US-based Ebola Related PPE Guidance

---------- October 30, 2014 ----------

Gore barrier-based PPE meeting IAB Recommendations

On October 24, 2014, the InterAgency Board (IAB) issued a guidance document entitled, *Recommendations on Selection and Use of Personal Protective Equipment for First Responders against Ebola Exposure Hazards*[1]. This guidance document intended for first responders is now the preeminent guidance established for proper assessment of Ebola-related threat levels, the associated recommended PPE, and appropriate handling procedures if contaminated. This guidance document should be reviewed carefully before making Ebola-related PPE decisions.

The IAB guidance document is organized around a matrix of Ebola Exposure Levels versus (Patient) Symptoms Presented. It establishes three levels of recommended PPE according to the risks associated with each cell of the matrix:

SOP-Recommended PPE
Low-Risk PPE
and, **High-Risk PPE**

In Appendix 1 of the guidance document, the IAB provides descriptions for both the High-Risk and Low-Risk PPE. With respect to garments, specifically, the key descriptors of these two categories include (see Note 1, below, and full IAB document for complete PPE descriptions):

High-Risk		Low-Risk
full body garment	---	(same)
durable material	---	disposable or more durable
viral penetration resistant material & seams	---	(same)
moisture vapor "breathable" (preferred)	---	(same)

In Appendix 2 of the guidance document, the IAB provides detailed specifications for each of the High-Risk and Low-Risk PPE descriptions. Again, specifically for garments, a few of the key specifications of these two categories include (see Note 1, below, and full IAB document for complete PPE detailed specifications):

High-Risk				Low-Risk
durable*:	tensile	≥ 250 N	---	tensile ≥ 50 N
	tear	≥ 75 N	---	tear ≥ 17 N
	seam	≥ 125 N	---	seam ≥ 15 N
viral:	passing results (ASTM F 1671)		---	(same)
"breathable" (preferred):				
	THL	≥ 450 W/m^2 (ASTM F1868, Proc. C)	---	(same)
	or, Ret	≤10kPam^2/W (ASTM F1868, Proc. B)	---	(same)
	MVTR	≥ 650 g/m^{2}24hr (ASTM E96 B)	---	(same)
	or, MVTR	≥6,000 g/m^{2}24hr (ASTM E96 BW)	---	(same)

* according to test methods in NFPA 1999-2013 edition

In addition to the detailed specifications in Appendix 2, the IAB also includes references to PPE listed on its Standard Equipment List (SEL) which would satisfy the PPE needs it delineates for the High-Risk and Low-Risk Ebola situations. The SEL designations for those items are provided below; Where the SEL item is preceded by "*Gore*," the PPE item is currently available and certified using Gore barrier materials (actual products shown in the following section).

High Risk

	SEL Designation	SEL Title
Gore	01CB-02-ENSM	Ensemble, Terrorism Incident Protective, NFPA 1994 Class 2
Gore	01CB-03-ENSM	Ensemble, Terrorism Incident Protective, NFPA 1994 Class 3
	01CB-04-ENSM	Ensemble, Terrorism Incident Protective, NFPA 1994 Class 4

	01EM-02-GARI	Garment, Emergency Medical, Single-Use, Interim
Gore	01EM-02-GARM	Garment, Emergency Medical, Multiple-Use, NFPA 1999
Gore	01SP-02-GRMT	Garment, Liquid Splash-Protective, NFPA 1992
	01SP-01-ENSN	Ensemble, Liquid Splash-Protective, Non-Encapsulating, NFPA 1992

Low Risk

	01EM-02-GARI	Garment, Emergency Medical, Single-Use, Interim

Note 1: (from the IAB document) "The PPE is recommended in terms of a garment, gloves, eye/face/respiratory protection devices, and footwear. However, the recommended PPE must form an "ensemble" of clothing and equipment that addresses the need for liquid penetration resistant interfaces (joints between different items of clothing and equipment, such as between gloves and garment sleeves) and the manner in which the ensemble is donned and doffed (particularly when contaminated)."

Note 2: There are no references in the IAB guidance document regarding the use of structural turnout gear for Ebola-related threats.

