



**RWANDA FDA GUIDALINES ON SPECIFICATIONS OF  
COVERALL PROTECTIVE CLOTHING**

**RWANDA FDA**  
Rwanda Food and Drugs Authority

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## FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018 to regulate matters related to quality, safety and efficacy of regulated products including medical devices. Specifically in its article 9, where the Authority is given powers to formulate regulations and guidelines for regulating the manufacture, import and export, distribution, sale and use of regulated products.

Based on the available evidence, including the recent publications, WHO continues to recommend droplet and contact precautions for those people caring for COVID-19 patients. WHO continues to recommend airborne precautions for circumstances and settings in which aerosol generating procedures and support treatment are performed, according to risk assessment. Personal protective equipments (PPE) including coverall for health care personnel in contact in COVID-19 patients is one effective measure within a package of administrative and environmental and engineering controls, as described in WHO's Infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care.

These guidelines provide guidance on the manufacturer of performance requirements for ergonomics, innocuousness, size designation, ageing, compatibility and marking of protective clothing. Adherence to these guidelines will ensure the quality standards of coverall on the market during this emergency situation.

  
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**RFDA**  
Rwanda  
Food and  
Drugs  
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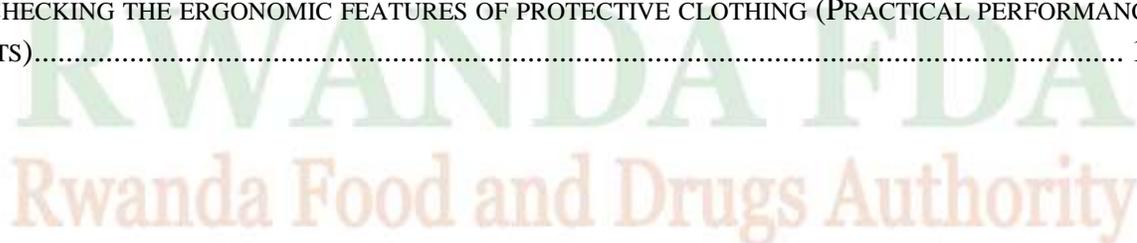
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**ABBREVIATIONS AND ACRONYMS**

<b>AAMI</b>	Association for the Advancement of Medical Instrumentation
<b>EN</b>	European Norms
<b>pH</b>	potential for Hydrogen
<b>PPE</b>	Personnal Protective Equipment



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## **INTRODUCTION**

Rwanda Food and Drugs Authority plays a critical role in protecting public health in Rwanda through ensuring the compliance of quality standard of regulated products including coverall protective clothing as in the category of medical devices. COVID-19 is currently known to spread through four means: contact (direct or via a fomite); droplet infection (droplets from the respiratory tract of an infected individual during coughing or sneezing are transmitted onto a mucosal surface or conjunctiva of a susceptible individual or environmental surfaces); airborne (transmission of infectious agents in small airborne particles, particularly during procedures such as intubation); and faeco-oral.

Coughing and sneezing can generate aerosol particles as well as droplets which can be prevented by using appropriate PPE including coverall protective clothing that should be used by health care professional in contact for those people caring for COVID-19 patients

WHO recommends among other preventives measures of COVID-19, healthcare providers should wear a coverall protective clothing when entering a room where patients with suspected or confirmed COVID-19 are admitted; importantly, coverall should not be considered as isolated interventions. Other protection includes hand hygiene, goggles or face shields, and gloves but globally stockpile of PPE is insufficient, particularly for coverall and respirators. It is in that regards that, Rwanda FDA is issuing this guidance to help manufacturers and expand the availability of coverall medical personnel for taking care of those people caring for COVID-19 patients

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## **1.2 BACKGROUND**

Currently, the outbreak of respiratory disease caused by a novel coronavirus that was first detected in Wuhan City, Hubei Province, China, has also been detected in Rwanda and WHO declared the Coronavirus outbreak (COVID-19) as pandemic.

