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

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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**

<table>
<thead>
<tr>
<th>Target population, setting and use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary target use population</strong></td>
</tr>
<tr>
<td>Health workers on the frontline providing patient care and heavy duty services in basic facilities under hot, humid conditions.</td>
</tr>
<tr>
<td><strong>Secondary target use population</strong></td>
</tr>
<tr>
<td>Health workers who will use PPE for protection from high risk exposure in advanced equipped medical facilities.</td>
</tr>
<tr>
<td><strong>Target use setting</strong></td>
</tr>
<tr>
<td>Health facilities and community environments where health workers on the frontline are at risk of exposure to virus shedding by patients or dead bodies.</td>
</tr>
<tr>
<td><strong>Intended use</strong></td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

*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.

*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 workforce in the affected countries, severely weakening health systems already crippled by an ongoing 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. 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.


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

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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Protect mucous membranes (throughout the working period)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rationale</td>
<td>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.</td>
</tr>
<tr>
<td>Desired performance</td>
<td>The mucous membranes must be protected for the entire working period.</td>
</tr>
<tr>
<td>Evidence</td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
</tr>
<tr>
<td>Technical specifications</td>
<td>• Face Masks/Shields</td>
</tr>
<tr>
<td></td>
<td>• Liquid and Viral Penetration Testing</td>
</tr>
<tr>
<td></td>
<td>• Materials Testing (human factors)</td>
</tr>
<tr>
<td></td>
<td>• Performance Requirements and Classification Standards</td>
</tr>
<tr>
<td>Knowledge gaps</td>
<td>• 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).</td>
</tr>
<tr>
<td></td>
<td>• Innovative design and smart engineering might be able to define an optimal style that effectively protects the wearer.</td>
</tr>
</tbody>
</table>
### b. Minimize the number of PPE element junctions

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Minimize the number of junctions where PPE elements connect. Design all junctions to be comfortable and leak-proof</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rationale</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Desired performance</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Evidence</strong></td>
<td>Studies on PPE junctions 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.</td>
</tr>
</tbody>
</table>
| **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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Provide a PPE design with no-fog and the range of vision to be as broad as possible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rationale</td>
<td>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.</td>
</tr>
<tr>
<td>Desired performance</td>
<td>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.</td>
</tr>
</tbody>
</table>
| 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 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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Enable communication (speaking, hearing and seeing)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rationale</td>
<td>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.</td>
</tr>
<tr>
<td>Desired performance</td>
<td>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.</td>
</tr>
</tbody>
</table>
| 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.  
• 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. |
| 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. |
### Use human factors design for size and comfort

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Use human factors design for movement, size and comfort</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rationale</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Desired performance</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
| **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.\(^9\)  
• 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.\(^10\)\(^,\)\(^11\)  
• 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.\(^12\) |
| **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. |

---

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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Able to protect for the duration of work period</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rationale</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Desired performance</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
| **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\(^{21}\). An occupational health study recommends a working period as lasting for 4 hours\(^ {23}\), 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\(^ {22}\). 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.

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).

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)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Able to withstand repeated disinfection (non-disposable PPE)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rationale</strong></td>
<td>Function and integrity should be maintained after multiple cleaning and disinfection procedures for PPE that is meant to be used again.</td>
</tr>
<tr>
<td><strong>Desired performance</strong></td>
<td>Inexpensive, non-corrosive and non-toxic cleaning and disinfection methods for cleaning reusable elements of PPE.</td>
</tr>
</tbody>
</table>
| **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 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). |
| **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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Manufacture packaging to withstand tropical climate storage conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rationale</strong></td>
<td>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 (&gt;28°C). Under these sub-optimal conditions, containers and packages broke apart and collapsed compromising PPE and contents during the EVD epidemic response.</td>
</tr>
<tr>
<td><strong>Desired performance</strong></td>
<td>The inner and the outer packaging should be designed to maintain their integrity under high humidity and high ambient temperatures.</td>
</tr>
<tr>
<td><strong>Evidence</strong></td>
<td>There is no published data regarding storage integrity of PPE packaging.</td>
</tr>
</tbody>
</table>
| **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 ingestion of humidity could lead to new types of container/storage resilience. |

