Target use setting	Health facilities and community environments where health workers on the frontline are at risk of exposure to virus shedding by patients or dead bodies.
Intended use	To serve as a guide for health workers, industry, engineers, innovators, medical and scientific researchers and others, the opportunity to re-think, energize and innovate for a better PPE system to protect the health worker.

Use of evidence from Severe Acute Respiratory Syndrome (SARS) and Respiratory Syncytial Virus (RSV) studies: This document focuses on evidence research from EBOV publications combined with generalized information from SARS and RSV infections studies. SARS and RSV can be transmitted through mucous membrane contacts via airborne or aerosolized virus. EVD is primarily transmitted through contact of infectious virus with mucous membranes. EBOV has not been proven to be transmitted by aerosol, despite animal studies designed to study this route[1,2].

Technical specifications for PPE are comprised of a complex set of product characteristics, standards and methods with most of the specifications applying to an individual PPE element or category (Figure 1, Appendix 3), which are used for procurement. Many of the existing standards apply to conditions relevant to the characteristics described in this document but none specifically addresses a *full PPE ensemble*-that is when different components are utilized together. Because there is scant technical data to support PPE protection effectiveness, little or no precise measurements or specifications on PPE can be presented so this topic should be targeted for research and clarity going forward.

1. Background

The 2014-16 epidemic of EVD in West Africa was the largest on record with over 28,500 cases and at least 11,000 deaths. Included among the many unique and tragic elements of the epidemic was the high number of infected HWs (over 900 cases and 500 deaths). The outbreak control relies on applying a package of interventions, namely case management, infection prevention and control (IPC) practices, surveillance and contact tracing, a good laboratory service, safe and dignified burials and social mobilisation"[3]

A WHO report[4] on HWs EBOV infections in Guinea, Liberia and Sierra Leone from January 2014 through March 2015 concluded that, depending on their occupation in the health service, HWs were at 21 to 32 times greater risk of contracting EVD. The causal relationship between the risks and the situations in which HWs were exposed to EBOV was difficult to identify. Some HWs may have been infected outside the healthcare setting where PPE may not have been used. However, in the settings where transmission likely occurred, inappropriate IPC practices were frequently observed. Multiple IPC failures were attributed to deficiencies in administrative, engineering and environmental controls as well as inappropriate use of, or lack of, PPE.

Complicated steps and possible inappropriate donning and doffing of PPE were considered sources of EVOD infection given the stressful, hot, humid working conditions in the West Africa tropical setting. Early in the epidemic, a variety of PPE products were distributed in West Africa which added to the uncertainty of what combination and sequence for donning and doffing would be safe. The PPE, as used by the HW-F, had limited breathability in very hot weather conditions, gave limited field of vision, did not allow for adequate communication among the workers or patients and interfered with culturally-respectful interactions in the communities. The EVD epidemic exacted a heavy price on the national health work force in the affected countries, severely weakening health systems already crippled by an on-going shortage of health workers and poor services. One of the many lessons learnt from the EVD epidemic was that protecting the HW is critical when working in an under resourced setting[5]. Investing in, and supporting, the HW's well-being is vital to ensuring better quality of health care services, a more resilient health system, and a safer and more comfortable PPE for HW-F is such an investment[6].

PPE is part of a comprehensive strategy to be used with other safety measures. HW infections can be prevented through practicing standard precautions and adopting IPC and OHS strategies to minimize risk of exposure. A reliable supply system that provides access to required materials is necessary. The escalating crisis and the unprecedented scale of the Ebola epidemic meant that there was a global shortage of available PPE with suppliers being over-stretched and unable to provide PPE of any sort. Early in the outbreak, except for a few organizations like Médecins Sans Frontières that prescribed strict PPE requirements, no consistent PPE standards were applied and there was no guidance on quality control of the PPE being used. To provide recommendations on product consistency and standards for each of the individual PPE elements (gloves, masks, eye protection, gowns, overalls, boots, aprons, etc.), the WHO published a rapid advice guideline for PPE with technical specifications in October 2014[7]. This guidance did not, however, include any standards for validating the protective effect of a *full combined* PPE ensemble for safety, usability and comfort. Even during the height of the outbreak, little was known about how to best use PPE to provide the safest coverage to the HW-F. Instead, HW at the frontline largely relied on anecdotal knowledge when using PPE. The critical point even now is that no standard exists to validate the combined protective effect of PPE elements with different styles and pieces.

The widespread impact of the EVD epidemic also highlighted the lack of evidence-based knowledge about the effectiveness of PPE and the challenges of standardizing PPE to protect the HW-F. Without a concerted effort to define effective PPE in settings where there is high risk of exposure, the HW-F will continue to face the same challenges: Ebola, Marburg and other highly contagious and life threatening diseases will continue to cause outbreaks in endemic areas and could emerge in unexpected regions.

PPE elements and their desired protective effects are at a point where innovative design, new fabrics, adoption of engineering approaches and harmonized practices can lead to a safer, more comfortable and culturally appropriate protective system commensurate with the risk. Such a system will allow for standardized procedures with the requisite training that will remove confusion, reduce heat stress and improve protection where it is needed most, so that the HW-F can provide effective care for patients, carry out high risk activities and remain safe.

2. Scope

The scope of this PPC document is to serve as a guide to address the unmet public health need for a PPE system that protects the HW-F in tropical climates while caring for patients and providing heavy duty essential health services. The characteristics described in this guidance are targeted for PPE used in health clinics, hospitals and communities in low resource settings where there is lack of advanced environmental controls and equipment. The purpose is to ensure harmonization in PPE design and its use to avoid confusion and exacerbating the risk of infections in HW-F. The principles of this PPC document can also be considered in risk reduction strategies in other healthcare settings.

3. Aim

This PPC document aims to provide guidance for industry, health workers, engineers, innovators, medical and scientific researchers and others, the opportunity to re-think, energize and innovate for a better PPE system for the HW-F responding to EBOV and Marburg virus outbreaks in tropical climates. WHO believes that integrating the PPC in a coordinated product or suite of products will result in a PPE system that will increase safety and comfort and address the public health need to protect the HW-F.

