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Short Communication

Establishment of the key Technical Indicators of Positive Pressure Biological Protective Clothing

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A B S T R A C T

Objective: Trying to establish the key technical indicators related to positive pressure biological protective clothing (PPBPC), providing technical support for the establishment of PPBPC standards in the future.

Method: We examined the protection standard systems established by the major standards organizations in China and other developed countries. We also analyzed the technical indicators of the gas-tight chemical protective clothing and ventilated protective clothing against particulate radioactive contamination which closely related to PPBPC. And tested the performance of a set of imported dual-purpose PPBPC to verify the fit of its technical indicators with the standards. We aimed to identify the status of China’s standards in the area of personnel protection and put forward feasible suggestions for the production of PPBPC in China.

Results: Developed countries in Europe and North America have a complete system of standard protective clothing. China should also strengthen the construction of standard protective clothing, especially PPBPC.

Conclusion: With the improvements in infectious disease prevention and control on a global scale, the demand for PPBPC continues to increase and consideration should be given to the establishment of standards for this.

1. Introduction

The Ebola virus disease epidemic, the Middle East Respiratory Syndrome pandemic, and the Zika virus outbreak in recent years have sounded the alarm. The globalization of infectious diseases has become a new form of epidemic.\textsuperscript{1–4} The World Health Organization (WHO) has initiated the establishment of a global early warning network and global public health intelligence network to response to infectious diseases, and has strongly urged countries worldwide to cooperate with each other to jointly prevent and control infectious diseases.\textsuperscript{5,6} The protection of the lives and health of frontline workers is a key point in the prevention, control, response, and research regarding communicable diseases. Schumacher et al. conducted a survey which showed that specialist registrars had the best knowledge of PPE requirements for severe acute respiratory syndrome (SARS), but had less so about those for anthrax, plague, Ebola virus, and smallpox.\textsuperscript{7} Respiratory protective equipment is still the preferred PPE when dealing with Ebola virus.\textsuperscript{8} The PPBPC is currently the world’s most commonly used high-grade PPE. The PPBPC, which provides the wearer with high-level body and respiratory protection, should be widely used in laboratories requiring high-level biosafety and during infectious disease rescue efforts.

The performance of the PPBPC directly affects the wearer’s safety. Manufacturers generally adopt the latest standards to guide the development and production of positive pressure protective clothing, to ensure high-quality performance. However, there is currently no international standard for PPBPC. To facilitate better understanding of the current worldwide standards related to the PPBPC, we reviewed the standards for protective clothing of developed countries around the world and compared these with those in China.

2. Standard profile

First, we searched for Chinese and foreign standards in the Wan Fang database, using “protective suit”, “chemical protective suit”,...
or “nuclear suit” as search terms. We retrieved 706 criteria, including 477 current standards. Of the 477 standards currently in force, 56 are from the International Organization for Standardization (ISO), 68 from the American Society for Testing and Materials (ASTM), 42 from the European Committee for Standardization (CEN), and 34 from the Chinese National Standards. The current standards set by three organizations—the ISO, ASTM, and CEN—include a total of 166 protective standards, accounting for one-third of the world’s protective field standards. Therefore, developed countries in Europe and North America can be considered authorities in this field.

The current standards retrieved included basic standards, product standards, and testing standards for various types of protective clothing. Research with respect to PPBPC usually refers to the provision of anti-chemical and anti-radioactive contamination positive pressure protective clothing and standards. Requirements, inspection, and testing methods for materials are established, which encompass assembly to overall performance. We focused on standards related to the development, production, and evaluation of PPBPC.