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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  
### 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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Standardized donning and doffing protocol with minimum steps</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rationale</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Desired performance</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
| **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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Dispose PPE in a non-toxic and environment-friendly manner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rationale</td>
<td>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.</td>
</tr>
<tr>
<td>Desired performance</td>
<td>As part of the full product life cycle, waste decontamination and disposal should avoid leaving toxic waste and negatively impacting the environment.</td>
</tr>
<tr>
<td>Evidence</td>
<td>No toxicity environmental data exist as to the harm of disposed materials from health settings.</td>
</tr>
<tr>
<td>Technical specifications</td>
<td>Environmental management systems may apply. There are no standards for PPE disposal</td>
</tr>
</tbody>
</table>
| 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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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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<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Organization</th>
<th>Country</th>
</tr>
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<td>Centers for Disease Control and Prevention</td>
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Nahoku SHINDO
Jose ROVIRA VILAPLANA
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

Sample organizations related to personal protective equipment for emergency response to Ebola virus disease outbreaks:

Each box represents an organization encountered in the procurement or donation of PPE during the 2014 Ebola outbreak. Arrows indicate organizations’ standards which refer to test methods from other organizations. Some examples are provided below.

ISO
International Standards Organization (162 member bodies)
- Largest body of relevant PPE standards, ISO-type standards
- Resistance to fluid penetration (ISO 16003, example: referred to in EN 14126)
- Thermal and water-vapour resistance (sweating guarded-hotplate test (ISO 10992))
- Human factors of respiratory protective devices (ISO 14605, type 3 and 4)
- Many other relevant PPE standards and specifications

CEN
European Committee for Standardization
- Largest body of relevant PPE standards, EN-type standards
- Respirator performance (EN 149)
- Face masks (EN 14683)
- Overall performance (EN 14605, type 3 and 4)
- Gown performance (EN 13798)
- Clothing providing protection against infective agents (EN 14126)
- Water resistance, hydrostatic pressure (EN 20411)
- Applies ISO standards as EN-ISO

ARSO
African Organization for Standardization (formerly African Regional Organization for Standardization)
- No relevant PPE standards yet

BSI (member body of ISO)
British Standards Institution
- Applies ISO standards BS-EN-ISO-type, in English

CEN (member body of ISO)
German Institute for Standardization
- Applies ISO standards EN-EN-ISO-type, in German

AFNOR (member body of ISO)
Association Francaise de Normalisation
- Applies ISO standards NF-EN-ISO-type, in French

JISC (member body of ISO)
Japanese Industrial Standards
- Water evaporation (JIS L 1099)

SCC (member body of ISO)
Standards Council of Canada
- Promotes efficient and effective standardization in Canada

ASTM International
- Formerly American Society for Testing and Materials
- Barrier performance (fluid/ particle penetration, (ASTM F1670/F1671)
- Physical performance (tensile strength, puncture resistance)
- May apply ANSI standards

NIOSH
National Institute for Occupational Safety and Health
- Respirators labeled N95, N99, (refers to ASTM and MIL, military specification) test methods

NFPA
National Fire Protection Association
- Standard on Protective Clothing and Ensembles for Emergency Medical Operations (NFPA 1999)

CSA
Canadian Standards Association
- Eye and face protection (CSA Z94.3.1)
- Provided technical support for PPE test development (Canadian users)

AAAMC
American Academy of Medical Instrumentation
- Gown performance (ANSI/AAMI PB70)

AATCC
American Association of Textile Chemists and Colorists
- Textile water resistance tests (AATCC 42, impact penetration)
- AATCC 127 (hydrostatic resistance)

EC
European Commission
- Issued Directives to improve health and safety at work and to ensure high quality PPE
- PPE directive 89/686/EEC (Medical Device directive 93/42/EC)

US FDA
Food and Drug Association
- Premarket notification clearance for gowns (510k), N95 respirators exempted
- Human Factors guideline for medical devices

Health Canada
- Develops and enforces regulations that have a direct impact on the health and safety of Canadians

Sample national bodies by specialty:

Sample national bodies by region:

Sample national bodies by type:

Sample regulatory agencies:
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. 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.