4. Objectives

- To provide a review and summary of current evidence on protective effects of PPE and applicable standards, and to identify the knowledge gaps related to safety, usability, comfort and disposal of PPE.
- To stimulate stakeholders to innovate, collaborate, design, engineer and plan for a PPE system that will increase safety and reduce the heat stress. This can be modified from current PPE already on the market or be a part of a re-imagined PPE system.
- To serve as a guide to develop a PPE system whose parts are intentionally designed with consideration of ergonomics and human factors to fit and allow for harmonized procedures on donning and doffing PPE processes. This should result in a standardized system that will remove confusion and mistakes at the user level.

5. Methodology

PPE and its effectiveness was the subject of a consultation in September 2014 which led to the rapid publication of a WHO guidance for PPE procurement and users[6]. This guidance was updated in 2016 to reflect additional knowledge and changes to PPE use[8]. In March 2015, a workshop to review PPE logistics and procurement approaches and demonstration of PPE innovations was convened to examine potential solutions.

This was followed by a meeting in November 2016 to review the challenges of the differences in PPE standards and identifying the most expeditious pathway forward. From the recommendations of this meeting, it was agreed that a thorough scoping, review and analysis of the evidence for the protective effectiveness of PPE was necessary. WHO then convened and invited experts to form the Advisory Committees for Innovative Personal Protective Equipment (AC). The AC undertook a thorough review and reading of available evidence and applicable technical standards. There were four AC-working groups: (1) laboratory evidence and research, (2) infection prevention and control and occupational health, (3) technical specifications and logistics and procurement and, (4) PPE users and trainers. Six months later, the AC met at the Third Global Forum for Medical Devices, Geneva, Switzerland, May 2017, to report on their findings and identified 10 specific characteristics for a PPE system that would be safer and more comfortable for use in tropical climates. A draft PPC document was then posted for open public comment through Pro-Med announcement, to the membership of professional societies and to PPE manufacturers as well as the participants from previous WHO workshops and consultations related to PPE use. One hundred and eight comments were received from 73 individuals and entities from all the sectors which the AC then reviewed, analyzed and incorporated relevant ones into this PPC document.

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[8] World Health Organization Personal protective equipment for use in a filovirus disease outbreak: rapid advice guideline. http://apps.who.int/iris/bitstream/handle/10665/251426/9789241549721-eng.pdf?sequence=1.

6. Preferred Product Characteristics

The following tables present ten PPC for PPE to be used by the HW-F. Details, graphics and supplemental information are provided in the appendices.

The list of PPC is not prioritized; they are organized into 3 interdependent groups for a more logical presentation. The groups are: design features, material performance and use desirability (Table 2). An innovation in one characteristic may modify the intended protective measure of another, so interoperability, risk assessment and effective protection will have to be considered. Each characteristic is described by why it is needed (rationale), what is desired as the outcome (desired performance), what is the current evidence that supports the need for this characteristic, what are the existing technical specifications that may apply to this characteristic and, finally, what are the knowledge gaps that will need to be filled to set technical and operational parameters for a future TPP.

Evidence is summarized based on the AC's research and analysis; for some characteristics, there is strong and relevant evidence along with qualitative input from PPE users; for other characteristics, there exist very little or no publicly available evidence but deemed very important from field use experience. The technical specifications for which PPE elements comply with can be complex and extended and are further explained in Appendices 2 and 3. Together, the AC identified the knowledge gaps that will need further investigation, research and stakeholder consultations to define the best evidence to support decisions for a safer and more comfortable PPE system.

Table 2. List of 10 PPC by group

	Group	Characteristics	
1	**Design feature**	a.	Protect mucous membranes
		b.	Minimize the number of PPE element junctions
		c.	Provide unobstructed range of vision
		d.	Enable communication capability
		e.	Use human factors design for size and comfort
2	**Material performance**	a.	Able to protect for the duration of work period
		b.	Able to withstand repeated disinfection (non-disposable elements)
		c.	Manufacture packaging to withstand tropical climate storage conditions
3	**Use desirability**	a.	Standardize donning and doffing protocol with minimum steps
		b.	Dispose PPE in non-toxic and environment-friendly manner

6.1 Design features

Design features highlight the critical areas and functions that the PPE must provide for the HW-F so that their duties can be carried out safely and in relative greater comfort.

a. Protect mucous membranes

Characteristic	Protect mucous membranes (throughout the working period)
Rationale	PPE should be designed to prevent exposure of the health worker at the frontline's mucous membrane areas (mouth, nose, and eyes) and skin from becoming contaminated with the body fluids of infected patients. PPE should also be constructed in a way that deters the health worker at the frontline from inadvertent self- contamination.
Desired performance	The mucous membranes must be protected for the entire working period.
Evidence	• There is limited evidence about how well currently available head and neck PPE protects the health worker at the frontline against EBOV infection, but several studies have evaluated how well masks and respirators (with or without face shields) protect against respiratory viruses. • Significant protective effect of consistent mask/respirator use (fluid resistant medical or surgical masks or surgical N95 respirators) during the SARS epidemic has been shown to protect the health workers[9,10]. Another study showed 99% reduction in transmission of respiratory viruses [OR=0.09, 95% CI (0.03-0.30)][11]. However, when masks/respirators become wet, especially in tropical climates, they become less effective. • Anecdotal evidence and strongly held beliefs of those who have treated EVD patients suggest that a large part of the health worker at the frontline's risk of infection may be around the mucous membranes of the face and head when exposed to patients' body fluids and waste.
Technical specifications	• Face Masks/Shields • Liquid and Viral Penetration Testing • Materials Testing (human factors) • Performance Requirements and Classification Standards
Knowledge gaps	• There is little consensus about the optimal combination, composition, re-usability, and amount of PPE to best protect mucous membranes. There is minimal evidence to support the need for full head and neck coverage beyond mucous membrane protection. There is a lack of standards for minimum performance criteria for hoods (head covering) and for testing the non-continuous regions of PPE (for neck). • Innovative design and smart engineering might be able to define an optimal style that effectively protects the wearer.

