# 

### **EBOLA VIRUS : LAKELAND RECOMMENDATIONS**



The following is Lakeland Industries' recommended <u>minimum specification</u> for protective coveralls to be used by healthcare workers exposed to the Ebola virus. Justification for our recommendation is detailed in this document:

- 1. A primary fabric that:
- 1.1. has been certified to EN 14126 and attained at least a class 3 rating when tested per ISO 16604:2004, (included in EN 14126)
   OR
- 1.2. has been tested and passed ASTM F1671,
- 2. Coveralls made of fabric compliant with 1.1 or 1.2 above, AND:
- 2.1. must have sealed seams that have been tested per ASTM F1670 and passed,
- 2.2. must have a storm flap that can be taped or sealed shut over the zipper,
- 2.3. must have a hood with elastic around the opening,
- 2.4. must have elastic around the wrists and ankles **OR**
- 2.5. Have been tested according to EN 14605:2005 and met the requirements for TYPE 4: "Protective Clothing Against Sprays and Splashes of Hazardous Liquids" certification.



# Protective Garment Selection and Use for Health Workers

A number of articles and guides have been published that are heavy on Ebola facts. Interesting as details about the virus may be, such detail is not necessarily useful in terms of ensuring provision of adequate protection against it.

Our aim here is to provide a clear and simple guide for garment selection and use for health care workers and those specifying garments for procurement



Critically the risk to healthcare workers is high, the dependence on protective clothing primary, the probability of identifying product failure low, and the consequences of failure grave. This combination of factors strongly indicates the need for increased safety margins in the garments selected.

Fortunately, we do have relevant standards and test methods for protective garments to aid us in the selection process. However, without a clear understanding of these standards it is all too easy to misunderstand or misinterpret the protection each offers.

Existing CE certification standards and ASTM test methods deal with the requirements extensively and provide a guide to the types and construction of garments required.

### Garment Fabric: EN 14126: Protection against Infectious Agents

AND INDUSTRIES EUROPE LTD



EN 14126 provides five test methods to assess fabric ability to protect against the mediums by which an infection might be carried. Note that the standard provides for tests on fabrics and makes no requirements on garment construction or seams (other than requiring testing to mechanical and flammability requirements as required for all protective clothing).

The five tests are shown in the table below:-

Fabric Tests incorporated in EN 14126: Protection against Infectious Agents Synthetic blood screening test to ISO 16603-2004 indicate likely breakthrough in the Not Applicable bacteriophage test EN 16604 below Resistance to penetration by Classes 1 to 6 ISO 16604:2004 contaminated liquids under hydrostatic 6 is Highest pressure Protection against biologically Classes 1 to 3 ISO 22611:2003 contaminated aerosols 3 is Highest Protection against Dry Microbial Classes 1 to 3 ISO 22612: 2005 3 is the Highest Penetration Protection against Mechanical Contact EN 14126: 2003: Classes 1 to 6 with Substances containing Annex A 6 is the highest contaminated liquids

There are several important points to consider in a risk assessment for health care workers involved in the ebola effort:-

- The virus is transmitted via contact with body fluids (blood, vomit, urine etc) and is <u>not</u>airborne. Thus the key issue is to protect against contact with body fluids resulting from patients coughing or contact with blood or other fluids. *This has clear implications for the type and construction of suitable protective clothing*
- As patient contact is necessary in the course of treatment, clearly worker training and the use of Personal Protective Equipment (PPE) are the primary protective mechanisms. As such the consequences of PPE failure should factor heavily in the selection process
- The work environment in West Africa is hot and humid and due to limited availability of PPE healthcare workers wear PPE for extended periods of time. As a consequence they perspire heavily inside the protective garments making detection of inward leakage of contaminated fluids problematic; they may suffer a garment failure and be unaware.
- Once contracted the virus may take up to 15 to 20 days to incubate. This means that workers could be infected for 15 or more days BEFORE showing any symptoms and the infection being recognised. The implication of this is that there may well be workers who are infected but have not yet been identified as such.
- The mortality rate from the current Ebola outbreak is about 50% to 55%. To put this in context with other viral outbreaks in recent history, the U.S. Department of Health and Human Services estimates mortality due to Avian Flu (H5N1) to have been about 60% for the 650 cases reported since 2003<sup>1</sup> and 9% to 12% for the 8,000 reported cases in the 2003 outbreak of SARS<sup>1</sup>. Whilst Avian Flu has a mortality rate about the same as Ebola, it was never easily transmitted from human to human and thus the number of reported cases is significantly lower and it is not a good base line for PPE selection.