### Table 3. Technical specifications and performance standards

<table>
<thead>
<tr>
<th>Category</th>
<th>Standards and Test Methods</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ASTM 573-88</td>
<td>Standard Test Method for Rubber-Deterioration in an Air Oven</td>
</tr>
<tr>
<td>Durability Testing (after X number of disinfection procedures and after storage, junctions, properties of PPE)</td>
<td>ASTM D 5034</td>
<td>Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)</td>
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<tr>
<td></td>
<td>ASTM D5587</td>
<td>Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure</td>
</tr>
<tr>
<td></td>
<td>ASTM D5733</td>
<td>Standard Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure</td>
</tr>
<tr>
<td></td>
<td>ASTM D1683</td>
<td>Standard Test Method for Failure in Sewn Seams of Woven Fabrics</td>
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<tr>
<td></td>
<td>ISO 13934-1</td>
<td>Textiles — Tensile properties of fabrics — Part 1: Determination of maximum force and elongation at maximum force using</td>
</tr>
<tr>
<td>Category</td>
<td>Standards and Test Methods</td>
<td>Description</td>
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<tr>
<td>Environmental Management (after X number of disinfection procedures)</td>
<td>ISO 14001</td>
<td>Environmental management systems</td>
</tr>
<tr>
<td></td>
<td>EN 420:2004</td>
<td>Protective Gloves. General requirements and test methods</td>
</tr>
<tr>
<td>Face Masks (covering mucous membranes)</td>
<td>ASTM F1862 / F1862M - 17</td>
<td>Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)</td>
</tr>
<tr>
<td></td>
<td>ISO 22609</td>
<td>Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)</td>
</tr>
<tr>
<td>Glove Testing (after X number of disinfection procedure, after storage)</td>
<td>ISO 11193-2</td>
<td>Single-use medical examination gloves - Specification for gloves made from poly (vinyl chloride)</td>
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<tr>
<td></td>
<td>ISO 11193-1</td>
<td>Single-use medical examination gloves - Specification for gloves made from rubber latex or rubber solution</td>
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<tr>
<td></td>
<td>ISO 10282</td>
<td>Single use sterile surgical rubber gloves - specification</td>
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<tr>
<td></td>
<td>EN 374:</td>
<td>Gloves Giving Protection from Chemicals and Micro-Organisms</td>
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<tr>
<td></td>
<td>EN 455 Part 1</td>
<td>2002: Requirements and testing for freedom from holes</td>
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<td></td>
<td>EN 455 Part 2:2011</td>
<td>Requirements and testing for physical properties</td>
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<tr>
<td></td>
<td>EN 420:2004</td>
<td>Protective Gloves. General requirements and test methods</td>
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<tr>
<td></td>
<td>ASTM D6319</td>
<td>Specification for nitrile examination gloves for medical applications</td>
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<tr>
<td></td>
<td>ASTM D3578-05</td>
<td>Specification for rubber examination gloves</td>
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<tr>
<td></td>
<td>ASTM D7160</td>
<td>Standard Practice for Determination of Expiration Dating for Medical Gloves</td>
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<td>ASTM D7161</td>
<td>Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions</td>
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<td>ASTM D412-2013</td>
<td>Standard test methods for vulcanized rubber and thermoplastic elastomers - tension</td>
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<tr>
<td>Human Factors Engineering (after X number of disinfection procedures,</td>
<td>AAMI TIR55</td>
<td>Human factors engineering for processing medical devices</td>
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<tr>
<td>Category</td>
<td>Standards and Test Methods</td>
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<tr>
<td>mucous membranes</td>
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<tr>
<td>Human Subject Testing (human factor design)</td>
<td>ASTM F2668</td>
<td>Standard Practice for Determining the Physiological Responses of the Wearer to Protective Clothing Ensembles</td>
</tr>
<tr>
<td>Liquid and Viral Penetration Testing (after X number of disinfection procedures, after storage, mucous membranes, junctions, property of PPE)</td>
<td>ISO 16603:2004</td>
<td>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</td>
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<td></td>
<td>ISO 16604:2004</td>
<td>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</td>
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<td>ISO 22610</td>
<td>Test method to determine the resistance to wet bacterial penetration</td>
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<td>ISO 22612</td>
<td>Test method for resistance to dry microbial penetration</td>
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<tr>