b. Minimize the number of PPE element junctions

Characteristic	Minimize the number of junctions where PPE elements connect. Design all junctions to be comfortable and leak-proof
Rationale	Many PPE doffing issues were around where PPE elements joined. Seals around junctions (glove and gown/suit, bonnet/eye-protection, face mask/eye protection, lower body/footwear) trapped contaminated splashes that led to difficulties in safe doffing.
Desired performance	The number of junctions where PPE elements meet should be minimized through design and, where junctions are, is able to provide enough seal to exclude liquid and viral penetration.
Evidence	Studies on PPE junctions[12,13,14,15] with observational opinions from PPE users identified leaky junctions as a source of greater risks and that junctions where PPE elements meet can complicate donning and doffing procedures.
Technical specifications	• Durability Testing Standards • Liquid and Viral Penetration Resistance Testing • Performance Requirements and Classification Standards
Knowledge gaps	• Little attention has been paid to the junctions and interoperability of PPE elements. Particularly, the junction between the sleeve of the clothing and the glove, or in the elements of face and head protection, are areas of concern as blood or body fluids can flow through the interfaces of the protective system worn by health worker at the frontline. • Research is needed to further employ and develop new materials or manufacturing techniques to improve barrier protection to best protect the health worker at the frontline while minimizing connecting junctions and testing how these junctions handle liquid and stress testing, especially under conditions of high heat and humidity. • Generally, only the primary material is tested for liquid penetration, viral penetration, or strength. Seams and junctions should also be tested and data should be reported by manufacturers. • There is a need for a globally developed standard test methods specifically designed for PPE that evaluates the fluid leakage at the junctions (e.g., fluid leakage through glove and protective clothing interface, discontinuous regions like zippers and seams) to compare the products/designs in terms of protection.

c. Provide unobstructed range of vision

Characteristic	Provide a PPE design with no-fog and the range of vision to be as broad as possible
Rationale	PPE worn for protection against EBOV infection often is used in hot, humid, tropical climates. Health worker at the frontline reported significant fog and sweat interference while performing clinical and heavy duty tasks every day. PPE users under these adverse working conditions experience visual obstruction and limited field of vision, impairing their ability to provide care.
Desired performance	The health worker at the frontline to have a clear field of vision unfettered by fogging, sweat and discomfort. The facial view should allow for full circle of vision, vertically and horizontally, while performing tasks. The visibility is such that the patient can see who is providing care.
Evidence	• Current PPE elements for protecting eyes and head are claimed to be fog and scratch resistant (especially for reusable items), under tropical climate use, fogging during use occurred with some frequency. Reusability depended on having appropriate decontamination that did not compromise the integrity of the items. • Use of power assisted air purifying respirators (PAPRs) allow for greater visibility and were used successfully in the field laboratory setting where working conditions[16] were confined and controlled. PAPRs would be difficult to use widely in ETUs because of their cost, cleaning and power support needs.
Technical specifications	Visibility and Eye Protection
Knowledge gaps	• Conduct research on the interoperability of the combined mask, head cover and face shields to provide effective protection with no-fog visibility. • Research on new materials, ventilation dynamics and human use design to reduce heat and generation of fog when wearing PPE.

d. Enable communication capability

Characteristic	Enable communication (speaking, hearing and seeing)
Rationale	Health worker at the frontline attending to EVD patients and wearing full-covered PPE could not communicate adequately with patients and co-workers, neither use the stethoscope, take notes nor hear clearly. Lack of communication increased the risk of the health worker at the frontline and those around them to make mistakes and exacerbate the stress in the health setting. Clear communication would allay fear and suspicion of the health worker at the frontline.
Desired performance	PPE that allows the wearer to speak, hear and see will improve communication with the patient, co-workers, community members and allow for better documenting medical records with greater ease.
Evidence	• Portable electronic vital signs monitoring the patient status has been experimented with as a pilot project but no communication enhancement has been developed for the health worker at the frontline wearing PPE[17] . • There is evidence that speech intelligibility measured by reverberation time must be within 0.4 and 0.5 seconds and no more than 20 decibels for background noise[18].
Technical specifications	Speech communication
Knowledge gaps	Need to conduct research that incorporates innovative design, use of alternate materials and communication equipment. These features could improve the ability to communicate (visual, audible and verbal), while maintaining safety of the health worker at the frontline.

e. Use human factors design for size and comfort

Characteristic	Use human factors design for movement, size and comfort
Rationale	Health worker at the frontline using PPE must be protected and stay comfortable duration of the work period, even in hot, humid weather conditions. Protection is paramount but correct sizing and reduction of heat stress is also important.
Desired performance	PPE that fits the wearer and does not restrict movement while reducing heat stress for the duration of the expected working period in the health setting will allow for better care and provision of services.
Evidence	• Simulation studies analyzing the impact of PPE worn for Ebola protection against EBOV infection while carrying out intensive care procedures were 1.2 to 3.6 times more physically demanding as compared to standard protection[19]. • Completed studies measuring thermal effects on manikins dressed in PPE used for EBOV found minimal heat stress effect on the health worker at the frontline with a mean work duration of 60-65.7 minutes[20,21.] • The Heat Strain Decision Aid is a tool which can be used to estimate maximum safe work to work-rest cycles to avoid over-heat casualty[22].
Technical specifications	• Human Subject Testing • Manikin Testing • Material Testing
Knowledge gaps	• Research should evaluate the impact of wearing a full PPE ensemble in hot, stressed conditions on mental acuity, body temperature, and heart rate to understand the thermal effects of PPE and can assist in defining an appropriate work-to-rest ratio. • Persons developing PPE need information about the amount of time a health worker at the frontline can safely and comfortably remain in PPE in tropical climates. • Important to devise and innovative mechanisms so PPE elements can be adjusted to fit physical differences in height, shape and weight.