Clearly in terms of the hazard presented by ebola infection (ie infection through contact with a body fluids etc) the critical tests are:-

• **ISO 16604** – resistance to penetration by contaminated liquids under hydrostatic pressure. This would translate in use to direct insult by blood, vomit, or other bodily fluids.

• **ISO 22611** – Protection against biologically contaminated aerosols. This translates in use to being in contact with a spray of infected body fluid such as from a cough or sneeze..

• **EN 14126 Annex 1** – Protection against mechanical contact with substances containing contaminated liquids. *This might translate in use to being in contact with soiled linens, contaminated clothing, dishes, etc.* 

Equivalent to EN ISO 16603 and ISO 16604 are ASTMF1670, "Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood" and ASTM F1671, "Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-borne Pathogens Using Phi-X174 Bacteriphage as a Test System" respectively. It should be noted that both ISO 16604 and ASTM F1671 employ Phi-X174 bacteriophage as the challenge microbe. Phi-X175 is smaller than the Ebola virus, measuring 27 nm<sup>1</sup> compared to the Ebola virus at 970 nm (length) x 80 nm (width).<sup>1</sup> Thus Phi-X174 can be presumed an adequate surrogate for the Ebola virus in barrier testing

Conclusion: While clearly all three of these tests are relevant, we recommend use of ISO 16604 as minimum specification requirement because at a class 3 rating it equates roughly to the ASTM F1671 test method widening the scope of this specification while maintaining the minimum performance criteria at a safe level. Furthermore we believe this level of exposure to be the most challenging to both the garment and the material it is made from.

### **Garment Construction & Seams**

Though EN 14126 contains no requirements regarding garment or seam construction, clearly the high hazard presented by ebola indicates construction is a critical consideration.

EN 14126 certification is intended to be combined with one or more CE garment Type certifications appropriate for the media containing the infectious agent. In this case liquids. The applicable CE standards are shown in the table below:

Protective Clothing Standards for Protection against Hazardous Liquids		
Standard	Description	Requirements
EN 13034:2005	Type 6: Protection against light or aerosol sprays of liquids	Pass / Fail
EN 14605:2005	Type 4: Protection against sprays and splashes of hazardous liquids	Pass / Fail
EN 14605:2005	Type 3: Protection against strong or "jet" sprays of hazardous liquids	Pass / Fail

# 1. Garment construction should not compromise fabric integrity

Type 6 compliant garments commonly employ simple stitched seams in their construction. The stitching process produces as many as 14 holes per linear inch through the barrier material, leaves a gap between the two pieces of fabric being joined and introduces a cotton thread that can act as a "wick" for liquids. After testing fabrics to assure barrier capability to infectious agents, it is counterintuitive to then construct a coverall using a method that compromises the integrity of the fabric and the garment.

Some Type 6 garments feature a "bound seam" – where a strip of fabric is wrapped around the butt edge of the seam during stitching. Whilst being an improvement on standard stitched seams *bound seams remain stitched* and suffer the same problem in having stitch holes which compromise the integrity of the garment and fabric.

#### 2. No inward leakage can be tolerated

Because of the work environment in West Africa and the duration that healthcare workers wear these garments, perspiration and condensation inside of the garments is likely to make detection of garment failure unlikely. Penetration to under clothing presents a number of problems.