The virus has been named “SARSCoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). SARS-CoV-2 has demonstrated the capability to rapidly spread, leading to significant impact on healthcare systems and causing societal disruption and deaths. The potential public health threat posed by COVID-19 is high, both globally and in Rwanda. Different higher institutions have communicated the preventive measures including. performing hand hygiene frequently with an alcohol-based hand rub if your hands are not visibly dirty or with soap and water if hands are dirty; avoiding touching your eyes, nose, and mouth; practicing respiratory hygiene by coughing or sneezing into a bent elbow or tissue and then immediately disposing of the tissue; wearing coverall clothing for medical personnel for taking care of those people caring for COVID-19 patient. Rwanda FDA believes that the current guidelines will help address these urgent public health concerns by clarifying the regulatory landscape of coverall, facilitating those who want to manufacture these products. This will increase their availability to the health care professionals in healthcare settings. Rwanda FDA issues these guidelines for guiding importers and local manufacturers in manufacturing appropriate coverall protective for prevention of COVID-19.

## **2. SCOPE OF THESE GUIDELINES**

These guidelines specify general requirements for ergonomics, innocuousness, size designation, ageing, compatibility and marking of protective clothing and the information to be supplied by the manufacturer with the protective clothing. This document is only intended to be used for coverall protective clothing

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### 3. DEFINITIONS

For the purposes of this document, the following definitions apply.

#### 3.1 Ageing

Change of one or more initial properties of protective clothing materials during the passage of time

#### 3.2 hazard

Situation which can be the cause of harm or damage to the health of the human body; there are different general types of hazards, e. g. mechanical hazards, chemical hazards, cold hazards, heat and/or fire hazards, biological agent's hazards, radiation hazards. Certain types of these hazards can, according to circumstances, derive from more specific hazards. Thus, a heat hazard can derive from contact heat, radiant heat etc. for each of which there can be separate test methods. Particular garments have been designed to give protection against the hazards encountered in specific types of activities. Examples of such garments are coverall that provide protection against chemicals.

#### 3.3 Risk

Combination of the frequency, or probability, of occurrence and the consequence of a specified hazardous event, the concept of risk always has two elements: the frequency or probability with which a hazardous event occurs and the consequences of the hazardous event.

#### 3.4 Performance level

Number that designates a particular category or range of performance by which the results of testing

#### 3.5 Protective clothing

clothing including protectors which cover or replace personal clothing, and which is designed to provide protection of one or more hazards

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### **3.6 Waist to waist over the shoulder length**

The maximum length measured from the plan to the waist

### **3.7 Torso**

Thorax and abdomen or section of the body to which the limbs, head and neck are attached

## **4. BASIC HEALTH AND ERGONOMIC REQUIREMENTS**

### **4.1 General**

The following paragraphs specify some basic health and ergonomic requirements relevant to coverall protective clothing

### **4.2. Coverall protective clothing shall be designed and manufactured as follows:**

Coverall protective clothing shall not adversely affect the health or hygiene of the user. The materials shall not, in the foreseeable conditions of normal use, release substances generally known to be toxic, carcinogenic, mutagenic, allergenic, toxic to reproduction or otherwise harmful. The following list of documents is given for information and as examples of documents to be examined acceptance of the coverall protective clothing

- Information supplied by the manufacturer could include evidence-based information confirming that the product does not contain any substances at levels that are known or suspected to adversely affect user hygiene or health,
- Materials specifications,
- Safety data sheets relating to the materials,
- Information relating to the suitability of the materials for use in medical devices, or other relevant applications
- Information relating to toxicological, allergenic, carcinogenic, toxic to reproduction or mutagenic investigations on the materials

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- Information relating to ecotoxicological and other environmental investigations on the materials. Materials should be selected to minimize the environmental impact of the production and disposal of protective clothing.