Certified PPE incorporating Gore materials and meeting IAB Recommendations

The following list shows the above four IAB SEL items for High-Risk and Low-Risk Ebola threats that are currently available and constructed with Gore barrier materials (i.e., those above preceded by "*Gore*"). The PPE manufacturer names are provided along with additional discriminating information.

High Risk

Gore 01CB-02-ENSM Ensemble, Terrorism Incident Protective, NFPA 1994 Class 2

Mfgr	Certif. #	Certif. Use	Style/Model	Comments
Blauer	SEI	1994 Chem/Bio Ensemble -Class 2	Multi-Threat	Dual Cert.: 1992 Ensm
LION	SEI	1994 Chem/Bio Ensemble -Class 2	Tactix MT-94	

Gore 01CB-03-ENSM Ensemble, Terrorism Incident Protective, NFPA 1994 Class 3

Mfgr	Certif. #	Certif. Use	Style/Model
Blauer	SEI	1994 Chem/Bio Ensemble -Class 3	Ext'd Response Team (XRT)
LION	SEI	1994 Chem/Bio Ensemble -Class 3	Ext'd Response Suit (ERS)

Gore 01EM-02-GARM Garment, Emergency Medical, Multiple-Use, NFPA 1999

Mfgr	Certif. #	Certif. Use	Style/Model	Comments
Blauer	SEI	1999 EMS gmt	9840/9845/9972	
Fire-Dex	UL 15148010301(/303)	1999 Multiple-use EMS gmt	USAR	Dual Cert.: 1951 R&R
Fire-Dex	UL 15148010401(/403)	1999 Multiple-use EMS gmt	Paradex	
Globe	UL 28522020401(/402)	1999 Multiple-use EMS gmt	Tech Rescue	Dual Cert.: 1951 R&R
LION	UL 29126010301(/303)	1999 Multiple-use EMS gmt	Tactix	Dual Cert.: 1951 R&R
Morning Pride / Honeywell				
	UL 28222060201(/202)	1999 Multiple-use EMS gmt	XXxCDual Cert.: 1951 R&R	
Ricochet	UL 29475010401(/402)	1999 Multiple-use EMS gmt	SR 602	Dual Cert.: 1951 R&R
Ricochet	UL 29879010301(/306)	1999 Multiple-use EMS gmt	FL / RV/ VS	

Gore 01SP-02-GRMT Garment, Liquid Splash-Protective, NFPA 1992

Mfgr	Certif. #	Certif. Use	Style/Model	Comments
Ansell	SEI	1992 Liquid Splash gmt	Sawyer Tower	
Lac-Mac	SEI	1992 Liquid Splash gmt	763 / 706 / 707	

Footnotes:

[1]- https://iab.gov/

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---------- October 24, 2014 ----------

Guidance relating to US-based PPE incorporating Gore barrier products

PPE Performance and Guidance

All of Gore's "CROSSTECH(R)" branded fabrics, the GORE(R) RT7100 moisture barrier, and all of Gore's "GORE(R) CHEMPAK(R)" branded fabrics used in NFPA 1994 certified garments achieve passing results for ASTM F 1671.

ASTM 1671 is the government and industry recognized test method for evaluating materials used in protective clothing for resistance to penetration by blood-borne pathogens.[1] It is the basis for the viral penetration resistance / blood and body fluid penetration resistance mandated as a part of the minimum performance requirements of multiple NFPA Standards (e.g., NFPA 1971 (structural fire fighting protective ensembles); NFPA 1999 (emergency medical response protective clothing); NFPA 1951 (technical rescue protective ensembles); and NFPA 1994 (CBRN terrorism incident protective ensembles))[2].

While the Gore barrier fabrics referenced above achieve passing ASTM F 1671 results, the end-item products they are currently incorporated into (i.e., garments, gloves, footwear, helmets, coveralls, etc.) are not ever specifically evaluated for overall blood-borne pathogen penetration resistance.

In each of the NFPA Standards referenced, there is included a whole garment integrity test (i.e., shower test) that uses surfactant-laden higher-velocity water spray to evaluate the garment (not gloves, footwear or helmets) for liquid (i.e., water) penetration resistance.