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[22] Potter et al. Mathematical prediction of core body temperature from environment, activity, and clothing: The heat strain decision aid (HSDA). *J Thermal Bio.* 2017; 64: 78-85.

Material performance describes the desired level of protection of the HW-F, ensure the protective effects of PPE will withstand disinfection and the PPE packaging can maintain its integrity in tropical climate.

a. Able to protect for the duration of the work period

Characteristic	Able to protect for the duration of work period
Rationale	An impermeable protective layer to cover areas that are likely to be splashed such as the front of the garment and above the neck mucous membrane areas. Pressure points (elbows, knees, and seat) of the PPE will need to be protective when pressure is applied. PPE covering the areas of less exposure does not need to be as liquid resistant. This protection should endure for the work period so that the health worker at the frontline is not subject to deleterious health effects while providing services.
Desired performance	The barrier resistance feature of the front of the PPE, preferably covering 180°, must be effective to provide a necessary protection between the health worker at the frontline and contaminated fluids. PPE at the back should provide adequate protection that exceeds the time needed to doff. The protection should be effective for the work period to beyond 40 minutes and up to 4 hours.
Evidence	• The ideal work period is undefined. During the Ebola response, most workers could only tolerate around 40 minutes in their PPE which severely impacted their ability to provide care[Error! Bookmark not defined.]. An occupational health study recommends a orking period as lasting for 4 hours[Error! Bookmark not defined.], but there is no definitive study that addresses this issue. • The protective effect of gowns is affected by the IPC practice, the type of PPE used and by the situation. Wearing a surgical gown was associated with a significant 77% risk reduction (OR=0.23, 95% CI 0.14-0.37) in the transmission of respiratory viruses to health worker at the frontline [23]. Protection may be compromised by tears and punctures during wear. For example, of 1,354 infection control professionals[24]. 45% (n=609) reported encountering tears or punctures in isolation gowns during wear. Nine of the 22 single-use isolation gowns currently available on the U.S. market were reported as meeting the AAMI PB70 liquid barrier penetration classification requirements at the level specified by the manufacturer[25]. • Penetration of simulated EBOV particles through saline-saturated PPE following testing for 30 minutes in 30-50% relative humidity[26] showed that particles were recovered from saturated N95 respirators and from surgical masks, meaning that liquid stress and saturation compromise the protection of these PPE elements. Existing standards are therefore not protective enough under conditions of heat and humidity, and must be examined and redefined.
Technical requirements	• Durability Testing Standards • Liquid and Viral Penetration Resistance Testing • Performance Requirements and Classification Standards
Knowledge gaps	• Little is known about how protective gowns and coveralls are after they become damp or wet. There is a lack of understanding about micro-perforations, how frequently they can occur, and how often PPE should be changed as a result. There is also little agreement about garment design (gown versus coverall), and whether an apron must or must not be used in conjunction. • Need for improved processes surrounding activities such as premarket testing and post-market evaluation of gowns according to standardized test methods by third party laboratories.

	• Manufacturers, engineers and designers should examine the different types of fabric and materials that may allow for better breathability, durability and liquid repellence. Fabrics may also be produced to have virucidal/bactericidal properties. Research and testing considerations are needed to determine if innovations in this area can yield desired outcomes.
	• There are standards defining minimum performance criteria for aprons, hoods, and boots/boot covers, or junctions (e.g., leakage at glove/body suit interface) but they lack harmonization and performance requirements making the PPE selection process more cumbersome[27].
	• Current test methods do not provide information that will improve PPE protective evidence, improvements should be:
	  ○ Using surrogates that are representative of current pathogen characteristics (Phi-X174 surrogate may not be representative of EBOV).
	  ○ Testing seams and junctions in addition to just the material.
	  ○ Evaluating testing approach as currently only new products are tested, used products are not tested, i.e. thus the effect of the mechanical stress to the PPE is not tested/simulated.
	  ○ Only 60 minutes' duration is used for ASTM F1670/1671 tests, effect of the duration of exposure is not tested.
	• Limited information on representative pressure type and on PPE as only hydrostatic pressure was used in the viral/liquid penetration tests, no mechanical pressure is applied (which may be more common in medical activities, such as leaning, kneeling)[28].
	• Limited representative pathogen mediums (blood, vomit, liquid faeces, sweat, etc.)
	  ○ The surface tension (42 dynes/cm) and the viscosity of the synthetic blood used in the penetration tests (ISO 16603 and ASTM F1670) may not be applicable for the other body fluids which may be more common during Ebola (vomit, diarrhoea).
	  ○ There is surface tension issues (instability) reported with synthetic blood which is used for the ASTM F1670 synthetic blood test.
	  ○ The surface tension of water is much higher compared to the surface tension of the most of the body fluids. Therefore, water resistance tests used for testing textiles (EN 20811, AATCC 42 and AATCC 127) may not simulate the conditions of actual use.
	• Need to remove the inconsistencies and harmonize testing protocols between labs to allow better comparison of PPE, removing the difficulties that exist now.

b. Able to withstand repeated disinfection (non-disposable PPE)