The examination shall determine whether the claim that the materials are suitable for use in the protective clothing or protective equipment is justified. Particular attention shall be paid to the presence of plasticizers, unreacted components, heavy metals, impurities and the chemical identity of pigments and dyes. Each layer of material of the protective clothing shall comply with the following requirements:

- a) Chromium VI content in clothing materials shall not exceed 3 mg/kg when tested with relevant test method
- b) All metallic materials which could come into prolonged contact with the skin (e.g. studs, fittings) shall have a release of nickel of less than 0,5 µg/cm<sup>2</sup> per week.
- c) Protective clothing material shall have a value greater than pH 3,5 and less than pH 9,5. The test method for textile materials shall be according to relevant validated test method
- d) Azo colorants which release carcinogenic amines shall not be detectable when test with internationally recognized test method
- e) Single use, fluid resistant, disposable, length mid-calf to cover the top of the boots, light colors preferable to better detect possible contamination, thumb/finger loops or elastic cuff to anchor sleeves in place.
- f) fluid penetration resistant: EN 13795 high performance, or AAMI PB70 level 3 performance or above, or equivalent
- g) blood borne pathogens penetration resistant: AAMI PB70 level 4 performance, or (EN 14126-B) and partial body protection ( EN 13034 or EN 14605), or equivalent

#### **4.2 Design of coverall protective clothing**

The design of protective clothing shall facilitate its correct positioning on the user and shall ensure that it remains in place for the foreseeable period of use, taking into account ambient factors, together with the movements and postures that the wearer could adopt during the course

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of work or other activity. For this purpose, appropriate means, such as adequate adjustment systems or adequate size ranges shall be provided so as to enable protective clothing to be adapted to the morphology of the user.

The design of protective clothing shall ensure that no parts of the body get uncovered by expected movements by the wearer. protective clothing shall be made in materials that can facilitate easy put on and taken off, that arm and knee and bending movements are possible; protected body areas do not appear during movements and the manufacturers information is adequate to explain the correct usage of the protective clothing, where applicable, coverall protective clothing design shall take into account other items of protective clothing or equipment from the same or other manufacturers which must be worn to form an overall protective ensemble. When two or more items are worn together, they should be compatible and each one shall comply with its own standard requirements. None of them has to reduce the performance of the other item(s) and the appropriate level of protection should be provided at interface areas between those products, for example in sleeve to glove, trousers to footwear, hood and respirator combinations and other combinations, mechanical strength, color fastness and fiber composition of garment used should also comply with relevant standards for the coverall made from textile.

#### **4. 3 Comfort of use of coverall protective clothing**

Protective clothing shall provide users with a level of comfort consistent with the level of protection required against the hazard which is present, the ambient conditions, the level of the user's activity, and the anticipated duration of use of the protective clothing. Protective clothing shall not

- Have rough, sharp or hard surfaces that irritate or injure the user;
- Be so tight, loose and/or heavy so that it restricts normal movement;

Protective clothing that imposes significant ergonomic burdens such as heat stress, or is inherently uncomfortable because of the need to provide adequate protection, shall be accompanied in the information supplied by the manufacturer by specific advice or warnings.

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Specific advice on the appropriate duration for continuous use of the clothing in the intended application(s) shall be given.

## **5. Ageing of coverall protective clothing**

### **5.1 General**

This clause is concerned only with the dimensional change caused by cleaning on the performance of the clothing and legibility of marking, washing and dry cleaning shall be in accordance with the manufacturer's instructions, on the basis of standardized processes. If the number of cleaning cycles is not specified, five cleaning cycles shall be performed. This shall be reflected in the information supplied by the manufacturer, where rapid deterioration in performance is caused by the use of cleaning procedures, the manufacturer, in the marking and/or in the information, shall indicate the maximum number of cleaning operations that may be carried out before the protective clothing has to be discarded. Manufacturers should typically indicate one or several of the various methods and processes or equivalent standardized processes for cleaning.

#### Dimensional change due to cleaning

If the manufacturer's instructions indicate that garments can be washed or dry cleaned, the test procedure for dimensional change for washing of protective clothing material shall be carried out in accordance with measurement of dimensional change. Changes in dimension due to cleaning of material for protective clothing shall not exceed  $\pm 3\%$  for woven materials and  $\pm 5\%$  for knitted material and nonwovens in either length or width, a sample shall be subjected to five cleaning cycles, if both industrial washing and domestic washing are permitted, only industrial washing shall be carried out. If the manufacturer includes instructions for washing or washing and dry-cleaning, the garment shall only be wash tested. If only dry-cleaning is allowed, the garment shall be dry-cleaned.