- If the worker does not change clothes, hand hygiene will not protect them if they later touch that soot that was contaminated with their hands.
- b. If penetration cannot be identified, all under clothing must be considered contaminated and handled and laundered accordingly presenting a greater possibility of viral contact for workers. Neither the WHO or CDC requires removal of under clothing as a part of PPE removal.
- c. Both WHO and CDC dressing and undressing procedures stress contacting garments on the inside where they are believed to be uncontaminated and rolling them inside out. Even with multiple hand hygiene steps in the undressing process, having contamination on under clothing remains problematic for infection control.

#### 3. CE Type certification does not mean that the garment will not leak.

Type 6, 4, and 3 performance criteria all specify maximum allowable inward leakage as a result of testing. Failure occurs only when the maximum is exceeded. The amount of inward leakage allowed is the same for all three tests, only the severity of the challenge exposure changes. Therefore, in order to reduce the potential for inward leakage users must select a coverall certified to an exposure that exceeds what will be encountered in actual use.

**EN 14605 Type 3** involves a strong jet of liquid – as from a pressure washer - directed at weak areas of the suit (seams, closures etc). Whilst ensuring a superior seal this is probably overkill for the situation where such strong jet sprays would be highly unlikely.

The Type 4 test consists of a test garment being sprayed with liquid from several nozzles. Whilst the spray pressure is not high, the volume of liquid is sufficient to soak the fabric so that it runs and pools in any creases or folds. In such a situation a liquid would seep through any holes in a stitched seam so a sealed seam is required.

The Type 4 test therefor constitutes in excess of the worst likely scenario for a health worker where they might be subject to a spray of body fluid from coughing or sneezing and is likely to exceed the decontamination process in terms of liquid volume.

# The tests for these standards are conducted on finished garments and involve a subject wearing the test garment in a spray cabin and being sprayed with a test liquid to identify any penetration inside the garment. The difference between the tests is in the pressure and volume of liquid applied. In this sense it is a simulation of a real world situation and is very similar to common decontamination procedures where disinfectants are sprayed on workers upon exiting contaminated areas.

For the purposes of protection against the ebola virus Lakeland believes the most relevant of these to be EN 14605 – Type 4: Protection Against Sprays and Splashes of Hazardous Liquids. Some consider Type 6 to provide adequate protection, but we disagree for the following reasons:

### Seam Types on disposable protective clothing





# EBOLA VIRUS : LAKELAND RECOMMENDATIONS



### **EBOLA VIRUS : LAKELAND RECOMMENDATIONS**

A garment certified to EN 14605 Type 4 AND to EN 14126 for infectious agent protection will be denoted on the label as:-

Conclusion: garment chosen for protection scenarios involving ebola should feature sealed seams (not stitched) and as a minimum meet the requirements of EN 14605 Type 4 garments for protection against sprays of hazardous liquids



EN14605: 2005 Type 4(B)

...the (B) indicating testing and certification to EN 14126

# Combination with other PPE and garment donning and doffing procedures

Having established that a garment certified to Type 4(B) - EN 14605 Type 4 for liquid spray protection (defines garment construction) and EN 14126 for protection against infectious agents (defines fabric requirements), it is important to realise that the way garments are used and combined with other PPE is AT LEAST as important as the garment itself:-

- Ensure that a garment of appropriate size for the user is selected. CE garments are sized according to a chest and body height size. Garments that are too small or too large are likely to be subjected to stress in use and thus run a higher risk of tears or damage through which a liquid can penetrate.
- Ensure the garment is donned and worn correctly in any hazardous areas.
   Remove boots or shoes when inserting legs and if possible sit down
   whilet doing as This minimizes the risk of damage. Basiase boots after
  - whilst doing so. This minimises the risk of damage. Replace boots after donning the garment legs and then stand to don the rest of the garment.
    Ensure all closures are securely and fully fastened and that where zip flaps use double-sided tape ensure the tape is fastened down with the
  - minimum of folds or creases.
     For this reason is it much easier for a second operator to fasten such
  - flaps appropriately
     It is always good practice to don such suits in pairs, each worker checking the others' to ensure the suit is worn and fitted properly.
- Other protective equipment must be worn with the suit, such as gloves, boots and masks. It is notable that almost all testing of chemical protective garments to the Type 4 spray test described above is conducted with joins between hood and face-mask, sleeves and gloves and ankles and boots sealed with a suitable liquid proof strong adhesive tape. This is because few garments would pass these tests without such sealing of joins with other PPE because the liquid would penetrate at the joins.
- Given the hazard presented by ebola securing these joins with such taping is likely to be required in most cases. Again it is much easier and more effective for a second worker to apply such tape and ensure a proper seal is achieved.