Characteristic	Able to withstand repeated disinfection (non-disposable PPE)
Rationale	Function and integrity should be maintained after multiple cleaning and disinfection procedures for PPE that is meant to be used again.
Desired performance	Inexpensive, non-corrosive and non-toxic cleaning and disinfection methods for cleaning reusable elements of PPE.
Evidence	• The WHO recommends disinfection of all PPE used for filoviruses with a 0.5% chlorine solution with sufficient time for disinfection to take place. WHO discourages spraying disinfectant on clinical treatment areas and on health workers. • Chlorine use is widely accepted but their disinfecting capability is quickly oxidized, so freshly made solutions should be accessible. Chlorine powder, due to its oxidation and corrosive properties in concentrated form, is considered dangerous goods so its shipping, storage and transportation are complicated and costly. • Cleaning and disinfection is a necessary component of standard precautions and infection prevention and control. An environment study[29] examining swabs from ETU surfaces showed that, in the immediate vicinity of EVD patients, 32% (n=22) of swabs from high-risk areas tested positive for EBOV RNA, including 16% (n=4) from health worker's PPE. None (0/19) of the specimens from low-risk areas (medical and nursing administrative tents, a laundry area, storage tents, and water chlorination points) tested positive. Swabs were more often RNA-positive when taken from areas near patients with a very high plasma viral load [OR=6.7, 95% CI (1.7-23.4)]. • After single chlorine spraying (not recommended by WHO), significant increase in eye symptoms ($p<0.001$) were recorded among 3 study groups: 500 health workers, 550 EVD survivors and 500 quarantined asymptomatic contacts. Survivors and health workers, in the same study, were affected with respiratory tract symptoms and skin irritation after multiple exposures to chlorine (in both groups, $p<0.001$)[30] .
Technical specifications	International guidelines include recommendations for the concentration, duration, and frequency of disinfectant use. Applicable specifications are examined after X number of disinfection procedures are listed here: • Durability Testing after X number of disinfection procedures • Glove Testing after X number of disinfection procedures • Human factors engineering for processing medical devices Liquid and Viral Penetration Testing after X number of disinfection procedures
Knowledge gaps	• Need comprehensive studies on the risks to health workers and patients associated with current disinfection by chlorine as recommended by WHO. • Define standards for testing the function of reusable materials after disinfection. • Identify information on the effect of the current disinfectants on their PPE products. Manufacturers may have this data. • Need for less toxic but effective disinfectants. Research should evaluate the optimal concentration of disinfection for PPE and other surfaces. • Identify alternative options for sprays and solutions, as chlorine may not always be readily available in ETUs. • Conduct research to understand the risks associated with various available disinfectants with different materials including the inclusion engineered virucidal/bactericidal effects.

c. Manufacture packaging to withstand tropical climate storage conditions

Characteristic	Manufacture packaging to withstand tropical climate storage conditions
Rationale	Proper storage often requires a dry and clean place that is not subject to temperature extremes. In tropical settings, the storage conditions are likely to be sub-optimal with high humidity (up to 90%) and temperatures (>28^{o}C). Under these sub-optimal conditions, containers and packages broke apart and collapsed compromising PPE and contents during the EVD epidemic response.
Desired performance	The inner and the outer packaging should be designed to maintain their integrity under high humidity and high ambient temperatures.
Evidence	There is no published data regarding storage integrity of PPE packaging.
Technical specifications	There is no test method or publicly available data on shelf life integrity or testing of PPE packaging. If PPE components such as gowns, gloves and other parts are packaged together, each of the individual components may need to be tested after storage for its integrity and performance standard(s). The following methods and testing may apply: • Accelerated Aging Testing • Durability Testing • Glove Testing (if included in the package) • Liquid and Viral Penetration Testing • Performance Requirements and Classification Standards • Performance Requirements for Medical Packaging
Knowledge gaps	• Identify information on package storage conditions already exists or if a study has been reviewed for this characteristic. Outcome data may exist with manufacturers on accelerated aging test and PPE durability. • Research on alternative and innovative container or packaging design that does not increase the overall package weight and offers enhanced rigidity and protection from ingression of humidity could lead to new types of container/storage resilience.

[23] Jefferson T et al. Physical interventions to interrupt or reduce the spread of respiratory viruses (review). *Cochrane Database Syst Rev*. 2010; 1: No: CD006207
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6.2 Use desirability

User desirability features two critical issues addressing risk reduction. One is the contamination of the HW-F and the other about the environment and communities where contaminated PPE is being disposed of.

a. Standardize and minimize donning and doffing steps

Characteristic	Standardized donning and doffing protocol with minimum steps
Rationale	Donning and doffing PPE are multi-step processes that can cause confusion and frustration for the health worker at the frontline. A standardized and easy to follow protocol is necessary to guide the health worker at the frontline through the steps for each process. For the donning and doffing process, the protocol must include a trained observer stationed at the doffing area to ensure protocol is executed appropriately.
Desired performance	PPE design should allow for intuitive but standardized doffing in a logical manner that minimizes the risk for self-contamination. The donning steps should be designed to facilitate the steps in doffing.
Evidence	• Studies comparing donning and doffing protocols showed significant less environment and body contamination when using a reinforced system that includes an observer specialist (at times referred to as a buddy) dedicated to doffing[31,32]. • Donning full PPE (a hazmat suit and a PAPR), took an average of 7.55 minutes (range: 5.2-13.47 minutes) and the doffing process took 4.06 minutes (range: 3.08-5.63 minutes)[33]. A significant difference (p=0.0488) was noted when comparing contamination versus speed of doffing with simple PPE sets: obvious levels of contamination (45.39 seconds average doffing time) versus minor levels of contamination (55.46 seconds average doffing time). The results of this study emphasize the need for simplifying and clarifying PPE protocols. • Fifty-one types of doffing PPE errors were documented when experienced health workers removed PPE in the presence of a trained observer. This study used surrogate viruses to trace where the highest risks were. The highest risk index actions were related to hand hygiene and removing the PAPR hood but the potential for self-contamination occurred throughout the observed doffing process[34].
Technical specifications	Multiple PPE guidelines on donning and doffing have been published[35]. While all protocols include instructions on donning and doffing recommended PPE, there is ***significant variation*** in the order of steps and the types of PPE.
Knowledge gaps	• Need to resolve the conflicting information about the appropriate order in which a health worker should don and doff PPE and define the exact roles and responsibilities of an observer. • Validate the use of an EBOV surrogate so that testing for contamination can be conducted safely outside of a high containment facility. This would expedite research and minimize risk. • Devise methods to detect user-error and PPE performance failure during the full-cycle PPE use (donning, working, doffing and disposal). • Use innovative design and monitoring methods to reduce risk of exposure throughout the ETU and especially of the high exposure areas.