<td></td>
<td>EN 20811</td>
<td>Determination of Resistance To Water Penetration—Hydrostatic Pressure Test</td>
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<tr>
<td></td>
<td>ASTM F1670</td>
<td>Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood. The test is for 60 minutes.</td>
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<tr>
<td></td>
<td>AATCC 42</td>
<td>Water Resistance: Impact Penetration Test</td>
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<td></td>
<td>AATCC 127</td>
<td>Water Resistance: Hydrostatic Pressure Test</td>
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<tr>
<td></td>
<td>ASTM F1291-05</td>
<td>Standard Test Method for Measuring the Thermal Insulation of Clothing Using a Heated Manikin</td>
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<td>ISO 15831</td>
<td>Clothing — Physiological effects — Measurement of thermal insulation by means of a thermal manikin</td>
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<tr>
<td>Materials Testing (human</td>
<td>ISO 11092</td>
<td>Textiles — Physiological effects —</td>
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<tr>
<td>Category</td>
<td>Standards and Test Methods</td>
<td>Description</td>
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<tr>
<td>design factor)</td>
<td>ISO/TS 16976-8</td>
<td>Measurement of thermal and water-vapour resistance under steady-state conditions (sweating guarded-hotplate test)</td>
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<tr>
<td>ISO 11092</td>
<td>Respiratory protective devices — Human factors — Part 8: Ergonomic factors</td>
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<tr>
<td>ISO 15496</td>
<td>Measurement of water vapour permeability of textiles for the purpose of quality control</td>
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<tr>
<td>ISO 9237</td>
<td>Textiles -- Determination of the permeability of fabrics to air</td>
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<td>AATCC 195</td>
<td>Liquid Moisture Management Properties of Textile Fabrics</td>
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<tr>
<td>ASTM D737</td>
<td>Standard Test Method for Air Permeability of Textile Fabrics</td>
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<tr>
<td>ASTM D3776</td>
<td>Standard Test Methods for Mass Per Unit Area (Weight) of Fabric</td>
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<tr>
<td>ASTM D1777</td>
<td>Standard Test Method for Thickness of Textile Materials</td>
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<tr>
<td>ASTM E96-80</td>
<td>Standard Test Methods for Water Vapor Transmission of Materials</td>
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<tr>
<td>ASTM F1249</td>
<td>Standard Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor</td>
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<tr>
<td>Performance Requirements and Classification Standards (properties of PPE, after storage)</td>
<td>EN 13795</td>
<td>European Standard for Surgical Drapes, Gowns and Clean Air Suits</td>
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<tr>
<td>EN 14126:2003</td>
<td>Protective clothing. Performance requirements and tests methods for</td>
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<tr>
<td>Category</td>
<td>Standards and Test Methods</td>
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<tr>
<td>Protective clothing against infective agents</td>
<td>ANSI/AAMI PB70</td>
<td>Liquid barrier performance and classification of protective apparel and drapes in health care facilities</td>
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<tr>
<td></td>
<td>NFPA 1999</td>
<td>Standard on protective clothing for emergency medical operations includes pre-conditioning of fabrics for flexing and abrasion prior to barrier testing</td>
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<tr>
<td>Performance Requirements for Medical Packaging</td>
<td>ISO 11607</td>
<td>Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems</td>
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<tr>
<td>Speech Communication (communications)</td>
<td>ISO 9921</td>
<td>Ergonomics — Assessment of speech communication</td>
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<tr>
<td>Testing of Packages (after storage)</td>
<td>ASTM F88</td>
<td>Standard Test Method for Seal Strength of Flexible Barrier Materials</td>
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<td>ASTM F2638</td>
<td>Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier</td>
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<tr>
<td>Visibility and Eye Protection (human design</td>
<td>86/686/EEC</td>
<td>EU standard directive on Personal Protective Equipment</td>
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<td>factors, mucous membranes)</td>
<td>EN 166:2002</td>
<td>Personal Eye Protection</td>
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<tr>
<td></td>
<td>ANSI/ISEA Z87.1-2010</td>
<td>American National Standard for Occupational and Educational Eye and Face Protection</td>
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