W. L. Gore & Associates, Inc. recommends the purchase of gear that meets or exceeds independent third party Standards, such as NFPA 1999 and NFPA 1994.

In addition to the ASTM 1671 and whole garment integrity (shower test) challenges, these two NFPA Standards have a performance option for aerosolized particle inward leakage resistance (a harder performance criteria to achieve). While none of the currently available end-items incorporating Gore barrier materials are evaluated against this performance option (evaluations are currently ongoing), currently certified NFPA 1994 ensembles incorporating Gore materials have to pass the Man-In-Simulant-Test, which evaluates whole ensembles for resistance to vapor permeation of a given test simulant.

In a document directed at healthcare workers, *Guidance on Personal Protective Equipment To Be Used By Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting on (Donning) and Removing (Doffing)*[3], the Centers for Disease Control and Prevention (CDC) has made the following two statements: 1) "In healthcare settings, Ebola is spread through direct contact (e.g., broken skin or mucous membranes of the eyes, nose, or mouth) with blood or body fluids of a person who is sick with Ebola, or with objects (e.g., needles, syringes) that have been contaminated with the virus." 2) "For all healthcare workers caring for Ebola patients, PPE with full body coverage is recommended to further reduce the risk of self-contamination."

In a separate document directed at healthcare workers, *Tightened Guidance for U.S. Healthcare Workers on Personal Protective Equipment for Ebola*[4], the CDC has also made the following statement: "The enhanced guideline is centered on three principles: * All healthcare workers undergo rigorous training and are practiced and competent with PPE, including putting it on and taking it off in a systematic manner, * No skin exposures when PPE is worn, * All workers are supervised by a trained monitor who watches each worker putting PPE on and taking it off."

The above two CDC documents and statements are directed at healthcare workers in US hospitals who are caring for Ebola patients - not to any first responder communities.

However, a third CDC document, *Detailed Emergency Medical Services (EMS) Checklist for Ebola Preparedness*[5], provides a checklist for US-based EMS agencies (particularly with respect to transport of infected patients) that has a section entitled, *Prepare to Protect* . Within this section of the checklist, the CDC makes the following statement: "Ensure that PPE meets nationally recognized standards as defined by the Occupational Safety and Health Administration (OSHA), National Institute for Occupational Safety and Health (NIOSH), Food and Drug Administration (FDA), or the InterAgency Board for Equipment Standardization and Interoperability (IAB)."

Specifically with respect to first responders/emergency response communities, the IAB[6] has recently published (10/24/14) a guidance document that addresses recommended PPE protection levels based upon varying threat levels associated with known or suspected Ebola exposures. As the IAB document is now the preeminent guidance established for first responders, please review this document for proper assessment of threat levels, the associated recommended PPE, and appropriate handling procedures if contaminated.

For a known or suspected Ebola exposure

With proven protocols still evolving from government agencies regarding the proper doffing and dispositioning of Ebola exposed PPE, it is Gore's recommendation at this time that if there has been a known or suspected exposure to the Ebola virus, all exposed/contaminated PPE gear should be doffed carefully (see IAB document) to prevent self-contamination, and the gear should be properly disposed of in accordance with federal, state, and local regulations.. Prospective decontamination procedures are addressed in the IAB guidance document, as well as, in the NFPA 1851 Standard[7].Even after potential decontamination procedures, it is still Gore's current recommendation that the gear with a known or suspected exposure to the Ebola virus be properly disposed of in accordance with federal, state, and local regulations.

Footnotes:

[1]- http://www.astm.org/Standards/F1671.htm
[2]- http://www.nfpa.org/codes-and-standards/document-information-pages
[3]- http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html (October 20, 2014)
[4]- http://www.cdc.gov/media/releases/2014/fs1020-ebola-personal-protective-equipment.html (October 20, 2014)
[5]- http://www.cdc.gov/vhf/ebola/pdf/ems-checklist-ebola-preparedness.pdf
[6]- https://iab.gov/
[7] - NFPA 1851 - Standard on Selection, Care, and Maintenance of Protective Ensembles for Structural Fire Fighting and Proximity Fire Fighting, 2014 Edition, Annex A, Section A.7.1.6, and specifically, A.7.2.3.6(1)

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