b. Dispose PPE in a non-toxic and environment-friendly manner

Characteristic	Dispose PPE in a non-toxic and environment-friendly manner
Rationale	A massive amount of waste can be generated in the healthcare setting including contaminated, discarded PPE. The waste in low resource settings is disposed by burning which produce smoke and ash close to habitations and can leave PPE parts intact. Waste residuals may be buried in pits and these are typically in unsecured sites.
Desired performance	As part of the full product life cycle, waste decontamination and disposal should avoid leaving toxic waste and negatively impacting the environment.
Evidence	No toxicity environmental data exist as to the harm of disposed materials from health settings.
Technical specifications	Environmental management systems may apply. There are no standards for PPE disposal
Knowledge gaps	• Need to study the harmful effects to communities and the environment on the current PPE disposal method. • Conduct research on the persistence of infectious virus in waste materials. • Use of biodegradable materials to reduce the volume of waste should be considered in the PPE system. • Need to evaluate potential beneficial energy generation from waste PPE for local consumption in low resource settings.

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[35] Médecins Sans Frontières, Informal Chapter on Infection Control for PPE, 2014; World Health Organization, "Clinical Management of Patients with Viral Haemorrhagic Fever: a Pocket Guide for Front-line Health Workers. Interim Emergency Guidance or West Africa," 2016; 120-126; Centers for Disease Control and Prevention, "Guidance on Personal Protective Equipment (PPE) To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE," 2015, https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html; European Center for Disease Prevention and Control, "Safe Use of Personal Protective Equipment in the Treatment of Infectious Diseases of High Consequence," Stockholm: ECDC; 2014.

7. Unmet needs

7.1. Research to fill knowledge gaps

There is limited evidence to inform about PPE effectiveness as used in low resource settings. This has led to choices being made with little evidentiary support. Much of the current knowledge is based on observational and experiential practices on site where often rapid decisions often must be made to adjust to an ever-changing PPE styles and inadequate supply chain. Such decisions are often made with more stringency than necessary out of abundance of caution rather than based on data. Such practices then become ingrained and difficult to change without evidence. This type of approach has led to outfits that allow for very little evaporative-cooling, so that most workers can only work for an average of 40 minutes, severely impacting a HW-F's ability to provide care and services. Significant knowledge gaps remain about PPE design, methods to reduce the impact of heat strain, to simplify donning and doffing PPE, to reduce wearer discomfort and to overcome limitations to vision and communications. In the past, these issues were not addressed once the outbreak was over when the global attention moved on to other issues. Incorporating the safety, usability and comfort features addressed in this document can provide the change and improve health care and services. However, these changes will have to be shown by R&D evidence that they indeed are improvements and need to be weighed against the costs of improved PPE.

7.2. Transmissibility of Ebola, Marburg and other diseases with that share similar transmission characteristics need further elucidation

These studies are challenging, expensive and require high biocontainment to conduct. Although it is clear that human-to-human transmission via blood and bodily fluids occurs, definitive studies on alternative routes of transmission of EBOV need to be determined. These resulting data will inform IPC strategy and PPE use.

7.3. Testing and standard development

Concomitant with new designs, technology and materials, the appropriate performance standards and testing protocols will have to be developed for a full PPE ensemble. Surrogates to simulate Ebola virus are needed for testing for viral exposure and contamination testing at lower biosafety levels. Standardized donning and doffing protocols that are harmonized are critical to reducing risk for PPE users allowing for consistent training on donning and doffing protocols and disposal.

7.4. Access to PPE

A supply challenge will remain for any future EVD or other outbreaks requiring the PPE system that meet the recommended characteristics in this document. The specialized types of PPE requested may not be realized without a routine system of production of the scale that was required for the 2014-2016 EVD epidemic. As there is not an ongoing commercial demand for such items, production capacity for them may not be immediately available in case of a health crisis. Innovative purchase strategies may be needed to ensure availability of the correct types of PPE to be worn.

8. Desired outcome using this guidance

The main goal is to reduce disease transmission and enable HW-F to safely provide the optimum care in stressful, hot and humid working conditions in low resource and austere settings. Adaptive technology will enable health providers to deliver better and more intensive care and treatments to save lives. New designs, technology and systems will improve the approach to work with communities, allow community-owned engagements in reducing risk of infections and to perform respectful burials and sanitation. Such innovations can provide greater safety and can also reduce costs and waste.

8.1. Engaging stakeholders

It will take engagement of stakeholders from many sectors including healthcare providers, healthcare industry, governments, intergovernmental organizations and medical philanthropic partners. The desired outcome is to be able to offer better protection of HW-F and incorporate broader use capability of the new PPE in other health settings. Stakeholders will have to develop a strategy that would be responsive to initiating rapid large scale production during an emergency response where this capability may be lacking.

8.2. Review and periodic updates

PPC are meant to highlight knowledge gaps and address them so that specific technical performance requirements can be developed towards developing a more technical and specific TPP with measurable and accurate performance characteristics of the desired product. WHO will continue to review and monitor new developments and share new knowledge through periodic updates at least once every 2 years to ensure advances and knowledge are evaluated and used to update PPE for the HW-F.