The key technical indicators of positive pressure protective clothing refer mainly to the standards of standards issued by ISO, ASTM, and CEN (Tables 1–3). In 1994, the CEN issued EN 270:1994 and EN 464:1994. EN 464:1994 stipulated the pressure detection method for airtight protective clothing. In 1994, the United States issued NFPA 1994, which is currently the updated 2001 version. In 1998, the European Union issued the standard EN 1073-1, which regulates the performance of the air supply system, and the intake and exhaust valves. In 2002, EN 943-1:2002 was issued, which addressed the material utilized by and the overall protection of gas-tight protective clothing (Type 1 and Type 2), with the performance and test methods being specified in detail. In 2002, the ISO issued ISO 16602:2002, which was revised in 2007. In 2003, the CEN issued EN 14126, which regulates the performance requirements and test methods of virus protective clothing, and specifies the requirements for the viral permeability of protective clothing fabric. The ASTM published ASTM F1671-07, the updated version of which is ASTM F1671/F1671M-13, ASTM F1670-08, and ASTM F2588-12 in 2007, 2008, and 2012, respectively. In 2015, the CEN updated its standard EN 943-1:2002 and issued EN 943-1:2015.

### 3. International standards on key indicators of positive pressure protective clothing

The key indicators mostly refer to the standard indicators according to the standards for protective clothing against radioactive contamination and chemical protective clothing.

| Table 1 | Standards issued by the International Standards Organization relating to PPBPC. |
|---------|---------------------------------------------------------------------------------|
| Standard | Standard name                                                                      |
| ISO 13688-1998 | Protective clothing—General requirements |
| ISO 13982-1 AMD 1-2010 | Protective clothing for use against solid particulates – Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing) |
| ISO 13982-1-2004 | Protective clothing for use against solid particulates – Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing) |
| ISO 13982-2-2004 | Protective clothing for use against solid particulates – Part 2: Test method of determination of inward leakage of aerosols of fine particles into suits |
| ISO 13994-2005 | Clothing for protection against liquid chemicals – Determination of the resistance of protective clothing materials to penetration by liquids under pressure |
| ISO 13995-2000 | Protective clothing – Mechanical properties – Test method for the determination of the resistance to puncture and dynamic tearing of materials |
| ISO 13996-1999 | Protective clothing – Mechanical properties – Determination of resistance to puncture |
| ISO 13997-1999 | Protective clothing – Mechanical properties – Determination of resistance to cutting by sharp objects |
| ISO 15384-2003 | Protective clothing for firefighters—Laboratory test methods and performance requirements for wildland firefighting clothing |
| ISO 16073-2011 | Wildland firefighting personal protective equipment—Requirements and test methods |
| ISO 16602-2007/Amd 1-2012 | Protective clothing for protection against chemicals—Classification, labeling and performance requirements |
| ISO 16603-2004 | Protective clothing for contact with blood and the body fluids—Determination of the resistance of protective clothing materials to penetration by blood and body fluids—Test method using synthetic blood |
| ISO 16604-2004 | Protective clothing for contact with blood and the body fluids—Determination of the resistance of protective clothing materials to penetration by blood-borne pathogens—Test method using Phi-X174 bacteriophage |
| ISO 17491-1-2012 | Protective clothing—Test methods for clothing providing protection against chemicals—Part 1 Determination of resistance to outward leakage of gases (internal pressure test) |
| ISO 17491-2-2002 | Protective clothing—Test methods for clothing providing protection against chemicals—Part 2 Determination of resistance to inward leakage of gases (inward leakage test) |
| ISO 17491-3-2008 | Protective clothing—Test method for clothing providing protection against chemicals—Part 3 Determination of resistance to penetration by a jet of liquid (jet test) |
| ISO 17491-4-2008 | Protective clothing—Test methods for clothing providing protection against chemicals—Part 4 Determination of resistance to penetration by a spray of liquid (spray test) |
| ISO 17491-5-2008 | Protective clothing—Test methods for clothing providing protection against chemicals—Part 5 Determination of resistance to penetration by a spray of liquid (manikin spray test) |
| ISO 22608-2004 | Protective clothing—Protection against liquid chemicals—Measurement of repellency, retention, and penetration of liquid pesticide formulations through protective clothing materials |
| ISO 22609-2004 | Protective clothing—Protection against infectious agents—Medical face masks—Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected) |
| ISO 22612-2005 | Protective clothing—Protection against infectious agents—Test method for resistance to dry microbial penetration |
| ISO 6529-2013 | Protective clothing—Protection against chemicals—Determination of resistance of protective clothing materials to permeation by liquids and gases |
| ISO 6530-2005 | Protective clothing—Protection against liquid chemicals—Test method for resistance of materials to penetration by liquids |
| ISO 6942-2002 | Protective clothing—Protection against heat and fire—Method of test: Evaluation of materials and material assemblies when exposed to a source of radiant heat |
| ISO/TR 11610-2004 | Protective clothing—Vocabulary |
3.1. Terms and definitions