### Summary

Garments selected for Ebola health workers should be:-

- Certified to EN 14126 : protection against infectious agents
- Attain a class 3 or higher rating when tested per ISO 16604
- Certified to EN 14605 Type 4 : garments for protection against sprays of hazardous liquids (requiring sealed seams)

### OR

- Constructed of material that passes ASTM F1671
- Has sealed seams that have been tested and pass ASTM F1671
- Has a storm flap over the zipper
- Has a hood with elastic around it
- Has elastic wrists and ankles
- Again it is good practice, once the full ensemble of PPE is donned and as a last stage before entering a critical area, for a second worker to visually check the suit, joins and other PPE before proceeding.

### Wearing the Protective Coverall

Where possible avoid placing stress on the suit through extreme or strenuous movement or activity. Whilst such suits are subject to "movement stress testing" before Type tests any movement such as crouching or squatting will cause stress at the seams (the crotch is generally the most susceptible area) that could result in damage that may go unnoticed at the time and not be recognised until doffing or at all

### Decontamination and Doffing of the Suit:

Users, health workers and safety officers are advised to follow WHO and CDC guidelines for doffing and decontamination procedures:-

### http://www.who.int/csr/disease/ebola/en/

http://www.cdc.gov/vhf/ebola/index.html?s\_cid=cdc\_homepage\_feature\_001



## **EBOLA VIRUS : LAKELAND RECOMMENDATIONS**

### Lakeland manufactured garments for Ebola

Lakeland manufactures two garments which meet the above requirements:-

### MicroMAX TS

MicroMAX fabric is a microporous film laminate which has been subjected to all the tests in EN 14126 standard; in every case the fabric achieved the highest class proving its effectiveness as a barrier against infected contaminants. At the same time it features a level of moisture vapour transmission which whilst not comprising actual breathability will make it slightly more comfortable to wear than a solid film barrier.



However, the standard MicroMAX NS garment is a Type 6 garment and features standard stitched seams making it unsuitable for applications involving a hazard such as ebola. Users therefor need to select the MicroMAX TS which features

- sealed (stitched and taped) seams
- a zip flap sealable with double-sided tape
- testing and certification to EN 14605, Type 4.



ChemMAX 1 is a solid HDPE barrier film primarily designed for hazardous chemical protection. The fabric has also been subjected to all the tests in EN 14126 and passes each test in the highest class. The garment features

- sealed (stitched and taped) seams
- a double zip storm flap and sealable outer flap
- certification to EN 14605 Type 4 AND Type 3.



The ChemMAX 1 garment construction makes it suitable for more critical / higher risk areas though as a solid film barrier has no breathability so is not comfortable to wear for long periods.

#### More Comfortable Lakeland Alternatives: Both MicroMAX TS and ChemMAX 1 are available in Cool Suit versions.



Both garments are certified to the required Type 4 and feature a breathable back panel covered by a flap of the garment fabric sealed at top and sides and open at the bottom. This allows some circulation of air into the garment so leads to a more comfortable garment that is easier to wear in warmer environments.

However, users should be aware that the interior breathable back panel underneath the outer flap has a lower level of liquid and particle protection than the main garment fabric and has not been tested to the EN 14126 fabric testing for infectious agents. *These suits would not therefor be suitable where there was a risk of any contaminant being sprayed or splashed up inside the back flap cover.* 

For more information on garment selection and use for ebola related or similar applications contact sales-europe@lakeland.com or visit www.lakeland.com