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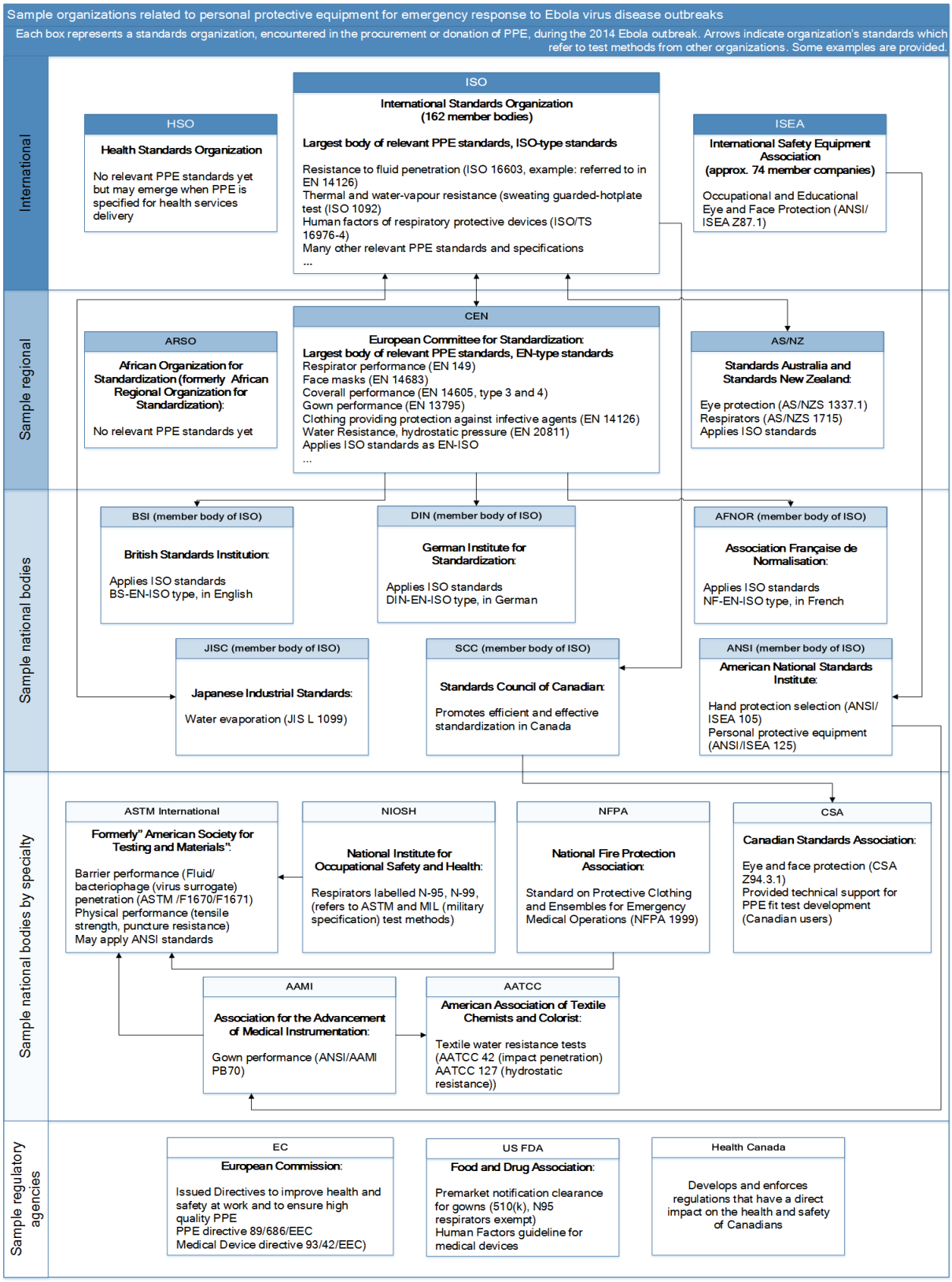
Appendix 2. Technical Specifications and Performance Standards for PPE

Multiple specifications and standards exist for PPE to ensure that products perform to meet performance requirements. The technical specifications and performance standards apply to individual PPE ensembles, garments, components and individual elements and by categorical functions. None exists solely for the preferred characteristics or for evaluating of a full PPE ensemble specifically for health worker at the frontline against Ebola virus. The compendium of technical specifications and performance standards are used by the PPE designers and the PPE industry to produce products that meet the requirements encoded in them. These requirements may differ for the international, regional and national markets. The complex web of organizations related to PPE that impacted the EVD response in 2014-2016 are presented in the diagram (Figure 1, Appendix 3) to show the interconnected relationships to each other and to their authoritative range (international, regional, and national) and also shown by their specialty and by the applicable regulatory body.

Appendix 3 Figure 1: Technical specifications and performance



characteristics

The specifications and standards with application to PPE and the preferred characteristics are summarized in Table 6. This is a representation of applicable standards. A list of standards has previously been provided by WHO rapid advice for PPE[1]. The national regulations used by other countries have not been listed because they are similar to, or have the same, parameters as those listed in the table. The standards listed are organized alphabetically by the category action and, within each category, listed by international, regional and national then specialty applications where they exist.

There is a lack of a harmonized standard for minimum performance requirements for health care PPE used against biological agents. There are several differences between ANSI/AAMI PB70 and EN 13795 surgical gown classifications. Because the test methods and performance requirements cannot be compared directly, it is difficult to assign equivalency between surgical gowns classified according to EN 13795 and ANSI/AAMI PB70. Similarly, for coveralls it is difficult to compare test methods and performance specifications used in different countries. In Europe, the EN 14126 standard typically is used to evaluate and classify coveralls used to protect from infectious agents and EN 13795 is used to evaluate and classify surgical gowns. Unlike surgical or isolation gowns (ANSI/AAMI PB70), there is no widely used classification standard in the United States. Coveralls with materials and seams tested against ASTM 1671 are specified in NFPA 1999. However, while originally designed for pre-hospital healthcare workers, NFPA 1999 could be used for hospital-based healthcare workers as well. A Centre for Disease Control and Prevention PPE-information tool has been designed to provide standards developers, manufacturers, purchasers, and end users of PPE with a comprehensive tool which allows general or advanced criteria searches of relevant U.S. federal standards, associated product types, target occupational groups, basic conformity assessment specifications, and accredited lab information[2].