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## **6. General size designation for coverall protective clothing**

Protective clothing shall be marked with its size based on body dimensions measured in centimeters. The size designation of each garment shall comprise the control dimensions. Exceptions shall be specified in detail in the manufacturer instructions. The size designation system is required especially for labelling. The Control dimensions (ranges expressed as centimeters or kilograms) shall for on the chest or bust girth and heights

The manufacturer can also designate additional measurements, e.g. the arm length, the inside leg length or the hip girth for women's garments. The value shall correspond to the actual value in centimeters of the user's body dimensions. The manufacturer for protective clothing shall take the following into account:

- That if there is a requirement for a zone or zones of protection there shall be a specified numerical relationship between the dimensions of the specific protective materials or constructions in the products, and the size of user.
- That it shall be possible to optimize PPE adaptation to user morphology by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate size range.
- That the proportions and the dimensions of the protective clothing shall reflect the needs of the users in the environments where it is to be used, with the clothing to be worn with it, and performing the normal tasks for which it is intended.

## **7. Marking of coverall protective cloths**

The marking shall be in the official languages of the state of destination for informative wording (e.g. warning phrases); The product itself or on labels attached to the product; Affixed so as to be visible and legible; durable to the appropriate number of cleaning processes. The marking and the pictograms should be large enough to convey immediate understanding and to allow the use of readily legible numbers. The use of numbers not smaller than 2 mm and pictograms not smaller than 10 mm (including the frame) is recommended. Numbers and pictograms are

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recommended to be black on white background, warning against mortal hazards should be on the outside of the product.

**The marking shall include the following information:**

- a) Name, trademark or other means of identification of the manufacturer or his authorized representative;
- b) Designation of the product type, commercial name or code;
- c) Size designation according to Clause 5
- d) Identification of the specific products guidelines;
- e) Pictograms and levels of performance
- f) As a type designation of a hazard or an application the pictogram shall be used as indicated in the marking requirements of the specific standard
- g) Single-use PPE shall be marked with the warning phrase “*Do not re-use*”

Information supplied by the manufacturer Protective clothing shall be supplied to the customer with information written at least in the official language(s) of the state of destination. All information shall be unambiguous. The following information shall be given

- a) Name and full address of the manufacturer and/or his authorized representative
- b) Number of the specific guidelines
- c) Explanation of any pictograms and levels of performance
- d) All main constituent materials of all layers of protective clothing.
- e) Instructions for use as appropriate to the guidelines
- f) Tests to be carried out by the wearer before use;
- g) Fitting; how to put on and take off;
- h) Instructions concerning appropriate use of the product to minimize the risk of injury;
- i) Limitations on use (e. g. temperature range);
- j) Instructions for storage and maintenance, with maximum periods between maintenance checks;

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- k) Complete instructions for cleaning and/or decontamination (e.g. cleaning temperature, drying process, pH value, mechanical action, maximum number of cleaning cycles, cleaning products);
- l) warnings against problems likely to be encountered, e.g. domestic washing of contaminated clothing, dangerous improper use;
- m) Details of additional items of protective clothing that need to be used to achieve the protection intended;
- n) Details of any significant ergonomic penalties of using the product such as a reduction of the field of vision, acuity of hearing or a risk of heat stress;
- o) Instructions on how to recognize ageing and loss of performance in the product, e.g. factors which may reduce the protection;
- p) Instruction and training if required, including the level of experience necessary for safe use of the protective clothing
- q) Instructions concerning repair. Repairs should not impair the performance of the clothing. Instructions should advise, for instance, repair by suitably qualified companies, or a warning not to do it yourself
- r) Reference to accessories and spare parts if relevant
- s) Type of packaging suitable for transport if relevant.
- t) Instructions for recycling, safe destruction and disposal as relevant (e. g. mechanical disruption or incinerating the product).