Gas-tight chemical protective clothing: Chemical protective clothing that is leak-tight when tested in accordance with the internal pressure test given in BS EN 464-1994.

Airtight chemical protective clothing was classified into three categories in EN943-1:2015, which are Type 1a, Type 1b, and Type 1c suit.

The definition of PPBPC refers to that of airtight chemical protective clothing, and the powered air positive biological protective clothing corresponds to Type 1b airtight chemical protective clothing. The long tube aeration type PPBPC corresponds to Type 1c airtight chemical protective suit (Type 1c protective clothing).

3.2. Material performance parameters

There are several standards in countries outside China that stipulate the physical properties of materials and test methods. The main indicators of protective clothing fabrics and window materials are shown in Table 4. A set of imported dual-purpose PPBPC was destroyed, and the physical properties of the fabric was tested, the results met the parameters specified by the standard.

3.3. Overall performance of protective clothing

3.3.1. Nominal protection factor/inward leakage

The protective factor is the most critical technical parameter of PPBPC. The United States Respiratory Protection Committee divides the protective factors into design protection factors, work protection factors, and special state protection factors. In EN 1073-1:2002 specifies that the nominal protection factor for airtight protective clothing should be greater than 50,000 and the inward leakage (IL) rate less than 0.002%. The protection factor is the reciprocal of the IL rate obtained during all activities. There is no requirement for a specific IL rate for long tube aeration-type PPBPC. Safety mainly depends on the quality of the air supply system. For powered air positive biological protective clothing, the IL rate should be less than 0.0025%.
3.3.2. Leak tightness

Leak tightness is another key indicator of positive pressure protective suit. The basic principle of the leak tightness test is to use a pressure decay method, that is, after inflating the protective clothing to a prescribed pressure, the leak tightness of the protective suit is evaluated by measuring the change in pressure within a specified time. The protective suit is first inflated to 1750 Pa and then maintained at 1650 Pa. The degree of pressure drop is measured within 6 minutes; an acceptable drop in pressure is no more than 300 Pa (3 mbar) (Table 5). Tested the leak tightness of this imported clothing, its pressure reduction value is less than 200 Pa.

3.3.3. Internal static pressure

EN 943-1:2015 specifies that the internal static pressure of the protective suit should not exceed 400 Pa. A pressure gauge is used to test the internal pressure of the protective suit under static conditions at the maximum designed air supply. For the long tube aeration-type PPBPC, the internal static pressure tested was 140–172 Pa and 242–274 Pa respectively in the minimum flow rate and in the maximum flow rate. For air-powered PPBPC, the internal static pressure was 133–150 Pa.

3.3.4. Noise

The positive pressure biological protective clothing will generate noise when worn. EN 1073-1:1998 and EN14594:2005 stipulate that the maximum noise level inside the positive pressure protective suit at the maximum flow rate should not exceed 80 dB(A). In general, when the noise level is higher than 75 dB (A), the wearer should use communication and noise protection equipment. For the long tube aeration-type PPBPC, the noise was 71.6 dB(A) and 79.5 dB(A) respectively in the minimum flow rate and in the maximum flow rate. For air-powered PPBPC, the noise was 67.2 dB(A).