Table 3. Technical specifications and performance standards

Category	Standards and Test Methods	Description
Accelerated Aging Testing (after storage)	**ASTM F1980**	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
	ASTM 573-88	Standard Test Method for Rubber-Deterioration in an Air Oven
Durability Testing (after X number of disinfection procedures and after storage, junctions, properties of PPE)	**ASTM D 5034**	Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
	ASTM D5587	Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
	ASTM D5733	Standard Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure
	ASTM D1683	Standard Test Method for Failure in Sewn Seams of Woven Fabrics
	ISO 13934-1	Textiles — Tensile properties of fabrics — Part 1: Determination of maximum force and elongation at maximum force using

Category	Standards and Test Methods	Description
		the strip method
Environmental Management (after X number of disinfection procedures)	**ISO 14001**	Environmental management systems
	EN 420:2004	Protective Gloves. General requirements and test methods
Face Masks (covering mucous membranes)	**ASTM F1862 / F1862M - 17**	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
	ISO 22609	Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
Glove Testing (after X number of disinfection procedure, after storage	**ISO 11193-2**	Single-use medical examination gloves - Specification for gloves made from poly (vinyl chloride)
	IS0 11193-1	Single-use medical examination gloves - Specification for gloves made from rubber latex or rubber solution
	ISO 10282	Single use sterile surgical rubber gloves - specification
	EN 374:	Gloves Giving Protection from Chemicals and Micro-Organisms
	EN 455 Part 1	2002: Requirements and testing for freedom from holes
	EN 455 Part 2:2011	Requirements and testing for physical properties
	EN 420:2004	Protective Gloves. General requirements and test methods
	ASTM D6319	Specification for nitrile examination gloves for medical applications
	ASTM D3578-05	Specification for rubber examination gloves
	ASTM D7160	Standard Practice for Determination of Expiration Dating for Medical Gloves
	ASTM D7161	Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions
	ASTM D412-2013	Standard test methods for vulcanized rubber and thermoplastic elastomers-tension
Human Factors Engineering (after X number of disinfection procedures,	**AAMI TIR55**	Human factors engineering for processing medical devices

Category	Standards and Test Methods	Description
mucous membranes)		
Human Subject Testing (human factor design)	**ASTM F2668**	Standard Practice for Determining the Physiological Responses of the Wearer to Protective Clothing Ensembles
Liquid and Viral Penetration Testing (after X number of disinfection procedures, after storage, mucous membranes, junctions, property of PPE)	**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
	ISO 16604:2004	Clothing for protection against contact with blood and body fluids -- Determination of resistance of protective clothing materials to penetration by blood-borne pathogens -- Test method using Phi-X 174 bacteriophage
	ISO 22610	Test method to determine the resistance to wet bacterial penetration
	ISO 22612	Test method for resistance to dry microbial penetration
	EN 20811	Determination of Resistance To Water Penetration—Hydrostatic Pressure Test
	ASTM F1670	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood. The test is for 60 minutes.
	ASTM F1671	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System
	AATCC 42	Water Resistance: Impact Penetration Test
	AATCC 127	Water Resistance: Hydrostatic Pressure Test
Manikin Testing (human factor design)	**ASTM F2370-05**	Standard Test Method for Measuring the Evaporative Resistance of Clothing Using a Sweating Manikin
	ASTM F1291-05	Standard Test Method for Measuring the Thermal Insulation of Clothing Using a Heated Manikin
	ISO 15831	Clothing — Physiological effects — Measurement of thermal insulation by means of a thermal manikin
Materials Testing (human	**ISO 11092**	Textiles – Physiological effects –

Category	Standards and Test Methods	Description
design factor)		Measurement of thermal and water-vapour resistance under steady-state conditions (sweating guarded-hotplate test)
	ISO/TS 16976-8	Respiratory protective devices —Human factors — Part 8: Ergonomic factors
	ISO 11092	Textiles — Physiological effects — Measurement of thermal and water vapour resistance under steady-state conditions (sweating guarded hotplate test)
	ISO 15496	Textiles - Measurement of water vapour permeability of textiles for the purpose of quality control
	ISO 9237	Textiles -- Determination of the permeability of fabrics to air
	ANSI/AAMI HE75:2009/(R)2013:	Human factors engineering – Design of medical devices
	ANSI/AAMI/IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices American National Standard
	AAMI TIR51:2014	Human factors engineering – Guidance for contextual inquiry
	AATCC 195	Liquid Moisture Management Properties of Textile Fabrics
	ASTM D737	Standard Test Method for Air Permeability of Textile Fabrics
	ASTM F1868	Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate
	ASTM D3776	Standard Test Methods for Mass Per Unit Area (Weight) of Fabric
	ASTM D1777	Standard Test Method for Thickness of Textile Materials
	ASTM E96-80	Standard Test Methods for Water Vapor Transmission of Materials
	ASTM F1249	Standard Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor
Performance Requirements and Classification Standards (properties of PPE, after storage)	**EN 13795**	European Standard for Surgical Drapes, Gowns and Clean Air Suits
	EN 14126:2003	Protective clothing. Performance requirements and tests methods for

Category	Standards and Test Methods	Description
		protective clothing against infective agents: Protective clothing, Re-usable, Infective materials, Biological hazards, Health and welfare facilities, Hospital equipment, Health and safety requirements, Safety measures, Performance, Performance testing
	ANSI/AAMI PB70	Liquid barrier performance and classification of protective apparel and drapes in health care facilities
	NFPA 1999	Standard on protective clothing for emergency medical operations includes pre-conditioning of fabrics for flexing and abrasion prior to barrier testing
Performance Requirements for Medical Packaging (after storage, mucous membranes, junctions)	**ISO 11607**	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
Speech Communication (communications)	**ISO 9921**	Ergonomics — Assessment of speech communication
Testing of Packages (after storage)	**ASTM F88**	Standard Test Method for Seal Strength of Flexible Barrier Materials
	ASTM F2638	Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier
	ASTM F1929	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration Visual Inspection
Visibility and Eye Protection (human design factors, mucous membranes)	**86/686/EEC**	EU standard directive on Personal Protective Equipment
	EN 166:2002	Personal Eye Protection
	ANSI/ISEA Z87.1-2010	American National Standard for Occupational and Educational Eye and Face Protection

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