### **8. Checking the ergonomic features of protective clothing (Practical performance tests)**

This clause specifies how some basic ergonomic features of protective clothing shall be checked using simple practical tests, ergonomic assessments are intended to reduce the risk of hazards to the user due to such parameters for example as poor design and fit, poor compatibility with other related items of PPE and poor compatibility with other items of clothing, the checking of protective clothing should be done by one or more experienced inspector who first read the information supplied by the manufacturer, and then examine the protective clothing. Simple

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practical tests are then carried out. A list of questions is provided below. The product is satisfactory if all the answers given are positive. The answers given to the questions may be YES, NO or CANNOT DECIDE. All “CANNOT DECIDE” responses should if possible be resolved by using additional subjects. Final decisions are made by the inspector(s).

The inspector may have difficulties deciding whether a product is acceptable or unacceptable. In such cases, it is recommended that the product should be compared with similar items on the market. If it is significantly worse ergonomically, without redeeming features such as enhanced protection, it can be regarded as unnecessarily uncomfortable. Care will need to be taken if there are no directly comparable products. Care will also have to be taken when protection against mortal danger is intended and ‘the state of the art’ does not allow comfortable conditions for users, nor perhaps conditions free of harm caused by the protective clothing. Carrying out (subjective) ergonomic assessments will more often result in recommendations for changes to improve protective clothing, than in finding the clothing absolutely does not comply with the minimum requirements of a product standard.

- Coverall protective clothing free from harmful features: Protective clothing should be inspected manually and visually to ensure it is free from any sharp or hard edges, protruding wire ends, rough surfaces or other items on the inner or outer surface of the clothing that are likely to cause harm to the user or others.
- Putting on, taking off and fit; The following points should be considered: The ease of putting on and removing the clothing with or without assistance as is appropriate for the type of clothing. The clothing should not be too tight for comfort and deep breathing is not restricted and there is no blood flow restriction anywhere.
- The clothing design at, for example the armholes and crotch, to check they are appropriately proportioned and positioned.
- Using simple practical tests, the inspector should check whether the information supplied by the manufacturer is sufficiently clear, complete and accurate so that users may be

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expected to use the clothing correctly, and avoid any hazardous errors in using the product.

- Operation of closures, adjustment and restraint systems and these should be considered: The adequacy of the range of adjustments available, the ease of operation and the security of closures and adjustment, whether the closures, adjusters and restraint systems appear strong enough to withstand the forces to which they are likely to be exposed to during body movements and the tasks for which the protective clothing is intended
- Coverage of the area intended to be protected, coverage maintained during movements and these should be considered: The adequacy of coverage of any specified protection zones by protective material or special constructions, that coverage is maintained during movements as extreme as it is anticipated a user would make.
- Freedom of movement; The wearer of the clothing should be able of standing, sitting, walking and stair climbing, raising both hands above the head, bending over and picking up a small object such as a pencil.
- The arms and legs of the clothing should not be so long that they interfere with hand and foot movements, the clothing should not be so loose that it flaps about or moves independently and inconveniently, there should not be points at which unexpected and unintended gaps open up between or within components of the clothing, there should not be any unreasonable restriction of movement at any joint.
- Compatibility with other PPE from the same manufacturer considering that protective clothing is normally worn as part of an ensemble should be compatible with representative examples of the rest of that ensemble, putting on and removing other items of PPE such as gloves and boots should be possible without difficulty.

#### **9. Reasons for concluding that a protective clothing product is unacceptable and not fit for use**

The following are reasons for concluding that a protective clothing product is unacceptable and not fit for use:

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- a. Subjects it should fit cannot wear it.
- b. It does not stay done up, or it will not stay in place.
- c. It compromises a vital function, such as breathing.
- d. Simple tasks to be performed wearing it are impossible.
- e. The subject refuses to continue the assessment due to pain.
- f. It prevents the wearing of other essential PPE.



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