3.3.5. Air supply system

For the long tube aeration-type PPBPC, which should be able to be quickly connected with the air supply system, the air intake valve should be adjustable and installed in a position that is convenient for the wearer to operate. The minimum adjustment flow of the intake valve should meet the minimum design static pressure of the protective suit. At the maximum air supply flow, the air supply system ensures that the average static pressure inside the protective clothing does not exceed 400 Pa.

3.3.6. Electric air supply system

For air-powered PPBPC, the air supply provided by the powered air supply system should not be lower than 350 L/min, and the filter used should have a filtration efficiency of more than 99.99%. Electric air supply systems should also have both a low battery alarm and a low air volume alarm. The supply air volume of the tested air supply system was 380–400 L/min, which met the requirements of the standard.

3.3.7. Exhaust valve

The positive pressure bio-venture exhaust device is composed of one or more exhaust valves that meet the requirements for maintaining the positive pressure of the air supply and exhaust gas balance. The exhaust valve mounted on the protective suit should be able to work normally after the overall air-tightness and IL rate are tested, and the IL rate should be maintained to meet the design requirements. The exhaust valve should be designed as a one-way valve. EN943-1:2015 stipulates the performance index of the exhaust valve. Under a pressure of ~1000 Pa, the pressure leakage caused by the exhaust valve within 1 min should not exceed 100 Pa. The connection strength between protective clothing and the exhaust valve should be able to withstand tensile forces of no more than 150 N for 10 s.

3.3.8. Practical performance evaluation

The MIST is one of the most widely used methods for evaluating protective clothing. ASTM F2588-12 specifies the standard test method (MIST) for protective clothing using human body simulation tests. MIST provides an assessment of the overall protective clothing system including the materials, seams, zippers, and other accessories. Ormond believes that the ability to detect lower levels of permeation or penetration under current standard conditions pushes analytical methods and instruments to their operating limits. Therefore, to more accurately evaluate airtight protective clothing, some changes to the standard method must be considered. Here we discuss potential approaches to make the MIST method more suitable for evaluating fully hermetic protective clothing. These methods include increasing the contact dose, changing the air sampler properties, enhancing the analytical detection limits, or any combination of these. Gao et al. believe that ASTM F 2588-06 provides a detailed description of the test procedure, but does not provide specific requirements for the design of the test chamber. Based on a literature survey of existing test chambers, and a review of the current and proposed standards and test methods, cabin design requirements will depend on the test
method chosen. Since the test conditions for aerosol/particle and vapor integration tests vary widely, a single chamber is unlikely to be used to test for all types of protective clothing.\textsuperscript{12}

EN943-2015 stipulates that airtight protective clothing should pass the practical performance test when worn by personnel for a testing time of 30 minutes.

3.3.9. Ergonomics

ASTM F2668:2011 stipulates the methods for testing the effect of protective clothing on human physiological indicators. Lee et al. believe that breathability and water vapor transmission rate are the indices of protective clothing for thermal comfort.\textsuperscript{13} Fukazawa has developed a movable, sweating manikin. With the aid of this human body model, heat and water vapor resistance of the protective suit can be measured in different temperature and humidity environments to characterize the comfort of the human body.\textsuperscript{14}

4. Chinese standards for protection

Compared to international standards, there are few domestic standards available for reference. The standard references in the development of PPBPC are GB24539-2009, GB30864-2014, GB/T 23465-2009, and RB/T 199-2015. In the performance test standards for protective clothing, there are a number of standards for the direct conversion of international standards, such as GB/T 20655-2006/ISO 13996:1999, GB/T 20654-2006/ISO 13995:2000, and YY/T 0689-2008/ISO 16604:2004.

5. PPBPC products in China and other countries

With increasingly frequent outbreaks of infectious diseases and the advances in infectious disease research, the number of biosafety level 4 (BSL-4) laboratories worldwide has increased. Therefore, there is an increasing demand for PPBPC. Some biosafety laboratories have led to outbreaks owing to poor management, further increasing people's awareness of the need for risk prevention.\textsuperscript{15} Choosing suitable protective clothing for BSL-4 laboratories is very important. Kümin et al. designed an experiment to compare models of different brands of PPBPC. Their results showed that there is no perfect product; there were positive and negative aspects of all products tested. This is also the case with the present study.\textsuperscript{16} China has a late start in researching positive pressure biological protective equipment. Currently, completed BSL-4 laboratories have adopted imported products. Since the “Twelfth Five-Year Plan” period, Chinese researchers have succeeded in overcoming the main technical problems of PPBPC and have developed positive pressure PPE that meets the international standards. Wang D conducted a performance comparison between a positive pressure biological protective clothing (type B) produced in China and a suit (type A) produced abroad. Both suits exhibited a similar performance in terms of convenience, comfort, noise, and so on, and met the current operational requirements for high-level biosafety laboratories.\textsuperscript{17}

At present, PPBPC can provide a high level of protection to wearers in terms of technology. The question that remains is, how can it be widely applied to front-line rescue personnel in an outbreak? This requires national attention and multisectoral cooperation, including financial resources for supporting, training, and educating. Hanoa et al. believe that the steps from “safe enough” to “absolutely secure” seem to be insurmountable in most countries owing to cost and logistics.\textsuperscript{18,19}

6. China’s standard formulation for positive pressure bioprotective clothing

China currently does not have special standards for positive pressure bioprotective clothing. In future, it is necessary to improve the construction of standard systems for protection areas and to carry out research and preparation of positive pressure bioprotective clothing standards. This will help in the development and production of positive pressure bioprotective clothing, and will also help promote the prevention and control of infectious diseases in China, as well as research on the pathogenic organisms associated with these diseases. Only by protecting the lives of frontline workers can we effectively carry out the tasks needed for infectious disease prevention and control.

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Table 5
Comparison of relevant indicators of different standards.

| Indicator          | GB 24539-2009 | EN 943-1-2015 | ISO 16602-2007 | EN1073-1-1998 | NFPA 1994 |
|--------------------|---------------|--------------|---------------|---------------|-----------|
| Inward leakage rate| Liquid Leakage| The long tube aeration type positive pressure bio-protective suit: NA | Request test, Graded Leakage Rate Data | NA | NA |
| Static pressure    | NA            | The positive pressure < 400 Pa when the air supply flow is 300 L/min | Average pressure difference < 1000 Pa, peak pressure difference < 2000 Pa, at the Maximum air flow | NA | NA |
| Leak Tightness     | Pressure drop is not more than 20% of initial pressure 1000 Pa in 4 min | Pressure drop does not exceed 300 Pa in 6 min, when the test pressure is 1650 Pa | Pressure drop is not more than 20% of initial pressure 1000 Pa in 4 min | NA | NA |
| Noise              | NA            | NA           | NA            | NA            | NA |
| Air supply system  | NA            | Meet the requirement of EN 12021 | NA | NA | NA |
| Intake valve       | NA            | Minimum adjustment flow: >Design minimum flow | Minimum adjustment flow: >Design minimum flow | NA | NA |
7. Conclusion

Establishment of a standard system and formulation of product standards are crucial for product development and production. With improvement in infectious disease prevention and control on a global scale, the demand for PPBPC continues to increase, and the establishment of standards that are applicable to PPBPC should be considered. With the development of new materials and the application of new technologies, safety and intelligent use should be continuously improved based on ensuring the safe development of PPBPC. Product updates and the revision of standards complement each other. We hope that the standards organizations in China and in other countries will consider these current needs and establish special standards for this type of protective clothing, and facilitate and promote its development and production.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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